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 House of Representatives Committee on Appropriations

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

May 10, 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 in 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. ASCO respectfully requests the Subcommittee appropriate $3.896 billion for the FDA for FY 2025.

Mitigating Drug Shortages

Generic drug shortages, including vital cancer medications, is a grave threat to patients with cancer across the nation. Shortages can directly affect treatment outcomes and patient quality of life due to treatment delays, compromised therapeutic regimens, and increased health

care costs. Moreover, drug shortages highlight a breakdown in the United States (U.S.) pharmaceutical supply chain and could pose significant national security threats.

The current FDA tools to mitigate acute shortages include expedited facility inspections, fast-tracked new and/or generic drug applications, and temporary importation of products from foreign manufacturing sources. FDA is engaged with stakeholders to identify issues and 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. This severely limits visibility into earlier stages of the supply chain, such as key starting materials (KSMs) and refined chemicals. It is important Congress ensures transparency into the entire supply chain, by 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 on shortages to the healthcare community, and incentivizing production.[i] 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% thanks to breakthroughs in diagnostics and treatments.[ii] Robust funding is necessary to sustain this progress - American lives depend on it. Despite the significant strides made, the nation will experience a historic high with over 2 million new cancer cases in 2024. 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]

The *21st Century Cures Act* established the OCE to promote a patient-centered, innovative, and collaborative regulatory environment. This resulted in collaborative efforts across the agency with many 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

Temporary policies granted during COVID-19, such as the use of telehealth and remote clinics, scans, and labs, avoided interruption of clinical trials while maintaining safe access to participation. 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.

Data collection that captures demographic characteristics, combined with clinical data, helps reduce health disparities by ensuring data for all patient populations are included in the development of treatments. Real-world data (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 continues to advocate for a single, flexible, risk-based regulatory framework for all in vitro diagnostics (IVDs) that would improve and incentivize the development of innovative, accurate, and reliable diagnostic tests. Without action unreliable tests that undermine clinical decision making and health outcomes will continue to proliferate.

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. The dramatic increase of youth e-cigarette use underscores the need for oversight by FDA. The FDA's 2023 National Youth Tobacco Survey showed that more than one in four youth reporting daily use of e-cigarettes and 9 out of 10 using flavored e-cigarettes.[iv] Surveys also show that over 20% of young adults and youth believe the misconception that e-cigarettes are harmless and not addictive.[v] ASCO strongly supports FDA's role in regulating flavored tobacco and electronic nicotine devices and ensuring America's young people do not have access to these products.

Thank you for your continued bipartisan support of patients with cancer through robust funding for the FDA. We look forward to working with you on the FY2025 budget to continue to advance cancer research and treatment. Please contact Katie Gifford at katie.gifford@asco.org with questions.

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[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