JULY | 2009

American Legislative Exchange Council

The State Factor

A PUBLICATION OF THE AMERICAN LEGISLATIVE EXCHANGE COUNCIL

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Answering the Critics

Five Reasons Why Pharmaceutical Marketing Helps, Not Hurts, Patients

INTRODUCTION

President Barack Obama has tagged health care as one of his priorities. Although the U.S. is a global leader in quality of treatment, so too is it the leader in cost of care. And access to medical treatment is complicated by America's patchwork of public programs, federal tax incentives, and private insurance policies. Rationalizing such a system is no mean task. As a result, the politics of reform remain ever-complicated, with policymakers routinely looking over their shoulder at the Clinton administration's disastrous experience in 1993 and 1994.

For years of political battle the pharmaceutical industry was a perennial whipping boy of Republicans as well as Democrats. Indeed, in the 2008 presidential race Sen. John McCain (R-Ariz.) was more hostile to drugmakers than was his Democratic opponent. Politicians have tended to demonize the drug industry, lumping companies that create life-saving products with the tobacco industry, polluters, and more.[1]

It is the industry's good fortune that President Obama does not appear to be looking for villains to blame. Pharmaceutical expenditures still may seem high, but the rapid spending increases of the 1990s appear to be over, with outlays up only 1.6 percent in 2007.[2] Moreover, cost must be compared to value provided. Medicine is not simply an expense. It is a tool to help patients. Also, drugs often cost less than do alternative treatments, such as hospitalization and surgery. There is no intrinsic reason to target pharmaceuticals any more than doctors' services or hospital charges.

Obviously, much can be said about the drug manufacturers, just as one can criticize most any industry. However, the very volume of criticism implicitly acknowledges the industry's importance. The value of "breakthrough" medicines is obvious. Critics often dismiss "me-too" products, but given variations among patients and conditions, these drugs also have obvious medical value. "Me-too" medicines also generate price competition with existing products. If pharmaceuticals didn't matter, no one would buy them. Many critics, it seems, simply want more lifesaving drugs without having to pay much, if anything, for them.

Unfortunately, pharmaceutical research and development is costly.[3] Thus, price controls, whether direct or indirect, will inevitably reduce creation of new medicines and thus treatment options available to patients.[4] This doesn't mean government should subsidize or otherwise favor the industry. But officials should not punish companies whose business is giving patients more and better treatment choices. Drugmakers deserve credit for doing good even if not everything they do is good.

Reason #1: Pharmaceutical Marketing Provides Vital Information to Patients and Doctors

One of the most controversial industry practices is marketing, both to consumers and doctors. Critics routinely complain about drug ads, especially direct-to-consumer

advertising (DTCA). Promotions targeting consumers are a relatively new phenomenon. Notes researcher Jacob Arfwedson: "The history of direct-to-consumer advertising of medicines is relatively short. The main reason is that for most of the 20th century, the products available were relatively few and not very sophisticated."[5] The first print DTCA came in 1981, with the first television ad appearing two years later. The U.S. Food and Drug Administration (FDA) then imposed a moratorium on such ads before publishing a set of guidelines. In 1997 the FDA relaxed the rules governing television advertising, spurring a marked shift to TV ads.[6] Overall spending on DTCA remains modest – about $4.8 billion in 2007, or about 42 percent of total marketing expenses.

[T]hose most hostile to the industry believe that companies which develop new medicines should then hide them away, never to be mentioned in polite company, whether in a patient's home or a doctor's office.

Also controversial are marketing efforts directed at professionals. Before the rise of DTCA, doctors were the principal target of industry advertising. Even today, physicians who prescribe medications remain the focus of much promotional effort. Professional advertising has generated little controversy, but drug companies have come under sustained fire for providing benefits, financial and other, to doctors.

Although industry marketing practices are not without problems, one suspects that those most hostile to the industry believe that companies which develop new medicines should then hide them away, never to be mentioned in polite company, whether in a patient's home or a doctor's office. The only time a physician would prescribe, or a patient use a drug, would be after accidentally discovering the existence of a particular pill.

In fact, the assault on pharmaceutical marketing really is an attack on the practice of all businesses. Virtually every company in America advertises, if nothing else paying to be in the Yellow Pages. Companies take out print ads and create jingles for the radio and expensive imagery for television. Firms mail out circulars and insert pop-ups online. Businesses also routinely offer promotional incentives, from products to cash. One of the great ironies, pointed out by Merrill Matthews of the Institute for Policy Innovation (IPI), is that numerous companies, advertisers all, joined the group Business for Affordable Medicine, which sought to limit pharmaceutical advertising.[7]

Information is an important lubricant for markets and yields numerous benefits to market participants. In particular, "consumer communication," as the Center for Medicine in the Public Interest (CMPI) terms it,[8] is critical for alerting both doctors and patients as to what medicines are available, and for what diseases. No single person, especially a general practitioner, can keep up with all of the information available on drugs, let alone health care. By one estimate every year some 1,700 articles are published in each of 325 professional journals on the 25 top medicines.[9] Drug producers use a variety of promotional efforts to stand out in this information flood. One may like or hate the industry's tactics, but there is nothing illegitimate about them.

