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April 30, 2019

Dr. Ned Sharpless  
Acting Commissioner  
U.S. Food and Drug Administration  
5630 Fishers Ln, Room 1061  
Rockville, MD 20852

Submitted via the Federal Rulemaking Web Portal: <http://www.regulations.gov>

**Re: Modifications to Compliance Policy for Certain Deemed Tobacco Products (FDA-2019-D-0661)**

Dear Acting Commissioner Sharpless:

The Blue Cross Blue Shield Association (BCBSA) is pleased to have the opportunity to respond to the “Modifications to Compliance Policy for Certain Deemed Tobacco Products” draft guidance as issued in the Federal Register on March 14, 2019 (84 FR 14120).

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies (BCBS Plans) that collectively provide healthcare coverage for one in three Americans. For more than 80 years, BCBS Plans have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBS Plans share the U.S. Food and Drug Administration’s (FDA’s) commitment to preventing the initiation of tobacco use among youth and young adults. Sales for e-cigarettes skyrocketed 800 percent with the introduction of vaping and flavored, near-vapeless devices. As FDA notes, these devices are being actively marketed to kids using tactics such as attractive packaging, flavors and social media promotion, with startling success:

- More than one-third of high school students have used e-cigarettes in the past year.<sup>1</sup>

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<sup>1</sup> Surgeon General, “Know the Risks, E-cigarettes & Young People,” Accessed Feb. 1, 2019 at <https://e-cigarettes.surgeongeneral.gov/getthefacts.html>

- Use among middle and high school students has more than tripled from 2013 to 2016 and continues to grow.<sup>2</sup>
- 85 percent of device users ages 12 to 17 use flavors that contain nicotine.<sup>3</sup>

E-cigarettes are not healthy for young people. The vapor contains harmful ingredients, including nicotine, which can impair brain development and cause addiction. Furthermore, the National Academies of Science, Engineering and Medicine (NASEM) found e-cigarette use among youth is a gateway to the initiation of cigarette smoking. As such, we believe curbing young adult use of these products should be a priority for the federal government.

In the context of enforcing the compliance of products already on the market, we support the FDA prioritizing enforcement of products targeted toward minors, specifically flavored electronic nicotine delivery system (ENDS) products and cigars. Furthermore, we support increased scrutiny on the easiest points of access (e.g., online retailers) for these products. BCBSA agrees focusing on these products and access points will have a meaningful impact on reducing access to, and use of, tobacco products by minors. As FDA notes, ENDS are the products most commonly used by youths and flavored cigars have the greatest likelihood of use by youths no longer able to obtain ENDS products.

In addition to the changes proposed by the FDA in this guidance, we encourage the FDA to include menthol- and mint-flavored ENDS products in its enforcement efforts. While we understand that these products may provide value to adults and are less commonly used by youths than other flavors, we believe there is a strong potential for youths to switch to these products as other flavors become less available. Therefore, including these products in enforcement efforts now will help to more quickly accomplish the ultimate goal of preventing youth use of tobacco products.

We also encourage the FDA to exercise its authority to take flavored ENDS off the market until the products undergo premarket review. Given youth preferences for these products as well as limited evidence of positive public health impacts from these products, BCBSA believes it is appropriate to require the products' manufacturers to substantiate claims these products are truly safe and effective before selling to consumers.

Finally, we encourage the FDA to support initiatives to increase the age of tobacco and e-cigarette use to 21. The National Academy of Medicine conducted a study of the public health outcomes of raising the minimum age of legal access to tobacco products to 19, 21 or 25 years of age and found increasing the minimum age would likely prevent or delay the initiation of tobacco use by adolescents and young adults.<sup>4</sup> The researchers found the greatest marginal increase in public health benefits would be seen by raising the age to 21. Six states have

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<sup>2</sup> Surgeon General, "Know the Risks, E-cigarettes & Young People," Accessed Feb. 1, 2019 at <https://e-cigarettes.surgeongeneral.gov/getthefacts.html>

<sup>3</sup> Campaign for Tobacco Free Kids, "The Flavor Trap: How Tobacco Companies are Luring Kids with Candy-Flavored E-Cigarettes and Cigars," Accessed Feb. 1, 2019 at [https://www.tobaccofreekids.org/microsites/flavortrap/full\\_report.pdf](https://www.tobaccofreekids.org/microsites/flavortrap/full_report.pdf).

<sup>4</sup> The National Academies of Science, Engineering and Medicine, "Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products" Accessed Feb. 1, 2019 at <http://www.nationalacademies.org/hmd/Reports/2015/TobaccoMinimumAgeReport.aspx>

already increased the tobacco age to 21,<sup>5</sup> with at least one additional state considering legislation. Furthermore, at least 430 localities have implemented similar laws.<sup>6</sup> In addition, in recent weeks Congress has expressed interest in a federal law that would raise the tobacco age to 21.

We appreciate your consideration of our comments on the FDA's proposed guidance and additional actions to address tobacco use by youths. We look forward to continuing to work with the FDA on preventing tobacco use among youth and young adults and other efforts to improve the health of Americans. If you have questions, please contact Anshu Choudhri at 202.626.8606 or [Anshuman.Choudhri@bcbsa.com](mailto:Anshuman.Choudhri@bcbsa.com).

Sincerely,



Kris Haltmeyer  
Vice President, Legislative and Regulatory Policy  
Blue Cross and Blue Shield Association

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<sup>5</sup> Campaign for Tobacco Free Kids, "U.S. State and Local Issues: Raising the Tobacco Age to 21," Accessed Feb. 1, 2019 <https://www.tobaccofreekids.org/what-we-do/us/sale-age-21>

<sup>6</sup> Campaign for Tobacco Free Kids, "U.S. State and Local Issues: Raising the Tobacco Age to 21," Accessed Feb. 1, 2019 <https://www.tobaccofreekids.org/what-we-do/us/sale-age-21>