



The FDA Is On A Quest To Snuff Out Tobacco Harm-Reduction

Jeffery Singer

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The Food and Drug Administration has dealt two deadly blows to tobacco harm reduction in the past two days. Yesterday the Biden Administration announced that the FDA will publish a proposed rule next year requiring tobacco companies to gradually eliminate practically all of the nicotine in cigarettes. Today, the Wall Street Journal reports the FDA plans to order all Juul menthol and tobacco-flavored e-cigarettes off the market in the U.S.

Juul has been the market leader in vaping products, but in recent years has slipped to number two, behind *Vuse* brand, marketed by tobacco maker Reynolds American. The FDA cleared e-cigarettes made by tobacco makers Reynolds American and NJOY Holdings, who now don't have to worry about competing with Juul. Cynics might think today's move reeks of cronyism. But those of us concerned with reducing the harms from tobacco smoking can only conclude that the past two days' moves signify the FDA is completely abandoning harm reduction.

First, consider the idea of reducing the nicotine in tobacco smoke. It is true that nicotine is the substance in tobacco to which one can become addicted, while the other components of tobacco smoke are responsible for smoking's organic harms—from cancer to cardiovascular disease. But, aside from its addictive potential, nicotine is, according to Public Health England, “relatively harmless.” This is from Britain's National Health Service “NHS Inform” website:

Although nicotine is a very addictive substance it's relatively harmless. It's the carbon monoxide, tar and other toxic chemicals in tobacco smoke that will cause serious damage to your health. Clean forms of nicotine are licensed to help smokers quit. These are much safer than smoking as they're nicotine only, don't have other additives or toxic chemicals, and are proven to be safe and effective.

Nicotine, like caffeine, is a stimulant that improves focus. Unlike caffeine, nicotine increases production of beta-endorphins that relieve anxiety, which may explain why some tobacco smokers light up when they want to calm down. Furthermore, nicotine might reduce the incidence of Parkinson's Disease and has stimulated research into its potential therapeutic applications for this affliction. It also may be potentially useful to treat depression, Tourette's Syndrome, Alzheimer's' Disease, and schizophrenia.

What's more, many tobacco smokers mainly smoke to enjoy the nicotine effects more than the flavor of tobacco, much like drinkers of alcoholic beverages often enjoy the relaxing feeling and

“buzz’ from the drink even more than its flavor. This explains why the government-funded research that led to the FDA’s nicotine-cutting decision found, “if cigarettes’ nicotine strength was reduced moderately, smokers would inhale more deeply or smoke more cigarettes to compensate and satisfy their nicotine cravings.” (Similarly, an alcohol drinker might consume more alcohol to achieve the desired effect if the alcohol content of the beverage is reduced.)

The research found that when the nicotine content of cigarettes was reduced by more than 95 percent, the smokers would tend cut back or quit—but the subjects were confined to hotel rooms, hardly a real-world experience. The real world, where black markets exist, might have many unintended consequences. And the researchers acknowledge that many of the study’s participants cheated by smoking regular cigarettes when they were only supposed to be smoking low-nicotine cigarettes. These stipulations to the study’s significant limitations apparently haven’t deterred the Biden Administration’s FDA from proceeding with plans to eliminate nicotine from cigarettes. A policy aimed at getting smokers to quit might easily wind up increasing tobacco consumption.

Next consider the FDA’s war on e-cigarettes. Begun in the Trump Administration, the FDA has increasingly restricted the availability of this proven tobacco harm reduction tool. In the United Kingdom, Public Health England tells primary care practitioners to suggest e-cigarettes to their tobacco-smoking patients as a cessation aid. PHE claims vaping is 95 per cent less harmful than smoking tobacco. Britain’s Royal College of Physicians advocates e-cigarettes for nicotine replacement therapy (NRT), stating:

In the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK. Randomized controlled trials in the UK have demonstrated that e-cigarettes are “significantly more effective” than other forms of nicotine replacement therapy, such as nicotine patches or nicotine gum.

The Trump Administration FDA started by banning flavored vaping products other than menthol and tobacco flavor, even while surveys repeatedly show that anywhere from 92% to 94% of former smokers who switched to vaping preferred the fruit-, candy- or menthol-flavored forms.

The ban on flavored vaping is rooted in the fact that teen vapers seem to prefer the fruit, candy or menthol flavors over the tobacco flavor. But e-cigarette sales to those under 18 have been prohibited since 2016, so the teens are already tapping the black or grey market in order to vape. And while teen vaping has been surging, teen tobacco smoking is at an all-time low. Yet research shows that fruit or candy flavored e-cigarettes are not determinants of teen vapers moving on to tobacco. And a study published in the May 2021 issue of *Nicotine and Tobacco Research* by researchers at Brown and Harvard Universities finds, “E-cigarette use is largely concentrated among youth who share characteristics with smokers of the pre-vaping era, suggesting e-cigarettes may have replaced cigarette smoking.” Dr. Natasha Sokol, once of the study’s authors, told *Filter* journalist Alex Norcia, “The decline in youth smoking really accelerated after the availability of e-cigarettes.”

Efforts to reduce teen vaping deprive adult tobacco smokers of a proven harm reduction strategy. It turns out that most adult tobacco smokers who wish to quit prefer flavored and menthol e-cigarettes as more effective substitutes. The FDA has not yet decided if it will ban menthol flavored e-cigarettes, which would further undermine tobacco smokers’ efforts to quit. A policy

intended for minors is hurting adults. Now there is evidence that many who had switched from tobacco to e-cigarettes are switching back to tobacco.

I have often said that Democrats think government prohibition works when it comes to cigarettes but not other drugs, while Republicans think government prohibition works for other drugs but not cigarettes. Sadly, the war on tobacco harm-reduction has been bipartisan, spanning Democratic and Republican administrations. We should not be surprised to see teen and adult smoking rates start back up, after years of decline.

Jeffrey A. Singer is a senior fellow at the Cato Institute and works in the Department of Health Policy Studies. He is President Emeritus and founder of Valley Surgical Clinics Ltd., the largest and oldest group private surgical practice in Arizona, and has been in private practice as a general surgeon for more than 35 years.