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"Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry"
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Mr. Chairman, Senator Smith, and Members of the Committee:

Thank you for the invitation to participate in today's hearing on pharmaceutical company relationships with physicians. My name is Marjorie Powell and I am the Senior Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is the nation's leading trade association representing research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients achieve longer, healthier, more productive lives.

Pharmaceutical education of health care providers, often referred to as "marketing and promotion" is a short-hand expression for interaction between pharmaceutical representatives and healthcare professionals regarding pharmaceutical treatments for patients. The role of pharmaceutical promotion is to educate health care professionals on the latest, most accurate information available regarding prescription medicines, which play an ever increasing role in healthcare.

Ethical relationships between healthcare professionals and prescription drug manufacturers are critical to the pharmaceutical industry's mission of developing and marketing medicines that allow patients to live longer, healthier, and more productive lives. Direct communication with healthcare professionals allows pharmaceutical

manufacturers to inform healthcare professionals about the benefits and risks of their products, provide scientific and educational information, support medical research and education, and obtain information and advice about their products through consultation with medical experts.

PhRMA Code on Interactions with Healthcare Professionals

PhRMA's member companies are committed to following the highest ethical standards as well as all legal requirements in their interactions with healthcare professionals. An expanded version of the "PhRMA Code on Interactions with Healthcare Professionals" ("the Code" or "the PhRMA Code") was adopted in 2002 to demonstrate our intention of interacting with healthcare professionals for the benefit of patients and to enhance the practice of medicine. The Code starts with the fundamental principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

The PhRMA Code sets out concrete rules that apply in particular situations. The Code, for example, states clearly that it is inappropriate for companies to provide to a healthcare professional entertainment or recreational activities, such as golf or theater tickets. Companies may provide modest meals in connection with presentations by pharmaceuticals representatives or other speakers, if meal is conducive to the exchange of information. Similarly, companies may offer healthcare professionals educational gifts that are primarily for the benefit of patients and are not of substantial value. The Code

does not condone offering items that are of only personal benefit to healthcare professionals.

The Code allows a company to engage healthcare professionals for bona fide consulting services, provided that the company has a legitimate need for the services and compensation is based on the fair market value of those services. In certain circumstances, a company may also provide financial support for conferences and professional meetings and for scholarships that permit medical students, residents, and others in training to attend these conferences. The Code provides that a grant, consulting arrangement, contract, gift, or other benefit may never be offered to a healthcare professional in exchange for agreeing to prescribe a product.

PhRMA Code Endorsed by Office of the Inspector General of the Department of Health and Human Services

Although adherence to the PhRMA Code is voluntary, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) has endorsed the Code as a measure for compliance with the legal requirements that govern pharmaceutical marketing practices.[1] The OIG is the agency within HHS that is responsible for protecting the integrity of government programs and for enforcing federal fraud and abuse laws that apply to the provision of goods and services to the government. In its Compliance Program Guidance for Pharmaceutical Manufacturers, the OIG provided its views on fundamental elements of pharmaceutical manufacturer compliance programs and principles that pharmaceutical manufacturers should consider when

[1] *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

developing and implementing an effective compliance program. The OIG stated that compliance with the PhRMA Code is not an absolute safe harbor, but noted that compliance would "substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."[2]

Lewis Morris, OIG's General Counsel, has explained that adherence to the PhRMA Code serves as an indicator of a company's commitment to compliance.[3] According to Morris, conduct inconsistent with the Code "indicates something about how that manufacturer is approaching its relationship to our programs and consumers."[4]

In addition to endorsement by the OIG, the PhRMA Code has received praise from individual federal prosecutors responsible for enforcing the fraud and abuse laws. James Sheehan, an Assistant U.S. Attorney in Philadelphia, stated at the time the current version of the Code was issued: "If people comply with this code as it is currently drafted, we are going to see, in my view, a major difference in how this industry operates, and I think a major difference in how it is perceived by consumers and physicians."[5] In particular he cited the limitations on entertainment, meals, and gifts to healthcare professionals as particularly significant.[6]

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[2] Id.
[3] "IG Rx Compliance Guide Sets PhRMA Marketing Code as Minimum Threshold," *The Pink Sheet*, Oct. 7, 2003.
[4] Id.
[5] "PhRMA Marketing Code Should Cover Preceptorships, Surveys," *The Pink Sheet*, June 10, 2002.
[6] Id.

