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# Direct-to-Consumer Advertising and the Demise of the Ideal Model of Health Care

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RONALD F. WHITE

In recent years, pharmaceutical companies have begun to market expensive new drugs directly to consumers via television ads. These new drugs target some of our most common medical problems, such as allergies, heartburn, erectile dysfunction, and attention-deficit disorder. Those same corporations, however, have come under fire for mass-marketing drugs previously approved by the U.S. Food and Drug Administration (FDA), but later deemed to be unsafe, including Rezulin, Fen-Phen, Vioxx, and Baycol. In 2001, Bayer Pharmaceutical's Baycol, a cholesterol-lowering drug, was withdrawn from the market under the cloud of approximately eight thousand pending lawsuits. Some critics of the FDA complain that the review process is too slow and deliberate, whereas others insist that it is too fast and reckless.

On June 15, 2005, Bristol-Myers Squibb announced a self-imposed ban on direct-to-consumer (DTC) advertising of new drugs until those drugs have been on the market for a year. For that first year, marketing efforts would emphasize direct-to-physician (DTP) advertising. Meanwhile, the American Medical Association continues to push the FDA for stricter governmental regulation of DTC advertising, and the American health-care system as a whole remains in a state of crisis. What's really going on here?

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Ronald F. White is a professor of philosophy at the College of Mount St. Joseph.

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The maze of regulations that envelopes the sale of pharmaceutical products in the United States has its roots in a longstanding, yet subtle, ideology that pervades the health-care industry as a whole: the belief that the provision of health care is not a business and that the distribution of its products and services requires paternalistic oversight by duty-bound physicians and government regulators. The dogged defenders of this ideology usually adopt the following premises as support for a system of medical paternalism: (1) health is a fundamental necessity; (2) the consumer often cannot adequately assess the absence or presence of disease; (3) treatment requires specialized expertise; (4) misdiagnosis, mistreatment, or nontreatment may have profound consequences; and (5) ill people are frequently rendered especially vulnerable to exploitation by their disease (Berger et al. 2001, 199). Often implicit is the hidden premise that “objective science” in the form of FDA-regulated clinical trials protects the public from unsafe or ineffective medical treatment.

The primary conclusion drawn from these premises is that health care, by its very nature, is not really a business, so it is exempt from the kind of moral scrutiny afforded other corporate entities. Until recently, this argument has gone unchallenged for the most part and has even been reaffirmed by medical ethicists. Despite fervent effort by the defenders of the status quo, however, market forces have begun to undermine this pervasive ideology. The rise of DTC advertising in the United States is an early sign of an impending revolution in health care.

In reality, health care has always been an economic activity that involves the exchange of products and services. Modern medicine’s hallmark has been the rapid rise in the number of persons who earn paychecks in that sector. In the United States, the health-care delivery system now employs at least 10 million, including 798,000 medical doctors and 208,000 pharmacists (Shi and Singh 2004, 3–4). U.S. health-care costs have spiraled. In 1960, they accounted for only 5 percent of our gross domestic product (GDP); in 2000, however, they accounted for at least 13 percent (AHRQ 2002, 1). Rising health-care costs have contributed to high-profile bankruptcies in the auto industry and elsewhere.

Despite these stark realities, the keepers of the status quo benefit greatly from maintaining the system. The various interest groups—whose lobbyists stalk the halls of Congress representing physicians, pharmacists, and drug companies—deploy a variety of cloaking devices to hide the health-care system’s economic foundations. The most obvious device has been our third-party payment system, which has numbed the system’s price sensitivity. In this misrepresented system, health-care sellers have been able to charge noncompetitive prices for their goods and services with impunity, in the guise that their transactions are not ordinary business activity.

At the cultural level, the obfuscation is much more subtle. How did Americans end up with a health-care system steeped in euphemisms, in which health-care buyers (disguised as “patients”) are routinely prescribed expensive patent-protected medical treatment by its sellers (disguised as “providers”) in the absence of antecedent bargaining over prices? And why do physicians, dentists, surgeons, hospitals, and pharmaceutical

companies routinely exchange ideology disguised as “information” behind a smoke-screen of arcane “scientific” language that most buyers cannot decode without professional translators? Of course, the most basic question is: Why do we tolerate a high-priced health-care system infested with artificial monopolies and shrouded in opacity?

