

part of this rulemaking the Secretary should look broadly at the various types of the food establishments in order to ascertain whether they should be exempted and shall exempt from registration those facilities that are not necessary to accomplish the purpose of this section. The Secretary should assure that implementation of this section does not unnecessarily disrupt the flow of commerce.

Section 306 requires the Secretary to promulgate a rule to provide for prior notice to the Secretary of food being offered for import. The prior notice is to occur between 24 and 72 hours before the article is offered for import. In circumstances where timely prior notice is not given, the article is to be held at the port until such notice is given and the Secretary, in no more than 24 hours, examines the notice and determines whether it is in accordance with the notice regulations. At that time, the Secretary must also determine whether there is in his possession any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. This determination by the Secretary should not delay or unnecessarily disrupt the flow of commerce.

Section 306 is not intended as a limitation on the port of entry for an article of food. In some instances, such as inclement weather, routine shipping delays, or natural disasters, a shipment of food may arrive at a port of entry other than the anticipated port of entry provided on the notice. When such situations arise, arrival at a port other than the anticipated port should not be the sole basis for invalidating a notice that is otherwise in accordance with the regulations. Also, the importer of an article of food is required to provide information about the grower of the article of food, if that information is known to the importer at the time that prior notice is being provided in accordance with the regulations. This provision only requires the importer to provide any information he has in his possession at the time that prior notice is being provided. The Secretary shall closely coordinate this prior notice regulation with similar notifications that are required by the U.S. Customs Service with the goal of minimizing or eliminating unnecessary, multiple or redundant notifications.

PERSONAL EXPLANATION

HON. HAROLD E. FORD, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. FORD. Mr. Speaker, regrettably, I was not present for the vote on final passage of H.R. 3529, the Economic Security and Worker Assistance Act, or the preceding motion to recommit.

Had I been present, I would have voted "Yea" on rollcall vote number 508, the motion to recommit, and "Nay" on rollcall vote 509 final passage of H.R. 3529.

UNITED STATES FOREST SERVICE AND FISH AND WILDLIFE SERVICE REPORTS

HON. GEORGE R. NETHERCUTT, JR.

OF WASHINGTON

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. NETHERCUTT. Mr. Speaker, the recent published reports about the planting of false evidence by biologists with the United States Forest Service and the United States Fish and Wildlife Service are alarming.

An internal Forest Service investigation has found that the science of the habitat study had been skewed by seven government officials: three U.S. Forest Service employees, two U.S. Fish and Wildlife Service officials and two employees of the Washington Department of Fish and Wildlife.

These officials, according to published reports, planted three separate samples of Canadian lynx hair on rubbing posts used to identify existence of the creatures in the two national forests. Had the deception not been discovered, the government likely would have banned many forms of recreation and use of natural resources in the Gifford Pinchot National Forest and Wenatchee National Forest in Washington State. The restrictions would have had a real-life devastating impact on the economy of Washington State.

Today I join with many of my colleagues in demanding that these employees, upon evidence of their guilt is established, be immediately terminated. It is unacceptable that these employees have simply been counseled for their planting of evidence. Federal employees should be held accountable for their actions—period.

Further, I support a complete review of the lynx study as well as a review of any other projects on which these employees may have worked. The integrity of these agencies and our future efforts to protect threatened and endangered species depends on these reviews. As a member of the Interior Appropriations Subcommittee, I intend to make sure that this kind of activity never happens again and that the agencies involved are not perpetrating a fraud on the American people. That is my highest responsibility.

BEST PHARMACEUTICALS FOR CHILDREN ACT

SPEECH OF

HON. BART STUPAK

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, December 18, 2001

Mr. STUPAK. Mr. Speaker, I rise tonight to urge Members to vote against the pediatric exclusivity bill, S. 1789. It is the product of a flawed negotiating process, a flawed legislative process, and a flawed regulatory process which was instituted back in 1997.

First approved in 1997, pediatric exclusivity granted drug companies an extra six-month extension on their patent if they would conduct a study to determine what the effects were on young people. The FDA sends a written request for a pediatric study to the drug company. Upon completion of the study, FDA grants a six month extension of the patent mo-

nopoly—the "pediatric exclusivity"—which the drug companies then use as a marketing tool to promote and increase the drug's sales.

What I find horrifying is the grant of exclusivity takes place after the drug company does its study but before anyone knows what is included in the results of the study. Nothing is said to the general public—which includes parents and pediatricians—or prescribing physicians about the safety, effectiveness, or dosage requirements. Under S. 1789, there is no requirement to change the labeling on the drug to reflect the changes that may be needed when the drug is dispensed to young people. There is no label to tell doctors, patients, and their families the proper dosage, or how to dispense or use the drug.

My argument has always been this: before you grant pediatric exclusivity to a pharmaceutical company and before this exclusivity is then marketed as being FDA approved for pediatric use, shouldn't you at least know what is the effect of the drug on young people?

Under current law—and this bill would extend current law after the study is completed, exclusivity is granted, but whether the drug helps or hurts young people remains a secret and is not disclosed to the doctors, patients, and their families for an average of 9 months. Shouldn't this information get out to these people before they ingest this medicine?

I have a chart, which I have used on the floor before. It highlights the problems with S. 1789, which does not require labeling changes until 11 months after the drug is being used in the pediatric population. How many of you would give your child a drug and not know whether it helps or harms your child until 11 months later?

There have been 33 drugs granted pediatric exclusivity. Only 20 have been re-labeled to reflect the results of the pediatric study, and even those label changes have taken an average of 9 months.

For 9 months, doctors, patients, and their families have no idea if the child is receiving the proper dosage or even if the drug is really safe!

Now why can't doctors, patients, and their families know this information before the grant of pediatric exclusivity is given? I was not allowed a chance to offer my amendment before the full House. My amendment is very simple and very commonsense: before pediatric exclusivity is granted, all drugs must be labeled especially for pediatric use.

Under other prescription drug patent extension programs, labeling is an absolute prerequisite to receiving patent extension. But not pediatric exclusivity. Why would we treat our children any differently?

For the love of me, I cannot understand why the majority does not want doctors, patients, and their families to know the effect of drugs may have on children!

What is the proper dosage? What is the efficacy? What is the safety level for our children?

Why do we wait an average of 9 months before we see proper labeling? Why must we wait to find out if a child has received the proper dosage?

Let us defeat this legislation. I urge a no vote.