CHAPTER 6

AMERICAN MEDICINE'S PERFECT STORM

A BRIEF HISTORY

In 1982, the National Governors Association sponsored a conference in New Orleans to explore innovative ways for states to control their unsustainably increasing health care costs. I presented research that I had done as a Robert Wood Johnson Fellow showing the benefit of offering inner city of Cleveland families covered by Medicaid the option of enrolling in a health maintenance organization that would give them access to private primary care doctors. For families who opted to join the HMO, hospital admissions and emergency room visits had plummeted, immunization rates and well-child care visits had improved, and costs had gone down. All the pilot programs being presented at this conference were variations on the same theme, and all came to the same conclusion: establishing a relationship between each Medicaid patient and a primary care doctor responsible for providing and coordinating all medical care improved the quality of care and, at the same time, decreased costs.

Several weeks later, I moved from Cleveland to Massachusetts to begin my career as a family doctor. Initially, the health insurance that most of my patients had, besides those with Medicare and Medicaid, did

not cover my services in the office. A few people had very expensive "Cadillac" health insurance that paid for all of their medical care and drugs. An equally small number were insured by the sole, recently started HMO in eastern Massachusetts, and were charged only a $3 co-payment for office visits. The people who had chosen to enroll in this plan agreed to access nonemergency medical care through their primary care (or covering) doctor only.

Over the next two decades, of course, all this changed: HMOs and managed care plans swept the country. Each year, more and more patients enrolled in these programs. It wasn't long before nearly all of my patients who weren't on Medicare or Medicaid were covered by some form of HMO or managed care plan.

What happened to health care costs? Per-person health care expenditures, adjusted for inflation, more than quadrupled over the following 20 years. Starting in 2001, premiums rose a whopping 43 percent over the next three years alone. Health care costs now account for one-seventh of the total GNP, up from 9 percent in 1980 to an estimated 15.5 percent in 2004. What seemed like a major crisis in 1982 now looks trivial. And as we have seen, all the while our health outcomes are lagging further and further behind those of the other wealthy industrialized countries.

How is it that those sweeping changes, adopted to control health care costs and improve the quality of care, had precisely the opposite effect? People tend to point a finger at one of two culprits: Many blame the HMOs and managed care companies for wresting control of medical decisions away from doctors and unreasonably restricting care in order to save money. Others blame the excessive power of the medical industries and particularly the drug companies, with their exquisitely honed marketing techniques, for the commercialization of medical practice.

Looking for the single cause of the poor performance of the American health care system is futile. The truth is closer to Pogo's discomforting epiphany: the enemy is us. We all have a relationship to the health care system: patients and potential patients, doctors and other health care professionals, researchers, workers in health care industries, health policy experts, government officials, lawmakers, and investors. We have all been pulled into this enormous and complex system by our hopes and fears, our myths and ideologies, our dedication and pursuit of scientific knowledge, and our personal and institutional aspirations. As the interests and energies of all these elements keep merging into an ever larger and more powerful system, a perfect storm is gathering that is producing enormously expensive and disturbingly ineffective health care, American style.

THE GOLDEN AGE OF HMOS AND MANAGED CARE

Nothing has had more impact on the practice of medicine in the United States than the rapid transition from traditional indemnity insurance to HMOs and managed care plans. And nothing could have produced more profound unintended consequences.

Prior to the era of managed care, indemnity insurance simply paid a contracted percentage of the bills for covered services, which rarely included office visits or prescription drugs. HMOs, on the other hand, offered to provide virtually complete health care coverage for a predetermined price. In return for this more complete coverage, patients who were enrolled in HMOs agreed to access medical care only through the HMO, usually through their primary care doctor. The burden of cost control is placed on the health care providers, whose responsibility, in addition to providing medical care, is to keep the cost of care within a defined budget. Managed care plans differ from HMOs in that the burden of cost control is not put directly on health care providers. Doctors are not prepaid and do not work on a fixed budget, but agree to accept a fee schedule for their services and participate in oversight of the quality and utilization of care—thus "managing" the care.

HMOs and managed care plans quickly came to dominate health insurance in the United States. They appealed to employers because of their promise of holding down insurance costs, which were increasing between 10 percent and 18 percent per year in the late 1980s and early 1990s. And they were attractive to patients because, unlike indemnity insurance, HMOs covered most medical services and drugs with relatively small co-pays—similar to the very expensive Cadillac indemnity plans. In addition, by paying for primary care and preventive services, and with long-term incentives that favored illness prevention, these plans

held out the promise of actually improving people's health. The prospect of a win-win insurance arrangement providing better care for less money, like the early HMO I studied in Cleveland, catalyzed the rapid change in U.S. health insurance. In the late 1970s, almost all employer-sponsored health insurance (95 percent) was the traditional indemnity type. By the end of the 1990s, HMO and managed care plans accounted for 92 percent of employer-based health insurance.

The period of the late 1980s and early 1990s was the golden era of HMOs and managed care plans. They appeared to have solved the problem of rising health insurance costs in a uniquely American way. Health care spending budgets that would have been unacceptable coming from the government were created by competing independent health plans, with employers choosing which to offer and employees usually (but not always) given a choice of several from which to choose. Positive coverage of the new plans by the media contributed to the enthusiasm. In 1990, stories about the new types of health insurance were twice as likely to be positive than negative. This market-based approach successfully tamed the double-digit percentage increases in health insurance premiums of the late 1980s and early 1990s, bringing the annual rate of increase down from a peak of 18 percent in 1989 to less than 2 percent by 1996.

PATIENTS BECOME CONSUMERS

Almost all of my patients welcomed the new plans. The broader insurance coverage meant that they no longer had to pay for their office visits or go through a lot of paperwork to collect from their indemnity insurance. And because family doctors take care of a broader range of problems than other primary care physicians, most of my patients already expected to discuss most of their medical problems with me before going to a specialist anyway. Besides the additional administrative burden of processing referrals to specialists, the added responsibility of functioning as the medical gatekeeper had little impact on my practice.

Despite the discounted fees, I preferred taking care of my patients on the new insurance plans. I could provide better care because patients were more willing to come in for routine exams and follow-up visits. Money

was removed as an impediment to the doctor-patient relationship. True, the low co-pay for office visits contributed to some nonessential patient-generated visits, but most of these served to increase the patients' trust and enhanced my ability to provide good care.

Patients were also grateful for the prescription drug coverage that was usually part of the new insurance plans. In 1965, prior to the advent of managed care, 93 percent of the cost of prescription drugs was paid directly by patients; by 1998 this was down to 25 percent. Between 1990 and 1997, out-of-pocket expenditures for prescription drugs by people who were covered by employer-based health insurance went down by 8 percent. During those same years, the actual per-person inflation-adjusted cost of prescription drugs in employer-based insurance plans tripled.

At the same time that the patients' out-of-pocket medical costs were going down, Americans' faith in the benefits of the latest medical science was high. Surveys done between 1992 and 2000 showed that half again as many Americans as Europeans described themselves as "very interested" in new medical discoveries (66 percent versus 44 percent), and almost twice as many Americans over the age of 65 were "very interested" in new medical discoveries as were European seniors (79 percent versus 42 percent). Almost half of Americans believed that health insurance or the government should "pay for all new medical technologies." One-third of Americans believed that "modern medicine can cure almost any illness for people who have access to the most advanced technology and treatment." And given their strong interest and faith in medical progress, Americans were overwhelmingly of the opinion that more rather than less money should be spent on "improving and protecting the nation's health," by an 11-to-1 margin.

Medical information was becoming available on the Internet, and the increasing media coverage of the latest "breakthroughs" in medical science further heightened public enthusiasm about the latest developments. (There was little awareness that most of this information had been made available to serve commercial interests; one study showed that the focus of 80 percent of Internet sites that address back pain is advertising, and only 12 percent of the sites were rated as "high-quality.")

The stage could not have been set more perfectly for prescription drug advertising to become a major force in American medicine. And so it did. In 1991 the drug companies spent a paltry $55 million on advertising drugs directly to consumers. Over the next 11 years, this increased more than 50-fold to over $3 billion in 2003. The ads appeal to viewers as independent decision makers—capable of forming their own opinions about which drugs they need—and resonate with the growing concern that HMOs and managed care plans tend to withhold the best care to save money.