Advertising and marketing are necessary for drugs no less than for colas. There are differences between the markets, to be sure, but one of the biggest is the level of consumer ignorance regarding health care. Many patients don't know much about their conditions or their treatment options, and often give extraordinary deference to doctors and other medical professionals who, irrespective of training and background, are fallible and rarely know as much as they believe would be best.

This industry model built on consumer ignorance might have been inevitable in the past, but the advent of the information economy is transforming health care. This process, combined with rising concern over the cost of medical care, "is driving the transition to a patient-directed health care system," argues Matthews.[10] The rise of DTCA, in particular, is part of that process.

However, much we as consumers hate this flood of often-obnoxious communication, advertising serves a basic purpose—providing information. Advertising tells us what products are available from whom or for how much; marketing helps consumers to be aware of different options that meet their desires. Some marketing works better than

others. Some practices are more useful than others. At the same time, deception occurs and perverse incentives arise. Nevertheless, on net companies would not spend money on advertising and marketing if they did not believe that it increased sales and thus revenue. Corporate executives might guess wrong, but money spent in this way is viewed as an investment, not a waste.

Reason #2:
Pharmaceutical Marketing Keeps Markets Competitive

Promotional efforts are most necessary in competitive markets. If there was only one automaker or cell phone company or online provider, such an operation would have little need to advertise. Who marketed anything in the Soviet Union? There was only one manufacturer and seller, so everyone knew where to go and what to buy. Spending money to speak to consumers in such a system really would have been a waste. But market economies are very different. And drugmakers, though possessing temporary patent production for newly-created medicines, compete vigorously with each other (through other patented drugs as well as generics) and with other forms of treatment (from diet to surgery to hospitalization). Suppressing ads might aid some market leaders; doing so would not benefit consumers.[11]

Reliance on advertising and marketing varies by industry, but there is no difference in principle between computer manufacturers and drugmakers. Admittedly health care is different from many other services, which makes the market more complicated. As a result, there is a greater role for trusted third parties to evaluate treatment options and offer advice—hence industry marketing directed at doctors. Nevertheless, this factor does not obviate the role of advertising and marketing. Argues John Calfee of the American Enterprise Institute (AEI): "The emerging evidence on DTC advertising is therefore consistent with a larger pattern in which marketing has been found to improve markets and increase consumer welfare," especially through "downstream effects such as lower prices, improved choices, and improved products."[12]

Indeed, cost-conscious patients shopping for medicines have a surprising number of options. Devon Herrick of the National Center for Policy Analysis points to drug substitution, bulk buying, mail-order pharmacies, pill splitting, generic medications, over-the-counter drugs, pharmaceutical assistance plans, Medicare drug plans, and state drug assistance plans.[13] Information is critical for consumers to take advantage of these and other opportunities. In general, more information for health care consumers is better.

Imperfect though the process might be, marketing promotes price competition and lowers prices.

Nevertheless, there is no "right" amount to be spent on advertising, just as there is no "right" price or "right" amount of research and development (R&D). There certainly is no "right" level of marketing to be prescribed by government. These all are judgment calls based on the interaction of supply and demand, changing market conditions, and impact of government regulations. Despite all of the concerns about DTCA, pharmaceutical manufacturers adjust advertising to reflect results, which means reducing or eliminating ads when they seem to be ineffective. In fact, ad spending fell in 2007 and the first half of 2008.[14]

Advertising plays another very important role in a market economy. Imperfect though the process might be, marketing promotes price competition and lowers prices.[15] This is why professionals—such as dentists, doctors, lawyers, and optometrists—long restricted advertising. Doing so limited competition and allowed these professionals to charge higher fees. Reducing restrictions on legal advertising and marketing took years, but the process greatly benefited consumers. The process continues in other professions—one recent study found that California eyewear providers who advertised charged 17 percent less than those who did not.[16] The Federal Trade Commission has attacked many such restrictions in the U.S. while the European Commission has been pushing similar deregulation in Europe.[17]

Comparative advertising is especially useful for consumers shopping for the best deal. For this reason, many professions have attempted to maintain restrictions on comparative ads even after relaxing overall restrictions. Pharmaceuticals no less than other goods and services are subject to comparison shopping. IPI's Merrill Matthews points to a number of areas where there are between two

and four drugs for the same disease or condition, and firms use advertising to compete.[18] Michael Neff, who managed drug purchases for California's public health care system, asked, "Do we want to see more head-to-head testing?" He answered: "You bet! Yes, sir!"[19]

Reason #3:
Pharmaceutical Marketing Keeps Prices Low

Attacks on the pharmaceutical industry's promotional efforts take several forms. Much of the fire is directed at advertising, particularly DTCA. Ads are criticized for allegedly driving up drug prices and increasing drug usage, both of which are purported to hike total pharmaceutical spending. A number of proposals have been advanced to limit or even ban drug advertising. Rep. Henry Waxman (D-Calif.), the new chairman of the U.S. House Energy and Commerce Committee, has proposed authorizing the FDA to temporarily ban DTCA when new medicines are released. Former U.S. Senate Majority Leader Bill Frist (R-Tenn.), a surgeon, called for a two-year moratorium on advertising for new drugs. Other legislators have suggested barring companies from deducting the cost of advertising in figuring their corporate income tax.

