

The drug industry's chokehold on America's health care

Joanne Laurier
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The Truth About the Drug Companies: How They Deceive Us and What to Do About It by Marcia Angell M.D., published by Random House, 304 pp.; *Overdosed America: the Broken Promise of American Medicine*, by John Abramson, M.D., published by Harper Collins, 332 pp.

Major pharmaceutical companies have been hit recently by an array of scandals regarding the safety of certain “blockbuster” drugs. Merck’s Vioxx, a leading arthritis and pain medication was withdrawn from the market after it was shown to have caused thousands of heart attacks and an estimated 55,000 deaths. Its leading competitor, Celebrex, manufactured by Pfizer, faces similar difficulties.

Other drugs, including over-the-counter remedies, are also being scrutinized for severe, unwanted side-effects. On December 18 the *Detroit Free Press* released its own analysis concluding that many thousands of Americans are getting sick and dying from prescription drugs prematurely entering the market.

Two recently-published books provide valuable insights and describe in devastating detail the operations of the pharmaceutical industry—the consequences of its domination of government agencies and the medical establishment. *The Truth About the Drug Companies: How They Deceive Us And What To Do About It* is written by Marcia Angell, M.D.; *Overdosed America: The Broken Promise of American Medicine* is authored by John Abramson, M.D.

A former editor-in-chief of the *New England Journal of Medicine* (NEJM), Angell witnessed the work of that prestigious journal come increasingly under the influence of the drug industry. She claims in the volume’s introduction that the pharmaceuticals began exercising “a level of control over the way research is done that was unheard of when I first came to the journal, and the aim was clearly to load the dice to make sure their drugs looked good.” (p. xviii)

The author of *Overdosed America*, Abramson, is a family doctor on the clinical faculty of Harvard Medical School. He was prompted to write his book because of what he perceived as the corporate takeover of medical research. Trained as a statistician, he “researched the research,” and found that “even the most respected medical journals seemed more like infomercials whose purpose was to promote their sponsors’ products rather than to search for the best ways to improve people’s health.” (p. xii)

Americans spend a staggering \$200 billion a year on prescription drugs out of worldwide sales of \$400 billion. From 1980 to 2000, prescription drugs tripled as a percentage of US gross domestic product. Since that time, PhRMA—the Pharmaceutical Research and Manufacturers of America—has consistently ranked by far as the most profitable industry, while its CEOs have raked in eight digit salaries combined with eight digit stock options. In 2002, the combined profits of the 10 drug companies in the Fortune 500 (\$35.9 billion) were more than the total profits of the other 490 businesses (\$33.7 billion).

Both Angell and Abramson contend that PhRMA began its astronomical rise in the late 1970s and early 1980s—particularly under Ronald Reagan.

In 1980, Congress enacted a series of laws, such as the Bayh-Dole Act (Senator Birch Bayh [D-Indiana] and Senator Robert Dole [R-Kansas]) that enabled universities and small companies to patent discoveries made through publicly funded research and then grant exclusive licenses to drug companies. Until that time, taxpayer-financed research was public property available to any company. The nascent biotech industry was thus given a tremendous boost. Through similar legislation, the National Institutes of Health (NIH)—the major distributor of tax dollars for medical research—was permitted to enter into deals that would directly transfer NIH discoveries to industry.

As Angell points out: “These laws mean that drug companies no longer have to rely on their own research for new drugs, and few of the large ones do. Increasingly, they rely on academia, small biotech start-up companies, and the NIH for that.” (p. 8) This, argues Angell, has changed the ethos of medical schools and teaching hospitals, who now see themselves as partners of industry and become “just as enthusiastic as any entrepreneur about the opportunities to parlay their discoveries into financial gain.” (p. 8) She cites the example of the Dana-Farber Cancer Institute, a Harvard hospital, which has a deal with the drug company Novartis, giving it rights to discoveries that lead to new cancer drugs.

In 1984, the Hatch-Waxman Act extended monopoly rights for brand-name drugs—drugs for which the manufacturer has marketing exclusivity. (After brand-marketing rights expire on a drug, generic copies can be produced by any manufacturer for a fraction of the cost. The monopoly status of a brand-name drug also translates into an exorbitant selling price by comparison with its generic equivalent.) Other congressional laws enacted in the 1990s have increased the patent life of brand-name drugs from 8 years in 1980 to 14 years in 2000.

