guidelines provide one important example of just how far the pendulum has swung toward the interests of the drug companies.

The obvious question is this: Who will benefit from expanding the number of Americans on statins from 13 million to 36 million? The most honest answer (though admittedly taken out of context) probably comes from the Morgan Stanley Dean Witter newsletter: "Who will benefit most from an expanding [statin] market? We have identified three likely incremental winners in the 2006 statin market—AstraZeneca, Schering-Plough, and an undisclosed marketing partner for Crestor." The newsletter continues: "there are not likely to be any outright losers." No mention is made of the patients and the doctors who are more concerned about their own and others' health and well-being than about pharmaceutical company profits. We are the losers.

CHAPTER 10

DIRECT-TO-CONSUMER

ADVERTISING, PUBLIC RELATIONS, AND THE MEDICAL NEWS

And so it's come to this: The American public can no longer blindly trust that its vaunted medical journals and world-class medical experts put the interests of patients first. Naturally, this makes us want to take matters into our own hands. This is a healthy instinct. Becoming well informed and reclaiming personal responsibility are the best antidote to a fundamentally flawed system.

But there's a hitch. Most of the information available to you (and your doctor) about the diagnosis and treatment of common medical problems comes from the drug and other medical companies themselves. The medical industry has finely honed its ability to mold public knowledge about the best medical care—slanting our beliefs in favor of the most profitable medical therapies. Its most obvious technique involves the nearly ubiquitous drug ads that pepper our television shows, newspapers, and magazines. More insidious—and, for that reason, potentially more influential—are the public relations campaigns that translate into seemingly unbiased news stories and nonprofit public awareness campaigns.

These marketing efforts are specifically designed to appear to inform the public about important health issues, but their real purpose is to

serve their sponsors' commercial interests. Health has little to do with the process, except that its singular importance, combined with recent advances in medical science and changes in medical insurance, has created what is probably the greatest marketing opportunity of all time. Whether the products actually improve our health is irrelevant. This may sound harsh, but just think back to hormone replacement therapy, or the pushing of Celebrex and Vioxx as safer arthritis remedies, or the exaggerations of the cholesterol guidelines.

Patients do indeed need to become medical consumers, but not just of drugs, doctors, and hospitals. We need to become critical consumers of medical knowledge itself. The first step is to understand where our medical information comes from.

LAUNCHING THE AD CAMPAIGNS

For years the pharmaceutical industry was allowed to market its drugs only to doctors. It did this through medical journals, continuing medical education, sponsored events, sales calls, and junk mail. Then, in 1981, the drug industry proposed that the FDA allow advertising directly to consumers, arguing that the public should not be denied access to the "knowledge" that would be provided by such marketing. Four years later, the pharmaceutical industry got its foot in the door when the FDA agreed to allow "direct-to-consumer" (DTC) advertising. But the rules were strict, and the content of the ads was, therefore, limited: Drugs could be mentioned by name, but advertisements that discussed the treatment of specific conditions were required to include a lengthy list of side effects and contraindications (situations in which the drug should not be used). As a result, the ads were vague and unfocused, primarily brand-awareness campaigns designed to smooth the way at the doctor's office.

Drug companies kept pressure on the FDA to loosen these restrictions. In 1997, the FDA changed its rules so that TV and radio ads could include the condition or conditions a drug was designed to treat without presenting all of the information previously required—only major side effects and contraindications had to appear in the ad itself (audiences

could be directed to a magazine ad or website for more complete information). For example, in a recent TV ad, after Zoloft whisks away clouds of depression, the words "See our ad in *Shape* magazine" flash briefly on the screen. Few television viewers—least of all depressed ones—are likely to search newsstands for specific magazines to find out about the side effects of advertised antidepressants.

The 1997 change unleashed an unprecedented onslaught of commercials. By 1999, the average American was exposed to nine prescription drug advertisements on television every day. The number of television ads increased 40-fold between 1994 and 2000. Suddenly it became a normal part of our everyday experience to be confronted with the idea that we or a loved one might be suffering from ED (erectile dysfunction, for those not in the know), arthritis pain, high cholesterol, nasal congestion, osteoporosis, heartburn, or even the heartbreak of toenail fungus. In the "teachable moments" created by these skillfully raised concerns, consumers are "educated" about readily available drugs to solve the problem.