Largely freed of concerns about out-of-pocket costs, enticed by advertising and media coverage of developments in medicine, and emboldened by a sense of autonomy, patients began requesting, and then demanding, specific tests, drugs, and procedures. Indeed, it became nearly impossible to convince many patients that more medical care was not necessarily better. Rather than adopting lifestyle changes that could prevent illnesses, many people began to believe that the latest "medical breakthroughs" were all that was needed to keep them healthy. Ethicist Daniel Callahan in his book *False Hopes* sums this up beautifully: "The market sells dreams and hopes as well as things." To exactly the same extent that a person is seduced by the false hopes and dreams offered by the medical industry's marketing efforts, the ability to trust his or her doctor, especially a primary care doctor, is eroded.

BACKLASH

It wasn't long, however, before the enthusiasm about HMOs and managed care plans started to wane. News stories about HMOs unreasonably withholding care became a dominant theme, and by 1997, critical stories were outnumbering positive ones by a seven-to-one margin. The health insurance industry added grist to the mill by imposing one-day obstetric hospitalizations for normal deliveries, selectively contracting with doctors so that long-standing doctor-patient relationships were disrupted, and trying to save money by avoiding high-cost patients like those with HIV/AIDS. Patients' rights legislation emerged as a major political issue as the public focused on restricted access to care. The public's esteem for managed care companies plummeted. In 1997, 51 percent of those surveyed said that managed care companies were serving patients well; that figure was down to 29 percent just four years later.

The data about the actual effect of managed care tell a very different story. The quality of care neither improved nor deteriorated under managed care. The stories about patients being rushed through doctors' offices turned out not to be true (like the myth of the estate tax causing the loss of the family farm). An article published in the *New England Journal of Medicine* showed that between 1989 and 1998, the frequency with which people saw their doctors did not change. There was no shortening of visits for managed care patients for either primary or specialty care visits; in fact, the duration of doctor visits actually increased by one to two minutes. Even the public anger at the withholding of care by overly aggressive or financially greedy "gatekeepers" turned out to be largely a myth: a study conducted by a nationwide managed care company, United Healthcare, showed that fewer than one in 100 requests for referrals were being denied, leading the insurer to drop its requirement for primary care approval of referrals. Still, as an American researcher observed in a Canadian medical journal, "Regardless of the evidence, there is a strong sentiment among both physicians and patients that managed care is harming quality of care." So what was the real problem?

Initial cost savings had come fairly easily. Doctors, hospitals, and other health care providers had little choice but to accept discounted fees in order to be included in the newly formed networks of health care providers; otherwise they risked losing access to their patients. These so-called volume discounts controlled prices during the transition to managed care, but the apparent solution was short-lived. Once the discounts had been factored in, this apparently exquisite solution to controlling costs—local health care budgets set by the marketplace instead of the government—became the problem. When there were no more cost savings to be squeezed out of the fees paid to health care providers, HMOs and managed care companies had only one avenue open: they had to start to really "manage" care, that is, control costs by eliminating unnecessary or wasteful care. (Of course, cutting down on advertising, executive salaries, and profits would have helped, too.)

Almost overnight, the hyperbolic hopes for managed care and appre-

ciation of the greater coverage quickly turned into hyperbolic vilification. In one survey, 59 percent of the people expressed negative feelings about HMOs and managed care in general, but 69 percent of the same people were satisfied with the actual care they were receiving from their own HMO or managed care plan. Of course there were abuses and mistakes on the part of the health insurers, but why the change in public opinion?

Each of the constituents of this complex system felt threatened by the limitation on medical expenditures. Though I have no proof, I strongly suspect that the parties that had the most to lose financially—the drug, medical equipment, and hospital industries; and the specialty care doctors—played the biggest role in fanning the flames of public disgruntlement. When public opinion turned so strongly against the measures necessary to control health care costs, the insurance companies had no choice but to loosen their management of care. Yearly increases in health insurance premiums once again started to balloon out of control, rising steadily from a low 2 percent annual increase in 1996 to 13.9 percent in 2003.

Ironically, the move into managed care created a historic opportunity for the medical industry. The cost-containment potential of HMOs and managed care plans was, initially, a serious threat to drug companies and medical device manufacturers. But the broader coverage offered by the new plans turned out to have the most profound unintended consequences: Instead of containing health care costs, HMOs and managed care plans facilitated the almost unrestrained increases in health care spending that followed. The captains of the drug and other medical industries certainly hadn't planned this, but they knew how to take advantage of opportunity when it came knocking on their door. After a brief period of clear skies, dark clouds could be seen gathering on the horizon.