PhRMA Code Similar to Codes of Other Health Care Associations

The PhRMA Code is similar in many ways to the American Medical Association's ethical opinion on "Gifts to Physicians From Industry," which was revised just before publication of the Code—except that it is stricter than the AMA guidelines on the topic of meals and entertainment.

Subsequent to the issuance of the PhRMA Code, a number of other industry associations released similar documents. AdvaMed, whose member companies develop medical devices, diagnostic products, and health information systems, issued its "Code of Ethics for Interaction with Health Care Professionals"[7] in September of 2003. The AdvaMed Code incorporates many of the same principles and limitations as the PhRMA Code. A year later, the Accreditation Council for Continuing Medical Education adopted the "Updated Standards for Commercial Support,"[8] which provides guidelines for providers of continuing medical education in the same spirit as the PhRMA Code.

The PhRMA Code has therefore become a de facto benchmark for industry practices among both member and non-member companies. A 2003 survey found that 96 percent of industry promotional meetings and events were compliant with the Code.[9] Today it is common practice for pharmaceutical companies to incorporate the provisions of the PhRMA Code into their compliance programs and standard operating procedures, and often explicitly refer to the Code in these materials. Lawyers rely on the Code when

[7] Available at: http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe_with_faqs_41505.pdf.
[8] Available at: http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
[9] Herman R. and Schonbachler D., *PhRMA Code: New Rules, Same Game*, Med. Educ. Meetings. Aug. 2004, at 8, 10.

advising their clients on compliance matters. In addition, the OIG requires pharmaceutical companies to have a compliance officer who reports directly to the president or CEO of the company. These compliance officers look to the PhRMA Code as a baseline in overseeing their companies' compliance efforts.

Value of Pharmaceutical Education of Health Care Providers

Published research has looked at whether physicians see value in pharmaceutical promotional and marketing efforts. One survey found that over 90 percent of physicians surveyed said that the education provided by pharmaceutical representatives about specific drug therapies was either "somewhat valuable" (53 percent) or "very valuable" (38 percent).[10] Another survey found that the "sources of greatest importance (to physicians) were those involving the transfer of information through the medium of personal contact."[11] This kind of contact comes mostly in the form of pharmaceutical representatives and industry-sponsored educational events.

The fact that pharmaceutical representatives interact with physicians, does not mean that doctors uncritically accept everything they are told. One study of physicians examined the relationship between doctors and pharmaceutical representatives and separated the discussions into "unsolicited" and "solicited." "Solicited" discussions involve requests from the doctor for information – for example, new study results, information on potential side effects of a medication, etc. "Unsolicited" discussions are those initiated by the pharmaceutical representative. The study found that physicians find

[10] 2002 BCG Proprietary Physician Survey (400 respondents), 2002, as reported in "Pharmaceutical Marketing and Promotion, Creating Access to Innovation," Economic Realities in Health Care Policy, Pfizer, 2003: 3(1):11.

[11] McGettingan P. et al., "Prescribers Prefer People: The Sources of Information Used by Doctors for Prescribing Suggest that the Medium is More Important than the Message," *British Journal of Clinical Pharmacology*, 51:184-189.

pharmaceutical representatives to be a highly credible source of information. Doctors did, however, exhibit some skepticism when they were approached with new information that they had not requested. One reason for this may be that information is often presented to doctors in a short meeting. The doctor then often returns to the pharmaceutical representative with questions once he/she has reviewed the information. Rather than unduly influencing doctors, as some critics suggest, pharmaceutical representatives appear to play a valuable role in providing important and timely information. The study suggests that while doctors are not easily persuaded by unsolicited information, those same physicians depend on industry representatives for credible data on the frequent occasions when they find the information useful or valuable.[12] Whether the information is solicited or unsolicited, it is derived from evidence approved by the Food and Drug Administration (FDA).

While some critics have questioned the reliability of information provided by pharmaceutical companies in their marketing to healthcare providers, the reality is that there are state and federal government regulations that govern the marketing of products and serious consequences exist for non-compliance. Only a product's scientifically proven capabilities, verified by the FDA, can be used in its marketing. Furthermore, pharmaceutical representatives depend on good, long-term relationships with physicians, relationships that are built on trust. If a medical representative provides information that a physician believes to be or later learns to be false, significant damage is done to that relationship, and the physician is less likely to rely on information from that

[12] Slotnick, H.B. et al., "How Physicians 'Learn' from Pharmaceutical Representatives: An Exploration," *The Journal of Continuing Education in the Health Profession*, Spring 1999: 19(2):84-96.

representative or company again. Finally, there is competition among sellers of medical products, so it is unlikely that incorrect information will go unchallenged for very long.

Helping Translate New Technologies and Therapies into Practice

An Institute of Medicine report issued in 2001 noted that medical science and technology have advanced at an unprecedented rate during the past half-century. In tandem, the complexity of healthcare has grown.[13] Faced with these rapid changes, our healthcare delivery system has fallen short in its ability to translate knowledge into practice and to apply new technology safely and appropriately. In fact, the report noted that it now takes an average of 17 years for new knowledge to be incorporated into practice, and even then the application is highly uneven. Pharmaceutical marketing and promotion plays a valuable role in the healthcare system by delivering the newest information regarding pharmaceutical therapies to physicians and helping to bridge this gap and translate new technologies into practice. Research suggests that without the information provided by pharmaceutical representatives, utilization of valuable medical innovation would decrease significantly.

In fact, according to an article in *Health Affairs*, variations in prescribing patterns from location to location are not nearly as severe as variations in diagnostics and surgical procedures. The authors suggest one explanation may have to do with the valuable role pharmaceutical representatives play in informing doctors. "Drug firms' marketing efforts may truly educate consumers and providers and lead to greater uniformity of practice."[14]

[13] "Crossing the Quality Chasm: A New Health System for the 21st Century," Institute of Medicine, March 2001.
[14] Dubois R. W., Batchlor E. and Wade S., "Geographic Variation in the Use of Medications: Is Uniformity Good News or Bad?" *Health Affairs*, January/February 2002: 21(1): 240-250.

Similarly, pharmaceutical marketing and promotion has played a valuable role in raising physician awareness of the most recent clinical practice guidelines, and thus improving health outcomes. According to an article in the *Journal of the American Medical Association* (*JAMA*)[15], "physician adherence to practice guidelines is critical in translating recommendations into improved outcomes. [The guidelines] successful implementation should improve quality of care by decreasing inappropriate variation and expediting the application of effective advances to everyday practice." However, "a variety of barriers undermine this process," such as physicians' lack of awareness and/or lack of familiarity with a guideline. In the case of high cholesterol, for example, in May of 2001, the National Institutes of Health updated their National Cholesterol Education Program [NCEP] guidelines. These guidelines called for greater numbers of individuals to be treated for high cholesterol. According to October 2002 article in the *American Journal of Managed Care*, "[c]oncurrent public and private efforts aimed at physicians and consumers were related to increased diagnosis and treatment. Physician-directed initiatives have included pharmaceutical industry marketing, continuing medical education programs, and promotion of NCEP guidelines. Consumer-directed initiatives have included direct-to-consumer advertisements sponsored by various pharmaceutical companies and patient education programs…."[16]

According to Francine Kaufman, M.D., then-President of the American Diabetes Association (ADA) and current head of the endocrinology division at Children's Hospital in Los Angeles, much progress has been made in diabetes care since 1995. While

[15] Cabana M., MD, MPH et al., "Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement," *JAMA*, October 22, 1999: 282(15).
[16] Dubois R. W. et al., "Growth in Use of Lipid-Lowering Therapies: Are we Targeting the Right Patients," *The American Journal of Managed Care*, October 2002: 8(10).

acknowledging that the management of diabetes is getting more complicated, with numerous new agents available, she stated, "I think the gap between the standard of care and what's going on out there is getting narrower." Kaufman credited associations like ADA and other groups with helping to narrow the gap, along with the role of the pharmaceutical industry educating physicians.[17]

