Support Necessary Funding for the Food and Drug Administration

Background
The Food and Drug Administration (FDA) is a vital partner in the safe and effective treatment of cancer and advancement of new cancer care therapies. For cancer patients, the FDA ensures that chemotherapy drugs are safe and available while shepherding ground-breaking treatments to market with the appropriate risk-benefit analysis. Congress must ensure that the FDA has the appropriate resources to keep pace with progress and combat new challenges in the field.

Drug Development
There are 12 million cancer survivors alive in the US today and this number is growing in no small part because of the new treatments FDA approves. ASCO has been particularly appreciative of and impressed by the work of the Office of Hematology and Oncology Products (OHOP). OHOP is responsible for making safe and effective drugs for cancer and hematologic conditions available to the American public. OHOP oversees development, approval, and regulation of drug treatments for cancer, therapeutic biologic treatments for cancer, therapies for prevention of cancer, and products for treatment of nonmalignant hematologic conditions.

OHOP had the highest number of new drug approvals of any therapeutic category in 2012 while operating at a funding level that did not reflect a higher workload relative to other offices. These efforts provide the basis for accelerating introduction of new treatments for cancer into practice. ASCO is concerned about the ability of the FDA in general and the OHOP specifically to continue to expand the scope and quality of their work with shrinking resources. This is not an area in which Congress can afford to cut corners; lives are on the line in this endeavor.

Drug Shortages
ASCO has worked closely with the FDA’s Office of Drug Shortages to deal with drug shortage crises and to help cancer patients get access to the drugs they so vitally need. This small office has been particularly overburdened by the increasing number of drugs that have been unavailable in the last two to three years. In part because of their determined efforts, we have seen new shortages decrease from the highs reached in 2011. Despite improvement, existing shortages remain unresolved and the problem is far from being solved. The FDA needs sufficient resources to continue to address drug shortages.

Increased Complexity
As oncologists understand more about the diseases known as cancer on a genomic level, we are able to develop targeted therapies which can produce long term remissions for many cancer patients. Cancer patients rely on the ongoing efforts of the FDA to grant timely approval of innovative, new medicines, some with companion diagnostics, for patients with important unmet medical needs while maintaining high standards for safety and effectiveness. In order to do this, FDA’s funding must allow it to keep pace with scientific complexity by supporting continuing education for its staff.