FDA’s Draft Guidance Will Improve Evidence Base for Older Adults with Cancer

Statement By American Society of Clinical Oncology (ASCO) President Howard A. “Skip” Burris III, MD, FACP, FASCO
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“We commend the U.S. Food and Drug Administration (FDA) for releasing draft guidance to encourage inclusion of older adults in clinical trials of drugs for the treatment of cancer. We thank Richard Pazdur, MD, director of the FDA Oncology Center of Excellence, for his leadership on this important issue.

"Older adults experience the majority of cancer diagnoses and deaths and make up the majority of cancer survivors. Unfortunately, the evidence base for treating this population is sparse because older adults are underrepresented in clinical trials. Oncologists, thus, have less evidence on how to treat older adults and must extrapolate from trials conducted in younger, healthier populations.

"This draft guidance signals to researchers and sponsors that clinical trials should include older adults with cancer when they can be safely and ethically enrolled. In particular, the guidance recommends sponsors include older adults in early phase studies; design trials that allow for participation of older adults; develop recruitment strategies targeted to older adults; report results for discrete age subgroups; and develop plans for capturing post-market data, along with other recommendations.

"The American Society of Clinical Oncology (ASCO) has been working alongside the FDA and others in the cancer community to improve the evidence base for the care of older adults
with cancer. Led by the late Arti Hurria, MD, FASCO, a leader in geriatric oncology, ASCO published a set of recommendations focused on ensuring clinicians and patients have the information they need to develop treatment plans for this population. In 2017, ASCO partnered with FDA to hold a Geriatric Oncology Workshop, which convened members of the oncology community, including clinicians, health care providers, patient advocacy groups, pharmaceutical representatives, academicians, and scientists, to discuss approaches to improve the evidence base for treating older cancer patients.

"We look forward to continuing our close collaboration with FDA as it finalizes and begins to implement this guidance."

**About ASCO:**

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at [www.ASCO.org](http://www.ASCO.org), explore patient education resources at [www.Cancer.Net](http://www.Cancer.Net), and follow us on Facebook, Twitter, LinkedIn, and YouTube.