Pharmaceutical marketing and promotion has also been credited with helping to improve treatment of mental illness. According to a study by David Cutler and Mark McClellan, through promotional activities, "manufacturers of SSRIs [medications used to treat depression] encouraged doctors to watch for depression and the reduced stigma afforded by the new medications induced patients to seek help." As a result, diagnosis and treatment doubled over the 1990s.[18]

Helping Patients Find the Right Medicine

Another important role that pharmaceutical promotion plays is providing free samples to physicians. Doctors may distribute samples to patients for several reasons – for instance, to get patients started on therapy right away, to help patients who might not be able to afford medicines on their own or to optimize dosing or choice of drug before committing to a particular course of treatment. These samples can allow the patient and physician to work together to determine what medicine is best for the patient. According to a *Wall Street Journal* article, "If you're open to switching prescriptions, ask your doctor for samples...Not only will you stave off having to pay, but doctors advise trying various medicines because they differ. Samples are 'an important way of trying to find

[17] Hitchens K., "Diabetes Care Closing the Gap Between Standards and Practice," Special Supplement to *Drug Topics*, October 2002: p. 2-27.
[18] Cutler D. and McClellan M., "Is Technological Change in Medicine Worth It?" *Health Affairs* September/October 2001: (20)5:11-29.

out which ones work' for patients, says Anthony Montanaro, chairman of the Asthma and Allergy Foundation's Medical-Scientific Council."[19] A poll of physicians reported that over 90 percent found product samples "valuable" or "extremely valuable" in their practices.[20]

While some industry critics have suggested that free samples may do more harm than good by encouraging people to take medications they may not need or take a newer medicine when an older medicine may be more appropriate, the available data on patients who receives samples and how doctors view the value of samples suggest that patients benefit from sample medicines and that samples are an important part of the healthcare safety net for low-income and uninsured patients. Researchers have examined physicians' decisions to distribute free samples to their patients: one study, funded by the U.S. Agency for Health Care Policy and Research, examined the use of samples in primary care practices. According to the study, samples were used in about 20 percent of all patient interactions across a wide range of diseases and conditions. The study concluded that with regard to the impact of pharmaceutical company representatives, patients "…profited in a spectrum of ways. While samples represented tangible cost savings, immediate relief and convenience to the individual patient….patient education materials facilitated further understanding of their diagnosis, potentially leading to a higher degree of satisfaction with their health care."[21]

[19] Saranow J. and Marcus A.D., "The Higher Cost of Sneezing – As Nonprescription Claritin Hits Shelves, Insurers Jack up Prices of Other Allergy Drugs," *The Wall Street Journal*, December 10, 2002.
[20] Boston Consulting Group, Physician Poll, 2002, as reported in "Pharmaceutical Marketing and Promotion, Creating Access to Innovation," Economic Realities in Health Care Policy, Pfizer, 2003: 3(1).
[21] Backer E. et al., "The Value of Pharmaceutical Representative Visits and Medication Samples in Community-Based Family Practices," *Journal of Family Practice*, September 2000: 49(9): 811-816.

Other research looked at the reasons doctors provided samples to some patients more than others. For example, in one study of the use of samples for 71 hypertension patients, nearly half of patients who received samples had no insurance.[22] A different survey of physicians looked at the key factors influencing physicians' decisions to distribute free samples. The authors found that the "patient's financial situation" was a considerable or strong influence 86 percent of the time and a patient's insurance status was of influence 63 percent of the time.[23]

Pharmaceutical Marketing as a Counterbalance to Other Aspects of the Healthcare System

Pharmaceutical marketing also plays a role as a counterbalance to other aspects of our health care system. Debate about pharmaceutical marketing and promotion virtually always seems to assume that it is the sole influence on prescribing, rather than one factor among the wide array of powerful influences in the health care system.

