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**Bill summary and list of supporters included (full letters of support available upon request

STATEMENT OF SENATOR EDWARD M. KENNEDY ON THE FDA REVITALIZATION ACT

This week, the Senate has the opportunity to set a new and better direction for the safety of the prescription drugs and medical devices that make such a profound difference in the lives of our people.

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 the FDA to see that food is free from contamination. They trust the FDA to make sure that the drugs they take are safe and effective. From prescription drugs to pacemakers to chemotherapy to the food we eat, the FDA protects the health of hundreds of millions of Americans, and monitors products that account for a quarter of the nation's economy.

The FDA should be the gold standard for safety but its luster has been tarnished in recent years by failure to protect the American people from unsafe drugs. The public was shocked that the arthritis drug Vioxx was able to stay on the market for 5 years, even though it nearly doubled the risk of heart attack and stroke. Antidepressants used by millions were found to increase the risk of suicide in adolescents. Millions of Americans have needlessly been put at risk, and they want action by Congress to reform and strengthen the agency.

We're responding now with bipartisan legislation that is the product of months of work in our committee. I commend my colleague in this effort, Senator Enzi, for his work on this proposal that will improve the way FDA oversees the safety of the drugs. Almost half of all Americans take at least one pill a day, so this legislation will make a difference in the life of every American family. Our proposals were also strengthened by our colleague from New Hampshire, Senator Gregg.

Safety is at its core. Our legislation was guided by the recommendations of the impressive report by the Institute of Medicine on the future of drug safety. Its major recommendations for reform are included in this legislation.

The Institute recommended improving surveillance so that signals of problems in drug safety can be caught early, and lives can be saved. In the case of Vioxx and similar drugs like Celebrex and Bextra, more widespread use of such databases would have saved lives in the past.

That's not conjecture- it's actual experience. A small number of health systems in America already use electronic records effectively and link them to safety databases. These systems Kaiser Permanente, the Mayo Clinic, and the Veterans' Administration all had the means to examine whether Vioxx and other drugs were being used effectively. They found that these drugs were being prescribed inappropriately, and took steps to curb this overuse. As a result, they approved the use of these medications only for patients who had no other options. Overuse went down, and safety improved.

The use of these databases should not be limited to the few health systems that currently use them. FDA should make use of every aspect of modern health care technology to safeguard the public's health. Mark McClellan, the former FDA Commissioner, calls these kinds of systems Ahealth IT for drug safety, and our proposal includes his recommendations.

Surveillance is essential, but effective action is needed when a safety problem is detected.

Each drug has unique risks and benefits. There can be no 'one size fits all' approach to drug safety. That is why our legislation includes a flexible but effective program for safety. We call it a Risk Evaluation and Management System. It can be tailored to the unique characteristics of each drug. It gives FDA the authority to act when action is needed to protect public health, but it also contains safeguards to prevent such action from being imposed when there is no reason to do so.

For some drugs, it is essential to require post-market studies. Yet FDA today lacks the basic authority to require such trials to be conducted. FDA can request them but it can't require them, and has few ways to see that they are completed. As a result, companies routinely promise to conduct studies that are never even started much less completed.

According to the New England Journal of Medicine, three quarters of post-market studies requested by the FDA have never been started, and only 11 percent have been completed and have filed their results with the FDA. It is absurd that the FDA can identify a public health need and request a study but can take no action when its request is ignored. Its only alternative is to enforce its request with the empty threat to withdraw the drug from the market a severe measure that FDA rightly only uses when there is a direct threat to patients. With no ability to take intermediate enforcement measures, FDA must stay on the sidelines while companies ignore their responsibilities.

In its recent report on drug safety, GAO pointed out the failure of the current system. Its report states, "In the absence of specific authority, FDA often relies on drug sponsors voluntarily agreeing to conduct such post-market studies. But the post-market studies that drug sponsors agree to conduct have not consistently been completed. FDA has little leverage to ensure that these studies are carried out, for example, by imposing administrative penalties."

Our legislation solves this major problem. It gives FDA clear authority to require the conduct of post-market studies when there is a public health need to do so, and it gives FDA the ability to assess fines on those who ignore their responsibilities.

Databases and post-market studies help detect problems, but FDA needs the ability to take other action to protect public health. Here too, current law is inadequate. FDA lacks clear authority to require measures to protect public health. When lives are on the line, doctors are making the critical decisions. But because FDA's authority is so unclear, it must first call the lawyers for their opinion as to whether the agency can act.

The Institute of Medicine identified this major weakness of current law and called on Congress to give FDA the authority to require risk management programs when needed to protect health.

These programs can be as simple as new information on a drug label, or an advisory notice to doctors, or as sophisticated as special monitoring programs for patients who use a particular drug. The legislation does not make the decision about which measures should be taken for which drugs but it does give FDA the authority to make the right choice for public health.

This authority has been lacking in the past. For Vioxx, it took 14 months to change the drug's label to warn doctors and patients of the danger. Because FDA had weak authority, it had to ask the manufacturer to change the label, voluntarily and the manufacturer stalled and stalled.

When patients are in danger, FDA should not have to wait to get legal opinions to decide how to protect health. It should be able to act immediately, and our bill gives them that authority.

