



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

RE: Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

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 for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. This proposed regulation is extremely important to ONS, because nurses caring for patients with cancer are directly involved in evidence-based tobacco prevention and cessation efforts to support improved health, well-being and survival outcomes.

As stated in our endorsed position statement on tobacco¹, drafted by the International Society of Nurses in Cancer Care (ISNCC), tobacco use and exposure to tobacco smoke are known human carcinogens and have contributed to a global epidemic and public health emergency. According to the CDC, "cigarette smoking is the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year, or about 1 in 5 deaths."² Patients who smoke often are blamed unfairly or blame themselves for causing a tobacco-related cancer. In fact, many became addicted to nicotine in their adolescence or youth by an industry that spends billions of dollars to promote a product that, if used as directed, kills up to 50% of its users.

Toward that end, ONS agrees with FDA that tobacco-related harms ultimately result from addiction to the nicotine in such products, causing repeated use and exposure to toxicants. In addition, we support FDA action to reduce the level of nicotine in these products, so they are minimally addictive or nonaddictive, using the best available science to determine a level that is appropriate for the protection of the public health. We note that nursing research in tobacco control and tobacco dependence treatment can contribute significantly to developing interventions for all persons who smoke, including people with a cancer diagnosis, but more efforts and support are needed to enhance the science in this area. We encourage FDA to work with ONS as it continues to develop policy in this area.

¹ <https://www.ons.org/advocacy-policy/positions/policy/tobacco>

² https://www.cdc.gov/tobacco/data_statistics/fact_sheets?adult_data/cig_smoking/index.htm.

Here are our comments on FDA's five requested areas:

SCOPE – ONS urges FDA to apply a tobacco product standard for the nicotine level in **all** tobacco products, not just combustible cigarettes. While combustibles are a good first start for FDA to tackle, ONS views e-cigarettes and other non-combustibles as a growing public health concern whose nicotine levels should also be regulated in the very near future. Research shows that while many adults use e-cigarettes as an attempt to quit smoking, most adult e-cigarette users do not stop smoking cigarettes and continue to use both products (known as “dual use”).³ Adolescents who have never smoked conventional cigarettes but try e-cigarettes (the most commonly used alternative tobacco products among adolescents), have been shown to be “more likely to progress to conventional cigarette smoking than their peers who do not.”⁴ These findings of nicotine addiction and health harms to both adults and adolescents using non-combustibles are worrisome to ONS, and we urge FDA to take action soon to protect public health and minimize cancer risk.

MAXIMUM NICOTINE LEVEL – ONS supports lowering the level of nicotine to a maximum of .4mg or lower in all tobacco products. This level is consistent with what the World Health Organization (WHO) has recommended to reduce addiction.⁵ In any tobacco standard though, it is important that the ratio of tar to nicotine stay around 1 to minimize addiction.⁶

In its effort to reduce nicotine levels to no longer support addiction, ONS cautions FDA to be mindful of how additives, including sugar, when mixed in tobacco products, can negate the lower nicotine levels by the way they metabolize in the body. *Tobacco Free Kids* reports that sugar additives “increase the addictive effect of nicotine and make it easier to inhale tobacco smoke.”⁷

Heating and burning tobacco, which produces many breakdown products of sugars, including acetaldehyde, enhances the addictiveness of tobacco in experimental animals.⁸ Thus, ONS recommends that FDA ban sugar and other additives in tobacco products that could counteract the lower nicotine level standard.

ANALYTICAL TESTING – ONS recommends that analytical testing of nicotine levels be checked and verified by independent labs since machine measures can lead to inaccurate results. When humans smoke, their lips cover the air holes in cigarettes, but machines cannot do that, resulting in air diluting nicotine and tar levels. FDA should encourage labs to develop new testing methods that mimic how lips cover cigarette holes to ensure accurate nicotine testing results. ONS favors the Canadian testing method that most closely accomplishes this and encourages FDA to conduct testing that is independent from the testing conducted by the tobacco industry.⁹

³ Quit Methods Used by US Adult Cigarette Smokers, 2014–2016
@ https://www.cdc.gov/pcd/issues/2017/pdf/16_0600.pdf

⁴ Adolescent Smoking Susceptibility in the Current Tobacco Context: 2014-2016, Olusegun Owotomo, MD, MPH and Julie Maslowsky, PhD

^{5, 6} <https://doi.org/10.1093/ntr/nty022>

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https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/product_manipulation/2014_06_19_DesignedforAddiction_web.pdf

⁸ https://ec.europa.eu/health/scientific_committees/opinions_layman/tobacco/en/l-2/5.htm

⁹ <https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/publicaties/2017/10/20/factsheet-iso-vs-canadian-intense-eng-engelstalig/Factsheet+ISO+vs+Canadian+Intense+ENG.pdf>

REDUCTION TECHNIQUES – Although this is not an area of ONS expertise, ONS sees value in researching new agricultural practices to reduce nicotine levels in tobacco, including genetically modified tobacco.

