



THE FACTS ABOUT
PHARMACEUTICAL
MARKETING &
PROMOTION

INTRODUCTION

Activities conducted as part of pharmaceutical marketing and promotion are an important component of educating and informing consumers and health care professionals about new treatments. Direct-to-consumer (DTC) advertisements aim to inform patients of important treatment options, while pharmaceutical sales representatives work to get accurate, up-to-date information on medicines to health care professionals.

These efforts have also been the subject of debate, with some questioning their value. This booklet offers facts about pharmaceutical marketing and promotion. We believe these facts are important to consider as the value of marketing and promotion are debated.

Since our last publication on marketing and promotion,¹ the pharmaceutical industry has worked to improve the dissemination of information about medical advances and to address concerns. One important change was the unanimous approval by PhRMA's Board of Directors of *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines*. These voluntary Principles express the commitment of PhRMA members to deliver DTC communications that are a valuable contribution to public health.

In addition, in 2008 PhRMA adopted a newly revised *Code on Interactions with Health Care Professionals*. The strengthened code reflects a commitment to maintaining the highest ethical standards in all marketing practices and to promote the best patient care possible.

This publication shows the role of marketing and promotion in speeding the dissemination of valuable improvements in medical care. It also highlights the important role that marketing plays in getting patients to discuss a range of health issues with their physicians, resulting in patients receiving needed treatment.

We hope that the information contained in this booklet will enhance dialogue surrounding pharmaceutical marketing and promotion by providing a perspective that often is not heard. We look forward to further exploration of how best to get patients into needed treatment, and how to more rapidly and appropriately disseminate valuable medical technology.

¹ Pharmaceutical Research and Manufacturers of America, "Tough Questions - Straight Answers Pharmaceutical Marketing & Promotion," (Washington, DC: PhRMA, Fall 2004) http://www.phrma.org/files/Tough_Questions.pdf.

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Pharmaceutical marketing is closely regulated by the U.S. Food and Drug Administration (FDA) to help assure that promotional materials are accurate, fairly balanced, and limited to information that has been approved by the FDA. Many pharmaceutical companies have also adopted voluntary pharmaceutical industry guidelines that lay out standards for interactions with health care providers and appropriate DTC marketing.

KEY FACTS

The facts below are a preview of the full content contained within this brochure. For more information on each Key Fact, go to the corresponding page number listed.

Marketing to Health Care Providers & Prescribing Patterns

- A 2008 physician survey by KRC Research found that the vast majority of physicians say their clinical knowledge (**92%**) and a patient's unique situation (**88%**) greatly influence their prescribing decisions. **35%** point to patients' coverage and formulary as an important factor in prescribing, while just **11%** say that pharmaceutical company representatives greatly influence them. Surveys by Boston Consulting Group and Tufts Center for the Study of Drug Development echo these findings.
- **1/3** of physicians report that they do not always discuss treatment options that are not covered by an insurer.
- Approximately **67%** of all prescriptions used in the United States are generic. This is a sharp increase in recent years—**49%** of prescriptions in 2000 were for generics—and one of the highest generic use rates in the world.

(See pgs 3-4)

Information to Health Care Providers

- Nearly **90%** of physicians are either very satisfied (**29%**) or somewhat satisfied (**59%**) with the information they received from company representatives, according to the KRC survey. The BCG survey yielded similar results with over **90%** of physicians believing information from representatives to be either very valuable (**38%**) or somewhat valuable (**53%**).

(See pg 5)

Samples

- The 2008 KRC physician survey found **69%** of physicians believe free drug samples are

either always useful (**52%**) or often useful (**17%**). **95%** of physicians surveyed agreed that samples allow patients to start immediate treatment and **84%** said that samples provide them with useful first-hand experience.

- A recent Kaiser Family Foundation survey found that **75%** of physicians frequently (**58%**) or sometimes (**17%**) give patients samples to assist them with their out-of-pocket costs.

(See pg 6)

Physician / Patient Relationship

- According to an FDA survey, a vast majority (over **90%**) of patients who asked about a drug reported that their physician "welcomed the question."
- The FDA survey also polled **500** physicians and found that:
 - **73%** believed that DTC ads helped patients ask thoughtful questions.
 - **53%** of physicians considered the number one benefit of DTC ads to be the better discussions they had with their patients about their health.
 - **91%** of physicians said the patient did not try to influence the course of treatment in a way that would have been harmful.

(See pg 8)

Underdiagnosis & Undertreatment

- American patients receive about **1/2** of recommended care, according to a landmark 2003 study by RAND Health.
- The RAND Study also found that for quality standards related to medication, patients on average failed to receive recommended care **30%** of the time.

Underdiagnosis & Undertreatment Continued

- Another RAND study published in the *Annals of Internal Medicine* found that **50%** of all quality problems in the use of medicines was accounted for by underuse, compared to **3%** accounted for by overuse.
- A Harvard University/Massachusetts General Hospital and Harris Interactive Survey found that:
 - **1/4** of patients who visit their doctor after seeing a DTC ad receive a new diagnosis.
 - **46%** of physicians felt that DTC advertising increased patients' compliance with prescribed treatment.
- By treating patients according to guidelines and by eliminating the underuse of high blood pressure medicines, **89,000** lives could be saved and **420,000** hospitalizations avoided annually.

(See pgs 9-11)

Patient Education

- A 2007 KRC Research survey found that:
 - **1 in 4** consumers sought more information after seeing a DTC ad.
 - **4 in 5** consumers agree that advertising for prescription medicines can educate people about health conditions and treatment options.
- A *Prevention Magazine* physician survey found that **70%** of doctors feel that ads help educate patients about available treatments. **67%** felt that the advertisements helped them have better discussions with their patients.
- The FDA's 2004 survey showed that in **88%** of cases when patients ask their physicians about a medicine as a result of seeing a DTC advertisement, they have the condition that the drug treats.
- A *Prevention Magazine* patient survey found that **80%** of patients who see medicines advertised on television are aware of the risk information presented, compared to **66%** aware of the benefits.

(See pg 12)

DTC & Prescribing Patterns

- A 2006 Government Accountability Office (GAO) report found that only **2–7%** of consumers who saw a DTC advertisement requested and ultimately received a prescription for the advertised drug.
- A 2002 study on the effect of DTC advertising on demand for pharmaceuticals revealed that DTC advertising may increase demand for a particular brand drug, but only if it has a "favorable status" on the insurer's formulary.

