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Schering-Plough

May 30, 2008

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

Dear Chairmen Dingell and Stupak:

This is in response to your request of May 20 for a statement from Schering-Plough on several issues you have raised regarding our direct-to-consumer (DTC) communications.

In your letter you state that you are concerned you did not receive assurances you wanted at the hearing related to DTC advertising. Let me assure you now, on behalf of Schering-Plough, that we are totally committed to accuracy and fair balance in our DTC advertising, broadcast and print, and will continue to be responsive to any issues raised by FDA.

You requested our position on six specific points:

1. Guidelines on the use of actors and health professionals in DTC advertisements. Schering-Plough broadcast DTC advertising will follow the American Medical Association's guidelines regarding the use of actors and health professionals in DTC advertisements. If we have an actor portray a physician or other health care professional in one of our ads, we will include a statement highlighting this fact. In the event that we use a real physician in an ad, we will include a statement disclosing that the physician in the ad was compensated.

2. Deferral of DTC advertising for a product until a valid outcomes study is completed and the results released. Schering-Plough's advertising is based on evidence from valid, well-controlled, clinical trials. What constitutes an outcome will differ depending on the therapeutic class. For example, for products approved for the relief of symptoms, such as antihistamines, efficacy of the drug is measured in terms of its effect on those symptoms, and claims in the ads derive from studies used in approving the drug.

   For products approved for treatment of particular medical conditions associated with serious disease, such as high blood glucose, blood pressure, or high LDL

cholesterol, efficacy of the drug is measured in terms of its effect in controlling these conditions, which, in turn, are linked to mortality and morbidity through extensive long-term studies. Drugs approved to control these conditions are used by physicians to help patients manage the conditions, and are advertised based on their measured effect on specific markers, supported by extensive clinical data. Patients can derive substantial benefit in improving their conditions from drugs that are proven effective in treating these conditions by the FDA, even though they have not yet been proven to prevent mortality or morbidity.

A blanket requirement that DTC advertising await the completion and release of an outcomes study would prevent the communication of treatment information to patients who could benefit substantially from controlling certain conditions (such as high blood pressure). Of course, we will include in our DTC advertisements any disclosure FDA requests concerning the status of outcomes data.

3. A two-year moratorium on DTC advertising of new products. Schering-Plough agrees that it is important to delay broadcast advertising on a new prescription product until we have had sufficient time to educate physicians on that product. The period of time necessary to provide a proper level of education will vary depending on the complexity and novelty of the drug and the experience the medical profession has with the science around both the drug and the class to which it belongs.

   A longer deferral of DTC broadcast advertising after launch, for up to two years, might be appropriate in certain instances, while a shorter deferral period, such as six months, might be appropriate for certain others. There is a big difference in the physician education and experience required with a novel, "first-in-class" product compared to a product that enters an established therapeutic class that is widely understood in the medical community. In any event, we will commit to a minimum period of six months for properly educating physicians before the launch of broadcast advertising after approval of a new product.

4. Market only on-label uses for prescription products in DTC advertisements. Schering-Plough agrees. Schering-Plough does not and would not advertise off-label uses for its prescription products in DTC advertisements.

5. Add the FDA's MedWatch toll-free phone number in DTC advertisements. Schering-Plough currently includes the FDA's MedWatch toll-free phone number in print advertisements, as is already required by law. As a further measure, the Company will commit to include a statement in television DTC advertisements directing consumers to our print ads for information on how to report any adverse events. This approach of directing consumers to our print ads for the 1-800 MedWatch number will allow time for the FDA to prepare, develop, create and run a public service campaign, as discussed by the FDA's Advisory Committee on Risk Communication, in order to educate consumers on adverse event reporting.

We are concerned, as the Advisory Committee noted, that some consumers would confuse reporting adverse events to the FDA with seeking medical advice. This could result in patients either delaying getting needed and possibly urgent advice from their physicians or not discussing side effects they might be experiencing with their physicians. Once this public health question has been resolved and the FDA has run their public service campaign, we would add the MedWatch number to our broadcast ads.

6. Add "black box" warnings in DTC ads for any product with such a warning. Schering-Plough does not currently engage in DTC broadcast advertising for any products that have a "black box" warning. Schering-Plough agrees that, were we to advertise such a product, we would ensure that the risks to patients from the use of the product, including the risks identified in the warning, were fully and prominently presented in the broadcast advertisement. This information, would, of course, also be fully and prominently presented in any DTC print ads.

I hope this information is fully responsive to your request.

Sincerely,

Fred Tarasi