



August 3, 2017

Ms. Caryn Cohen, M.S.  
Tobacco Products Scientific Advisory Panel  
Food and Drug Administration  
Center for Tobacco Products  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Comment Letter RE: FDA-2017-D-3001**

Dear Ms. Cohen,

Thank you for the opportunity to comment on a product application under your review.

Molina Healthcare ("Molina") has for close to four decades been serving the poor and underserved who are insured through government-sponsored healthcare programs, engaging in Medicaid markets in thirty states and Puerto Rico. We have launched a successful business in the Health Insurance Marketplaces in nine different states. In addition, our Medicare Medicaid Program (MMP) for dual eligible individuals has more enrollees than any other MMP plan in the country. We have been serving the neediest members of the Medicare Advantage program through our Dual Eligible Special Needs Program (D-SNP) product for close to a decade. Today, we are one of the ten largest health insurers in the country, serving more than 4.5 million low-income members in 12 states and Puerto Rico.

As health care providers, we see firsthand that smoking remains the nation's leading preventable cause of death and disease. Reducing tobacco consumption is one of the most important way to protect and improve public health. People who stop smoking greatly reduce their risk for disease and early death, and quitting smoking is the best possible way to reduce the risk associated with smoking. According to the Centers for Disease Control and Prevention (CDC), over 18 percent of U.S. adults smoke cigarettes and about one in five deaths are caused by smoking<sup>1</sup>.

Molina's smoking cessation program uses a combination of telephonic outreach by multi-disciplinary team of Care Managers, providers and pharmacy engagement to support the smoking cessation needs of our members. The team works closely with contracted providers and pharmacists to identify appropriate cessation aids when available. We believe that helping our members reduce unhealthy behaviors, such as quitting tobacco use, will improve their ability to manage pre-existing illnesses or chronic conditions. Molina is supportive of scientific review of newly developed technologies that would improve our ability to help our membership improve their health.

It is our understanding that on May 24, 2017 FDA accepted a Modified Risk Tobacco Product Application for substantive scientific review, formally beginning the regulatory assessment process. In order to promote and protect public health, we encourage the TPSAC to rigorously evaluate the scientific and health claims made in this application, and any subsequent applications for Modified Risk Tobacco Products.

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<sup>1</sup> Babb S, Malarcher A, Schauer G, Asman K, Jamal A. Quitting Smoking Among Adults — United States, 2000–2015. *Morbidity and Mortality Weekly Report* 2017;65:1457–1464.



We want to thank the FDA and the Tobacco Products Scientific Advisory Panel (TPSAC) for their commitment to reducing this risk, and to improve public health through the scientifically rigorous and thorough regulation of new tobacco products. Please let us know if we can be helpful to you in your efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "J. White", written over a light blue horizontal line.

**Joseph White**  
Interim Chief Executive Officer