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STATEMENT OF SENATOR EDWARD M. KENNEDY ON THE NOMINATION OF DR. MARGARET HAMBURG TO BE FDA COMMISSIONER

As Entered into the Record

The FDA's mission is to oversee the safety, effectiveness, and security of the nation's food supply, drugs, medical devices, biologics, and cosmetics. It helps expedite innovations to make these products even safer, more effective, and more affordable, before, during, and after approval.

These responsibilities are enormous. The agency regulates approximately $1 trillion of consumer goods, and about 25% of consumer spending in the United States. It covers approximately 80% of the nation's food, including 60% of fresh fruit and vegetable imports and 75% of seafood imports, $275 billion in drug sales, $60 billion in cosmetics sales, and $18 billion in sales of vitamin supplements each year. Its responsibilities have grown significantly over the years, but its ability to meet them has not kept up.

We have recently seen recalls on pet food, peanut butter, pistachios, lettuce, spinach, ground beef, chicken pot pie, and frozen pizza. Drugs like Vioxx, Baycol, Bextra, Seldane, and Tequin were approved, and then removed from the U.S. market, for safety reasons. Contaminated heparin recently made its way to our shores and killed 80 Americans.

It's been clear for some time that the agency has been chronically underfunded. Its budget per American citizen each year amounts to little more than the cost of a fast food meal. The regular intake of fast food is not the well balanced diet we need to be healthy, and it can't be good for the FDA either.

The agency needs more than additional funds, however. Morale is low. In recent years, science has often taken a back seat to political pressure. It's a sad state of affairs when a court rules that the "FDA acted in bad faith and in response to political pressure" and orders the agency to base a decision on science.

On its website at the end of 2007, the FDA published a report, "FDA Science and Mission at Risk." The report concluded, "The FDA cannot fulfill its mission because its scientific base has eroded … its scientific workforce does not have sufficient capacity and capability… [and] its scientific organizational structure is weak."

It is abundantly clear that the agency needs strong, new leadership to improve morale and make it once again the world class agency that Americans can trust to protect the health of their families. I'm very pleased, therefore, that President Obama has nominated Dr. Margaret Hamburg to lead the FDA as its new Commissioner.

Dr. Hamburg is widely respected for her expertise in community health, bio-defense, and nuclear, biological, and chemical preparedness. Her expertise is valuable for problems we now face, such as combating food-borne illness, cooperating with other agencies to address the new flu outbreak and drug-resistant diseases, and protecting our food and drug supplies.

Dr. Hamburg graduated from Harvard Medical School, and completed her residency training at what is now New York Presbyterian Hospital-Weill Cornell Medical Center, one of the top-ten hospitals in the nation, and a center of excellence. She conducted research on neuroscience at Rockefeller University in New York, and later on neuropharmacology at the National Institute of Mental Health on the NIH campus in Bethesda.

She then served in the Office of Disease Prevention and Health Promotion, and later focused on AIDS research when she became Assistant Director of the National Institute of Allergy and Infectious Diseases at NIH.

In 1990, she joined the New York City Department of Health and Mental Hygiene as Deputy Health Commissioner, and within a year was promoted to Commissioner. The job was complex and demanding, and she faced many responsibilities and severe budget constraints. She improved services for women and children and instituted needle-exchange programs to reduce the spread of HIV. She curbed the spread of tuberculosis, and initiated the first public health bio-terrorism defense program in the nation. During this time, she also held academic positions at Columbia University School of Public Health and Cornell University Medical College.

Her leadership was especially impressive on tuberculosis, which was the leading infectious killer of youths and adults in the 1990's and had become resistant to standard drugs. Some of the newer drugs required patients to take pills every day for up to two years, and not completing the full course of treatment encouraged the development of drug resistant strains. In response, health care workers went to patients' homes to help them complete the drug regimen. In a 5 year span, the TB rate in New York City fell by 46% overall, and 86% for the most drug-resistant strains. Her innovative treatment plan has become a model for health departments world-wide.

In 1993, Dr. Hamburg was President Clinton's first choice for the newly-created position of federal AIDS coordinator, but she declined because she was pregnant with her first child. Today, her children's birth certificates have her name in two places: one as their mother, and the other as Health Commissioner. When President Clinton asked her in 1997 to be Assistant Secretary for Policy and Evaluation at the Department of Health and Human Services, she accepted.

She was also one of the youngest persons ever to join the Institute of Medicine when she was elected in 1994.

In 2001, she became Vice President for Biological Programs at the Nuclear Threat Initiative, which is dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons. She has advocated broad reforms in public health infrastructure and policy,

from local health departments to the national agency, in order to meet the dangers of modern bioterrorism.

Dr. Hamburg will face many challenges as FDA Commissioner, and she is obviously well-qualified to deal with them. She has impressive experience in both clinical practice and research, and her experience in preparedness makes her ideal to manage disease outbreaks. Influenza A, the "normal" flu, hospitalizes more than 200,000 Americans a year and kills more than 35,000. We don't have a full sense yet of the severity of the new H1N1 flu, but it is obviously a novel virus which has dangerous potential and has quickly spread throughout the world. There is an urgent need to confirm the new Commissioner so that she can begin setting a better course for the FDA on food, drug, and cosmetic safety. We can't afford to wait.

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