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BEFORE THE

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On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to appear at this hearing today on direct-to-consumer (DTC) advertising. I am Marjorie Powell, Senior Assistant General Counsel at PhRMA.

The first print advertising of prescription medicines designed to reach consumers started in the early 1980's. From the 1980's until the mid-1990's, most pharmaceutical advertising was confined to print – newspapers and magazines. In 1997, the Food and Drug Administration (FDA) issued a draft guidance that made possible electronic or broadcast advertising of prescription medicines. This draft guidance was finalized in 1999.¹

DTC advertising refers to information provided by pharmaceutical manufacturers to consumers, with the content of such information subject to regulation by the FDA. DTC advertising's purpose is to inform and educate consumers about treatable conditions, the symptoms that may help them identify the diseases, and available therapies. Research demonstrates that DTC advertising helps educate patients about medical conditions and treatment options, encourages dialogue between patients and physicians, prompts large numbers of Americans to discuss illnesses with their physicians for the first time, and promotes improved compliance with physician-prescribed treatments.

In light of the documented, pervasive patterns of undertreatment of serious medical conditions, such as asthma, depression, high cholesterol, diabetes, and many others, such outreach to patients is desperately needed. The failure to treat many patients—including those who are well insured for prescription drug costs—early in the course of disease leads to much avoidable suffering, higher health care costs, avoidable hospitalizations, and lost productivity for workers and employers. Notably, the critics of DTC advertising, such as some payers, discuss the human and economic costs of undertreatment addressed by DTC advertising.

DTC advertising also helps counterbalance other aspects of our health care system. Critics of DTC advertising, such as Blue Cross Blue Shield managed care companies, complain about the information provided to patients through DTC advertising, but do not highlight the fact that they routinely use a

wide array of powerful tools to affect which medicines patients will receive. The power of these tools is illustrated by new research in the journal *Health Affairs*, which reports that nearly one-third of physicians do not discuss treatment options with patients when those options would not be covered by the patient's insurer.² DTC advertising is thus a vital source of information about treatment options that balances the enormous power that corporations hold over patients' health care and the information patients receive about their treatment options.

Despite claims by some critics, there is no evidence that DTC advertising encourages inappropriate prescribing of prescription medicines. Utilization of pharmaceuticals is increasing for several reasons, including changing standards of medical care (evidenced, for example, by treatment guidelines) that emphasize greater use of medicines, the development of new and improved medicines, and treatment of previously untreated or undertreated patients. Notably, these trends are reflected in the growing use of disease management, which is perhaps the leading health care quality improvement and cost containment strategy in today's health system. While disease management programs often produce substantially increased spending on prescription medicines, they also lead to overall health care savings through avoidance of hospitalizations and other costly services and to better health outcomes.

There is no evidence to suggest that DTC advertising affects the price of medicine. To the contrary, studies that have examined this have found that there is no direct relationship between the amount of money spent on DTC advertising and price increases for a prescription drug.

In light of the extensive findings about the benefits of DTC advertising for patients, we believe the time has come to shift the burden in this debate to those who favor policies that would suppress the provision of FDA-regulated information to patients. The data support asking a new set of questions about DTC: How would patients be harmed if they were less likely to report untreated conditions to their physicians? How would patients be harmed if they were less likely to know about new treatment options? How would patients be harmed if they knew less about the risks and side effects of taking medicine? And what is the payers' and other critics' plan for ending the pervasive patterns of undertreatment that cause so much avoidable suffering and cost for patients?

It also is time to recognize that the debate about DTC advertising has been framed by false assumptions. While DTC advertising is pointed to by some critics as driving spending on prescription medicines to unaffordable levels, the fact is that prescription medicines account for just ten cents out of the health care dollar. According to data reported to the National Committee for Quality Assurance (NCQA) by managed care companies themselves, in 2001, HMOs spent an average of just \$32.45 per member per month on prescription medicines (in the commercial sector)—including the combined cost of brand name and generic drugs, and prescription benefit manager and pharmacy services.³ Moreover, this figure includes both what the HMO spent directly and the patient's own out-of-pocket spending on medicines. In light of this modest cost and the fact that underuse of medicines is itself generating large, avoidable

costs, we hope that the Committee will reject the erroneous claims and focus on how we can best get patients information they need to obtain the best possible medical care.

DTC Advertising and the Physician-Patient Relationship

DTC advertising strengthens the patient-physician relationship, by prompting patients to tell their physician about previously undisclosed conditions—communication that is an essential foundation for a good physician-patient relationship—and also by educating patients about the risks as well as benefits of treatment options.

Physicians should and do remain in control of prescribing medicines. Survey data consistently show that when patients ask a physician to prescribe a DTC-advertised medicine, many receive a different medicine or a non-pharmaceutical alternative. Results from the 2002 FDA survey of consumers found that, among the minority of respondents who said advertisements had caused them to talk with a physician and ask for a drug, less than half said their doctor gave them the prescription drug they asked about.⁴

According to *Prevention Magazine's* 2002 survey, 32 percent of consumers, or an estimated 61.1 million people, have talked with their doctor about an advertised prescription medicine. Of those consumers, 29 percent asked their doctors to give them a prescription for the medicine they saw advertised. Sixty percent of consumers who ask about advertised medicines say their doctors have recommended non-drug therapies in response to their questions.⁵

DTC advertising's purpose is to encourage patients to talk to their physicians about their medical conditions and treatment options. In fact, every television advertisement for a prescription must include a message that viewers should ask their physician or pharmacist about the product. Such discussions are beneficial – for the patient in gaining an understanding of the physician's treatment recommendation, and for the physician in gaining a better understanding of the patient's needs. Notably, results from the 2002 FDA consumer survey found that most patients prompted by DTC advertising to discuss a drug with their doctor stated that their doctor welcomed the question (93%), discussed the drug with the patient (86%), and reacted as if the question were an ordinary part of the visit (83%).

The physician-patient relationship is strengthened, not weakened, when, as surveys show, DTC advertising prompts a patient to talk with a physician for the first time about a previously undiscussed condition, improves patient compliance with physician-prescribed treatment regimens, or adds to patient information of medicines' risks and side effects and who should not take a drug. The 2002 *Prevention Magazine* survey found that 24.8 million Americans spoke with their doctor about a medical condition for the first time as a result of seeing a DTC advertisement.

Another survey found that the majority of physician respondents believe that patients' awareness of DTC advertisements had a beneficial effect on office visits. Additional benefits of DTC advertising noted in the survey included:

- 85 percent of physicians treating high cholesterol conditions and 83 percent of physicians treating mood/anxiety disorders report that the drug discussed were appropriate for the patient.
- 54 percent of physicians treating high cholesterol conditions and 55 percent of physicians treating mood/anxiety disorders agree that the advertisement was influential in getting the patient to discuss their condition with a medical professional.
- For both high cholesterol and mood/anxiety disorders, 80 percent or more of physicians were satisfied with the outcome of office visits where advertisements were mentioned.⁶

A survey by the National Medical Association (NMA), the nation's oldest and largest African-American medical association, representing more than 25,000 African-American physicians, found that DTC advertisements raise disease awareness and bolster doctor-patient ties. According to NMA President, Dr. Lucille Perez:

Doctors are finding that these ads are helping our patients talk to us about medical conditions they're at risk for. When you consider that the majority of drugs advertised can treat the diseases that disproportionately affect the African-American community, there is incredible potential. These ads can increase disease awareness that may be a beneficial tool to decrease the rampant disparities in the health of the community. The NMA will advocate for increasing the awareness of the disease states in such advertisements. Further, we must view them as one of several tools that are potentially beneficial to the physician-patient dyad.⁷

DTC Advertising and its Value to Patients

Informing Patients

In addition to encouraging discussion between patients and physicians, surveys indicate that DTC advertising makes consumers aware of new drugs and their benefits, as well as risks and side effects with the drugs advertised. The results from the FDA's 2002 consumer survey indicate:

- 90 percent of consumers surveyed recalled seeing television advertisements that contained information about the "benefits of the drug"
- 90 percent recalled information about "risks or side effects," and

- 89 percent recalled information about “who should not take the drug,” and
- 86 percent recalled “how to get more information.”

