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**Chair of the Board**  
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**Statement for the Record prepared for:**  
**Agriculture, Rural Development, Food and Drug Administration, and Related Agencies**  
**United States House Committee on Appropriations**  
**Regarding funding for the Food and Drug Administration (FDA), FY 2021**  
**March 31, 2020**

The Association for Clinical Oncology (ASCO), the world's leading professional organization representing nearly 45,000 physicians and other professionals who treat people with cancer, applauds the subcommittee for its long-standing commitment to robust federal funding for programs within the FDA, including the Office of Hematology and Oncology Products (OHOP) and the Oncology Center of Excellence (OCE). ASCO applauds your leadership in securing a \$89 million increase for the FDA in fiscal year (FY) 2020 and appreciates the opportunity to weigh in on FY2021 appropriations for the FDA. ASCO respectfully requests the subcommittee appropriate the following:

- **Food and Drug Administration (FDA):** \$3.28 billion (not including the \$70 million authorized by the *21<sup>st</sup> Century Cures Act*)
- **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 role and impact: since 2006 the FDA has approved over 150 new cancer drugs. Between August 2018 and July 2019 alone, the FDA approved 17 new anti-cancer therapeutics, bringing new promise to patients. Since 1991 the cancer mortality rate has declined by 29 percent. Between 2016 and 2017 we experienced the largest single-year drop in cancer mortality ever reported—a 2.2 percent decline—progress that would not have been possible without new, innovative treatments<sup>1</sup>. The number of new approvals in oncology 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.

In 2019, the FDA approved a first-of-its-kind cancer therapy that can be used to treat any kind of cancer that has a specific genetic marker. This is the third cancer therapy approved by the FDA that targets treatment based on specific characteristics of a tumor, instead of the part of the body where it originated. Recently, the FDA delivered its first approval of a tumor-agnostic therapy and the first adaptive 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 2019 have changed the treatment paradigms for lung, prostate, and bladder cancer. There are currently more than 1,500 immuno-oncology clinical trials in some stage of development indicating the potential for continued expansion in treatment options for many cancers.

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. Robust funding is critical to support important ongoing and innovative work throughout the FDA, including the Office of Hematology and Oncology Products (OHOP). OHOP plays an indispensable role ensuring safe and effective drugs for cancer and hematologic conditions are available to the American public. We applaud the work of the office's highly trained and dedicated employees and the Administration's efforts to recruit and retain a competitive workforce. This is not an area where 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.

While there is great progress, we know that in 2020 more than 1.8 million Americans will be diagnosed with cancer, and an estimated 606,000 Americans are expected to die. The *21<sup>st</sup> Century Cures Act*, which became law in 2016, established an "FDA Innovation Account," which authorized additional funding subject to the annual appropriations process. The law authorizes \$70 million for this account for FY 2021, which is critical funding to support the FDA's ability to accelerate innovation and increase patient involvement in research. As part of the Innovation Account, the Oncology Center of Excellence (OCE) was created, with a mission to achieve patient-centered regulatory decision making through innovation and collaboration.

ASCO fully supports the mission of the OCE and appreciates the subcommittee funding the OCE under the FDA's authority, allocating \$20 million for FY2020. Given the continued, 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. It is also vital to provide the OCE with the resources it needs to implement a cross-disciplinary review process and ensure the efficient review of oncology products. Therefore, ASCO supports the Administration's FY2021 budget request of \$20 million for the OCE, of which \$5 million will be directed towards developing treatments for rare cancers. ASCO looks forward to continuing to work with Congress and the FDA on achieving the OCE's mission and ensuring the agency's success.

