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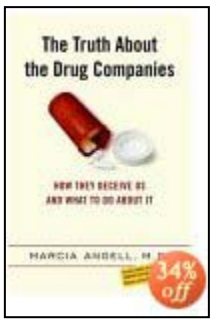
The Truth About the Drug Companies: What To Do About It

By **John Mack**



You can't go to a pharma industry conference these days without hearing at least one expert speaker recommending that pharma executives read the book "The Truth About the Drug Companies: How They Deceive Us and What to do About It," written by Marcia Angell, MD, former editor in chief of *The New England Journal of Medicine*. It's not often that you see pro-industry pundits recommend a book that "tears pharma a new one," as some would say.

Having great respect for these people—including Richard Vanderveer, Chairman & CEO, V2 GfK and an advisory board member of this newsletter and Rob Nauman, Principal, BioPharma Advisors and member of the PHARMA-MKTING discussion group—I necessarily went right out and bought the book.

Kudos from Pundits

"Pharma executives need to read this book in order to achieve balance in their own understanding of the industry," says Nauman. "Too often individuals within the industry cannot admit that some of what Angell says is really going on, because the industry is managed in various 'silos' and the overall issues are often things they are not addressing in their role."

"…this volume is much more than simple entertainment," says Peter Rost, a Vice President of Marketing at Pfizer Inc., in his Amazon.com review of the book. "It is quite possibly one of the best analyses of the state of the U.S. drug industry today, complete with footnotes backing up every statement the author makes."

> "This book has a lot of buzz going for it. Industry executives should read it defensively and be ready to answer questions at cocktail parties. I am a firm believer in counteracting bad press."
>
> – Richard Vanderveer

What Are Her Points?

Angell really hammers the industry on its marketing, clinical development, and lobbying practices. At the end, she makes several recommendations for what should be done to "save … this important industry…mainly from itself." Whether or not we agree with her remedies, saving this is a goal we all should focus on, especially as our incomes depend upon healthy, profitable pharmaceutical companies.

Here's a short list of problems for which Angell suggests remedies:

1. Drug companies produce too many me-too drugs and too few innovative ones
2. Drug companies have too much control over clinical research on their own products.
3. The Food and Drug Administration (FDA) is too much in the thrall of the industry it regulates
4. Drug companies have too much influence over medical education about their own products.

There are other problems Angell discusses such as pricing, patents, and transparency, but I'd like to focus only on the above issues for this review.

Research vs. Marketing

Angell doesn't buy the drug companies' argument that the price of new prescription drugs in the U.S. is high mainly because it supports the huge investment in scientific research done by the industry. She suggests that research costs are not as high as the industry claims. She uses industry data to estimate the pretax cost of developing a new drug to be $265 million per drug (vs. $802 million estimated by a much-cited Tufts study) and that much of this might be really marketing under the guise of Phase IV studies.

Angell, like so many pharma critics, suggests that much more money is spent on drug marketing than on research for new drugs. The pharmaceutical industry, of course, vigorously disputes this. "The R&D vs. marketing argument is not working any more," says Vanderveer. "A dollar spent on that argument is a dollar wasted as far as I am concerned."

Whatever the cost, Angell argues that large R&D expenditures "ought to raise the question of whether we are getting our money's worth." On average only 12 innovative drugs, which Angell defines as new molecular entities that have received priority review by the FDA, are approved each year. Not only that, of the seven innovative drugs approved in 2002, only three were from American companies and "publicly funded medical research—not the industry itself—is by far the major source of innovative drugs. …if prices and profits in excess of any other industry are indeed a stimulus for innovation," says Angell, "drug companies have not kept their part of the bargain."

"R&D is stagnant," says Terry Nugent, VP Marketing, Medical Marketing Service, Inc., "No one hates that more than the people who are paying for it—companies and investors."

Angell further claims that seventy-seven percent of the industry's output consists of "leftovers" or me too drugs classified by the FDA as being no better than drugs already on the market to treat the same conditions. She cites a "crucial weakness" in the law that new drugs only have to be proved "effective" and not "more effective than (or even as effective as) what is already being used for the same condition." She favors head-to-head comparisons rather than showing that a drug is better than nothing at all (placebos). "The last thing drug companies want," says Angell, "is a head-to-head comparison."

"Perhaps Angell is right," says John Hoey, M.D. in a review of the book published in the New England Journal of Medicine. "We must change the way we manage research and the development and distribution of new drugs. Not only are health and health care at risk, but so are the research enterprise and the reputations of universities and governments. The integrity of scientific research is too important to be left to the invisible hand of the marketplace."