(See pgs 13-14)

DTC Advertising & Drug Prices / Spending

- According to the Federal Trade Commission, "[DTC advertising] can 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 their treatment options...Consumers receive these benefits from DTC advertising **with little, if any, evidence that such advertising increases prescription drug prices.**" [Emphasis Added]
- "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."
 - Congressional Budget Office, 2006
- Total promotional spending 2006 – **\$12.0** billion
 - DTC – **\$4.8** billion
 - Office promotion, hospital promotion, and journal advertising – **\$7.2** billion
- Total R&D spending 2007 – **\$58.8** billion

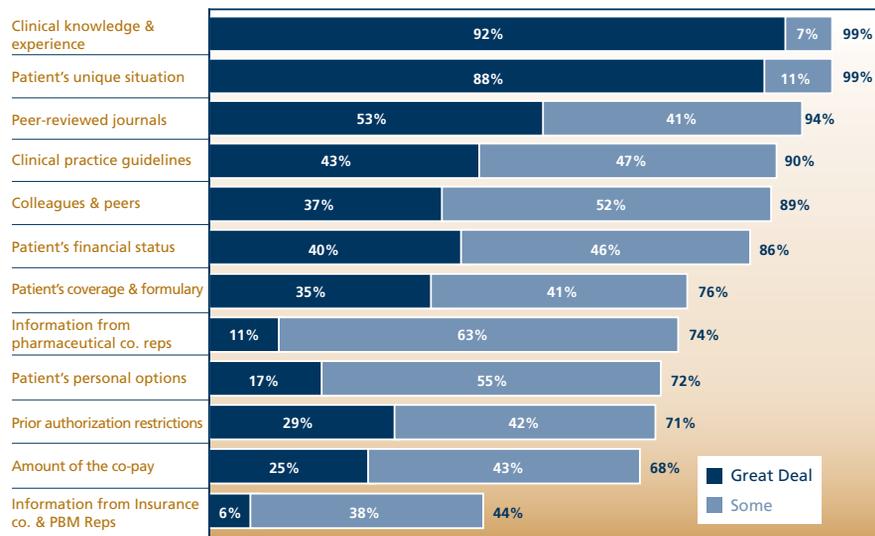
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MARKETING TO HEALTH CARE PROVIDERS & PRESCRIBING PATTERNS

Pharmaceutical sales representatives provide doctors with important information about new treatment options that is factored into prescribing, but studies find that many other factors, including insurers' policies, affect prescribing decisions, often with greater impact. In fact, about 2 out of 3 medicines prescribed in the U.S. are generic—much higher than in nearly all other developed countries.

CHART 1: Factors Physicians Consider in Prescribing Medicines

Percent Saying Great Deal or Some Influence on Prescribing Decisions



Source: Pharmaceutical Research and Manufacturers of America, KRC Research: Survey of Physicians' Opinions About Pharmaceutical and Biotech Research Company Activities and Information, n=501, 2008.

Pharmaceutical marketing to health care providers is an important part of keeping physicians up-to-date about new treatments and their risks and benefits. However, it is only one factor among many in the health care system.

For instance, health plans may strongly influence prescribing through formulary design and utilization management strategies, among other factors. A recent KRC Research survey sponsored by PhRMA found that by far the most important factors in prescribing are a physician's clinical knowledge and experience and the

patient's unique situation. Journal articles, clinical guidelines and formularies are all factors that physicians consider more than pharmaceutical company representatives² [See Chart 1].

Two surveys, one by The Boston Consulting Group (BCG) and the other by the Tufts Center for the Study of Drug Development, echoed these findings. In the BCG survey, 54% of physicians reported that formularies have a major impact on prescribing decisions, 50% identified peers, and 47% identified clinical guidelines, compared to 14% who

²KRC Research, "Physicians' Opinions About Pharmaceutical and Biotech Research Company Activities and Information," n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

said pharmaceutical representatives have a major impact.³ The Tufts Center for the Study of Drug Development found that among factors influencing prescribing decisions in 2007, physicians considered the following to be “very important”: continuing medical education (68%), information from peers (43%), and payer’s decisions (37%). Only 13% of physicians considered information from pharmaceutical companies “very important.”⁴

Research published in *Health Affairs* reports that one-third of physicians do not always discuss treatment options when those options would not be covered by the patient’s insurer.⁵

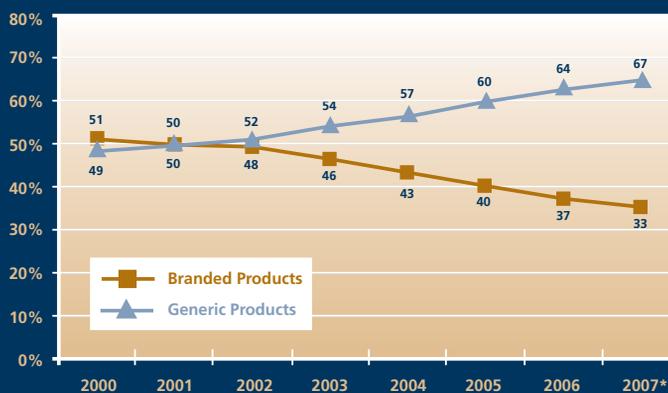
It is also important to note that approximately 67% of all prescriptions dispensed in the U.S. in 2007 were for generic drugs,⁶ up from 49% in 2000.⁷ Moreover, the U.S. has one of the highest generic market shares of any developed country.⁸ These facts clearly demonstrate that the regulated information conveyed through pharmaceutical company marketing of brand medicines is only one of many factors that physicians consider when making prescribing decisions.

The range of influences on prescribing extends beyond those identified 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 “gaining momentum.” In the public sector, some Medicaid programs have recently hired physicians and pharmacists to visit doctors’ offices and encourage them to prescribe generics.⁹ Counterdetailing by payers and their agents to influence prescribing decisions is not subject to FDA regulation, while detailing by pharmaceutical companies is FDA-regulated.

Counterdetailing is only one of many payer tactics to influence physician prescribing. The *Health Affairs* study also reported that Blue Cross Blue Shield of Florida sends letters to doctors who are low prescribers of generics. In addition, other health plans plan to distribute generic drug samples to contracted physicians.¹⁰ According to *The Wall Street Journal*, during a three-month program in 2007, Blue Cross Blue Shield of Michigan paid doctors for switching patients from the brand statin they had been taking to a different statin’s generic copy.¹¹ The physician survey by KRC Research found that 80% of physicians have been asked by an insurer to switch a prescription to a different drug—not merely a generic copy of the drug they prescribed.¹²

CHART 2: Brand and Generic Shares of Prescriptions Filled: 1996-2007



Source: PhRMA Analysis of National Prescription Audit™ data from IMS Health, data through 3rd Quarter of 2007.

³ Boston Consulting Group, 2002 BCG Proprietary Physician Survey, n=399, 2002.

⁴ Tufts Center for the Study of Drug Development, *Outlook 2008*, (Tufts CSDD: Boston, 2008).

⁵ M. Wynia et al., “Do Physicians Not Offer Useful Services Because of Coverage Restrictions?,” *Health Affairs* 22, no.4 (July/August 2003): 190-197.

⁶ Pharmaceutical Research and Manufacturers of America, *Analysis of National Prescription Audit™ data from IMS Health*, data through 3rd Quarter of 2007.

⁷ IMS Health, October, 2007.

⁸ M. Danzon and M.F. Furukawa, “Price and Availability of Pharmaceuticals: Evidence from Nine Countries,” *Health Affairs Web Exclusive*, 29 October 2003, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1> (accessed 25 March 2008).

⁹ J. Malkin et al., “The Changing Face of Pharmacy Benefit Design,” *Health Affairs* 23, no.1 (2004) 194-199, page 198.

¹⁰ *Ibid.*

¹¹ V. Fuhrmans, “Doctors Paid To Prescribe Generic Pills,” *The Wall Street Journal*, 24 January 2008.

¹² KRC Research, “Physicians’ Opinions About Pharmaceutical and Biotech Research Company Activities and Information,” n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

INFORMATION TO HEALTH CARE PROVIDERS

Government regulates the marketing of pharmaceuticals, and companies strive to provide reliable, valuable information. Delivering this information is key to making physicians aware of the latest advances.