THE DIMINISHING ROLE OF PRIMARY CARE DOCTORS

Comparisons both within the United States and between countries show that access to comprehensive, family-oriented primary care service is the distinguishing characteristic of health care systems that are both effective

at producing good health and efficient at controlling costs. Nonetheless, American medicine has become heavily dominated by specialty care over the past 40 years. In 1965 there were as many primary care doctors as specialists in the United States. Since then, the ratio of primary care doctors to the U.S. population has remained about the same, while the ratio of specialists has more than doubled.

Most health policy experts recommend that between 42 percent and 50 percent of doctors in the United States should be primary care doctors. Instead 31 percent of doctors in the United States practice primary care and 69 percent are specialists. In order to correct this imbalance, the Council on Graduate Medical Education (a body established by Congress to make recommendations about the supply and distribution of doctors to the U.S. Department of Health and Human Services) recommended training at least 50 percent of physicians as primary care doctors. In 1998, this goal was not being met. Only 36 percent of U.S. medical students that year reported that primary care was their first choice of specialty. And to show how quickly the medical environment is changing, only four years later, interest in primary care among U.S. medical students plummeted by 40 percent, so that only about one out of five students (21.5 percent) identified primary care as his or her first choice.

A number of factors turn medical students away from careers in primary care. The intellectual culture within the academic medical centers where students are trained is dominated by specialists, whose ideals of "good" and "real" medicine are very different from the kinds of challenges faced by primary care doctors. A survey of medical students showed that only three out of 1000 thought that good students were encouraged to go into primary care fields. Most doctors are in their late twenties or early thirties when they finish their training. They finish with an average debt of over $100,000, at just about the time they want to start a family and get on with their lives. The starting salary for many specialties is more than twice that of primary care doctors. And to make this choice even more difficult, the boundary between professional responsibilities and personal time is often more blurred in primary care than in other specialties.

Nobody can blame these young doctors for not choosing primary care—it takes a tremendous amount of commitment and idealism to choose a career that is not supported by role models in training, carries

less prestige among peers, intrudes more into one's personal life, and pays far less than most other specialties. A bright and concerned Harvard Medical School student lamented to me that he really wanted to become a pediatrician and take care of children in a community-based practice, but his enormous debt was forcing him into a more lucrative subspecialty. The same story is heard over and over.

In addition to the growing imbalance between primary care doctors and specialists, the ever-present threat of malpractice litigation is also increasing the cost of American medical care. This threat may provide some protection to patients and allow recourse for substandard care, but the justice meted out is inconsistent. In a *New York Times* op-ed piece, Philip K. Howard, author of *The Collapse of the Common Good: How America's Lawsuit Culture Undermines Our Freedom*, commented that most of the doctors who do commit malpractice are not sued, and most of the lawsuits brought against doctors are about situations in which malpractice was not committed. Nonetheless, the current medical malpractice system consistently distorts our medical care. Doctors are aware of the risk of a malpractice suit lurking in every patient visit. Three-fifths of doctors in the United States admit that they do more diagnostic testing than is necessary because of the threat of litigation. And why not? The risk of ordering an extra test is nil, but the threat of a lawsuit because of a test not ordered is ever present—even when the likelihood of serious disease is very low and reasonable professional judgment would say the test was not necessary.

These extra tests can and often do set off a cascade effect, requiring even more tests to follow up on abnormal results, many of which then turn out to be normal. With the specter of malpractice looming, doctors feel justified in ordering almost any test, including tests in which they have a financial interest.

The rising cost of malpractice insurance is causing a rebellion among doctors forced to pay the price for our litigious culture (and a few bad doctors) regardless of their own track record and commitment to quality care. Some, caught between the ever-present fears of litigation and the mounting costs of insurance, are shielding their assets and practicing without insurance, while others are leaving the practice of medicine altogether.

At the same time that all of this is happening, the medical information available to doctors (and to their patients) is increasingly dominated by commercial interests. The skies are darkening.

DRUGGING THE WATCHDOGS

Within the FDA, the doctors, scientists, and statisticians are dedicated to making sure the data about drugs and medical devices presented by manufacturers justify their claims of safety and efficacy. But the FDA is understaffed, underfunded, and under pressure, according to its own employees. Even worse, the FDA has fallen under the influence of the drug and medical-device industries, so much so that it was labeled "a servant of industry" by Dr. Richard Horton, the editor of the British journal *The Lancet*.