Angell offers several solutions to address the problems she sees inherent in pharmaceutical-sponsored clinical research. Among these are:

- FDA regulations should require that new drugs be compared not just with placebos but with old drugs for the same condition ("accomplished easily by congressional legislation")
- Strengthen the FDA as an independent agency. ("It is now so dependent on the pharmaceutical industry [e.g., user fees] that it has become big pharma's handmaiden.") Repeal the Prescription Drug User Fee Act, increase public support, and keep experts with financial ties to the industry off FDA advisory committees.
- Create an Institute for Prescription Drug Trials to "ensure that clinical trials serve a genuine medical need and to see that they are properly designed, conducted, and reported."

Pharmaceutical companies like to refer to themselves as "research-based." Angell says most big pharmaceutical companies are "hardly that." She suggests that they could better be described as "idea-licensing" and "marketing" companies. "That isn't a bad thing," says Vanderveer. "Pharma companies *should* emphasize that they are marketing companies. We are in the communications business and are a channel between development and consumers. This is a good thing."

> "Dr. Angell lives in a socialist dream world in Harvard Yard, which has no more relationship to reality than Harry Potter's school for wizards."
>
> – Terry Nugent

"While I believe that clinical development of new drugs as it is currently practiced is broken," says Nauman, "Angell's solution to do all clinical research in academic institutions swings the pendulum too far in the opposite direction. Academia has its own priorities – e.g., publish or perish – and there is no guarantee that pure academic clinical research will result in better products."

"Pharma companies should not hold back smaller innovations that fulfill unmet medical needs by not developing compounds that they deem are not profitable," says Nauman. "They should sell their proprietary rights off, have smaller companies to complete the clinical development, and then partner with them to commercialize the drugs." Nugent agrees. "The solution," he says, "is perhaps to get these brilliant people focused on fighting disease instead of each other. Spin them

off into little biotech empires with incentives—i.e., money—to get their acts together."

"The problem is that many of Angell's solutions are extreme and don't offer much compromise," says Matthew Holt, healthcare strategy consultant and author of The Healthcare Blog. Holt is concerned that extreme positions will cause pharma to "circle the wagons rather than engage in a dialog with critics to effect real change."

Education vs. Marketing

Angell suggests that pharma companies get out of medical education. Since education comes out of drug companies' marketing budgets, "that should tell you what's going on," says Angell.

According to figures cited in Angell's book, over 60 percent of the costs of continuing medical education in 2001 was paid by pharmaceutical sponsors (ACCME reports that for 2003, pharma companies provided $943,608,302 for direct sponsorship of CME programs with a total income of $1,774,516,395. That works out to 53%. If you add in a good chunk of the $183,293,597 in advertising and exhibits income that pharma is probably responsible for, I am sure the 60% number is a valid estimate). Angell points out that many ACCME accredited organizations are for-profit companies hired by drug companies. These MECCs (Medical Education Communications Companies), as they are called, promise to get audiences "to take action that benefits your product." This represents too much of a conflict of interest according to Angell and backs up her claim that there is a close connection between medical education and drug marketing.

> "A political tidal wave is building which will forever change both the industry and many of its infamous business practices. It is sad to note that the drug industry today is equally poorly regarded as the tobacco companies, and this is a testament not only to the shortsighted foolishness of their management, but also to the fact that you can fool some of the customers some of the time, but not all of them all the time."
>
> – Peter Rost

Among the solutions offered by Angell:

- Medical schools should teach students about drugs and not leave this up to industry-sponsored programs and teaching materials.
- Teaching hospitals should regard drug company representatives just as they do other salespeople—don't let them traipse around at will, promoting their wares.
- The medical profession should take responsibility for continuing medical education. There should be no private medical education industry hired by the drug companies.
- Professional associations should be self-supporting even if it means raising member-ship dues to gain independence from drug companies.
- Direct-to-consumer (DTC) advertising should be prohibited in the United States just as it is in other advanced countries. (The exception being New Zealand. –ed.).

DTC advertising is facing a challenge from the public, regulators, and legislators even as more and more money is channeled into it by pharma companies (perhaps getting their last licks in before the hammer falls). "DTC's visibility is starting to blowback big time," says Nugent, "and it cripples the learned intermediary defense in the most expensive tort cases. Get it off TV and on to the Web—better, faster, cheaper."

Angell also gives advice to patients about questions they should ask their physicians. For example, "Do you make time for visits from drug company representatives?" If the answer is yes, Angell says you should consider changing doctors. "I think she is right," say Vanderveer. "Docs shouldn't make any time to see reps unless they have something new to say. And industry executives should stop running to conferences on improving physician access and should think more about how rep visits can be more valuable to docs."

Tough Years Ahead?

A good point for pharma marketers to take away from this book is that 2000 marks the beginning of a perfect storm for the pharmaceutical industry. "Get ready for 5 years of change," says Vanderveer.

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