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July 15, 2010

The Honorable Kathleen Sebelius
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

We would like to thank you again for taking the time to meet with SWHR and would like to take this opportunity to follow up with you one of our priority issues, increased appropriations to strengthen the Food and Drug Administration (FDA). As you work to develop the President's budget for Fiscal Year 2012, we respectfully urge you to make the FDA one of your top priorities.

As you know, FDA is tasked with guarding the safety, efficacy, and security of human drugs, biological products, and medical devices. These products represent approximately 25 percent of consumer spending in the U.S.; however, FDA continues to face severe resource constraints due to years of chronic underfunding and an exponential increase in the agency's public health responsibilities. Serious threats such as the recent H1N1 Influenza Virus and the increasing globalization of the products FDA regulates has posed new challenges to the FDA, without an appropriate adjustment in staff or resources.

Consistent funding increases over a sustained time period are essential to restoring the FDA's capacity to handle a rapidly growing list of complex public health responsibilities. FY 2010 staffing levels from budget authority appropriations remains the same as it was in 1994. With over 80% of FDA's budget allocated toward its scientists and staff, it is time to carefully consider the impact and ramifications of **not investing** sufficiently into the human collateral that has made the FDA the world leaders in drug and food safety. Until sound and sustainable investments are made in FDA's staff, training, and infrastructure, it will be forced to act in a reactionary way against threats to food and drug security, rather than in an offensive strategic approach.

One area that FDA is greatly suffering is in its information technology (IT) systems. As recently as 2007, the Science Board Report, requested by then Commissioner von Eschenbach, found FDA's IT systems to be insufficient and incapable of handling the current demands placed on the FDA, thus preventing the Agency from fulfilling its mission. In its capacity as a monitoring body, the FDA's IT system is one that must function around the clock, and at its present state it simply cannot keep up with current scientific data, new technology, and technological advances. The move towards electronic health records and increasing advances in health IT will only strain the current system further.

FDA receives large volumes of information for evaluation and review in

applications from manufacturers. FDA reviewers, in some instances, must manually comb through the submitted drug trial reports and digital data in as many as twelve different formats when evaluating a new device or drug's safety and effectiveness. Frequently, reviewers must handpick data from stacks of paper reports to form their own data comparisons. This process is time consuming, making the review process less efficient, more error-prone, and culminates in delayed results and access to important treatments and information for patients and consumers.

The insufficient nature of the FDA's current IT infrastructure also hinders it from being able to track women, men, or other subpopulations separately in clinical trials. This is a matter of critical importance to SWHR and to the population at large. Currently, FDA has general guidance and regulatory authority to require that the data collected during research of a new drug's safety and effectiveness be analyzed by sex, race, and ethnicity; however, this requirement is generally not adequately enforced- if enforced at all. FDA should be able to determine how many women participated in a clinical study, both by recruitment and retention rates. The FDA's IT system should also be able to account for any sex or gender based differences in study results, as well as information about the ways drugs may differ in various populations, in all stages of clinical trials- from Phase I to the post-market review process.

It is within this critical "watchdog" capacity that the Office of Women's Health at FDA (OWH) operates. The OWH supports sex-and gender-based research, providing scientific and policy expertise on sex and gender sensitive regulatory and oversight issues, and endeavoring to correct sex and gender disparities in areas for which FDA is responsible-drugs, devices, and biologics. Despite exhausting its budget each year, OWH continues to provide women with invaluable tools for their health. OWH funds high quality, scientific research to serve as the foundation for FDA activities to improve women's health and as part of its educational outreach to consumers and patients, and has used its website to serve as a vital tool that includes free, downloadable fact sheets on over one hundred different illnesses, diseases, and health related information for women.

Continued chronic underfunding of FDA affects public health, hinders the economy and compromises national security. SWHR requests at a minimum a twenty percent increase over the FY 2011 budget, so that the FDA may sufficiently improve upon its current operations while also rebuilding its IT infrastructure. These improvements are critical to propel the agency into the 21st century, as well as the age of personalized medicine.

Thank you for your leadership on this important issue.

Sincerely,

Phyllis Greenberger, MSW
President and CEO

Martha Nolan, JD
Vice-President of Public Policy