According to the Institute of Medicine, science and technology have been advancing at an unprecedented pace in recent years.¹³ Despite this, diffusion into practice is slow: One study found that medical research takes 17 years to be incorporated into clinical practice.¹⁴ Pharmaceutical marketing plays a valuable role by delivering the newest information on medicines to physicians and helping to translate new technologies into practice.

This information must be reliable. State and federal government regulations govern the marketing of products, and serious consequences exist for non-compliance. Only a product's scientifically proven properties, verified by the FDA, can be discussed in its marketing. Furthermore, pharmaceutical representatives strive to provide the most accurate information in order to build credibility and earn the trust of physicians over time.

Published research has looked at whether physicians see value in pharmaceutical promotional and marketing efforts. A 2008 KRC Research survey reported that nearly 90% of physicians were either very satisfied (29%) or somewhat satisfied (59%) with the information they received from company representatives.¹⁵ A 2002 BCG survey yielded similar results.¹⁶

The value of disseminating information to physicians is evident in a study by Harvard

“There is a clear need for interactions between physicians and the pharmaceutical industry to ensure the free flow of valid scientific information. When the information is accurate and complete, physicians have the necessary tools to make the right prescribing decisions.”²⁰
– American Medical Association, Testimony

economist David Cutler and then-Stanford researcher Mark McClellan. Through promotional activities for a then-new treatment for depression, “Manufacturers of SSRIs [depression medications] encouraged doctors to watch for depression and the reduced stigma afforded by the new medications induced patients to seek help.”¹⁷ As a result, diagnosis and treatment for depression doubled over the 1990s. However, underdiagnosis and undertreatment remain high: 16.2% of Americans suffer from a depressive disorder, of those, only 51.6% receive treatment.¹⁸

Physicians evaluate information from a range of sources, including continuing medical education, journal articles, clinical practice guidelines, and company representatives. They consider many aspects of information from representatives to be useful: 95% say information about drug interactions is useful, 95% value information about the latest drugs and treatments, 92% find answers to specific questions they have useful, and 90% appreciate information about patient assistance programs.¹⁹

¹³ Institute of Medicine, *Crossing the Chasm: A New Health System for the 21st Century*, (Washington, DC: National Academy Press, March 2001).

¹⁴ E.A. Balas and S.A. Boren, “Managing Clinical Knowledge for Health Care Improvement,” *Yearbook of Medical Informatics 2000: Patient-centered Systems*, (Stuttgart, Germany: Schattauer, 2000), 65–70.

¹⁵ KRC Research, “Physicians’ Opinions About Pharmaceutical and Biotech Research Company Activities and Information,” n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

¹⁶ Boston Consulting Group, *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* 3, no. 1, (Pfizer: 2003): 11.

¹⁷ D. Cutler and M. McClellan, “Is Technological Change in Medicine Worth It?” *Health Affairs* 20, no.5 (September/October 2001): 11-29.

¹⁸ R. C. Kessler, P. Berglund, O. Demler et al., “The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R),” *The Journal of the American Medical Association* 289, no.23 (18 June 2003): 3095-3105.

¹⁹ KRC Research, “Physicians’ Opinions About Pharmaceutical and Biotech Research Company Activities and Information,” n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

²⁰ American Medical Association, “Paid to Prescribe?: Exploring the Relationship Between Doctors and the Drug Industry,” *Statement to the Special Committee on Aging, United States Senate*, (Washington, DC: Statement of Robert M. Sade, 27 June 2007) <http://aging.senate.gov/events/hr176rs.pdf>, (accessed 29 August 2007).

SAMPLES

Samples provide many benefits to patients, allowing them to begin treatment sooner and helping them find the right medicine.

Another role that pharmaceutical promotion often plays is providing samples to physicians. Doctors may distribute samples to patients for several reasons—for instance, to get patients started on therapy right away, to optimize dosing or choice of drug before committing to a particular course of treatment, and sometimes to help patients who might not be able to afford medicines on their own.

A 2008 KRC Research survey found 69% of physicians believe free drug samples are either always useful (52%) or often useful (17%).²¹ Ninety-five percent of physicians surveyed agreed that samples allow patients to start immediate treatment and 84% said that

samples provide them with useful first-hand experience. According to the chairman of the Asthma and Allergy Foundation's Medical-Scientific Council, samples are "an important way of trying to find out which [medicines] work for patients."²²

Although the main role of samples is to allow patients to try a medicine before filling a full prescription and to start treatment right away, in some cases physicians provide samples to help patients who are financially struggling. A recent Kaiser Family Foundation survey found that 75% of physicians frequently (58%) or sometimes (17%) give patients samples to assist them with their out-of-pocket costs.²³ In the survey by KRC Research, 93% of physicians said drug samples helped them assist those patients who are uninsured or in need of financial assistance.²⁴

key fact

"[Samples provide] a clear and direct benefit to patients who have a medically indicated need for treatment, but lack the resources to obtain the necessary care."²⁵

– *American Medical Association, Testimony*

²¹ KRC Research, "Physicians' Opinions About Pharmaceutical and Biotech Research Company Activities and Information," n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

²² J. Saranow and A.D. Marcus "The Higher Cost of Sneezing – As Nonprescription Claritin Hits Shelves, Insurers Jack up Prices of Other Allergy Drugs," *The Wall Street Journal*, 10 December 2002.

²³ Kaiser Family Foundation, *National Survey of Physicians*, Toplines, November 2006, <http://www.kff.org/kaiserpolls/upload/7584.pdf> (accessed 10 December 2007).

²⁴ KRC Research, "Physicians' Opinions About Pharmaceutical and Biotech Research Company Activities and Information," n=501, 2008, sponsored by Pharmaceutical Research and Manufacturers of America.

²⁵ American Medical Association, "Paid to Prescribe?: Exploring the Relationship Between Doctors and the Drug Industry," *Statement to the Special Committee on Aging, United States Senate*, (Washington, DC: Statement of Robert M. Sade, 27 June 2007) <http://aging.senate.gov/events/hr176rs.pdf>, (accessed 29 August 2007).

"GIFTS" TO HEALTH CARE PROVIDERS

PhRMA's member companies are committed to following the highest ethical standards and all legal requirements in their interactions with health care professionals. In 2008, they adopted a newly revised code that, among other things, redefines the narrow category of educational items company representatives can give to health care professionals.

In 2008, the PhRMA Board adopted a newly revised *Code on Interactions with Health Care Professionals* (the "PhRMA Code"), reflecting a commitment to working with health care professionals for the benefit of patients. The PhRMA Code starts with the fundamental principle that a health care professional's care of patients should be based—and should be perceived as being based—solely on each patient's medical needs and the health care professional's medical knowledge.

The PhRMA Code reaffirms that interactions between company representatives and health care professionals should be focused on providing information on products, scientific and educational information, and supporting medical education. Thus, the revised Code prohibits distribution of non-educational items, such as pens, mugs, and other "reminder" objects adorned with a company logo to health care professionals. The Code acknowledges that such items may foster misperceptions that company interactions with health care professionals are not based on informing them about medicines.

