



**CITIZENS
AGAINST
GOVERNMENT
WASTE**

Thomas A. Schatz, *President*
1100 Connecticut Ave., N.W., Suite 650
Washington, D.C. 20036
cagw.org

March 21, 2018

Commissioner Scott Gottlieb, M.D.
Food and Drug Administration
Dockets Management Staff
HFA-305
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Attention

Docket Number FDA-2017-D-3001
Modified Risk Tobacco Product Applications (MRTPA) by Philip Morris Products S.A.
Applications for 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, fraud, abuse, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was established to follow up on the work of the President's Private Sector Survey on Cost Control, also known as the Grace Commission.

According to Philip Morris Products S.A. (PM), the lit end of a cigarette can reach 1600°F. High temperatures cause the tobacco to release chemicals, including harmful and potentially harmful constituents (HPHC), which lead to cancer and other health problems associated with smoking. The Food and Drug Administration (FDA) has stated more than 70 chemicals in cigarette smoke are linked to cancer.

PM's Tobacco Heating System, or IQOS, is a heat-not-burn product and consists of a tobacco stick or plug made from tobacco powder, a holder that heats the stick to a temperature of less than 600°F, and a charger. 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. Thus, the IQOS aerosol contains significantly lower levels of HPHCs than 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 an adult smoker. As a result, users will be more likely to move away from

smoking cigarettes. Smokers switching to less harmful tobacco products will not only help save lives, it will help save valuable healthcare dollars in Medicare, Medicaid, and private health insurance.

Under the Family Smoking Prevention and Tobacco Control Act (TCA), the FDA was given premarket review authority over any new tobacco product that was not commercially marketed in the U.S. as of February 15, 2007. Section 918 of the law also required the FDA to submit to Congress a report on how best to regulate, promote, and encourage the development of innovative products and treatments, including those with nicotine and no nicotine, to better achieve, in a manner that best protects and promotes the public health: (A) total abstinence from tobacco use, (B) reductions in consumption of tobacco, and (C) reductions in the harm associated with continued tobacco use.

In April 2013, the FDA submitted its Section 918 report to Congress, and noted, the “MRTP [Modified Risk Tobacco Product] pathway may provide an important mechanism for the development of innovative harm-reduction products, particularly if manufacturers can develop products that substantially reduce toxicity, addictiveness, or both.”

On July 28, 2017, the FDA released its comprehensive regulatory plan to protect kids and significantly reduce tobacco-related disease and death. The agency restated its commitment to “encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect kids and help smokers quit cigarettes.” And, to strike an “appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes,” the FDA extended the timelines to submit product review applications for electronic nicotine delivery systems, such as e-cigarettes, until August 2022.

Comments

Despite what the FDA is supposed to do and has stated it will do to encourage the development of new tobacco products and treatments that will reduce harm, CAGW was disappointed with the approach and outcome the Tobacco Products Scientific Advisory Committee (TPSAC) took at its January 24 and 25, 2018 meeting concerning PM’s MRTPAs for its IQOS products.

Looking at the data submitted by PM, the IQOS would seem to fit into FDA’s 2018 Strategic Policy Roadmap to pursue key public health initiatives, like taking “a fresh look at products that can deliver satisfying levels of nicotine to adults who want access to it without burning tobacco.”

Almost from the beginning of the meeting, it became clear that the majority of advisory committee members were opposed to the IQOS being advertised and sold as a MRTP, even though the data presented showed that the new tobacco product did reduce harmful chemicals and that smokers are switching to PM’s heat-not-burn technology in growing numbers in other countries.

TPSAC members dismissed studies from Japan and Italy showing that smokers switched to the IQOS in large numbers and that in post-market observations, exclusive use of the IQOS reached 72 percent and 61 percent respectively, as opposed to using cigarettes or both, in those countries.

Some members raised questions that indicated a lack of knowledge concerning and a disregard of the presentation by PM at the meeting, such as by repeatedly asking about the temperature at which the HeatStick reaches combustion, even though PM had consistently made clear the IQOS is a heat, not burn technology. To light a HeatStick on fire would be a misuse of the product.

Other committee members looked for additional excuses not to approve the product, claiming that the IQOS was too high tech and sophisticated for some people, the label required “very high literacy levels,” and for “populations who have been left behind, this is just too complex for them,” or “this stuff is just way too complex for the average Joe.”

People “left behind” are perfectly capable of using new technological products, such as smart phones. According to a February 5, 2018 Pew Research Report, 92 percent of individuals with an income below \$30,000 have a cell phone and 67 percent use a smart phone. Therefore, it would seem logical that populations “left behind” have the capability of understanding how to use a product such as the IQOS. Furthermore, the Centers for Disease Control and Prevention has found that current cigarette smoking was the highest among persons with no high school degree or a graduate education degree certificate; 24.1 percent and 40.6 percent respectively. These are the very people the FDA should want to encourage to switch from cigarettes to the IQOS, or other non-combustible tobacco products, such as e-cigarettes.

Indeed, PM pointed out in their presentation that there is a learning curve for any new technological product, like when a person uses a smartphone for the first time. PM stated their experience in overseas markets has enabled them to design a marketing strategy that would maximize their reach to adult smokers, enabling them to switch the smoker completely to the heat-not-burn technology, and at the same time limit access to the product by non-smokers and youth.

Other advisory committee members seemed to suggest the system might be too dangerous to sell because 5 percent of the people that tested the product used it inappropriately, such as chewing a tobacco plug or trying to insert a regular cigarette into the holder. No doubt a lot of new products are used incorrectly until people become more familiar with them. But, even after a product has been in commercial use for years and even when given clear directions are provided for its use, there are many items that continue to be used inappropriately by the public. That is not an excuse for failing to approve a product such as the IQOS.

The committee was tasked by the FDA to answer a series of questions regarding the data presented by PM concerning the IQOS product.

One question the FDA asked the committee was as follows:

Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: ‘Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.’?

Even though many of the committee members noted that PM was going in the right direction, or that continuing to smoke would be far more harmful than using the IQOS, or that the data

presented was certainly convincing that HPHCs are reduced, eight members of the TPSAC voted no, with one abstention.

The FDA also asked the committee the following question:

Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: ‘Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.’?

Ironically, in this case there were eight yes votes and one no vote affirming that the IQOS is a modified risk tobacco product.

In other words, even though the data showed the IQOS reduced harmful chemicals that cause cancer, lung, and heart disease, the TPSAC does not want to give PM the ability to tell smokers that important information on the IQOS label.

Conclusion

As of May 2017, there have been 35 MRTPAs submitted to the FDA. The FDA has refused to accept some, others the agency has refused to file because the application may be incomplete, and others have been denied. Presently, there is no tobacco product on the market with a MRTP order, even though the TCA was signed into law in 2009 and compliance guidance was issued in March 2012.

Currently, there are 37.8 million adult smokers, or 15.5 percent of the U.S. population. Some smokers have turned to vaping. A January 2018 study by the National Academies of Sciences, Engineering, and Medicine, found “There is conclusive evidence that completely substituting e-cigarettes for conventional cigarettes reduces users’ exposure to many toxicants and carcinogens present in conventional cigarettes.”

Based on the data presented by PM, the IQOS also provides less exposure to toxins that cause cancer, heart, and lung disease. CAGW respectfully asks the Center for Tobacco Products to not follow the advisory committee’s recommendations, and instead, authorize the marketing of IQOS as a MRTP. Doing so would allow PM to promote that its product reduces harm and allow current American smokers to have access to a tobacco product that would help them to break free from smoking cigarettes.

Sincerely,

Thomas Schatz