Pfizer Inc
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Jeffrey B. Kindler
Chairman of the Board
Chief Executive Officer

May 30, 2008

BY HAND DELIVERY
ATTN: Mr. John Sopko

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
The Honorable Bart Stupak
Chairman, Subcommittee on Oversight and Investigations
United States House of Representatives
Ford House Office Building, Room 316
Washington, D.C. 20515-6115

Dear Chairmen Dingell and Stupak:

By letter dated May 20, 2008, you asked several questions of Pfizer Inc related to direct-to-consumer ("DTC") advertising. We appreciate the opportunity to respond to your questions. Pfizer is committed to responsible advertising that anticipates and addresses the needs of patients and doctors by increasing awareness of our products, educating consumers about the conditions that they treat, and encouraging patient and doctor discussion about those conditions.

Specifically, your letter asked if Pfizer would commit to certain guidelines. Our responses follow each of your requests below:

1. **Will Pfizer commit to follow the American Medical Association's guidelines regarding the use of actors and health professionals in DTC advertisements?**

Yes. Pfizer is committed to ensuring greater clarity in our advertising regarding the presentation of healthcare professionals as spokespeople. We are currently working internally to ensure that the recent AMA guidelines regarding the use of actors and healthcare

professionals in DTC advertisements are fully incorporated into our DTC advertising when applicable.

2. **Will Pfizer commit to not market products in DTC advertisements until a valid outcomes study of the product is completed and results are released?**

Pfizer cannot agree to this request because we believe that such an agreement could be detrimental to the public health. Pfizer can only market a product after extensive and rigorous studies have demonstrated that the product is effective for its intended use and its risks are appropriate relative to its benefits. FDA and the company work together prior to approval to ensure that an appropriate clinical program has been developed and executed. FDA does not always mandate that an outcomes study is required either prior to approval or as a post-approval commitment. While outcomes studies may be appropriate for drugs in certain therapeutic areas, they may not be in others. Additionally, outcomes studies are lengthy and time consuming; to deny patients information about an approved product pending the completion of an outcomes study may be detrimental to the public health.

3. **Will Pfizer commit to place a two-year DTC advertisement moratorium on new prescription drug products, as recommended by the Institute of Medicine?**

Pfizer has committed to and abides by a minimum six-month moratorium on DTC advertising following approval of a new drug product. Based on our research we believe this is ample time to fully educate prescribers about such a product's benefit/risk profile.

We do not believe that a two-year moratorium for all products serves the best interests of patients, since it denies them potentially important information about new and fully approved treatment options and delays potential alleviation of symptoms and progress in treating diseases.

The goal often cited for such a moratorium is to facilitate further evaluation of a new product's benefit/risk profile. Pfizer firmly believes that a two year moratorium on DTC advertising is not an effective way of achieving this goal. Other mechanisms, such as those outlined in the REMS provisions of the Food and Drug Administration amendments Act of 2007 (FDAAA) and the appropriate use of post-marketing surveillance studies, are more appropriate strategies for the ongoing study of a drug's

benefit/risk profile than restricting patient access to information on new treatment options through a two year moratorium.

4. **Will Pfizer commit to not market off-label uses for prescription products in DTC advertisements?**

Yes. The Federal Food, Drug and Cosmetic Act and FDA's implementing regulations prohibit the marketing of pharmaceutical products for off-label uses in DTC advertisements or elsewhere. Pfizer is committed to complying with all laws and regulations regarding the promotion of prescription products in all forums.

5. **Will Pfizer commit to add the Food and Drug Administration's (FDA) toll-free MedWatch phone number in all your DTC advertisements?**

Pfizer will defer to FDA's guidance as to this request. FDAAA currently requires that all print DTC advertisements include the MedWatch telephone number and Web site address. Pfizer is complying with this law. As to television advertisements, given the potential for the MedWatch information to detract from important required risk information in DTC television advertisements, the FDA, in conjunction with its Risk Communication Advisory Committee, is evaluating the appropriateness of including the MedWatch telephone number in DTC television advertisements. Under FDAAA, the FDA will issue guidance regarding this issue. Pfizer will abide by the expected FDA guidance.

6. **If a product of Pfizer is required by FDA to include a "black box" warning in its labeling, will Pfizer, Inc commit to add these "black box" warnings in DTC ads for any such product?**

Yes. Pfizer has always been committed to including important safety information – including the safety information from "black boxed" warnings – in DTC advertisements. Recognizing that black box warning language is often complex and technical, Pfizer has worked with FDA, and will continue to do so, in order to develop language encompassing such safety information in our DTC advertisements that is clear, concise and easily understood by consumers.

Although we agree with many of your proposed guidelines, we recognize that we have different points of view on others. In addition, we share a common goal of protecting and improving the public health.

Accordingly, I can commit that Pfizer will work with you toward that goal. Should you have any questions, please don't hesitate to contact me or Anthony Principi in our Washington, DC office at 202-783-7070.

Sincerely,

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations