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EDITOR'S PAGE

Scott Gottlieb's Resignation as FDA Commissioner Is a Loss for Translational Medicine

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On March 5, 2019, Dr. Scott Gottlieb announced that he was resigning as the commissioner of the U.S. Food and Drug Administration (FDA). Although many people were initially skeptical that Dr. Gottlieb would be effective leader at the FDA, given his prior antiregulatory comments as well as his ties to major pharmaceutical firms, there is a growing consensus that he has been an effective champion for important public health care policies, including the opioid epidemic, drug pricing, and teen vaping. Moreover, as will be discussed below, he has also been a strong advocate for the development of new drug and device therapies, which will have important implications for cardiovascular translational medicine.

Under Dr. Gottlieb's leadership, the FDA's Center for Drug Evaluation and Research (CDER) approved a record high of 62 new therapeutic drugs in 2018, which exceeded the prior record of 53 approvals in 1996 (1). Dr. Gottlieb also announced that the FDA was planning to create a 52-person Office of Drug Evaluation and Science that would have its own director and 3 separate divisions, including a Division of Biomedical Information and Safety Analytics, charged with use of information technology in clinical trial decision making; a Division of Clinical Outcomes Assessment, responsible for patient-focused efficacy and patient safety endpoints; and a Division of Research and Biomarker Development that monitors genetic scans and new biomarkers (2,3). Dr. Gottlieb indicated that "The office is just one component of a very broad reorganization of the Office of New Drugs," and "This is going to be the new paradigm and it's going to be how we modernize the drug review process" (3).

Dr. Gottlieb also modernized the review process for new regenerative medicine products, including novel cell and gene therapies. On November 16, 2017, the FDA expanded upon the regenerative medicine provisions in the 21st Century Cures Act by releasing 4 guidance documents that were designed to expedite the review and approval processes for regenerative medicine therapies. Although the review process would still require performing clinical trials, the guidance documents provided increased clarity with respect to the pathways for developing new therapies in the field of regenerative medicine, while still ensuring the safety of these new products (4). In the same news briefing, Dr. Gottlieb also took aim at unproven stem cell therapies: "Alongside all the promise, we've also seen products marketed that are dangerous and have harmed people….With the policy framework the FDA is announcing today, we're adopting a risk-based and science-based approach that builds upon existing regulations to support innovative product development while clarifying the FDA's authorities and enforcement priorities. This will protect patients from products that pose potential significant risks, while accelerating access to safe and effective new therapies" (4).

Finally, Dr. Gottlieb pushed for a new regulatory framework to evaluate the safety and efficacy of the proliferation of novel diagnostic tests that are being offered to personalize medical care. He indicated that the FDA would endorse "a more modern, flexible approach to promote the extraordinary innovation that's already well underway in this space, while ensuring patient protections." He also stated that he hoped that there would be "a compelling new paradigm for the cancer research community," and "the FDA would seek to establish collaborative communities of scientists, clinicians, test developers, and patients to help support the agency's decision making" (5).

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I suspect that there will be many who believe that Dr. Gottlieb could have done more during his tenure as the FDA commissioner. However, as the Editor-in-Chief of a journal that seeks to accelerate the translation of new scientific discoveries into new therapies that improve clinical outcomes for patients afflicted with or at risk for cardiovascular disease, I would like to join with the many other health care organizations and patient advocacy groups who have praised Dr. Gottlieb for his efforts to use innovation as way to improve the public health. As always, we welcome comments and suggestions from investigators in academia and industry, patients, societies, and all of the governmental regulatory agencies about your thoughts about Dr. Gottlieb's tenure at the FDA, either through social media (*#JACC:BTS*) or by e-mail (jaccbts@acc.org).

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