DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

May 8, 2007

The Honorable Bart Stupak
House of Representative
Washington, D.C. 20515-2201

Dear Mr. Stupak:

Thank you for taking the time to allow me to meet with you in person to discuss some of your concerns with regard to the Food and Drug Administration (FDA).

I respect and appreciate your commitment to assuring the scientific integrity of the decisions made by the FDA. In that context, you were kind enough to provide me with a copy of your very meticulous analysis of information regarding the drug isotretinoin (Accutane®). In addition to reviewing the scientific articles you provided, I also took the liberty of calling professional colleagues who are world-class experts in the field of retinoids. Although I do not consider myself to be an expert, I developed a working knowledge of these compounds during my career at the University of Texas MD Anderson Cancer Center when Vitamin A analogues were proposed for the treatment of cancer, including superficial bladder cancer.

As you correctly point out, there is evidence that isotretinoin has effects on numerous tissues within the body including the central nervous system. The functional correlate of these biologic effects is complex and remains the subject of scientific inquiry. A review of even a portion of the literature indicates conflicting as well as inconclusive evidence with regard to behavioral effects that are causally related to the drug. Thus, I believe we are both in complete agreement that there is need for continued investigation and careful monitoring of this drug as it is being used in patients. As with all drugs, scientific investigation must be integrated with availability of the drug for physicians to provide essential therapy for conditions such as severe recalcitrant nodular acne.

In addition to restrictions such as the iPLEDGE program, the FDA will continue to explore opportunities to further inform and guide patients and physicians as to the proper indications and precautions for using this medication. The Web site we launched in late March was one such effort and I am grateful for your input on its content. Please be assured that the changes in the language defining the indication were immediately made to reflect that its use is for severe recalcitrant nodular acne.

I am committed to a constant ongoing process of gathering scientific data to inform our decision making process at the FDA. As a physician, I have always realized that we make decisions based on the best data that is available at the time, but we must always be open to having these decisions modified by new information. I will continue to work with you and others to be certain this process is rigorous and effective at the FDA.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs