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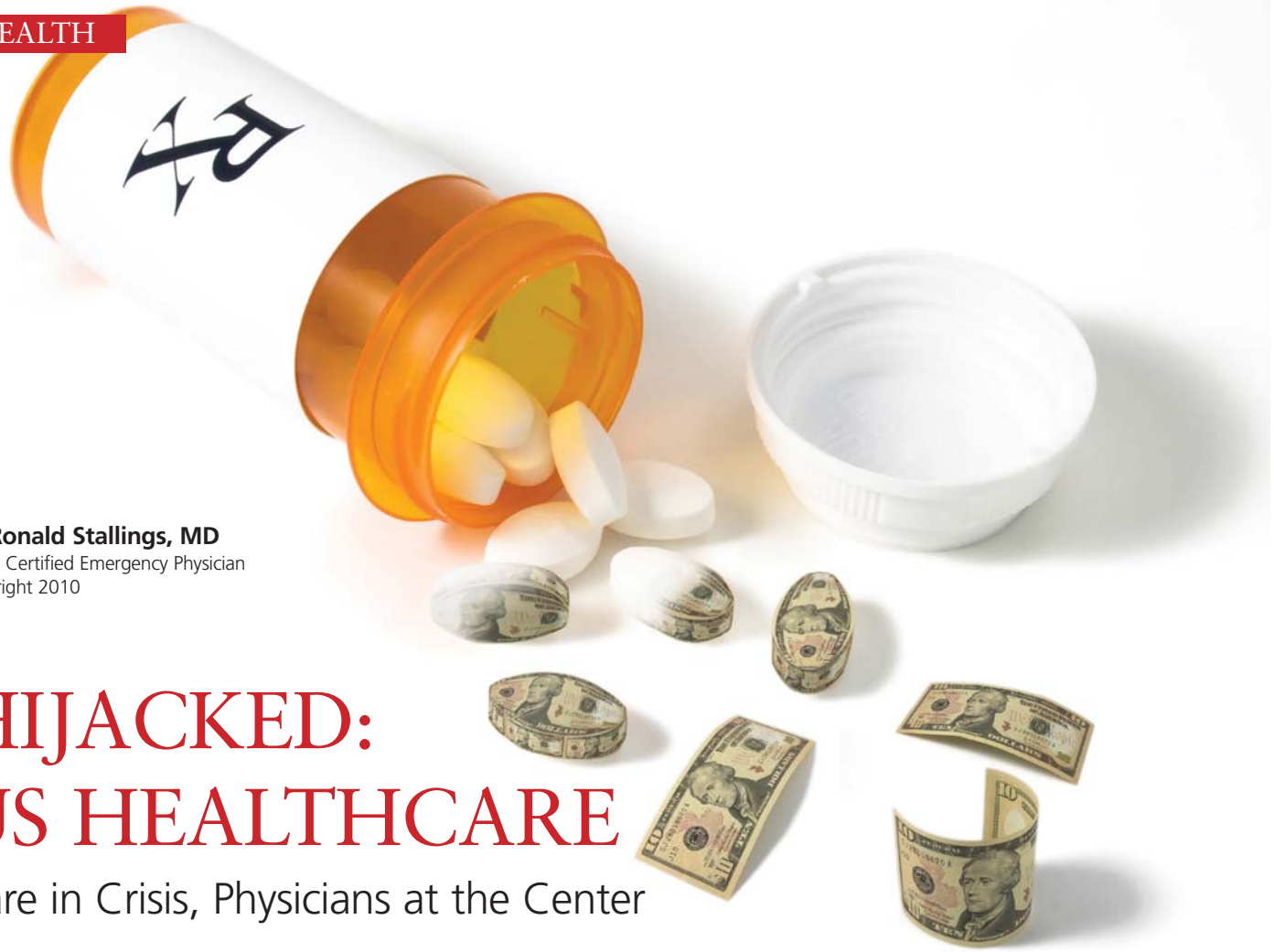


by Ronald Stallings, MD
Board Certified Emergency Physician

HIJACKED: US HEALTHCARE

Care in Crisis, Physicians at the Center

A Babe in the Woods

My patients that night, a group of young accident victims with head and neck fractures, had made my 24 hour ER shift especially exhausting. The early morning drive east along the Columbia River from the Oregon coast was lulling me to sleep. It is a beautiful drive, but the beauty is repetitive, and that morning it was blurring in and out of focus. My eyelids lifted and fell like lead.

The endless forms that I'd had to fill out that night on each of the patients had taken their toll, too. The forms are designed to facilitate patient evaluation, but I think they are really designed to squeeze the maximum billing out of each patient visit.

As I drove along, the next choice I made changed my life forever. I decided to fight off sleep by listening to a medical education tape series that I subscribe to. Barely able to focus, I snapped the tape into the player. The voice said,

The former editor of the New England Journal of Medicine states that it is no longer possible to believe most of clinical research published, or rely upon the judgment of trusted physicians or authoritative medical guidelines. The FDA, as of twelve years ago, is entirely funded by the pharmaceutical companies.

