

October 15, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Dear Acting Commissioner Sharpless,

The American Optometric Association (AOA) appreciates the opportunity to provide these comments in response to the notice of proposed rulemaking “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,” Docket No. FDA-2019-N-3065 (August 16, 2019).¹ The AOA is the leading authority on quality eye care and an advocate for our nation's health, representing more than 44,000 doctors of optometry, optometric professionals, and optometry students. The AOA serves the needs of the public and health professionals through the provision of evidence-based clinical practice guidelines that promote prevention, identification, treatment, and management strategies for eye and vision conditions/diseases to improve the nation's health.

Doctors of optometry take a leading role in patient care with respect to eye and vision care, as well as general health and well-being. As primary health care providers, doctors of optometry have extensive, ongoing training to examine, diagnose, treat, and manage ocular disorders, diseases, and injuries including age-related macular degeneration and cataracts. They also play an important role in the management of systemic diseases with ocular manifestations including diabetes, hypertension, cardiovascular disease, and neurologic disease. Doctors of optometry deliver up to 80 percent of all primary vision and eye health care provided through Medicaid in the United States. Recognized as Medicare physicians for more than 30 years, doctors of optometry also provide medical eye care to more than six million Medicare beneficiaries annually.

The AOA applauds the Food and Drug Administration's (FDA) proposed rule establishing new tobacco health warning labels for cigarette packaging and advertisements. We fully support the inclusion of color graphics depicting the negative health consequences of smoking alongside these new textual warning statements. We are particularly pleased to see that the FDA includes two required warnings concerning the serious impacts of smoking on eye and vision health, namely age-related macular degeneration (AMD) and age-related cataracts. The AOA previously urged the FDA to consider requiring these warnings following the 2014 Surgeon General's report, *The Health Consequences of Smoking: 50 Years of Progress*, which confirmed the causal relationship between cigarette smoking and AMD. We are grateful that the FDA has been receptive to these appeals and firmly believe that the public will benefit significantly from warnings educating them about the lesser-known link between smoking and vision loss.

Include vision loss warnings in final ruling

¹ <https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements>

Loss of vision is a serious, significant public health concern. As such, AOA strongly advocates for the inclusion of the two proposed warnings related to vision loss in the final ruling, along with all 13 of the proposed warnings. AOA believes that finalizing all 13 warnings, which encompass a wide range of adverse health effects that touch varied socioeconomic, cultural, and ethnic communities in the United States, will best promote greater public understanding of the negative health consequences of smoking.

Because the use of tobacco products is related to several ocular pathologies including AMD, cataracts, dry eye, and reduced night vision, doctors of optometry have long been committed to educating their patients about the dangers of tobacco use. The AOA provides numerous resources to members to assist doctors in engaging their patients on these issues. While the AOA is dedicated to our existing public health campaigns regarding tobacco use and eye health, we believe that the FDA's requirement for cigarette packaging and advertising to include warnings that tobacco use causes AMD and cataract is a necessary next step to improve the visual health outcomes of the public.

We believe there would be a significant positive impact if the public better understood the link between cigarette smoking and vision loss. We know that vision loss is consistently ranked as a top fear across the country. A 2016 study published in JAMA Ophthalmology found through a nationwide survey that respondents across all ethnic and racial groups described loss of eyesight as the worst ailment that could happen to them, even when ranked against conditions including loss of limb, memory, hearing, or speech.² AOA's 2016 Eye-Q survey of people with diabetes showed that loss of vision is also a major fear among members of this group, who report that they are three times more concerned about blindness as a diabetes-related side effect than they are about the next largest side effect, kidney failure.³ Worsened quality of life and loss of independence were the most common concerns associated with vision loss.

There is also a societal cost associated with vision loss, as the financial impact of visual disability is substantial: in 2013, the total economic burden of vision loss and blindness in the United States was estimated to be \$139 billion, and treatment of eye-related disorders totaled more than \$68.8 billion in annual direct medical costs.⁴ The highest productivity losses from visual impairment are seen in high-income countries such as the United States.

