

**Testimony before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

**Statement of
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Good morning Mr. Chairman, Ranking Member Shimkus and Members of the Subcommittee.

My name is Jim Sage, and I am the Senior Director and Lipitor Team Leader for Pfizer, which means that I am responsible for the U.S.-based marketing activities for Lipitor® (atorvastatin calcium) ("*Lipitor*"). Pfizer is the world's largest research-based biomedical and pharmaceutical company. Our people work to discover, develop, manufacture and deliver quality, safe and effective prescription medicines to patients. We have a leading portfolio of medicines that prevent, treat and cure diseases across a broad range of therapeutic areas and that are used to improve the health and lives of millions of Americans.

On behalf of Pfizer, I want to thank you for the opportunity to briefly address a few key issues relating to Pfizer's television commercials for *Lipitor*, including:

- Pfizer's use of direct-to-consumer advertising;
- the value of *Lipitor*;
- Dr. Robert Jarvik's role as spokesperson.

Regarding direct-to-consumer television advertising, Pfizer is committed to responsible advertising that anticipates and addresses the needs of patients and doctors. Pfizer develops safe and effective medicines to prevent and treat the world's most serious

diseases. In 2007, we invested \$7.6 billion in research and development. We use DTC to increase awareness of our products, to educate consumers about the conditions that they treat and to increase patient and physician discussion about those conditions.

Unlike most other industries, pharmaceutical companies cannot sell products directly to the people who use them. Instead, these products must be prescribed by physicians. As a result, the prescribing doctor's role is indispensable when considering the DTC issue.

Pfizer believes in the importance of DTC advertising in helping to address critical healthcare needs in this country. We know from research that consumers need and want healthcare information to make educated decisions. However, many consumers face barriers to proper diagnosis and treatment, including lack of information, denial, embarrassment, stigma, low health literacy, coverage, safety concerns and lack of urgency. There is substantial evidence that DTC advertising educates consumers and motivates them to: seek additional information about their medical condition and corresponding treatment options; consult their physicians for diagnosis and appropriate treatment; and follow the treatment plans directed by their physicians.

DTC ads encourage an active partnership between patients and their doctors. Millions of Americans suffer from treatable medical conditions that remain undiagnosed, untreated or under-treated. This is certainly the case with high cholesterol, as only half of those with this condition have been diagnosed and only half of those diagnosed receive treatment. Elevated LDL cholesterol is one of the most common risk factors for cardiovascular disease. Heart disease and stroke continue to be leading causes of death and disability in the United States. Statins, including *Lipitor*, have played an important

role in addressing the risks of heart disease when diet and exercise alone are not enough. 2005 data from the United States Centers for Disease and Control show that since 1999, deaths from cardiovascular heart disease have dropped by more than 25%, and deaths from stroke have fallen by 24%. A number of factors have contributed to this, including advancements in available treatment options for major risk factors – including cholesterol reduction.

Lipitor itself has been studied for about 15 years in more than 400 clinical trials, including more than 80,000 patients. *Lipitor* was in research and development for nearly a decade before coming to market. Our commitment to research did not stop there but continued with several landmark trials published in leading peer-reviewed medical journals, including the *New England Journal of Medicine*, *the Lancet*, *the Journal of the American Medical Association*, and *the Journal of the American College of Cardiology*. These trials helped form the basis for current understanding of cardiovascular risk and for updated cardiovascular disease prevention guidelines. In fact, six of these trials have since been cited by independent guideline bodies as impacting current standards of care.

What we've learned from this research is that, when diet and exercise alone are not enough, *Lipitor* is a safe and effective medicine to:

- Significantly lower LDL by 39-60%; and
- Significantly reduce the risk of heart attack and stroke in a broad range of patients with common risk factors like hypertension, diabetes or history of heart disease

Now, let's turn from the science that has proven *Lipitor's* safety and effectiveness to our company's television advertising campaign for *Lipitor* featuring Dr. Jarvik.

Pfizer asked Dr. Jarvik to appear in *Lipitor* advertisements because he is recognized for his work related to the human heart. Dr. Jarvik honestly and sincerely embraced our heart health campaign. He and Pfizer believe the ads were an effective way to deliver an important preventive health message to a large number of people by encouraging them to reduce the risk of heart disease through diet and exercise as well as consultation with their doctors about the importance of managing cholesterol.

Dr. Jarvik received his M.D. degree from the University of Utah College of Medicine in 1976. Although not a practicing physician, he has devoted his entire career to medical science related to the human heart. He has invented medical devices to help patients with advanced heart disease, and has collaborated with other physicians and scientists on these activities. As Dr. Jarvik has said publicly, he has “the training, experience, and medical knowledge to understand the conclusions of the extensive clinical trials that have been conducted to study the safety and effectiveness of *Lipitor*.” Both Pfizer and Dr. Jarvik are confident that the statements included in the ads fairly represent the scientific data about *Lipitor*.

An important objective of the Jarvik advertising campaign for *Lipitor* was to highlight the importance of diet and exercise in reducing cardiovascular risk. When diet and exercise are not enough, adding medication such as *Lipitor* may be an important consideration for doctors and patients to discuss.

Some have asked why Pfizer decided to stop using Dr. Jarvik in our advertising. We chose Dr. Jarvik to participate in these ads because he is a nationally prominent expert with the knowledge and experience to speak intelligently and sincerely about the benefits of *Lipitor*. Unfortunately, the way Dr. Jarvik was presented in these ads has

created misimpressions and distractions from our goal of encouraging patient and physician dialogue about the leading cause of death in the world: cardiovascular disease. Going forward, we are committed to ensuring there is greater clarity in our advertising regarding the presentation of spokespeople.

In summary, Pfizer believes that it's important to educate consumers about the risks associated with elevated cholesterol and the value of *Lipitor* as a potential treatment option. We believe that DTC ads are an effective way of accomplishing that objective.

Thank you, I look forward to answering any questions you may have.