Licensed to Ill

Increasingly, drug companies aren't just selling cures. They're also marketing disease.

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One of the biggest concerns in the United States today is that health care costs keep accelerating upwards, growing faster than inflation, faster than our paychecks. But no one seems to be able to agree on why, exactly, costs are climbing so rapidly. About a decade ago Paul Krugman argued, quite convincingly, that health care keeps getting more expensive simply because Americans keep demanding the latest and most expensive treatments, and are prepared to pay good money to get it—well, some of them, at least. As such, rising health care costs *per se* are nothing to fret over: modern medicine keeps getting better and we should expect to pay more for it.

Fair enough, but here's an alternate theory: health costs are zooming upwards in part because millions of more-or-less healthy Americans are being misled into thinking that they actually have diseases and disorders that require expensive medical treatment. No? Too outlandish? Consider this story. In 1998, Lilly, one of the world's largest pharmaceutical companies, was on the verge of losing its patent on fluoxetine (more commonly known as Prozac) worth over $2 billion annually. However, if Lilly could find a new use for the drug, the patent could be extended. That year, Lilly helped fund a "roundtable" of researchers to gather in Washington D.C., along with staff from the Food and Drug Administration to discuss a scientifically controversial condition called "premenstrual dysphoric disorder" (PMDD), which had only recently, and after much controversy, been included in the appendix of the Diagnostic and Statistical Manual—the bible of psychiatric disorders—as a disorder "under evaluation." But the Lilly-funded researchers soon published an article in a small medical journal suggesting, falsely, that the debate was over and that PMDD could now be considered a "distinct clinical entity," distinct from the stress and tension that can accompany ordinary PMS.

Lilly has not said what role it played in turning the "roundtable" into a journal article, but by 1999, the article helped convince the FDA to approve the use of fluoxetine to treat PMDD—and extended the patent until 2007. Lilly simply repackaged the drug in lavender pill-form, renamed it Serafem, and began marketing it to women. Never mind that independent researchers questioned whether PMDD even existed as a condition. Never mind that Europe's drug regulators raised serious questions about PMDD and criticized Lilly's clinical trials that purported to show the benefits of Serafem. Never mind that even the industry-friendly FDA was appalled at Lilly's television ads, with their too-vague tagline: "Think it's PMS? It could be PMDD." Undaunted, Lilly continued its advertising barrage, trying to convince women who thought they were experiencing regular PMS-related distress that, *actually*, they might well have a serious disorder that required heavy medication. Soon thereafter, both Pfizer and GSK got their own anti-depressants approved for treating PMDD. For all intents and purposes, the "debate" over whether PMDD was a disorder—let alone requiring medication with serious side-effects—was over. Industry money had carried the day.

From a pharmaceutical company's perspective, the big money can be made not only by selling drugs to the sick, but by selling drugs to the *healthy*, the people who don't even know that they need drugs yet. A recent *Reuters Business Insight* report, designed for drug company executives, suggested that the drug companies can reap billions by "creat[ing] new disease markets." That involves convincing people that "problems they may previously have accepted as, perhaps, an inconvenience"—such as, for instance, the distress that can accompany PMS—are in fact "worthy of medical intervention." In other words, nothing short of the medicalization of everyday troubles. Cheerfully, the report believes that drug companies are up to the task: "The coming years will bear greater witness to the corporate sponsored creation of disease."

If it sounds ominous, it is. As Ray Moynihan and Alan Cassels document in their new book, *Selling Sickness*, the "corporate sponsored creation of disease" is rapidly gaining ground, often with appalling results. To be sure, many diseases are obviously very real and the latest treatments can often do a world of good. But some health problems are so mild or temporary—high-blood pressure, for instance, or menopause—that powerful treatments can often do more harm than simply leaving it alone. Yet that hasn't stopped drug industry from tapping its multi-billion dollar marketing budget to "raise awareness" for new illnesses or ginning up scare stories over light medical conditions. The gap between "marketing messages and scientific truths… is often as wide as it is frightening," say the authors, and this book is an attempt to bridge that gap.

Here are some strategies for marketing illnesses. The first thing to do is to hire a PR firm to "brand" a certain condition. When GSK, an American drug company, wanted to repackage its best-selling anti-depressent, Paxil, to treat "social anxiety disorder"—a questionable variation of "social phobia" that requires medication rather than therapy—it hired PR firm Cohn & Wolfe to help raise awareness about the condition. Slogans were developed: "Imagine being allergic to people." Posters depicting sad men and women brought to light the symptoms, which only *seem* like normal nervousness to the untrained eye: "You blush, you sweat, shake—even find it hard to breath. That's what social anxiety disorder feels like." Journalists were faxed press releases so that they could write up attention-grabbing stories about the new disorder in the *New York Times* and *Wall Street Journal*. (Does the deadline-pressed journalist need a bit of color for her story? No problem! Patient-advocacy groups, usually funded by drug companies, can provide patients to interview.) GSK even got University of California psychiatrist Murray Stein to vouch for the drug. Stein, it turns out, was a paid consultant to seventeen drug companies, including GSK, and had run company-funded trials of Paxil to treat social anxiety disorder.