The AOA thus reaffirms the need to include eye and vision health-related warnings in the FDA final rule. We would next like to offer a few changes to the current proposal regarding AMD, diabetes, and cataract.

AMD

Gendered and ethnic considerations for graphic depictions of AMD

We applaud the vital inclusion of AMD, the leading cause of vision loss in adults over age 50,⁵ in the FDA's proposed rule. However, it is important to note the gender differential of AMD. According to the National Eye Institute (NEI), women generally have a longer life expectancy than men and are therefore more likely to develop age-related eye diseases such as AMD.⁶ In 2010, 65 percent of AMD cases in the U.S. were in women compared with 35 percent in men.⁷ By 2050, NEI estimates that the number of people with AMD is expected to more than double from 2.07 million to 5.44 million. As such, the AOA suggests that the proposed photorealistic image of a man with AMD be changed to that of a woman, to reflect the demographic with higher risk for the disease.

² <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2540516>

³ <https://www.aoa.org/newsroom/aoa-annual-survey-reveals-misconceptions-about-diabetes>

⁴ <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2540516>

⁵ <https://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/macular-degeneration>

⁶ <https://nei.nih.gov/eyedata/amd>

⁷ <https://nei.nih.gov/eyedata/amd>

There is also an ethnic disparity of AMD to consider: while white Americans will continue to account for the majority of cases, Hispanic Americans will see the greatest rate of increase, with a nearly six-fold rise in the number of expected cases from 2010 to 2050.⁸ Furthermore, a 2006 NEI study found that Hispanic adults are the ethnic group least likely to have heard of common eye conditions such as AMD or diabetic eye disease, and were also the least likely to have their eyes examined.⁹ Due to the predicted increase of AMD in Hispanic populations together with the information gap and therapeutic intervention gap associated with this group, Hispanic Americans are particularly vulnerable to the eye-related risks of smoking. AOA therefore proposes that FDA consider depicting a Hispanic individual in the graphic image accompanying the AMD warning.

Focus AMD warning on effects, rather than treatment, of the disease

The current proposed image accompanying the AMD warning is that of an older man with AMD who is “receiving an injection in his right eye to prevent additional vessel growth.” AOA is concerned that this image depicts a treatment, rather than the effects, of the disease. To depict the effects of AMD, we propose that FDA instead utilize one of the commonly cited images produced by NEI, which depicts a child or group of children from the vantage point of a person with AMD.¹⁰ The image is blurred, and the faces of the children are covered with large dark spots due to the deterioration of central vision caused by AMD. We are concerned that the current image of a man receiving an eye injection will unintentionally create fear and distance between patients and necessary medical interventions and/or treatments.

Diabetes

Diabetes and vision loss

Diabetes is the leading cause of vision loss for Americans between the ages of 20-74.¹¹ In 2017, through comprehensive, dilated eye examinations, doctors of optometry diagnosed more than 401,000 cases of diabetic retinopathy in patients who were unaware they had type 2 diabetes. Patients with undiagnosed type 2 diabetes are at risk of developing microvascular and macrovascular complications, including visual impairment and blindness, hypertension, renal failure, heart disease, and stroke. In 2010, 800,000 people worldwide were blind and 3.7 million were visually impaired due to diabetic retinopathy, an increase of 27 percent and 64 percent, respectively, from 1990 to 2010.¹² The number of Americans age 40 years or older with diabetic retinopathy and vision-threatening diabetic retinopathy is projected to triple by 2050, from 5.5 million (in 2005) to 16 million for diabetic retinopathy, and from 1.2 million to 3.4 million for vision-threatening diabetic retinopathy.¹³

Rephrase the diabetes warning to a more effective public health message

The need for appropriate intervention and treatment for patients with diabetes will continue to increase if we are to prevent vision loss or blindness in the growing diabetic population. Because of the ocular manifestations of diabetes and the important, long-term role doctors of optometry play in diagnosing and treating patients with diabetes, AOA is thankful for the FDA’s inclusion of a warning that tobacco use causes type 2 diabetes.

