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FOR IMMEDIATE RELEASE

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SAFE Glen Cove Coalition: FDA Receives Authorization to Regulate Synthetic Nicotine

On March 15th, President Joe Biden signed a $1.5 trillion omnibus spending bill to fund the federal government through September. One of the provisions of the bill amends the definition of "tobacco product" in Section 201(rr) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). It stipulates "any product made or derived from tobacco, or containing nicotine from any source that is intended for human consumption." 21 U.S.C. 321(rr). are now under the U.S. Food and Drug Administration's (FDA) tobacco regulatory authority. Hence these products originally formulated with tobacco-derived nicotine that were refused or denied authorization by FDA, then modified to use synthetic nicotine instead (and that is the only modification), will be banned on April 13, 2022. Further, Manufacturers of these products will not be given an opportunity to submit a new tobacco product application (PMTA) to FDA for premarket approval. This effectively prevents them from getting around this required process.

The law will become effective 30 days after the bill's enactment. Any synthetic nicotine product currently on the U.S. market as of April 14, 2022, can remain on the market for an additional 30 days until May 14, 2022 the ("Synthetic Nicotine PMTA Submission Deadline"). Manufacturers of synthetic nicotine products wishing to take advantage of FDA's compliance policy and enforcement discretion after that date must submit a premarket tobacco product application (PMTA) to FDA by the enforcement date. If a PMTA is submitted in a timely manner, the product(s) may remain on the market for an additional 90 days after the effective date, i.e., until July 13, 2022. After July 13, 2022, any synthetic nicotine product not authorized by FDA must come off the market.

In addition to the PMTA submission requirement, manufacturers of synthetic nicotine products will be subject to all requirements of regulations for tobacco products. Most likely the FDA shall provide detailed guidance and deadlines for these requirements in the eminent future. This refers to all Tobacco Control Act requirements for tobacco product establishment registration i.e.: product listing; ingredient listing; label compliance; and health document submissions, among others.

Despite the National decline in combustibles, the surge in youth vaping is very alarming and still requires a call to action. Recent needs assessments conducted by SAFE and the Glen Cove School District indicated that vaping is very popular among students. In response to this, the School and Parent Committees of the SAFE Glen Cove Coalition are working proactively to educate youth and their parents regarding the dangers of vaping.

With April's "Take Down Tobacco Day" this is great time to commit to Quitting, and for creating awareness of the dangers of e-cigarettes to our youth. For help Quitting contact the American Lung Association- Lung Helpline at: 800-Lung-USA or the N.Y. State Smokers' Quitline at 866-NY-QUITS (866-697-8487).

SAFE, Inc. is the only alcohol and substance abuse prevention, intervention and education agency in the City of Glen Cove. Its Coalition is concerned about tobacco use and vaping seeking to educate and update the community regarding its negative consequences in collaboration with Carol Meschkow, Manager- Tobacco Action Coalition of Long Island. To learn more about the SAFE Glen Cove Coalition please follow us on ww.facebook.com/safeglencovecoalition or visit the Vaping Facts and Myths Page of SAFE's website to learn more about how vaping is detrimental to your health www.safeglencove.org.