It is claimed that advertising raises costs. The exact formulation of this charge varies, but it typically mirrors the claim that drugmakers spend more on promotion and administration than on R&D. Industry critic Marcia Angell went so far to claim that instead of the pharmaceutical companies needing high prices to cover R&D, "it would make more sense to argue that they need the high prices even more to cover their marketing costs."[20] The theory, then, is that if manufacturers spent less on marketing and advertising—which are usually lumped with administrative costs—prices would fall.

The latest numbers (from 2004) that include the cost of drug samples found that the latter accounted for $15.9 billion of $27.7 billion in total marketing costs. That is, more than half of what is commonly counted as "promotion" actually is a direct patient subsidy.

However, cost estimates for marketing have been commonly inflated for years. Pharmaceutical marketing accounted for $13.8 billion in 1999. Yet more than half of total outlays—$7.2 billion in that year—was for free samples of drugs, which are first given to doctors but then usually passed on to patients. In the latter case, they act as a price discount.[21] In 2002 the cost of samples ran $10.5 billion—again, more than half of the $19.1 billion spent on pharmaceutical marketing in total. (This was well below the $30.3 billion in R&D expenditures for that year.)[22] The latest numbers (from 2004) that include the cost of drug samples found that the latter accounted for $15.9 billion of $27.7 billion in total marketing costs.[23] That is, more than half of what is commonly counted as "promotion" actually is a direct patient subsidy.

The most recent estimates do not incorporate the cost of samples and show spending to be relatively static. According to IMS Health, total pharmaceutical promotional outlays ran $10.7 billion in 2003, $11.9 billion in 2004, $11.4 billion in 2005, $12.0 billion in 2006, and $11.5 billion in 2007. In 2007—the last year for which numbers were available—drugmakers spent $417 million on professional journal advertising, $4.8 billion on DTCA, and $6.3 billion on sales reps and associated activities.[24]

Whatever the level of outlays, profit-making businesses normally spend money only if doing so is expected to bring in more revenue. The return might be indirect (for example, administrative expenses are necessary to operate, but yield no revenue directly) or direct (for example, advertising is expected to increase sales, and thus revenue). But marketing outlays are an investment intended to increase sales. For example, Pfizer does not run ads on Viagra for purposes of corporate vanity; rather, the company wants to encourage more people to purchase more of the drug, and in doing so win customers away from competing products.

Thus, the apparent assumption of many critics of marketing and especially advertising—that medicines are magically and costlessly created and should be hidden away, with patients and doctors expected to engage in a high-minded and public-spirited search for appropriate remedies—would result in few drugs produced. Notes researcher Jacob Arfwedson: "A new product may not achieve

the status of economic good (be it an apple, an aircraft or a medicine) without consumers being aware of its existence."[25] Which is why industries spend, sometimes heavily, on promotion.

To the extent companies succeed in promoting their products, whether for approved or non-approved purposes, the result should be more sales and more revenue. For instance, the Henry J. Kaiser Family Foundation reported in 2003 that every dollar spent on DTCA resulted in an extra $4.20 in sales.[26] More money means more profits, obviously, but also more money for R&D. Moreover, additional money increases the incentive to spend more on R&D. That is, if each drug brings in more cash, there is greater reason to spend more money developing new products. Not all ads work—and there is a diminishing return on marketing efforts. But arbitrarily cutting pharmaceutical promotion likely would both reduce the number of medicines produced and increase the price of those remaining.[27]

Thus, while cutting marketing would reduce production costs, University of Chicago Law Professor Richard Epstein observes that of advertising, "by expanding the consumer base, it lowers the average costs consumers pay per unit."[28] This is why there is no correlation between marketing expenses and product prices. Peter Pitts, then at the FDA, reported: "brands that spend more heavily on DTCA do not necessarily cost more than their less heavily advertised competition."[29] IPI's Merrill Matthews observed that over-the-counter drugs remain inexpensive even though they tend to be heavily advertised, while some of the most expensive new drugs, such as Gleevec, are rarely advertised.[30]

Reason #4:
Pharmaceutical Marketing Creates Better-Informed Patients

Consumer ignorance is never positive except for monopoly providers—whether public or private—which prefer not to be questioned. In fact, there has been growing pressure in Europe to eliminate the European Union's (EU) ban on DTCA in the name of patients. Despite sustained resistance from the EU bureaucracy, notes researcher Jacob Arfwedson, "patients as consumers are getting impatient to access better information on treatments and will not take no for an answer, regardless of safety issues or budget constraints."[31] Peter Pitts, now of CMPI, observed: "A recent consumer survey in Europe asked people in Great Britain, the Czech Republic, France, Germany, Italy, the Netherlands, Spain and Sweden what reforms would most likely increase their quality of care. In every nation, by a large margin, the answer was 'giving patients more information about their illness.'"[32] The EU is moving, despite strong opposition from self-styled public health advocates, towards allowing companies to provide "information" to patients, though not DTCA.[33]

Patient advocates in Canada's nationalized system also complain about the lack of information available to them. The fight over pharmaceutical advertising reflects broader complaints about politicized care throughout Europe, including the United Kingdom, where people are effectively being injured and killed because the government has decided that they are not worth the cost of treatment.