Celebrities, too, can help bring new diseases to the public eye—as football star Ricky Williams did in 2002 after revealing that he had social anxiety disorder. His appearances on *Oprah* and other talk shows generated a wave of publicity for GSK, and Paxil, although few of the shows disclosed that Williams was being paid by the company to raise awareness for the disease, and rarely was it mentioned that doctors had long known about severe withdrawal effects associated with Paxil.

Oftentimes celebrities can be paid to say things that drug companies could never get away with: In 2002, supermodel Lauren Hutton appeared in a *Parade* magazine cover story—a newspaper insert seen by over 70 Americans—telling her audience that her "No. 1 secret" for dealing with menopause was hormone therapy. Perhaps lost on most readers was the fact that Hutton had signed a contract with Wyeth, a drug company offering hormone therapy for menopause, and that under FDA regulations the company itself could never have made such one-sided claims. (Many doctors dispute that menopause should even be considered a medical condition, and the most comprehensive trials on hormone therapy, run in 1998, found that drugs did no better than placebos at treating symptoms of menopause, and might even increase a woman's chance of having a heart attack. Wyeth, resilient as ever, responded to the trial results with a new marketing campaign to remind women and doctors of the dangers of estrogen loss at menopause.)

Everywhere one looks, drug money is sloshing about. During the 1990s, the U.S. National Institute of Health's cholesterol guidelines estimated that 13 million Americans could benefit from treatment with statins—new cholesterol-lowering drugs. In 2001, a new panel of experts revised that number upwards, to 36 million. In 2004, another panel updated the guidelines again, to 40 million, a number that included many Americans with relatively low risk of a future heart attack. Why was this? Was it actually true that statins could now benefit not only the sick, but the healthy as well? It's possible. But it's hard to ignore the fact that eight of the nine experts who wrote the 2004 guidelines also serve as paid speakers, consultants, or researchers to drug companies—companies that stood to reap billions from overnight changes that relabeled healthy people as sick and created a new market for statins.

This doesn't mean the experts deliberately fudged the results, although many researchers who aren't on the take, such as Dr. John Abramson of Harvard, believe that statins, while useful for those who have suffered heart attacks, offer very little benefit to healthy individuals, and may even cause harmful side-effects. Rather, the problem is that it's impossible to trust industry-funded numbers. A 2002 study estimated that almost 90 percent of those who write guidelines for their peers have financial conflicts of interests with drug companies. Combine that with the knowledge that, as Moynihan and Cassels write: "The industry's sponsorship is strategic, systematic, and systemic." That sponsorship is designed to portray conditions that often are not very well understood as severe, widespread, and, above all, treatable with drug therapy. That's not to say that doctors are being paid to go against their better judgment and shill for drug companies. But it does put the objectivity of medical science into severe doubt.

Where is the Food and Drug Administration in all of this? Disturbingly, on the take. Over 50 percent of the agency's budget for reviewing drugs comes from the pharmaceutical industry, and not surprisingly, officials are loath to offend their paymasters. In 2000, FDA researchers recommended that the agency consider pulling a controversial medication from the market. Lotronex, a new drug manufactured by GSK, had been used to treat irritable bowel syndrome, a condition that can be extremely debilitating for some, but relatively minor for others. The condition, of course, had been played up by a GSK marketing campaign suggesting that some 45 million Americans were affected by the condition, although that was very far from the scientific consensus. The trouble was that FDA researchers had discovered two horrific side effects of Lotronex: Some users would experience constipation so severe that impacted feces could perforate the inner bowel wall and lead to fatal infections; other users were contracting isachaemic cholitis, a potentially fatal condition in which the blood can stop flowing to the bowels. Many drugs, of course, can have severe side effects; what was shocking here is that many patients were, potentially, being unnecessarily exposed to such gruesome risks.

