

policing a civil war and toward counterterrorism, which requires fewer troops and gets many more of them out of harm's way. That is what our bill does. It is what the American people want. It is what the facts on the ground demand.

I urge the President to strongly reconsider this threat to veto this legislation. If he does, he will be making a terrible mistake, one that all of us and maybe even he will come to regret. I urge the President to sign the supplemental because it gives our troops and veterans the resources they need. It honors the sacrifices of those serving in Iraq with a change in mission that is long overdue, and it is my hope that one day we will all be able to say that we have accomplished our mission in Iraq. But until we change our mission and put in place a winning strategy, that day will continue to elude us.

I yield the floor.

The PRESIDING OFFICER. Under the previous order, the Senate will stand in recess.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate will stand in recess until the hour of 2:15 p.m.

Thereupon, the Senate, at 12:46 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. CARPER).

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007—Continued

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, on the bill under consideration at the present time, it is my intention to—and I have already placed at the desk two amendments, 987 and 988.

Briefly, what is the order right now?

The PRESIDING OFFICER. The Senator is recognized. The Senator has as much time as he may consume.

Mr. INHOFE. Today I have submitted amendments to S. 1082 requiring parental consent for intrusive physical exams administered under the Head Start Program. Young children attending Head Start Programs should not be subjected to these intrusive types of physical exams. We had an incident in my town of Tulsa, OK, where we felt that their rights, children's rights, were violated. They were subjected to different types of intrusive examinations. I will be bringing this up at an appropriate time.

Secondly, briefly, as I see the manager of the bill is here, we will be introducing an amendment No. 988, having to do with protecting children from parents being coerced into administering a controlled substance or psychotropic drug in order to attend school.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. INHOFE. Mr. President, I ask unanimous consent to withdraw my amendments, No. 988 and No. 987, with the intention to resubmit them when a substitute is made in a few minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. INHOFE. Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Mr. President, I believe the Food and Drug Administration Revitalization Act before us today raises and addresses issues that are critically important to the public's health and well-being. Congress has a historic opportunity to strengthen and increase knowledge about drug safety and effectiveness, bring more transparency to the process of drug approval and surveillance, as well as reassess the goals of the prescription drug and medical device user fee programs, and fortify and expand essential safety programs for children. The FDA Revitalization Act strikes a careful balance between these many important priorities and objectives.

Recent serious adverse drug events related to several widely used drugs on the market underscore the urgency with which we should address and improve drug safety in this country. Moreover, as the population ages and science inevitably advances, more and more drugs will come to market, presenting potentially groundbreaking health benefits to the public, but simultaneously increasing the need for sophisticated mechanisms for monitoring and assuring drug safety.

The FDA Revitalization Act is an opportunity to improve our current system of drug approval and drug monitoring, but it also adeptly anticipates changes in the future of prescription drugs and consumer safety brought about by advances in science and an ever expanding market for prescription drugs.

The primary mechanism this bill uses to strengthen drug safety is to strengthen and rearticulate the FDA's authority. The bill clarifies, and in some cases fortifies, the FDA's authority with regard to drug safety. Currently, if the FDA detects a problem, or a potential problem with a drug post approval, they have few options beyond what is often referred to as the "nuclear option." That is, pulling a drug from the market. While the FDA's authority to pull a drug from the marketplace is a powerful tool, it is a blunt instrument. In order to prevent problems from spiraling into major public health crises, the FDA needs intermediary authority. The FDA's reluctance to pull a

drug, potentially a drug upon which millions of Americans depend to manage an illness, unless it is overwhelmingly certain that the action is necessary, is understandable. However, prescription drug users suffer as a result since the "nuclear option" offers a forceful, but ultimately limited response. Pulling a drug from the market potentially delays action and places individuals at major health risks in the interim. On the flip side, pulling a drug prematurely may needlessly deny patients important, and in some cases, singular, treatments for their health needs. This bill offers what I believe is a good solution to this paradox; one that considers input from patients rights organizations, industry representatives, and the FDA, but ultimately places patients at the top of the list.

The risk evaluation and mitigation, REMS, system, the primary tool in the drug safety title of this bill, bolsters the FDA's intermediary authority to require drug manufacturers to monitor and provide important information regarding their products. By so doing, the FDA can actively require drug companies to provide information about the medications millions of Americans are taking and not just passively request drug companies to comply.

Most importantly, the REMS system focuses the FDA's efforts and resources on postmarket surveillance. Increased drug user fees would be used to review REMS as well as for general drug safety surveillance. User fee revenue will increase by \$50 million to fund drug safety activities, of which \$30 million is authorized for the routine drug surveillance once they are marketed. Many of us would like to eliminate the need for industry paid user fees, but this arrangement, agreed on by industry and the FDA, offers the best workable solution in this strained budget environment.

Another important objective of the FDA Revitalization Act is to improve the integrity of the agency and to enhance transparency on its actions. I am pleased that this bill improves the public's access to information about clinical trials and, more importantly, the results of those trials. The bill enhances patient enrollment in trials by requiring late phase II, as well as phase III and phase IV clinical trials on drugs are registered in a publicly available database. This will improve the public's knowledge of important and potentially life saving clinical studies. The bill also creates a publicly available database of the results of those trials. This means, for instance, that a parent who wishes to understand why a much-talked about treatment for juvenile diabetes failed to advance past a clinical trial stage can track the progress of a treatment using this database. It is important that we empower patients and consumers to gather information from primary sources so