A survey by Kaiser Family Foundation confirmed the FDA survey results. The Kaiser survey found that a large majority of those who viewed a DTC advertisement said that the advertisement did an excellent or good job telling them about the condition the medicine is designed to treat (84%), the potential benefits of the medicine (72%), and who should take the drug (66%).⁸

As a *New England Journal of Medicine*⁹ article points out, DTC advertising is concentrated among a few therapeutic categories. These are therapeutic categories in which consumers can recognize their own symptoms, such as arthritis, seasonal allergies, and obesity; or for pharmaceuticals that treat chronic diseases with many undiagnosed sufferers, such as high cholesterol, osteoporosis, and depression; and for pharmaceuticals that enhance quality of life, such as those for skin conditions and hair loss. These advertisements help consumers recognize symptoms and seek appropriate care.

Empowering Patients

DTC advertising empowers consumers and enhances public health. The FDA has stated, “It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe there is a certain public health benefit associated with letting people know what’s available.”¹⁰ A 1999 survey by *Prevention Magazine* found that consumers give high marks to pharmaceutical advertising. Of those surveyed, 76 percent felt DTC advertisements allowed them to become more involved in their own health care. The survey established that, “the benefits of DTC [direct-to-consumer] advertising could go far beyond simply selling prescription medicines: these advertisements play a very real role in enhancing the public health.”¹¹

A study released by the National Health Council, whose constituency includes nearly 50 of the country’s leading patient organizations representing nearly 100 million Americans with chronic diseases and/or disabilities, notes the positive impact DTC advertising can have, “The more information patients have, the more effective they can be in working with their doctor to make decisions about their health care....The Council recognizes that DTC advertising provides important information to consumers and patients, which is beneficial to their health.”¹²

The benefits of advertising have been recognized by other elements of the health care sector who also advertise, including hospitals, doctors and insurers. Pharmaceutical manufacturers are not the only participants in the health care sector who advertises.

Underdiagnosis and Undertreatment of Disease

DTC advertising appears to help address some of the problems related to undertreatment and underdiagnosis of disease. DTC advertising brings patients

into doctors' offices and allows physicians to treat people who might otherwise go undiagnosed or untreated. As stated previously, the 2002 *Prevention Magazine* survey found that 61.1 million Americans since 1997 were prompted by a DTC advertisement to talk to a doctor about a medical condition they previously had not discussed.¹³ According to *DTC Monitor* findings, 28 percent of those who contacted a doctor because of DTC advertising report that it was the first time they talked to their doctor about a condition. In addition, 22 percent reported that the advertising prompted them to talk to a doctor earlier than they would have otherwise.¹⁴

Surveys of DTC advertisements for genital herpes provide compelling results. The Centers for Disease Control (CDC) estimate that 45 million Americans over age 12 carry the virus that causes genital herpes. Yet, only about 4.5 million Americans, or just one in ten, are being treated. Surveys indicate that DTC advertisements have helped increase the number of patients aware of the disease and have increased the number of newly diagnosed patients. For example, 34 percent of physicians surveyed by Scott-Levin stated that they had seen a significant increase in the number of newly diagnosed patients after advertisements for medicines to treat genital herpes began to air.¹⁵ In another survey, 67 percent of consumers who were aware of a genital herpes advertisement felt that the advertisements provided a valuable service in educating the public.¹⁶

According to a new Harvard/Harris survey, DTC advertising led to the diagnosis of a large number of "high priority" conditions. The survey found that, one-quarter of adult patients who visited their physician after seeing a DTC ad received a new diagnosis of a condition. Some of the most common new diagnoses that were discovered as a result of these visits --high cholesterol, hypertension, diabetes, and depression -- are often underdiagnosed and undertreated in the general population. Furthermore, the survey found that approximately 43 percent of new diagnoses and 51 percent of existing diagnoses were for "high priority" conditions according to the Agency for Healthcare Research and Quality (AHRQ) and Institute of Medicine (IOM) criteria.

On June 26, 2003, *The New England Journal of Medicine* published, "The Quality of Health Care Delivered to Adults in the United States." The study, which was conducted by RAND Health, the nation's largest independent health-policy research organization, and funded by The Robert Wood Johnson Foundation, found that nearly half of all adults in the United States fail to receive recommended health care.