The answer to all these questions is that the realities of health care have been obscured by an ideology that masks multiple layers of what business ethicists would otherwise call conflict of interest. The FDA, which regulates pharmaceutical products, contributes significantly to the preservation of this deeply rooted ideology that masks the economics of health care and at the same time surreptitiously lines the pockets of health-care providers.

The most prolific source of this culturally based self-deception can be traced to the Hippocratic, Judeo-Christian, and Western liberal ideologies, which together portray the health-care industry as a physician-directed coterie of charitable “professions” that operate outside of the laws of economics. This ideology has also been influenced by endemic scientism, which fosters the cultural belief that medicine is an applied science, like engineering, and that we can rely on those objective and altruistic scientists to construct a risk-free society. Consequently, most of what constitutes traditional medical ethics today systematically ignores the presence of a lumbering elephant in the room: virtually everyone involved in the provision of health care today gets a hefty paycheck signed by a corporation.

After years of interminable debate by medical ethicists over issues purged of underlying economic reality—abortion, reproductive assistance, euthanasia, and stem-cell research—the time seems ripe for a more realistic approach. Americans should acknowledge that health care is an industry and therefore should be subjected to the kind of scrutiny other businesses receive. As a case study, I focus my discussion here on DTC advertising of pharmaceutical products. I suggest that as long as we choose to ignore the elephant in plain sight, we will not be able to make sense of prescription-drug laws, DTC advertising, and the health-care crisis in the United States. Our socially constructed inability to distinguish between truth and mere ideology has perpetuated the status quo and impedes meaningful reform of the health-care system.

I begin by briefly describing the pharmaceutical elephant, explaining why the Hippocratic, Judeo-Christian, and some Western liberal medical models fail to elucidate the real ethical issues associated with marketing medicines. In the end, I suggest that meaningful health-care reform requires that we abandon the status quo, admit that health care is a business, and hold the various health-care providers to the same moral and legal standards that we apply to other businesses. In short, I argue that business ethics provides a more plausible, reality-based approach to DTC advertising, and perhaps to most other issues, than does traditional medical ethics.

## The Pharmaceutical Elephant

Let us begin with a broad description of the elephant in the room, that obvious behemoth among us whose existence we simply refuse to acknowledge.

1. Health care has always been an industry, or a coterie of highly profitable industries, including insurance corporations, hospitals, and the pharmaceutical industry.
2. Since the early twentieth century, health-care business institutions in the United States have wielded great social, economic, and political clout through professional organizations, corporations, industrywide political action committees (PACs), and so forth. In recent years, pharmaceutical corporations have become especially prosperous and well situated politically among the various components of the health-care industry. Surprise! They act like other corporations outside of the health-care system.
3. Government directly or indirectly influences the health-care industry's competitive environment. In recent years, government has been especially hospitable to the pharmaceutical industry. This hospitality is basically "corporate welfare" disguised as "regulation," which includes generous patent protection for twenty years or more, governmentally funded research, cooperative regulatory agencies, and mountains of industry-friendly legislation.
4. There is a health-care crisis in the United States. The medical profession, the pharmaceutical industry, and the government all contribute significantly to this crisis by conspiring to maintain the status quo through masking economic reality and thereby stifling meaningful reform efforts.

Although prevailing mythology still singles out pharmaceutical corporations as the primary purveyors of corporatism in medicine, that storyline does not begin to capture the real picture. Developments in the pharmaceutical industry merely reflect what has been happening in the health-care industry as a whole for more than a century. Across the board, health care has become increasingly occupied by a wider variety of corporate entities: insurance companies, supply companies, and inpatient and outpatient facilities. A wide variety of PACs has emerged, dedicated to the advancement of the self-interest of its stakeholders, which include professional associations, unions, industrywide associations, and professional lobbyists and lobbying firms. If the pharmaceutical industry differs from the other segments of the health-care industry, it does so only in terms of its visibility, size, profitability, and lobbying acumen (White and Fraley 1997). However, this corporate elephant has remained for the most part invisible to the naked eye because it has been shrouded in ideology.