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However, nationalized systems continue to work overtime to deny people knowledge of the medical products and services to which their governments deny them access. As European analyst Joshua Livestro has observed: "To fans of socialized medicine, patients actually taking steps to seek earlier and better treatment of their medical problems probably sounds like a nightmare scenario: it would put even more pressure on limited government resources."[35] But earlier and better treatment is in the interests of patients and their communities as well. American health care would not be improved by the government following Europe in attempting to keep patients ignorant and quiescent.

In the U.S., the benefit of industry promotion can be seen from the harm caused in the one area where federal law and regulation continue to restrict drug advertising. It often is not worth the time and expense for a pharmaceutical firm to win separate agency approval for every new use of a medicine already proved to be safe. Writes Alexander Tabarrok of the Independent Institute, "There have been numerous instances in which the FDA has reduced the speed at which beneficial new drugs, and beneficial new uses of old drugs, have been widely adopted."[36]

However, since the medicines are legally available, doctors often prescribe them for "off-label" purposes. However, the FDA prevents companies from promoting these formally unapproved but informally recognized alternative uses of drugs. The agency further impedes treatment by preventing companies from even distributing articles relating how cancer drugs have demonstrated their effectiveness in combating other forms of cancer.[37]

Drug information is particularly useful in reaching people who have not been diagnosed despite having treatable conditions, such as diabetes, high cholesterol, and hypertension.

These marketing restrictions prevent many patients from receiving the best available treatment. Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, complained to a U.S. House subcommittee: "The excessive zeal of the FDA in this arena is exerting a chilling effect on the sharing of information within the medical community on whom our treatment and our very lives depend. FDA's policy stifles education by denying individuals with cancer access to valuable information about medically appropriate indications from the pharmaceutical sponsors who are often the best sources of up-to-date information."[38]

Reason #5:
Pharmaceutical Marketing Helps Improve Health Outcomes

The best test of DTCA might be its impact on people's health. But little hard data exists—even how to measure such an effect is hard to say.

More information likely means better health. For instance, observes AEI's John Calfee: "The documented gaps between research findings and physician practices are notoriously difficult to close."[39] Advertising can help bring the two closer together.

DTCA may be even more important for patients. One impact seems to be to make patients more likely to follow prescription schedules.[40] But there are more basic benefits.

Linda Golodner, president of the National Consumers League (NCL), observed: "With DTC ads, large numbers of consumers are made aware of medical conditions and treatments that they may otherwise not know exist." Are consumers misled? Not likely. Golodner adds: "they're smart; most recognize that the ads are tools for selling products and evaluate them accordingly."[41]

Drug information is particularly useful in reaching people who have not been diagnosed despite having treatable conditions, such as diabetes, hyperlipidemia (high cholesterol), and hypertension.[42] A 1999 survey conducted by *Prevention* magazine estimated that consumer ads had caused some 25 million people to talk for the first time with their doctors about particular health problems.[43] Explained the National Institute for Health Care Management Research and Educational Foundation: "To their credit, the ads have apparently raised awareness of many medical conditions."[44] Similarly, observed Dr. Richard Dolinar, an endocrinologist from Arizona, "I think more patients are coming in for treatment just to see if a drug they have seen advertised might help them with a problem."[45]

Golodner similarly argued that "Often ads help destigmatize conditions that may have otherwise gone untreated due to patient embarrassment and limited medical knowledge."[46] This may particularly be the case for mental health. Oscar Morgan of the National Mental Health Association believed that ads helped "open the door" in this field, "removing some stigma and providing information to persons who may not have otherwise known about or been able to identify depression. They may seek help and get better."

Dr. Seymour Diamond, founder of the Diamond Headache Clinic and director of the Inpatient Headache Unit at Chicago's St. Joseph's Hospital, explained that he once opposed DTCA out of fear that inappropriate drugs might be prescribed. But he told the *Chicago Tribune* why he changed

his mind: "Probably the greatest advance in the treatment of headache in the last 20 years has been the discovery of the triptan group of drugs like Imitrex. The fact that there was advertising for triptan drugs drove many patients to ask their physicians about this therapy, or, if the doctor wasn't aware of it, to come to clinics like ours and seek help."[47]

The survey group led by Harvard's Joel S. Weissman also came to a positive conclusion:

> *First, we found that a sizable portion of patients with DTCA visits reported seeing physicians for clinically important conditions and that many visits resulted in new diagnoses. Some of the most common new diagnoses that were discovered as a result of these visits—high cholesterol, hypertension, diabetes, and depression—are often underdiagnosed and undertreated in the general population. Very few visits were for cosmetic or lifestyle problems.*
>
> *Second, we found that DTCA visits resulted in health care actions taken on behalf of patients that went beyond the expected prescribing of drugs, both advertised and not.*
>
> *Third, given concerns over the possible adverse health consequences of DTCA, our study is notable for what it does not show. We failed to find large negative health consequences for patients on a number of health-related aspects, including symptom relief, improved laboratory results, and ease of taking the drug, and for the most part found no difference by whether the patient took the drug that was advertised or some other drug. There seemed, in fact, to be a small advantage in relief of side effects among patients who switched their medications to the advertised drug after their visit, although the number of respondents was small. At a minimum, therefore, we did not detect widespread adverse effects of DTCA based on self-reported health status.*[48]

