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Statement for the Record prepared for:  
Agriculture, Rural Development, Food and Drug Administration, and Related Agencies  
United States Senate Committee on Appropriations  
Regarding funding for the Food and Drug Administration (FDA), FY 2020  
April 12, 2019

The American Society of Clinical Oncology (ASCO), the world’s leading professional organization representing over 45,000 physicians and other professionals who treat people with cancer, thanks the subcommittee for its long-standing commitment to federal funding for programs within the FDA, including The Office of Hematology and Oncology Products (OHOP) and the establishing of the Oncology Center of Excellence (OCE). ASCO applauds your leadership in securing a $269 million increase for the FDA in fiscal year (FY) 2019, the largest increase for the agency in five years, and appreciates the opportunity to weigh in on FY2020 appropriations for the FDA. ASCO respectfully requests the subcommittee appropriate the following:

- **Food and Drug Administration (FDA):** $3.33 billion  
- **Oncology Center of Excellence (OCE):** $20 million

Harnessing Innovation: Therapies & Therapeutics

The FDA touches the lives of every American, especially those with cancer. As the agency charged with regulation of drugs, vaccines, and medical devices, the importance of FDA’s ability to carry out its mission cannot be overstated. In oncology, the FDA has a significant impact: last year alone, FDA approved 19 new treatments for patients with cancer and expanded the use of 38 others, bringing new promise to people with cancer\(^1\). The number of new approvals in oncology in recent months is just one example of the FDA’s profound impact on Americans—and its ability to respond to the scientific progress and innovation underway across the country. Just recently, the FDA delivered its first approval of a tumor-agnostic therapy and the first adoptive T-cell and gene therapy for cancer, demonstrating that the breakthrough therapy designation and other new approaches in oncology drug development have led to a more efficient review and approval process. Research results on other immunotherapies and targeted therapies released in 2018 have changed the treatment paradigms for lung, prostate, and bladder cancer.

As more innovative breakthroughs in biosimilars and diagnostic tests are developed, the FDA’s role in ensuring safe and effective products is more important than ever. The Administration’s proposed funding increase would provide necessary funding to advance several offices and programs within drugs, devices, and biologics. Robust funding for the FDA is critical
to support important ongoing and innovative work such as that at OHOP. OHOP plays a crucial role ensuring safe and effective drugs for cancer and hematologic conditions are available to the American public. We applaud the work of these offices’ highly trained and dedicated employees and the Administration’s efforts to recruit and retain a competitive workforce. This is not an area in which Congress can afford to cut corners; American lives depend on the safe and effective development of drug therapies. ASCO looks forward to continuing to work with OHOP on prevention, treatment, and diagnosis of the many forms of cancer. We note that this important work cannot be sustained without consistent and adequate funding for the FDA in general and the OHOP in particular.

Over 1.7 million Americans will be diagnosed with cancer this year, and an estimated 607,000 Americans are expected to die from cancer in 2019. In addition, there are currently an estimated 15.5 million cancer survivors in the United States\(^\text{ii}\). Given the staggering burden of cancer and the drastic impact it has on families across the country, it is critical that Congress continue to provide the FDA resources that will support the OCE and its ability to speed progress in this new era of targeted and combination therapies for patients with cancer. ASCO fully supports the mission of the OCE to achieve patient-centered regulatory decision-making through innovation and collaboration and appreciates the subcommittee funding the OCE under the FDA’s authority, allocating $20 million for FY2019. ASCO will continue to work with Congress and the FDA on achieving the OCE’s mission and ensuring the agency’s success. It is also vital to provide the OCE resources it needs to implement a cross-disciplinary review process and ensure the efficient review of oncology products. Therefore, ASCO supports the Administration’s FY2020 budget request of $20 million for the OCE.

**Addressing Drug Shortages**

The FDA is also instrumental in helping to mitigate the effect of drug shortages, which continue to be of great concern to the oncology and wider medical communities. In order to help prevent and overcome drug shortages, the FDA uses tools such as expedited facility inspection, expedited new and/or generic drug applications, and the exercise of discretion with respect to the temporary importation of products from foreign manufacturing sources. The agency may also urge manufacturers to increase production in specific situations to meet anticipated increases in demand. The FDA has held public meetings and solicited stakeholder and public input in its efforts to identify additional solutions to this problem, and its work in this area is critical to daily patient care. In addition to its dedicated staff in the Office of Drug Shortages, the FDA last year created an interagency Drug Shortages Task Force which includes officials from FDA, the Centers for Medicare and Medicaid Services (CMS), Assistant Secretary for Preparedness and Response (ASPR), the Veterans Affairs Department (VA), and Department of Defense (DoD) to also help address this issue.

**Combatting Tobacco Use**

The application of the FDA’s public health mission also continues to evolve as new and different tobacco products such as electronic cigarettes and flavored tobacco products come to market. FDA regulation of these products is necessary to help stem the tide of new cancer cases. The dramatic increase in youth use of e-cigarettes underscores the need for appropriate oversight by FDA. Between 2017 and 2018, use of e-cigarettes soared by 78 percent among high school
students and by 48 percent among middle school students. More than 3.6 million middle and high school students are now e-cigarette users – an alarming increase of 1.5 million students in just one year \(^i\). ASCO has supported the FDA’s growing role in ensuring flavored tobacco and electronic nicotine devices are properly regulated, specifically ensuring American youths do not have access to these products.

ASCO’s members set the standard for cancer care world-wide and are leaders in translational and clinical research aimed at improving the screening, prevention, diagnosis, and treatment of cancer. ASCO advocates for policies that provide access to high-quality care for all patients with cancer. Our efforts are also directed toward supporting oncology clinical and translational research that is critical to improving the lives of our citizens and that can inform cancer services for people worldwide. ASCO again thanks the subcommittee for its continued support of patients with cancer in the United States through consistent and appropriate funding for the FDA. We look forward to working with all members of the subcommittee on an FY2020 budget that continues to advance cancer research and treatment in our country.

Thank you for this opportunity and we look forward to continuing to work with the committee to advance these important health priorities. Please contact Kristin Palmer at Kristin.Palmer@asco.org with any questions.

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\(^i\) Campaign for Tobacco Free Kids, Electronic Cigarettes and Youth Fact Sheet; https://www.tobaccofreekids.org/assets/factsheets/0382.pdf