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Testimony 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 2027

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The Association for Clinical Oncology (ASCO), the world's leading professional organization representing over 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 has consistently worked to ensure that the FDA has the funding it needs to conduct its important work. ASCO respectfully requests the Subcommittee appropriate \$3.522 billion for the FDA for FY 2027.

Mitigating Drug Shortages

Generic drug shortages, including vital cancer medications, are 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 has been 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 some 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.

Despite statutory requirements that manufacturers report to the FDA permanent discontinuance, interruption in manufacturing, and the expected duration, compliance remains low.ⁱ The current processes do not account for spikes in demand, and issues with compliance are compounded by the FDA's aging technology infrastructure, which challenges its ability to use the data reported. 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.ⁱⁱ ASCO urges enhanced support for this important FDA role.

Harnessing Innovation Through Regulatory Flexibilities

More than 40% of Americans will be diagnosed with cancer at some point in their lives. There are many types of cancer, and they can differ greatly in the ways they grow, spread, and respond to treatment. Thanks in large part to federally funded breakthroughs in diagnostics and treatment, there are an estimated 18.1 million cancer survivors in America, and remarkably, the five-year survival for all cancers is now 70%.ⁱⁱⁱ With new treatments improving both the length and quality of life in patients with cancer, we are approaching a time where many types of cancer are considered chronic diseases.

Despite significant strides made in preventing and treating cancer, it remains the second leading cause of death in the U.S., and the leading cause of death in people younger than 85. In 2026, over 2 million new cancer cases are expected to be diagnosed, and more than 626,000 people will die from these diseases.^{iv}

As cancer care becomes more complex and increasingly personalized, it is more important than ever to ensure participation in clinical trials by individuals reflective of the epidemiology of the disease. All patients should have an opportunity to participate in and benefit from research, including clinical trials. Unfortunately, certain barriers prevent many patients from participating. Innovative trial designs and "simpler" trials, including adaptive and pragmatic trial designs, novel surrogate endpoints, and use of Real-World Evidence (RWE), are needed to modernize evidence generation and keep pace with the advances in precision medicine.

Data collection that captures personal patient information, combined with clinical data, ensures data for all patient populations are included in the development of treatments. Real-world data (RWD) has the potential to supplement clinical trial data to establish real-world effectiveness and toxicity, especially in oncology.

The *21st Century Cures Act* tasked the FDA with implementing the Real-World Evidence Program and Draft Guidance, describing how RWE, derived from RWD, 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 required post-approval studies. 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, now in its 10th year, is a clinical trial that uses precision medicine to match patients with advanced cancer to targeted treatments based on their tumor's genomic profile and 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.

Temporary policies granted during the public health emergency, such as the use of telehealth and remote clinics, scans, and labs, avoided interruption of clinical trials and maintained access to participation. ASCO urges permanent extension of these flexibilities, which are set to expire at the end of 2027, to increase overall patient participation in trials. ASCO is eager to work with Congress and the Administration to increase the use of more patient-centric and decentralized clinical trial designs.

Creating a Framework for Laboratory Developed Tests

ASCO continues to advocate for legislation to meet the challenge of ensuring patients' access to advanced diagnostics, including 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 congressional 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 490,000 Americans and costing over \$241 billion annually.^v Nearly 90% of adult daily smokers first try smoking by age 18.^{vi} The FDA's recent National Youth Tobacco Survey showed that more than 1.6 million youth, including 7.8% of high schoolers, reported using e-cigarettes in 2024. Alarmingly, 42.1% of high school e-cigarette users reported use on 20 days or more a month, including nearly 30% who reported daily use, a sign that youth are becoming addicted.^{vii} ASCO was pleased to see the Supreme Court's April 2, 2025, decision that the FDA was within its

power to regulate the sale of certain flavored e-cigarette products. While we support FDA’s continued role in regulating flavored tobacco and electronic nicotine devices and ensuring America’s young people do not have access to these products, ASCO was concerned to see the recent approval to market two fruit-flavored vapes, the first marketing approval of e-cigarettes in flavors other than tobacco or menthol. We are concerned that these flavors overwhelmingly appeal to young people and will lead to increased youth tobacco usage.

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 FY2027 budget to continue to advance cancer research and treatment. Please contact Katie Gifford at katie.gifford@asco.org with questions.

ⁱ Section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2011.

ⁱⁱ 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>

ⁱⁱⁱ American Cancer Society. *Cancer Facts & Figures 2026*. Atlanta: American Cancer Society; 2026.

^{iv} American Cancer Society. *Cancer Facts & Figures 2026*. Atlanta: American Cancer Society; 2026.

^v Campaign for Tobacco-Free Kids; <https://www.tobaccofreekids.org/problem/toll-us>

^{vi} CDC, Youth and Tobacco Use; <https://www.cdc.gov/tobacco/php/data-statistics/youth-data-tobacco/index.html>

^{vii} 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>