Proposed Modernization of FDA's Drug Review Office

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June 4, 2018 By Food and Drug Administration (FDA)

Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed modernization of FDA's drug review office

Scientific and medical advances are giving the FDA more opportunities to more fully address diseases and illness. Whereas one time all that patients may have hoped for was the ability to control a chronic disease, and perhaps slow its advance or lessen its insidious effects, more patients today can expect the ability to arrest the march of illness or achieve an outright cure.

However, with this progress comes more complexity. Not only challenges related to the science of how drugs are discovered, but also the manner in which they're developed. For very novel drugs targeting unmet needs, this often doesn't follow the traditional three phases of clinical trials.

To promote the most promising opportunities and address the corresponding intricacy of these new endeavors, the FDA has introduced many fundamental advances in how it evaluates drugs for safety and effectiveness, as well as the manner in which clinical trials are guided. These include adaptive approaches to clinical development such as the introduction of seamless trial designs or master protocols or tissue agnostic product approvals. Each allow us to better marry the scientific prospect more closely to the approaches that can best unlock these opportunities.

So do the introduction of new scientific domains into the development and review process. This includes the more widespread use of modeling and simulation, the greater use of real-world evidence in the pre- and post-market setting, and the adoption of better tools for collecting and evaluating more real-time safety information after products are approved.

Some advances in our own processes are going to be achieved through more modern and scientifically rigorous approaches to how we collect and evaluate clinical data as part of the drug development process. But other features of our modernization require us to also change the way that we configure the structure and function of our process for reviewing this information.

To advance these public health goals, the director of our Center for Drug Evaluation and Research (CDER), Dr. Janet Woodcock, has proposed to her center an important series of new steps to

modernize the organization and functions of CDER's Office of New Drugs.

One principal aim of these proposed changes is to elevate the role of our scientists and medical officers to take on even more thought leadership in their fields. Our professional staff members are our house officers. They are the backbone of our process and the heart of our public health mission. We want to give our clinicians and scientists more time, better tools and greater support to advance the clinical and regulatory principles that the FDA uses to evaluate new drugs for safety and efficacy. One goal of this modernization of our process, for example, will be the ability to issue much more product-specific guidance documents. We'll develop hundreds of new clinical guidance documents and make sure they stay up-to-date to reflect the latest science.

We believe that some of the new organizational structures we're considering could also allow our review staff to have more time for reviewing and providing feedback to sponsors on clinical protocols. One goal is to engage sponsors earlier in the development process to ensure that trial designs are efficient and structured in the most effective way to identify risks and measure benefit. Equally important, there will also be more ability to engage external stakeholders, such as disease specialists, academic researchers and regulatory partners at other agencies. And with patient-focused drug development becoming a reality, ongoing relationships and interactions with patient groups are becoming an important part of our regulatory practices.

We believe that part of these modernization efforts will be enabled through increased organizational efficiency and possible structural changes that would ultimately flatten the overall matrix of our review process. As part of this effort, for example, we're considering creating many new therapeutic-specific divisions that'll have more ability to engage in discrete areas of medicine.

The goal is to make sure that the drug review divisions are therapeutically focused to promote efficient review and provide greater scientific leadership to academic, industry and patient groups. We believe this will deepen internal collaboration and enhance external scientific exchange.

In turn, outside stakeholders and patients, who are focused on specific therapeutic areas, will have more points of contact to the therapeutic areas they're most focused on. In the past, our structure was organized in a way to match our workload to our different divisions and offices. The goal was to make sure that there was balance across the different offices and divisions. So our organizational structure doesn't always follow the subdivisions of medicine. That's why we think these proposals may create a superior structure – one that's based on the optimal clinical and public health configuration. In turn, we'll then staff these different divisions in a way that matches our manpower to the flow of applications and critical tasks like post-market safety.

The proposed structural changes under consideration are one key element of this modernization effort, but the heart of our proposal is the reforms aimed at improving how we do our work.

Our goal is also to make the scientific disciplines that conduct review more tightly integrated around a common review process, and a common review template that's more easily collaborated around. We want to make the entire review process more integrated across the discrete areas of science and regulatory expertise that are critical components of informing our overall mission.

We also want to make the entire review process and the development of the key review memos better organized, so that our medical staff can document their findings more efficiently and spend more of their time on advancing scientific work in their fields. According to our own assessment, we believe the new alignment and processes will improve efficiency by 20 percent at a minimum overall. This is, in part, the result of better workflow and workforce management and greater internal collaboration across the different review functions. The additional efficiency we achieve will be channeled toward the development of more product guidance and thought leadership. We'll engage the external community more closely in our work, especially patients who inform our patient-focused drug development, with the aim of advancing more modern regulatory principles.

This proposed modernization of the organization and function of our Office of New Drugs is a major undertaking. It's the culmination of the work and leadership of Dr. Woodcock and her talented team. It reflects her longstanding commitment to advancing the public health by making sure our science and organization match the complexity and opportunity of the novel products that we're tasked with evaluating. As in all our work, the goal is to make sure that we continue to fulfill our mission and meet the aspirations of patients, and protect and promote the public health.

I'm fully committed to these efforts, and support Dr. Woodcock in these important endeavors.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

This statement was originally published on the Food and Drug Administration website on June 4, 2018.

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