The explosion of drug ads in the 1990s was exquisitely coordinated with the transition of large numbers of Americans to health plans that covered the cost of prescription drugs. Drug companies could now "help" consumers realize that they had the power to request or demand expensive new brand-name drugs from their doctors (and their greedy insurance plans) for which they had to pay only a small fraction of the real cost. This became a nearly perfect system for maximizing demand, untempered by the usual discipline of cost in a well-functioning market.

As Christopher Lasch wrote in 1979, long before the advent of advertising prescription drugs to the public, "Advertising serves not so much to advertise products as to promote consumption as a way of life." Beyond promoting specific drugs, these expertly crafted commercial messages carry strong but unspoken themes that make prescription drug use seem like a routine part of life. First, the ads create the impression not only that can health and happiness be achieved by using the right drugs, but that drugs are *necessary* for health and happiness. Then the ads evoke a positive emotional connection to the drug, and finally challenge the viewer to take action. Viewers are encouraged to discuss the drug with their doctor (in the office, "discuss" usually morphs into "request" or

"demand"), a suggestion that taps into every viewer's desire to take charge of his or her health. Meanwhile, this powerful commercial message, the alleged purpose of which is to help improve health and enjoyment of life, diverts attention from the healthy life habits that usually play a far greater role than advertised drugs in preventing illness and achieving happiness.

CLARITIN: THE FIRST DRUG BORN OF THE NEW ADVERTISING ERA

Claritin, a formerly prescription antihistamine used to control allergic symptoms, was far and away the most heavily advertised prescription drug in the two years following the FDA's 1997 rules change. And indeed, the unprecedented advertising blitz for Claritin was an unparalleled success. It certainly convinced many of my patients that they needed not just *any* allergy medicine, but Claritin and only Claritin. They resisted the idea that there were equally good and perhaps even better ways to relieve their allergy symptoms than a new (and therefore less well tested) drug. Moreover, they were unconcerned about Claritin's cost (more than $2.10 per day): most had prescription drug coverage as part of their health insurance. With an advertising budget greater than that of Budweiser beer or Coca-Cola, Claritin took off: sales grew from $1.4 billion in 1997 to $2.6 billion in 2000.

One question was not addressed in the advertising campaign: How well does Claritin relieve allergy symptoms?

In a well-researched article about Claritin in the *New York Times Magazine* in 2001, writer Stephen Hall reported that the FDA medical officer assigned to review the application for Claritin concluded that the dose approved by the FDA, 10 mg, was only "minimally effective versus placebo." The company's own tests had shown that Claritin relieved allergy symptoms only 11 percent better than the placebo (that is, 11 percent better than nothing). The FDA officer further noted that 40 mg was the "minimum effective dose" for Claritin and requested that Schering-Plough, the manufacturer, perform tests on a higher dose. According to a former FDA official, Schering-Plough resisted. Its reason? At the higher

dose, Schering-Plough would risk losing the all-important right to claim that its drug was "nonsedating." Drowsiness can be an annoying side effect of the older and far less expensive allergy pills. With the primary focus of the marketing campaign for Claritin being that it did not cause drowsiness, marketing a more effective dose that could no longer be sold as "nonsedating" just wouldn't do.

It is hard to make the argument that the $2.6 billion spent on a minimally effective drug for what is usually a relatively minor affliction was the best use of the nation's health resources. In fact, while we were spending billions on Claritin, an experienced researcher could not get a relative pittance in funding to determine if a fraction of an $0.08 pill called chlorpheniramine (brand-name Chlor-Trimeton, sold without a prescription) would be as effective as, or more effective than, Claritin, without causing sedation. As the patent to Claritin expired, it was made available without prescription, and Schering-Plough's marketing support for the drug decreased precipitously. The first drug to come of age in the new era of drug advertising was the first to fade away—it no longer made business sense for its manufacturer to sustain the huge advertising budget.