My eyes popped wide open. The speaker had my full attention. I suddenly knew that what he was telling me was the real reason behind my sabbatical leave the year before. And I thought about my present work place. The one and only meeting that I was ever asked to attend at that hospital was a marketing session. How could this be? How could the field of medicine I had dedicated 25 years of my life to have taken such a drastic wrong turn? How had the forces of self interest turned a once ethical institution into an establishment that places profits over people? Like a raging flood down the Columbia River, I felt a rush of memories—the irritants, the contradictions, the corruption I'd seen first-hand--it all poured over me.

American Medical Care has been hijacked by a variety of corporate, financial and pharmaceutical interests in a way that few fully understand. For the most part, American Medical Care no longer serves the patient. And, most sickening of all, physicians are often the willing instruments of that system.

That day I also wondered if the medical use of marijuana, which I had been ambivalent about, could possibly be part of the solution for medical care in the U.S. And I wondered if it also might save me from the guilt and outrage I was feeling?

Two years have passed since that pivotal day. I have read books and articles, talked with people here and in other countries. In the U.S., it seems that the hijacking is just about complete. It will take persistent hard work over a long period of time to turn this situation around and I want to begin by telling you about what I have learned.

Not Your Parents' History Lesson: A Short History of Drugs and Supplements

Many of the wonder drugs that transformed human health during the last hundred years are natural substances that have been in use for centuries. Penicillin, for example, was used by South American indigenous physicians some 800 years ago. Greenwald, Blackman, Dowell, Pascual, and Woodbury in their 1998 Time article, "Herbal Healing," reviewed some history,

Ephedra, the main ingredient of some over-the-counter asthma treatments, has relieved breathing problems in China for 5,000 years. An estimated 25% of all modern pharmaceutical drugs are derived from herbs, including aspirin (from white willow bark), the heart medication digitalis (foxglove), and the cancer treatment Taxol (Pacific yew tree). There might have been no sexual revolution without the birth-control pill, derived from a Mexican yam.

Studies have shown that wine, which has been available to many cultures throughout the centuries, is a major factor in the reduction of cardiovascular disease and longevity.

U.S. Doctors more commonly prescribed medicinal herbs before World War II and before the advent of wonder drugs like penicillin (Greenwald, et. al., 1998).

Also, less parochial minded individuals are turning to cannabis, which has been shown to be scientifically effective and has been used for thousands of years for a myriad of illnesses.

All of the alternative medications are popular, in part, because they are usually cheaper than prescription medications (Yan, 2009).

Linda Marsa, in her book *Prescription for Profits* notes that most of the reasons for the improved health of the world, in developed countries where infections had not been a major factor in morbidity and mortality, can be attributed to better sanitation of water and food as well as improved safety conditions at work and elsewhere.

It is, she says, "…impossible to overstate the importance of the discovery of penicillin…Common potentially deadly illnesses, after penicillin came on the scene, became relatively minor ailments. And the unprecedented collaboration between government and industry to mass-produce penicillin was a spectacular demonstration of what a well-financed, cooperative research effort could accomplish." (Marsa, 1997, p. 22)

Bacterial and parasitic diseases are the second leading cause of death worldwide. According to a report on antibiotic research released in 2009 by the London School of Economics and Political Science, 175,000 deaths are attributed to hospital-acquired infections each year in Europe alone (Harrell, 2009).

Despite the importance of effective antibiotics, the number of different antibiotics available to treat infections when they do occur is dwindling because pharmaceutical companies have neglected to invest in the development of new types of drugs (Harrell, 2009).

It is true in general that the development of any new drugs is declining sharply because the big money is to be made in lifestyle drugs and making small changes in existing drugs to seek approval to market them for treatment of other conditions.

My own trips to Central and South America have helped me understand the reasons that microbes have mutated and why we are losing the battle against them, with little help from the pharmaceutical industry. In many countries a person does not need a physician's prescription to buy an antibiotic. Patients who are experiencing flu-like symptoms will, at the encouragement of their pharmacist, self-medicate for a viral or other illness for which antibiotics are completely ineffective. This, of course, ruins the effectiveness of an antibiotic when it is needed to treat an infection. I contend that doctors and pharmacists, almost single handedly, are responsible for an infection epidemic that is sweeping the nation: MRSA [Methicillin-resistant Staphylococcus aureus]. MRSA is a potentially lethal disease caused by an over prescription of antibiotics, usually for viral illnesses for which there is no cure.

Laura Blue, in an October 17, 2008 Time Magazine article discussing MRSA, noted that, "The last two decades of the 20th century saw nearly zero progress, and in those years several disease-causing bacteria evolved resistance to commonly used drugs. Researchers at the Centers for Disease Control and Prevention found that more than 40% of staph infections in the U.S in 2006 were MRSA-- a bug that now kills more Americans a year than AIDS."

There are several reasons why it's not cost-effective for

pharmaceutical companies to invest in antibiotic research, according to a London School of Economics report cited by Eben Harrell's 2009 article in Time, "The Desperate Need for New Antibiotics." Here are the reasons.

"The course of antibiotic treatment is typically short because the drug helps patients get better quickly.
"Doctors tend to write fewer prescriptions for an effective antibiotic so that their patients will be less likely to develop resistance to the drug.

"And then, when resistance to a certain antibiotic inevitably develops, the drug becomes obsolete."

And, as we know, if it is not profitable, industry won't invest research dollars.

Underlying the criticisms is the understanding that products like Clarinex, Crestor, and Botox waste resources, keep drug spending high, and distract the industry from doing really important work....all the brainpower that is devoted to tweaking Claritin (to keep the patent going) or developing Botox and other "Lifestyle drugs" could have been used to cure cancer (and AIDS) (Hawthorne, 2005, p. 277).

Or, of course, developing new antibiotics.

How did we get to a point where drug companies are manipulating our healthcare system for their own profits? How did we get to a point where government agencies support the interests of Wall Street and Big Pharma and leave the rest of us with the world's most costly (2.3 trillion dollar a year) sick-care system that rewards us with a life expectancy that ranks 42nd in the world and is, by all accounts, broken? I will relay to you what I have found.

The Problem: Pharmaceutical Companies

Our Expense and Their Profits

Americans now spend a staggering $420 billion a year on prescription drugs, and that figure is growing by about 12 percent a year. When considering Pharma profits, as Dr. Marcia Angell writes in her 2004 book, *The Truth About the Drug Companies*, it is useful to note that "…the median net return for all other industries in the Fortune 500 is only 3.3 percent of sales, while Pharma has netted a whopping 18.5 percent. With the collapse of Lehman Brothers as well as many other commercial banks, the banks' financial records have come under intense scrutiny. Evidence shows, according to Dr. Angell, that "…commercial banking, itself no slouch as a well-connected and aggressive industry, runs a distant second at 13.5 percent." (Angell, 2004, p. 11) In Jacky Law's *Big Pharma*, 2006, the author notes,

Consider the world's top players. Just ten drugs earned no less than $48.3 billion in 2003. Each of these products on its own represents more income than most companies see in a lifetime. Leading the table was Pfizer's Lipitor which earned $10.3 billion, followed by another cholesterol reducing drug, Merck's Zocor, which had sales of $6.1 billion (Law, 2006, p.8).

How did they do it? According to Dr. Angell,

Before its patent ran out…the price of Schering Plough's top selling allergy pill, Claritin, was raised thirteen times over five years, for a cumulative increase of more that 50 percent, over four times the rate of general inflation (Angell, 2005, p. xii).

In 2001 the ten American drug companies in the Fortune 500 list… ranked far above all other American industries in average net return, whether as a percentage of sales (18.5%), of assets (16.3%), or of shareholders' equity (33.2%). These are astonishing margins (Angell, 20005, p. 11).

Drug Industry's Fiction that Research is their Biggest Expense

As Dr. Angell tell us,
Big Pharma often claims that it spends more money on research than on marketing, a claim that is easily shown to be untrue. According to the SEC and shareholder reports for 2001, the biggest drug companies spent, on the average, 35 percent of their revenues on marketing and administration. That is, approximately 19 billion dollars, but the figure leaves another 35 billion in expenses unaccounted for by Research and Development or other costs (Angell, 2005, p. 136).

I imagine that the other 35 billion in expenses are used for the gray area marketing activities which drug companies call "education," which include seminars for physicians and presentations at medical conferences.
Ilaria Passarani, health policy officer at the European consumer organization BEUC, commented,

"These major drug companies should be focusing on innovative medicines, but this report says they actually spend 23% of turnover on marketing and promotional activities, a third more than the 17% they spend on research and development" (Cendrowicz, Time, Nov. 28, 2008).

As an example of the global reach of pharmaceutical advertising, when I was in east Africa in 1998, in a very remote area of Kenya, I was approached by two young men. They were the picture of health and they had only two questions for me. "Do you know Mike Tyson?" and "How can we get some Viagra?"

The Inflated Cost of US Drugs

Because of the influence of the pharmaceutical industry on government, inflated drug prices have burdened U.S. patients and taxpayers with unnecessarily high costs for years. Although it is against the law, people have found a solution in buying drugs from Canada,

…where government regulation kept prices some 70 percent lower than in the United States (Hawthorne, 2005, p.163).

So how is the American consumer grappling with the cost? As Dr. Angell notes, *"They (low-income patients) may trade off drugs against home heating or food. Some people try to string out their drugs by taking them less often than prescribed, or sharing with a spouse…Not only do these low-income patients go without needed treatment but their doctors sometimes wrongly conclude that the drugs they prescribed didn't work and prescribe yet others." (Angell, 2005, p xii)*

Boosting Profits by Prescribing for Lifestyle Benefits

Cialis is the third of the highly advertised impotence drugs, approved in November 2003. When Pfizer launched Viagra in 1998 it insisted that the drug was aimed at older men suffering from a diagnosed medical condition called erectile dysfunction. But as the ads with beautiful blondes and hulking sports stars made clear, that strategy was quickly abandoned, and now all three brands are basically pitched to younger men like expensive sex toys. Indeed, the fastest-growing group of Viagra users from 1998 to 2002 were men aged 18 to 45 according to a survey by the pharmacy benefits manager Express Scripts, Inc. (Hawthorne, 2005, p.276).

Neglecting Urgent Human Needs to Pursue Profit

I and many of my colleagues believe that development of lifestyle drugs drains the resources of the industry when those same resources would be better suited to research on HIV/AIDS and other life threatening disorders.

In 2004, the total number of new active substances approved for use by the FDA had dwindled to a new low of just 23, down from 31 recorded in 2003, and 29 in 2002. Of those 23 new pharmaceuticals, says Ian Lloyd, Managing Editor of the Global Pharma Research Database, only four can be described as significant therapeutic advances (Law, 2006, p. 10).