## **The Ideal Model of Biomedical Ethics**

The long-prevailing model of biomedical ethics can be traced to the Hippocratic and Judeo-Christian traditions. The common thread of this ideology, which I call the *Ideal Model of Health Care*, is the belief that health-care provision is rooted in ideal altruism or selfless devotion to the interests of others, often at the expense of the provider's own interest. Again, it would be convenient if we could argue that health care used to be based on ideal altruism and that at some point it became corrupted by

the rise of corporate greed. In reality, however, health care has never been a bastion of ideal altruism. It has always been based on self-interested “reciprocal altruism,” or the “you scratch my back and I’ll scratch yours” philosophy, and therefore has been more akin to business than to altruistic charity. Over time, the Ideal Model has disguised reciprocity in a complex cloak of ideology.

The cloak itself has evolved over time. Today, the Ideal Model is reflected in the widespread belief that health-care providers, especially physicians and nurses, are professionals who operate on the basis of a fiduciary relationship with patients, which in turn implies moral duties beyond what one would expect from other businesses.

The concept of professionalism that underlies the Ideal Model promotes the belief that those who pursue certain occupations (doctors, lawyers, politicians, accountants, engineers, and others) are guided by altruistic moral ideals beyond the pursuit of self-interest. Scientists, for example, are regarded as professionals who are selflessly dedicated to the discovery of Truth, regardless of its economic implications. It is also assumed that the judgments these professionals make are impartial, unbiased, and independent of self-interested, market-based decision making (Davis and Stark 2001). When agents other than those situated within the medical professions violate this sacred trust under the guise of professionalism, they are legally and morally sanctioned for having a conflict of interest. Indeed, only within this socially constructed sphere of professionalism does conflict of interest become a moral issue. However, the moral outrage associated with conflict of interest is rarely directed toward various components of the health-care industry because health care is not widely regarded as a business.

This mirage is sustained in part by professional organizations that spout lofty Hippocratic ideals in their bylaws and in their codes of ethics, but rarely enforce these ideals. On close examination, professionals are often indistinguishable from people who are employed in the less idealized occupations. Nevertheless, in the real world, professional organizations relentlessly and often stealthily and indirectly advance the self-interest of their constituencies by shaping public policy.

So professionalism is not synonymous with unbridled altruism or monastic poverty. Indeed, on those rare occasions when government looks seriously into Medicare and Medicaid fraud, it finds the main culprits to be not patients, but opportunistic, well-situated health-care professionals, especially physicians. Moreover, in the real world, laboratory scientists are not always objective purveyors of the Truth, as recent revelations of fraud in the Korean stem-cell research program illustrate.

Medical ethics also contributes to the smokescreen that obscures the economic realities of health care. Surveying the most commonly used textbooks in biomedical ethics, one finds a standard repertoire of issues, such as research ethics, reproductive assistance, abortion, euthanasia, genetic testing, and genetic screening. The common denominator is an idealized approach, which perpetuates the notion that genuine moral issues must be considered apart from economic reality. This feat is most often accomplished by couching moral discourse in terms of metaethical theories, usually

rights-based moral theories and other abstract principles, such as beneficence, liberty, utility, and justice. The hallmark of the Ideal Model is the notion of a right to health care, which also nurtures the widespread belief that economic analysis is irrelevant to ethical discourse in health care.

Unmentioned in this discourse is the basic economic context of real-world health care: managed-care organizations, research laboratories, fertility clinics, abortion clinics, and hospitals are for the most part owned and operated as corporate entities that earn healthy profits for shareholders, pay high salaries to various professionals, pay corporate taxes, and compete with other providers for health-care dollars.

From the ethereal perspective of medical ethics, the analysis of moral issues, such as informed consent in medicine, tends to focus on the metaphysics of free will rather than on earthly economics. This focus virtually guarantees the marginalization of discussion of the financial incentives that underlie flow of medical information in our culture. A good recent example of how the Ideal Model distorts moral and legal issues is the Schiavo case in Florida. Most of the public discussion in that case centered on who has the right to decide whether or not to withhold Terry Schiavo's nutrition and hydration. Little or no public discussion, however, dealt with who ought to assume the duty of paying for her nursing home, physicians, nurses, physical therapists, and drugs (not to mention lawyers). No one discussed how much these various sellers of health care were charging, who paid the lawyers and the many medical experts testifying in the court cases, or how much were they paid.