In 1992 Congress passed the landmark Prescription Drug User Fee Act, effectively putting the Food and Drug Administration (FDA) on the pharmaceutical industry’s payroll, according to Angell. To expedite approval of drugs, the law authorized drug companies to pay user fees to the FDA, making the governmental agency dependent on the industry it regulates. Today, industry-paid FDA employees constitute more than half of the agency’s staff involved in approving drugs. The FDA now generally approves drugs faster than counterpart agencies anywhere in the world. Since the law was enacted, 13 prescription drugs, causing hundreds of deaths, have had to be withdrawn from the market.

The origin of the FDA is not discussed extensively by either Angell or Abramson, but a brief historical review would be in order. The agency was established in 1906, by the Food and Drug Act, partially in response to exposures such as muckraker Upton Sinclair’s famous novel, *The Jungle*, treating the appalling conditions in Chicago’s slaughterhouses.

Several medical disasters in 1937 and 1938 compelled President Franklin Roosevelt in the New Deal era to sign the Food, Drug and Cosmetic Act of 1938, which brought cosmetics and medical devices under government control and required that drugs be labeled with adequate directions for safe use. The quarter century that followed the

1938 bill saw a vast expansion of the pharmaceutical industry. As science matured and patent laws changed—making possible the profitable control of a drug by the company that owned it—the industry discovered, developed and marketed drugs, some of which no doubt had important value in treating disease.

Drug companies also used the 1938 law to devise the concept of prescription drugs—drugs available only through physicians at a price set by the companies.

Anti-regulatory action began under the Carter administration, but Reagan slashed the FDA's enforcement budgets in earnest. The routine actions by which the agency kept contaminated foods and problem drugs off the market—seizures, injunctions and prosecutions—dropped dramatically. The limits of the FDA budget paved the way for the 1992 bill, which provided additional funds for the agency—by putting it at the service of the pharmaceutical industry.

Bringing the companies into the drug approval process was vital for the pharmaceuticals because patents on new drugs are usually obtained before clinical testing begins, thereby eating into a drug's 20-year patent life—the time it can be sold without competition. To maximize profitability, the drug companies are under pressure to shorten the trials so that marketing the drug can get underway.

As public opposition to rapacious drug pricing has grown, Angell reveals that the industry's media campaign to counter this centers on its claims to be innovative. "Big pharma likes to refer to itself as a 'research-based industry,' but it is hardly that." (p. 73) In reality, the budget of the drug companies for research and development is dwarfed by massive marketing expenditures. Only a handful of important drugs have been developed—mostly based on taxpayer-funded research—in recent years. (R&D costs are tax-deductible.) This despite the fact that the number of clinical trials under way in any given year is staggering. In 2001, about 2.3 million American were involved in an estimated 80,000 studies.

"The great majority of 'new' drugs are not new at all but merely variations of older drugs already on the market. These are called 'me-too' drugs. The idea is to grab a share of the established, lucrative market by producing something very similar to a top-selling drug," (p. xvi) writes Angell. For example, there are six cholesterol-lowering drugs (Mevacor, Lipitor, Zocor, Pravachol, Lescol and the newest, Crestor). She continues: "But instead of investing more in innovative drugs and moderating prices, drug companies are pouring money into marketing, legal maneuvers to extend patent rights, and government lobbying to prevent any form of price regulation." (p. xix)

In 2002, of the 78 drugs approved by the FDA, only 17 contained new active ingredients and only 7 were classified as improvements over their older versions. Consequently, trouble may be looming for PhRMA. Some of the top-selling drugs, representing combined sales of some \$35 billion a year, are scheduled to go off patent within a few years of each other.

Pharmaceuticals also extend the life of a blockbuster drug that is going off patent by creating another drug just different enough to qualify for a new patent and then shifting users to the new drug. AstraZenaca's Nexium, a revamped version of the company's older drug, Prilosec, is a case in point. Shortly before the patent for Prilosec was set to expire, the FDA approved Nexium, which became the most heavily advertised drug in the US. "Today's purple pill is Nexium, from the makers of Prilosec," became a well-aided sound bite. After Nexium sales outstripped Prilosec's, the latter became a non-prescription drug, selling for a fraction of Nexium's cost.