The FDA used to be famous for moving at a glacial bureaucratic pace. In 1980, the General Accounting Office of Congress reported that the FDA was inadequately staffed to keep up with its workload. In 1988, political action by AIDS activists drew attention to the very real need for quicker access to potentially lifesaving drugs. The ensuing political crisis resulted in the 1992 passage of the Prescription Drug User Fee Act, otherwise known as PDUFA. The drug companies agreed to pay a $300,000 fee for each new drug application; in return, the FDA's Center for Drug Evaluation and Research promised to adhere to a speedier timetable for the new drug approval process. According to a 2002 GAO report, a little more than half the cost of reviewing new drug applications was funded by user fees from the drug industry.

New-drug approval certainly became quicker. With PDUFA funds, the FDA was able to increase the staff at the Center for Drug Evaluation and Research, or CDER, from 1300 to 2300, all assigned to expedite new-drug applications for patented (not generic) drugs. In the four years following the enactment of PDUFA, the median length of time the FDA took to decide on priority new-drug applications dropped from 20 months down to six months. At the same time, the average number of new drugs approved doubled.

Funding by drug companies may have seemed like a good idea for the cash-strapped FDA, but what about protecting the consumer from

the drug companies' influence? How unbiased can CDER be when half its budget comes from the drug companies themselves? An anonymous survey done by Public Citizen in 1998 revealed that FDA review officers felt that standards had declined as pressure to approve new drugs increased. The FDA medical officers who responded to the survey identified 27 new drugs that had been approved within the previous three years that they felt should not have been. A similar report on CDER by the inspector general of the U.S. Department of Health and Human Services, published in March 2003, found that 58 percent of the medical officers said that the six months allotted for review of priority drugs is not adequate, and that one-third of respondents did not feel comfortable expressing their differing opinions. In the FDA's own *Consumer Magazine*, Dr. Janet Woodcock, director of CDER since 1994, wrote that tight deadlines for drug approval were creating "a sweatshop environment that's causing high staffing turnover."

The most dangerous consequence of these changes was that the number of drugs approved by the FDA but later withdrawn from the market for safety reasons increased from 1.6 percent of drugs approved between 1993 and 1996 to 5.3 percent between 1997 and 2000. Seven drugs that had been approved by the FDA after 1993 were withdrawn from the market because of serious health risks. The *Los Angeles Times* reported that these drugs were suspected of causing more than 1000 deaths (though the number of deaths could actually be much higher because reporting of adverse drug events to the FDA is voluntary). Even though none of these seven drugs was lifesaving, according to the *Los Angeles Times*, "the FDA approved each of those drugs while disregarding danger signs or blunt warnings from its own specialists." All told, 22 million Americans, one out of every 10 adults, had taken a drug that was later withdrawn from the market between 1997 and 2000.

The blood sugar–lowering diabetes drug Rezulin is one of the drugs that was approved in haste by the FDA—and later withdrawn, but much too late for many Americans. The details of the story were first presented in 2000 in a Pulitzer Prize–winning series of investigative reports by David Willman of the *Los Angeles Times*. Remarkably, as quickly as medical news travels, this story had no "legs" and went largely unheeded. Three years later David Willman wrote a similar story showing that the same problems were still there.

Dr. Richard Eastman was the director of the NIH division in charge of diabetes research, and in charge of the $150 million Diabetes Prevention Program study. This large study was designed to determine whether diabetes could be prevented in people at high risk (overweight and with mildly elevated blood sugar levels) by drugs or by lifestyle interventions. In June 1996 Dr. Eastman announced that Rezulin had been selected as one of the two diabetes drugs to be included in the study—a real victory for Warner-Lambert, the manufacturer of Rezulin.

Also in 1996 Warner-Lambert submitted Rezulin to the FDA for approval, and it became the first diabetes drug to be given an accelerated review. The medical officer evaluating the new drug application, Dr. John L. Gueriguian, was a 19-year veteran of the FDA. His review recommended that Rezulin not be approved: the drug appeared to offer no significant advantage over other diabetes drugs already on the market, and it had a worrisome tendency to cause inflammation of the liver. Warner-Lambert executives "complained about Gueriguian to the higher-ups at the FDA." Dr. Gueriguian was then removed from the approval process for this drug. When the Advisory Committee met to decide on the approval of Rezulin, they were not informed of Dr. Gueriguian's concerns about liver toxicity. The FDA approved Rezulin in February 1997, and brisk sales soon earned it "blockbuster" status.