For example, according to research published in *Health Affairs*, one-third of physicians do not discuss treatment options when those options would not be covered by the patient's insurer.[24] A survey of physicians conducted by the Boston Consulting Group found that payors have much greater influence over prescribing decisions than patient requests or pharmaceutical representatives. The survey asked how much formularies, peers, practice guidelines, patient requests, pharmaceutical representatives, and information found on the Internet) had on their prescribing decisions. Fifty-four

[22] Zweifler J. et al., "Are Sample Medicines Hurting the Uninsured?" *Journal of the American Board of Family Practice*, September–October 2002: 15(5): 361-366.
[23] Spiller L. and Wymer W., "Physicians' Perceptions and Uses of Commercial Drug Information Sources: An examination of Pharmaceutical Marketing to Physicians," *Health Marketing Quarterly*, 2001: 19(1): 91-106.
[24] Wynia M. et al., "Do Physicians Not Offer Useful Services Because of Coverage Restrictions," *Health Affairs*, July/August 2003: 22(4).

percent of physicians responded that formularies had a major impact on prescribing decisions, as opposed to 36 percent who said they had a minor impact. Peers (50 percent) and clinical guidelines (47 percent) also had a major impact in terms of physician prescribing decisions. In contrast, pharmaceutical representatives (14%), the Internet (9%), and patient requests (24%), had much smaller impacts on physician prescribing behavior.[25]

Moreover, debate about marketing and promotion rarely, if ever, begins with an acknowledgment that generic medicines now represent 63 percent of all prescriptions filled today, according to IMS Health.[26] In fact, this percentage has grown rapidly—just 8 years ago, it was 47 percent. In contrast, in most European countries, where pharmaceutical marketing and promotion is curtailed by legal restrictions, the percentage of prescriptions that are generic is significantly lower. This clearly demonstrates the power of several influences other than pharmaceutical marketing and promotion to determine which medicines patients receive.

The range of influences on prescribing extend beyond those identified in the Boston Consulting Group survey of physicians discussed above. For example, a study in *Health Affairs* noted that physician counterdetailing by insurance companies and pharmacy benefit managers to encourage the use of generics is "finally gaining momentum." For example, Blue-Cross/BlueShield of Florida sends letters to doctors that are low prescribers of generics. According to the study, other health plans are planning to distribute generic drug samples to contracted physicians. In the public sector, some Medicaid programs have recently hired physicians and pharmacists to visit doctors'

[25] 2002 BCG Proprietary Physician Survey, n=399
[26] http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm

offices and encourage them to prescribe generics.[27] Some states have adopted counterdetailing programs aimed to provide information about alternative treatments to physicians participating in the state-funded health care programs. For example, Vermont and Pennsylvania have implemented counterdetailing programs, and Oregon has an extensive program to inform physicians about medicines that the state has determined are, on average, more cost-effective. It is worth noting that counterdetailing and other efforts by payors and their agents to influence prescribing decisions are not subject to FDA regulation, while detailing by pharmaceutical companies is FDA regulated.

Economic Value of Pharmaceutical Marketing and Promotion

As the U.S. population grows and ages, its health care needs continue to expand. Diseases that affect the elderly, such as Alzheimer's, and chronic conditions, such as diabetes, are becoming increasingly prevalent. In fact, according to the Centers for Disease Control and Prevention, chronic conditions account for 75 percent of total health care spending today.[28] Public health officials have shown growing concern over the increasing incidence of diabetes, obesity, depression, asthma, hypertension and many other conditions. Today, many patients with these conditions are not treated at all or are not treated according to recommended guidelines. In fact, there is wide-scale underdiagnosis and undertreatment of many common, chronic diseases. In a landmark study RAND researcher Elizabeth McGlynn and colleagues reported that underuse was the principal quality of care problem associated with use of medicines in seven of nine

