United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

August 24, 2005

Via Electronic Transmission

The Honorable Lester M. Crawford, D.V.M., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Crawford:

Thank you for the Food and Drug Administration's (FDA) timely response to my letter dated June 24, 2005. I requested that the FDA address questions and provide documents related to non-arteritic anterior ischemic optic neuropathy (NAION) and the use of drugs prescribed by physicians to treat erectile dysfunction (ED), including Viagra, Cialis and Levitra.

In particular, I asked the FDA to describe, in detail, any actions that will be taken to ensure that patients are informed of NAION and its association with ED drugs. The FDA stated in a letter dated July 20, 2005, that Patient Information Sheets for each ED drug have been posted on the FDA's website that include information about possible vision loss and patients who may be at risk for NAION. That letter also stated that information was provided to over 50,000 individual subscribers by e-mail through MedWatch, the FDA's safety information and adverse event reporting program.

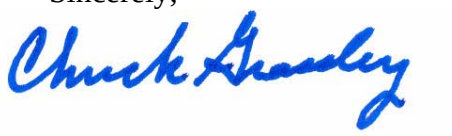
According to IMS Health, a company that monitors prescription drug sales across the nation, prescriptions for ED drugs in 2004 totaled more than 18 million, including 13.9 million prescriptions for Viagra, 2.6 million prescriptions for Cialis, and 2.1 million for Levitra. Although there is a possibility that the 50,000 subscribers to the MedWatch e-mail list and individuals who have accessed the Patient Information Sheets may now be aware of the NAION risks associated with ED drug use, there are millions more who remain in the dark. It seems likely that many millions of men with ED drugs sitting in their medicine cabinets have not visited the FDA's website and/or seen the media reports about the risk of permanent vision loss. In addition, it is unlikely that these millions of men have followed up with the physicians who prescribed them the medication because ED drugs are typically used on an as-needed basis. Dr. Crawford, who will inform these patients and consumers of the concerns that have come to light with regard to the use of ED drugs? Has the FDA considered initiating other action(s) to inform adequately these millions of patients about NAION and its association with ED drug use? More importantly, in the future, how will the FDA attempt to inform patients who do not

require regularly scheduled physician follow-up about important safety information regarding their medications?

Finally, the FDA has still not addressed two issues that concern me. Why did it take so long for the FDA to negotiate the label changes for ED drugs and to notify the public of the NAION risk associated with ED drugs? The FDA has a duty to notify the public promptly about a serious risk associated with a drug and identified in the post-market. Permanent blindness surely is such a serious risk.

In closing, I look forward to hearing from you regarding this important matter by no later than September 14, 2005.

Sincerely,



Charles E. Grassley
Chairman