United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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Tuesday, March 20, 2007

Grassley urges FDA to educate and inform public about acetaminophen

Senator asks for an accounting of delayed response to advisory committee recommendations

WASHINGTON — Sen. Chuck Grassley said the Food and Drug Administration needs to undertake an educational effort to better inform the public about acetaminophen safety.

"Acetaminophen is a common drug that gets used frequently and without concern," Grassley said. "People might not even realize how much they're taking because it appears in so many over-the-counter products used to treat headaches and head colds."

Grassley said he's making a public appeal to the FDA because the drug-safety agency waited four years after receiving a recommendation from one if its own advisory committees that it needed to try to reduce accidental overdoses of acetaminophen before it proposed a rule last December that would strengthen warnings on acetaminophen products and adopt other public safety measures.

In fact, in a letter sent today to the FDA Commissioner, Grassley said he found it remarkable that the FDA issued its proposed rule exactly two weeks after he had written the FDA to ask for an update on the agency's acetaminophen safety efforts. Grassley said he made this inquiry because nothing had happened following the September 2002 advisory committee recommendations. Today, he asked the FDA Commissioner to account for the multi-year delay.

The FDA advisory committee reviewed data in 2002 showing that acetaminophen overdoses cause more than 50,000 emergency room visits and 458 deaths in the United States each year.

The text of Grassley's letters of March 20, 2007 and December 12, 2006 to the FDA Commissioner on this subject follows here.

March 20, 2007

Andrew C. von Eschenbach, M.D.
Commissioner

U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities of the Food and Drug Administration (FDA). In this capacity, I must ensure that FDA upholds its responsibility to the public's safety by properly regulating the nation's drug supply and ensuring that American consumers have the information they need about the drugs they use.

On December 12, 2006, I wrote to you asking what actions FDA had taken to promote acetaminophen safety. Exactly two weeks after the date of my letter, FDA released a Proposed Rule "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling." While I am certainly heartened that FDA took this regulatory action so soon after my letter, I remain troubled that FDA's action came more than four years after an advisory panel determined that public safety required that FDA take action. In my first letter, I requested a briefing to update me on the current status of safety issues related to acetaminophen, and I specifically asked that the FDA staff "be prepared to describe any actions FDA has taken subsequent to the advisory panel meeting, including the process of FDA's consideration of safety warning or labeling changes, or other actions to decrease accidental overdoses."

FDA's Congressional Affairs Office promptly arranged for my staff to be briefed by several members of FDA's Office of Nonprescription Products. This briefing was conducted by telephone on January 10, 2007. Thank you for making your staff available for that briefing. The staff members answered some of my questions about the FDA's actions on acetaminophen but were not adequately prepared to present sufficient detail on other aspects of FDA's actions, or lack thereof, that are of interest to me.

As you know, on September 19, 2002 the Nonprescription Drugs Advisory Committee (Advisory Committee) met to discuss safety issues related to the use of acetaminophen, the active ingredient in Tylenol and numerous other drug products commonly used to relieve pain and fever. At that meeting, the Advisory Committee reviewed data showing that acetaminophen overdoses cause more than 50,000 emergency room visits and 458 deaths in the United States each year. The Advisory Committee unanimously voted that accidental acetaminophen overdosing is a significant problem, and that FDA should take action to try to reduce accidental overdoses. The Advisory Committee discussed numerous potential regulatory strategies to promote safety, including additional safety warnings, revised product labeling, package size limitations, and other packaging changes.

While I am certainly pleased that FDA released a Proposed Rule on acetaminophen safety so quickly after I expressed interest in this pressing public health concern, I remain puzzled why it took FDA more than four years after the Advisory Committee meeting to initiate

the notice and comment rule making process. I also recognize that FDA's regulatory action to date involves only a Proposed Rule, such that no implementation of any proposed safety measures has yet occurred. In that Proposed Rule, FDA outlined a plan to strengthen the warnings on acetaminophen products and sought public comment on other safety precautions that had been discussed by the Advisory Committee. Troublingly, it is now more than four years since the Advisory Committee identified the public safety need for FDA action, yet it appears that FDA has still not implemented measures to protect the American public. The January 10, 2007 telephone briefing made me aware of FDA's limited public education efforts in 2004, over one year after the advisory panel meeting, but your staff's vague recollection of the program and limited details of its operation suggest this was not a major public health initiative. Coupled with the lengthy time it took for FDA to address patient safety issues with Vioxx, I am concerned that these delays may reflect a pattern of FDA failing to act on patient safety issues with the celerity necessary to protect the public's health.

