



**ASSOCIATION CHAIR
OF THE BOARD**

Lori J. Pierce, MD, FASCO, FASRO

ASSOCIATION TREASURER

Jason R. Westin, MD, MS, FACP

ASSOCIATION DIRECTORS

Ethan M. Basch, MD, MSc, FASCO

Elizabeth A. Mittendorf, MD,
PhD, MHCM, FASCO

Xylina T. Gregg, MD

Lynn M. Schuchter, MD, FASCO

Michael A. Thompson, MD,
PhD, FASCO

Everett E. Vokes, MD, FASCO

Eric P. Winer, MD, FASCO

NON-VOTING DIRECTOR

Chief Executive Officer

Clifford A. Hudis, MD,
FACP, FASCO

June 10, 2022

The Honorable Patty Murray
Chairwoman
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor & Pensions
United States Senate Washington, D.C. 20510

Dear Chairwoman Murray and Ranking Member Burr,

The Association for Clinical Oncology (ASCO) applauds your bipartisan commitment to reauthorizing the Food and Drug Administration (FDA) user fee programs and expanding the Agency's authorities to protect patient safety. We are pleased to support provisions in the *Food and Drug Administration Safety and Landmark Advancements Act of 2022* (FDASLA) that will have a meaningful impact on cancer care.

ASCO is the world's leading professional society representing physicians who care for people with cancer. With nearly 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality cancer care.

We applaud your bipartisan commitment to moving FDASLA in a timely manner to prevent any disruption in the approval of safe and effective therapies for patients by the FDA. We encourage you to work with your counterparts in the House to ensure the final bill includes a combination of provisions from both reauthorization packages. Within the Senate package, specifically, we are pleased to see provisions to strengthen the Accelerated Approval Program and provide the FDA with oversight of laboratory developed tests (LDTs) and in vitro clinical tests (IVCTs). However, we respectfully ask for a few adjustments to these two sections:

Title V, Section 506. Modernizing accelerated approval

ASCO has long supported the accelerated approval and complementary expedited review programs, which provide patients with the earliest possible access to potentially life-saving therapies, instead of requiring them to wait for confirmation of long-term endpoints, such as survival. We believe that despite the accelerated approval program's success to-date, additional authorities for

the FDA could strengthen the program. We are pleased to see the FDASLA would give the FDA additional tools and flexibilities to advance this pathway with the growing need and to ensure completion of confirmatory trials, requiring sponsor progress reports, and outlining procedures by which the FDA could withdraw an accelerated approval. However, the creation of an intra-agency coordinating council to oversee the use of the accelerated approval program would have the unintended consequence of slowing down the FDA's ability to approve these therapies quickly, potentially undermining the purpose of the program altogether. ASCO appreciates the concern that the therapies quickly approved by this program do not come at the expense of ensuring only safe and effective drugs are available to Americans, however, the other authorities, requirements, and clarifications in this section would alleviate this concern and eliminate the need for a council. We urge the Committee to drop the inclusion of a council as FDASLA moves forward.

Title VIII, Subtitle C. In vitro clinical tests

ASCO believes that reforming the regulatory framework for clinical laboratory diagnostics is essential to protect patients and ensure access to innovative and high-quality testing. We are encouraged to see that language to create a distinct regulatory framework for in vitro diagnostics was included in the FDASLA. We are pleased to see the version introduced improved the transparency provisions, includes a reasonable risk based regulatory standard for tests, and streamlines oversight for existing tests. We are also pleased to see that the Committee included authorized appropriations for implementation. In our comments to the committee on the draft legislation in May we noted our concern that a lack of funding would come at a significant cost to the FDA prior to its ability to collect user fees. There are still a few remaining concerns within this subtitle we would like the Committee to address during this amendment process:

Modified Test Exemptions

We would like to bring to your attention what could simply be a drafting error, but as written could create a potential loophole for tests needing premarket review. As written, the modified test exemption would allow any developer to modify their own test, and also allow labs to modify other developer's tests without premarket review. In the language on page 82, line 21, the two categories of requirements for exemption are currently joined with an "or": "**or constitutes a significant** change to the indications for use." The "or" should be an "and" as this final condition of exemption to not constitute a significant change to the indications for use is extremely important.

Resources

Additionally, as noted, we thank the Committee for including resources to ensure the FDA is able to carry out this new mandate upon enactment of this legislation. However, the resources section contains provisions that could be an obstacle for the agency to properly utilize these funds. Specifically, the language does not allow FDA to apply user fees to postmarket activities. As many tests still will not be subjected to premarket review, the ability to conduct postmarket surveillance is an important tool for patient care. We urge the Committee to clarify resources in this category can be used for postmarket surveillance.

ASCO also supports the following in the FDASLA:

- Enhancing existing FDA flexibilities and authorities to simplify, expedite hiring for scientific, technical, and professional roles (Section 701).

In addition to the provisions noted above in FDASLA, ASCO strongly supports several additional provisions in the House user fee agreement package, the *Food and Drug Amendments of 2022*, including:

- Ensuring clinical trials are representative of diverse populations by requiring drug and medical device manufacturers to submit clinical trial diversity action plans to FDA early in their development process (Sections 501-506).
- Improving the FDA's review for safety and efficacy of medical products, including cell and gene therapies, drugs for rare diseases, and novel medical devices (Section 707).
- Providing FDA with tools to ensure the agency can conduct thorough safety inspections efficiently (Sections 721-729).
- Strengthening program integrity for the Accelerated Approval pathway and preserving patient access to approved treatments by ensuring that drugs show clinical benefit through postapproval studies in a timely manner and streamlining the process for withdrawing approvals for drugs that fail to show a clinical benefit (Section 804).
- Improving the use of real-world data (Section 805).
- Codifying the FDA's longstanding interpretation of the *Orphan Drug Act* to ensure that the scope of the orphan drug exclusivity is clarified to apply only to the same approved use or indication within such rare disease or condition instead of the same disease or condition (Section 811).

As Congress continues consideration of this must-pass legislation and the additional policy provisions, I urge you and your colleagues to ensure the above remain included throughout the process. These provisions go a long way to strengthening the FDA's ability to increase innovation and ensure patients receive the best possible treatments. We are committed to working with you as the legislation advances. If you have any questions, please contact Kristin Stuart, Associate Director of Congressional Affairs, at Kristin.Stuart@asco.org or 571-483-1646.

Sincerely,



Lori J. Pierce, MD, FASCO, FASTRO
Chair of the Board
Association for Clinical Oncology