Informational discussions by company representatives provide health care professionals with valuable information about new medicines that can lead to improved patient care. The new

Code states that company representatives are permitted to offer an occasional meal as long as it is modest, and only offered in the office or hospital setting, in conjunction with educational presentations. Limiting these meals to the office or hospital setting, instead of restaurants, ensures that the meal is merely incidental to the substantive communication between the representative and the health care professionals in a professional setting.

The revised PhRMA Code reaffirms that representatives should not give health care professionals any items for personal benefit or provide tickets to any recreational or entertainment events. It allows a company to engage health care professionals for bona fide consulting services, provided that the company has a legitimate need for the services, the arrangement is not a reward or inducement to prescribe a particular medicine, and compensation is based on the fair market value of those services.

The revised PhRMA Code contains a compliance mechanism, requiring companies that state their intentions to follow the Code to certify annually that they have policies and procedures in place to foster compliance. PhRMA will identify on its website the companies that intend to follow the Code and the status of their compliance certifications.

DTC & PHYSICIAN / PATIENT RELATIONSHIP

Many physicians and patients report that DTC advertising enhances their communication.

Pharmaceutical advertising increases communication between the physician and patient. According to a 2004 FDA survey of patients, over 90% of patients who asked about a drug reported that their physician “welcomed the question.”²⁶

An FDA survey polled 500 physicians and found that 73% believed DTC ads help patients ask thoughtful questions, and 53% of physicians considered the number one benefit of DTC ads to be the better discussions they had with their patients about their health. The overwhelming majority of physicians (91%) said the patient did not try to influence the course of treatment in a way that would have been harmful.²⁷

Many doctors find that, overall, DTC advertising benefits patients and helps strengthen the patient/physician relationship. Research published in 2004 in *Health Affairs* reported that 70% of surveyed doctors reported that ads help educate patients about available treatments. Sixty-seven percent felt that the advertisements helped them have better discussions with their patients.²⁸

Another physician survey published in 2006 in the *Journal of the National Medical Association* echoed these findings, reporting that 66% of African American physicians surveyed attested

According to an FDA survey of patients, over 90% of patients who asked about a drug reported that their physician “welcomed the question.”²⁶

– FDA Survey, 2004

to the positive benefit that advertisements for prescription drugs have on patients. The survey revealed several clear trends: “African American physicians see DTC advertising as providing substantial educational benefits; physicians believe that DTC advertising helps rather than hurts the doctor-patient relationship; and African American physicians see the benefits of DTC advertising outweighing its drawbacks.”²⁹

²⁶ K. Aikin, J.L. Swasy, A.C. Braman, “Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results, Final Report,” (Washington, DC: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 19 November 2004) http://www.fda.gov/cder/ddmac/Final%20Report/FRfi_nal111904.pdf (accessed 30 October 2007).

²⁷ *Ibid.*

²⁸ J. S. Weissman et al., “Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising,” *Health Affairs Web Exclusive*, 28 April 2004, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.219v1> (accessed 25 March 2008).

²⁹ Albert Morris et al., “For the Good of the Patient, Survey of the Physicians of the National Medical Association Regarding Perceptions of DTC Advertising, Part II, 2006” *Journal of the National Medical Association* 99, no. 3 (March 2007), <http://www.nmanet.org/images/uploads/Publications/OC0287.pdf> (accessed 25 March 2008).

UNDERDIAGNOSIS & UNDERTREATMENT

Studies report significant underdiagnosis and undertreatment of serious conditions that affect millions of Americans. While these conditions, such as diabetes and cardiovascular disease, can often be treated effectively, left untreated they generate poor health outcomes and high health costs for avoidable hospitalizations. Pharmaceutical marketing and promotion help address this problem by raising awareness of disease symptoms and treatments and prompting patients to see their doctor.

Getting patients into needed therapy is one of the most important roles of DTC advertising. By helping to reduce underdiagnosis and undertreatment, DTC ads benefit patients and the health care system.

For the majority of diseases, research shows that underdiagnosis and undertreatment are common.³⁰ A landmark 2003 study conducted by RAND Health found that U.S. patients fail to receive about half of all recommended health care. The study found that medicines are underused in numerous situations for many conditions. Notably, for quality standards related to medication, patients on average failed to receive recommended care 30% of the time.³¹ Another RAND study assessed quality problems in the delivery of pharmacotherapy and identified 50% of all problems as underuse of needed medicines while overuse accounted for 3% of problems.³²

Pharmaceutical marketing and promotion help address underuse by encouraging patients to talk to their doctors about conditions that may otherwise have gone undiagnosed or untreated. In fact, one survey found that 56 million Americans in 2006 had conversations with their doctors after seeing a DTC ad.³³

A survey by Harvard University/Massachusetts General Hospital and Harris Interactive found that one-quarter of adult patients who visited their physician after seeing a DTC ad received a new diagnosis.³⁴ Some of the most common new diagnoses—high cholesterol, hypertension, diabetes, and depression—are often underdiagnosed and undertreated in the general population [See Chart 3].

The Harvard study also showed that even after patients leave the office, the benefits persist: 46% of physicians felt that DTC advertising increased patients' compliance with prescribed treatment.³⁵ This is an important benefit

³⁰ See for example, J.D. Kleinke, "Access Versus Excess: Value-Based Cost Sharing for Prescription Drugs," *Health Affairs* 23, no. 1 (January/February 2004): 34-47.

³¹ E. A. McGlynn et al., "The Quality of Health Care Delivered to Adults in the United States," *The New England Journal of Medicine* 348, no.26 (26 June 2003): 2635-2645.

³² T.P. Higashi, G. Shekelle et al., "The quality of pharmacologic care for vulnerable older patients." *Annals of Internal Medicine* 140, no. 9 (4 May 2004): 714-20.

³³ Prevention Magazine, *The National Survey on Consumer Reaction to DTC Advertising of Prescription Medicines*, 2007.

