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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

Access Health of Muskegon Michigan is a comprehensive health plan which provides health care services to many of the working poor in our community. Our mission is to provide creative, innovative health and coverage solutions to drive affordable and high quality care experiences that lead to optimal health.

Since 1999 Access Health has created innovations that provide affordable coverage to eligible uninsured individuals and their families, backed by programs that help them make healthier choices to reach optimal health. We also help community businesses maintain a healthy workforce through population health management. Access Health's coverage model over the years has demonstrated sustainable achievement of the triple aims of health reform: better health care, better health quality, and lower healthcare costs.

Access Health provides classes, programs, resources, and healthcare coverage to lead our community on a path toward healthier lifestyles. We know that being healthy isn't always easy, so our approach is to show you how to take small, realistic step. For instance, every member of Access Health who smokes is requires to take a smoking cessation class every year. But despite our best efforts, many of our members continue to smoke.

Smoking remains the leading preventable cause of premature disease and death in the United States. Reducing tobacco consumption is one of the most important ways to protect and improve public health. According to the Centers for Disease Control and Prevention (CDC) about one in five deaths are caused by smoking and among all current U.S. adult cigarette smokers, nearly 7 out of every 10 (68.0%) reported in 2015 that they wanted to quit completely.

The Scientific evidence is clear: 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. There are substantial benefits to quitting smoking at any age. Cessation counseling and medications improve smokers' chances of quitting, and have an even greater effect when

combined. However, as the Surgeon General reported in 2014, "Evidence-based interventions that encourage quitting and prevent youth smoking continue to be underutilized." While adult smoking has declined over the last several decades, a wider array of tools to help people with more effective tobacco control options is critically important.

Patients who smoke clearly need more tools to help them quit. But if they cannot quit, these patients need strategies to dramatically reduce the harm that smoking can cause. "Quit or die" is simply not an alternative that meets the standards of the Hippocratic oath when other innovations are available that may help save lives. The development of novel products that are scientifically proven to be less harmful may be important alternatives to traditional cigarettes.

Doctors and other care givers, however, need to be certain that these products are safe and that that they do not cause other unintended harms before recommending them as an alternative for patients who have had difficulty quitting. Of course, it is critical that people who do not smoke won't start because there is a new less risky alternative, especially young adults or children.

On May 24, 2017, the U.S. Food and Drug Administration accepted a Modified Risk Tobacco Product Application (MRTPA) for substantive scientific review, formally beginning the regulatory assessment process.

In order to promote and protect public health, we strongly encourage the FDA to rigorously evaluate the scientific and health claims made in this application, and any subsequent applications for Modified Risk Tobacco Products in accordance with the law.

As such, we look to the Food and Drug Administration (FDA) to provide physicians and patients with the evidence that any such new product meets these important standards.
Family Smoking Prevention and Tobacco Control Act of 2009 requires new tobacco products be reviewed by FDA prior to being introduced on the market and that products marketed with claims of reduced harm or risk of tobacco-related disease actually do reduce harm or risk of disease. If these products are deemed by FDA to be safer than conventional cigarettes, long term post market studies should be required to ensure that the risks from these products do not change over time. It is also important that they do not increase risk for the population as a whole, that these products be available on the market for people who cannot or will not quit smoking altogether.
We applaud 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.