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Caryn Cohen, M.S.
Office of Science
Center for Tobacco Products
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re:
Tobacco Products Scientific Advisory Committee Meeting
January 24-25, 2018

Dear Committee Member:

Citizens Against Government Waste (CAGW) is pleased to provide comments before the Food and Drug Administration's (FDA) Tobacco Products Scientific Advisory Committee (TPSAC) on the Philip Morris Products S.A. (PMI) modified risk tobacco product applications (MRTPA) for the iQOS system with Marlboro Heatsticks, iQOS system with Marlboro Smooth Menthol Heatsticks, and iQOS system with Marlboro Fresh Menthol Heatsticks.

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW is the legacy of the President's Private Sector Survey on Cost Control, also known as the Grace Commission.

Over-regulation by the FDA could remove or keep many innovative tobacco harm-reduction devices from the U.S. market, ultimately harming people. Smokers often find it difficult to quit smoking, even after using nicotine-containing patches, chewing gum, and prescription drugs. Millions have found success using electronic nicotine delivery systems (ENDS), such as e-cigarettes and vaporizers. Sales of vaping products have increased from \$20 million in 2008, a year after the first vaping products appeared in the U.S., to an estimated \$4.4 billion in 2017.

In alignment with the growth of e-cigarettes, a July 26, 2017 study by researchers at the University of California San Diego found that Americans are quitting smoking in higher numbers for the first time in 15 years and that e-cigarettes have played a role. Head researcher Shu-Hong Zhu, Ph.D. stated, "Our analysis of the population survey data indicated that smokers who also used

e-cigarettes were more likely to attempt to quit smoking, and more likely to succeed. Use of e-cigarettes was associated both with a higher quit rate for individuals as well as at the population level; driving an increase in the overall number of people quitting.”

Many countries are beginning to recognize the benefits of ENDS and similar non-combustible products. Most notably, on July 18, 2017, England’s Department of Health (DoH) announced its tobacco control plan, “Towards a Smokefree Generation: A Tobacco Control Plan for England.” The DoH stated that in 2016, an estimated 2 million consumers in England had used e-cigarettes to completely stop smoking and 470,000 were using them as a tool to help them stop smoking. Recognizing that quitting smoking is difficult, the DoH stated, “evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products.”

Going a step further, Public Health England, an executive agency within DoH, produced guidance for employers and other organizations regarding e-cigarette policies to encourage the use of e-cigarettes and similar novel technology. It recommended that these types of products should not be covered by smoke-free legislation, and should not be routinely included in the requirements of an organization’s smoke-free policy.

Comments

Philip Morris’s iQOS system and Heatsticks is another promising new tobacco harm-reduction product that will help people quit smoking. Its heat-not-burn technology is another alternative to smoking cigarettes, just as e-cigarettes or vaporizers have done for millions of Americans. According to the Centers for Disease Control and Prevention, 15.1 percent of U.S. adults, or 36.5 million people, were smoking cigarettes in 2015; seven in 10, or 68 percent of smokers, wanted to stop; and, more than half, or 55.4 percent made an attempt in to stop smoking.

It is the burning of tobacco, where the lit end of a cigarette can reach 1600°, that causes the release of toxic chemicals, which lead to cancer and other health problems associated with smoking. The PMI iQOS system heats tobacco to a temperature of less than 600°F. Instead of smoke, an aerosol is created composed mainly of water and glycerol. Since there is no combustion, many of the chemical reactions that occur with burning do not take place and therefore, the aerosol contains significantly lower levels of harmful or potentially harmful constituents (HPHCs) than conventional cigarette smoke. Because the iQOS replicates the taste of tobacco and nicotine delivery, the ritual characteristics of cigarettes are maintained, which are important for appealing to and acceptance by adult smokers. As a result, users will be more likely to move away from smoking cigarettes.

The iQOS system fits well with the FDA’s plans to shift downward the trajectory of tobacco-related disease and death that was discussed in its comprehensive regulatory plan released on July 28, 2017. Currently, the iQOS is available for sale in Japan, as well as in cities in 31 other countries, including Germany, Italy, Romania, Russia, Switzerland, the United Kingdom, and Duty Free markets. According to PMI, more than 3.7 million adults have switched from cigarettes to iQOS.

PMI has made available data on the website PMIScienceUSA.com that shows utilization of the iQOS reduces the amount of toxic chemicals that enter the body compared to smoking conventional cigarettes. For example, HPHCs have been found to be, on average, 90 percent lower than those found in a cigarette. In addition, the levels of chemicals classified by the International Agency for Research on Cancer as Group 1 carcinogens were reduced on average by more than 95 percent compared to a conventional cigarette.

In clinical trials carried out in Japan and the United States, smokers who switched from cigarettes to the iQOS were exposed to reduced levels of 15 HPHCs, including carbon monoxide, acrolein, benzene, and butadiene, compared to smokers who continued to smoke. The reductions in levels of the HPHCs for the iQOS users were similar to levels seen in smokers that quit smoking for the duration of the study.

Questions have been raised as to whether ENDS-type products act as a gateway to smoking. According to a study by Lynn Kozlowski, Ph.D. and Kenneth Warner, Ph.D., “Adolescents and E-cigarettes: Objects of Concern May Appear Larger Than They Are,” published in the online January 27, 2017 edition of *Drug and Alcohol Dependence*, the answer is not likely. They examined the findings of major studies on whether e-cigarettes cause a substantial danger to the health of young people and found several deficiencies that give the impression there is a strong link between e-cigarette use and subsequent smoking. Lead author Kozlowski said, “Our analysis focused on the risks for moving from e-cigarettes to cigarettes. There is little evidence that those who have never smoked cigarettes or never used other tobacco products and first try e-cigarettes will later move on to cigarette usage with great frequency or daily, regular smoking.”

It is far more likely that youth, who experiment with other substances will also explore e-cigarettes or combustible cigarettes. Co-author Warner noted that all the studies show there is a “connection between kids who vape and future experimentation with smoking. But we know that these kids are different from those who do not vape. Even if there is a small gateway effect, it is totally swamped by the overall trend toward less and less smoking.”

Similarly, with regard to perception and behavior assessment on whether nonsmokers would be interested in using an iQOS product, PMI has found that there is negligible interest among adult never-smokers and former smokers.

Conversely, PMI found there appears to be substantial potential for current smokers to switch to iQOS, indicating the product provides an experience that is as close to smoking as possible but, with less exposure to harmful chemicals. Real life results of this phenomenon have occurred in other countries, such as Japan, where more than 70 percent of iQOS users have fully switched over from smoking as of December 2016.

Conclusion

Studies and evidence of changes in behavior in other countries show that pioneering tobacco products, such as e-cigarettes, are successful in moving people away from smoking. It is important for the FDA to carry through on its commitment to strike “an appropriate balance

between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.” That is why CAGW urges the TPSAC to recommend approval of PMI’s MRTPAs for the IQOS system and Heatsticks.

Sincerely,

Thomas Schatz