In many cases, companies have hidden evidence of safety problems. Our bill addresses this abuse by including a public database of all clinical trials and their results. A company will no longer be able to conduct a trial, and then hide the results if they don't show what the company wanted.

Some would say that any increase in drug safety will inevitably decrease access to needed drugs. But that's a false argument. Consider the situation now when FDA is confronted by a new drug that may pose safety risks or where additional study may be required. With little expectation that those risks will be mitigated by voluntary approaches and with no ability to ensure that the studies are conducted, FDA might reasonably conclude that the risks of approving the drug are too great.

Under our legislation, the calculation is reversed. With this bill in place, FDA could allow patients to have access to the drug, secure in the knowledge that effective safety measures were in place.

That's not just my judgment it's the judgment of a coalition of advocacy organizations representing over 30 million patients. This coalition, the Alliance for Drug Safety and Access, wrote Congress a letter saying: "This legislation gives the FDA the ability to continue to study the safety of drugs after approval, flexible enforcement tools necessary to ensure compliance with these new safety protections, and additional funding to support these new activities.

Allowing the agency to act on clear safety signals could actually allow the FDA to approve drugs more quickly, knowing it will have the ability to respond on behalf of patients if safety concerns appear post-market."

That's the balance our legislation strikes: greater safety, hand-in-hand with better access.

As our debate continues, I'll discuss additional aspects of the legislation especially its new ideas for accelerating drug development, its renewal of our commitment to safe and effective drugs for children, and its provisions to improve drug science and increase the transparency of the FDA.

I'm also working with my colleagues from Iowa and Kansas, Senator Harkin and Senator Roberts, on ways to refine our provisions on direct-to-consumer advertising, to make certain they are consistent with the Constitution.

I'm also working with Senator Durbin and other colleagues on the committee on proposals on food safety and on pet food. These bipartisan proposals are being readied for floor action shortly, and I look forward to further discussion of them. Our committee will continue to work to improve the ways that FDA can monitor and improve food safety.

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 that FDA has lost in recent years. The legislation we are now considering represents a bipartisan consensus on the best way to get the job done.

**Below is a summary of the bill

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 a user fee program under which drug companies can submit direct-to-consumer television advertisements to FDA 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. The partnership will aggregate data from Federal and private health 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). 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 steps up user fee revenue annually, including \$25 million authorized for the routine surveillance of drugs once marketed to reach the \$100 million called for by the IOM.

Direct to Consumer Ads (DTC) – The bill as reported allows FDA to impose a moratorium on DTC in rare circumstances. We are evaluating whether requiring expanded safety information in DTC ads, coupled with fines for misleading ads may be an alternate way of achieving the goal of accurate information to consumers.

IMPROVING THE SCIENTIFIC ENVIRONMENT AT FDA

Transparency -- The bill 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. HHS 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 implements the agreement between the FDA and the medical device industry groups. It reauthorizes the medical device user fee program, streamlines the third part review program, and provides for electronic registration of device manufacturing plants.

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 are safe and effective for pediatric populations. BPCA provides increased market exclusivity to drug manufacturers to encourage the determination of safety and efficacy of drugs in pediatric populations. The bill contains a three month adjustment on exclusivity if the annual U.S. sales of the drug exceed \$1 billion. Products earning less than \$1 billion continue to receive six months of exclusivity.

Subtitle B – Pediatric Research Improvement

Subtitle B reauthorizes the Pediatric Research Equity Act to make it more effective at ensuring that drugs for children are safe and effective. If a company chooses not to pursue pediatric exclusivity for an already marketed drug under the Best Pharmaceuticals for Children Act, the Secretary can require the submission of pediatric data for such drug. This authority has never been utilized for drugs that are already approved, 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. 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 with certain drugs.

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. It 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.

Miscellaneous Provisions

The bill contains two amendments adopted in committee: one on medical marijuana and the other on drug labeling. It also makes a technical correction to two bills enacted last year: the BARDA legislation and the NIH reauthorization.

Supporters of the Chairman's Mark:

Jim Guest, President and CEO of Consumer's Union
William G. Lang IV, VP Policy and Advocacy of the AARP
Dwight Reynolds, MD, FHRS, President of the Heart Rhythm Society

AIDS Alliance for Children, Youth & Families
The Alliance for Drug Safety and Access

- AIDS Treatment Action Coalition
- American Academy of Pediatrics
- American Academy of Child and Adolescent Psychiatry
- American Psychiatric Association
- Christopher and Dana Reeve Foundation
- Elizabeth Glaser Pediatric AIDS Foundation
- National Multiple Sclerosis Society
- National Organization for Rare Disorders (NORD)
- Parkinson's Action Network
- Tourette Syndrome Association
- American Association of Colleges of Pharmacy

American Brain Coalition
American Pediatric Society
American Thoracic Society
Arthritis Foundation
Association of Medical School Pediatric Department Chairs
Children's Cause for Cancer Advocacy
Consumers Union
Heart Rhythm Society
National Association of Children's Hospital
National Research Center for Women and Families
Society for Cardiovascular Angiography and Interventions
Society for Pediatric Research
Dana Farber Cancer Institute (Drug Safety Provisions)