



December 3, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Re: Urgent request to protect America's youth by assert FDA's authority to regulate synthetic nicotine e-cigarette products as drugs.

Submitted by e-mail.

Dr. Woodcock:

The undersigned medical, scientific, and public health organizations urge you to take immediate action to regulate synthetic nicotine e-cigarette products. FDA's inaction on synthetic nicotine products, and in particular the Center for Drug Evaluation and Research's failure to assert its authority over synthetic nicotine products, has created a marketing loophole that e-cigarette manufacturers are exploiting. Urgent action must be taken to prevent the e-cigarette industry from exploiting this perceived regulatory loophole to further market addictive nicotine products to our nation's youth.

Youth e-cigarette use continues to be an urgent public health issue. As documented in the 2021 Youth Tobacco Survey results, over 2 million middle and high school students use e-cigarettes. More concerning, is the intensity of e-cigarette use by youth, with a quarter of youth e-cigarette users reporting daily use. For many of these youth, daily use means the beginning of a lifetime of nicotine addiction and subsequent adverse health consequences.

The FDA's Center for Tobacco Products is finally exerting its regulatory authority. After years of delay and enforcement discretion, FDA is finally taking initial steps to provide effective regulation of tobacco products and, in the process, will provide some protection for our nation's youth from the predatory marketing practices of the e-cigarette industry. However, if the e-cigarette industry can escape regulation by switching from tobacco-derived nicotine to synthetic nicotine, all FDA's efforts will be for naught.

And it is clear that the e-cigarette industry will explore every possible option to escape FDA regulation. Puffbar, the most popular e-cigarette among youth with 26.1 percent of the youth market, has publicly stated that it has switched to synthetic nicotine and does not intend to comply with FDA regulation. Other e-cigarette manufacturers are following suit and have announced their intent to switch to synthetic nicotine to avoid FDA regulation.

The issue of synthetic nicotine is not new. During the Obama and Trump Administrations, the medical and public health community has consistently communicated to FDA the need to develop a regulatory response to synthetic nicotine. To date, the agency has failed to take effective action.

Synthetic nicotine is a drug. Synthetic nicotine clearly falls under the legal definition of a drug and clearly is within FDA's regulatory authority to regulate as a drug. Synthetic nicotine has well described physiological effects. Synthetic nicotine is included in e-cigarette products expressly for the known physiological effects of nicotine. FDA has recognized the known effects of nicotine on the human body including satisfaction of addiction, stimulation, sedation, and appetite suppression.

The risk of e-cigarettes products to our nation's youth is real and immediate. While EVALI cases have dropped from their peak in 2019, pediatric academic medical centers continue to see new EVALI cases on a monthly basis. These new EVALI cases include patients who used adulterated or "off the street" e-cigarette products and branded nicotine-only e-cigarette products. The health consequences of long-term e-cigarette addiction are yet unknown but may include significant adverse health effects.

It is imperative that FDA act swiftly on synthetic nicotine products to protect the health of our nation's youth. The undersigned medical organizations urge FDA's Center for Drug Evaluation and Research to immediately clarify the regulatory status of synthetic nicotine products and assert its authority to regulate synthetic nicotine products as drugs.

We look forward to the agency's urgent action on this matter.

Sincerely,

American Academy of Pediatrics

American Association of Cardiovascular and Pulmonary Rehabilitation

American Association of Respiratory Care

American College of Cardiology

American College of Chest Physicians

American College of Preventive Medicine

American Public Health Association

American Thoracic Society

Society for Research on Nicotine and Tobacco

The Society of Thoracic Surgeons