



## Oncology Nursing Society

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July 16, 2018

Leslie Kux  
Associate Commissioner for Policy  
US Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

<https://www.regulations.gov>

### **RE: Docket No. FDA-2017-N-6107 for “Regulation of Premium Cigars”**

Dear Ms. Kux:

The Oncology Nursing Society (ONS) appreciates the opportunity to provide our perspective on the FDA’s advance notice of proposed rulemaking (ANPRM) to obtain information about patterns of use as well as the public health impacts of premium cigars to inform FDA regulation.

As a 39,000 member nursing organization dedicated to caring for patients with cancer, ONS is alarmed by the growing problem of nicotine addiction in our nation and the harmful effects of tobacco use, which can lead to cancer, other diseases and death. ONS strongly supports FDA’s efforts to regulate tobacco and to combat this growing public health crisis. To do this effectively and maximize public health benefit, ONS urges FDA to lift the current exemption and regulate premium cigars in the same manner as all other tobacco products.

ONS supports eliminating FDA’s special treatment for premium cigars, because research shows that they do indeed cause harm, they have cancer-causing elements, and both youth and young adults are using them, elevating harmful health risks. As NCI has made clear, “there is no safe level of tobacco use,” and people who use any type of tobacco product are strongly urged to quit.”<sup>1</sup>

Smoking cigars can cause upper respiratory problems and a variety of head and neck cancers, including cancers of the mouth, throat, and larynx. Research has shown that “head and neck cancer risk was elevated for those who reported exclusive cigar or pipe smoking” and suggests that “cigar and pipe smoking are independently associated with increased risk of head and neck cancers.”<sup>2</sup> Research has also shown that “although cigar and pipe smoking are not as common as cigarette smoking, ...cigar and pipe smoke may contain equivalent, or in some instances higher, doses of carcinogens such as benzo[*a*]pyrene compared with cigarette smoke.”<sup>2</sup>

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<sup>1</sup> <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco>

<sup>2</sup> Cigarette, Cigar, and Pipe Smoking and the Risk of Head and Neck Cancers: Pooled Analysis in the International Head and Neck Cancer Epidemiology Consortium <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3755640/>

ONS urges FDA to reconsider the current premium cigar regulation exemption, especially in light of its 2016 final deeming regulation findings that “all cigars pose serious negative health risks, the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and premium cigars are used by youth and young adults.”

ONS urges FDA to uphold the same public health standard for premium cigars as other tobacco products and is concerned that FDA dilutes its message about the harmful effects of tobacco if it makes any exemptions for particular classes of tobacco products. ONS feels strongly that continuing this exemption gives the wrong message to the public, and to young people in particular, that it is okay and not harmful to smoke cigars. In comments to the FDA on a tobacco standard for nicotine in combustible cigarettes, ONS recommends the maximum level of nicotine be set at .4MG or less. ONS recommends the same .4MG maximum be the standard for premium cigars to lessen nicotine addiction, recognizing however that continuing to smoke premium cigars, even with lower nicotine levels, still causes harm.

Additionally, ONS urges FDA to require the same warning labels and restrictions on advertising, marketing, and distribution of premium cigars as is required for other tobacco products. As the FDA has reported, both youth and young adults use premium cigars and should be made aware of both the risks of addiction and harm to health, including potential risk of developing cancer.

Finally, ONS believes that nurses can play a vital role in helping to educate and inform the public about the addictive nature of nicotine and the harmful health impacts caused by smoking premium cigars and using other tobacco products. Nurses can assist in tobacco prevention efforts by encouraging non-smokers never to start smoking and by helping smokers to quit, utilizing FDA approved and evidence-based smoking cessation methods. Quitting tobacco use is a matter of survival for many patients with cancer, and oncology nurses are committed to helping them stop their nicotine consumption to ensure the best health outcomes. ONS encouraged FDA to reach out to nurses and to ONS as the agency develops this and other policies related to tobacco use.

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We appreciate the opportunity to comment on the regulation of premium cigars. If you have any questions about our comments, please contact Dede Sweeney, ONS Director of Government Affairs, at [dsweeney@ons.org](mailto:dsweeney@ons.org).

Sincerely,

The Oncology Nursing Society

#### ***About ONS***

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.