COUNTERVAILING EFFECTS – To prevent and reduce countervailing effects from a new tobacco standard, FDA must inform the public that cigarettes are still harmful to the health of those who continue to smoke them, even if they are less addictive for those new to smoking, and that alternatives can be just as dangerous. Nurses can play an important role in informing and educating patients on the difference on how lower-nicotine cigarettes impact addiction vs causing health harm, including cancer risk. They can also help discourage the practice of adding nicotine in liquid or other forms to tobacco products that have had nicotine levels reduced. ONS supports efforts to better educate nurses, other healthcare professionals and the public on harms to one’s health that persist even with tobacco products that have lowered nicotine levels.

Adolescents -ONS urges FDA to clearly and carefully inform young people that while cigarettes with lower nicotine levels may be less addictive, they are still harmful to their health and cause cancer. Lab research has shown that adolescents who smoke Very Low Nicotine Cigarettes (VLNC) may still have a hard time quitting. A 2018 article recommends that “if the FDA mandates a reduced nicotine content standard for cigarettes, educational campaigns will be needed to correct misperceptions about RNC cigarettes' addictiveness and potential to aid cessation as well as inform consumers about their safety risks.”¹⁰

Adolescents may as a result of the lower nicotine standard turn to alternative tobacco products, such as e-cigarettes or “JUUL,” which all have very high levels of nicotine, or they may become “dual users” of VLNC and these other products. A pod fluid of JUUL, which is becoming increasingly popular among young people, can be the near equivalent of a pack of cigarettes (44.8 ± 0.6 and 61.6 ± 1.5 mg/mL respectively, corresponding to a benzoic acid/nicotine molar concentration ratio of 0.97 to 1).¹¹ ONS believes more needs to be done to discourage its use, particularly among youth.

Patients with Cancer - While FDA’s tobacco standard policy goal may be to reduce addiction in the overall population, it is imperative that patients with cancer quit consuming nicotine immediately to improve their health and survival outcomes. According to the Surgeon General, smoking cigarettes can cause cancer-specific deaths, and quitting smoking improves the prognosis of cancer patients and survivors, reducing their risk of second primary cancers, such as lung cancer.¹²

ONS supports FDA-approved smoking cessation methods, and oncology nurses will continue to utilize evidence-based interventions in their care of patients with cancer. While ONS would be pleased if a lowered nicotine standard helps patients with cancer to quit smoking, we are greatly concerned these patients may mistakenly believe that these are safer products and or turn to alternatives which they mistakenly think are less harmful or addictive.

¹⁰ 2018 article “Examining risk perceptions among daily smokers naïve to reduced nicotine content cigarettes” <https://www.ncbi.nlm.nih.gov/pubmed/29718357>

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5342216/>

¹² <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf>

IMPLEMENTATION – ONS recommends that implementation of a tobacco standard to lower nicotine levels **not** be a gradual one. Rather, FDA should define the maximum level of nicotine allowed and then move swiftly with implementation. FDA would need to give industry a limited timeframe to comply with the new standard, but ONS discourages a year by year approach, because this would inevitably open the door for lawsuits and delay any positive public health outcomes. Research clearly shows there is no benefit in gradually easing smokers off nicotine versus a hard quit. According to Cochrane research, there are comparable quit rates for patients who quit abruptly and those that reduce cigarettes before their quit day.¹³

CONTRABAND – Although this is not an area of ONS expertise, ONS supports authorizing FDA to use all powers at its disposal to ensure there is no increase in contraband as a result of a new tobacco standard reducing levels of nicotine in combustible products. Without enforcement efforts, ONS is concerned that smokers will seek out nicotine in other ways and perpetuate addiction and harmful health outcomes.

To conclude, ONS urges FDA to reduce nicotine levels in combusted cigarettes and all tobacco products. ONS believes that nurses can play a vital role in helping to educate and inform the public and patients with cancer about the addictive nature of nicotine and the harmful health impacts caused by both combustible and noncombustible tobacco products. Nurses can assist in tobacco prevention efforts by encouraging non-smokers never to start and by helping those who smoke 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.

We appreciate the opportunity to comment on an FDA tobacco standard for nicotine levels. If you have any questions about our comments, please contact Dede Sweeney, ONS Director of Government Affairs, at 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.

¹³ “Reduction versus abrupt cessation in smokers who want to quit” <https://www.ncbi.nlm.nih.gov/pubmed/20238361>