The development of new antibiotics appears to take a back seat to high profits that pharmaceutical companies find in lifestyle drugs such as cholesterol-lowering drugs, Viagra, Propecia, etc. (Harrell, 2009).

Designing New Conditions and New Drugs to Treat Them

Jacky Law, in her 2006 book *Big Pharma*, described how Irritable Bowel Syndrome, as well as other diseases, was a disorder fostered by pharmaceutical companies to sell their drugs. "Their marketing machine is very methodical: The first step of the strategy was to set up an advisory board with one key opinion leader from each state of Australia. The job of this doctor would be to provide advice to the corporate sponsors of current opinion in gastroenterology and on 'opportunities for shaping it'. Further work included developing 'best practice guidelines' for diagnosing and managing IBS." (Law, 2006, p. 58)

Law goes on to explain how osteoporosis [in addition to such conditions as Attention Deficit Hyperactivity Disorder (ADHD), Restless Leg Syndrome (RLS), and Fibromyalgia (FM)], is a classic example of how corporations have changed the way populations think about disease, in this case about bone loss. In the case of osteoporosis treatments, you have to take the costly drugs for several years to show the slightest drop in risk. Also the risk is not equal across racial lines. For instance black people are less like to develop osteoporosis than whites though it is marketed to African Americans equally (Law, 2006, p. 59).

The Invention of Pre-Hypertension and Pre-Diabetes

Disorders have been reclassified in order to develop a great number of patients. A good example of this redefinition has taken place with anti-hypertension medications. According to Dr. Angell, "High blood pressure was defined for many years as BP above 140/90. An expert panel then introduced something called pre-hypertension in 2003, which is between 120/80 and 140/90. Overnight, people with blood pressures in this range found they had a medical condition." (Law, 2006, p. 48).

I have seen the same use of bogus science and playing fast and loose with diabetes. I have an aunt who is in her late 70's. I told her that her blood sugar of 120, which without medication has never gone higher than 130, is not diabetes like her MD stated. Nevertheless, because she trusts her physician, in her mind it just has to be so, regardless of the textbooks and reference material that I sent her and my encouragement to get a second opinion.

Corporate Strategies to Promote New Medical Conditions

In many cases, the formula is the same. Groups and/or organizations are orchestrated, funded, and facilitated by corporate interests, often via their PR and marketing infrastructure. A key strategy of the organizations is to

target the news media with stories designed to create fears about the condition or disease and draw attention to the latest treatment. The media is a poster child for this use of the "stay tuned for the film or story at 11:00" style of journalism.

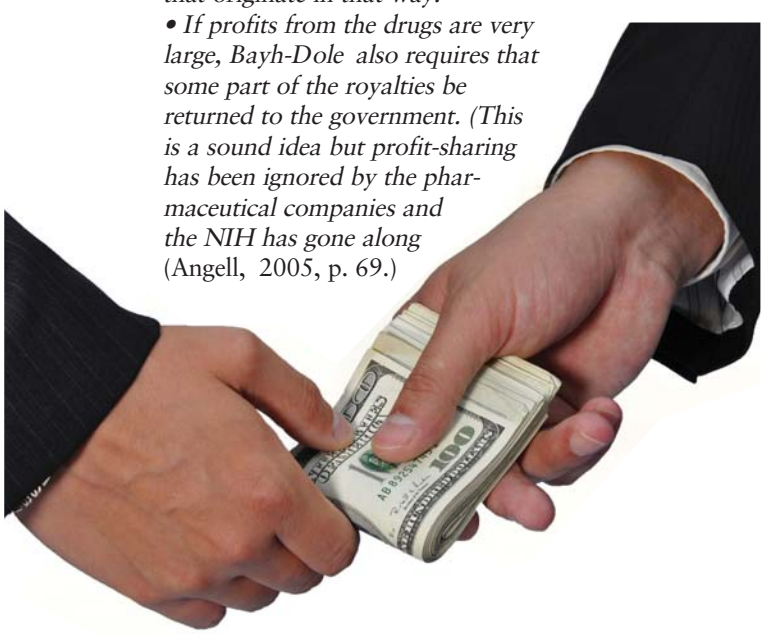
Company-sponsored advisory boards supply the "independent experts" for these stories, consumer groups provide the "victims", and PR companies supply media outlets with the positive spin about the latest breakthrough medications (Law, 2006, p. 52).

The Unholy Partnership between Congress and Big Pharma--Good Intentions Gone Wild

In 1980, Senators Birch Bayh and Bob Dole teamed up to sponsor a bill that would give companies exclusive licensing rights to discoveries arising from federally funded research and would encourage academic scientists to seek commercial applications for their work. Although it accelerated the process of commercializing inventions developed within universities and government, one effect of the bill was to decrease the crucial element of sharing information among scientists (Marshall, 1996, p. 1359).

The Bayh-Dole Act and, also in 1980, the Stevenson-Wydler Act allowed the NIH to specify that certain taxpayer-supported work in medical schools, teaching hospitals, and small biotech companies will not be patented but will remain in the public domain. Bayh-Dole makes the following requirements:

- *Work licensed to drug companies must be "available to the public on reasonable terms."*
- *Work patented and licensed under the terms of Bayh-Dole must be reported to the National Institutes of Health (NIH) so that the NIH can keep track of drugs that originate in that way.*
- *If profits from the drugs are very large, Bayh-Dole also requires that some part of the royalties be returned to the government. (This is a sound idea but profit-sharing has been ignored by the pharmaceutical companies and the NIH has gone along* (Angell, 2005, p. 69.)



The result of the Bayh-Dole Act is 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 bio tech start-up companies, and the NIH, for the discovery of new drugs. At least a third of the drugs marketed by the major drug companies are now licensed from universities or small biotech companies, and these tend to be the most innovative new discoveries (Angell, 2005, p. 8).

The HIV/AIDS drug AZT, for example, is a good illustration of Bayh-Dole in action. AZT (Zidovudine) was the first drug on the market to treat HIV/AIDS. Sold under the brand name Retrovirus, it was originally manufactured by the drug company Burroughs Wellcome, then by the much larger British firm GlaxoSmithKline. The profits went at first to Burroughs Wellcome and then to GlaxoSmithKline, but the research and most of the development was done in government and university laboratories (Angell, 2005, p. 24)

To benefit from taxpayer-funded scientific research, many international pharmaceutical companies are locating their facilities near MIT (Angell, 2005, p. 13).

European companies, too, are now locating their research and development operations in the United States. They claim it is because we don't regulate drug prices, but more likely it is because they want to feed on the research output of American universities and the NIH. In other words, it's not private enterprise that draws them here but the very opposite---publicly sponsored research enterprise (Angell, 2005, p.xvii).

Of the seven innovative drugs approved in 2002, only three came from members of the Pharmaceutical Research Manufacturers of America (PhRMA). …Nothing from any major American drug company. (Angell, 2005, pp. 55-56).

And the research was all paid for by the taxpayer-funded NIH.

Now primarily a marketing machine to sell drugs of dubious benefit, the drug industry uses its wealth and power to co-opt every institution that might stand in its way, including the US Congress, the Food and Drug Administration, academic medical centers, and the medical profession itself. Most of its marketing efforts are focused on influencing doctors, since they must write the prescriptions (Angell, 2005, p. xviii).

How the Industry Addresses Drug Safety Problems

The Problem with Avandia

For the 200 million diabetics worldwide, the past few years have brought some disturbing findings about risks

that may be associated with certain diabetes drugs. Recent concerns that Avandia might cause cardiovascular problems, for example, have led some experts to call for it to be pulled from the market, although it remains available today (Payne, 2009).

Some studies link Avandia to increased cardiovascular risks such as heart attack and death, a serious concern considering that people with diabetes face two to four times the risk of cardiovascular disease compared with the general public. A 2007 meta-analysis published in the The New England Journal of Medicine found that people taking Avandia had a higher risk of heart attack and death from cardiovascular causes. More recently, a study published in the Archives of Internal Medicine, found that the risk of death and heart failure for older people with diabetes seems to be greater in those taking Avandia than those taking Actos, another medication in the same class. Nevertheless, the study funded by GlaxoSmithKline, nicknamed the RECORD trial, found that taking Avandia did not seem to increase the risk of heart attack or death (Payne, 2009).

The FDA says that it will require GlaxoSmithKline to conduct a cardiovascular outcome trial on Avandia to provide a definitive answer to the question of Avandia and an unacceptable risk of cardiovascular disease (Payne, 2009).

Speaking on the subject of Avandia, Sidney Wolfe, editor of worstpills.org and Director of Health Research Group at the nonprofit Public Citizen reminds us, "Any drug that is worth anything needs to decrease the risk of cardiovascular disease." (Payne, 2009)

As a physician, my distrust of studies sponsored by the manufacturer of the product being studied is well founded. Again and again the industry has manipulated studies. The evidence is clear.

How the Industry Ignores Cheap but Effective Drugs

High Blood Pressure Treatments

A major study, the ALLHAT Antihypertensive Trial, reported in the Journal of the American Medical Association 2002, demonstrated that a common water pill was just as effective for lowering blood pressure and actually better for preventing some of the devastating complications of high blood pressure, mainly heart disease and strokes, than blood pressure medications promoted by the drug companies. The Director of the National Heart, Lung, and Blood Institute was unequivocal in his conclusion. "ALLHAT shows that diuretics are the best choice to treat hypertension, both medically and economically." (Angell, 2005, p. 96)

At that time, Norvasc, a product of Pfizer, Inc., was the most heavily advertised drug in The New England Journal of Medicine. Not surprisingly, there were no advertisements for the common water pill. As a result, of the top fifty drugs used by senior citizens in 2001, Norvasc was the second most commonly used and diuretics like the one that proved superior in ALLHAT appeared nowhere on that list (Angell, 2005, p. 97).

How the Industry Tests the Effectiveness of New Drugs

Drug companies can't market a new drug until they have carried out a clinical trial to show that the drug is safe and effective compared to a sugar pill. That, however, raises another problem. Can we believe in the accuracy of those trials? After all, that crucial last stage of research and development is usually sponsored by the company that makes the drug, even if the early research was done elsewhere. Is there some way that companies are able to rig clinical trials to make their drugs look better than they are? Unfortunately, the answer is yes. Trials can be rigged in dozens of ways, and it happens all the time (Angell, 2005, p. 95).