Initially, Lotronex was pulled, but after much lobbying, GSK convinced the FDA to reapprove the drug 18 months later, over the objections of the agency's staff. Here the picture gets murky: "The real reasons why the FDA was so keen to bring this drug back, are not clear." Indeed, Lotronex does provide undeniable benefits for people suffering from severe symptoms of irritable bowel syndrome. But striking a balance between ensuing that those who need the drug get it, without exposing the relatively healthy from potential side-effects, requires an objective agency with the public interest first and foremost in mind. Moynihan and Cassels write: "Whether the established regulators like the FDA, with its recent history of close communication with drug companies, are the appropriate bodies to be forging this new role, is highly questionable." Highly questionable is one way to put it. Or, as Fran Hawthorne wrote in her book, *Inside the FDA*: "Yes, the pressure behind the scenes can be that heavy-handed. Yes, the drug companies carry that much clout." So much for public oversight.

The problems with overselling illnesses are legion, and go well beyond the fact that powerful drugs—often with equally powerful side-effects—can be pushed on patients who simply don't need them. Oftentimes, the marketing campaign focuses heavily on the neurobiological basis for disease, without so much as glancing at the social, cultural, or environmental factors that can contribute to some medical conditions. Female sexual dysfunction, for instance, has been reduced to a blood-flow problem that needs to be treated with pills, rather than understood as the complex event it quite obviously is. Oftentimes the emphasis on biology can preclude alternative treatments. In 2003, Americans spent $1.7 billion on Fosomax, a drug to treat "low bone density," although both the seriousness of low bone density and the effectiveness of the drug are hotly disputed. While it's true that drugs to treat bone density can sometimes prevent painful and costly hip fractures, often a change in diet and lifestyle is just as effective, at a fraction of the cost. Likewise, a public anti-smoking campaign could, potentially, do as much to reduce heart attacks in the United States as all those expensive drugs to lower high blood pressure.

Note also that drug companies often push the latest and most expensive medications, even if they are no more effective than cheaper variations. (One study by publicly-funded researchers showed that the world was wasting billions of dollars a year on expensive drugs to treat high-blood pressure when cheaper substitutes would work just as well or better.) Taken all together, it soon becomes clear that the medicalization of daily life—the "corporate sponsored creation of disease"—is bankrupting the health care system with a flood of potentially unnecessary treatments. Drug companies often push to get conditions classified as disorders so that treatments can be covered by medical insurers, which in turn can push up premiums, along with the cost of taxpayer-funded programs like Medicare. Not only that, but health resources are being directed to healthy people in developed nations rather than to severe diseases among the poor—such as the AIDS epidemic that is devastating Africa. And perhaps most damaging of all, the overselling of illness may begin to undermine the credibility of scientists genuinely trying to understand disease and mentally disorders.

Can the "corporate sponsored creation of disease" be controlled? *Selling Sickness* is rather short on solutions, but in fairness, solutions are genuinely hard to come by. One thing Moynihan and Cassels do neglect to discuss, however, are the economic and legal forces driving the push to sell sickness. The patent system, as currently structured, offers a strong incentive to find and promote new diseases—Lilly was going to lose its patent on Prozac, so it discovered PMDD, repackaged the drug as Serafem, and extend its patent another seven years. Indeed, as Marcia Angell has pointed out in *The Truth About Drug Companies*, the pharmaceutical industry has brought to market only a handful of truly innovative drugs in recent years. Most of the money is to be made through gaming the patent system: either by creating slight variations on existing drugs—changing a few molecules to turn, say, daily Prozac into weekly Prozac can extend a patent another 20 years—or by finding new diseases for existing drugs to cure. Perhaps the time has come for Congress to reform the patent system.

Moynihan and Cassels also suggest the creation of publicly funded institutions to "rigorously review all of the available scientific studies about a particular treatment, and come up with an unbiased summary of how it works." Indeed, more unbiased information about illnesses and their treatments would benefit consumers—although it would actually have to reach them to be effective. Yet so long as industry-funded patient advocacy groups are raising "awareness" about the latest disease sweeping the nation, so long as young bleary-eyed hospital interns are offered late-night pizza and coffee by friendly drug reps, so long as credulous journalists writing for glossy magazines will write up breathless reports like "Living with Adult ADD," unbiased information will be hard to come by.

What really needs to happen is that public gatekeepers—especially journalists and doctors—need to be more aware of what is going on. Moynihan and Cassels give some signs that this is happening: Carla Johnson, a medical reporter for the Spokane *Spokesman-Review* recently wrote an attention-grabbing expose on the medicalization of female sexual dysfunction after she grew suspicious of a faxed press release claiming that 43 percent of women suffer from the condition. Meanwhile, the American Medical Student Association, "literally the face of tomorrow's physician," has been engaging a "PharmFree" campaign to convince its members not to accept handouts from drug companies trying to ingratiate themselves to the next generation of doctors. But in addition to all that, a wider cultural change may need to take place—perhaps a new understanding that not every condition of daily life reduces down to neurobiology, and that there's not necessarily a pill for every problem.

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