Via Electronic Submission

September 19, 2019

Ned Sharpless, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Subject: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Proposed Rule (Docket No. FDA-2019-N-3065)

Dear Dr. Sharpless:

The American Society of Clinical Oncology (ASCO) welcomes the opportunity to provide comments regarding the Proposed Rulemaking on Required Warnings for Cigarette Packages and Advertisements, 21 CFR Part 1141 (84 Fed. Reg. 42754, August 16, 2019) (NPRM). ASCO represents more than 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practice for the prevention, diagnosis, and treatment of cancer are available to all Americans.

ASCO applauds the FDA for fulfilling the requirement in the Family Smoking Prevention and Tobacco Control Act and working to implement the use of new graphic warning labels on cigarette packaging and advertisements. Graphic warning labels are an effective way to deter youth and nonusers from initiating tobacco use and encourage current tobacco users to quit.1,2 Implementing the requirement of graphic warning labels in the United States could result in a decrease of between 5-8 million adult smokers.3 ASCO agrees that additional education is needed to ensure the public understands the many negative health consequences of using cigarettes and other tobacco products. We also encourage the Agency to continue moving forward on efforts to protect the adolescent population via additional tobacco regulations to significantly reduce tobacco-related disease as part of the FDA comprehensive plan for tobacco and nicotine regulation.

As an organization dedicated to the prevention and treatment of cancer, ASCO is actively engaged in promoting the rapid reduction and ultimate elimination of tobacco products and exposure to environmental tobacco smoke. In addition to curbing tobacco use in the general population, it is essential to address tobacco use among the estimated 16.9 million cancer survivors, for whom remaining tobacco-free is essential for preventing cancer recurrence and other adverse health outcomes.\(^4\) Tobacco has been shown to pose unique risks to individuals already diagnosed with cancer, including increased risk of treatment-related complications, compromised effectiveness of treatment, and increased risk of a second primary cancer.\(^5\) Continued use of tobacco can also lead to complications with surgery and slow recovery, increased risk of other serious ailments such as cardiovascular or respiratory disease, and potential exacerbation of adverse effects of chemotherapy including immune suppression, weight loss, and fatigue.\(^4\) Tobacco has a direct impact on cellular function, decreasing the efficacy of chemotherapy and radiotherapy\(^6\); therefore, quitting tobacco may improve response rates and survival, as well as lower the risk of developing a second cancer.\(^7\)

ASCO believes it is part of the oncology community’s responsibility as health care professionals and cancer researchers to explore and address the devastating consequences of tobacco use and continue to educate and help patients with cancer quit.\(^5\) We therefore also encourage the FDA to include cessation support information such as the National Network of Tobacco Cessation Quitlines in the packaging and advertising of cigarettes. Quitlines are one of the most accessible cessation resources, and benefit the public’s health by increasing quit rates.\(^8\) Including information on the Quitlines could also help states achieve the recommended reach of 8-13% of their current smokers.\(^8\)

Thank you for consideration of our comments. We look forward to working with the FDA to enhance federal regulation of tobacco products and reduce the human and economic toll of tobacco use. If you have any questions, please do not hesitate to contact Karen Hagerty, MD, Director of Regulatory Affairs, at 571-483-1762 or Karen.Hagerty@asco.org.

Sincerely,

Howard A. Burris III, MD, FACP, FASCO
President
American Society of Clinical Oncology

\(^6\) Warren GW, Cartmell KB, Garrett-Mayer E, Salloum RG, Cummings KM. Attributable Failure of First-line Cancer Treatment and Incremental Costs Associated With Smoking by Patients With Cancer. JAMA Netw Open. Published online April 05, 20192(4):e191703. doi:10.1001/jamanetworkopen.2019.1703