The market for existing drugs is also expanded by redefining what constitutes medical need or illness. For example, the cutoff for high cholesterol has been lowered over the years, from more than 280 milligrams per deciliter to 240 and now to below 200. Although many doctors will recommend diet and exercise to achieve that level, it may be easier for the patient to take a prescription. The expansion of the definition

increases the demand for medication by millions of customers. The cholesterol-lowering drug Lipitor was the top-selling drug in the world in 2002, followed by its competitor Zocor. Similar processes are at work with remedies for other ailments, such as hypertension.

While me-too, or copycat, drugs flood the market—proliferating in many cases because of an industry-created demand—there are growing shortages for life-saving medicines, as companies try to free production capacity for drugs with bigger market potential. Angell reports that in 2001 there were serious shortages of drugs to treat premature infants, antidotes for certain drug overdoses, and an anti-clotting drug for hemophilia, as well as drugs used for cardiac resuscitation and gonorrhea and vaccines against flu and pneumonia, among other much-needed remedies. This season's flu vaccine shortage in the US imperiled thousands of high-risk sections of the population, including the elderly, children, pregnant women and those with chronic and life-threatening diseases such as cancer.

The situation is particularly stark in relation to the development of drugs for life-threatening diseases common in underdeveloped countries. In contrast to the cornucopia of drugs to treat erectile dysfunction, mood disorders, hay fever and heartburn, the pharmaceuticals are largely uninterested in developing drugs to treat widespread tropical diseases like malaria. Under the Clinton administration, the pharmaceuticals vehemently opposed South Africa's threat to produce or import generic drugs to control its raging HIV/AIDS epidemic. While the Clinton administration was eventually forced to back off from its warning of trade sanctions at the behest of the drug industry, the Bush administration stood alone among 143 World Trade Organization countries in opposing the relaxation of patent protection for HIV/AIDS medicines for Third World countries.

Angell cites some of the more egregious examples of direct-to-consumer (DTC) advertising. DTC was made legal in 1981 and extended in 1997 by allowing that only *major* side effects and contraindications had to be included in the media ads. The sky was then the limit: GlaxoSmithKline and its co-marketer Bayer signed a deal with the National Football League to promote Levitra, the me-too erectile dysfunction competitor of Viagra. Angell quips: "In fact, to watch the 2004 Super Bowl was to wonder whether football *causes* erectile dysfunction." (p. 116) Pfizer, the maker of Viagra, then phased out its old and tired promoter Bob Dole in favor of baseball star Rafael Palmeiro. The company also sponsors a Viagra car on the NASCAR circuit.

The explosion of drug ads in the 1990s coincided with the transition of many Americans to HMO-type health plans that covered the cost of prescription drugs. Researchers from Dartmouth Medical School found, among other things, that two out of five ads attempted to medicalize ordinary life issues. ("Routine hair loss or a runny nose, for example, became a medical problem requiring treatment with expensive prescription drugs." p. 154) Not only was advertising a boon for the drug industry, but it has also become the financial staple of many media outlets; most medical journals are also dependent on drug ads for survival. DTC ads are prohibited in every other advanced capitalist country except New Zealand.

Angell asks: "If prescription drugs are so good why do they have to be pushed so hard?... Important new drugs require very little marketing. Me-too drugs, by contrast, require relentless flogging, because companies need to persuade doctors and the public that there is some reason to prescribe one instead of another." (p. 133) Or perhaps instead of a far-cheaper, over-the-counter drug with equal or better benefits.

Big advertising agencies have become involved in the PhRMA direct-to-consumer advertising bonanza. Madison Avenue giants such as Omnicom, WPP and Interpublic are cashing in. Omnicom owns a medical education and communication company that ghostwrote the articles that turned Neurontin, a drug originally approved for a very limited use affecting only around 250,000 people, into a blockbuster taken by millions. This was

accomplished by marketing the drug for unapproved (“off-label”) uses. Angell notes that such practices are “illegal.”

