**From:** A Message from the Commissioner
**Sent:** Wednesday, July 13, 2011 3:41 PM
**To:** FDA-Wide
**Subject:** A Message from the Commissioner

Dear Colleagues,

I am writing today to let you know about some changes that I will be making to the agency's management structure. As you probably recall, back in January, I told you that I was initiating a review of the Office of the Commissioner. As I explained at that time, this review was driven by the expanding and rapidly changing nature of the Agency's responsibilities, and the need for a management structure that reflects these changes and best supports your efforts.

I consulted with former Commissioners, as well as with HHS Secretary Sebelius, and considered many options before arriving at the structure that I am announcing today.

The most important thing driving my consideration of this is the changing nature of both the Agency and the job of Commissioner.

Today, the Agency faces several key challenges:

First, we are a very large agency, with an incredibly broad span of responsibility. We regulate products that account for between 20 and 25 percent of every consumer dollar spent in the U.S. and that total more than a trillion dollars annually. For the most part, these are products that people rely on in fundamental ways every day.

Second, as technology and science continue to evolve, we are faced with the challenge of making sure that new ideas translate into the products and opportunities that people need and count on to protect their health. Innovative products that are truly transformative create unique scientific and regulatory challenges, and FDA must be a consistently powerful catalyst for innovation.

Third, we have seen the dramatic transformation of globalization – more products, more countries, more access by consumers and companies to global supplies – and this presents an enormous challenge to FDA in ensuring the safety and quality of the products we regulate.

Finally, we continue to be faced with administrative challenges. In these difficult economic times, our agency's budget requires constant attention. And, simply providing the support and services for our 12,000 plus employees – everything from phones to IT to office space on our beautiful, growing White Oak campus – is a daunting job.

I take very seriously my responsibility to lead FDA along a path that will meet these challenges. One crucial part of this responsibility is to create a structure in the Commissioner's Office that best supports your efforts and reflects the changing nature of the Agency.

The structure of the Office of the Commissioner that I inherited was created in 1970, when the FDA consisted of three Centers and a field office. By 2011, we had grown to seven Centers, and a

Commissioner's Office with more than 1,600 staff. Over the years, as Congress created new programs that cut across Center responsibilities, those programs were placed by default in the Office of the Commissioner.

The new organizational alignments more accurately reflect the agency's responsibilities, subject matter expertise and mandates in an ever more complex world, where products and services do not fit into a single category.

Let me begin by saying that, for most of the FDA, this organizational alignment will likely not have a significant impact on you or your day-to-day work.

The most obvious change you will see is that the Agency's programs, in terms of a reporting chain to me, will be divided into "directorates" that reflect the core functions and responsibilities of the Agency. This new management structure will enable the Office of the Commissioner to better support the agency's core scientific and regulatory functions, and help tie together programs that share regulatory and scientific foundations. I will rely on the leadership of these directorates to help provide the necessary direction and coordination needed by an Agency of this scope.

I am establishing a new Deputy Commissioner for Medical Products and Tobacco, who will provide high-level coordination and leadership across the Centers for drug, biologics, medical devices, and tobacco products. The Centers will, of course, remain as discrete management entities under their current expert leadership. In addition to this strategic role with the Centers, this position will oversee our Special Medical programs.

I am pleased to announce that Dr. Steven Spielberg, former Dean of Dartmouth Medical School and currently Director of the Center for Personalized Medicine and Therapeutic Innovation at Children's Mercy Hospital in Kansas City, has accepted this position. In this role, Dr. Spielberg will serve as both advocate and a support for Center Directors in their important work for FDA.

I will also be creating a directorate focused on grappling with the truly global nature of today's world -- food and drug production and supply, as well as the science that undergirds the products we regulate -- so that the FDA can move from being a regulator of domestic products to one overseeing a worldwide enterprise.

To oversee this transformation, I have asked Deborah Autor, now Director of CDER's Office of Compliance, to take on the role of Deputy Commissioner for Global Regulatory Operations and Policy. In this position, Deb will provide broad direction and support to the Office of Regulatory Affairs and to the Office of International Programs, with a mandate from me to make response to the challenges of globalization and import safety a top priority in the years to come. Dr. Murray Lumpkin, who has served with dedication and accomplishment as Deputy Commissioner for International Programs and Director of the Office of International Programs, will take on a new role as Senior Advisor and Representative for Global Issues. In this role, he will be charged primarily with special projects that draw on his expertise working with counterpart regulatory agencies on issues of global regulatory harmonization, governance and capacity-building.

The third directorate is the previously established Office of Foods, which we created to make our oversight of FDA's food and feed program a more seamless enterprise. That task is even more important today as Mike Taylor leads the implementation of the Food Safety Modernization Act.

The fourth directorate will be a new Office of Operations, headed by a Chief Operating Officer. The COO will oversee the agency's administrative functions, such as human resources, facilities, information technology, finance, and other activities that provide support to your organizations. Within this Office, I am bringing the budget formulation and budget execution functions together under a CFO position. We have initiated a search to fill the Chief Operating Officer position.

The Office of the Chief Scientist, charged with our important efforts to improve FDA's science and address issues of cross-cutting scientific concern, will continue to do so. The National Center for Toxicological Research will report to the Chief Scientist, Dr. Jesse Goodman, and, like the other Centers, will remain a discrete management entity within this new directorate model.

Within the new, smaller, immediate office of the Commissioner, John Taylor will remain as Counselor and will have the additional responsibility to oversee the policy and planning functions, the Office of Legislation, and the Office of External Affairs. I want to thank John for serving as acting Principal Deputy these past months, in addition to his duties as Counselor. He has tirelessly supported me and the Agency with enthusiasm, energy, expertise, and good humor.

You can find revised organizational charts, reflecting this realignment at http://inside.fda.gov:9003/AboutFDA/FDAStaffInformation/OrgCharts/default.htm. In addition, I will share a video message of this announcement shortly. Your managers will be available to answer any questions you might have in the coming days.

In closing, I want to take a moment to thank you so much for all that you do. FDA is an extraordinary place, with so many highly-dedicated professionals and support staff who are committed to promoting and protecting public health. You accomplish a tremendous amount every day and I am grateful for all of your work. These organizational changes are intended to help further your important work and the mission of this remarkable Agency.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs