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Congress of the United States
House of Representatives
Washington, DC 20515-2107
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Lester M. Crawford, D.V.M, Ph.D
Acting Commissioner of Food and Drugs
US Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 1547
Rockville, MD 20857

Dear Dr. Crawford:

On December 22, 2004, I sent you a letter requesting more information about the FDA MedWatch system and ongoing effort to provide the public with comprehensive and accurate information about drugs, biologics, and devices. I still have not received a response to my inquiry. Since I sent my last letter there have been additional concerns raised about the side effects of FDA approved drugs. The extensive media attention focused on the potential side effects and complications associated with drugs including Vioxx, Celebrex, Tysabri and Bextra, has the potential to be extremely confusing for consumers.

While I believe that all health care decisions need to be made in conjunction with a health care professional, it is important for consumers to have access to complete and accurate information so that they can educate themselves about the prescription and over-the-counter drugs that they are taking. In addition to consulting with their health care professionals, consumers should be able to turn to a trusted and reliable source to seek out more information about the potential side effects of a drug, biologic or device.

If consumers do not know what warning signs to look for, they may not seek medical attention for potentially serious health conditions. For example, Bextra has been found to be associated with a serious and potentially life-threatening skin reaction. Unless consumers know what symptoms they should look for if taking Bextra, they may not recognize a potentially fatal skin rash. Consumers who were taking Bextra or are taking another prescription medication with potential side effects should have a place where they can go to find complete, accurate and unbiased information about the medication or device.

Since the FDA is the place people turn to when they have questions about the safety or efficacy of drugs, the FDA has a responsibility to provide consumers with user-friendly, comprehensive, accurate and timely information about all drugs and devices on the market and those that have been recently removed from the market.

On April 11, 2005, the FDA had health information about specific drugs of concern ([Bextra Information](#), [Celebrex Information](#), [Crestor Information](#), [Elidel Information](#), [Protopic](#)

Information, Tysabri Information, Vioxx Information) listed prominently on the website. This is an important resource. However, specific information about symptoms or side effects were not readily apparent. Further, consumers and healthcare professionals alike need access to this information on all available drugs, biologics and devices.

I urge the FDA to create an interactive, user-friendly web-based database where consumers and healthcare professionals can find complete, accurate and timely information about the known side effects of drugs on the market and recently removed from the market.

In order to facilitate public awareness of the site, I would recommend using an easy to remember URL such as www.sideeffects.gov or www.druginfo.gov. This site could also include new press releases about side effects, symptoms, and pictures of side effects when appropriate, health warnings as well as a point of access for consumers and healthcare providers to report their own adverse events. Further, I urge the FDA to launch a national education campaign to raise awareness of this new healthcare information resource.

If we want consumers to take personal responsibility for their health, then the government must provide the tools that help people to make informed health decisions.

I would like some more information regarding the FDA's efforts in this area. I request your assistance in providing answers to the following questions:

1. Does the FDA have any plans to create an interactive, user-friendly website where consumers and healthcare professionals can find complete, accurate and timely information about the known side effects of drugs, biologics and devices on the market and recently removed from the market?
2. If so, can you please provide me with the details of these plans and the timeline for implementation?
3. What resources are needed from Congress to facilitate implementation of this website?
4. If the FDA does not have any plans to create a database of prescription drug information, why has the FDA decided not to provide consumers with this information?

Thank you for your attention to this important issue. If you have any questions regarding this request, please do not hesitate to contact Ms. Katharine Reinhalter or Mr. Jeffrey Duncan on my staff at 202-225-2836. I look forward to your prompt reply.

Sincerely,



Edward J. Markey
Member of Congress