[27] Malkin J. et al., "The Changing Face of Pharmacy Benefit Design," *Health Affairs*, 2004: 23(1): 194-199.
[28] Centers for Disease Control and Prevention, Chronic Disease Overview, http://www.cdc.gov/nccdphp/overview.htm

diseases studied and 83 of 103 individual quality measures.[29] Likewise, a study in California – using claims data from 3 of the 10 largest health plans to determine the appropriateness of prescription medication use based upon widely accepted treatment guidelines – found that "effective medication appears to be underused."[30] Of the four therapeutic areas examined in the study – asthma, congestive heart failure (CHF), depression, and common cold or upper respiratory tract infections – asthma, CHF and depression were undertreated. A study by Medco researchers found that increased compliance or adherence to prescription drug treatment regimens can result in reduction of medical costs.[31] For diabetes, the average incremental drug cost for a 20 percent increase in drug utilization was $177 and the associated disease related medical cost reduction was $1251, for a net savings of $1074 per patient (an average ROI of 7.1:1). For cardiovascular conditions, the average ROI for a 20 percent increase in drug utilization was 4.0:1 (hypertension) and 5.1:1 (hypercholesterolemia). Recent press reports explain that leading-edge employers are taking steps, such as reducing copays for both brand and generic drugs, to increase use of medicines by employees with conditions such as diabetes, in an effort to achieve better health outcomes and lower overall costs.[32]

Undertreament exacts a cost – for example, one study found that untreated depression costs employers over $30 billion per year.[33] Another study found that if all

[29] McGlynn E.A., "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine*, June 26, 2003: 348(26): 2635-2645.
[30] Gilberg K. et al., "Analysis of Medication Use Patterns: Apparent Overuse of Antibiotics and Underuse of Prescription Drugs for Asthma, Depression and CHF," *Journal of Managed Care Pharmacy*, 2003: 9(3): 232-237.
[31] Sokol M. et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, 2005: 43(6): 521-530.
[32] Freudenheim M., "To Save Later, Some Employers are Offering Free Drugs," *New York Times*, February 21, 2007; Freudenheim M., "New Urgency in Debating Health Care," *New York Times*, April 6, 2007; and Aetna, "New Preventive and Chronic Medications Option," August 2005.
[33] Finkelstein J.B., "Mental Health Parity Extended Another Year," *Am News*, December 2, 2002.

patients with high blood pressure were treated with medicines according to recognized guidelines, 89,000 lives could be saved and 420,000 hospitalizations avoided annually—on top of the 86,000 lives saved and 833,000 hospitalizations avoided by those using antihypertensive medicines.[34] As discussed above, pharmaceutical marketing and promotion plays a role in increasing treatment rates, improving the quality of life for patients and lowering overall costs.

New medicines help avert surgeries and trips to the ER, prevent disability, and improve quality of life for patients everywhere. The benefits ripple beyond individual patients to society in general. For example, findings by a Columbia University researcher indicate that new medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000.[35] Some new medicines and vaccines help prevent disease; others cure or alleviate previously fatal or debilitating conditions. Innovative new medicines also make it possible to prevent or slow the progress of many diseases and avoid costly hospitalization and invasive surgery. For example, between 1980 and 2000, the number of days Americans spent in the hospital fell by 56 percent. As a result, Americans avoided 206 million days of hospital care in 2000 alone.[36] New medicines clearly played an important role in this improvement.

Increased spending on pharmaceuticals often leads to lower spending on other forms of more costly health care. New drugs are the most heavily promoted drugs, a point critics often emphasize. However, the use of newer drugs tends to lower all types

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[34] Cutler D. et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, January/February 2007: 26(1): 97-110.
[35] Lichtenberg F.R., "The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001," National Bureau of Economic Research, Working Paper No. 9754 (Cambridge, MA: NBER, June 2003).
[36] MEDTAP International Inc., "The Value of Investment in Health Care: Better Care, Better Lives," (Bethesda, MD: MEDTAP, 2003).

of non-drug medical spending, resulting in a net reduction in the total cost of treating a condition. For example, on average replacing an older drug with a drug 15 years newer increases spending on drugs by $18, but reduces overall costs by $111.[37]

Innovative medicines not only extend life and lower spending on other forms of health care but can also make life itself better for patients. New medicines can improve quality of life for patients suffering from long-term illnesses or help patients remain independent by preventing disability. Patients' lives are often improved by medicines because the medicines can avert complications or limit the severity of a sickness. For example, one study found that inner-city children who had asthma, but were enrolled in a comprehensive disease management program that included appropriate medications, experienced significant quality of life improvements. As their symptoms decreased and their capacity for activity rose, they reported greater emotional well-being.[38]

Continued discovery of new medicines helps strengthen the U.S. economy by making it possible for workers to go back to their jobs sooner and to be more productive when they are at work. One study showed that 50 percent of workers receiving a drug injection for a migraine attack returned to work within two hours, compared to only 9 percent of workers who received a placebo.[39]

Pharmaceutical R&D v. Marketing and Promotion

In debates about pharmaceutical marketing and promotion, it is often claimed that pharmaceutical companies spend more on marketing and advertising than on research and

[37] Lichtenberg F.R., "Benefits and Costs of Newer Drugs: An Update," National Bureau of Economic Research Working Paper, No. W8996 (Cambridge, MA: NBER, June 2002).
[38] Munzenberger P.J. and Vinuya R. Z., "Impact of an Asthma Program on the Quality of Life of Children in an Urban Setting," *Pharmacotherapy*, 2002: 22(8): 1055-1062.
[39] Cady R.C. et al., "Sumatriptan Injection Reduces Productivity Loss During a Migraine Attack: Results of a Double-Blind, Placebo-Controlled Trial," *Archives of Internal Medicine*, May 11, 1998: 158:1013-1018.

development (R&D) of new drugs. The facts do not support this claim. In 2005, pharmaceutical manufacturers spent an estimated $7.2 billion[40] on pharmaceutical professional promotion (which includes costs associated with sales activities of pharmaceutical representatives that are directed to office-based physicians, hospital-based physicians and directors of pharmacies, and advertising for prescription products appearing in medical journals) and $4.2 billion on direct-to-consumer (DTC) advertising, according to IMS Health.[41] This $11.4 billion compares to $51.3 billion in total R&D spending by the biopharmaceutical industry, according to Burrill & Company. PhRMA members alone spent $39.9 billion on R&D in 2005.[42]

Uwe Reinhardt of Princeton University has explained how marketing and promotion costs often are inaccurately characterized in policy debates. According to Reinhardt, "…the [selling, general and administration or SGA] category represents many expenses other than selling expenses and should not be seen as an estimate purely of outlays on marketing, as the industry's critics occasionally do."[43] Harvard economist Joe Newhouse notes, "One sometimes hears it said that the industry would have more money for R&D if it would cut down its marketing costs. This comment reflects misunderstanding of the economics of the industry. If a firm did so, it would be less profitable and have would attract less capital for R&D or would have fewer internally generated funds to invest."[44] And the Federal Trade Commission has stated that DTC advertising does not significantly affect prescription drug prices: "[DTC advertising] can

[40] IMS Health, Integrated Promotional Services™ and CMR, 5/2006.
[41] Id.
[42] Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2006* (Washington, D.C.: PhRMA, March 2006).
[43] Reinhardt U.E., "Perspectives on the Pharmaceutical Industry," *Health Affairs*, September/October 2001: 20(5): 136-149.
[44] Newhouse J.P., "How Much Should Medicare Pay for Drugs?" *Health Affairs*, January/February 2004: 23(1): 89-102.

empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about treatment options…Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices. DTC accounts for a relatively small proportion of the total cost of drugs, which reinforces the view that such advertising would have a limited, if any, effect on price."[45]

Thus, as the Congressional Budget Office recently reported, "The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."[46] At the same time, marketing and promotion play an important role in informing physicians and patients about the fruits of this investment—new medicines that improve and save lives.

Conclusion

Pharmaceutical marketing and promotion provides value to physicians by allowing pharmaceutical research companies to inform healthcare providers about the benefits and risks of new medicines in accordance with FDA regulation, provide educational and scientific information, support medical research and education, and obtain information and insight about our products through consultation with medical experts. Published research has reinforced the value physicians see in promotional and marketing efforts and the PhRMA Code confirms our commitment to interact with

[45] Federal Trade Commission, Comments before the Department of Health and Human Services Food and Drug Administration in the Matter of Request for Comments on Consumer-Directed Promotion (Docket No. 2003 N-0344), December 1, 2003.
[46] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006.

healthcare professionals for the benefit of the patient and to enhance the practice of medicine.