Because vested financial interests are considered irrelevant to real moral issues, they go unmentioned in discussions of health-care ethics. As a result, health care is the only sector in which bargaining discourse between buyers and sellers over the price of products and services is routinely excised.

Besides contributing to a great deal of confusion in medical ethics, this economic blind spot has helped to stifle efforts at health-care reform. In recent years, for example, defenders of the Ideal Model have attacked DTC marketing of pharmaceutical products. They argue that such advertising harms patients by blurring that traditionally inviolable line of demarcation between scientific medicine and normal business enterprise.

## **The Real World of Business Ethics**

As a matter of principle, orthodox business ethics accepts the notion that corporations are entities motivated by self-interest; that is, they are "money machines" designed to earn income for stakeholders. The traditional corporate stakeholder groups include stockholders, employees, consumers, financiers, suppliers, and local communities. In the real world, these groups sometimes cooperate with one another, not out of ideal altruism, but out of reciprocal altruism in a search for mutual benefit. In the absence of any compelling motivation to cooperate, stakeholders compete with one another. Cooperation among stakeholders is facilitated through the forging of voluntary contracts. Government's primary role is to protect the system from endemic opportunism, or the human propensity to cheat and break promises in pursuit of self-interest.

Within this context, conflicts of interest serve as a subterfuge for opportunism. Science, in the real world, is also a business in the sense that the information and products born out of scientific inquiry are sold by self-interested corporations that sign the paychecks of the scientists they employ.

Every good course in business ethics covers a core of issues that elucidate these complexities, especially conflict of interest, truth in advertising, and of course the ever-present potential for corruption. Corporations that buy and sell “science,” however, are rarely subjected to the same moral scrutiny directed toward other businesses. As it turns out, the Ideal Model typically masks these very issues.

## The FDA and the Ideal Model

The American tradition of cloaking the economic realities associated with the pharmaceutical industry can be traced back to changes over time in the FDA. A quick look at the history of the FDA’s regulation of pharmaceutical advertising reveals the rise of a system steeped in conflict of interest under the guise of medical paternalism.

Today, government regulation of pharmaceutical products takes place on three fronts: the research and development of products, the labeling of products, and the marketing of products. In all three categories, it is assumed that the regulatory process is based on objective science, although the FDA’s effectiveness in all three areas has been subject to serious debate.

From 1938 until 1948, the Federal Trade Commission (FTC) regulated drug advertising. After allegations of misleading advertising, Congress passed the FDA Act of 1962, known as the Kefauver-Harris amendments, which set up the extensive approval processes in effect today and shifted regulatory responsibility for drug advertising from the FTC to the FDA (ACP 1998). Henceforth, pharmaceutical products would be treated differently than other products. Two main classes of pharmaceutical products were defined: potentially dangerous prescription drugs (most notably narcotics), whose sale requires a physician gatekeeper; and relatively safe over-the-counter (OTC) drugs, whose sale does not.

Medical paternalism is based on the principle that experts, usually physicians, justifiably violate their patients’ liberty in order either to provide benefits or to remove harms. These benefits and harms are usually represented under the authority of objective science. The major presumption here is that health-care consumers (disguised as patients) cannot make informed pharmaceutical choices without the assistance of learned intermediaries—licensed, knowledgeable, and beneficent physicians and pharmacists who have been legally ordained as the gatekeepers of prescription drugs. Government, physicians, pharmacists, and pharmaceutical companies collectively continue to prop up this system with a well-crafted ideology, which includes the myth that prescription-drug laws, supported by objective science, are designed to enhance patient safety.

Indeed, most Americans still believe the myth that paternalistic physicians and regulators protect us from unsafe drugs and that prescription drugs become OTC drugs seamlessly after their safety and effectiveness have been proven scientifically.