Covering all bases, the pharmaceutical companies also fund a major portion of the costs of continuing medical education for physicians. They financially endow the meetings of professional organizations, such as the American College of Cardiology and the American Society of Hematology, where much of the continuing education for doctors takes place. This is combined with the \$11 billion worth of “free samples” the drug companies gave doctors in 2001.

“Marketing a disease is the best way to market a drug,” notes the well-known breast cancer expert, Dr. Susan Love. Abramson quotes Love in *Overdosed America* in regard to the marketing of Premarin, a hormone replacement therapy (HRT) drug. In an attempt to overcome bad publicity that linked the drug to cancer in 1975, Premarin was rehabilitated as a drug to prevent osteoporosis. With the help of the National Osteoporosis Foundation and a *New England Journal of Medicine* report on the positive effects of estrogen on heart disease, Premarin sales in 1992 once again soared to their 1975 levels. One out of five postmenopausal women in the US was taking hormones. Premarin use increased another 40 percent over the next three years and in 1995 became the most frequently prescribed brand-name drug in the US.

In 1998, the results of the first randomized controlled clinical trial of HRT were published, establishing that HRT increased women’s risk of heart disease by 50 percent. Despite this, Premarin was still the third most frequently prescribed drug in the country. Premarin’s demise came with the well-publicized Million Women Study in 2003.

Abramson writes: “Twenty million American women have taken HRT not only to relieve symptoms such as hot flashes and vaginal dryness but also believing that hormones would protect their hearts, decrease Alzheimer’s and Parkinson’s disease, prevent tooth loss and diabetes, strengthen their bones, preserve sexual function and urinary continence, improve the quality of their lives, and increase their longevity. The women who took HRT had access to the best care that American medicine had to offer: Compared with the population at large, they were more likely to have graduated from college, were wealthier, and were more likely to have received preventative care. Despite this, they unwittingly exposed themselves to increased risks of breast cancer, heart attack, stroke, Alzheimer’s disease and blood clots.” (pp. 70-71)

Related to this development is the marketing of drugs for osteoporosis—a disease whose risks were largely unknown until the HRT educational campaign was initiated in 1982. Drugs such as Fosamax and Actonel became approved by the FDA. However, a 2001 study in *NEJM* showed that even women with severe osteoporosis derived only small benefit from these drugs. Although these drugs increase the score on bone-density tests, they do not necessarily contribute proportionately to fracture resistance. This is because the new bone, as a result of taking the osteoporosis drugs, is formed primarily on the cortical bone—the outer part of the bone. Neither drug affects the locations of the body that have an internal structure of trabecular bone, bone that provides additional strength in areas of the skeleton most vulnerable to fracture, such as hips, wrists and spine.

“In the final analysis,” argues Abramson, “the ‘disease’ of age-related osteoporosis is not a disease at all, but the quintessential example of successful ‘disease mongering.’ The drug industry has succeeded in planting the fear that bones will suddenly and without warning ‘snap’ in women who had naively believed they were healthy.” (p. 219) He further states: “The net effect of drug treatment on the risk of serious illness in the highest risk women? Nothing—except the cost of the drug” (p. 214). Citing the NIH’s Study of Osteoporotic Fractures, the author reveals that regular exercise achieved twice the reduction in hip fractures compared to Fosamax use in women over 65.

One of the most serious risks attendant on the commercialization of

medicine, according to both Angell and Abramson, is “polypharmacy,” the taking of several prescriptions at once. Both authors point out that very few drugs have only one side effect. Besides the real possibility of drug interactions, multiple drug taking likely leads to one of the drugs interfering with organ function. It would be extremely difficult to gauge with complete accuracy the implications of all the various side effects—short term and long term—of multiple prescriptions on an individual. Drug testing is generally not slanted to produce such an evaluation. In any event, multiple prescription takers don’t all imbibe the same drug cocktails.

