AUTHORIZATION OF VUSE SOLO BY THE U.S. FDA

Talking Points for Tobacco Control Advocates

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KEY MESSAGES

The U.S. Food and Drug Administration (FDA) recently announced that it authorized the sale of Vuse Solo, an e-cigarette sold by R.J. Reynolds Vapor Company, a subsidiary of Reynolds American, Inc. and British American Tobacco. Outside of the U.S., Vuse is sold by British American Tobacco, the world's largest publicly traded tobacco company.

While the FDA did authorize the sale of the Vuse Solo in tobacco flavor, it denied multiple applications for other flavored Vuse Solo cartridges and has previously denied applications for thousands of other flavored e-cigarettes. Vuse Solo in tobacco flavor is the only e-cigarette and the only Vuse sub-brand that FDA has authorized to be legally sold in the U.S. at this time.

Critically, the FDA specifically stated that its decision to authorize the sale of Vuse Solo tobacco-flavored e-cigarettes "does not mean these products are safe or 'FDA approved.' All tobacco products are harmful and addictive and those who do not use tobacco products should not start" (emphasis added).

The FDA also stated that it does not mean that the agency has endorsed the product nor the use of it, and FDA informed Reynolds, "you may not make any express or implied statement or representation in a label, labeling, or through the media or advertising, that the new tobacco products … are approved by FDA."

It is, however, extremely important to note that this decision is based on a unique set of U.S. laws and a regulatory framework that is not replicated in any other country.

Governments considering how to regulate e-cigarettes or any other tobacco product should not default to the decision of the FDA. Each country should make its own determination based on its own laws and circumstances. Many countries can and should implement restrictions stronger than those in the United States including but not limited to bans on flavored e-cigarettes and restricting the amount of nicotine in e-cigarettes.

KEY MESSAGES (CONTINUED)

Importantly, the FDA decision does not change the fact that there is inadequate evidence that e-cigarettes are effective at helping smokers quit. Even according to FDA's own review, "The extent to which the new products (or ENDS in general) facilitated cessation was unknown…". In addition, FDA acknowledged that it is unknown if the few smokers who were able to completely stop smoking were able to maintain their cessation status over time.

The authorization of Vuse Solo is particularly concerning as this e-cigarette contains very high levels of nicotine (57mg/ml), similar to Juul, which has been recognized as a primary cause of the youth e-cigarette epidemic in the U.S. This nicotine level is almost three times the nicotine concentration legally permitted in Canada, the UK and Europe. In authorizing these Vuse products, the FDA has both downplayed the potential for abuse of this highly addictive product and ignored real world evidence of the impact of such high levels of nicotine.

Globally, British American Tobacco markets e-cigarettes like Vuse through massive influencer marketing campaigns and in a variety of ways designed to appeal to youth. Without restrictions, e-cigarettes threaten to undo decades of progress in driving down rates of tobacco use worldwide.

The World Health Organization (WHO) has concluded that e-cigarettes are "undoubtedly harmful" and kids who use e-cigarettes are two times more likely to use a traditional tobacco product. Additionally, exposure to nicotine by children and adolescents can have long-lasting, damaging effects on brain development. Nicotine can also pose significant risks to pregnant women and the growing fetus.

The WHO recommends that countries that have not banned e-cigarettes should consider regulating them as harmful products. This is consistent with the general obligations of the WHO Framework Convention on Tobacco Control, which require 182 Parties to implement measures for preventing and reducing nicotine addiction.

These measures include increased taxes on tobacco products, bans on tobacco marketing, smoke-free public places and warning labels on tobacco products.

True progress in ending the global tobacco epidemic is being driven by committed governments, public health advocates and evidence-based public health policies, not by tobacco companies seeking to sell more addictive products.