Doctors rely for their information on medical journals, textbooks, seminars, medical education courses, and, unfortunately, drug company marketing. Textbooks and the beliefs of so-called "Thought Leaders" are no better than the evidence on which they are based, and that evidence, in most cases, comes from research reports in medical journals, so it is crucial that those reports be unbiased. Increasingly, clinical research on drugs is sponsored by the companies that manufacture them.

The Industry's Efforts to Build New Markets for Existing Drugs

The drug industry works in various ways to raise profits without making any useful scientific contribution. They test uses of existing drugs to be used for other conditions so that they can expand the market for approved drugs. And they package new disease "conditions" that can be treated with existing drugs.

For example, most young women experience some premenstrual tension from time to time . Lilly's launch of the prescription drug Sarafem made premenstrual symptoms a disease---now called "premenstrual dysphoric disorder" (PMDD). Sarafem, the treatment for PMDD, is the same as Prozac, a commonly prescribed antidepressant, but marketed at a higher price (Angell, 2005, p. 86).

Lax controls coupled with huge potential financial gain from lifestyle diseases led US attorney Richard Scruggs to take on Swiss drug company Novartis a few years ago for allegedly inventing the condition ADD. This was a serious charge, alleging the manufacturer of the their top selling ADD drug, Ritalin, had conspired with the APA to package up common behavioral traits – such as being unable to concentrate for long on everyday tasks- and define them as a single disorder……(Hawthorne, 2005, p. 254).

How the Industry Skirts the Question of Effectiveness

The Emergence of Biased Research

Dr. Angell comments on the increasing control exercised by the pharmaceutical industry.

Drugs companies have considerable control over the way the research is carried out and reported. That is new. Until the 1980s, researchers were largely independent of the companies that sponsored their work. Drug companies would give a grant to an academic medical center then step back and wait for the faculty researchers to report the results. Now, however, companies are involved in the details of research from design of the study through analysis of the data to the decision whether to publish the results. This has made bias extremely likely. Researchers don't control clinical trials any more; sponsors do (Angell, 2005, p. 100).

"I saw companies begin to exercise 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." The deceptive methods include comparing new drugs to sugar pill instead of testing their effectiveness in comparison to drugs currently in use." Angell says that these are tactics that are difficult to spot when reviewing research. Angell notes that in her tenure as editor of the New England Journal of Medicine, they would reject such studies, but later would see them published in other journals (Angell, 2005, page xviii).

Beginning in the 1980s, when drug companies became richer, more powerful, and more profit-driven, they became less willing to sit back and wait for academic researchers to produce research results. Instead of relying on academic centers, companies turned to the new for-profit research industry that grew up to serve them (Angell, 2005, p. 100).

The doctors are not themselves trained researchers, so they do what they are told or risk losing their lucrative deals with the for-profit research contractors. The contract research organizations, in turn, answer only to big pharma (Angell, 2005, p. 101).

Many researchers have lost their independence but have profited greatly in doing so. This was the case when I worked at a "Doc in the Box" in Vancouver, Washington where an investigational study involving asthma was being conducted. As clinic staff, we were given no guidelines except to refer anyone with a wheeze to the study. Of course the owner of the clinic was paid very well for each person inducted into the study. In hindsight, I see why the owner of the clinic, a very wealthy doctor who was involved in a number of money-making projects, devoted so much of his time and attention to this aspect of his empire.

They [doctors] have lucrative financial arrangements with drug company sponsors that would have been impossible twenty years ago. Researchers serve as consultants to companies whose products they are studying, become paid members of advisory boards and speakers' bureaus, enter into patent and royalty arrangements together with their institutions, promote drugs and devices at company-sponsored symposiums, and allow themselves to be supplied with expensive gifts and luxury trips (Angell, 2005, p. 103).

At the same time, many research studies sponsored by drug companies exclude the researcher from having any knowledge of the outcome or giving them access to complete data (Angell, 2005, p. 103).

I heard an emergency medicine device presentation delivered by a Harvard researcher who addressed an audience of physicians. He proclaimed loudly that he had no financial connection to the product and at the same time told his audience that they were "backward idiots" if they were not using the product. In the course of the presentation, the speaker did disclose that he had been hired by a law firm to give expert testimony in defense of another product line that the same manufacturer had produced. I would also guess that he had not come to speak to us without compensation. He was listed as a

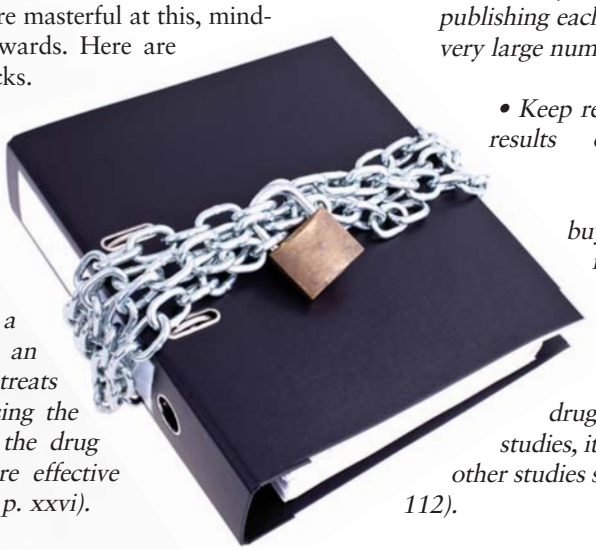
member of a speakers' bureau, a bureau no doubt funded by a pharmaceutical manufacturer.

