January 4, 2018

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

RE: Docket No. FDA-2017-N-5994

Dear Ms. Cohen:

The Hispanic Leadership Fund is a nonpartisan advocacy organization dedicated to promoting public policy the strengthens liberty, opportunity, and prosperity for all working American families. On behalf of our members across the country I write today to the Tobacco Products Scientific Advisory Committee to support authorizing the Modified Risk Tobacco Product applications published June 15, 2017 as they prepare for their public meeting on the 24th and 25th of January of this year.

As the committee knows, the Family Smoking Prevention and Tobacco Control Act of 2009 authorizes the FDA to ensure that tobacco products marketed with claims of reduced harm or risk of tobacco-related disease do so.

According to the Centers for Disease Control, 480,000 people die every year in the United States due to smoking, and smoking-related illnesses cost over $300 billion yearly, including medical expenses and lost economic productivity. But despite massive public campaigns and other large-scale and costly efforts in recent years, millions of Americans will continue to smoke.

In this context, recent comments from Mitch Zeller, the director of the FDA's Center for Tobacco Products, are particularly striking. "Newer and more novel forms of delivering nicotine…could be incredibly helpful to curtail cigarette smoking," he noted. "At the end of the day, it's not nicotine that causes disease and death. Shouldn't we be thinking about various forms of nicotine delivery?"

We agree with Mr. Zeller's assessment, as well as the FDA's own comment in the Tobacco Deeming Regulation in the Federal Register on May 10, 2016 stating that "FDA believes that the inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."

It is also worth noting that just last month, the United Kingdom's Food Standards Agency's Committee on Toxicity issued an important statement on non-combustible products, concluding that they "are likely to be less risky than smoking conventional cigarettes."

The FDA recognizes that harmful or potentially harmful constituents (HPHCs) are the likely causes of smoking-related diseases. Indeed, the tobacco combustion that takes place during cigarette smoking, where temperatures can reach 1600° F or higher, breaks down tobacco into harmful chemicals.

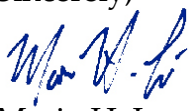
Heating tobacco without combustion, however, produces an aerosol that is not the result of the chemical reactions that result from combustion and contains lower levels of toxicants compared to cigarette smoke.

The MRTP application in question features a patented IQOS system. This alternate form of nicotine delivery eliminates 95 percent of toxic chemicals that are present in cigarettes as well as about 70 cancer-causing chemicals present in tobacco smoke.

The public health benefits are simply too great to ignore. The FDA has an opportunity to recognize the realities and science involved in tobacco consumption, and allow consumers to use products that will substantially lower the negative effects of tobacco consumption through combustion.

These reasons outline precisely why the Tobacco Products Scientific Advisory Committee should recognize the merits of approving the Modified Risk Tobacco Product applications submitted by PMI.

Sincerely,



Mario H. Lopez
President