rate children's environment, presenting a far more compelling message.

Hopefully, in the years to come we will look back and see how ridiculous we were to have believed that biomedicine alone—without considering the health consequences of how we live our lives—could possibly provide optimal health. The measure of America's recovery from this era of commercially distorted medicine will be the extent to which real and effective encouragement of healthy ways of living is reintegrated into the best medical care available—not replacing, but supported by, the appropriate clinical application of biomedical science.

CHAPTER 14

HEALING OUR AILING HEALTH CARE SYSTEM, OR HOW TO SAVE $500 BILLION A YEAR WHILE IMPROVING AMERICANS' HEALTH

There was a time not so long ago when breakthroughs in medical science were driven more by health needs than by the search for corporate profits. Perhaps the best example is the research that produced the polio vaccine, one of the truly great breakthroughs of modern medicine. In 1955, amid the great fanfare that accompanied the initial release of the vaccine, Dr. Jonas Salk was asked who owned the patent. He replied, "Well, the people, I would say. Could you patent the sun?"

American medicine has changed a lot since then, especially in the last 10 or 15 years. Many of these changes come not from medical science itself, but from the changed purpose for which medical knowledge is created and disseminated. Most of us take for granted that the well-established rules of science ensure the validity of medical research, regardless of the purpose for which the research is undertaken or the context in which it is performed. Nothing could be further from the truth.

The privatization of the majority of clinical research, the diminished role of universities as impartial overseers of medical knowledge, and the drug and medical-device industry's growing influence on government have all contributed to the changed role of medical knowledge in our society. The goal of performing rigorous medical studies is often replaced

by the goal of creating the perception that rigorous medical studies call for increased use of the sponsors' products.

In this climate, the editors of the most respected medical journals have warned that they cannot protect their readers from the pro-industry bias seeping into many of the scientific articles they publish. Nonetheless, publication in respected medical journals still anoints research findings as the scientific evidence upon which good doctors confidently base their clinical decisions. It is not simply due to the "play of chance" that the odds are five times greater that new products will be supported by commercially sponsored studies than by studies with noncommercial sponsorship. The bias is, at best, difficult and often impossible for even the most careful readers to spot, let alone unravel. And simply knowing that it exists is not enough to protect readers from being misled.

If we are to begin to solve the crises in American medicine, we first need to stop pretending that the current organization of the production and dissemination of medical knowledge is serving the public's interest. The ideal of "well-ordered science" (a phrase coined by philosopher Philip Kitcher in his book *Science, Truth, and Democracy*) is often replaced in commercially sponsored medical research by the ideal of profit-maximizing science. Dr. Andrew Bodnar, a senior vice president at Bristol-Myers Squibb, summarized this issue when he told the *New York Times*, "In a science-driven organization, the notion of marketing versus science is really a false dichotomy." Disciplined science performed by impartial researchers and openly shared with professional colleagues and the public is often replaced with games of cat and mouse in which corporate sponsors do their best to hide both the ways that their scientific results have been spun, and the results that can't be spun. But medical research is not a game, and, as Kitcher points out, the more important the consequences, the higher the scientific standards should be.

This is the mother of all sleights of hand: the transformation of medical science from a public good whose purpose is to improve health into a commodity whose primary function is to maximize financial returns. As a result of this sleight of hand, the gap is widening between the scientific evidence that impartial experts (not paid or threatened by the medical industry, not biased by other personal concerns, and granted unrestricted access to all of the evidence) would agree upon and the perceptions that actually drive American health care. This growing gap is at the core of the crisis in American medicine. And why are we surprised? The drug companies have no more responsibility to oversee the public's health than the fast-food industry has to oversee the public's diet.

The substitution of narrow corporate interests for medical progress has produced some dramatic excesses. When the manufacturer of Paxil performs nine clinical studies on the treatment of adolescents for depression and finds that Paxil is no more effective than placebos and, in fact, significantly increases the frequency of "emotional lability" (including suicidal thoughts and attempts), it's no problem. The company publishes one study that shows a benefit, fails to publish the other eight, and markets away. When British drug authorities spill the beans? No problem. A task force of the American College of Neuropsychopharmacolgy is convened, and concludes that the new antidepressants are safe for adolescents after all. Too bad the task force didn't have access to some of the information that was available to the British drug authorities. But perhaps that didn't seem like so much of a problem, because, according to the *New York Times*, "Critics of the medicines noted that 9 of the 10 task force members had significant financial ties to the pharmaceutical industry. . . ." (However, the task force insisted that no industry money financed their report.) What to do when the FDA epidemiologist in charge of analyzing all the antidepressant studies involving children concludes, just like the British drug authorities, that twice as many children treated with the new drugs (except Prozac, which is available as an inexpensive generic) became suicidal, and that the FDA should therefore discourage doctors from treating children with these drugs? Just bar the expert from testifying at the FDA's public hearing. Then don't make him available for an interview with the *New York Times*, which reported the story on April 16, 2004.