A recent survey found that industry-sponsored research was nearly four times as likely to be favorable to the company's product as NIH-sponsored research. That is in accord with a large body of evidence showing that researchers with industry connections are far more likely to favor company products (Angell, 2005, p. 106).

In the case of the calcium channel blockers to control high blood pressure, for instance, one survey of seventy articles about their safety found that 96% of the authors who were supportive of the drugs had financial ties to the companies that manufactured them, while only 37 percent of authors who were critical had such ties (Angell, 2005, p. 107)

Research Tricks

Big Pharma spends an enormous amount of its immense resources to circumvent and manipulate the system of drug evaluation. They are masterful at this, mindful of the enormous rewards. Here are some of the research tricks.



Compare the new drug's effectiveness to that of a placebo. Research bias can be built into a study of effectiveness if the new drug is compared to a sugar pill rather than an older effective drug that treats the same condition. Using the sugar pill comparison, the drug may appear to be more effective than it is (Angell, 2005, p. xxvi).

When this method is used, even serious readers may automatically conclude that it is better than older drugs already in use. Other practices noted by Dr. Angell include comparing the new drug's effectiveness with an effective older drug but lowering the dose of the older drug in the trial so it will appear ineffective or, giving too high a dose of the older drug so it will have side effects. Researchers may test the drug's safety by enrolling only young subjects in a trial of a drug intended for use by older people. Because young people generally experience fewer side effects, the drug will look safer in these trials than it would in practice. Also, the trial can be designed to be too brief to be meaningful, they may present only part of the data—the part that makes the product look good—and ignore the rest. (Angell, 2005, pp. 107-108).

Also, the researchers or the drug company may choose to suppress negative results. An empirical survey of article publishers demonstrated that they are more likely to publish positive results. The journal editors' rationale is that people want to read positive and useful information rather than negative information.

Companies Aggressively Seek FDA Approval for New Drugs

The Pharmaceutical Company's first task in getting approval is to build a clinical case by designing trials both pre and post approval to show their product in the best possible light. These are the publishing tricks:

- *Report your trial's results only at the point when they come out well. Publish the helpful 6-month results, but bury the weak 12-month results.*
- *Test it against a small group of rivals, to show it is as good.*
- *Conduct your trial across a number of countries, publishing each result separately to suggest that a very large number of trials back your drug.*
- *Keep republishing "positive trials." Negative results can be buried in an obscure journal.*
- *Let the journals know that you will buy millions of dollars worth of reprints if they review your product favorably (Law, 2006, pp. 45-46.)*

The FDA may approve the drug on the basis of minimal evidence. If the drug shows positive results in only two studies, it may be approved even if a majority of other studies show negative results (Angell, 2005, p. 112).

How the Industry Extends the Life of Its Patents

In a Time Magazine article, November 28, 2008, Leo Cendrowicz described charges brought against European drug makers for artificially inflated prices.

By using patent lawsuits and other delaying tactics to prevent cheaper generic medications from entering the market, the drug manufacturers cost European consumers up to $4 billion over an eight-year period ending in 2007. European Union Competition commissioner Neelie Kroes contends, "Market entry of generic companies and the development of new and more affordable medicines is sometimes blocked or delayed at significant cost to healthcare systems, consumers, and taxpayers."

The damning indictment was part of a 400-page, interim Commission report based on evidence collected during

January raids at the headquarters of some of the world's biggest drug companies, including US companies Pfizer and Johnson and Johnson, Britain's GlaxoSmithKline, Anglo-Swedish giant AstraZeneca, and Sanofi-aventis of France. The other companies known to be raided were Wyeth, Merck, Bayer Schering Pharma, and Roche, as well as generic firms Teva and Sandoz.

The most common tactic allegedly involves filing multiple patent applications often for the same medicine—so-called patent clusters—that stake out an extremely broad claim for a drug's intended use and physical form. This may include use as a liquid, a capsule or a pill. In one case, the E.U. found 1,300 patents for a single medicine.

…..generic medicines can cost as much as 90% less than branded drugs: total savings gained by copycat drugs [cheaper forms marketed after the patent expires] …amounted to at least $17 billion over the 2000-2007 period examined by the Commission.

How the Industry Promotes the Effectiveness and Safety of their New Drug

For years any change in my practice was based on journal articles and seminars. Most of the time, the new treatments were just old pills in new bottles, usually at a higher price.

Editor of the British medical journal, Lancet, Dr. Richard Horton, quoted in *Big Pharma*, describes the industry's methods.

"A pharmaceutical company will sponsor a scientific meeting. Speakers will be invited to talk about a product, and they will be paid a hefty fee… for doing so. They are chosen for their known view about a particular drug or because they have a reputation for being adaptable in attitude towards the needs of the company paying their fee."

The meeting takes place and the speaker delivers a talk. A pharmaceutic communications company will record this lecture and convert it into an article for publication, usually as part of a collection of papers emanating from the symposium. This collection will be offered to a medical publisher for an amount that can run into hundreds of thousands of pounds. The publisher will then seek a reputable journal to publish the papers based on the symposium, commonly as a supplement to the main journal.

The important point is that there is very little peer review in a whole raft of journals that pose as science journals. Their process of publication has been reduced to marketing dressed up as legitimate science…" says Horton (Law, 2006, p. 47).