Even the *Journal of the American Medical Association* has acknowledged: "Nearly everyone agrees that it was important to advise high-risk consumers about a new vaccine for pneumococcal pneumonia. Many of those consumers are generally in good health and not visiting a physician on a regular basis. Promotion to physicians alone would not have brought the vaccine to the health high-risk consumer." [49] A survey of men with prostate cancer found that the majority of respondents desired more information; Dr. Jay Gillenwater, president of the American Foundation for Urologic Disease, explained that "The results of our survey clearly indicate the need for more comprehensive and actionable information about current treatment options for prostate cancer."[50] Only one-fifth of European women suffering from osteoporosis receive treatment, which caused Per Wold-Olson, president of Merck's European Human Health division, to argue that the present EU ban on pharmaceutical communication with patients is deadly.[51]

Increasing consumption of new drugs may lead to significant improvements in public health.

Anecdotes demonstrating the importance of patients learning more about their diseases and treatment options abound. Wrote Jamie Reno of *Newsweek*, who suffered from non-Hodgkin's lymphoma:

> *I found out about the [experimental drug] Bexxar trial myself. I didn't rely on my doctors, and neither should you. Unfortunately, when you learn you have a life-threatening disease, you're often too sick and/or scared to do much research. So you take your doctor's word. That's what I did. Big mistake. My first oncologist, at a renowned cancer hospital, never shared one bit of information about the lymphoma research I've since learned is going on.*[52]

In sum, the health benefits of advertising are potentially significant. As noted earlier, Columbia's Frank Lichtenberg argues that DTCA focuses the attention of patients on newer medicines, a health positive since in general newer drugs improve patient longevity, quality of life, and productivity. He argues: "Increasing consumption of new drugs may lead to significant improvements in public health."[53]

Answering the Critics

Nevertheless, not everyone is convinced as to the benefit of pharmaceutical marketing. Even granting the general argument for consumer knowledge, some industry critics deny the benefits of industry advertising in this case. Here are some of those common criticisms—and answers.

Does Pharmaceutical Marketing Cause Too Many People to Use Too Many Drugs?

Although we live in an economic system in which the role of the consumer is widely extolled, DTCA receives sharp criticism. The basic complaint against ads for consumers is that they work. That is, advertising helps increase demand, which in turn raises drug expenditures.[54] The U.S. General Accounting Office (GAO) concluded: "DTC advertising appears to increase prescription drug spending and utilization."[55]

Undoubtedly, DTCA has an impact—otherwise drugmakers would not spend their money that way. However, the role of ads in rising drug spending should not be overplayed. Researchers at Harvard Pilgrim HealthCare found that DTCA had surprisingly little effect, in some cases, involving heavily-advertised drugs. Explained the head of Harvard Pilgrim's Drug Policy Research Group, Stephen Soumerai: "People tend to think if DTC advertising wasn't effective, drug companies wouldn't be doing it. But, as it turns out, the decision to market medicine directly to consumers is based on scant evidence."[56] A growing industry realization that DTCA is not as effective as hoped may be behind the slowdown in advertising spending noted earlier.

There is no clear correlation, let alone evidence of causation, between volume and prices and DTCA spending.

In any case, even at the height of the pharmaceutical spending boom, the Henry J. Kaiser Family Foundation reported that "DTC advertising is an important, but not the primary, driver of growth in prescription drug spending."[57] Similarly, contended Richard Manning and Alison Keith of Pfizer, the "facts call into question the claims by some that advertising is a primary driving force for pharmaceutical spending."[58] There is no clear correlation, let alone evidence of causation, between volume and prices and DTCA spending.[59] Whatever the role of advertising, a lot of other factors, including an aging population and lower treatment thresholds, also play a significant role; Manning and Keith also write that "the impact of such spending is overwhelmed by other important market dynamics."[60] Indeed, the startling decline in annual spending increases, from 9.9 percent between 1997 to 2007, to only 1.6 percent in 2007, demonstrates the important impact of other factors.[61]

Moreover, it is a mistake to treat pharmaceutical use and spending *per se* as a negative. The rising use of medicines, even if promoted by DTCA, is not the same as inappropriate use of medicines. First, drugs often are alternatives to more expensive alternative treatments, including hospitalizations and surgeries. In such cases the early use of pharmaceuticals is likely to reduce costs from unnecessary emergency room visits, hospitalizations, and other treatments.