It is difficult, however, to determine the long-term safety and effectiveness of new drugs scientifically when the FDA has neither the mandate nor the resources to monitor new drugs after they are marketed to the public.

In fact, the political processes that oversee the transition from prescription to OTC status are hardly scientific; to the contrary, they are woefully steeped in conflict of interest. The distinction between prescription and OTC drugs not only preserves pharmacists and physicians' lucrative gatekeeper function, but also determines how much pharmaceutical companies can charge for any given drug. Therefore, it is no accident that OTC status tends to follow the expiration of patents more than it follows scientific evidence of safety and effectiveness. Indeed, many prescription drugs that have long been proven to be both safe and effective (for example, statins, birth-control pills, Viagra, insulin, and nicotine patches) remain locked away in high-priced prescription heaven. The most recent drug to make the transition from prescription to OTC status was Prilosec in 2003, which corresponded to the expiration of its patent. Since then, only two drugs have been presented to the FDA for approval of OTC status, and both were rejected (Howley 2005, 246). When a drug is denied OTC designation, industry-friendly FDA rules require four years before reapplication.

Physicians and pharmacists serve as paternalistic gatekeepers to the extent that they actually protect patients from harmful drugs. Since the advent of managed care, however, that gatekeeper function has been surreptitiously expanded to include regulating the flow of expensive medical treatment in the interest of third parties, especially insurance corporations. Again, in any other sector of the economy, this dual responsibility would be flagged as an obvious conflict of interest, but not necessarily in medicine.

Paternalism also often serves as a mask for surreptitious political machination. Of course, the ongoing drug war in its various manifestations is the most obvious example of the confusion between paternalism and mere politics. A more subtle example, however, appears in the FDA's recent decision to ignore the recommendations of two of its own scientific advisory committees and to withhold OTC status from Barr Laboratories' so-called morning-after pill (also known as Plan B or levonorgestrel).

How do relatively safe and effective drugs get locked away in prescription heaven? The petitions requesting OTC classification must go initially before an advisory panel of twenty-three paternalistic physicians who are keepers of the status quo. On the one hand, they often languish over remote possibilities of harm to patients; on the other hand, they are no doubt acutely sensitive to the potential economic harm to fellow physicians wrought by reduced office visits. In short, the processes that oversee the transition from prescription to OTC status are not entirely paternalistic, as the ideology suggests. In reality, the whole process is contaminated by conflict of interest and political machination.

## **DTP Advertising of New Drugs**

Marketing is the cornerstone of all economic activity. In any natural market, buyers must know what sellers have to offer and how much those offerings will cost.

All corporations employ an army of well-paid professionals to market their products or services to consumers. Through the rose-colored lens of the Ideal Model, however, marketing has been disguised as therapeutic education—that is, the efficient conveyance of objective, value-neutral information intended to expand physicians' knowledge. Although exponents of the model insist that this activity is not advertising, it looks in practice a great deal like advertising.

Before the early 1980s, pharmaceutical advertising disguised as educational material routinely targeted physicians. DTP advertising strategies included office visits by pharmaceutical “reps,” who dispensed information about new drugs, along with free samples. Other marketing strategies nurtured reciprocity by targeting professional associations, such as the American Medical Association. This activity included pharmaceutical companies' purchase of expensive full-page ads in medical journals, their purchase of large numbers of reprints of research articles favorable to their products, and their sponsorship and purchase of journal supplements (Smith 2003, 1202). Another effective strategy they employed was the underwriting of junkets to exotic resorts, disguised as educational opportunities or scholarly meetings, and paying physicians exorbitant honoraria to speak at pharmaceutical conventions and shareholder meetings.

In any transparent business environment, this kind of activity would raise red flags signaling bribery, corruption, and even “payola.” Indeed, most of the scientific research on the safety and efficacy of drugs has been generated by employees of the pharmaceutical corporations disguised as objective clinical researchers. Systemic conflict of interest therefore not only corrupts the medical industry's economic foundations, but also surreptitiously undermines the scientific objectivity of medical institutions, especially professional associations and journals.