What is disturbing is that I, along with probably a majority of physicians, put an enormous amount of credence into these studies which are of dubious quality. These studies result in changes to our practice, unneeded extra healthcare costs, and, in some cases, death and disability for our patients.

How the Industry Advertises its Drugs

Television advertisement of drugs, sanctioned by the FDA, has increased in frequency and sophistication in recent years.

To pharmaceutical industry executives, some doctors, some consumer groups, and FDA officialdom, this is just an example of the government doing its job and trying to educate the public. But to most doctors, many consumer groups, and other critics, this is salesmanship, not education, and something as serious as medicine--something that can have horrible side effects, that can save lives if used properly or kill people if something goes wrong – should not be pitched like toothpaste (Hawthorne, 2005, p. 254)

Often advertising is designed to educate about newly discovered disorders for which the pharmaceutical industry has found a drug treatment. However glitzy and sexy the advertisements and movies may be (see the film *Love and Other Drugs*, 2011), they are nothing more than promotions along with loopholes and subliminal maneuvers that enable pharmaceutical companies to influence patients, influence lawmakers, and reap huge profits.

The pharmaceutical industry is everywhere in Washington, all but writing the Medicare prescription drug bill, fielding more lobbyists than there are members of Congress, flinging gifts and trips at doctors and trying to prevent double-blind drug trials that pit one drug against another, instead of against a placebo (Angell, 2005, p.106)

Drug Companies Defend their Higher Priced Drugs Against All Challengers

In her 1997 book *Prescription for Profits*, Linda Marsa describes Genentech's promotion of their drug t-PA to illustrate the tactics drug companies use to maintain the market for their higher-priced drugs. T-PA, used in cases of heart attack, costs an estimated $2,000 per dose. When research scientists investigated the effectiveness and safety of a less expensive drug, streptokinase, or a combination of t-PA and streptokinase to lower costs, Genentech attacked the study by spreading rumors that,

in cases of heart attack, the control group would receive a placebo and that patients would have to pay their own costs. (Marsa, 1997, p. 211) Doctors, after hearing word of this deception, refused to refer their patients to the study.

Despite evidence to the contrary, Genentech still contends that its drug t-PA, a very costly medication, is more beneficial than Streptokinase, a less expensive alternative.

The studies comparing t-PA and the less expensive streptokinase, titled TIMI and GISSA-2, showed that while streptokinase was linked to greater numbers of bleeding problems and allergic reactions, t-PA was linked to higher incidences of strokes and re-occlusion (Marsa, 1997, p. 204). Another very large study, the International Study of Infarct Survival, ISSI-3…showed that t-PA was not more effective than less expensive medications, and that t PA had a higher risk of strokes. Marsa reported that "Oxford's Rory Collins, one of the British ISIS-3 researchers, said that if U.S. doctors used streptokinase, 'it would save more than $100 million each year.'" (Marsa, 1997, p. 213)

Myocardial infarctions can be caused by a combination of events, i.e. vessel narrowing or spasms, plaques, and blood clots, to name a few; though the majority of them may include or be solely caused by vasospasms which inexpensive beta blockers can control. Attention is diverted away from that important cause because beta blockers are cheap to make and have slimmer profit margins.

I am not convinced that t-PA is our end point drug and that it is the most effective drug to treat most MIs, especially given a more cost-effective, equally effective, and less-promoted alternative. After all, in most post mortem heart samples of diagnosed heart attacks, no blood clots or arterial blockage can be found. This raises the question of hype versus scientific clarity.

What I find most disturbing is that as an emergency physician I am a front-line physician for t-PA use and it appears that I and my colleagues are, through our ignorance, being manipulated and pressured into using t-PA instead of an equally effective and less expensive medication. My personal survey of in-hospital pharmacies revealed that Streptokinase, once at a cost of $800, is no longer available. t-PA is now the only choice available and it has doubled in price to a whopping $4,000 a dose. What was once obscure to me is now clear. My sabbatical leaves were a reflection of the lunacy and corruption in my field.

Academic Researchers Face Growing Conflicts of Interest

University research facilities, once the setting for disinterested scientific study have, since the 1990's, formed public-private partnerships with pharmaceutical companies. The public universities' historic need for funding made them vulnerable to infusions of cash from the pharmaceutical giants once the government put laws in place to encourage that relationship.

A 1996 Harvard survey of 210 U.S. companies that fund academic scientists reached some disturbing conclusions. The study revealed that the ethical dilemmas and practical problems sparked by industrial intrusions on campus…were now endemic and magnified a thousand fold. …the evidence was overwhelming that companies did, in fact, dictate what research was conducted by government supported scientists (Marsa, 1997, p. 253).

Drug Company Sponsorship of Patient Advocacy Groups

Another form of marketing disguised as education is the sponsorship of patient advocacy groups. Many of these groups are simply fronts for drug companies. Dr. Angell notes, "People who suffer from a certain disease are looking for a support network devoted to expanding awareness of the disease and they are pleased to find one." (Angell, 2005, p. 151-152). The groups they find, however, may be just another marketing tool for a drug company.

Drug companies also set up patient advocacy groups as magnets for people with specific diseases. These groups can be rich sources of patients for clinical trials. Most human subjects are now recruited through these kinds of efforts, not referred by their doctors. They are usually