Second, advertising may help reduce regional and other variations in use. For instance, Dr. Robert DuBois studied the use of statins and concluded that "Despite significant pharmaceutical promotion in the latter '90s, [there was] no change in the appropriateness of statin use" and "[s]ignificantly less geographic variation in use of medications than procedures."[62]

Third and most important, doctors prescribe, hospitals administer, and people take medicines because the benefits exceed the costs. If the pharmaceuticals are used properly, increased demand should be seen as a positive—more people are receiving better treatment. Frank Lichtenberg of Columbia University emphasizes the benefits of newer drugs: "In the aggregate, the benefits to society of new drugs exceed their costs by a substantial margin."[63]

Indeed, there seems to be significant agreement that pharmaceuticals are underutilized in treating a number of conditions, especially involving the elderly. The result is "many avoidable deaths, along with costly avoidable emergency room visits, hospitalizations, and nursing home admissions."[64] In such areas, at least, any DTCA-sparked increase in pharmaceutical use likely would result in a clear public health benefit. Paul Rubin of Emory University figures that failing to advertise the benefits of aspirin alone may have been killing tens of thousands of people a year.[65]

The most serious criticism of DTCA is that ads are irrelevant or misleading, causing patients to demand products which are not good for them.[66] The GAO has weighed in.[67] The World Health Organization also has taken aim at consumer-oriented ads. The international body contended that there is "an inherent conflict of interest between the

legitimate business goals of manufacturers and the social medical and economic needs of providers and the public to select and use drugs in the most rational way."[68]

No doubt, DTCA suffers from the same sort of infirmities that bedevil advertising for other products. As in any industry, ads vary in quality. Consumers make mistakes. And in the area of health, patients arguably have a more difficult time making reasoned judgments about which goods and services best meet their needs. Still, argues researcher Jacob Arfwedson: "drugs are exactly like other products to the extent that they are produced to satisfy a given demand."[69] Many other offerings in the marketplace also are complicated and potentially dangerous. In no other area, however, do policymakers suggest responding by keeping consumers ignorant.

In fact, as the medical marketplace evolves in a more consumer-oriented direction, advertising can play an important role in informing and empowering patients. Expanded knowledge is particularly important in what has traditionally been a physician-led process—patients can ask better questions and make better judgments if they know more of the available options. Patients' desire for greater knowledge is obvious from greater reliance on the Internet for health information.[70] Advertising plays an obvious role in an "information age" in which people have much greater opportunities to educate themselves.

Ironically, many medical professionals complain about the uneven quality of the information available on the Internet, but restricting industry ads inflates the role of online sources, where there is virtually no policing of the accuracy of claims made.[71] In fact, argues Lloyd Millstein, DTCA rose along with managed care, "and that is no accident. One of the benefits that managed care holds is that patients assume more responsibility for their own health."[72]

Does Pharmaceutical Marketing Diminish the Importance of Doctors?

Any potential for harm, either to a patient's health or finances, is mitigated by the role of doctors. Pharmaceuticals have a circuit breaker not present in most economic transactions—the most significant and expensive medications require a prescription. Doctors remain a gatekeeper, often prescribing other brands, generics, older products, or nothing. This may be the most important reason that "pharmaceuticals are not typical consumer products," as Dr. Stephen Soumerai of Harvard Pilgrim HealthCare observed.[73]

Surveys indicate that between 33 and 40 percent of patients cite ads as prompting them to discuss health issues with a doctor. (Family and friends came in first at 51 percent, which arguably is a more worrisome factor, given the degree of misinformation that exists among these sources.) Three to five percent of doctors' visits were prompted by DTCA.[74]

Many other offerings in the marketplace also are complicated and potentially dangerous. In no other area, however, do policymakers suggest responding by keeping consumers ignorant.

A study by Henry Young and Richard Kravitz of the University of California Davis and Earler Lipowski of the University of Florida concluded that the ads promoted a "shared decision-making process," including the "initiation of discussions about treatment options, efficacy, appropriateness, and risks."[75] A survey conducted by two professors on the faculty of the Harvard Medical School, and several others, found that DTCA prompted 35 percent of respondents "to have a discussion about an advertised drug or other health concern during a visit with a physician." A number of patients raised new concerns, while "nearly one in four were given new diagnoses."[76]

CMPI's Peter Pitts views the result as a significant health care positive: "[E]arlier detection combined with appropriate treatment means that more people will live longer, healthier, more productive lives without having to confront riskier, more costly medical interventions later on."[77] Moreover, he adds, advertising may help defeat "noncompliance, which is estimated to cost our healthcare system billions of dollars a year in increased emergency room visits, unnecessary surgeries, expensive hospital stays, and lost productivity."[78]

Admittedly, surveys suggest that doctors are equivocal about this result. Depending on the poll, small pluralities of physicians either view consumer ads as somewhat positive or often to some degree negative.[79] The common com-

plaint is that DTCA causes patients to pressure doctors for a prescription, resulting in "a negative effect on prescribing appropriateness."[80] Of course, sometimes the prescription is appropriate, but the "problem" is that patients prefer to pop pills than to make difficult lifestyle changes, such as a change of diet.[81] In some cases, then, the real objection seems to be alerting patients that there may be an alternative to the regimen preferred by the physician.

Patient requests also can run against health plans which seek to strictly control costs. One-fourth of surveyed physicians say that while patient requests for brand-name drugs are increasing as a result of the ads, they are also receiving specific directions from managed health care programs against prescribing non-covered drugs. This can add more strain to the physician/health plan and physician/patient relationships.[82] Yet it seems wrong to blame ads if health plans restrict access to newer medications.

But if these ads are encouraging dialogue of any nature between doctors and their patients, this can hardly be a bad thing.