DTP advertising was never a promising long-term strategy for marketing pharmaceutical products, nor was it ever a model of medical ethics or business ethics (Smith 2003). The system worked most efficiently when relatively few new drugs were entering the market. As the number of new drugs increased, physicians' office hours became overrun with reps bearing more information, pens, pads, and free samples. Medical journals quickly became littered with full-page drug advertisements. How many pages of new drug advertisements does it take before we begin to suspect that medical journals might be serving the conflicting interests of scientific objectivity and financial gain?

By any objective measure, DTP advertising has always been plagued by conflict of interest, as self-interested pharmaceutical companies lavished gifts and perks on the duty-bound gatekeepers. When the news media finally exposed this hotbed of conflicting interests, the keepers of the status quo scrambled to eliminate the most egregious incentives, but they never got at the paternalistic roots of the problem.

In the 1980s, as traditional DTP advertising became less and less effective and as the “me-too” drug market became more competitive, pharmaceutical companies began to entertain the idea of marketing prescription drugs directly to consumers via the mass media.

## DTC Advertising

In the early stages, several companies began to experiment with product-specific forms of DTC advertising, which included Merck, Sharp, and Dohome's ad in *Reader's Digest* for its drug Pneumovax (Lyles 2002, 76). In 1983, as that new marketing strategy began to expand and take root, the FDA requested a moratorium until it could reevaluate its longstanding policy against DTC advertising. In 1985, the moratorium was lifted without much change in FDA policy. That standing policy included a requirement that all advertisements that stated the product name or the illness to be treated must include a "brief summary" listing potential side effects. Although this policy seemed to work well enough for print ads, it obviously did not work for thirty-second television ads. To circumvent FDA requirements, pharmaceutical companies launched a mysterious DTC marketing campaign consisting of oblique television ads that omitted the name of the drug and the name of the illness.

In 1993, the American Medical Association and the FDA got together to reevaluate the guidelines for DTC advertisements for pharmaceutical products and medical devices. Their proposed policy change, however, merely reaffirmed the Ideal Model by forcing DTC advertising to conform to DTP standards, which conveniently protected the interests of the well-situated stakeholders. The "change" would expand the FDA's oversight of drug advertising, protect the physicians' required office visits, maintain the pharmacists' gatekeeper status, protect the medical journals' advertising revenues, and shield the "me-too" drug market from head-to-head competition—all in the guise of "fair balance."

In 1997, after passage of the FDA Modernization Act, the FDA became less adversarial toward pharmaceutical companies, liberalized the rules governing DTC advertising, and lessened the level of scrutiny (Calfée 2002, 24). These changes led to more DTC advertising and high profits for an industry already well known for its profitability.

Although the lion's share of pharmaceutical advertising still targets physicians, between 1991 and 1999, DTC advertising increased from \$55 million to \$1.8 billion (Matthews 2001, 7). According to the U.S. General Accounting Office (GAO), from 1997 to 2001, spending increased from \$1.1 billion to about \$2.7 billion (GAO 2002, 9). By 2001, the industry was spending about \$4 billion a year on television and print ads in addition to the amounts spent on DTP advertising (Berger et al. 2001, 197). Today consumers are routinely exposed to expensive television, radio, Internet, and print advertising targeting specific patient populations. Of course, pharmaceutical companies are still reaping those hefty profits. Although the stalwart defenders of the Ideal Model still complain that DTC undermines paternalistic doctor-patient relationships, the reality is that health-care consumers appreciate being informed of the availability of new drugs, and they seem to be more active in health-care decision making. As an unanticipated consequence, the new drug market has begun to look like an industry.

Yet government regulations crafted by the major stakeholders in the health-care industries continue to thwart free-market reforms in health care in general and in the pharmaceutical market in particular. FDA standards for both DTP and DTC advertising

stipulate truthful disclosure of the indications, contraindications, and side effects. But in a cultural environment steeped in the Ideal Model, the government's regulation of pharmaceutical advertising faces daunting epistemological challenges.

From the standpoint of business ethics, false or misleading advertising is universally regarded as immoral and illegal. For pharmaceutical products, however, "truth in advertising" is hampered by the nature of the information, which is cloaked in arcane scientific language and adorned with impenetrable and often misleading or erroneous statistical data. In the absence of transparency, pharmaceutical "truth" has become socially constructed by physicians, pharmacists, and even lawyers and juries who are legally empowered to serve as the translators and interpreters of this otherwise inscrutable, if not unreliable, information.

Moreover, consumers of pharmaceutical products have also been impeded by the kind of information that the FDA requires pharmaceutical researchers to ferret out in clinical studies. FDA guidelines require testing for safety and effectiveness relative to placebos, but they do not mandate testing relative to well-established OTC drugs and prescription drugs already on the market. This institutionally enforced blind spot has created a pharmaceutical market crowded with expensive "me too" drugs, while physicians have no FDA-validated scientific basis for prescribing an inexpensive older drug (whose patent has expired) instead of an expensive, patent-protected new drug. Indeed, it is highly likely that many, if not most, of the "me too" drugs on the market today are less safe and less effective than the older drugs, but for the most part no one really knows.

To advertise truthfully that a new drug is safer or more effective than an old drug, drug companies would have to conduct expensive head-to-head clinical studies, which might not turn out in their favor. Moreover, thanks to the industry-friendly regulatory processes, old drugs that have been proven safe and effective are less profitable than new drugs. From the industry's standpoint, why waste money mass marketing old drugs whose profitability has been undermined by competition from inexpensive generic alternatives? In a market plagued by artificial monopoly, imperfect information, and conflict of interest, we now have a system in which reliable old drugs are less likely to be advertised and less likely to be prescribed than patent-protected new drugs whose safety and effectiveness remain shrouded in mystery.

Under the Ideal Model of Health Care, normal risk taking is distorted by the illusion of scientific objectivity. No other industry is legally required to divulge so much unreliable, useless, and contradictory information in its advertising in order to protect the public from so many remote or unproven harms. After all, television advertisements for sports utility vehicles are not required to divulge potential rollovers; cell phone advertisements are not required to divulge potential auto accidents; and fast-food chains are not required to divulge potential obesity from consumption of their products. The problem here is that under our current physician-centered system, the most powerful stakeholders—physicians, pharmacists, and trial lawyers—benefit from a zero-risk standard of drug safety.

Again, it is important to note that the FDA has not clearly demonstrated any measurable degree of competence in regulating drug research, drug labeling, or drug

advertising. Even if the regulation of pharmaceutical advertising made sense, the FDA's Division of Marketing, Advertising, and Communication is not empowered, nor does it have the resources, to preapprove advertisements effectively. What is clear is that the process is infested with conflict of interest.

We can be thankful that the information revolution has begun to undermine both the Ideal Model's foundations and the information monopoly that has shielded the health-care industry from outside scrutiny. Today, consumers can easily find decoded health-care information without paying for a visit to a doctor's office. They need only go to the public library and check out consumer magazines, books, and videos; or they can stay home and surf Internet sites such as WebMd.com and MayoClinic.org. Millions of price-sensitive consumers of health care who do not have health insurance mine these same sources every day for both diagnostic information and competitive prices for their drugs.

## Conclusion

The Ideal Model's obfuscation of the U.S. health-care system is not a conspiracy orchestrated by immoral professionals and corporations. It is a more subtle, socially constructed malady shrouded in arcane language, euphemisms, conflict of interest, and bad science. Most individual physicians, pharmacists, drug company executives, and FDA regulators are dedicated, if misguided, defenders of that failed system.

In the United States, the Ideal Model's cornerstone of care has been the third-party payment system, which has created a price insensitivity that has insulated buyers of health care from its real costs. In this situation, pharmaceutical companies have been able to charge noncompetitive prices for prescription drugs, doctors have been able to charge noncompetitive fees for office visits, and pharmacists have been able to charge noncompetitive fees for their services. And, of course, until recently, this economic windfall, gained under the oversight of state paternalism, has been realized without visibly gouging patients. However, the current health-care crisis began with the inevitable onset of price sensitivity.