You don't like the way the study of an expensive drug for blood pressure is going? A nonissue—just stop the study before the results reach statistical significance.

Endovascular Technologies (a wholly owned subsidiary of Guidant, the company that manufactures implantable defibrillators) manufactured a $10,000 device to repair aortic aneurysms that dangerously malfunctioned in a third of the 7600 patients in whom it had been used. Did this frequency of malfunction stop Endovascular Technologies? No. The

company reported 7 percent of these events to the FDA and sold on. According to a plea agreement entered into with the United States government in 2003, the company belatedly disclosed another 2628 serious malfunctions and 12 deaths. No problem. It agreed to pay $92 million to cover criminal and civil penalties and then picked up with business as usual on other products.

Your drug company just received an official warning letter from the FDA for the "false and misleading" marketing of Celebrex, Vioxx, Pravachol, or OxyContin? No problem. The FDA's corrective action is unlikely to displace the false information already firmly planted in the public's mind.

And the list goes on. Controlling medical costs in this near free-for-all commercial grab is not just impossible, it is a contradiction in terms. Does it make sense to talk about reducing national expenditures for cars or clothes or beer? Medical care, by far the largest consumer commodity in the United States, is now no different.

THE ILLUSION OF ACCESS: THE MEDICARE RX BILL

Like any well-functioning consumer market, the medical industry does its best to stimulate ever-greater demand. In this context, being assured of ongoing access to "the best" medical care is as much a contradiction as controlling medical costs. The Medicare prescription drug bill is a perfect example.* This bill was supposedly designed to improve senior citizens' access to the prescription drugs they need. For those with the lowest incomes, it will make prescription drugs more accessible—with the drug companies receiving full price from a segment of the market that would not otherwise have been able to afford these drugs. However, according to the Consumers Union and 19 labor union and public interest groups, after the new prescription drug "benefit" takes effect, the average Medicare patient, who spent $2318 out of pocket for prescription drugs in 2003, will spend $2911 out of pocket in 2007. Ostensibly designed to

*The actual name of this legislation, signed into law by President George W. Bush on December 8, 2003, is the Medicare Prescription Drug Improvement and Modernization Act of 2003.

decrease the financial burden of prescription drugs for senior citizens, the legislation will do just the opposite.

How can this happen? Expenditures for prescription drugs have been increasing seven times faster than the rate of inflation, but the 2003 legislation *specifically prohibits* the federal government from using its purchasing power to negotiate prices with drug makers, as is done successfully by the Veterans Health Administration and Defense Department (and by Canada and the European countries—which is why their drug prices are so much lower than those in the United States). The U.S. government will pay the full price as set by the drug companies, while the need for the drugs will be determined largely by industry-sponsored research, industry-sponsored guidelines, industry-sponsored continuing education and marketing for doctors, and industry-sponsored advertising and public relations campaigns. At the same time, importation of drugs from countries with lower prices has been effectively blocked.

But even this does not capture the depth of the problem. PhRMA was successful in helping to defeat an amendment to the Medicare prescription drug bill that would have funded research to determine the comparative effectiveness and value of the drugs senior citizens are struggling to afford. A quick look at the 15 most frequently prescribed drugs for seniors in 2003 shows that, before coming up with a very expensive plan to provide access to these drugs, it would be wise to determine which drugs actually provide effective and efficient treatment for senior citizens.

Celebrex 200 mg was the sixth most frequently prescribed drug for American seniors in 2003. As we saw in Chapter 3, when the results from the second half of the manufacturer-sponsored study (not included in the article published in JAMA) are taken into account, as FDA reviewers deemed appropriate, Celebrex offers no significant advantage over much less expensive anti-inflammatory drugs, and may actually cause more GI problems when taken for longer than six months.

The second and tenth most frequently prescribed drugs for seniors are Norvasc 5 mg and 10 mg for blood pressure control, costing $549 and $749 per year, respectively. Evidence shows, however, that, for most people, neither is as effective at preventing the complications of high blood pressure as a diuretic that costs only $29 per year, hydrochlorothiazide—the forty-second most frequently prescribed drug.