However, reports of fatal liver toxicity due to Rezulin soon started to appear. Notwithstanding reports of deaths in the United States as well as in Japan, and the withdrawal of the drug from the United Kingdom because of liver toxicity in December 1997, Dr. Eastman and his colleagues decided to continue treating volunteers in the Diabetes Prevention Program study with Rezulin. Only after Audrey LaRue Jones, a 55-year-old high school teacher, died of liver failure in May 1998 did Rezulin stop being given to the volunteers in the study. Warner-Lambert maintained that Rezulin was not responsible for the liver failure that led to her death.

Despite the mounting reports of liver problems in the United States, Rezulin was not withdrawn from the U.S. market until March 2000. By that time, $1.8 billion worth of the drug had been sold. The *Los Angeles Times* reported that, all told, Rezulin was suspected in 391 deaths and linked to 400 cases of liver failure. Looking back on his experience, Dr. Gueriguian told the *Los Angeles Times*, "Either you play games or you're going to be put off limits . . . a pariah."

Another FDA medical officer and former supporter of Rezulin, Dr. Robert I. Misbin, was threatened with dismissal by the FDA. His offense? He provided a copy of a letter to members of Congress from himself and other physician colleagues at the FDA expressing concern about the FDA's failure to withdraw Rezulin from the market after the FDA had linked it to 63 deaths due to liver failure. Dr. Janet B. McGill, an endocrinologist who had participated in Warner-Lambert's early studies of Rezulin, told the *Los Angeles Times* that Warner-Lambert "clearly places profits before the lives of patients with diabetes."

In retrospect one wonders why the NIH and FDA continued to support Rezulin long after it was known to be associated with so many deaths. One particularly troubling aspect of Rezulin's seemingly privileged treatment was provided by David Willman's series in the *Los Angeles Times*: Dr. Eastman, while in charge of diabetes research at the NIH and overseeing the $150 million study in which Rezulin was included, was receiving $78,455 from Warner-Lambert on top of his $144,000 annual salary from the NIH. Between 1991 and 1997, Dr. Eastman had received, according to the *Los Angeles Times*, "at least $260,000 in consulting-related fees from a variety of outside sources, including six drug manufacturers." None of this was part of the public record, but the financial relationship with Warner-Lambert had been approved by two of Dr. Eastman's superiors. And Dr. Eastman was by no means alone. In fact, the *Los Angeles Times* reported that no fewer than 12 of the 22 researchers who were overseeing the $150 million government-sponsored diabetes study as "principal investigators" were receiving fees or research grants from Warner-Lambert.

One would think that, once these drug companies' lucrative consulting contracts with high-ranking NIH officials with direct responsibility for the companies' products had been brought to the light of day, a firewall would have been quickly erected. Hardly. In December 2003, David Willman wrote an article titled "Stealth Merger: Drug Companies and Government Medical Research," in which he identified multiple examples of NIH officials receiving payments of *hundreds of thousands of dollars* from drug companies.

"Subject No. 4" died while participating in a drug study at the National Institutes of Health on June 14, 1999. She was Jamie Ann Jackson, a 42-year-old registered nurse, married and a mother of two. Mrs. Jackson was the second person who had died while participating in NIH studies of a drug named Fludara, marketed by Berlex Laboratories. This drug, which had been used to treat leukemia since 1991, was being tested to see if it helped patients with autoimmune diseases. No more patients were enrolled in the study after the second death, but the study continued with the patients already enrolled for another nine months, and terminated only when five of the remaining 12 patients developed abnormalities in their blood tests. Dr. Stephen I. Katz was the director of the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases, which was conducting the study. According to the *Los Angeles Times*, between 1996 and 2002 Dr. Katz received more than $170,000 in consulting fees from the German drug manufacturer Schering AG. (It was during this time period that the fatal study of Berlex's drug Fludara was being conducted.) These details are important because Berlex is a wholly owned subsidiary of Schering AG, described as its "U.S. business unit." Dr. Katz told the *Los Angeles Times* that he had been "unaware of any relationship between Berlex and Schering AG," and therefore unaware of a potential conflict of interest. But, according to the *Los Angeles Times*, "Katz declined to identify when he learned that Berlex was the U.S. affiliate of Schering AG."

