Everett E. Vokes, MD, 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 Senate Committee on Appropriations

Regarding funding for the Food and Drug Administration (FDA), Fiscal Year 2025

May 8, 2024

The Association for Clinical Oncology (ASCO), the world's leading professional organization representing nearly 50,000 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 Food and Drug Administration (FDA), including the Office of Oncologic Diseases (OOD), and the Oncology Center of Excellence (OCE). ASCO appreciates that, during a challenging funding environment, the Subcommittee's bipartisan leadership ensured level funding for the FDA in fiscal year (FY) 2024, allowing the FDA to maintain its important work. We appreciate the opportunity to comment on FY 2025 FDA appropriations. ASCO respectfully requests the Subcommittee appropriate $3.896 billion for the FDA.

Mitigating Drug Shortages

The shortage of generic drugs, including vital oncology medications, poses a grave threat to the health and well-being of patients with cancer across the nation. These shortages can result in treatment delays, compromised therapeutic regimens, and increased health care costs, all of which can exacerbate the already daunting challenges patients face. The consequences of drug shortages extend far beyond mere inconveniences; they can directly affect treatment outcomes and patient quality of life. Moreover, drug shortages highlight a break down in the United States (U.S.) pharmaceutical supply chain and could pose significant national security threats.

The FDA has some capacity to mitigate acute 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. However, the agency lacks access to actionable information. While the FDA possesses information about finished product manufacturers and active pharmaceutical ingredients (APIs), it is not always aware of which API supplier(s) a manufacturer utilizes or the quantities involved. Moreover, visibility into earlier stages of the supply chain, such as key starting materials (KSMs) and

refined chemicals, is severely limited. It is important that FDA has the resources it needs to ensure transparency into the entire supply chain.

It is well known that the supply chain for pharmaceuticals is opaque. ASCO and others have advocated for years for more insight into the supply chain, including requiring manufacturers to report more actionable information to the FDA, in a useable format, to give the agency an earlier and more holistic picture of the actual and anticipated supply of any given drug.

ASCO and other stakeholders have recommended 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.[i] The FDA plays an important role in each of these functions, and ASCO urges enhanced support for this important FDA role.

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.[ii] 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 the significant strides made in preventing and treating cancer, it remains the second leading cause of death in the U.S. In 2024, the nation will experience a historic high with over 2 million new cancer cases. While cancer diagnoses have traditionally been more common among older Americans, there is a noticeable shift, with individuals aged 50 to 64 growing in numbers for people with cancer. Alarmingly, colorectal cancer diagnoses are on the rise among those under 50, and cervical cancer incidence is increasing among women aged 30 to 44.[iii]

Enacted in 2016, the *21st Century Cures Act* established an "FDA Innovation Account," which authorized additional funding subject to the annual appropriations process. The Innovation Account established the 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 Congress to provide robust support to continue this successful strategy for innovation.

The Need for Diversity in Research and Accessible Data

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 granted during the COVID-19 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, which are set to expire at the end of this year, to increase both overall participation and enhanced diversity of patients in trials. 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, we continue to learn the importance of Real-World Data (RWD). Data collection that captures demographic characteristics such as race/ethnicity, sexual orientation, gender identity, socioeconomic status, age, combined with clinical data such as stage of disease and comorbidities, 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 *Cures Act* 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), an initiative overseen by ASCO's affiliate, the American Society of Clinical Oncology. TAPUR relies on real-world insights to improve the quality of care for all patients. The promise of usable RWD cannot be understated, and the FDA requires the necessary resources to translate this promise to reality.

Creating a Framework for Laboratory Developed Tests

As Congress considers legislative action to meet the challenge of ensuring patients' access to advanced diagnostics, ASCO has advocated for many years for a flexible, risk-based regulatory framework for all in vitro diagnostics (IVDs) that would not only improve but also incentivize the development of innovative, accurate, and reliable diagnostic 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 2023 National Youth Tobacco Survey showed that more than 2.1 million children used e-cigarettes in 2023, with more than one in four youth reporting daily use of e-cigarettes and 9 out of 10 using flavored e-cigarettes.[iv] 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.[v] The FDA is critical 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 FY2025 budget to continue to advance cancer research and treatment. Please contact Katie Gifford at katie.gifford@asco.org with questions.

***

[i]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
[ii] American Cancer Society, Cancer statistics, 2024, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820
[iii]American Cancer Society, Cancer statistics, 2024, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820
[iv] 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
[v] ASCO National Survey; https://www.asco.org/about-asco/press-center/news-releases/national-survey-reveals-one-five-young-adults-regularly-uses-e