If the ads do anything, they force doctors to offer an explanation while saying no. Even that seems to bother some physicians. For instance, Dr. Sandra Adamson Fryhofer of Emory University denounced drug ads because "Not only do we have to take time to explain to these patients the nature of the medical problem they have, and whether it needs to be treated with drugs, but we also have to discuss whether the drug they have seen promoted is their best option."[83]

In short, the real pressure being felt by physicians "does not concern a push to get the specific product 'as seen on television'; it is the time pressure felt in responding to the patient's questions. As practitioners are often paid a set and regulated fee per patient, extensive Q&A may not necessarily be their first priority," but this is a problem of the payment system, not DTCA.[84] While a docile, uninformed patient might be convenient for a particular doctor in a particular case, it certainly is not healthy for the overall medical system. Explained IPI's Merrill Matthews: "The medical profession is legendary for producing doctors with big egos. The notion that patients are somehow bullying doctors into prescribing something the doctor doesn't think the patient should have is almost ludicrous. That is not the average doctor, nor is it the average patient."[85]

Since the role of physicians is to serve patients, there is no good reason why they should not be prepared to explain to a patient why a particular advertised drug is not appropriate. NCL's Linda Golodner argued: "Critics attack such ads for provoking patients to ask their doctors for expensive drugs for which they may not have a medical need. But if these ads are encouraging dialogue of any nature between doctors and their patients, this can hardly be a bad thing."[86] Perhaps a patient won't believe them and will change physicians as a result, but that's no reason to ban DTCA. The right attitude is reflected by Dr. Richard Dolinar, who said "If advertising sometimes results in patients' asking for a drug that is inappropriate, I will say so."[87]

Increased demand also makes products available that would otherwise be unprofitable. The problem of so-called "orphan drugs" is that demand is too low to warrant companies spending the necessary R&D expenditures. To the extent that advertising arouses latent demand, companies will be more willing to invest in riskier ventures. Thus, advertising does not compete with R&D; rather, the two are complementary, since, as noted earlier, marketing hikes revenues and investment returns, making more money available for and increasing the incentive for R&D. Even as drugmakers advertise, they devote a larger share of sales to R&D than does the medical industry generally, or computer makers and software developers, or automakers.

Does Pharmaceutical Marketing Encourage Professional Conflicts of Interest?

Also widely criticized, though for very different reasons, are promotional efforts directed at physicians. Some states, such as Minnesota, limit doctor payments or require public disclosure. Last year Massachusetts enacted perhaps the strictest law in the nation, and others, such as New York, are considering legislation to ban most gifts. Similar efforts are afoot at the national level. Sen. Chuck Grassley (R-Iowa) unsuccessfully attempted to attach the "Physician Payment Sunshine Act" to a Medicare bill; he says he intends to try again.

Some observers charge that these promotional programs also are "a major contributor" to increased phar-

maceutical spending.[88] (The same issue afflicts device-makers.)[89] However, the more serious concern is that these efforts skew the role of physicians, who are supposed to be gatekeepers when it comes to prescribing drugs. Activists have routinely criticized all manner of gifts to physicians.[90] Vermont's Attorney General William Sorrell asserted: "It is particularly troubling that the industry is paying large sums of money to influence prescribing practices involving psychiatric drugs."[91]

Many promotional items, such as free pens and notepads, help alert people to new products—who among us does not have a bank calendar, dentist's magnet, or hotel pen?—but are unlikely to have much impact on physician behavior. As dermatologist Dr. George Hruza put it, purchasing such items "is basically just a rounding error in the expense of running a practice."[92] Nice meals may gain a hearing for a new drug, but seem unlikely to cause a doctor to prescribe inappropriate medications. Consultancies and speaking fees may turn doctors into advocates with other doctors, but so long as the latter are aware of any relationship they are likely to discount the advice they receive. Most of these promotional efforts look worse than their likely impact.

Moreover, Sally Pipes, president of the Pacific Research Institute, warns that too much (or the wrong form of) disclosure can create more problems than it solves. Of the Massachusetts health reform plan, for instance, she warned: "publishing a list of doctors who have been involved in financial transactions through the state's many academic research programs and clinical trials with pharmaceutical companies suggests that there is something wrong with these associations, even though the payments are neither illegal nor unethical." She adds, doctors may become increasingly reluctant to participate in clinical trials, believing "that the unwanted public attention is not worth their participation."[93]

The National Association of Pharmaceutical Representatives declared Massachusetts to be the worst state for drug sales and marketing. It first pointed to the rule's compliance costs, and then noted that companies feared that the disclosure requirement "threatens the integrity and security of proprietary information belonging to companies pursuing research and product development initiatives with partner firms, doctors, hospitals, or other organizations. In contrast to FDA disclosure laws and the Physician Payments Sunshine Act pending in Congress, the Massachusetts law requires public disclosure of any collaborative relationship or industry partnering soon after such actions are first initiated—risking exposure of product development plans to competitive firms."[94] New York's proposed legislation would add additional barriers to clinical research, such as banning interim payments after meeting study milestones.[95]

Academia, hospitals, and insurance plans all have an incentive to police limits on conflicts of interest. Obviously, one can argue that these efforts have been insufficient and government should play a role. But stricter regulation should not turn into a campaign "smearing academic-industry collaboration," in the words of AEI's Dr. Sally Satel: "Such blanket condemnation of all associations with the companies that invent and produce countless life-saving healthcare products will surely have real costs to society. These partnerships are vital to medical progress."[96] In brief, industry-physician collaboration, far from being a *per se* evil, is a necessary aspect of medical research and development.

