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STATEMENT OF SENATOR EDWARD M. KENNEDY ON FDA REVITALIZATION ACT

EXECUTIVE SESSION OF HELP COMMITTEE

****Summary of bill below**

"In this week of great tragedy and sorrow for our nation, it is difficult to turn our attention to anything other than the unbearable grief of the families who have lost loved ones in the shootings at Virginia Tech. Our hearts and prayers continue to go out to them, even as we turn our attention to other issues.

Today, our committee considers legislation that affects every American family B the safety of the drugs we take and the medical devices that improve lives and alleviate suffering.

Every day, families across America rely on the Food and Drug Administration in ways they may not 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 anti-cancer pills to the foods we eat, FDA protects the health of hundreds of millions of Americans. It oversees products that account for a quarter of the US economy, and it 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, inadequate legal authority, and absent leadership. Congress has begun to take steps to correct these serious problems, but much more work lies ahead.

Last year, the Senate approved a new leader for FDA, which had been left without a full Commissioner for more than four of the last six years.

Effective leadership is essential, but it is not enough. FDA must also have the resources to keep up with the growing complexity of the scientific decisions it makes. Our legislation renews two basic programs at FDA, the user fee program for drugs and the similar program for medical devices. All of us would prefer that FDA rely less on user fees and more on appropriated funds, and legitimate questions have been raised about the agency=s need for these programs. But if adequate funding is not supplied by Congress, the user fees are essential for effective and timely reviews of drugs and devices.

Our legislation makes important changes in the user fee program, authorizing the fees to be devoted to drug safety needs, such as improved surveillance and the review of advertising.

Additional resources will help FDA make decisions based on the best available science. But the agency also needs new authority to implement those decisions. The confidence of millions of Americans in the drugs they take was shaken when the pain medicine Vioxx was withdrawn because of its serious side effects. It became clear that FDA's ability to protect the public was hamstrung by weak legal authority that kept it from taking swift and effective action. Inaction by Congress is no longer an option.

Today, the committee is considering common sense bipartisan reforms to give FDA the authority it needs to protect public health and to expedite the delivery of safe and effective new drugs and medical devices to the patients who need them.

The legislation before us also includes important provisions to encourage the testing of medicines for children, so that they too may reap the benefits of this new century of the life sciences. We're grateful for the leadership and vision of our colleagues on the committee, Senator Dodd, Senator Alexander, and Senator Clinton for these important measures that will do so much to improve the lives and enhance the health of the nation's children.

The legislation is based on the drug safety legislation that Senator Enzi and I introduced earlier this year, with important improvements suggested by members of our committee during the discussions that preceded the markup.

The bill establishes a new way to oversee drug safety that is flexible enough to be tailored to each new drug, yet strong enough to allow decisive action when problems are discovered. When needed, a new drug may be approved under a Risk Evaluation and Mitigation Strategy. For drugs with little risk, the strategy might not be required, or it might be as simple as a request to report side effects and a label with safety information, as are currently required for all drugs. For drugs that raise major potential safety concerns, the strategy might require additional clinical trials, a program to train physicians in using the drug safely, or even limits on advertising to the public.

We have strengthened the structure by including proposals to encourage the use of electronic databases to detect potential safety problems early, so that FDA can take timely action—such as through notice to doctors, warnings on the label, or additional studies to assess the risk.

A second major element of our legislation is a public registry of clinical trials and their results. A central clearinghouse for this information will help patients, providers and researchers learn more about particular drugs and diseases and make better health care decisions. The public will know about each trial underway be able to review its results, and patients will know about clinical trials in which they wish to participate.

Our bill recognizes that innovation is the key to medical progress by establishing a new center, the Reagan-Udall Institute for Applied Biomedical Research, to develop new methods to accelerate research for medical breakthroughs.

Finally, the bill helps preserve the integrity of scientific review by strengthening FDA's safeguards against conflicts of interest on its scientific advisory committees.