Understanding how drug patents work can be difficult because the drug companies use so many legal ploys to extend their valuable exclusive rights to manufacture and sell drugs like Claritin. Drug patents are supposed to last for 20 years from the date the patent application is filed. As the drug companies reasonably argue, the patent clock is ticking while the drug is being studied and going through the FDA approval process. According to PhRMA, the effective life of patents after drugs come on the market is about 11 to 12 years. Schering-Plough was unsuccessful in its final attempt to extend its patent on Claritin. The manufacturer's argument went like this: it still owned the patent on the chemical into which Claritin is metabolized after being taken (sold as Clarinex). Therefore, Schering-Plough argued, its patent would be infringed if people were allowed to swallow a generic form of Claritin and metabolize it into a chemical on which Schering-Plough still held the patent. The U.S. Court of Appeals for the federal circuit did not agree.

The next drug to take center stage in direct-to-consumer advertising was Vioxx. Merck spent more than $160 million to advertise this new and supposedly "improved" arthritis drug to consumers in 2000—half again

more than its closest rival and $20 million more than the previous record set by Claritin in 1999. Overcoming the lack of scientific evidence that Vioxx provides better relief or is safer for most patients than its less expensive competitors, sales of Vioxx grew more than any other drug in 2000, to $1.1 billion.

The real purpose of DTC advertising is revealed in the drugs that patients most frequently request. In 2001, these were Claritin, Viagra, Celebrex, Vioxx, and Allegra (another nonsedating prescription antihistamine)—not exactly the kind of drugs for which creating greater demand through advertising is going to improve health or head off disease at an early stage.

EDUCATION OR PROPAGANDA?

Nonetheless, the drug companies claim that their ads provide an important educational service. As explained by Alan Holmer, president of PhRMA, in a recent issue of JAMA, direct-to-consumer advertising "is an excellent way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments."

Studies show, however, that drug ads usually stay away from the facts that count. Researchers from Dartmouth Medical School found that only 13 percent of drug ads in magazines used data to describe drug benefits; the remaining 87 percent relied on vague statements. Not a single ad in the study mentioned the cost of the drug. Only 27 percent of ads presented the cause of or risk factors for the disease, and only 9 percent clarified myths and misconceptions about the disease. The positive effects of lifestyle change were mentioned in less than 25 percent of the ads and fewer than three out of 10 acknowledged that other treatments were available. 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.)

Widespread public misconceptions about drug ads contribute to their effectiveness. An article in *Health Affairs* reported that half of all respondents in a survey conducted in Sacramento County, California, believed that the government approved each drug ad before it was shown to the public, and 43 percent believed that only "completely safe" drugs could be advertised. Neither belief is true. Moreover, Americans with less education find drug ads to be more credible than do those with more education. Perhaps most telling, the survey showed that the people who are most misinformed about drug ads are also the most supportive of direct-to-consumer drug advertising.

The drug companies capitalize on the public's naïveté about their marketing techniques. Two-thirds of drug ads create a positive emotional association with the drug they represent. Recall for a moment the image of the former Olympic champion Dorothy Hamill lacing up her skates—a beautiful aging athlete smiling and renewed. Who wouldn't want to feel like that? The ad indelibly links her moment of joy to the name Vioxx in every viewer's mind. As Ernestine McCarren, general manager of Ehrenthal & Associates, an advertising agency specializing in direct-to-consumer ads, explained in an interview for a trade magazine, "We want to identify the emotions we can tap into to get that customer to take the desired course of action. If you can't find that basic insight, you might as well forget everything else."

DISEMPOWERING THE DOCTOR-PATIENT RELATIONSHIP

Advertisers know that their challenge is to evoke emotional responses that are strong enough to override traditional doctor-patient relationships. Does it work? The facts speak for themselves: more often than not, doctors accede to patients' requests. As my patients' ideas about the best approach to their medical care became increasingly influenced by the drug ads, I would try to help them understand how this process serves the drug companies' interests, not their health. Often I was successful, but once it became clear that a patient was unwilling or unable to reconsider, I often gave in (unless there was a real danger, such as a patient with a history of heart disease requesting Vioxx).

Working within tight time constraints, doctors are reluctant to be drawn into these difficult discussions and usually go along with their

patients' requests for advertised drugs. A study done by the FDA in 2002 showed that patients receive prescriptions for requested drugs 50 percent of the time. A study published in the *British Medical Journal* showed that doctors in Vancouver, British Columbia, and Sacramento, California, prescribed requested drugs about three-quarters of the time. (Canadian patients made these requests less than half as often as American patients. Direct-to-consumer advertising is not allowed in Canada, but some drug ads arrive in American magazines and over cable television.) A study done by *Prevention* magazine in 1999 showed that doctors prescribed requested prescription drugs 80 percent of the time.

The drug industry would probably argue that these successful requests are evidence of their excellent consumer education, and that better-informed patients get better medical care. Doctors, however, have a different opinion. Not surprisingly, most doctors do not agree with the drug industry's claims that advertising "can help to improve public health because a number of leading diseases are underdiagnosed and undertreated" or because it "enhances the patient-physician relationship." More than four out of five family doctors feel that direct-to-consumer advertising is not a good idea. Interestingly, although primary care doctors consistently express unfavorable opinions about the impact of DTC advertising on medical care, dermatologists have a positive view, perhaps reflecting the increase in visits generated by advertisements for skin products.

At its best, the trust between doctor and patient creates the opportunity for open discussion of symptoms, fears, models of disease, life circumstances, and expectations. Once all of these are on the table, an optimal approach can be developed to meet individual patient's needs. Often approaches and solutions to health problems emerge through these open encounters that had not been previously apparent to either the doctor or the patient. Rarely can the best solutions be achieved simply by prescribing a drug and being done with the issue.

From my perspective as a family doctor, I found the requests for specific drugs deleterious to both the process and content of good doctoring. Once a patient made a request for a specific drug, the success of the visit from the patient's point of view became defined by whether or not the drug was prescribed. At that point, it became hard to recoup the full

potential of the encounter. I was less able to broaden discussion beyond the use (or not) of the latest drugs to more effective ways to control symptoms and preserve health—like avoiding allergens or adopting a more active lifestyle.

PROTECTING SPEECH OR PROTECTING PROFITS?

It seems obvious to Americans that drug companies should be allowed to advertise. DTC drug ads have become such a prominent part of our cultural landscape that they seem completely normal, appropriately protected by the First Amendment. But outside the United States, DTC advertising is anything but normal, allowed in only one other industrialized country in the world, New Zealand, with a population of only 4 million people. An editorial in the *Canadian Medical Association Journal* summed up the issue: "By being marketed in media traditionally used to flog cars, fast food and shampoo, prescription drugs have become name-brand commodities, enveloped in the kind of fantasy and desire that surrounds the purchase of lifestyle products."

The European Union voted in 2003 to continue its ban on DTC drug ads. In the debate, consumer groups argued that medical information should be disseminated by independent national sources, not drug companies. A spokesperson for the European Union went even further, saying that the ban on drug company ads was not sufficient to protect its citizens from commercially sponsored misinformation coming from the United States. "The problem is you now have all sorts of medical data and claims on American websites," he said, "and that issue is still not being addressed."

In the United States the rights of commercial speech are given far greater priority than in the other countries—a balance that is tipping ever more in favor of commercial activity. With the explosion of marketing for prescription drugs, for example, an expansion of oversight by the FDA would seem essential. (After all, it took only 11 days after the 1997 rule change for Schering-Plough to be cited for two advertising infractions about its marketing of Claritin.) Yet just the opposite has occurred. The number of letters citing drug companies for advertising violations

declined from an average of 95 in 1999 and 2000 to only 27 in 2002 and 24 in 2003. Why the precipitous drop when the number of ads was increasing?

In August 2001, at a time when the FDA was without a commissioner, President George W. Bush chose an accomplished lawyer, Daniel Troy, to be the FDA's new chief counsel. Daniel Troy had extensive experience in First Amendment issues, with a particularly strong record in defending the right of commercial speech. He successfully represented the Brown & Williamson Tobacco Corporation before the Supreme Court in the company's bid to block the FDA from assuming regulatory authority over tobacco products. He was also part of a legal team that sued the FDA to allow drug companies to promote "off-label" (non–FDA-approved) use of prescription drugs, partially bypassing the FDA's review process. In short, one of the FDA's chief adversaries became its chief counsel.

Three months after Troy had assumed his new position, the Department of Health and Human Services instructed the FDA that all letters to drug companies concerning marketing violations must be reviewed by its Office of the Chief Counsel prior to being sent out. In a 2002 report, the U.S. General Accounting Office (GAO) noted that prior to this change, letters had been issued within several days of identifying a violation, but the additional legal review was taking so long, an average of 41 days and as many as 78, that "misleading advertisements may have completed their broadcast life cycle before FDA issued the letters."