Three of the top fifteen drugs for seniors are cholesterol-lowering statins. We don't know how many of those are being prescribed to prevent recurring heart attacks, the situation in which statins are most effective. We do know, however, from the PROSPER study that high-risk elderly patients with no previous history of heart disease have no fewer heart attacks when they are treated with a statin for three years. But they do develop significantly more cancer. Furthermore, the first statin introduced to the market, Mevacor, is now available as a generic drug, lovastatin, which costs less than half as much as the brand-name drugs and has never been shown to be any less effective at preventing heart attacks in people over the age of 65. (In the Prove It study, the people over the age of 65 derived no greater benefit from Lipitor than from Pravachol, one of the earlier statins.) Lovastatin, however, did not make the top 50 list.

Vioxx made the top 15 as well, despite a little-known fact buried in data from the manufacturer's own study: treating 100 patients over the age of 65 with Vioxx instead of naproxen will lead to 2.5 additional serious cardiovascular complications each year. To put the risk of Vioxx in perspective, treating patients over the age of 65 with Vioxx instead of naproxen is about four times more likely to *cause* a cardiovascular complication than a statin is likely to prevent one, even in patients who have already had a heart attack.

Two of the top 15 drugs are stomach acid–blocking drugs costing about $4.60 a day. One of these, Prilosec, is now available without a prescription for about $0.62 a day—and even this price will soon come down with generic competition. I found that most patients with symptoms of heartburn could be started on the more powerful acid-blocking drugs, then switched to less strong medication, such as ranitidine (brand name Zantac) once their symptoms were under control. If symptoms recurred, patients could easily be switched back to one of the more powerful drugs.

The third most frequently prescribed drug for seniors is Fosamax for osteoporosis. One wonders how many of the women taking this drug actually benefit, since, as we have seen, it does not reduce fractures when used to prevent osteoporosis. And for women over 70—even those with severe osteoporosis—Fosamax's cousin, Actonel, significantly reduces the risk of hip fractures only in women who have already had spine fractures. Meanwhile, how many women taking these drugs are aware of the research showing the significant benefits of exercise in preventing fractures and, more important, improving overall health and longevity?

Those are 10 of the 15 best-selling drugs for seniors. If the government's real goal were to increase senior citizens' access to the most effective medications, its first step would have been to determine the best care based on the best scientific evidence available, helping patients and doctors to make informed decisions. Instead, the Medicare prescription drug bill simply opens the public coffers to pay full price for expensive brand-name drugs. One might conclude that the purpose of this drug bill was to transfer wealth from the taxpayers to the drug companies rather than to ensure senior citizens access to the most effective drugs at the lowest possible cost to themselves and to the federal government. As an unnamed drug lobbyist told the *New York Times* when this legislation was being debated, "Having both houses of Congress Republican-controlled was great. Like in Monopoly, when you get to add hotels."

As if that weren't bad enough, Congress was not even allowed to see Medicare's own estimate of the real cost of the prescription drug bill before it voted (this estimate was $100–$200 billion higher than the projected cost that the Bush administration was presenting to Congress). Medicare's chief actuary, Richard S. Foster, told the *New York Times* that he had been ordered not to provide this information to Congress and ordered not to respond directly to Congressional requests for data. Foster said that his understanding was that Medicare officials "would try and fire me" for doing so. The *Times* reported that the director of Medicare, Thomas A. Scully, denied having threatened to fire Foster, but did acknowledge having instructed Foster to "withhold certain information from Congress."

Just six weeks after the president signed the bill, the price tag was publicly acknowledged to be fully one-third higher than the $400 billion Congress had been promised. How did this happen? Thomas Scully had received an ethics waiver in May of 2003 that allowed him to continue to work on the drug bill while he was seeking employment in the private sector. One month after receiving the waiver, he changed the long-standing practice of allowing Medicare actuaries to report requested information directly to Congress. Under the new rules, actuarial infor-

mation had to go through Mr. Scully (reminiscent of the change at the FDA that required all letters to drug companies about marketing violations to be reviewed by the office of the chief counsel). At least some of Medicare's estimates of the cost of the drug bill were sent to the White House; but they weren't sent to Congress. According to the *Wall Street Journal*, within weeks of the final vote on the bill, Scully told Foster, "We can't let that [estimate] get out." In March 2004, Foster told the *New York Times*, "There was a pattern of withholding information for what I perceived to be political purposes, which I thought was inappropriate."

