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BEFORE THE

**SENATE SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE**

SEPTEMBER 29, 2005

Mr. Chairman, Ranking Member Kohl and Members of the Committee, 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 Paul Antony, M.D., Chief Medical Officer at PhRMA.

DTC advertising has been proven to be beneficial to American patients. And, continuing regulatory oversight by the FDA helps ensure that the content of DTC advertising informs and educates consumers about medical conditions and treatment options. PhRMA and its member companies have a responsibility to ensure that ads comply with FDA regulations. We take that job seriously. We want to continue to be a valuable contributor to improving public health.

DTC Advertising can be a powerful tool in educating millions of people and improving health. Because of DTC advertising, large numbers of Americans are prompted to discuss illnesses with their doctors for the first time. Because of DTC advertising, patients become more involved in their own health care decisions, and are proactive in their patient - doctor dialogue. Because of DTC advertising, patients are more likely to take their prescribed medicines.

PhRMA's Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines

PhRMA and its member companies have long understood the special relationship we have with the patients that use our innovative medicines. Despite the very positive role DTC advertising plays in educating patients about health issues and options, over the years, we have heard the concerns expressed about DTC advertising – that some ads may oversell benefits and undersell risks; that some ads may lead to inappropriate prescribing; that some patients may not be able to afford the advertised medicines; and that some ads may not be appropriate for some audiences. Some doctors have also complained that drug companies launch advertising campaigns without helping to educate doctors in advance. Although actual practice and data on the effects of DTC advertising

differ from these concerns, PhRMA recognized our obligation to act. On July 29, 2005, PhRMA's Board of Directors unanimously approved *Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines* (see Appendix A). These principles help ensure that DTC advertising remains an important and powerful tool to educate patients while at the same time addressing many of the concerns expressed about DTC advertising over the past few years.

First, PhRMA member companies take their responsibility to fully comply with FDA advertising regulations very seriously. Our advertising is already required to be accurate and not misleading; it can only make claims supported by substantial evidence; it must reflect the balance between risks and benefits; and it must be consistent with FDA-approved labeling. However, patients, health care providers and the general public expect us to do more than just meet our exacting legal obligations, and our Guiding Principles do go further.

Our principles recognize that at the heart of our companies' DTC communications efforts is patient education. This means that DTC communications designed to market a medicine should responsibly educate patients about a medicine, including the conditions for which it may be prescribed. DTC advertising should also foster responsible communications between patients and health care professionals to help the patient achieve better health and a better appreciation of a medicine's known benefits and risks. Specifically, the Principles state that risk and safety information should be designed to achieve a balanced presentation of both risks and benefits associated with the advertised medicines.

Our Guiding Principles recognize that companies should spend appropriate time educating health care professionals about a new medicine before it is advertised to patients. That way, providers will be prepared to discuss the appropriateness of a given medication with a patient.

Current law provides that companies must submit their DTC television advertisements to FDA upon first use for FDA's review at its discretion. Companies that sign onto these Guiding Principles agree to submit all new DTC television ads to the FDA before releasing these ads for broadcast, giving the Agency an opportunity to review consistent with its priorities and resources. Companies also commit to informing FDA of the earliest date the advertisement is set to air. Should new information concerning a previously unknown safety risk be discovered, companies commit to work with FDA to "responsibly alter or discontinue a DTC advertising campaign."

In addition, the Principles encourage companies to include, where feasible, information about help for the uninsured and underinsured in their DTC communications. Our member companies offer a host of programs that can assist needy patients with their medicines.

The Principles also recognize that ads should respect the seriousness of the health condition and medicine being advertised and that ads employing humor or entertainment may not be appropriate in all instances.

As a result of concerns that certain prescription drug ads may not be suitable for all viewing audiences, the Guiding Principles state that, "DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved."

Signatory companies are committed to establishing their own internal processes to ensure compliance with the Guiding Principles and to broadly disseminate them internally and to advertisers. In addition, PhRMA's Board unanimously approved the creation of an office of accountability to ensure the public has an opportunity to comment on companies' compliance with these Principles. The office of accountability will be responsible for receiving comments from the general public and from health care professionals regarding DTC ads by any company that publicly states it will follow the principles. The PhRMA office of accountability will provide to these companies any comment that is reasonably related to compliance with the Principles. Periodic reports will be issued by the PhRMA office of accountability to the public regarding the nature of the comments. Each report will also be submitted to the FDA.

PhRMA's Board also agreed to select an independent panel of outside experts and individuals to review reports from the office of accountability after one year and evaluate overall trends in the industry as they relate to the Principles. The panel will be empowered to make recommendations in accordance with the Principles. The Principles will go into effect in January 2006.

