

May 30, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515-6115

The Honorable Bart Stupak
Chairman
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives
Washington, DC 20515-6115

Dear Chairman Dingell and Chairman Stupak:

In letters to Merck & Co., Inc. ("Merck") and Schering-Plough, Inc., ("Schering-Plough") you posed questions related to the policies of each company and to those of the Merck/Schering Plough (MSP) Pharmaceuticals joint venture related to direct-to-consumer (DTC) advertising. These letters followed the questioning at the Subcommittee on Oversight and Investigations hearing on May 8, at which I testified on behalf of MSP Pharmaceuticals. I understand that Merck and Schering-Plough will each respond to your questions. I welcome this opportunity to amplify the responses I provided at the Hearing on behalf of MSP Pharmaceuticals.

First, MSP does agree that its DTC advertisements will follow the current American Medical Association policy (H-105.988 Direct-to-Consumer (DTC) Advertising of Prescription Drugs and Implantable Devices) regarding the use of actors and health care professionals in DTC advertisements. Specifically, we will continue to identify instances in which an actor is portraying a physician. In addition, if our advertisements include a physician, we will identify that the physician has been compensated for appearing in the advertisement.

Second, MSP does not believe it is necessary to wait until the completion of a valid outcomes study before beginning DTC advertising. Instead, our DTC advertisements are consistent with the FDA approved labeling that may include measures of outcomes or measures of validated surrogate measures. In order to ensure that patients needing treatments have timely access to medicines to help treat their condition, it is important and scientifically valid for the FDA to use well-studied surrogate measures as a basis for approving medicines. We believe DTC advertising is one important way to provide the public and physicians with helpful information on these approved medicines consistent

with approved labeling so that patients who need treatment are aware of available treatment options that they can discuss with their doctors.

Third, regarding a moratorium on DTC advertising for new drugs, as I mentioned in the hearing, MSP does follow the PhRMA guidelines which require that physicians are adequately educated about the risks and benefits of a new drug prior to the initiation of DTC advertising. Accordingly, MSP has not applied one specific timeframe to determining when to begin broadcast DTC advertising. Rather, MSP considers the physician's need for sufficient information to help inform their discussions with patients and the need that patients may have to learn about new treatment options. While a combination product containing two currently marketed products that are well-known to many physicians may be appropriate to advertise using broadcast DTC sooner, we recognize that it may take six months to appropriately educate physicians about other new treatment options.

Accordingly, MSP agrees that a six month time window is reasonable for new products and will commit to delay the beginning of DTC advertising for new products until a minimum of six months after product approval. We will also continue to evaluate physicians' awareness of each specific product and its approved labeling before determining that it is appropriate to begin a DTC broadcast campaign after the initial six month window following product launch.

Fourth, MSP agrees not to market products in its DTC advertising for off-label uses. As I mentioned at the hearing, this is a current, FDA-enforced legal requirement and we both support it and comply carefully with it. The content of our advertisements is based on FDA approved labeling.

Fifth, Section 906 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) requires print DTC advertisements to include FDA's 1-800 MEDWATCH phone number. We support and comply with this requirement. In addition, MSP is also planning to include the FDA's 1-800 MEDWATCH phone number on our product-specific websites.

FDAAA also required FDA to conduct a study to determine whether the 800 number is appropriate for inclusion in DTC television advertisements. We look forward to learning about FDA's findings that will come from this study and will certainly comply with future FDA guidance relating to whether this additional information in a DTC broadcast advertisement would be helpful. In the meantime, we are currently evaluating whether there is an appropriate way to direct consumers to our DTC print advertisements or consumer websites to find out how to report information on side effects. We will, of

Page Three
May 30, 2008

course, submit any such proposals to the FDA for FDA's consideration of whether any such additional information may be helpful to consumers.

In addition, consistent with DDMAC's Guidance Document, Consumer-Directed Broadcast Advertisements (August 1999), MSP already includes a toll-free telephone number for consumers to call for the approved package labeling. Consumers who call MSP's toll-free number are able to provide information to MSP about possible side effects they may have experienced while taking one of our medicines. MSP reports such adverse experience information to the FDA in accordance with FDA regulatory requirements.

Sixth, MSP does not market nor does it expect to market a product with a "black box" warning. If, in the future, MSP does have a product with a FDA-required black-box warning, MSP would certainly add appropriate information relating to the black box warning, consistent with FDA regulations and guidance, to any DTC broadcast advertisement for that product.

On behalf of MSP, I appreciate the opportunity to provide this additional perspective to you. If I can be of further assistance in your review of DTC advertising, please let us know.

Sincerely,



Deepak Khanna
Senior Vice President and General Manager