As the number of uninsured patients rises and more and more patients find themselves unable to pay for their drugs, the government and the other keepers of the status quo have responded with stop-gap measures, such as adding a prescription-drug benefit to Medicare, regulating new drug advertisements on television, and calling for postmarket monitoring of new drugs. Although these institutional reforms still do not seriously challenge the health-care system's ideological foundations, health consumers are beginning to ask pointed questions. Is it realistic to expect small businesses disguised as medical practices to serve as objective and dutiful guardians of patients' interests while those same businesses are contractually obligated to managed-care organizations, professional organizations, pharmaceutical corporations, and government regulators?

The stalwart defenders of the Ideal Model argue that DTC pharmaceutical advertising misinforms gullible consumers, encourages excessive drug consumption, increases

health-care costs, strains doctor-patient relationships, and undermines the quality of patient care (Matthews 2001, 1). But those often well-meaning defenders rarely mention the more positive consequences of DTC advertising, including increased patient awareness of new drugs participation in health-related decision making, increased competition between alternative drugs, and lower prices for consumers. Nor do they look closely at the economic and moral costs associated with maintaining a system that hides economic reality behind a wall of misinformation and that disguises conflict of interest as paternalism. After all, we still have a growing problem of prescription-drug abuse, expensive and unsafe drugs that sneak past an FDA blinded by conflict of interest, and a growing number of patients who simply cannot afford to pay for an office visit in order to gain access to drugs protected by artificial monopolies. Nevertheless, most of the bulwark that supports the old system stands firm. Health-care consumers are still expected to take time off from work, pay for a visit to a physicians' office, and go to a pharmacist with a prescription.

Although prescription-drug laws are portrayed in the ideology as paternalistic, the system clearly benefits primarily physicians, pharmacists, and pharmaceutical companies, and just as clearly it does not benefit the growing numbers of health-care consumers without insurance coverage. As the number of uninsured patients has grown, market forces have begun to take over. For the elderly, this change is evidenced by an increased reliance on the Internet for medical information as well as by trips to Mexico and Canada to make drug purchases, not to mention more frequent use of less costly nontraditional medicine.

Despite the ongoing war of words over DTC advertising, the business environment for health care is rapidly moving away from the old hierarchical physician-directed system and being replaced by a more decentralized system in which patients can gain access to health-care information without paying for expensive "learned intermediaries." Of course, stakeholders who benefit from maintenance of the status quo will not go down without a political fight.

In the United States, these powerful stakeholders still look to government to protect their vested interests—hence, the meteoric rise in the number of lobbying firms and scandals. It is no secret that the laws that regulate corporations are heavily influenced (if not written) by the very corporations subject to the regulation. Typically, the most powerful corporations prefer regulations that minimize exposure to competition (Congress Watch 2001), which explains why we are still saddled with long-running patents, why safe and effective drugs are locked away in prescription heaven, and why scientific research is corrupted by conflict of interest.

As the elephant continues to lumber about the premises, the keepers of the status quo continue to ignore it. Most medical ethicists still harbor the illusion that health care is a moral system whereby physicians, pharmacists, and pharmaceutical companies selflessly care for us out of duty-bound beneficence and charity. When health-care providers act like corporations, they argue, it is a sign of moral decay. Unfortunately, many, if not most, medical ethicists think that the best way to deal with immorality in health care is to empower the government to control and regulate that behavior. Substantive health-care

reform, however, cannot proceed until we acknowledge that although physicians, pharmacists, and pharmaceutical corporations are important stakeholders in the health-care industry, the advancement of their interests does not necessarily advance the interests of the other stakeholders, especially consumers. Fortunately, the informational monopoly has already been broken and the conflicts of interest that underlie paternalism's darker side have been partially exposed. DTC advertising is a sign of the looming decentralization of health care in this country. Traditional medical ethicists and the institutions of government ought to recognize that development and take business ethics more seriously.

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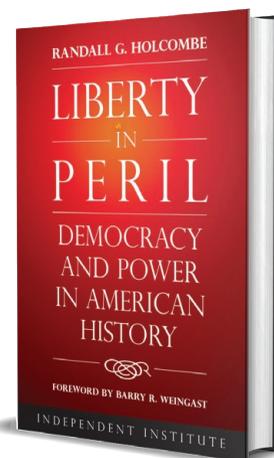
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