According to researchers on the RAND study, "the deficiencies in care...pose serious threats to the health of the American public that could contribute to thousands of preventable deaths in the United States each year." More specifically, the study found that only 45 percent of patients with diabetes received the care they need; only 68 percent of patients with coronary artery disease received recommended care; only 45 percent of heart attack patients received medications that could reduce their risk of death; only 54 percent of

patients with colorectal cancer received recommended care, and less than 65 percent of patients with high blood pressure received recommended care. According to lead study author Elizabeth A. McGlynn, Ph.D., Associate Director of RAND Health, "Even people who had health insurance and access to health care services failed to receive some elements of good care. This suggests that just being able to get in the door to see a doctor is no guarantee that you'll receive the care you need."

For nine of the fifteen conditions that were selected and classified by RAND to determine underuse or overuse of health care services, medicines are the recommended treatment option. Of those nine conditions, underuse of medicines occurred in seven of them. These conditions include: asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, hyperlipidemia, and hypertension. According to the data set used in the RAND study, 83 of the 103 measures of quality for medication treatment or immunization showed undertreatment.

The Rand Study, as well as other recent studies published in *The Journal of American Medicine*¹⁷ (JAMA) and *Health Affairs*,¹⁸ highlight the underuse of needed medications and other healthcare services in the U.S.

- According to a nationally representative study of 9,090 people aged 18 and up published in JAMA, about 43 percent of participants with recent major depression are getting inadequate therapy.
- According to the article in *Health Affairs*, "During the course of a year, 31 percent [of physicians] reported having sometimes not offered their patients useful services because of perceived coverage restrictions. Among these, 35 percent reported doing so more often in the most recent year than they did five years ago."
- In addition, according to data from the NCQA's *Quality Compass*® 2002, there is significant undertreatment of asthma and depression of patients in managed care plans. Data reported in NCQA for people with asthma shows that, for each of three age groups examined, approximately two-thirds of the commercial population with asthma met the standard for use of appropriate medications. These scores are several points higher than observed in earlier years, but the remaining gap (one-third of patients) suggests that initiatives to increase appropriate use of medicines to treat asthma would be highly beneficial.
- In addition, in 2001 NCQA reported that relatively low percentages of the commercial population with depression received care meeting quality standards for antidepressant medication management. In particular, only 40.1 percent of patients with depression "received effective continuation phase treatment by remaining on antidepressant medication continuously in the six months after the initial diagnosis and treatment."

Reasons for underuse cited in the RAND study include availability of information on health care performance at all levels, non-adherence to practice guidelines, and an outdated health information system. The authors of the RAND study recommend “a major overhaul” of the “current health information system, with a focus on automating the entry and retrieval of key data for clinical decision making and for the measurement and reporting of quality” and “establishing a national base line” for performance to “asses the effect of policy changes and to evaluate large-scale national, regional, and state efforts to improve quality.”

De-Stigmatizing Disease

DTC advertising also encourages patients to discuss medical problems that otherwise may not have been discussed because the disease was either thought to be too personal or that there was a stigma attached to it. For example, a *Health Affairs* article examined the value of innovation and noted that depression medications, known as selective serotonin reuptake inhibitors (SSRIs) have led to significant treatment expansion. Pharmaceutical manufacturers of SSRIs have advertised them to consumers. Prior to the 1990's, it was estimated that about half of the persons who met a clinical definition of depression were not appropriately diagnosed, and many of those who were diagnosed did not receive clinically appropriate treatment. However, in the 1990's with the advent of SSRIs, treatment has been expanded. According to the article, “Manufacturers of SSRIs 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 for depression doubled over the 1990's.¹⁹

Encouraging Compliance

Another benefit of DTC advertising is its ability to encourage compliance with physician-prescribed treatment regimens. Lack of compliance is a critical problem in achieving effective medical care. According to the 2002 *Prevention Magazine* survey, 17 percent of consumers said DTC advertising made it more likely (versus 2 percent less likely) they would take their medicine regularly and 12 percent of respondents reported that DTC advertisements made them more likely to refill prescriptions.²⁰