However, we believe the proposed warning (“Warning: Smoking causes type 2 diabetes, which raises blood sugar”) fails to effectively convey the gravity of the disease or the numerous, serious health problems associated with type 2 diabetes. According to the American Diabetes Association, type 2 diabetes can cause or increase the risk of skin infections, glaucoma, cataracts, nerve damage,

⁸ <https://nei.nih.gov/eyedata/amd>

⁹ <https://nei.nih.gov/kap>

¹⁰ <https://www.nih.gov/health-information/nih-clinical-research-trials-you/age-related-macular-degeneration-amd>

¹¹ <https://www.aoa.org/optometrists/tools-and-resources/diabetes-and-eye-health>

¹² <https://www.aoa.org/documents/CPG3EyeCareOfThePatientWithDiabetes2ndEdition.pdf>

¹³ <https://www.aoa.org/documents/CPG3EyeCareOfThePatientWithDiabetes2ndEdition.pdf>

ketoacidosis, kidney disease, high blood pressure, and stroke, among other serious complications. The proposed warning's focus on heightened blood sugar, which is not unique to diabetes or itself inherently dangerous, does not carry the weight that referencing any one of these diabetic complications could.

AOA emphasizes the need to finalize a warning that smoking causes type 2 diabetes, but proposes the warning be written as one of the following:

1. WARNING: Smoking causes type 2 diabetes, which is a leading cause of blindness.
2. WARNING: Smoking causes type 2 diabetes, which can cause blurry vision.
3. WARNING: Smoking causes type 2 diabetes, which causes numbness in the hands and feet.
4. WARNING: Smoking causes type 2 diabetes, which raises your risk for stroke.

Cataract

Consider the inclusion of a woman in graphic

AOA supports the inclusion of a warning about the link between smoking and developing cataract. As previously mentioned, since women generally have a longer life expectancy than men in the United States, they are therefore more likely to develop age-related eye problems.¹⁴ As such, we propose the FDA include a woman in the graphic to accompany the cataract warning, so that the demographic with a higher likelihood of developing the condition can better relate to the graphic.

Final remarks

AOA is aware that graphic warnings can be helpful in preventing non-smokers from becoming smokers; however, the impact of these warnings alone are not likely to have such a significant impact on those who are already addicted to cigarettes. Because of this, we suggest that FDA also require the inclusion of a resource to help people quit smoking on all packaging and advertising. We suggest that the National Cancer Institute (NCI) quit hotline, 1-800-QUIT-NOW, be included alongside all warnings as a resource for those individuals who are already addicted.¹⁵ Including graphic images of disease can create and/or perpetuate shame on to people who are addicted to cigarettes but want to quit. We urge the FDA to work to reduce nicotine levels, restrict tobacco advertising, provide resources for quitting, and decrease the use of e-cigarettes and vaping, especially among youth.

The loss of vision from smoking is entirely preventable. We applaud FDA's efforts to reduce the number of people who are visually impaired due to their lack of education surrounding the less-known adverse effects of smoking. AOA and its members stand ready to support this rule in any way we can and will remain actively involved in ensuring patient education and understanding of these important health issues.

Thank you for the opportunity to provide these comments. If you have any questions, please contact AOA's Regulatory Policy Specialist, Emily Dalgo, at edalgo@aoa.org.

Sincerely,



Barbara L. Horn, O.D.
President, American Optometric Association

¹⁴ <https://nei.nih.gov/eyedata/amd>

¹⁵ https://www.cdc.gov/tobacco/quit_smoking/cessation/pdfs/1800quitnow_faq.pdf