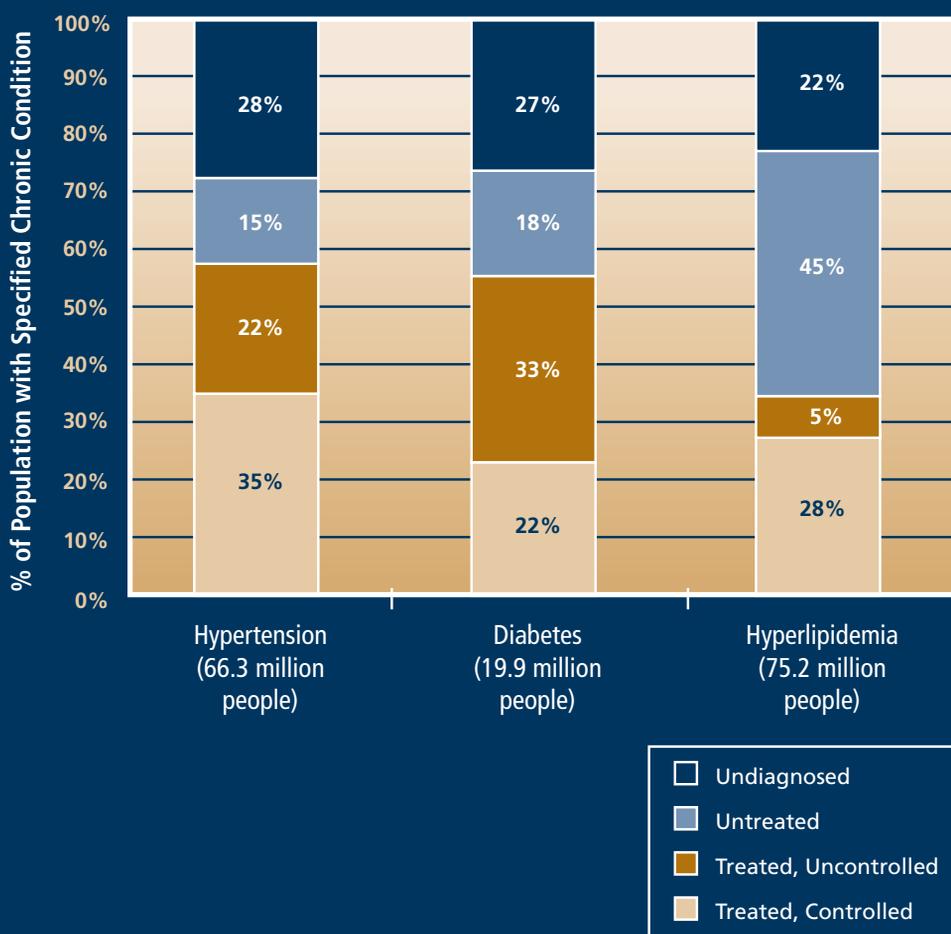
³⁴ J. S. Weissman et al., "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs Web Exclusive*, 28 April 2004, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.219v1> (accessed 25 March 2008).

³⁵ *Ibid.*

*R*AND Researchers examining over 100 quality indicators found “greater problems with underuse than overuse.”³⁶

– Elizabeth McGlynn, Ph.D., M.P.P., et al., *New England Journal of Medicine*

CHART 3: Millions of Americans Undiagnosed and Untreated



Source: PhRMA tabulation of 2004 National Health and Nutrition Examination Survey, November 2007.

³⁶ E. A. McGlynn et al., “The Quality of Health Care Delivered to Adults in the United States,” *The New England Journal of Medicine* 348, no.26 (26 June 2003): 2635-2645.

UNDERDIAGNOSIS & UNDERTREATMENT Continued

because when patients fail to take needed medicines as prescribed by their physicians, the result is worse health outcomes and higher hospital and nursing home costs; in fact, nonadherence has been estimated to cost the U.S. \$100–300 billion annually in avoidable health spending and lost productivity.³⁷

An article in the *New England Journal of Medicine* found that DTC advertising is concentrated among a few therapeutic categories. These are therapeutic categories encompassing chronic diseases with many undiagnosed sufferers, such as high cholesterol, osteoporosis, and depression, or therapeutic areas in which consumers can often recognize their own symptoms, such as arthritis and seasonal allergies.

Patients with one or more chronic diseases currently account for 85% of health care spending.³⁸ Early and consistent treatment is key to controlling this expense. According to a study in the *Journal of the American Board of Family Practice*, patients with chronic disease were more likely to disclose health concerns to their doctors and seek preventive care as a result of seeing DTC advertisements.³⁹

Research shows that addressing the undertreatment gap can have great benefits. A 2007 study in *Health Affairs* examined use of high blood pressure drugs and found that an additional 89,000 lives could be saved and 420,000 hospitalizations avoided annually if all patients with hypertension were treated according to guidelines, on top of the 86,000 lives already saved and 833,000 hospitalizations avoided thanks to these medicines.⁴⁰

In addition to improved outcomes, reducing underuse and increasing adherence to medicines can lead to cost offsets. For example, a 2005 study by MEDCO Health found that every additional dollar spent as a result of improved adherence to medicines to treat diabetes, hypertension, and high cholesterol yields savings of \$4–\$7.⁴¹

Nonadherence has been estimated to cost the U.S. \$100-300 billion annually in avoidable health spending and lost productivity.³⁷

³⁷ H. Shorter, "Noncompliance with medications: An economic tragedy with important implications for health care reform." *Task Force for Compliance Report*, 1993; M.R. DiMatteo, "Variations in Patients' Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research," *Medical Care* 42, no. 3 (March 2004): 200-9.
³⁸ G. Anderson, analysis, prepared for PhRMA, of the Medical Expenditure Panel Survey, 2004.
³⁹ E. Murray et al., "Direct-to-Consumer Advertising: Public Perceptions of Its Effects on Health Behaviors, Health Care, and the Doctor-Patient Relationship," *The Journal of the American Board of Family Practice* 17, no. 1 (February 2004): 6-18.
⁴⁰ D. Cutler, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs* 26, no. 1 (January/February 2007): 97-110.
⁴¹ M.C. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care* 43, no. 6 (June 2005): 521-530.

PATIENT EDUCATION & EMPOWERMENT

DTC advertising creates awareness of diseases and treatment options and empowers patients with information.

A major goal of DTC advertising is to inform and educate consumers about diseases, their symptoms, and available therapies. Research shows that many patients gain valuable information from ads.

In fact, an FDA survey released in 2004 found that in 88% of cases when a patient asked their physician about a medicine as a result of seeing a DTC advertisement, they had the condition that the drug treats.⁴²

According to a 2007 survey conducted by KRC Research for the Advertising Coalition, “advertising for prescription medications makes people better-informed patients by prompting them to seek more information about a disease or drug and helping them recognize that a problem they have can be treated.” The research found that one in four consumers—or 59 million Americans—sought more information after seeing an ad for a medication and four in five consumers agree that advertising for prescription medications can educate people about health conditions and treatment options.⁴³

This point was echoed in *Prevention Magazine’s* 2007 survey, which found that over 70% of people agree that DTC advertisements

key fact

“In 88% of cases when a patient asks their physician about a medicine as a result of seeing a DTC advertisement, they have the condition that the drug treats.”⁴²

– *FDA Physician Survey, 2004*

“allow people to be more involved with their healthcare” and “tell people about new treatments.”⁴⁴

The survey also showed that DTC provides patients with information about the risks as well as benefits of medicines. Eighty percent of patients who see medicines advertised on television are aware of the risk information presented. Half say that they pay “a lot of attention” to the risk information. About 66% are aware of the benefits of the drug, and nearly a third report paying particular attention to this information.⁴⁵

⁴² K. Aikin, J.L. Swasy, A.C. Braman, “Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results, Final Report,” (Washington, DC: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 19 November 2004) <http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf> (accessed 30 October 2007).

⁴³ KRC Research, “Survey Finds that Advertising for Prescription Medication Helps Patients Understand and Seek Treatments,” Press Release, 11 April 2007, http://www.krcresearch.com/images/tac_survey_apr2007.pdf.

⁴⁴ Prevention Magazine, *The National Survey on Consumer Reaction to DTC Advertising of Prescription Medicines*, 2007.

⁴⁵ *Ibid.*

DTC & PRESCRIBING PATTERNS

A majority of physicians report not feeling pressure to prescribe requested medications. In fact, many physicians recommend lifestyle changes and other treatments when patients request a specific medicine.

While there is a perception that DTC advertising leads to inappropriate prescribing, research indicates that doctors are not likely to prescribe a drug simply because it was requested.

A 2006 Government Accountability Office (GAO) report found that only 2–7% of consumers who saw a DTC advertisement requested and ultimately received a prescription for the advertised drug.⁴⁶

Furthermore, patients who ask about a prescription medicine as a result of seeing a DTC ad often receive other recommendations from their doctor, indicating the independent professional judgment regularly exercised by physicians. According to a 2006 *Prevention Magazine* survey, 77% of patients who talked to their doctor as a result of a DTC ad say their doctor talked to them about health and lifestyle changes; 55% say their doctor talked to them about a generic prescription alternative; and 51% talked about a non-prescription option, such as an over-the-counter product.⁴⁷

It is clear that DTC does not determine prescribing patterns; the U.S. has one of the developed world's highest generic use rates, at 67% of all prescriptions,⁴⁸ even though DTC advertising is absent from most other markets. Moreover, the rate of generic medicine use has continued to rise in recent years, since the advent of DTC in the United States [See Chart 2 on p. 4].

Other factors, such as benefit design and payers' utilization management techniques, contribute to the high generic use rate. In fact, a 2002 study on the effect of DTC advertising on demand for pharmaceuticals revealed that DTC advertising may increase demand for a particular brand drug, but only if it has a favorable status on the insurer's formulary.⁴⁹

A November 2006 Kaiser Family Foundation survey found that physicians are likely to recommend other options besides a requested medicine [See Chart 4]. When asked about a specific medicine by a patient, 50% of doctors report that they frequently recommend lifestyle or behavior changes, while some recommend over-the-counter options (18%), a different prescription (14%), or no treatment (14%). Just 5% say they often give the patient a prescription for the medicine requested.⁵⁰

A 2006 Government Accountability Office (GAO) report found that 2-7% of consumers who saw DTC advertising requested and ultimately received a prescription for the advertised drug.⁴⁶

⁴⁶ United States Government Accountability Office, *Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, (Washington, DC: GAO, November 2006).

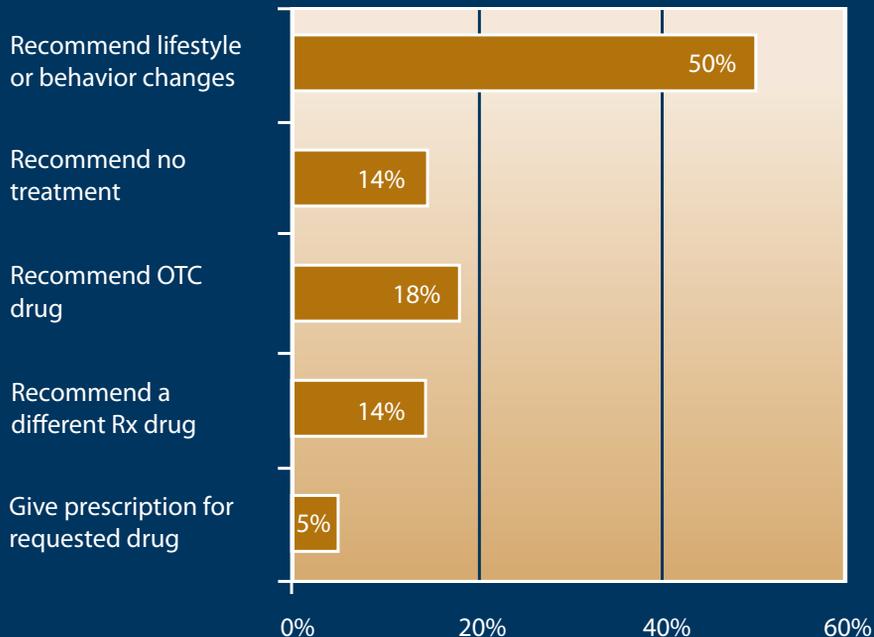
⁴⁷ *Prevention Magazine, Annual Survey, 2006.*

⁴⁸ Pharmaceutical Research and Manufacturers of America, *Analysis of National Prescription Audit™ data from IMS Health*, data through 3rd Quarter of 2007.

⁴⁹ M. Wosinska, "Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products," *HBS Marketing Research Paper No. 02-04*, (October 2002), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=347005.

⁵⁰ Kaiser Family Foundation, *National Survey of Physicians, Toplines*, November 2006, <http://www.kff.org/kaiserpolls/upload/7584.pdf> (accessed 10 December 2007).

CHART 4: When asked by a patient about a specific treatment, physicians frequently...



Source: Kaiser Family Foundation, "National Survey of Physicians, Toplines", November 2006, <http://www.kff.org/kaiserpolls/upload/7584.pdf> (Accessed 10 December 2007).

An FDA survey of physicians released in 2004 showed that the vast majority of physicians do not feel pressured to prescribe prescription drugs when requested by their patients as a result of seeing a DTC ad. Seventy-eight percent of primary care physicians, when asked for a prescription for a specific brand name drug, felt little or no pressure to prescribe a medicine.⁵¹

According to *Prevention Magazine's* 2007 survey, 56 million Americans talked with a doctor about a specific medicine that was advertised. Between 2002 and 2006, among those who discussed a specific medicine that was advertised with their doctor, 73% just talked about the medicine, while only 25% asked the doctor to prescribe the medicine. Fewer than half of these patients received a prescription for the advertised drug.⁵²

Finally, medication may not be the most appropriate treatment for a given patient—diet, exercise, and prevention are important components of Americans' health and wellness.

To help ensure that patients are provided with this type of information, the PhRMA DTC Principles state that, "DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition." The DTC Principles also encourage companies to promote health and disease awareness as part of their DTC advertising. For more on the DTC Principles see page 19 ["Government and Industry Regulation" section].⁵³

⁵¹ K. Aikin, J.L. Swasy, A.C. Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results, Final Report," (Washington, DC: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 19 November 2004) <http://www.fda.gov/cder/ddmac/Final%20Report/FRfi%20nal111904.pdf> (accessed 30 October 2007).

⁵² Prevention Magazine, *The National Survey on Consumer Reaction to DTC Advertising of Prescription Medicines*, 2007.

⁵³ Pharmaceutical Research and Manufacturers of America, *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines* (Washington, DC: PhRMA, 2005).

DTC ADVERTISING & DRUG PRICES / SPENDING

Government agencies and independent experts report no direct relationship between drug marketing and drug prices.

It is commonly claimed that advertising results in higher prices, but experts agree there is no direct relationship between marketing and the price of medicines. According to Emory University professor Paul Rubin, Ph.D., "Economic theory suggests there is no predictable link between advertising for a product and the price of that product. Advertising sometimes can result in higher prices, sometimes in lower prices." Based on an analysis comparing 33 drugs that were advertised directly to consumers and 43 that were not, Professor Rubin concluded that "there was no link between advertising and price changes."⁵⁴

Comments from the Federal Trade Commission (FTC) to the FDA in December 2003 also suggest that advertising does not increase prescription drug prices, stating that, "[DTC advertising] can 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 their treatment options...Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices."⁵⁵

Researchers at Villanova University studied the relationship between DTC advertising and the price of drugs in five major therapeutic classes and concluded that "price is not found to increase as a direct result of DTC advertising. DTC advertising increases consumer awareness of treatment options available in the pharmaceutical industry without diminishing competition."⁵⁶

Another analysis examined National Institute for Health Care Management (an association of health insurers) data from 2001 and found that a comparison of drugs based on DTC expenditures shows no significant relationship with increases in cost per prescription.⁵⁷

key fact

"It is very unlikely that [DTC advertising] is a major factor in either the size or rate of growth of pharmaceutical spending."⁵⁸

– John E. Calfee

⁵⁴ P.H. Rubin, "The Economics and Impact of Pharmaceutical Promotion," *Economic Realities in Health Care Policy* 3, no. 1 (December 2003): 6-17.