This is particularly important given the estimated costs of non-compliance. According to an article in the *Journal of Research Pharmaceutical Economics*, 5.5 percent of all hospital admissions are due to non-compliance, which results in \$8.5 billion annually in unnecessary hospital expenditures, plus another \$17-\$25 billion in estimated indirect costs.²¹

A June 2001 study by Pfizer and RxRemedy found that the percentage of diabetes, depression, elevated cholesterol, arthritis and allergy patients who remained on therapy after six months was significantly higher when the patient asked for a medicine with prompting from DTC advertising than when the patient was prescribed a medicine without such prompting.²² This suggests the

advantages of consumers being involved with their health care and DTC advertising's role in encouraging such involvement.

What Accounts for Growth of DTC Advertising and Why it Plays a Valuable Role in the Health Care System

Patients are increasingly turning to the growing volume of accessible health care information and thus, are moving us towards a more patient-focused health care system. Given this trend, DTC advertising is widely employed throughout our health care system—managed care organizations, hospitals and doctors all advertise to consumers. Unlike much other health care information, DTC advertising for prescription medicine is subject to intense scrutiny for accuracy and balance by FDA regulators. Every DTC advertisement – in print or electronic form – must:

- Be accurate and comply with the drug's FDA-approved labeling; and
- Contain "fair balance" – that is, an explanation of the risks and effectiveness of the drug.

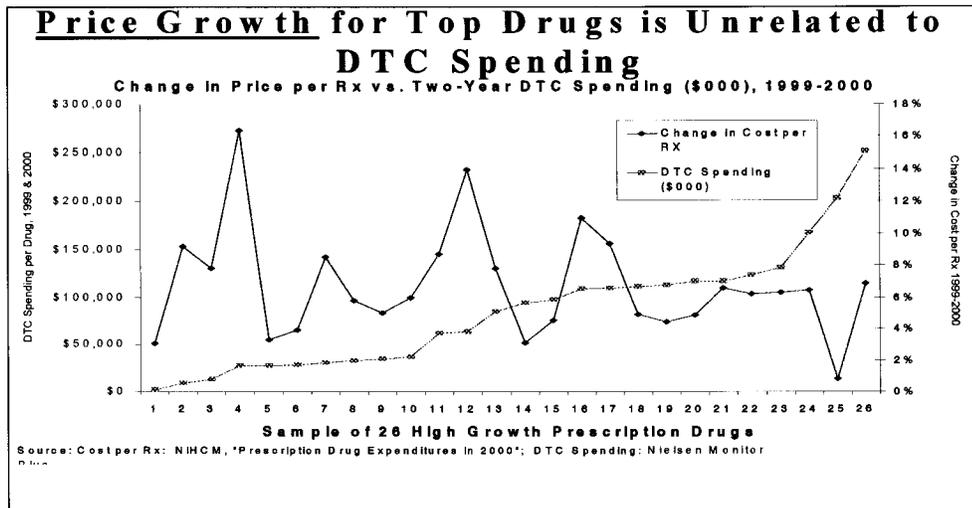
Every print advertisement must include a detailed description of the risks. Every electronic advertisement must include a statement on the major risks and provide additional ways for consumers to obtain more information. Strict FDA requirements help make DTC advertising of prescription drugs reliable and accurate.

Another environmental change that increases the value of DTC advertising of medicines is its ability to balance efforts by other health system participants, such as managed care plans, to influence the delivery of medical care. The strongest tools used by third parties to influence which medications patients receive may include: provider payment incentives that are linked to provider prescribing and dispensing patterns; formularies, which typically are structured in part based on the managed care plan's financial considerations; variable patient cost-sharing arrangements, again based in part on financial considerations; therapeutic interchange; and prior authorization. In light of these strategies designed to influence the medicines that patients receive, patients' ability to obtain information about their treatment options through DTC advertising is a healthy development that helps add balance to the system. With so many parties, including those critical of DTC advertising, using such care-limiting incentives yet encouraging patients to assume increased responsibility for their medical care, it is surprising that conveying FDA-regulated information to consumers has engendered controversy.