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The Industry Responds

Drugmakers are responding to criticism. Last year the industry tightened its marketing code and established the *PhRMA Code on Interactions with Healthcare Professionals*. Pharmaceutical Research and Manufacturers of America (PhRMA) head Billy Tauzin announced: "We have heard the voices of policymakers, healthcare professionals and others telling us we can do better."[97] The revised rules address most areas of controversy: non-educational gifts of even nominal value are banned; meals outside of the office must be modest and those not provided in connection to

speaker programs are banned; new criteria govern the selection of consultants and speakers; and conference events and locations are regulated.[98] Of particular significance, the PhRMA code urges transparency, with public release of the standards for doctor training and compensation, as well as caps on physician payments.[99]

The code is voluntary, though California and Nevada enacted rules tied to company compliance with the PhRMA regulations. Naturally, industry critics view the revised marketing code as a tactic to avoid tougher government oversight.

CMPI's Peter Pitts contends that the provisions are "well-worded, well-enforced, and well-followed." The real objective of those who reject the industry code, in his view, is to eliminate pharmaceutical marketing. He argues that

Of particular significance, the PhRMA code urges transparency, with public release of the standards for doctor training and compensation, as well as caps on physician payments.

"The people who say the [C]odes aren't working believe that a code of compliance should mean reduced marketing." However, he adds, "That is wishful thinking on their part and it is not in the best interests of public health."[100]

In any case, the new code deserves a chance to work. Industry analyst Cole Werble observed last year: "Now that the threat has passed for this session, PhRMA has a chance to try to make its voluntary code satisfy the demands for changes to marketing practices."[101] That appears to be Billy Tauzin's view: "We had better self-police and stop doing the things that cause so much criticism, or we're going to get legislated and regulated by government."[102]

Even some analysts who believe that DTCA is appropriate nevertheless advocate that the FDA improve its oversight of such advertising. In its assessment of DTCA, the GAO warned that "FDA's oversight of DTC advertising has limitations." The GAO was particularly concerned that the agency did see all DTCA and was unable to issue regulatory letters in a timely fashion.[103]

PhRMA also has moved to issue guidelines on DTCA, such as not using actors as doctors without acknowledgment and celebrity endorsers who have not used the product.[104] Dr. Sidney Wolfe of the Public Citizen's Health Research Group, which works assiduously to suppress consumer choice in favor of government control throughout the health care system, complained that the industry rules "are designed as a desperate attempt to fend off real regulation of drug ads."[105] And, in fact, more effective company compliance with PhRMA's principles governing DTCA would ameliorate many of the concerns over how drugmakers present information to consumers. The bottom line, however, should be an affirmation of the legitimacy of DTCA.

Ironically, today's tough economic climate may achieve what legislation has not—reducing DTCA. For instance, GlaxoSmithKline announced in early January that it was going to reduce consumer ads, in an attempt to both spend cash more wisely and dampen criticism of industry practices.[106]

Conclusion

The pharmaceutical industry likely will never be "just another business." Every major U.S. manufacturer spends, sometimes heavily, on overhead. Every major U.S. manufacturer markets its products. Every major U.S. manufacturer attempts to maximize revenues. Yet, at least in the pre-bailout world, no one argued that, say, carmakers were ripping the rest of us off because they spent more to advertise than to develop the cars of the future.

Drugmakers are different, and are likely to remain in the limelight, if not in the direct crossfire, as the Obama administration moves forward on health care reform. Even some analysts well-disposed towards the industry contend that pharmaceutical marketing needs a more positive focus. Argues analyst Michael McCaughan: "The goal cannot be simply to increase sales. The goal should be to ensure the widest appropriate use of life-improving or life-extending medicines. Marketing done right means a medicine reaches more of the right people; it maximizes the benefit society receives from medical science." He goes on to suggest combining the codes governing DTCA and physician marketing, since "if the goal is to benefit patients, then it is nonsensical to consider sales force activities and DTC as in any sense separate. If either the patient or the physician

lacks the necessary information to make an informed therapeutic choice, then the marketing campaign failed."[107]

At the same time, drugmakers are under increasing pressure. Blockbuster drugs have slowed and profits are down. *Pharmaceutical Business Review* noted: "An ongoing trend in the pharmaceutical industry has been the vast number of job cuts made in an effort to cut costs, in response to disappointing financial results driven by the patent expiries of key products and resulting generic erosion. Price pressure and low reimbursement rates, which are impacting upon company revenues," were additional factors. Writing early last year, the Review noted: "Consequently, sales and marketing departments will have to adjust and adapt new strategies if they are to maintain acceptable levels of performance."[108]

But as these market processes evolve, government should regulate with a light hand. Other than restrictions on fraudulent or misleading marketing and advertising practices, companies should be left free to communicate with doctors and patients. As Peter Pitts puts it, "Let patients have access to information from every source and then let them speak with their physicians. That's when good things happen." ■

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The views expressed in this paper are solely those of the author.

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