In response to the concerns raised about increased public misinformation resulting from these delays, FDA commissioner Mark McClellan wrote a letter to Representative Henry A. Waxman (D-CA), saying that a goal of completing legal reviews of FDA notification letters within 15 days would be established. The result? A report issued by the Special Investigations Division of the U.S. House of Representatives' Committee on Government Reform—Minority Staff in January 2004 found that the average delay had increased from 41 days in 2002 to 177 days for many of the ads in 2003.

One thing about direct-to-consumer advertising is not in question: since the advertising began in earnest in 1991 it has been a financial boon for the drug industry. Since 1991, when spending on DTC advertising was a mere $55 million, expenditures on drugs have increased at about

four times the rate of expenditures on hospital or physician services. Melody Petersen reported in the *New York Times* that in 1998 the largest drug companies generated $22.50 in sales for every dollar spent on advertising to consumers and primary care doctors. It should come as no surprise, then, that the biggest drug companies increased their marketing budgets by more than 32 percent each year for the next three years. For comparison, marketing expenditures in France and England, which don't allow DTC advertising, went down 4 percent annually during the same period. Between 1991 and 2003, spending on DTC ads in the United States increased 58-fold, reaching $3.2 billion per year.

During the same years, drug industry profit margins have skyrocketed from about 12 percent of revenues (net of all research and development expenses) in 1991 to 18 percent of revenues in 2001, while the rest of the Fortune 500 industries averaged 5 percent or less.

UNDER THE RADAR SCREEN: PUBLIC RELATIONS

Even more insidious than misleading advertising is the subtle influence of public relations campaigns. At least with advertising, the fundamentally commercial purpose of the message is clear. With public relations campaigns, news stories and supposed public service messages from nonprofit organizations about a particular drug or issue just seem to emerge spontaneously, usually with no obvious connection to a commercial source. Public relations firms earn their keep by skillfully blurring the line between independent news and commercially planted "information." With repetition in trusted sources—television, newspapers, radio, and magazines—the messages carried in these so-called news stories gradually take hold. It is a very effective way to influence both public opinion and health policy.

The issue of counterfeit drugs provides a good example. In the past few years, many American senior citizens have been taking bus rides to Canada to buy prescription drugs to avoid prices in the United States that average up to 70 percent higher. Others are ordering drugs by mail and over the Internet from Canadian pharmacies. This end run around the high price of drugs in the United States is costing the drug companies sig-

nificant profits—about $350 million to $650 million worth of drugs are purchased by Americans at the lower Canadian prices each year. PhRMA wanted to curb this trend, especially while Medicare prescription drug coverage was being debated on Capitol Hill.

As if out of nowhere, the safety of drugs purchased from other countries became a major issue in the United States. In July 2003, FDA Commissioner Mark McClellan announced a new initiative to protect Americans from counterfeit drugs that were purportedly being substituted for drugs that were "safe and effective." For example, an article in the September 22, 2003, *Wall Street Journal* was headlined "Fakes in the Medicine Chest." The article reported that the FDA had noted an alarming increase in counterfeit prescription drugs entering the United States. According to this report, state and federal regulators said that counterfeits may get into the United States through a "growing number of online vendors [who] promise cheaper Canadian or 'generic' drugs." The same story was all over the news. But there was something odd about the big concern over drugs imported from Canada. A spokeswoman for the Canadian drug authority told the *Wall Street Journal*: "We're not aware of any counterfeit activity at this time."

Appearing on the very same page of the *Wall Street Journal*, but with a much smaller headline, was an article that explained the real story behind the story. "Drug Companies Cry 'Danger' Over Imports," by Scott Hensley, reported that PhRMA had hired a public relations firm, Edelman, to help it develop an effective "communications campaign" to stop drug importation. The first step was to find the themes that would have the greatest impact. Focus groups of people without insurance coverage for drugs (like many senior citizens covered by Medicare alone) were convened. Edelman found that people were not fazed by the illegality of importing drugs. But Edelman was successful in finding an issue that did get people's attention: "fear and accountability 'move the needle' of consumer perceptions." Edelman's report, according to Hensley, suggested that PhRMA could create doubts about the wisdom of saving money by importing drugs if they focused on the "safety and effectiveness" of drugs bought from foreign sources.

The PR campaign to raise concern about the safety of imported drugs has succeeded in the short term: included in the Medicare prescription drug bill are provisions that make drug importation cumbersome and therefore unlikely. Ironically, as pointed out in a *New York Times* editorial, "While the drug industry has been railing against the dangers of foreign imports, it has increasingly transferred its own production to foreign factories to save on labor costs." So it turns out that the biggest importer of foreign drugs is the American pharmaceutical industry itself. Just how concerned is the drug industry about protecting the public from the danger of imported drugs? While 1300 people were being added to the division of the FDA that approves new drugs (to decrease new drug approval time), 1000 were being taken off other FDA surveillance duties, including inspection of drug manufacturing sites. And the real truth about counterfeit drugs from Canada? Jirina Vlk, spokesperson for Health Canada, the equivalent of the FDA, told me on January 28, 2004, that she was not aware of any counterfeit drug's *ever* having been sent from a registered Canadian pharmacy or pharmacist to the United States.

Public relations campaigns are also waged in support of specific drugs. This occurs both around the initial introduction of a new drug and to help a drug that is not living up to its anticipated market potential. For example, Eli Lilly thought it had a real winner in 2001 when the FDA approved Xigris. This breakthrough high-tech drug had been shown to improve the survival rate of people who were critically ill with septic shock—an extremely serious condition caused by bacterial infection in the bloodstream, which is responsible for 225,000 deaths in the United States each year. The *New England Journal of Medicine* published a report in 2001 showing that Xigris decreased the mortality rate from this dreaded condition by 6.1 percent, saving the life of 1 out of every 16 patients treated. Another article in the NEJM concluded that Xigris was "relatively cost-effective when targeted to patients with severe sepsis."

The future of Xigris (and Eli Lilly) seemed bright. According to *Business Week*, Xigris had "one of the higher profit margins in the business." But sales were soon lagging far below projections: up to $475 million in sales had been projected for 2002, but actual sales came in at less than a quarter of that. Sales for 2003 had been projected to be as high as $700 million, but Eli Lilly's data from the first two quarters of 2003 showed Xigris sales of only $72 million, less than one-ninth of projections. Why was Xigris such an underperformer?

It turns out that the study published in the *New England Journal of Medicine* didn't tell the whole story. Data provided to the FDA by Eli Lilly showed that of the six extra patients out of 100 who survived after being treated with Xigris, only one had been well enough to be discharged from the hospital 28 days later. The other five were still too sick to go home, and some of them were still in the ICU. The FDA reviewer who analyzed these data concluded that "without longer follow-up, the ultimate outcomes of the hospitalized patients cannot be determined."

Furthermore, Xigris is very expensive, costing about $6800 for each patient treated. Medicare and Medicaid agreed to Eli Lilly's request to cover half of the cost of Xigris as a new medical technology, but this still leaves hospitals paying about $3400 for each patient treated.

With sales lagging so far behind projections, Eli Lilly did the only reasonable thing: it fired the public relations firm that had been in charge of the Xigris account and looked for a new one that could do a better job. According to the *Wall Street Journal,* the winning proposal was titled "The Ethics, the Urgency, and the Potential." The new campaign would focus the public's attention not on the merits of the drug itself but on a word that evokes terror and anger in most Americans when it comes to health care: rationing.

In an article titled "To Sell Pricey Drug, Eli Lilly Fuels a Debate Over Rationing," the *Wall Street Journal* reported that Eli Lilly's new PR firm developed a strategy to convince the public that use of Xigris was being unethically withheld from critically ill patients. Eli Lilly then committed $1.8 million to fund, according to the *Boston Globe,* a task force charged with developing "national guidelines for the rationing of expensive intensive-care unit treatment—and to get doctors to openly admit they withhold care from patients who would benefit the least."