One month after the Medicare prescription drug bill was passed, Mr. Scully announced that he had accepted a position with a law firm that, according to the *Times*, represents many companies in the health care industry affected by the new prescription drug bill, and is a registered lobbyist for Johnson and Johnson and the National Association for Home Care.

An article published in *Health Affairs* in February 2004 shows that once coverage for prescription drugs for Medicare patients becomes effective, prescription drug costs are likely to increase even more than predicted. The study found that use of Celebrex and Vioxx more than doubles when senior citizens have insurance that covers at least 75 percent of the cost of prescription drugs. (The Medicare prescription drug bill will provide 75 percent coverage.) The authors conclude that health policymakers should "be concerned with potential overuse of drug therapy by Medicare beneficiaries once the benefit is implemented." Surely the use of expensive drugs by senior citizens will skyrocket—regardless of their proven value—unless measures are taken to base prescription drug use on the real scientific evidence.

If the crisis in American medicine were simply due to the rising cost of ever more effective care, there would be no choice but to cobble together the least noxious combination of increased spending and rationing. But the bad news about American medicine—and, paradoxically, the good news as well—is that the primary problem is not the escalating cost but the low quality of medical care that results when those with health insurance receive too much of the wrong kind of care and those without health insurance receive too little of the care that is necessary. Dr. Donald Berwick, one of the nation's leading crusaders for improving quality in medicine and an author of the Institute of Medicine's report "Crossing the Quality Chasm," states the problem succinctly: "Hundreds of billions of dollars are being flushed away because care isn't related closely to need."

Commercial interests are so successful in appearing to represent the public's interest that doctors, health policy experts, and the public are unable to discern the commercial distortions of the medical knowledge upon which they rely. "Quality of care" is now defined largely in ways that best serve the financial interests of drug and other medical industries rather than the health needs of the American people.

In this context, the most urgent challenge facing American medicine is not how to guarantee adequate access, but first to determine "access to what?" Nor is it even how to ensure quality of care, because this presumes that the available scientific evidence is adequate to make that determination. The most important health care issue in the United States today is whether our current method of creating medical knowledge realizes the full potential of medical science to improve our health, and whether this knowledge is then best applied to clinical practice and communicated effectively to the public. By these standards, American medicine is clearly failing to fulfill its promise.

RESTORING THE INTEGRITY AND PURPOSE OF CLINICAL RESEARCH

The first step in reorienting American medicine toward the effectiveness the American people have a right to expect and are more than paying for would be to relieve the foxes of their responsibility for guarding the henhouse. How absurd to have more than half the budget of the FDA division that approves new drugs (the Center for Drug Evaluation and Research, CDER) paid directly by the drug companies' user fees because the federal government is unwilling to provide adequate funding. Completely invisible to the public, officials at the National Institutes of Health are allowed to participate in lucrative consulting contracts with the drug companies. Experts with financial ties to the drug companies dominate the FDA's Advisory Committees and the panels that write the clinical guidelines that define the standards of care for practicing doc-

tors. The medical industry even funds the majority of doctors' continuing education.

The production and implementation of medical knowledge in the United States is by now so riddled with conflict of interest at virtually every level and every stage that nothing less than a new independent national public body is needed to protect the public's interest in medical science. Such a body must have the independence and expertise of the Institute of Medicine (part of the National Academies of Science), which would be well suited to accept responsibility for evaluating the scientific evidence. Lessons from the past show that this public body would require maximum insulation from political and commercial influence, on the model of the Federal Reserve Board—long and staggered terms, no financial ties to industry, and secure funding from Congress—to avoid evisceration when its findings were not to the liking of powerful interest groups. Surely the health of the American people and almost $2 trillion in annual expenditures are important enough to warrant such rigorous oversight.

This new independent board would have a threefold mission. First, it would ensure that medical research was designed, conducted, analyzed, and disseminated with the primary purpose of improving health and in accordance with accepted scientific standards. Second, it would provide oversight in developing clinical guidelines for the prevention, diagnosis, and treatment of specific medical problems and overall health through independent analysis of all the available scientific evidence.* Third, it would identify, fund, and oversee research when important scientific evidence was lacking. For example, the absence of evidence from randomized controlled trials precludes informed recommendations about whether routine bone mineral density testing for postmenopausal women has any clinical benefit, or whether drug therapy, lifestyle modification, or both will best prevent hip fractures in women with osteoporosis. Although clinical trials to study these two issues might not be advantageous to the companies that make bone density testing equipment or drugs for osteoporosis (and therefore would be unlikely to be funded by them), such trials would certainly be beneficial to American women.

