FOR IMMEDIATE RELEASE: January 26, 2011
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KOHL URGES PROMPT ACTION ON FDA DRUG LABELING FOR PREGNANT WOMEN AND NEW MOTHERS

Critical research and drug data languishes for years in FDA review process

WASHINGTON, D.C. – Today U.S. Senator Herb Kohl asked Health and Human Services Secretary Kathleen Sebelius to expedite the Food and Drug Administration's final review of a rule that would improve drug labeling for pregnant women and new mothers. The draft rule, which was issued in 2008, has been pending in FDA's Center for Drug Evaluation and Research for nearly three years.

"We are constantly testing and developing new drugs and treatments, but our labeling of these medicines for mothers-to-be is stuck in the 70's," Kohl said. "The FDA started to remedy this glaring problem in 2008 but, to date, has fallen short of solving it. There needs to be a sense of urgency at the FDA to get this guidance out and implemented, otherwise mothers, pregnant women and their doctors have no choice but to rely on a flawed relic of the past to help them make critical health care decisions for both mother and baby."

In his letter to Secretary Sebelius, Kohl writes: "As the nation's principal agency for protecting the health of all Americans, I urge you to ensure the prompt finalization of a proposed rule currently pending at the Food and Drug Administration (FDA) regarding drug labeling for pregnant and lactating women. Any further delay will only unacceptably harm the health of women across America."

The FDA's current system of drug labeling was initiated in 1975 and required drug labeling to include a "sub-section on a drug's ability to cause birth defects and other effects on reproduction and pregnancy."

Kohl writes: "It is widely acknowledged among advocates, doctors and even some at the FDA that the current system is confusing and leads to over simplification. It is my understanding that the proposed rule, which also includes guidance for drug companies on establishing pregnancy registries to identify women using certain drugs, is still under initial review at CDER where staff is reviewing approximately 73 comments it received from stakeholders in August of 2008."

Full text of Kohl's letter to Sebelius is attached below.

January 26, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Dear Secretary Sebelius:

As the nation's principal agency for protecting the health of all Americans, I urge you to ensure the prompt finalization of a proposed rule currently pending at the Food and Drug Administration (FDA) regarding drug labeling for pregnant and lactating women. The proposed rule, which was issued in 2008, has been pending in FDA's Center for Drug Evaluation and Research for nearly three years. Any further delay will only unacceptably harm the health of women across America.

Pregnant women get sick or become pregnant with existing chronic conditions that often require medical treatment. In fact, an estimated 75% of all pregnant women use 4-6 prescriptions or over-the-counter drugs at some time during their pregnancy. In addition to general safety questions about how certain drugs will impact the health of the woman and fetus, researchers have even less information on how the body of a pregnant woman metabolizes a drug and therefore what dosage is required for effective treatment.

Since 1975, FDA has required drug labeling to include a sub-section on a drug's ability to cause birth defects and other effects on reproduction and pregnancy. Currently, products must be classified under one of five letter categories—A,B,C,D, and X. It is widely acknowledged among advocates, doctors and even some at the FDA that the current system is confusing and leads to over simplification. In recognition of the current system's failures, FDA issued a proposed rule in 2008 that would replace the letter categories with more detailed, narrative descriptions and include information on fertility, pregnancy, and breast-feeding. It is my understanding that the proposed rule, which also includes guidance for drug companies on establishing pregnancy registries to identify women using certain drugs, is still under initial review at CDER where staff is reviewing approximately 73 comments it received from stakeholders in August of 2008.

Secretary Sebelius, like you, I am committed to ensuring that patients have the information they need to make informed medical decisions. Without improved drug labeling, doctors and patients are forced to make treatment decisions with limited information and research. Too much time has passed and continued delay in finalizing the proposed rule will only add to unnecessary exposure to ineffective drugs or ineffective dosing of effective drugs, both of which prevent patients from receiving appropriate therapies. In order to best understand why it has taken so long to move this issue forward, I would like to request a comprehensive timeline of the pregnancy labeling initiative from inception to the present. I ask that your office report back to me as soon as possible with a status report on the progress of the final rule and present an expected timeline for this rule's progression through the multi-agency review process. I urge you to finalize the rule promptly and ensure its timely movement through FDA, HHS and the Office of Management and Budget.

Thank you for your attention to this matter. I look forward to hearing from you.

Sincerely,

Herb

Kohl
U.S. Senator

CC: Margaret A. Hamburg
CC: Francis Collins