No doubt the critical care doctors on this task force are seeking a legitimate forum in which to develop guidelines to help health professionals with the often agonizing ethical dilemmas that routinely arise in the care of critically ill patients. And no doubt the task force's report will merit very careful attention for its suggestions about the most responsible and ethical ways to approach these problems. But Eli Lilly's largesse has another goal as well. The task force's report and guidelines are at high risk of falling prey to a public relations clamor about the rationing of

medical care for critically ill patients, with underuse of Xigris woven seamlessly into the "debate." One could easily see the case for Xigris developing as an extension of the patients' rights issue—inappropriately withholding potentially lifesaving drugs from critically ill patients. Rational public debate about the use of Xigris will be at risk of getting drowned out by the public's emotional response to news reports about de facto rationing. If this happens, the public relations campaign will almost certainly have succeeded in its primary goal of increasing sales of Xigris. Besides, only 265 additional patients have to be treated with Xigris to cover the cost of the ethics task force.

Commercially sponsored public relations campaigns also use nonprofit organizations very effectively to get their message out. Consider the story of social anxiety disorder, or SAD. An investigative article in *Mother Jones* by Brendan Koerner tells the story of how this "disease" was virtually created to sell the cure. According to the psychiatric diagnostic manual, SAD is (or, probably more accurately, was) an "extremely rare" condition. Nonetheless, SmithKline Beecham, the manufacturer of the antidepressant Paxil, hired a PR firm to coordinate a broadly targeted educational campaign about the "disease" through three nonprofit organizations: the American Psychiatric Association, the Anxiety Disorders Association of American, and Freedom From Fear. Within a month after the FDA's approval of Paxil for the treatment of SAD, articles about this "underdiagnosed illness" appeared in the *New York Times* and *Vogue* magazine. The PR campaign was deemed such a success that it earned recognition as the "Best P.R. Program of 1999" by the New York chapter of the Public Relations Society of America. Not surprisingly, Paxil sales increased by 25 percent between 1999 and 2000.

When for-profit money gets cycled through nonprofit organizations, especially trusted service and professional organizations, the commercial goals of the donors become nearly invisible.

THE GOOD NEWS NARRATIVE

Have you ever noticed how much good news about medical progress is on television and in newspapers? With this constant stream of break-

throughs, you would think that by now we would have cured all diseases known to humanity two or three times over.

The narrative is familiar: A medical problem is described; one or more patients suffering from the disease are introduced with whom the viewer or reader can readily identify; experts are interviewed to explain why the discovery or procedure is a breakthrough in terms readily understandable to the public; and the story concludes with a calculation of how many people can be helped by this latest discovery. Temporizing opinions are often included for balance, but the criticism is rarely enough to quash the excitement. Our underlying faith that medical science is progressing in its battle against suffering and death is confirmed. The medium that brought us the message has successfully captured our attention. And the interests of the advertisers are supported by this rosy narrative. All at the same time.

A good example was provided by the press coverage that followed the publication of a 2002 article in the *New England Journal of Medicine*. Researchers concluded that an inexpensive test that measures the level of inflammation in the body, C-reactive protein, or CRP, can predict a person's risk of developing cardiovascular disease (heart attack, ischemic stroke, coronary revascularization, or cardiovascular death) even better than cholesterol levels. The *New England Journal of Medicine* reported that among 28,000 women followed over eight years, the 20 percent with the highest CRP levels were 2.3 times more likely to develop cardiovascular disease than were the 20 percent with the lowest levels. The researchers also concluded that much of this risk would not have been identified by measuring cholesterol levels alone. Finally, according to the article's authors, identifying people with elevated CRP levels would allow "optimal targeting of statin therapy." In other words, people with high levels of CRP would be well advised to take statins to decrease their risk of cardiovascular disease.

According to my nonrandom sample, three major newspapers (the *Boston Globe*, the *New York Times*, and the *Washington Post*) and two newsmagazines (*Time* and *Newsweek*) each carried a story about the potential benefit of the new CRP test. Without exception, the stories were enthusiastic: "groundbreaking," "the most promising advance in a long time," "paradigm-shaking," "extremely important," and "a home run"

were among the accolades. It is safe to assume that much of the reading public concluded that this was an important medical breakthrough and requested CRP tests from their doctors.

What's wrong with this story? The research was spun to make a very small diagnostic improvement look like an important medical "breakthrough" and in the process distract attention from the things that can be easily done to decrease the risk of cardiovascular disease.

The NEJM article reported that the women with the highest CRP levels had 2.3 times more risk of developing cardiovascular disease than the women with the lowest levels. That sounds like a lot. But this is the *relative* risk; comparison of the ratio of the low risk of disease in one group to the even lower risk of disease in another can make very small differences seem very big. The women in this study were quite healthy, and their average age was less than 55, so their underlying risk of suffering heart attacks, strokes, or blocked arteries was quite small. For example, among 1000 women with the highest CRP levels, there was only slightly more than one (1.3) additional episode of cardiovascular disease each year than among 1000 women with the lowest CRP levels. All five publications reported that women with elevated CRP levels had double the (relative) risk of cardiovascular disease, but only the *Washington Post* mentioned anything about absolute risk, reporting that the increase was "very small." With all the talk about "most promising advance in a long time" and "home runs," readers had few clues that the dramatic-sounding relative risk translated into a minimal absolute risk of about 1 in a 1000.

Nonetheless, concern about even this level of risk is not unreasonable. So how much would statin therapy help? An article by the same group of researchers published in JAMA in 2001 showed that a daily dose of 40 mg of Pravachol significantly reduced CRP levels. But remember: reduction of CRP is a surrogate end point (not clinically important in and of itself), and statins have never been shown in randomized clinical trials to significantly reduce the risk of cardiovascular disease in women without heart disease. Nonetheless, assuming (very generously, because no benefit has yet been proven) that taking Pravachol could decrease the risk of cardiovascular disease in women with higher CRP levels by 40 percent, less than one episode of cardiovascular disease per 1000 women

would be prevented each year. Forty milligrams of Pravachol per day cost about $1650 per year. This works out to $2 million (in drugs alone, not counting the extra lab tests and doctor visits) to prevent a single episode of cardiovascular disease among healthy women with elevated CRP levels—if in fact Pravachol has any benefit at all. You don't have to be a doctor to understand that there might be better ways to spend that much money on 1000 women over the course of a year to improve their health and the quality of their lives.

What's the harm in all this excitement about something that may not be a real breakthrough? The hype creates false hope that moves us further away from real prevention, most of which has to do with a healthy lifestyle, and drains resources needlessly from far more effective health interventions.

Is the reporting of the CRP story typical? Unfortunately it is. A study of 207 medical news stories on television and in newspapers shows that fewer than one in 10 presented data on absolute risk reduction and only three out of 10 mentioned cost. Only four out of 10 disclosed the financial ties of "experts" to the products they were presenting or discussing. How many times have you ever heard a researcher who worked on a drug company–sponsored study express a negative or even ambivalent opinion in an interview? There is a reason why drug companies establish financial ties with experts. Interviews of these enthusiastic authorities are often better described as infomercials than dispassionate science reporting.

Why the tendency for the media to present medical research in such hyperbolic and uncritical terms? People like to read good news more than bad, and they like to hear about progress and hope. There is another reason, too, though it is an impolite subject. Gloria Steinem, founding editor of *Ms.* magazine, stated it quite succinctly: "You don't get product ads unless you praise the product."

With advertising of prescription drugs and other medical products having emerged as a major source of revenue for all media (especially television—the greatest source of people's health information), the pressure to have news content that supports or at least does not directly oppose advertisers' interests has grown. And therein lies the Achilles' heel of the media when it comes to medical reporting. Even if medical reporters had the scientific and statistical expertise to cut through commercial spin (an unfair expectation, given that it involves untangling the work of the medical industry's best and brightest), could they report the truth and stay in business? Unlikely.

The public needs access to independent expert opinion that can counterbalance the enormous influence that the medical industry wields over our beliefs about the best approach to health and medical care. Unfortunately, with rare exceptions (Center for Medical Consumers, the University of British Columbia Therapeutics Initiative, and Public Citizen's worstpills.org are examples of unbiased sources of information), we are left with medical reporting that is handicapped by a structural disadvantage: the public's interest gets overwhelmed by the financial resources, political influence, and marketing expertise of the drug industry. As a result, the public often gets commercially biased medical news, and is left more vulnerable than ever to the explicit appeals of advertisers and the subtle persuasion of public relations campaigns.

The successful mass marketing of drugs, tests, and procedures to American consumers—regardless of their true health value—explains a great deal about how the myth of excellence in American medicine is sustained. While there certainly have been many real breakthroughs in research and practice, it turns out that most of the medical news, especially the commercially advantageous news, is too good to be true. Americans, as patients, consumers, and taxpayers, are paying an enormous price for that deception.