*The United Kingdom developed an agency to perform this function in 1999, the National Institute for Clinical Excellence (NICE). Its role is defined as providing "patients, health professionals and the public with authoritative, robust, and reliable guidance on current 'best practice.'" It does this with a budget of less than $30 million per year.

To accomplish this threefold mission, the new body would need authority to require that all clinical trials were registered at the outset, with a clearly identified research design ("protocol"), including the duration of the study, the outcomes, and adverse effects to be measured. This would put an end to the current "Heads, I win. Tails, you lose" situation in which studies that support their sponsors' interests are published quickly while unfavorable results are published slowly or not at all and therefore never become part of our medical knowledge. Although registration of all clinical studies may seem like a simple and obvious way to improve the benefit that society derives from medical research, the drug companies, through their trade organization PhRMA, have stated: "Sponsors [of clinical research] do not commit to publish the results of every exploratory study performed, or to make the designs of clinical trial protocols available publicly at inception, as in a clinical trial registry."

The new body would also have the power to require that studies include people of similar age, gender, and medical condition to those to whom the results would be applied. Comparison with proven therapies (not just placebos)—including lower-cost treatments, generic drugs, and lifestyle interventions—would be required before a new drug could be considered the "best therapy." The body would also have the authority to require that studies be continued long enough to determine the benefits and side effects of the various treatments and strictly forbid interrupting a study for "commercial reasons."

The body would have the authority to require that clinical research measure the most important clinical outcomes, such as serious illnesses, overall mortality, and the quality of life—not merely intermediate end points such as bone mineral density, blood pressure, cholesterol level, and the amount of plaque in arteries.

Probably the single most important change that the fully empowered regulatory body could implement would be requiring transparency in medical research—making all research data available for external audit

and public scrutiny. Nontransparency is now the norm for commercially sponsored medical research in much the same way that it had become the norm in accounting and business practices in companies such as Enron and Worldcom, and with much the same results—though the magnitude of the cost in dollars and health still remains a well-kept secret. Medical researchers must have access to all the results of their studies, perform their own analyses of the data, write up their own conclusions, and submit the report for publication to peer-reviewed medical journals. Research data must also be made available to peer reviewers for medical journals and to the new oversight body for independent evaluation.

How would these standards be enforced? Only studies that met these standards would be certified by the new body—thus establishing an effective performance threshold for validation of clinical research. This certification would become part of the peer-review process for medical journals—publication could be restricted to certified research or articles' certification status could be clearly identified for readers. Certification would also be identified in all the scientific evidence presented to doctors in marketing material and continuing education. The public would be similarly informed about the certification status of research referred to in advertising and presented in the media. If drug companies threatened to withdraw advertising, the cost of public funding for the journals would be a pittance compared with the savings to the public that would result from basing medical care on unbiased scientific evidence.

Of course, the medical industry would do everything in its enormous power to prevent having to relinquish its control over medical knowledge. But what purpose is served by the current situation, in which the public's interest in effective and efficient health care is subjugated to the commercial goals of the medical industry?

Would this oversight of the relevance and integrity of clinical research bring commercial funding to a halt? The drug and medical-device industries might use such a scare tactic to quash the growing public demand to rein in their excesses. Such a threat, if not simply posturing, would reveal industry's need to bias research in order to make the undertaking worthwhile from a business perspective. If this were true, then all the more reason to return responsibility for producing medical knowledge back to the government, shielded from commercial

distortion. Yes, it would be expensive in the short run to lose industry's enormous financial contribution to medical research, but the net result would save Americans hundreds of billions of dollars each year as medical care became redirected away from commercial goals and back to the goal of producing the best health with the greatest efficiency.

PROVIDING QUALITY HEALTH CARE TO ALL AMERICANS

In January 2004 the Institute of Medicine reported that 18,000 Americans die unnecessarily each year as a result of not having health insurance. This death toll is six times greater than the one we experienced on September 11, 2001—and it's happening every year. Have you ever wondered why the United States, the country with the highest per capita gross domestic product (except for tiny Luxembourg), is alone among industrialized nations in not providing health care coverage to all of its citizens? Our lack of universal coverage becomes even more puzzling when we realize that, according to an ABCNews/*Washington Post* poll conducted in the fall of 2003, four out of five Americans support universal health care and are willing to sacrifice their tax cuts to pay for it.