## **Addressing Drug Shortages**

Drug shortages can delay or prevent patients from getting the care they need. A variety of factors ranging from environmental disasters to issues with manufacturing standards can disrupt the supply of medical drugs, threatening patient care. The reality of possible drug shortages has been highlighted by the outbreak of COVID-19, as many drug components are made exclusively in the Wuhan region of China. While it is crucial the U.S. has the tools necessary to address these possible shortages – this is not a new challenge. The U.S. has faced shortages in the recent past, most notably after Hurricane Maria devastated Puerto Rico and pharmaceutical factories there. It is imperative that drug shortages be addressed immediately should they arise, but also that the Administration, Congress, and stakeholders work together on long-term solutions.

After a period of decline, there has been a recent increase in reported drug shortages, and in 2018 the FDA reported 186 new shortages, up 27 percent from 2017<sup>ii</sup>. The FDA is instrumental in helping to mitigate the effect of drug shortages. 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 input in its efforts to identify additional solutions to this problem, and its work in this area is critical to daily patient care.

ASCO supports several proposals to address medical and drug shortages that the Administration included in the Department of Health and Human Services FY2021 FDA Budget. They include expanding the FDA's authority to require manufacturers to label products with the longest possible expiration date that the FDA agrees is scientifically justified, expanding the authority for the FDA to require application holders of certain drugs to conduct periodic risk assessments to identify the vulnerabilities in their manufacturing supply chain and develop plans to mitigate risk, and clarifying the FDA's authority to obtain detailed drug listings, regardless of whether they were directly or indirectly imported into the U.S. ASCO urges the subcommittee to continue to support the FDA's role in mitigating drug shortages.

### **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. In the FDA's own 2019 National Youth Tobacco Survey, results on e-cigarette use show that more than 5 million U.S. middle and high school students are current e-cigarette users, and this number is growing<sup>iii</sup>. Unfortunately, surveys show that young adults and youth hold many misconceptions about e-cigarettes, with over 20 percent believing e-cigarettes are harmless and not addictive.<sup>iv</sup> ASCO has supported the FDA's growing role in ensuring flavored tobacco and electronic nicotine devices are properly regulated, specifically ensuring America's young people do not have access to these products. We were pleased to see Congress pass and the President sign legislation to raise the minimum age for purchasing tobacco and e-cigarette products from 18 to 21 years of age. There is still more work to be done to ensure a new generation does not become addicted to nicotine and tobacco products.

### **Ensuring Access to COVID-19 Tests for Cancer Patients and Survivors**

While not necessarily a factor within the FY2021 Agriculture, Food and Drug Administration, and related agencies appropriations bill, ASCO and the providers we represent feel it is imperative to highlight is the critical need for cancer patients, survivors and their caregivers have access to COVID-19 testing. Cancer patients are particularly vulnerable during this crisis. Patients with cancer may need testing if they are showing symptoms of COVID-19, if they have been potentially exposed to infected individuals, or if it is clinically indicated prior to certain treatments. In addition, many people with cancer have more than one

chronic condition, are immunocompromised, and at an elevated risk for complication or poorer outcomes.

ASCO has worked to provide information and other resources to guide oncology professionals as they deal with the impact of the virus on their patients and staff. We continue to hear overwhelming concern from members about the inability to secure appropriate testing for cancer patients who represent a high-risk group in the current outbreak. We recommend the government provide laboratories with the regulatory flexibility and resources needed to expedite and expand testing. As a professional medical association focused on the care of patients with cancer, it is our responsibility to emphasize the critical needs of cancer patients and their caregivers today.

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. We thank 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 FY2021 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](mailto:Kristin.Palmer@asco.org) with any questions.

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<sup>i</sup> ASCO, Clinical Cancer Advances 2020; <https://www.asco.org/research-guidelines/reports-studies/clinical-cancer-advances-2020>

<sup>ii</sup> FDA, Drug Shortages: Root Causes and Potential Solutions; <https://www.fda.gov/media/131130/download>

<sup>iii</sup> FDA, Youth Tobacco Use: Results from the National Youth Tobacco Survey; <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>

<sup>iv</sup> ASCO National Survey; <https://www.asco.org/about-asco/press-center/news-releases/national-survey-reveals-one-five-young-adults-regularly-uses-e>