We believe these Principles will help patients and health care professionals get the information they need to make informed health care decisions.

The Value of DTC Advertising

Informing and Empowering Consumers

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. They help consumers recognize symptoms and seek appropriate care. According to an article in the *New England Journal of Medicine*, 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.

DTC advertising gets patients talking to their doctors about conditions that may otherwise have gone undiagnosed or undertreated. For example, a study conducted by RAND Health and published in the *New England Journal of Medicine* found that nearly half of all adults in the United States fail to receive recommended health care.¹ 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.” The study found underuse of prescription medications in seven of the nine conditions for which prescription medicines were the recommended treatment. Conditions for which underuse was found include asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, hyperlipidemia and hypertension. Of those seven conditions for which RAND found underuse of recommended prescription medicines, five are DTC advertised.

The Rand Study, as well as other studies, 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.²
- A 2004 study published in the *Archives of Internal Medicine*, found that, “In older patients, failures to prescribe indicated medications, monitor medications appropriately, document necessary information, educate patients, and maintain continuity are more common prescribing problems than is use of inappropriate drugs.”³
- A May/June 2003 study published in the *Journal of Managed Care Pharmacy*, which examined claims data from 3 of the 10 largest health plans in California to determine the appropriateness of prescription medication use based upon widely accepted treatment guidelines, found that “effective medication appears to be underused.” Of the four therapeutic areas of study—asthma, CHF, depression, and common cold or upper respiratory tract infections—asthma, CHF, and depression were undertreated. The researchers concluded that “the results are particularly surprising and disturbing when we take into account the fact that three of the conditions studied (asthma, CHF, and depression) are known to produce high costs to the healthcare system.”⁴
- According to a study released in May 2005 by the Stanford University School of Medicine, among patients with high cholesterol in moderate and high-risk groups, researchers found fewer than half of patient visits ended with a statin recommendation. Based on the findings, the researchers say physicians should be more aggressive in investigating statin therapy for

patients with a high or moderate risk of heart disease, and that patients should ask for their cholesterol levels to be checked regularly.⁵

Increasing Communication between the Doctor and Patient

A vast majority of patients (93 percent) who asked about a drug reported that their doctor “welcomed the questions.”⁶ Of patients who asked about a drug, 77 percent reported that their relationship with their doctor remained unchanged as a result of the office visit, and 20 percent reported that their relationship improved.⁷ In addition, both an FDA survey of physicians (from a random sample of 500 physicians from the American Medical Association’s database) and a survey by the nation’s oldest and largest African-American medical association, found that DTC advertisements raise disease awareness and bolster doctor-patient ties.

The doctor-patient relationship is enhanced if DTC advertising prompts a patient to talk to his doctor for the first time about a previously undiscussed condition, to comply with a prescribed treatment regimen, or to become aware of a risk or side effect that was otherwise unknown. A 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. Similarly, the FDA patient survey on DTC advertising found that nearly one in five patients reported speaking to a physician about a condition for the first time because of a DTC ad.⁸

PhRMA and its member companies believe it is vital that patients, in consultation with their doctors, make decisions about treatments and medicines. Prescribing decisions should be dominated by the doctor’s advice. While our member companies direct a large majority of their promotional activities toward physicians,⁹ such promotion in no way guarantees medicines will be prescribed.

According to a General Accounting Office report, of the 61.1 million people (33 percent of adults) who had discussions with their physician as a result of a DTC advertisement in 2001, only 8.5 million (5 percent of adults) actually received a prescription for the product, a small percentage of the total volume of prescriptions dispensed.¹⁰ Indeed, an FDA survey of physicians revealed that the vast majority of physicians do not feel pressure to prescribe. According to the survey, 91 percent of physicians said that their patients did not try to influence treatment courses in a way that would have been harmful and 72 percent of physicians, when asked for prescription for a specific brand name drug, felt little or no pressure to prescribe a medicine.

De-Stigmatizing Disease

DTC advertising also encourages patients to discuss medical problems that otherwise may not have been discussed because it was either thought to be too personal or that there was a stigma attached to the disease. For example, a *Health Affairs* article examined the value of innovation and noted that depression medications, known as selective serotonin reuptake inhibitors (SSRIs), that have been DTC advertised, have led to significant treatment expansion. Prior to the 1990's, it was estimated that about half of those persons who met a clinical definition of depression were not appropriately diagnosed, and many of those 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.¹¹

Utilization and DTC Advertising

According to reports and studies, there is no direct relationship between DTC advertising and the price growth of drugs. For example, in comments to the FDA in December 2003, the FTC stated, "[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...Consumer receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices."¹² Notably, since January 2000, the CPI component that tracks prescription medicines have been in line with overall medical inflation.