The key to understanding this paradox is that the medical industries maximize profits by providing the most care possible to those who pay full or almost full price. As long as the definitions of "quality of care" and the price structure of drugs, devices, and procedures are determined largely by commercial interests, universal health care will continue to appear unrealistic and in some vague way "un-American." Yet the additional cost of covering all Americans is estimated to be $34–$60 billion annually—a trivial sum compared with the extra $500 billion spent each year on medical care "informed" by the findings of commercially biased science.

The prospect of extending health care coverage to the uninsured would jeopardize the medical industry's excess profits and almost certainly trigger a demand for accountability: Americans of all political stripes would demand evidence of the real value that they (and the uninsured) were receiving for their tax dollars. Ideally, the independent federal oversight body I've described would determine the benefits to be

included in universal coverage, based upon all of the scientific evidence (meaning that commercial sponsors of research would not be allowed to keep their data hidden). The cost of this care, according to the best evidence currently available, would be about one-third less than the current cost of commercial insurance or Medicare. The privileged profiteering of the drug, medical device, medical equipment, and hospital industry would be sharply curtailed.

However, the most serious threat posed to these industries under such a system would be the public realization that people covered by the universal health plan were receiving higher-quality care and better health outcomes than the people with regular insurance. When that happened, many Americans would demand similarly high value, low cost health insurance, effectively extending to all Americans coverage for medical services, drugs, tests, procedures, and therapies based upon certification by the independent federal body. All Americans would then be winners—the currently uninsured and the insured alike—as the quality of their health care improved and their costs declined as the result of objective standards of medical excellence replacing our current commercially based standards of care.

MARKET FAILURE OR MARKET SUCCESS?

As the leaders of the Commonwealth Foundation wrote in *Health Affairs* at the end of 2003, "The inability of the health care industry to improve care sufficiently on its own and to increase the value that Americans receive for their dollars is an indication of private market failure."

The failure of the market to serve Americans' medical needs is certainly demonstrated by the combination of our poor health status compared with that of other industrialized countries, the low quality of our medical care (barely half of the standards for basic medical care are being met, according to a study done by the Rand Corporation and published in the NEJM in December 2003), and the singularly high cost of our medical care. But these are just symptoms of a more fundamental problem, which is not market failure, but market success. The medical industries have thrived as health care spending in the United States increased

more than fivefold and the percentage of our GDP devoted to health care rose from 8.8 to 15.5 between 1980 and 2004.

How could the market have allowed the medical industries to thrive while serving Americans' health needs so poorly and inefficiently? The problem is not with the market itself, but with the inadequate information and flawed incentives that currently shape our health care market. Drug companies earn higher profits when more people use expensive drugs, not when more people achieve better health. Doctors and hospitals are paid more for doing more, largely without regard for evidence of improved health outcomes (examples are the rapid increase in the number of MRI machines, excess capacity for neonatology and invasive cardiac procedures that lead to excess use, and the approximately 12,000 deaths that occur each year as the result of unnecessary surgery). Health care providers that deliver high quality, efficient care are financially penalized for not delivering a higher volume of more intensive services, beneficial or not (referred to as the "perverse incentive").

Four fundamental changes are necessary to redirect American medicine toward what most agree is its rightful mission: to best improve the health of all Americans most efficiently.

First, accurate and transparent information is essential to support wise decision-making at all levels. Whether individuals are deciding about the best approach to their own health, or patient and doctor are deciding together about the best therapy, or purchasers of health care and government agencies are trying to improve the quality and control the costs of care, everyone needs much better information than is currently available. The federal board described earlier would go a long way toward making good information available to all.

Second, the mix of physicians needs to be rebalanced. The research of Dr. Barbara Starfield and her colleagues at Johns Hopkins, as well as the research of Dr. Elliott Fisher and his colleagues at Dartmouth, shows that, despite our faith in the latest high-tech medical care, the areas of the country that have higher concentrations of specialist physicians have both higher health care costs and worse health care outcomes; the areas that have more primary care physicians have lower health care costs and better health outcomes. However, because of the financial, lifestyle, and intellectual incentives that are brought so heavily to bear on medical stu-

dents and practicing doctors, interest in careers in primary care is plummeting. The percentage of graduates of American medical schools entering family practice residencies declined by almost half between 1997 and 2004 (from 17.3 to 8.8 percent). What ought to be the basic unit of good health care, the primary care doctor-patient relationship, is at risk of soon becoming an endangered species.

Third, policy makers and payers should focus their attention on health care systems (groups of doctors, hospitals, and other medical services)—especially on figuring out how to reward them for providing the right care in the right amount, for achieving high levels of patient satisfaction, and, most important, for improving the health of the people they serve.

