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Feb 27, 2020

Dr. Stephen Hahn
FDA Commissioner
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Commissioner Hahn:

New data shows that traditional tobacco products including cigarettes, smokeless tobacco and cigars are at historic lows, but the use of vapor products by teens is on the rise. We write to urge you to focus FDA's full array of resources to implement and enforce "T21", the policy that President Trump recently signed into law.

The latest data from the National Institute of Health's (NIH) Monitoring the Future survey shows that 3.7 percent of high school aged children used cigarettes once in the past 30 days. However, the same data shows that use of vapor products has risen to 18.1 percent¹. Due to this startling data, the President signed legislation into law that raised the federal minimum age to purchase any tobacco product to 21 in December of 2019. This provision is a significant step forward in reducing access to vapor products among our nation's youth. We understand that about 80 percent of high school seniors will turn 18 before they graduate. Enforcement of the new age restriction is important because prior to raising the age of purchase, approximately 74 percent of youth report gaining access to vapor products through social sources², according to the FDA. This policy will provide a significant barrier to youth access and FDA must strictly enforce this new standard.

In order for T21 to be fully enforced, the FDA must also take responsibility to effectively implement it. Clear, organized enforcement plans need to be communicated by the FDA to regulated stakeholders.

On January 2, 2020, the FDA announced it had finalized an enforcement policy that would reduce the use of vapor products among our youth. Many of the media reports highlight

¹ Monitoring the Future dataset, University of Michigan, 2019. <http://www.monitoringthefuture.org/data/data.html>. (The survey is funded by the National Institute of Drug Abuse (NIDA), which is housed in the National Institutes of Health (NIH). The survey is conducted by the University of Michigan).

² ALCS analysis of Population Assessment of Tobacco and Health (PATH) Study, Wave 3 data (2015-16). PATH is a joint project of the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA).

concerns that the policy is limited to closed cartridge-based systems and allows for the continued marketing of tobacco and menthol flavors. Additionally, the media reported that the guidance continues to allow open-system products to continue to sell a wide-variety of flavors. However, the agency is required to take enforcement action against any tobacco product that FDA believes appeals to youth, regardless of category. We expect that FDA will utilize this important enforcement action and urge the agency to move swiftly to remove these products from the marketplace.

Finally, we are aware that all tobacco products will be required to file a premarket tobacco application (PMTA) to FDA by May 12, 2020. This is an important step to ensure that the framework of the underlying statute is faithfully enforced, and the products are appropriate for the protection of public health. Raising the federal minimum age to purchase tobacco products to 21, enforcing FDA's vapor guidance appropriately, and responsible manufacturers providing applications to FDA to remain on the marketplace is a framework that was sorely missing. Congress and the Administration took decisive action and we urge FDA to continue to use the tools available to achieve our shared goal of eliminating youth tobacco use.

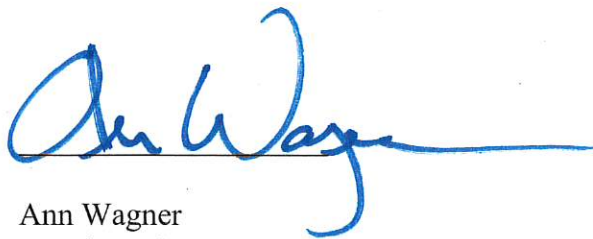
Sincerely,



Cathy McMorris Rodgers
Member of Congress



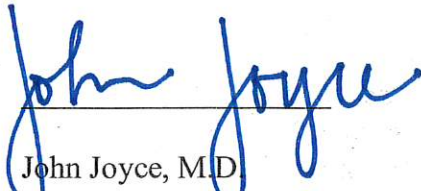
Michael T. McCaul
Member of Congress



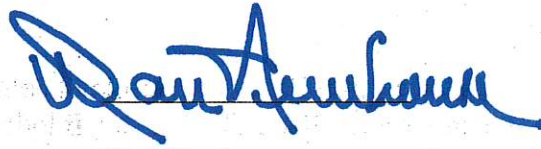
Ann Wagner
Member of Congress



David Rouzer
Member of Congress



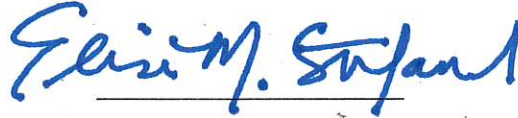
John Joyce, M.D.
Member of Congress



Dan Newhouse
Member of Congress



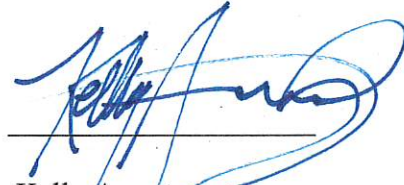
Greg Pence
Member of Congress



Elise M. Stefanik,
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Larry Bucshon, M.D.
Member of Congress



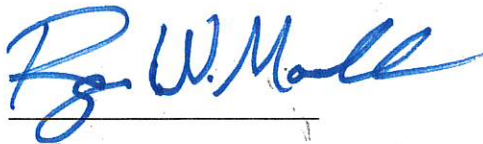
Kelly Armstrong
Member of Congress



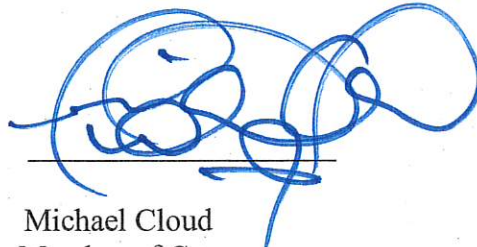
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