⁵⁵ 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. 2003N-0344), (Washington, DC: FTC, 1 December 2003).

⁵⁶ M.L. Capella et al., "Does DTC Advertising Raise Price? The Impact of Pharmaceutical Advertising on Consumers' Price Sensitivity," working paper, http://www.brandweeknrx.com/files/dtc_drug_advertising_and_drug_prices_study.pdf, (accessed 18 October 2007).

⁵⁷ L. R. Manning and A. Keith (2001), "The Economics of Direct-to-Consumer Advertising of Prescription Drugs," *Economic Realities in Health Care* 2, no. 1 (2001): 3-9.

⁵⁸ JE Calfee, "An Assessment of Direct-to-Consumer Advertising of Prescription Drugs," *Clinical Pharmacology & Therapeutics*, Vol. 82, No. 4, (October 2007): 357-360.

“[DTC advertising] can 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 their treatment options... Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices.”⁶⁴

– Federal Trade Commission, 2003

Promotion also is not a major cause of increased spending on health care overall or on medicines. Medicines account for about 10 cents of every health care dollar spent in 2006, according to recent data from the Centers for Medicare & Medicaid Services (CMS).⁵⁹ Prescription medicine spending increases have decelerated by more than half in recent years, from 18.2% in 1999 to 5.8% in 2005, and to 8.5% in 2006. Spending growth in 2006 was the second lowest level since 1995, despite the fact that millions of seniors and disabled persons

gained comprehensive prescription drug coverage for the first time in 2006 through Medicare Part D. According to CMS, growth in drug spending in 2006 “was influenced primarily by increased use and other nonprice factors that outweighed relatively stable drug price growth.”⁶⁰ A recent release from IMS Health projects that going forward pharmaceutical sales growth will be between 3% and 6% through 2012.⁶¹

A 2003 study by the Kaiser Family Foundation found that just 12% of spending increases on medicines’ small share of health costs result from DTC advertising. The other 88% is a result of other factors such as new products, increased use of existing products, lower treatment thresholds, the aging population, and price changes. Since DTC advertising gets patients into treatment for previously undiagnosed and untreated conditions, this 12% share of the increase is not surprising.⁶²

Increased use of medicines is a long-term trend—a PhRMA-supported study by Cerner LifeSciences found that over the last 25 years, clinical practice guidelines have evolved to increase the role of medicines in health care.⁶³ Guidelines have changed to recommend earlier use of medicines and use for extended periods to help prevent and control a range of chronic diseases.

⁵⁹ Centers for Medicare & Medicaid Services, *National Health Expenditures*, 9 January 2007, www.cms.hhs.gov/NationalHealthExpendData; A. Catlin et al., “National Health Spending in 2006: A Year of Change for Prescription Drugs,” *Health Affairs* 27, no. 1 (January/February 2008): 14-29.

⁶⁰ *Ibid.*

⁶¹ IMS Health, “IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion,” Press Release, 12 March 2008, http://www.imshealth.org/ims/portal/front/articleC/0,2777,6599_3665_83470499,00.html (accessed 12 March 2008).

⁶² M.B. Rosenthal et al., *Demand Effects of Recent Changes in Prescription Drug Promotion*, Kaiser Family Foundation, June 2003. and N. Masia, Presentation at the FDA DTC Public Hearing, 23 September 2003, www.fda.gov/cder/ddmac/p4masia/P4Masia.ppt (accessed 18 October 2007).

⁶³ R.W. Dubois and B. Dean, “Evolution of Medicines in Clinical Practice Guidelines: Why More People Use More Medicines,” (Washington, DC: PhRMA, 2006).

⁶⁴ 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. 2003N-0344), (Washington, DC: FTC, 1 December 2003).

SPENDING ON PROMOTION AND R&D

Pharmaceutical companies are very research intensive and spend significantly more on research and development than on marketing and promotion.

The pharmaceutical industry is research-driven. According to the Congressional Budget Office, “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.”⁶⁵

In 2006, the research-based pharmaceutical industry spent \$56.1 billion on R&D⁶⁶—significantly more than all combined drug promotional activities reported for 2006, which totaled \$12.0 billion (the most recent data

available) by IMS Health.^{67,68} PhRMA member companies alone spent \$43.4 billion on R&D⁶⁹—again, considerably more than was spent on all promotional activities, which include DTC advertising, office and hospital promotion (often referred to as “detailing”), and journal advertising.

Claims about the amount of spending on marketing often *incorrectly* categorize all selling, general, and administrative expenses (marketing and non-marketing costs) in estimates of “marketing costs,” producing an overstatement of marketing costs. According to Princeton professor Uwe Reinhardt, “...the [selling, general, and administrative] 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.”⁷⁰

Furthermore, the entire industry’s DTC advertising accounts for \$4.8 billion of total promotion. This represents DTC advertising in media such as magazines and television.

The remaining \$7.2 billion expended on marketing and promotion in 2006 was spent on office promotion, hospital promotion, and journal advertising.⁷¹ This includes all direct costs of marketing such as sales representatives’ salaries and training.

key fact

“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.”⁶⁵

– *Congressional Budget Office, 2006*

⁶⁵ Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, (Washington, DC: CBO, October 2006).

⁶⁶ Burrill & Company, *Analysis for PhRMA*, 2008, Includes PhRMA research associates and nonmembers; Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA 2008).

⁶⁷ IMS Health, *Integrated Promotional Services™ and CMR*, July 2007.

⁶⁸ Total Promotion refers to IMS Health data defined as: DTC, Retail Value of Samples, Office & Hospital Promotion (Sales Rep Contacts), and Journal Advertising. IMS did not publish 2006 data for Retail Value of Samples.

⁶⁹ Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 2007).