Drug company lobbyists, doling out tens of millions of dollars, are extremely well connected to both Republicans and Democrats. Drug company influence reaches deep into the Bush administration. Defense Secretary Donald Rumsfeld was CEO, president and chairman of G.D. Searle, a major drug firm that merged with Pharmacia and was then bought out by Pfizer. The elder George Bush was on Eli Lilly’s board of directors before becoming president. The 2003 meeting of PhRMA featured Bush the elder, Secretary of Health and Human Services Tommy Thompson, former FDA Commissioner Mark McClellan and the chairman of the Republican Senatorial Campaign Committee, Senator George Allen (R-Va.).

Last year, former FDA chief McClellan, brother of White House press secretary Scott McClellan, delivered a speech in Mexico in which he excoriated other advanced countries for regulating drug prices, demanding that the gap between the high costs of drugs in the US and those of other countries be bridged by the latter raising their own drug prices.

“The heavy hand of big pharma is felt at all levels of government. Nothing demonstrates that influence more plainly than the prescription drug benefit added to Medicare in late 2003,” writes Angell in *The Truth About the Drug Companies*. (p. 193) Described by both authors as a gargantuan bonanza for PhRMA, the Medicare “reform” is dealt with in more detail by Abramson. He notes that not only will the drug plan cost seniors more money (an average Medicare recipient who spent \$2,318 out-of-pocket for prescription drugs in 2003 will spend \$2,911 in 2007), but the bill also specifically prohibits the federal government from negotiating prices with drug manufacturers. PhRMA also helped defeat an amendment that would have funded research to determine which drugs actually provide safe and effective treatment—a worthwhile endeavor considering that 3 of the top 15 drugs most frequently prescribed for American seniors in 2003 were Celebrex, Vioxx and Fosamax!

While *The Truth About the Drug Companies* and *Overdosed America* have their independent areas of focus, there is much overlapping material. The contamination of science and the scientific process is a theme seriously addressed by both Angell and Abramson. Unfortunately, their works confirm that an in-depth analysis does not automatically lead to adequate conclusions.

Angell’s book ends with a whimper not a bang as she promotes the notion that “most of the changes could be achieved with simple congressional legislation.” Although she does mention that the pharmaceutical industry should be “regarded much as a public utility,” demanding that its books be opened, her basic advice is to strengthen the FDA; require that new drugs be compared not just with placebos but with older drugs for the same ailments; curb monopoly marketing rights; and prohibit direct-to-consumer advertising. As is often the case these days with many such powerful exposés, the ensuing recommendations appear as an impotent wish list attached to the faint hope that the powers-that-be can be persuaded to take the moral high ground and eliminate their anti-social excesses.

On a somewhat different note, Abramson correctly states that the failure of the market to serve American’s medical needs is not a “market failure, but a market success.” He adds: “Drug companies earn higher profits when more people use expensive drugs, not when people achieve better

health. Doctors and hospitals are paid more for doing more, largely without regard for evidence of improved health outcomes.... Health care providers that deliver high quality, efficient care are financially penalized for not delivering a higher volume of more intensive services, beneficial or not (referred to as the ‘perverse incentive’).” He goes on to say the “[A]merican politics, science, and health care has created an imbalance between corporate goals and public interest that is no longer self-correcting. In fact, it has become resistant to correction” (pp. 254-256).

An advocate of universal health care, Abramson pushes for his version of reforming the system. He believes that extending coverage to the uninsured would trigger a demand for accountability from industry and government, thereby resurrecting the medical watchdogs. If Americans would stop thinking that universal health care is “un-American,” then commerce and the state would fall into line.

In fact, extricating medical science from the clutches of the conglomerates is bound up with a far greater social transformation, which requires an attack on the foundations of the present economic system. The present disastrous state of health care in America, which results in tens of thousands dying prematurely each year as the result of a lack of coverage, is the logical outcome of a medical system entirely subordinated to profit. Protest and public awareness will not halt the process, nor will futile appeals to a bought-and-sold Congress.

The only rational solution to the crisis is a socialist program of providing universal, comprehensive medical coverage paid for by the government and turning the giant pharmaceutical firms into public utilities so that they can become the instruments for medical-scientific breakthroughs beneficial to all.

Despite their political limitations, *The Truth About the Drug Companies* and *Overdosed America* draw a disturbing picture of the inhuman character of production-for-profit in the medical sphere. The books are an important contribution to exposing the utter incompatibility of the present state of affairs with the health and welfare of the population.



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