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**STATEMENT OF SENATOR EDWARD M. KENNEDY ON THE PASSAGE OF
THE FOOD AND DRUG AMENDMENTS ACT OF 2007**

(As Prepared for Delivery)

Every day, families across America rely on the Food and Drug Administration in ways they barely realize. When they put dinner on the table, they are counting on FDA to see that it is free from contamination. When they care for a sick child, they are trusting FDA to make sure the drugs prescribed are safe and effective. From pacemakers to treatments for cancer to the foods we eat, FDA protects the health of millions of Americans, and oversees products that account for a quarter of the US economy. The agency does all this on a budget that amounts to less than two cents a day for each citizen.

An agency that does so much so well deserves to be supported and strengthened. Yet too often, the opposite has been true. FDA's vital mission has been jeopardized by inadequate resources, occasionally insufficient legal authority, and absent leadership.

Americans are worried about the safety of the products they use – from food to toys to drugs – and they are right to be worried. Dangerous lapses in safety oversight have exposed American families to intolerable risks from lead paint in toys, to bacteria in foods, to drugs that cause unreported and lethal side effects. The right response is comprehensive, considered and bipartisan legislation – and that's what the Senate has approved.

The prestigious New England Journal of Medicine editorialized earlier this year that the bill was “the most important drug-safety legislation in a century.”

Earlier this week, the House of Representatives approved this bipartisan measure by a broad bipartisan margin of 405 to 7. Our House colleagues from all parts of the political spectrum united to send that bill to the Senate with a resounding bipartisan endorsement. I am pleased that the Senate did the same, sending that bill to the President with a unanimous voice of approval.

The stakes could not be higher. Funding for the FDA's vital safety mission has reached the breaking point. If we had not acted, the FDA Commissioner would have sent a letter today to over 2,000 employees informing them that their jobs were slated for termination.

Each of those individuals is a trained and experienced professional with many career options in academia or industry – yet each of them has made the decision to devote themselves to public service. If those talented public servants had left the agency, the consequences would have been with us for years – in terms of slower access to

medicines for patients, weaker safety oversight and loss of America's competitive edge in the life sciences.

FDA has an urgent need for these funds. Its work load has increased massively in recent years but its resources have not kept pace. Since 1990, the number of adverse events submitted to the FDA has increased by over 1,300 percent, but the agency's resources have increased only 130 percent. The legislation provides over \$400 million this year for the review of drugs and medical devices at FDA, and over \$50 million for needed safety reforms to give these talented professionals the tools they need to do the job we are counting on them to do.

The bill before us is not just about resources – far from it. It is a strong and comprehensive measure to improve the safety of the medicines we rely on, and it takes important steps toward a safer food supply and less expensive prescription drugs.

At the heart of our proposal is a new way to oversee drug safety that is flexible enough to be tailored the characteristics of particular drugs, yet strong enough to allow decisive action when problems are discovered. For drugs that pose little risk, these actions might be as simple as a program to report side effects and a label with safety information – items that are currently required for all drugs. Drugs that raise major potential safety concerns might require additional clinical trials, a program to train physicians in using the drug safely, or a requirement that the prescribing physician have special skills.

A second major element of our legislation is a public registry of clinical trials and their results. A complete central clearinghouse for this information will help patients, providers and researchers learn more and make better health care decisions. Now, the public will know about each trial underway, and will be able to review its results.

Our bill recognizes that innovation is the key to medical progress by establishing a new center, the Reagan-Udall Foundation, to develop new research methods to accelerate the search for medical breakthroughs. During the discussions that led to consideration of this bill, we heard time and again that there was a major need for better research tools to aid FDA in evaluating the safety of drugs and devices and help researchers move through the long process of developing these products more effectively.

If new research tools and better ways to evaluate the safety and effectiveness of drugs could be developed, patients will benefit from quicker drug development. If current procedures can be made more effective, then the cost of developing new drugs will drop.

The Reagan-Udall Foundation sets up a way to develop these new tools – not so they can help just one researcher or one company, but so they can help the entire research enterprise.

The bill helps preserve the integrity of scientific review by improving FDA's safeguards against conflicts of interest on its scientific advisory committees – not through

a rigid policy that could deny FDA needed expertise, but through a flexible approach that will reduce the number of waivers given for conflicts of interest at FDA overall.

The bill also takes action on the abuse of citizens petitions. FDA has a common sense policy to allow ordinary citizens or medical experts to submit petitions to the agency about drugs that it is considering approving. This procedure should be used to protect public health – but too often, it is subverted by those who seek only to delay the entry onto the market of generic drugs.

Even if the petitions are found to be meritless, they will have accomplished their mission – delaying access for consumers to safe and lower cost medicines. Some petitions do present legitimate public health concerns, and FDA should not ignore them. The critical test of any proposal on citizen petitions is that it strike a balance so that the abuse of citizens petitions is prohibited, but those petitions that have genuine safety information are reviewed.

The proposal the Senate approved strikes that balance. It rightly states that the mere filing of a citizen petition should not be cause for delay, but allows FDA to delay the approval of a generic application if it determines that doing so is necessary to protect public health. This is the right approach. It prevents abuse, but protects health.

The legislation also includes important reforms of direct to consumer, or DTC, advertising. I want to thank Senator Roberts and Senator Harkin for working with Senator Enzi and me and with many members of the committee on this important provision.

Instead of the moratorium included in our original bill, the current proposal puts in place strong safety disclosures for DTC ads, coupled with effective enforcement. Under current law, safety disclosures can be an afterthought – a rushed disclaimer read by an announcer at the conclusion of a TV ad while distracting images help gloss over the important information provided. Our proposal requires safety announcements to be presented in a manner that is clear, conspicuous and neutral, without distracting imagery. We also give FDA the authority to require safety disclosures in DTC ads if the risk profile of the drug requires them.

Our legislation also takes important first steps toward a safer food supply. These are only first steps, and our committee will work on a comprehensive package of food safety legislation later in the fall – but they are important steps. Consumers and FDA have too little information about contaminated food. Our bill creates a registry and a requirement to report food safety problems. Consumers will have information about recalls at their fingertips, and FDA's response will not be slowed by antiquated and inefficient reporting systems. Our bill also establishes strong, enforceable quality standards for the food we give our pets, to guard against the problems of tainted pet food that we have seen in recent months.

In this new era of the life sciences, medical advances will continue to bring immense benefits for our citizens. To fulfill the potential of that bright future, we need not only brilliant researchers to develop the drugs of tomorrow, but also strong and vigilant watchdogs for public health to guarantee that new drugs and medical devices are safe and beneficial, and that they actually reach the patients who urgently need them. Congress has ample power to restore the luster the FDA has lost in recent years, and this bipartisan consensus bill can do the job. I congratulate my colleagues on approving this legislation, and look forward to working with them on its effective implementation.

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