I request that FDA provide my Committee staff with an informational briefing on the history of FDA's actions to promote acetaminophen safety. It would be helpful for staff knowledgeable about the regulatory initiatives and any public education campaigns to attend this briefing. FDA staff should be instructed to take adequate time to prepare for the briefing, such that they will be able to provide detailed information in response to questions. I hope you will instruct your staff to review documents or other agency records as necessary to refresh their memories, so that they will be prepared to speak authoritatively about FDA programs with the required level of detail to address my concerns. FDA staff should be prepared to provide detailed information regarding the following issues:

1. More than four years elapsed between the Advisory Committee meeting on September 19, 2002 and FDA's release of the Proposed Rule on December 26, 2006. I understand that FDA is not obligated to adopt Advisory Committee recommendations, but if FDA ultimately decided to adopt some of the Advisory Committee's suggestions, why did it take so many years for FDA to issue this Proposed Rule?

2. When does FDA anticipate a final rule would be published and implemented? Does FDA plan to implement any safety measures to protect the public in the meantime?

3. What other regulatory options, besides notice and comment rulemaking starting with a proposed rule, does FDA have authority to use to implement safety warnings, revised product labeling, package size limitations, and other packaging changes for over the counter drugs? For example, could FDA use an Interim Final Rule or other expedited process? How long would any such other regulatory or sub-regulatory options require to implement? How did FDA decide to proceed with a Proposed Rule as opposed to an expedited process?

4. What other actions did FDA take between September 19, 2002 and December 26, 2006 to promote acetaminophen safety?

5. At the January 10, 2007 briefing, FDA staff stated that FDA made some efforts to educate the public about acetaminophen safety in 2004. Unfortunately, the staffers were not prepared to describe these programs in detail and information was limited to their vague

recollections. What were the nature and scope of any educational programs or public safety campaigns undertaken by FDA? What media outlets were used to disseminate public safety announcements or other educational information? Who developed the educational messages? How much money did FDA spend on this campaign? How many individuals does FDA estimate were reached by these efforts? What information does FDA have on whether the efforts achieved any positive impact?

6. Does FDA plan to pursue any public educational initiatives to promote acetaminophen safety or public awareness of acetaminophen overdose risks?

Thank you for your prompt attention to this matter.

Sincerely,
Charles E. Grassley
Committee on Finance
Ranking Member

December 12, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

As a senior member of the United States Senate and as Chairman of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities of the Food and Drug Administration (FDA). In this capacity, I must ensure that FDA upholds its responsibility to the public's safety by properly regulating the nation's drug supply and ensuring that American consumers have the information they need about the drugs they use.

I understand that the Nonprescription Drugs Advisory Committee (Advisory Committee) met on September 19, 2002 to discuss safety issues related to the use of acetaminophen, the active ingredient in Tylenol and numerous other drug products commonly used to relieve pain and fever. At that meeting, the Advisory Committee reviewed data showing that acetaminophen overdoses cause more than 50,000 emergency room visits and 458 deaths in the United States each year. While some of these overdoses involve suicide attempts and suicide gestures, the Advisory Committee recognized that many reflect accidental overdoses.

The Advisory Committee unanimously voted that accidental acetaminophen overdosing is a significant problem, and that FDA should take action to try to reduce accidental overdoses.

The Advisory Committee discussed numerous potential regulatory strategies to promote safety, including additional safety warnings, revised product labeling, package size limitations, and other packaging changes.

We would appreciate a briefing to update us on the current status of safety issues related to acetaminophen. During the course of that briefing, please be prepared to describe any actions FDA has taken subsequent to the advisory panel meeting, including the process of FDA's consideration of safety warning or labeling changes, or other actions to decrease accidental overdoses.

Thank you for your prompt attention to this matter, and I would appreciate that a briefing date be identified no later than December 13, 2006.

Sincerely,
Charles E. Grassley
Committee on Finance
Chairman