The FTC comments referenced above also note, "DTC advertising accounts for a relatively small proportion of the total cost of drugs, which reinforces the view that such advertising would have a limited, if any, effect on price."¹³ Likewise, a study by Harvard University and the Massachusetts Institute of Technology and published by the Kaiser Family Foundation found that DTC advertising accounts for less than 2 percent of the total U.S. spending for prescription medicines.¹⁴

One study in the *American Journal of Managed Care* looked at whether pharmaceutical marketing has led to an increase in the 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..."¹⁵ The study concluded that "greater overall use did not appear to be associated with a shift towards patients with less CV [cardiovascular] risk."

Pharmaceutical utilization is increasing for reasons other than DTC advertising. As the June 2003 study of DTC advertising commissioned by the

Kaiser Family Foundation found, “[O]ur estimates indicate that DTCA is important, but not the primary driver of recent growth [in prescription drug spending].”

Other reasons pharmaceutical utilization is increasing, include:

- **Improved Medicines** – Many new medicines replace higher-cost surgeries and hospital care. In 2004 alone, pharmaceutical companies added 38 new medicines and over the last decade, over 300 new medicines have become available for treating patients. These include important new medicines for some of the most devastating and costly diseases, including: AIDS, cancer, heart disease, Alzheimer’s, and diabetes. 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.”¹⁶
- **New Standards of Medical Practice Encouraging Greater Use of Pharmaceuticals** – Clinical standards are changing to emphasize earlier and tighter control of a range of conditions, such as diabetes, hypertension and cardiovascular disease. For example, new recommendations from the two provider groups suggest that early treatment, including lifestyle changes and treatment with two or more types of medications, can significantly reduce the risk of later complications and improve the quality of life for people with type 2 diabetes.¹⁷
- **Greater Treatment of Previously Undiagnosed and Untreated Conditions** – According to guidelines developed by the National Heart, Lung, and Blood Institute’s National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP), approximately 36 million adults should be taking medicines to lower their cholesterol, a number that has grown from 13 million just 8 years ago.¹⁸
- **Aging of America** – The aging of American translates into greater reliance on pharmaceuticals. 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.¹⁹

While some assume that DTC advertising leads to increased use of newer medicines rather than generic medicines, generics represent just over 50 percent of all prescriptions (generics are historically not DTC advertised). In contrast, in Europe, where DTC advertising is prohibited, the percentage of prescriptions that are generic is significantly lower. Likewise, it is worth noting that while broadcast DTC has been in place since 1997, the rate of growth in drug cost

increases has declined in each of the last 5 years and in 2004 was below the rate of growth in overall health care costs.²⁰

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 \$111.²¹

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.²²

Opponents also 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. However, in 2004, pharmaceutical manufacturers spent an estimated \$4.15 billion²³ on DTC advertising, according to IMS Health, compared to \$49.3 billion in total R&D spending by the biopharmaceutical industry, according to Burrill & Company. PhRMA members alone spent \$38.8 billion on R&D in 2004.

Conclusion

DTC advertising provides 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; encourages patients to discuss medical problems with their health care provider that may otherwise not be discussed due to a stigma being attached to the disease; and encourages patient compliance with physician-directed treatment regimens.

Given the progress that continues to be made in society's battle against disease, patients are seeking more information about medical problems and potential treatments. The purpose of DTC advertising is to foster an informed conversation about health, disease and treatments between patients and their health care practitioners. Our Guiding Principles are an important step in

ensuring patients and health care professionals get the information they need to make informed health care decisions.

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

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12 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), December 1, 2003.

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33 American Association of Clinical Endocrinologists, "Physicians Urge Diabetes Patients to Be Aggressive With Their Own Care," Press Release, (Washington DC: AACE, 2 February 2005)
<<http://www.aace.com/pub/press/releases/index.php?r=20050201>> (accessed 18 March 2005).

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20 See, B. Strunk et al., "Tracking Health Care Costs: Declining Growth Trend Pauses in 2004," Health Affairs W5 (June 21, 2005): 286-295.

21 Frank R. Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," National Bureau of Economic Research Working Paper, No. W8996 (Cambridge, MA: NBER, June 2002).

22 Tufts Center for the Study of Drug Development, "Disease Managers Say Increased Spending on Prescription Drugs Cuts Hospital Inpatient Costs," Press Release, March 12, 2002.

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