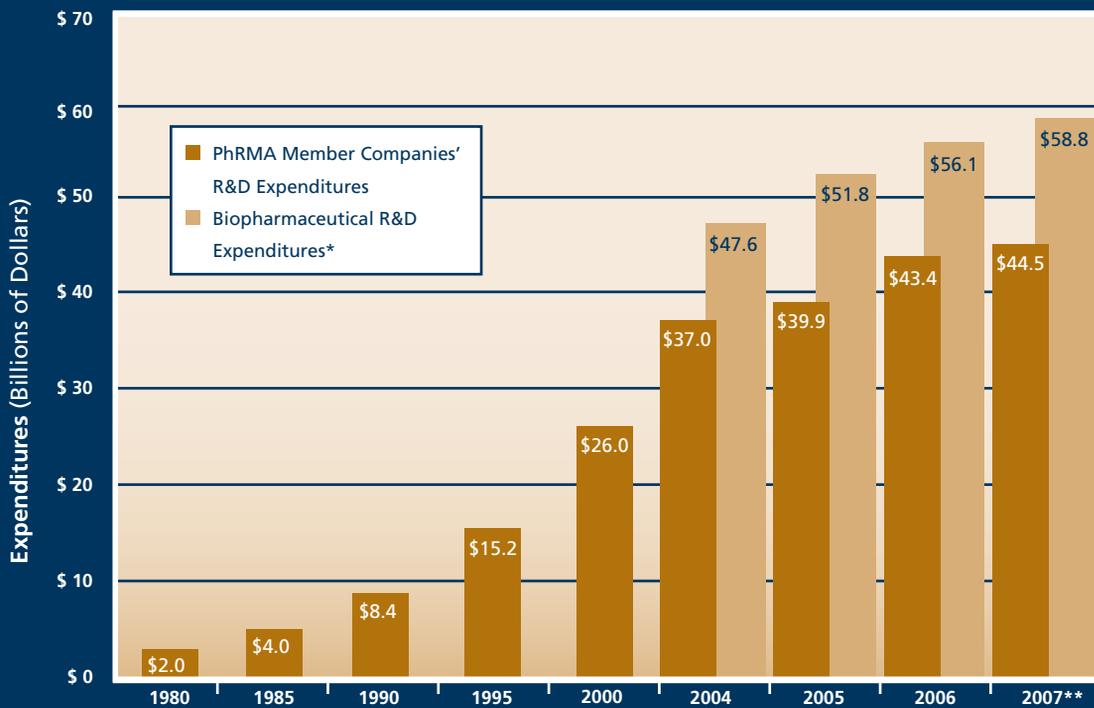
⁷⁰ U.E. Reinhardt, “Perspectives on the Pharmaceutical Industry,” *Health Affairs* 20, no. 5 (September/October 2001): 136-149.

⁷¹ IMS Health, *Integrated Promotional Services™ and CMR*, July 2007.

“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 would attract less capital for R&D or would have fewer internally generated funds to invest.”⁷²

– Joe Newhouse, Ph.D., Economist, Harvard University

CHART 5: Pharmaceutical Research Companies’ R&D Spending



Sources: Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2008; and Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2008).

*The “Biopharmaceutical R&D” figures include PhRMA research associates and nonmembers; these are not included in “PhRMA Member Companies’ R&D Expenditures.” PhRMA first reported this data in 2004.

**Estimated.

⁷² J.P. Newhouse, “How Much Should Medicare Pay for Drugs?” *Health Affairs* 23, no. 1 (January/February 2004): 89-102.

GOVERNMENT & INDUSTRY REGULATION

Pharmaceutical marketing is closely regulated by the U.S. Food and Drug Administration (FDA) to help assure that promotional materials are accurate, fairly balanced, and limited to information that has been approved by the FDA. Many pharmaceutical companies have also adopted voluntary pharmaceutical industry guidelines that lay out standards for interactions with health care providers and appropriate DTC marketing.

Federal law strictly regulates promotional activities by pharmaceutical companies. Under the Federal Food, Drug, and Cosmetic Act, promotional materials must present accurate information and fairly represent both the benefits and the risks of the drugs promoted. Pharmaceutical representatives are also held to strict state and federal regulations that govern their interactions with health care professionals.

Prescription drug advertising is regulated primarily by the FDA. In contrast, advertising for virtually all other consumer products is regulated only by the Federal Trade Commission (FTC). While the FTC helps to assure that advertising is truthful and not misleading, FDA regulations on prescription drug advertising go much further. In fact, the regulations specify, among other things, that prescription drug ads cannot omit material facts, including risk information, and the materials must present a “fair balance” between benefit and risk information.

Further, for print ads, the regulations specify that significant risks addressed in the product’s FDA-approved labeling must be discussed in the brief summary. For broadcast ads, the regulations require that ads disclose the most significant risks that appear in the labeling. They are also

required to contain a brief summary of “all necessary information related to side effects and contraindications” or make adequate provision for dissemination of the product’s FDA-approved labeling (and the risk information it contains) in connection with the ads. Of course, all of this is vastly different than advertising for all other products, which rarely mention risks or side effects associated with the product’s use.

The FDA’s Division of Drug Marketing and Communication (DDMAC) is responsible for prescription drug advertising oversight to help assure that ads are in compliance with the FDA’s rules and regulations. Although pharmaceutical manufacturers are not required by law to submit their broadcast advertisements to DDMAC for prior review, many voluntarily do so.⁷³ In fact, PhRMA’s *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines* (“PhRMA DTC Principles”) recommends that companies submit all television ads to the FDA before airing. If an advertisement is in violation of regulations, the FDA can prevent it from running or require that the violating promotion be stopped immediately. It can also require a remedial campaign to correct any misimpressions that may have been left by an advertisement.⁷⁴

⁷³ N.M. Ostrove, *op. cit.*

⁷⁴ *Ibid.*

DDMAC also monitors prescription drug promotion to physicians in many venues, including audio conferences for physicians, pamphlets distributed at professional meetings, conversations between industry representatives and physicians at professional meetings, mailings to health care professionals, advertisements in professional journals, and the like. In addition to the drug advertising oversight by the FDA, two voluntary PhRMA Principles provide guidelines for marketing and promotion:

The newly revised **Code on Interactions with Health Care Professionals**, which is described in detail on page 7 [“Gifts” to Health Care Providers section], provides guidelines for interactions with health care professionals, which should be aimed at relaying medical information for the benefit of patients.⁷⁵

The revised Code incorporates several significant changes, including the prohibition of distributing non-educational items including pens, mugs, and other “reminder” objects with a company name or logo to health care professionals and their staff. The newly revised Code also forbids company sales representatives from taking health care professionals to a restaurant for a meal, although they may provide occasional modest meals in a health care professional’s office or hospital in connection with informational presentations. Companies must also train all representatives who visit health care professionals about relevant laws, regulations, and industry codes of practice that govern interactions with health care professionals. Representatives are to be assessed periodically to ensure compliance

with relevant laws and standards of conduct with appropriate action to be taken in response to misconduct.

The 2005 **Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines** offer guidelines for enhancing the educational value of DTC advertisements.⁷⁶ To address common criticisms of DTC ads these guiding principles recommend that:

- Risks and safety information in DTC ads should be presented in clear, understandable language.
- DTC ads should be submitted to the FDA before releasing the ads for broadcast, although current law does not require this.
- DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.
- Companies are encouraged to include information about programs to help the uninsured patients in DTC ads.
- Ads should not air until a reasonable amount of time has elapsed so that health care providers have sufficient time to learn about the new medicine.
- DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved.

Following implementation of the guidelines, many noticed improvements in the advertisements. For example, a January 2006 story in *Advertising Age* reported, “...Are they compliant? So far, so good... Where pharma stood out was in complying with the more important aspects of the guidelines that dealt with communicating risk benefits...”⁷⁷

⁷⁵ Pharmaceutical Research and Manufacturers of America, *PhRMA Code on Interactions with Healthcare Professionals* (Washington, DC: PhRMA, 2008).

⁷⁶ Pharmaceutical Research and Manufacturers of America, *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines* (Washington, DC: PhRMA, 2005).

⁷⁷ R. Thomaselli, “Big Pharma keeps its New Year’s resolution; Ads mostly comply with guidelines,” *Advertising Age* (9 January 2006).

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