DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"Legislative Hearing on 21st Century Cures"

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RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Committee, we are Dr. Janet Woodcock, Director of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health (CDRH). Thank you for inviting us to testify before the House Subcommittee on Health, Committee on Energy and Commerce, regarding the Committee's 21st Century Cures (Cures) proposal. We share your desire to accelerate the development of safe and effective medical products.

We would like to thank Chairman Upton and Representatives Pallone and DeGette for reaching out to FDA over the past many months to ask for our insights on potential opportunities to reduce the costs and time involved in studying new medical products, while at the same time continuing to protect patients who will use these products. We also want to recognize Congress' critical role in establishing user fee programs that have led to faster product reviews and greater collaboration between the Agency, companies, and other stakeholders. While working together with the Committee on the Cures legislation, we are continually cognizant of the agreements made between the Agency and the industry and enacted by Congress under the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA), and appreciate the importance of ensuring that new provisions not impede or conflict with the important ongoing work pursuant to those user fee agreements.

With your partnership, FDA has been successful in accelerating drug and medical device review times, even as FDA's regulatory review process has remained the gold standard worldwide. FDA's drug review times are consistently faster than all other advanced regulatory authorities

around the world, and American patients are the first to receive innovative new drugs more often than patients in other countries. In 2014, FDA approved the largest number of new drugs in almost 20 years, including more drugs for rare diseases and more new therapeutic biological products than ever before, and the greatest number of new drugs approved for "orphan" diseases since Congress enacted the Orphan Drug Act over 30 years ago.

Since 2011, FDA has made meaningful progress in reducing review times for devices approved or cleared through the 510(k) and Premarket Approval (PMA) processes, and continues working to further reduce the total time to review medical devices while maintaining standards for approval that the American public and the global population depend upon.

We appreciate the opportunity to provide input throughout the development of this legislation. As we have previously indicated to the Committee, we believe there are opportunities to accelerate medical product development by:

1. Supporting patient-centered medical product development. We are pleased that you have included provisions to help us incorporate patients' voices into FDA's decision-making regarding the benefits and risks of new products;
2. Encouraging development and qualification of biomarkers;
3. Utilizing real-world evidence in the review process;
4. Reducing barriers to use of central IRBs for device trials; and
5. Strengthening FDA's ability to hire and retain highly qualified experts.

We are encouraged that these themes have been addressed in this legislation and look forward to providing additional feedback on specific proposals as we evaluate the details of this draft.

We also intend to work with the Committee on the provisions of the draft that remain placeholders. Among the additional areas where we have appreciated the opportunity to work with the Committee on the draft provisions and look forward to our continued discussions is the issue of biomarker development. FDA supports the development and use of biomarkers in the review process. We appreciate that the Committee has been working with FDA and stakeholders to refine this section of the draft. We look forward to continuing to work with you to ensure that this language supports the qualification of biomarkers and other drug development tools without diverting resources from drug review activities.

FDA also appreciates the opportunity to work with the Committee and stakeholders to ensure that medical software is regulated in a manner that ensures appropriate oversight of higher-risk software to protect patient safety, while limiting requirements on other products. In many cases software is essential to the safe functioning of medical devices used in the diagnosis, testing, and treatment of patients. In addition, FDA recognizes the interest of manufacturers in communicating with health insurers about health care economic information and is evaluating this new language. FDA shares the Committee's goal of advancing the development of new antibiotics through a new approval pathway focused on drugs intended for limited populations of patients with few or no available treatment alternatives and streamlining the process for updating

antibiotic breakpoints. We look forward to continuing to work with the Committee on issues, including the inclusion of a branding element within the labeling of such products that will alert the health care community that these products are special, and should be treated as such, and provisions related to meetings and agreements.

We look forward to providing you with additional feedback as we review this new draft and to ensuring that it meets our shared goal of accelerating innovation, while ensuring the safety and effectiveness of products, allowing for FDA's efficient review of drugs and medical devices. The American public benefits from the efficient and expeditious development and review of innovative medical products, and the safety and effectiveness of those products depends on the high quality of the input and review from FDA.