Congress of the United States Washington, DC 20515

March 11, 2024

The Honorable Joseph R. Biden President of the United States of America The White House 1600 Pennsylvania Avenue, NW Washington, DC 20500

Dear Mr. President:

We are writing to urge the Food and Drug Administration (FDA) to expedite consideration of long-pending applications for smoke-free tobacco products that could improve public health by providing adult smokers access to less harmful options.

In recent weeks there have been calls on the FDA to ban certain nicotine-containing products due to the potential of underage use. There is no debate: youth should not have access to nicotine-containing products, nor should youth be subject to marketing or advertising of these products on social media. Congress has taken several steps to help address these challenges, including raising the legal age to purchase tobacco and nicotine-containing products to 21 years of age and bringing synthetic nicotine products under the purview of FDA and its mission to protect and promote the public health.

According to data from the Centers for Disease Control and Prevention, in the past only 1 in 10 adult smokers quit smoking. These consumers deserve to have alternative, less harmful products available to make informed choices of their own or may make it easier to quit. We cannot allow scare tactics and misinformation to keep 30 million adult smokers in the U.S. from making informed decisions and providing them with information about and access to alternative products that present less risk than continued smoking.

Rather than banning products that have proven effective in converting smokers or reducing cigarette consumption, the FDA must utilize the regulatory approval framework provided by Congress fifteen years ago. Since the *Family Smoking Prevention and Tobacco Control Act of 2009* was signed into law by President Obama, the FDA has received over 26 million applications to market innovative smoke-free products. However, the FDA has authorized fewer than 50 product applications (of which less than 10 are commercially available products) and many other applications have been waiting over three years for official review. Meanwhile,

during this same period, FDA has authorized thousands of combustible cigarette product applications, as measured by CTP's own performance metrics.

Not only has the FDA's inaction continued to deprive American smokers with greater choice, but it has also contributed to the proliferation of illicit nicotine-containing products coming into the U.S. from markets like China, many of which are intentionally designed to appeal to youth.

This is a matter of public health. According to an ever-increasing amount of scientific research, smoke-free products hold enormous potential for current smokers to quit by switching to these less harmful products. We must continue to work together to prevent underage use of these alternative products, and we urge your administration to encourage the FDA to review smoke-free product applications more effectively and efficiently and to make those determinations on sound science.

Sincerely,

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Cc: The Honorable Robert M. Califf, M.D. Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993