

**Lori J. Pierce, MD, FASTRO, FASCO**

**Chair of the Board**

**Association for Clinical Oncology**

**Statement for the Record prepared for:**

**Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and  
Related Agencies**

**United States House of Representatives Committee on Appropriations**

**Regarding funding for the Food and Drug Administration (FDA), Fiscal Year 2024**

**April 10, 2023**

The Association for 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, bipartisan commitment to robust funding for programs within the FDA, including the Office of Oncologic Diseases (OOD), and the Oncology Center of Excellence (OCE). ASCO applauds the Subcommittee's bipartisan leadership securing a \$226 million funding increase for the FDA in fiscal year (FY) 2023. We appreciate the opportunity to comment on FY 2024 FDA appropriations. ASCO respectfully requests the Subcommittee appropriate \$3.914 billion for the Food and Drug Administration (FDA).

**Harnessing Innovation: Therapies & Therapeutics**

Over the last 30 years the cancer death rate has fallen 33%, progress that would not have been possible without innovative treatments.<sup>1</sup> The pace of scientific insight is speeding breakthroughs in diagnostics and treatments. The FDA has been crucial to ensuring these advances are safe, effective, and available to patients with cancer. Robust funding is necessary to sustain this progress. American lives depend on it.

Despite remarkable progress, cancer remains the second most common cause of death in the United States (U.S.). In 2023, over 1.9 million new cancer cases will occur, and over 609,000 people will die from cancer.<sup>ii</sup> Enacted in 2016, the *21<sup>st</sup> Century Cures Act* established an “FDA Innovation Account,” which authorized additional funding subject to the annual appropriations process. The Innovation Account established the Oncology Center of Excellence (OCE) to promote a patient-centered, innovative, and collaborative regulatory environment. This resulted in collaborative efforts across the FDA with OCE, OOD and many other offices working together to navigate this new era of targeted and combination therapies for patients with cancer. ASCO urges robust support to continue this successful strategy for innovation.

### **Addressing Drug Shortages**

Drug shortages disrupt cancer care and often lead to disease progression. Over the last several years, natural disasters, quality problems, manufacturer consolidation, disruptions to raw ingredient supplies, and other international emergencies have broken the U.S. drug supply chain.

A recent survey of U.S. oncology pharmacists reported frequent oncology drug shortages in 2020, leading to delays or disruptions in treatment and clinical research. They also led to increased risk of medication errors and adverse outcomes.<sup>iii</sup> The FDA mitigates shortages using tools such as expedited facility inspection, fast-tracked new and/or generic drug applications, and temporary importation of products from foreign manufacturing sources. FDA is actively engaged with stakeholders to identify issues and possible solutions to sustain a healthy drug supply chain.

ASCO and other stakeholders also have recommended<sup>iv</sup> ways to improve resiliency of the nation’s drug supply, including creating redundant product for critical drugs, establishing a multi-stakeholder advisory panel to address key issues, enhancing communication to the

healthcare community in the context of shortages, and streamlining regulations to incentivize production. ASCO urges continued support for this important FDA role.

### **The Need for Diversity in Research, Accessible Data, and Creating a Framework for Laboratory Developed Tests**

The COVID-19 pandemic's major disruption of cancer clinical trials and drug development highlights the need for efficiency and new flexibilities in the drug approval process. On average, review and approval for new cancer therapies takes six months before the treatment becomes readily available to all patients.

We believe there is an opportunity to build on lessons learned from flexibilities deployed during the public health emergency. Relevant agencies, such as NIH and FDA, quickly issued temporary policies that avoided interruption of clinical trials while maintaining safe access to participation. Some examples include the use of telehealth and remote clinics, scans, and labs. ASCO urges extension of these flexibilities to increase both overall participation and enhanced diversity of patients in trials, even after the public health emergency ends. ASCO is eager to work with Congress and the Administration to increase the use of more diverse, patient-centric and decentralized clinical trial designs.

In addition to highlighting the need to make clinical trials more accessible and diverse, COVID-19 demonstrated the importance of Real-World Data (RWD). Data collection that captures demographic characteristics including race/ethnicity, sexual orientation, gender identity, socioeconomic status, age, stage of disease, comorbidities, etc. helps reduce health disparities by ensuring data for all patient populations are included in the development of treatments. Sources of RWD include electronic health records, insurance claims, patient registries, and digital health

solutions outside of conventional clinical trials. Additionally, RWD can supplement clinical trial data to establish real-world effectiveness and toxicity, especially in oncology.

The *21st Century Cures Act* in 2016 tasked the FDA with implementing the Real-World Evidence (RWE) Program and Draft Guidance, describing how RWE can contribute to review of safety and effectiveness in regulatory submissions. It also required the FDA to explore use of RWE for additional indications of approved drugs and in post-approval study requirements. The FDA also is working with the National Cancer Institute (NCI) on data sharing and data aggregation. These continued efforts are important to the Targeted Agent and Profiling Utilization Registry (TAPUR) and CancerLinQ, two initiatives overseen by ASCO's affiliate, the American Society of Clinical Society. Both rely on real-world insights to improve the quality of care for all patients. The promise of usable RWD cannot be understated, but the FDA requires resources to translate this promise to reality.

ASCO supports recent bipartisan congressional efforts to consolidate regulation of Laboratory Developed Tests (LDTs) and in vitro diagnostic tests under a single FDA framework. This framework would create a flexible, risk-based regulatory system incentivizing development of advanced, reliable tests. Without action, current oversight of these tests could lead to unreliable tests that undermine clinical decision making and health outcomes.

### **Combatting Tobacco Use**

Tobacco is the leading preventable cause of death in the U.S., killing more than 480,000 Americans and costing \$170 billion annually. Nearly one in three heart disease deaths, one in three cancer deaths, and nearly eight in 10 chronic obstructive pulmonary disease (COPD) deaths are caused by tobacco use. The dramatic increase in use of e-cigarettes among youth underscores the need for oversight by FDA. The FDA's 2022 National Youth Tobacco Survey showed that

more than 2.5 million children used e-cigarettes in 2022. Studies show that young people who use e-cigarettes are more likely to become smokers.<sup>v</sup> Unfortunately, surveys also show that young adults and youth hold many misconceptions about e-cigarettes, with over 20% believing e-cigarettes are harmless and not addictive.<sup>vi</sup> The FDA is important to stemming the tide of new tobacco-related cancer cases. ASCO strongly supports FDA's role in regulating flavored tobacco and electronic nicotine devices, specifically ensuring America's young people do not have access to these products.

We thank the Subcommittee for its continued bipartisan support of patients with cancer through robust funding for the FDA. We look forward to working with members of the Subcommittee on the FY2024 budget to continue to advance cancer research and treatment. Please contact Katie Gifford at [katie.gifford@asco.org](mailto:katie.gifford@asco.org) with questions.

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<sup>i</sup> American Cancer Society, Cancer Facts and Figures 2023; <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>

<sup>ii</sup> American Cancer Society; <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>

<sup>iii</sup> National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey; <https://ascopubs.org/doi/full/10.1200/OP.21.00883>

<sup>iv</sup> Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation's Healthcare Critical Infrastructure; <https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-security.ashx>

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

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