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Primary Care

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September 14, 2017

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Division of Dockets Management (HFA-305)
Rockville, MD 20852

Re: Comment to docket No: FDA-2017-D-3001

Dear Dr. Gottlieb:

As a primary care physician, I work with my patients daily on quitting smoking. They understand that smoking is an extreme hazard to their health, but despite efforts to quit on their own or using the variety of stop smoking aids on the market, many of them continue to struggle to quit, and each day they continue to smoke they put themselves at more and more risk of serious disease and premature death.

In some cases, where my patients cannot or will not quit smoking, I have to switch to a harm-reduction approach and encourage them to cut back so as to minimize the negative effects of this habit. But my toolbox is very limited and I strongly believe we are in need of more alternatives and strategies to help our patients minimize their exposure to the damaging products of tobacco combustion.

I was delighted to see that the Food and Drug Administration has been taking steps recently to expand your approach to tobacco and nicotine regulation. Based on your article in the New England Journal of Medicine, you clearly understand the central issue, which is that while nicotine is not a completely benign compound, it is the products of tobacco combustion that are causing the majority of harm to the population at this time. Reducing the use of combustible tobacco products would greatly improve the health of our citizens.

As you stated in your article, the law provides the FDA with a regulatory tool to improve access to non-combustible tobacco products and thereby reduce the harm from smoking. The Family Smoking Prevention and Tobacco Control Act of 2009 lets FDA review and approve Modified Risk Tobacco products and gives the FDA the power to bring potentially reduced risk products to market prior to granting permission to make claims of reduced risk or harm to patients.

While we don't yet know enough about the long-term effects of non-combustible tobacco products, the FDA has a well-developed system for monitoring the effects of these products over time. Bringing them to market would not only help millions of people in this country with another meaningful option to reduce their risk of harm from smoking, it would enable the US to do its own research on the impact of these products and adjust policy over time accordingly.

I have reviewed some of the data presented in the Modified Risk Tobacco Product Application by Phillip Morris International for the iQOS heated tobacco system and heat sticks, and am impressed by the apparently dramatic reductions in exposure to many of the chemicals released by tobacco consumption that are linked to the development of chronic pulmonary and cardiovascular disease as well as cancer. However, as a physician, I support a careful review of that data by the FDA so that I can confidently recommend these products should they be allowed to come to market.

I sincerely hope that if your review is consistent with the claims made in the Phillip Morris application that you will expeditiously approve these products to be brought to market. Uptake in other countries, such as Japan, has been very rapid, with the promise of a dramatic and accelerated reduction in smoking-related diseases. I have asked my long-time smoking patients who can't seem to quit whether they would consider such a product as a way to reduce harm to themselves and those around them, and their response has been very enthusiastic – they clearly understand the damage they are doing but need our help to find ways to decrease their exposure.

I look forward to hearing the results of your review of this application.

Sincerely,

Erika Bliss, MD