And, finally, the government cannot simply stand by as a paid-off sugar daddy to the medical (and especially the drug) industry. Well-functioning markets require active government oversight to make sure that the public's interests are being served. The medical watchdogs need to be revived, and the industry money that has become a staple of their otherwise meager diet needs to be withdrawn and replaced with adequate, stable funding from noncommercial sources. The FDA and NIH should be independent of, instead of seamlessly interwoven with, the drug and medical device industries. Drug company lobbying can no longer be allowed to stand in the way of legislation that clearly serves the health interests of the American people, such as setting aside less than $0.02 per prescription in the Medicare prescription bill to determine the best drugs and therapies for seniors, or simply allowing the market to function so the government can negotiate the best price from drug makers to obtain the best value for American senior citizens.

RECLAIMING RESPONSIBILITY FOR YOUR HEALTH

Don't forget the good news. You can take charge of many of your biggest health risks. The recommendations about a healthy lifestyle may at first seem too simplistic, but the research repeatedly shows that this is the best way to stay healthy. The challenge comes not in knowing what to do to optimize your health, but in integrating these simple recommendations

into daily habits. Genuine change requires the exercise of real autonomy. This means a willingness to accept responsibility for maintaining your own health, with a realistic view of economic conditions and environmental factors, setting goals, honestly confronting resistance, and getting help when necessary to overcome that resistance. It also means a willingness to let go of old habits to make room for growth.

Though it may seem antiquated in our era of high-tech medicine, the foundation of good medical care is an ongoing relationship with a primary care physician with whom you feel comfortable (sometimes in conjunction with a nurse practitioner or physician's assistant). The two essential components of such a relationship are that the patient trust the provider and have confidence in his or her competence, and that the provider have a sense of who the patient is and be willing and able to understand the patient's concerns. Perhaps a third essential component is the patient's being able to share his or her concerns about the commercial distortion of health care, and the ability for patient and doctor to decide together how to proceed in the context of this uncertainty.

How can you become a better health care consumer? The next time you hear about a medical "breakthrough," try to determine who sponsored the study and whether the experts interviewed disclosed any financial ties to the products being discussed. Go a step further: see if the results are presented as relative risk (people who took the new drug were *x* percent less likely to develop a disease than the people who didn't take the new drug) or as absolute risk reduction (taking the new drug protects *x* number of people out of 100 from developing the disease). The second approach provides much more information about the real benefit of the drug or therapy. Notice whether lifestyle and other interventions are discussed in addition to expensive drugs as a part of the solution. Most of all, immunize yourself from the drug companies efforts to convince you that you desperately need their advertised products. If you really needed the product, it is unlikely that the drug companies would be spending money on advertising. Remember, there aren't many ads for insulin on TV.

Since leaving medical practice to research and write about these issues, I have found problems far more profound than I ever suspected—

and I have found far more opportunity for Americans to improve their health as well. I am still a physician and want to do my best to help people achieve better health and a sense of well-being. So what can we do?

Ultimately, the issue is not the quality of our medical science, but the political context in which American medicine unfolds. The overwhelming power that the drug and other medical industries now wield over American politics, science, and health care has created an imbalance between corporate goals and public interest that is no longer self-correcting. In fact, it has become resistant to correction. If democracy is to be more than a ritual dance choreographed by powerful corporations in this postindustrial "information age," government must actively protect the integrity of the information on which we rely to guide our personal and political choices. As individuals we have the opportunity to reclaim responsibility for much of our health through intelligent lifestyle decisions and informed use of medical care. As citizens we must demand that our government restore the balance between public health and corporate profits, so that the drug, medical-device, and other medical industries can only achieve their goals by effectively and efficiently maximizing Americans' health. Needless to say, these industries, as well as many doctors whose high-priced specialty services would not be needed in such high volume in a more efficient health care system, will do everything possible to prevent reform, as they have so successfully done in the past.