Increased Pharmaceutical Utilization and the Role of DTC Advertising

Payers' have questioned the effect of DTC advertising on prescription drug prices. However, the evidence shows there is no direct relationship between DTC advertising and the price growth of drugs.²³ For example, one

popular osteoarthritis drug had the highest DTC advertising spend of any brand-name medicine in 2000. Yet, the price increase from 1999 to 2000 was 3.9%, less than half a percent above the consumer price index (CPI). A common mood and anxiety disorder drug had no DTC advertising spending in 2000, but the price increase was roughly equal (3.1%) to the price increase for the most heavily advertised osteoarthritis drug. Neither price increase was out of line with CPI.²⁴



It is also important to remember that spending on pharmaceuticals remains a small portion of the health care dollar. Of every health care dollar spent in the U.S., only about 10 cents is spent on prescription medicines. While drug spending continues to grow, it remains a very small share of national spending.

DTC advertising may affect utilization, by prompting treatment of more patients for previously untreated conditions and improved compliance. If so, this is a positive development. Proper use of pharmaceuticals is often the most effective and least expensive form of health care. Notably, the FDA testified in July 2001 that “there is no evidence that [DTC advertising] is increasing inappropriate prescribing.”²⁵

According to a 2002 study on cholesterol-lowering statins, which are DTC-advertised, there is “no statistically significant effect from any form of advertising and promotion on new statin prescriptions or renewals and no evidence of adverse market effects from advertising...”²⁶ These findings are supported by another recent study that looked at whether pharmaceutical marketing has led to an increase in use of medications by patients with marginal indications. The study found that high-risk individuals were receiving lipid-lowering treatment “consistent with evidence-based practice guidelines” despite the fact that “a substantial portion of patients continue to remain untreated and undertreated...”²⁷ The study concluded that “greater overall use did not appear to be associated with a shift towards patients with less CV [cardiovascular] risk.” As Jack Calfee,

American Enterprise Institute, has observed, "On the whole, increases in drug utilization seem to be driven primarily by the fact that health care organizations, physicians, and patients find many of the newer drugs to be extremely valuable. In fact, there is strong evidence that many of the most effective drugs are underused, rather than overused...."²⁸

There are a multitude of reasons why pharmaceutical utilization is increasing other than DTC advertising. In fact, according to a June 2003 study of DTC advertising commissioned by the Kaiser Family Foundation and conducted by researchers at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School, "[O]ur estimates indicate that DTCA is important, but not the primary driver of recent growth [in prescription drug spending]."²⁹ Other reasons pharmaceutical utilization is increasing, include:

- Development of Improved Medicines
- New Standards of Medical Practice Encouraging Greater Use of Pharmaceuticals
- Treatment of Previously Untreated Conditions
- Greater Attention to Preventing and Managing Disease
- Structural Shift to Prescription Drugs
- Aging of Population

1. **Improved Medicines.** The development of new and improved medicines accounts for much of the increase in prescription drug spending. For example, new medicines for serious mental illnesses are revolutionizing treatment. According to a study prepared for the Department of Health and Human Services, "[n]ew medications are not simply more costly than older ones. They may be more effective or have fewer side effects; some may treat conditions for which no treatment was available."³⁰

2. **New Standards of Medical Practice Encouraging Greater Use of Pharmaceuticals.** According to guidelines set forth by an advisory group to the National Heart, Lung and Blood Institute in May 2001, 36 million Americans should be taking cholesterol-reducing drugs.³¹ However, because high cholesterol does not cause obvious symptoms and detection requires a blood test, as few as 42 percent of those affected by it have been diagnosed.³² According to the Institute's Director, if the recommendations were followed, heart disease would no longer be the leading cause of death.³³ In another example, medical standards for diagnosing, treating, and monitoring diabetes have changed significantly. In the late 1990s, the level of fasting blood glucose used for diagnosing diabetes was lowered from 140 mg/dl to 126 mg/dl because studies showed that patients with the higher fasting blood sugar levels were already developing the complications of diabetes when they were diagnosed.³⁴ Diagnosing patients earlier and providing them with

appropriate medications can help regulate blood sugar levels and prevent or delay these complications.

3. **Treatment of Previously Untreated Patients.** The number of Americans treated for depression has grown from 1.7 million to 6.3 million over the last decade. A primary reason was the broadening of pharmaceutical options available to treat depression, including a new class of antidepressants that tend to have fewer side effects.³⁵ These new medications have lowered the total cost of treating depression at the same time they have made treatment more effective – accounting for much of the decline in health insurers' spending on mental health. While pharmaceutical treatments have advanced, the price of treating acute major depression fell by 25 percent over 1991-95.³⁶ This reflects, among other things, increasing the pharmaceutical component and reducing the intensity of psychotherapy.
4. **Greater Attention to Preventing and Managing Disease.** Increased emphasis on diagnostic and screening programs, which increase the odds of identifying conditions that might otherwise go undiagnosed until an illness becomes acute, often means greater drug use. For example, the number of Americans diagnosed with diabetes jumped 49% from 1990 to 2000.³⁷ Likewise, disease-management – a strategy embraced by many health plans – often involves greater use of medicines. In a year-long disease-management program for about 1,100 patients with congestive heart failure run by Humana Hospitals, pharmacy costs increased by 60 percent, but a 78 percent drop in hospital costs produced \$9.3 million in net savings.³⁸
5. **Structural Shift to Prescription Drugs.** In a *Health Affairs* article, J.D. Kleinke explained that a shift from traditional medical services to consumption of medical products is taking place. Kleinke noted that the clearest example of this is a decade-long reduction in hospital admissions and lengths of stay.³⁹
6. **The Aging of America.** The aging of America translates into greater reliance on pharmaceuticals to restore and/or maintain health. For example, congestive heart failure affects an estimated 2 percent of Americans age 40 to 59, more than 5 percent of those aged 60 to 69, and 10 percent of those 70 or more.⁴⁰

Economic Value of DTC Advertising

Increased spending on pharmaceuticals often leads to lower spending on other forms of more costly health care. New drugs are the most heavily advertised drugs, a point critics often emphasize. However, the use of newer drugs tends to lower all types 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 \$111.⁴¹

The Tufts Center for the Study of Drug Development reports that disease management organizations surveyed believe that increased spending on prescription drugs reduces hospital inpatient costs. “Since prescription drugs account for less than 10 percent of total current U.S. health care spending, while inpatient care accounts for 32 percent, the increased use of appropriate pharmaceutical therapies may help moderate or reduce growth in the costliest component of the U.S. health care system,” according to Tufts Center Director Kenneth I. Kaitin.⁴²

How Much Does DTC Advertising Cost

Opponents of DTC advertising often try to compare the amount of money spent by drug companies on marketing and advertising to the amount they spend on research and development of new drugs.

IMS Health reports that \$21 billion was spent in 2002 on all pharmaceutical promotion for all pharmaceutical manufacturers, including non-PhRMA members.⁴³ (This is data that is publicly available.) This includes \$12 billion in free samples and \$2.6 billion on DTC advertising. In comparison, PhRMA members spent an estimated \$32 billion in R&D in 2002.⁴⁴ ***In fact, IMS is the data source the General Accounting Office (GAO)⁴⁵ used in its recent report in which it reported that pharmaceutical manufacturers spend significantly more on R&D than on all promotional activities combined.***

DTC Advertising and Commercial Free Speech

DTC advertising, like all speech that “propose[s] a commercial transaction,” is commercial speech.⁴⁶ Since DTC advertising is a form of commercial free speech it is constitutionally protected by the First Amendment.⁴⁷ The U.S. Supreme Court has defined commercial free speech as “expression related solely to the interests of the speaker and its audience.”⁴⁸ Accordingly, the government is only allowed to challenge such acts or practices that are deceptive, lack proper substantiation, or are unfair.⁴⁹ The term “deceptive” means information that is misleading or omitted for purposes of changing the consumer’s perception.⁵⁰