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 brilliant researchers to develop the drugs of tomorrow, and also strong and vigilant watchdogs for public health to guarantee that new drugs and medical devices coming into use are safe and beneficial, and actually reach the patients who urgently need them. Congress has ample power to restore the luster that FDA has lost in recent years. The legislation we propose represents a bipartisan consensus on the way to get the job done."

The Food and Drug Administration Revitalization Act

Title I—Prescription Drug User Fees

Title I codifies the user fee agreement reached by drug and biotech industries with the FDA. It establishes an overall amount for user fees of nearly \$393 million for 2008 (which will be adjusted upward based on 2007 workload). It includes the expansion of use of drug user fees by nearly \$30 million for post-approval drug safety programs.

Title I also includes the FDA-industry proposal to provide for a voluntary user fee program under which drug companies can submit direct-to-consumer television advertisements to the

agency for review before they are distributed.

Title II—Drug Safety

Subtitle A—Risk Evaluation and Mitigation Strategies

A system of routine active surveillance for post-market drug safety will be established through a public-private partnership. The partnership will aggregate data from Federal and private health databases and support the analysis of utilization and safety data from these databases. Active surveillance will occur for every newly approved drug.

Using a risk-based approach, drugs and biologics may be approved with risk evaluation and mitigation strategy (REMS). The REMS will be tailored to fit the safety profile of the drug in question. For drugs with new chemical entities, the REMS will be reviewed at 18 months and three years. For other drugs, review will occur at three years, although for all drugs, FDA has the authority to require a review if there are public health reasons to do so. The mark requires that personnel from offices for drug safety are integrated into the drug review process.

Minimal Elements of a REMS —

- FDA-approved professional labeling;
- A timetable for periodic assessment of the REMS.

Additional Elements of a REMS ----

For drugs with out of the ordinary risks, the REMS may include additional elements to protect patient safety, such as:

- Special training for doctors who prescribe the drug;
- Additional studies conducted after approval.

Compliance — Civil money penalties for violation of any component of a REMS.

Resources — Increased drug user fees would be used to review REMS and for FDA's general drug safety surveillance. This subtitle increases user fee revenue by \$50 million from the agreement between industry and the FDA to fund drug safety activities and authorizes \$30 million for the routine surveillance of drugs once marketed.

IMPROVING THE SCIENTIFIC ENVIRONMENT AT FDA

Transparency -- The mark includes important measures to promote transparency, such as posting of the action package for approval for drugs (including scientific commentaries), as well as requiring notice of the actions of the Drug Safety Oversight Board, and a report on the involvement of safety staff in drug review activities at FDA.

Improving Science -- The bill includes additional measures to improve science at FDA, including the establishment of an Office of the Chief Scientist, and putting in statute a required consultation with the Drug Safety and Risk Management committee on priority drug safety questions and on the effectiveness of aspects of the REMS process.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

Subtitle B establishes a foundation to lead collaborations amongst the FDA, academic research institutions, and industry directed to improving the process of drug development and evaluation. Collaborative research projects will be selected that are designed to bolster R & D productivity, provide new tools for improving safety in drug evaluation, and in the long term make drug development more predictable and manageable. This institute will be financially

supported by both industry and the government.

Subtitle C—Clinical Trials

Clinical Trials Registry — To enhance patient enrollment and provide a mechanism to track subsequent progress of trials, clinical trials of late Phase II, Phase III and Phase IV would be required to register in a publicly available database. Certain basic pieces of information would be placed in fields in the database entry, while the bulk of the information would be in summary documents.

Clinical Trials Results — To ensure that results of trials are made public, and that patients and providers have the most up-to-date information, publicly available information (including the FDA's action package on a drug) will be deposited in a publicly available database. Device clinical trials to support FDA approval or clearance are also included, as well as pediatric postmarket surveillance. FDA will be given regulatory authority to require inclusion of results for trials not covered by publicly available information. Civil monetary penalties will enforce these requirements.

Subtitle D—Conflicts of Interest

Subtitle D requires pre-disclosure of conflicts of interest of advisory committee members, and greater efforts by FDA to identify non-conflicted members.

Title III—Medical Device User Fees

The legislation included in this section implements the agreement between the Food and Drug Administration and the medical device industry groups. The legislation reflects the notice published in the Federal Registry. Congress was provided this legislation less than 24 hours prior to the required Committee deadline for filing. The Committee will continue reviewing this proposed legislation. Congressional changes, as required, will be incorporated prior to the floor.

Title IV – Pediatric Medical Products

Subtitle A – Best Pharmaceuticals for Children

Subtitle A would reauthorize the Best Pharmaceuticals for Children Act and improve its provisions in order to make it more effective at ensuring that drugs for children are safe for pediatric populations.

BPCA provides increased market exclusivity to drug manufactures to encourage the determination of safety and efficacy of drugs in pediatric populations. The bill contains a three month cap on exclusivity if the annual U.S. sales of the drug exceed \$1 billion when the written request for pediatric studies is accepted by the drug manufacturer. Products earning less than \$1 billion continue to receive six months of exclusivity.

The bill is a five authorization and will expire in 2012.

Subtitle B – Pediatric Research Improvement

Subtitle B would reauthorize the Pediatric Research Equity Act and improve its provisions in order to make it more effective at ensuring that drugs for children are safe for pediatric populations.

In order to improve coordination with the pediatric exclusivity provisions of the *Best Pharmaceuticals for Children Act (BPCA)*, PRIA would expand an internal FDA committee to review all issues of pediatric-related labeling and assessments. Doing so ensures that a drug under PRIA or BPCA is reviewed by experts with pediatric expertise.

If a company chooses not to pursue pediatric exclusivity for an already marketed drug under the *Best Pharmaceuticals for Children Act*, the Secretary has the authority to require the

submission of pediatric data for such drug. This authority has never been utilized, in part due to the lengthy administrative process required to invoke such authority. PRIA would streamline this administrative process and help get essential pediatric data for important drugs, while preserving the ability of companies to meet and discuss testing with the agency. It would also expand the ability of the Secretary to use this authority in cases where such data would represent a benefit to a large number of children, or help us to learn more about risks associated with certain drugs.

The bill would require two reports – one from the Institute of Medicine and one from the GAO – that would allow us to have better data on the number and ways in which the pediatric rule is used, and evaluate its contributions to ensuring overall pediatric drug safety.

Subtitle C - Pediatric Medical Devices

Subtitle C modifies the existing humanitarian device exemption (HDE) for medical devices to allow profit for HDE-approved devices specifically designed to meet a pediatric need.

Maintains existing requirement that a humanitarian use device is limited to one that treats and diagnoses diseases or conditions that affect fewer than 4,000 individuals in the U.S. per year. No profit will be allowed for a device used in more than 4,000 individuals. The HDE exemption expansion sunsets in 2013 and a GAO report assessing the HDE exemption expansion and its impact on patients and manufacturers is required.

The bill establishes a mechanism to allow FDA to track the number and types of devices approved specifically for children or for conditions that occur in children, as well as the approval times for premarket applications and HDEs.

NIH will be required to designate a contact point or office to help innovators and physicians access existing funding for pediatric medical device development and directs NIH, FDA, and AHRQ to submit a plan for pediatric medical device research that identifies gaps and proposes a research agenda for addressing them.

Demonstration grants will be established for non-profit consortia to promote pediatric device development, including “matchmaking” between inventors and manufacturers and connecting innovators and physicians to existing Federal resources, including FDA, NIH, the Small Business Administration, VA and others.

The bill grants explicit authority to the FDA’s Pediatric Advisory Committee to monitor pediatric devices and make recommendations for improving their availability and safety.

This approach incorporates several recommendations of the Institute of Medicine including improving the postmarket surveillance of medical devices used in children.

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