Courageous leadership is urgently needed to redirect American health care—not unlike the leadership provided by President Teddy Roosevelt a century ago when the enormously concentrated power of the railroad, steel, and oil "combines" similarly threatened the public's interests. Government needs to be re-empowered, and a good place to start might be public hearings that investigate the commercial distortion of our medical knowledge. The first "case" might be an investigation of the process by which Celebrex and Vioxx, two drugs of very limited clinical value, have become blockbusters in the United States but not in the rest of the world (nearly 80 percent of all sales occur in the United States). Such hearings could publicly review the unprocessed data from the manufacturers' own studies that have been submitted to the FDA; expose the discrepancies between these data and the articles that reported the "scientific evidence" about the two drugs,

published in our two most respected medical journals; inform the public about the financial ties between each of the four authors of the clinical practice guidelines issued by the American College of Rheumatology in 2000, which recommended the use of these drugs, and at least one of the manufacturers of Celebrex and Vioxx; show that in 2001 (when these drugs were becoming established as the standard of care) they were the two most heavily advertised to the public and two of the most heavily marketed to doctors; show how drug company–funded continuing education has persuaded doctors to prescribe these drugs; show how the FDA has known this whole story since February 2001 and, despite issuing Warning Letters to the manufacturers of both Celebrex and Vioxx about false and misleading marketing, has not effectively corrected doctors' and the public's erroneous beliefs about the true clinical value of these drugs; and, finally, show how all these tactics were masterfully orchestrated to produce $5.3 billion of COX-2 inhibitor sales in the United States in 2003.

Public hearings investigating the commercial bias in the 2001 update of the cholesterol guidelines would be similarly revealing. The public has the right to know that the recommendations that guide their medical care are not nearly as "evidence based" as they claim to be; that many of the references cited to support key recommendations do not provide that support; that the directions of the estimations and extrapolations presented in the guidelines tend to justify the use of more statin drugs; and that these guidelines are driving up sales of cholesterol-lowering statin drugs while diverting doctors' and the public's attention away from far more effective and far less expensive ways to prevent heart disease.

This brings me to the end of my story. I hope that I have answered Mrs. Francis's question about why I chose to leave my practice to write this book, and that I have helped to improve the health of more people than I might have otherwise. I also hope that in sharing what I have learned about the distortion of our medical knowledge with hardworking colleagues I will have inspired some to become more critical consumers of scientific evidence and the recommendations of "thought leaders" on the payroll of the drug and other medical industries.

I will have succeeded in my task if I have motivated some readers to be more regular about exercise, adopt a healthier diet, stop smoking, and think more critically about the relationship between their own needs and goals and those that are externally imposed by the push of the market. My greatest hope is that this book will inspire readers to consider the responsibility of citizenship in this time of excessive medical profiteering and corporate influence, and to take up one of the most important challenges of our time: high-quality health care for all based on the translation of well-ordered science into accurate, unbiased medical information.

We have come to a critical juncture, and our future depends on our willingness to act on our country's highest ideals. In this sense, the health we seek for ourselves, for our families, and for all Americans is a metaphor for something greater even than physical well-being: wholeness and connectedness that extend beyond the narrow confines of the biomedical-commercial paradigm of medicine.

NOTES

PREFACE TO THE PAPERBACK EDITION

xiii **British drug authorities had mandated a similar warning:** Alan Cowell, "Second Thoughts on Restricting Drugs To Treat Depression in Adolescents," *New York Times*, September 21, 2004.

xiii **nine studies showing just the opposite:** Gardiner Harris, "Expert Kept From Speaking At Antidepressant Hearing," New Warnings Sought on Antidepressants," *New York Times*, April 16, 2004.

xiii **outside experts agreed with its own:** Gardiner Harris, "Antidepressant Study Seen to Back Expert," *New York Times*, August 20, 2004.

xiii **FDA belatedly mandated the highest level of caution:** Gardiner Harris, "FDA Toughens Warning on Antidepressant Drugs," *New York Times*, October 16, 2004.

INTRODUCTION

xvii **securities analysts were receiving bonuses:** Speech given by Lori Richard, director of the Office of Compliance Inspections and Examinations, U.S. Securities and Exchange Commission, to the Financial Women's Association, May 8, 2002. Viewed at http://www.sec.gov/news/speech/spch559.htm. Accessed January 30, 2004.

xvii **three times the average:** Henry J. Kaiser Family Foundation, "Prescription Drug Trends: A Chartbook Update," November 2001. Viewed at http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=1 4267. Accessed January 31, 2004.

xvii **increased by more than $1000:** Milt Freudenheim, "Workers Feel Pinch of Rising Health Costs," *New York Times*, October 22, 2003.

xvii **$469 for the average American family:** Paul Krugman, "The Tax-Cut Con," *New York Times*, September 14, 2003.

xvii **an additional $469 per year:** Freudenheim, op. cit.

xvii **half of all personal bankruptcies:** "Harper's Index," *Harper's Magazine*, August 2002.