The FDA’s Division of Drug Marketing and Communication (DDMAC) is in charge of drug advertising oversight to ensure that DTC advertisements for prescription drugs are in compliance with FDA’s rules and regulations determining “fair balance” and “adequate provision” of information about benefits and risks and sources to obtain additional risk and benefit information. Because DTC advertisements are highly regulated, and because companies have an interest in ensuring their ads are accurate and provide fair balance, pharmaceutical companies routinely subject all DTC advertisements and other

promotional material to rigorous medical, regulatory and legal review before they are ever disseminated. Although pharmaceutical manufacturers are not required by law to submit their broadcast advertisements to DDMAC for prior review, a majority of sponsors do voluntarily submit them for DDMAC's review and comment at some point before the materials are finalized.⁵¹ If an advertisement is in violation of FDA rules or regulations, FDA does have remedies. For example, FDA can require that the violative promotion be stopped immediately. It can also require that the manufacturer conduct a remedial campaign to correct any misimpressions left by the advertisement.⁵²

Most surveys of patients and physicians have demonstrated that DTC advertisements are an effective tool to educate and inform consumers about their health and health care choices. Government cannot impose restrictions on commercial free speech, including DTC advertising, unless warranted by some essential governmental interest. The current FDA regulatory system helps ensure that advertisements abide by the necessary requirements and that they provide reliable and accurate information to consumers.

Conclusion

DTC advertising provides tremendous value to patients by making them aware of risks and benefits of new drugs; it empowers patients and enhances the public health; it plays a vital role in addressing a major problem in this country of undertreatment and underdiagnosis of disease; DTC advertising encourages patients to discuss medical problems with their health care provider that may otherwise not be discussed due to a stigma attached to the disease; and it encourages patient compliance with physician-directed treatment regimens.

Although drug expenditures in recent years have continued to rise, prescription drugs still remain a very small share of total health care spending, constituting only 10 cents out of every health care dollar. To the extent that drug spending is increasing, increased utilization of pharmaceuticals is driving that increase, not price increases. Although DTC advertising may affect utilization, by prompting treatment of more patients for previously untreated conditions and improving patient compliance with physician directed treatment, this is a positive development. Proper use of pharmaceuticals is often the most effective and least expensive form of health care.

DTC advertising clearly is here to stay, and will best realize its potential as physicians "develop strategies for helping their patients evaluate this information and make appropriate and informed treatment choices."⁵³ With such a diversity of treatment options available for acute and chronic diseases, patients need the guidance that only a trusted health professional can provide. The health care system is stronger as a consequence. DTC advertising does not replace that relationship; rather, its purpose is to encourage an informed discussion between patient and physician.

This concludes my written testimony. I would be happy to answer any questions or to supply any additional materials by Members or Committee Staff on this or any other issue.

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- ¹ Food and Drug Administration, Guidance for Industry: Consumer-Directed Broadcast Advertisements, 1999. <www.fda.gov/cder/guidance/index.htm> (7 January 2002).
- ² Wynia M., VanGeest J., Cummins D., and Wilson I., "Do Physicians Not Offer Useful Services Because of Coverage Restriction," *Health Affairs*, Vol. 22, No. 4, July/August 2003.
- ³ Pharmaceutical Research and Manufacturers of America, "How Much Do Managed Care Companies Spend on Prescription Medicines," Spring 2003, available at www.phrma.org. The source for data contained in PhRMA's publication is *Quality Compass*® and is used with the permission of the National Committee for Quality Assurance ("NCQA"). Any analysis, interpretation, or conclusion based on these data is solely that of the authors, and NCQA specifically disclaims any such analysis, interpretation or conclusion. *Quality Compass*® is a registered trademark of NCQA.
- ⁴ Kathryn Aikin, Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results <<http://www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out/KitHMCC2002out.PPT>> (17 July 2003).
- ⁵ 5th Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, Emmaus, PA, Rodale, 2001-2002.
- ⁶ DTC Cholesterol and Mood Anxiety Disorders Doctor Dialogues, Market Measures Interactive, Fielded July 2001. <www.mmi-research.com> (7 January 2002)
- ⁷ "African American Doctors Say DTC Ads Raise Disease Awareness, Bolster Doctor-Patient Ties," Press Release, National Medical Association, April 10, 2002; Sharon D. Allison-Otley, MD, Karen Ruffin, BA, and Kimberly B. Allison, BS, "To Do No Harm," Survey of the Physicians of the National Medical Association Regarding Perceptions on DTC Advertisements, April 10, 2002.
- ⁸ Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising, Kaiser Family Foundation, November 2001.
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