

June 9, 2008

The Honorable John D. Dingell
Chairman

The Honorable Bart Stupak
Chairman, Subcommittee on Oversight and Investigations

Committee on Energy and Commerce
U.S. House of Representatives
Room 316 Ford House Office Building
Washington, DC 20515-6115

Dear Chairmen Dingell and Stupak:

Thank you for your letter of May 20, 2008, which sets out a number of questions regarding the Pharmaceutical Research and Manufacturers of America's (PhRMA's) Guiding Principles on Direct-to-Consumer (DTC) Advertising About Prescription Medicines (Guiding Principles). PhRMA appreciates and welcomes the Committee's feedback on our Guiding Principles, and shares the Committee's interest in making DTC advertising of prescription medicines as informative, clear and educational as possible.

As you know, DTC advertising is already one of the most regulated forms of advertising. The commitment of PhRMA members to providing accurate and educational information to patients and healthcare professionals through DTC advertising is evidenced by our Board's unanimous approval of our Guiding Principles in 2005. Our Guiding Principles, which took effect in January 2006, provide general guidance for companies to consider in any individual DTC advertising. As such, they represent an additional layer of self-regulation on top of FDA's oversight.¹

Your letter comes at a good time, as we are at this very time reviewing our Guiding Principles to assess whether updates or enhancements are needed. As a consensus-driven organization comprised of more than 30 member companies, any potential changes to our Guiding Principles must be carefully considered, so that companies that wish to follow the Principles may feasibly implement any new standards that are set. Proposed changes to the Guiding Principles must be reviewed and approved by the PhRMA Board.

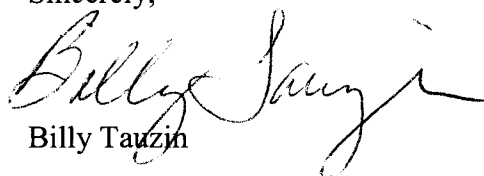
¹ Under FDA's statutory and regulatory authorities, DTC advertising must: be accurate and not misleading; make claims only when supported by substantial evidence; reflect fair balance between risks and benefits; and be consistent with FDA-approved labeling. Our Guiding Principles likewise incorporate these standards.

Our internal process for reviewing our Guiding Principles is progressing well. As part of this process, we would welcome the opportunity to discuss our thinking with you and Committee staff and to hear from you about your concerns. We also commit to updating the Committee as soon as we have completed our internal process, and have secured Board approval of any updates. While your letter has identified several concerns with respect to the Guiding Principles, I cannot, of course, tell you what the PhRMA Board will or will not approve until our process is complete.

Certainly, patients and healthcare professionals deserve nothing less than our best efforts to ensure that all DTC advertising of prescription medicines complies with FDA requirements and meets the standards set forth in our Guiding Principles. DTC advertising, when done appropriately, provides many benefits to consumers and our healthcare system. It can increase awareness of diseases and educate patients about treatment options. This awareness starts important doctor-patient conversations about health, which in turn often result in a greater likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated.² DTC can also prompt patients to comply with prescribed treatment regimens, which, when not complied with, have been estimated to cost the United States \$100-300 billion annually in lost productivity and avoidable health spending.³

We look forward to meeting with you and your staff at your convenience and to the opportunity for further dialogue as we move forward.

Sincerely,



Billy Tauzin

² In fact, one survey showed that in 2006, 56 million Americans had conversations with their doctors after seeing a DTC advertisement. Prevention Magazine, The National Survey on Consumer Reaction to DTC Advertising of Prescription Medicines, 2007. See also J. S. Weissman et al., "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," Health Affairs Web Exclusive, April 28, 2004.

³ H. Shorter, "Noncompliance with medication: An economic tragedy with important implication 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.