Drs. Eastman and Katz were certainly not the only high-ranking officials at the NIH to receive consulting fees from the drug industry. Another official had accepted $1.4 million plus stock options over an 11-year period, while at least one of the companies for whom he was consulting was involved with the work of the laboratory he directs at the National Institute of Allergy and Infectious Diseases.

The financial conflicts of interest at the NIH are by no means isolated examples of drug company influence on the government oversight of the drug industry. Because crucial recommendations about drug approval and drug labeling are made at the FDA's Advisory Committee meetings, federal law "generally prohibits" the participation of experts who have financial ties to the products being presented on these committees. An article in *USA Today* in September 2000 shows, however, that the FDA granted so many waivers—800 between 1998 and 2000—that 54 percent of the experts on these all-important Advisory Committees had

"a direct financial interest in the drug or topic they are asked to evaluate." And this 54 percent figure does not take into account that FDA rules do not even require an Advisory Committee member to declare receipt of amounts less than $50,000 per year from a drug company as long as the payment is for work not related to the drug being discussed.

The storm clouds grew even darker as the government institutions responsible for protecting the public's interest became dependent on drug company largesse.

THE GREAT AMERICAN DRUG LOBBY

None of this would have been possible, of course, without the insatiable appetite of politicians for industry dollars. Lobbying efforts on behalf of the drug industry are unrivaled. It spent $177 million on lobbying in 1999 and 2000, $50 million more than the next closest industry, insurance. The drug industry hires 625 lobbyists, more than one for each member of the House and Senate. The drug industry's $20 million in campaign contributions for the 2000 election seems downright stingy compared with the insurance industry's $40 million. (Could this be playing any role in President Bush's desire to privatize Medicare?) The $20 million, however, doesn't include the approximately $65 million for so-called issue ads aired by Citizens for Better Medicare. Though this organization appeared to be a grassroots movement, it was in fact funded primarily, if not exclusively, by the drug industry, and its ads tended to benefit candidates who supported the drug industry's legislative goals.

Money from the drug industry has been pouring into politics, with the balance of support tipping progressively more toward the Republicans, who received about 76 percent of the drug industry's financial largesse in the 1999–2000 election cycle. It's not often that we get to see what this money actually buys, the actual quid pro quo laid out in black and white. But a letter from Jim Nicholson, the chairman of the Republican National Committee, to Charles Heimbold, chairman and CEO of Bristol-Myers Squibb, made public as a result of legal challenges to the constitutionality of the McCain-Feingold campaign finance reform law, shows how this can work. The letter, written in April 1999, was delivered

at a time when pressure for a bill to provide prescription drug benefits to senior citizens was beginning to mount. The drug industry was jockeying for a bill that would enhance its bottom line by providing Medicare funds to purchase its drugs, while at the same time blocking the federal government from using purchasing power to negotiate lower prices (as Medicare has done so successfully with payments to doctors and hospitals).

In the letter, Nicholson expresses his approval of "forming a pharmaceutical coalition" that will provide the "perfect vehicle for the Republican Party to reach out to the health care community and discuss their legislative needs." The letter goes on to say, "We must keep the lines of communication open if we want to continue passing legislation that will benefit your industry." The penultimate paragraph describes just how to keep those lines open, including a request for a $250,000 donation from Bristol-Myers Squibb to the Republican National Committee. With tens of billions of dollars a year on the line for the drug industry, what was a mere $250,000?

Perhaps the storm clouds were being actively seeded.

Drug companies, government, doctors, patients, insurers. Health care costs keep rising, with no end in sight, and despite the myths about the excellence of our medical care, we are not realizing commensurate improvements in our health. The American health care system keeps edging ever closer to the breaking point. Many factors are contributing, but in the eye of the storm is a single factor: the transformation of medical knowledge from a public good, measured by its potential to improve our health, into a commodity, measured by its commercial value. This transformation is the result of the commercial takeover of the process by which "scientific evidence" is produced. How this takeover occurred, and how it affects the quality of the medical information that well-informed, dedicated doctors rely on to make clinical decisions, is the subject of the next chapter.