



Will Trump snuff out e-cigarettes?

President Trump promised to ban flavoured e-cigarettes, but 11 weeks later, they are still on the shelves. Susan Jaffe reports from Washington.

When US President Donald Trump announced a plan on Sept 11 to prohibit the sale of most flavoured electronic cigarettes, more than 450 people in the USA had a mysterious lung disease associated with vaping, and six had died, according to the Centers for Disease Control and Prevention (CDC). The ban would be finalised within 30 days, said Health and Human Services Secretary Alex Azar.

The number of cases of the lung disease has since soared to 2290, as of Nov 20, in 49 states, Washington, DC, and the US Virgin Islands. 47 e-cigarette smokers (vapers) have died, according to the CDC. However, as this report went to press, officials from the Trump administration would not disclose when the promised ban would be issued.

The ban reportedly stalled after Trump met with industry lobbyists earlier this month, who warned that such a decision would lead to the loss of thousands of jobs, according to news sources. They also said a ban would probably cost him votes in battleground states he needs to win re-election next year.

Trump's apparent willingness to delay or block the policy ignited protests from public health groups, medical associations, and members of Congress. "He has shown he is more swayed by the tobacco industry and politics than by our children's health", Senator Patty Murray of Washington state said last week at a hearing of the Senate Committee on Health, Education, Labor and Pensions, where she is the senior Democrat.

The delay in the ban proposed by the US Food and Drug Administration (FDA) is "unusual", said Bridget Dooling, a research professor at George Washington University's Regulatory Studies Center, who also

reviewed proposed rules and policies at the Office of Management and Budget (OMB) for more than a decade. The ban cleared the OMB on Nov 4.

"The policy making process is not stalled—it continues to move forward", said White House spokesman Judd Deere, shortly before Trump convened a meeting on Nov 22 that

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brought together nearly two dozen public health advocates supporting the ban and the conservative groups and industry representatives who oppose it.

Trump questioned both sides for an hour, but more than once the discussion descended into a shouting match. One of the few points of agreement centred on raising the minimum age for e-cigarette purchasers from 18 years to 21 years.

"21, we're going to be doing that", Trump said, according to a meeting transcript. Despite the current age limit of 18 years, e-cigarette use by middle school and high school students increased from 3.6 million in 2018 to 5.3 million in 2019, according to the CDC. In 2018, 67% of high school students and 49% of middle school students who used tobacco products in the past 30 days reported using a flavoured tobacco product. The flavours include mango, bubblegum, cherry and melon, and mint.

However, Trump worried that a blanket ban of most candy-flavoured or fruit-flavoured e-cigarettes would increase the risk of counterfeit e-cigarettes being sold on the black market.

"They're going to be selling stuff on a street corner that could be

horrible", Trump said. "That's the one problem I can't seem to forget... instead of having a flavour that's at least safe, they're going to be having a flavour that's—that's poison." In response, an industry representative noted that counterfeits are already available and that most of the people who became sick were using e-cigarettes containing additives such as tetrahydrocannabinol (THC) and vitamin E acetate.

In September, Juul—the company with the largest share of e-cigarette sales—voluntarily took all but its menthol-flavoured and tobacco-flavoured products off the market. However, another manufacturer told Trump that flavoured Juul products are still available in some stores.

Matthew Myers, president of the Campaign for Tobacco-Free Kids, reminded Trump: "We have 5.3 million kids who are addicted, and it's separate from the lung disease... a million kids a day are using these products repetitively with addiction." Banning the flavours would make e-cigarettes less appealing to children, Myers said. His group would allow only tobacco-flavoured products to be sold. "What we're talking about doing is removing



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For more on Scott Gottlieb's resignation see [World Report](#) *Lancet* 2019; 393: 1086–87

For the article on the Food and Drug Administration's independence see https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.051857rfr_dat=cr_pub%3Dpubmed&url_ver=Z39.88-2003&rft_id=ori%3Arid%3Acrossref.org&journalCode=hlthaff

the flavours that have fuelled the epidemic among our kids.”

Nevertheless, others are concerned that nicotine-addicted smokers who use fruit-flavoured or candy-flavoured e-cigarettes will switch to the tobacco-flavoured products. The only way to prevent more young people from becoming addicted is to ban all e-cigarettes, countered Patrice Harris, president of the American Medical Association, which last week adopted a resolution supporting an immediate ban on all e-cigarette products except those approved by the FDA as smoking cessation aids. The FDA has yet to approve any e-cigarettes for that purpose.

Manufacturers and retailers at the meeting also told Trump that a total ban would force 10 000 small e-cigarette shops to close, and could also put the companies that make the flavours and the devices out of business. The industry representatives estimate that as many as 160 000 direct and related jobs would be lost. Furthermore, they say a total ban would take away a safer alternative from former smokers of tobacco cigarettes, since e-cigarettes may contain less nicotine.

“If e-cigarettes, in fact, help adults quit smoking, then the manufacturers should submit the evidence to FDA”, Harris said in a statement after the meeting. “Until then, we are asking the government to ban flavours, which has everything to do with placing another generation at risk of nicotine dependence.”

Even if a ban on flavours or all e-cigarettes was put in place, they could be back on the market if the FDA approves them. The FDA had set a deadline of 2022 for applications with safety studies, but the deadline was brought forward to May 12, 2020, following a successful lawsuit against the FDA by the American Academy of Pediatrics, the Campaign for Tobacco-Free Kids, and other organisations. Companies that miss the deadline must take their products off the market or else face enforcement action.

The FDA declined to comment on how much time the companies will have to withdraw those products or how long the review process will take.

Although the lung disease that has affected some vapers has been associated with certain additives, “we still don’t know which flavours are associated with these substances, which particular products or brands”, said Peter Briss, medical director for the CDC’s National Center for Chronic Disease Prevention and Health Promotion. “There are hundreds of different e-cigarette or vaping devices and there are thousands or perhaps tens of thousands of different liquid brands that may contain more than one compound or substance.”

Some products use prefilled, disposable, flavoured cartridges or pods containing flavoured nicotine, such as those made by Juul. Other e-cigarettes require users to fill the device with a nicotine liquid purchased separately, and vape shops can mix in preferred flavours. Both types use a rechargeable battery that plugs into a computer.

When 29 patients from ten different states had fluid from their lungs tested, all had evidence of vitamin E acetate, Briss said. CDC investigators suspect it might be used as a thickening agent for e-cigarettes containing THC. However, “the evidence is not yet sufficient to rule out other chemicals of concern”, Briss said.

In the absence of federal action, seven states have enacted temporary emergency bans on the sale of flavoured e-cigarettes, and Massachusetts bans the sale of all e-cigarettes. Legislation pending in Congress would take similar steps.

The decision to replace this patchwork of rules with a nationwide ban is up to President Trump. “It is a chain of command”, said Robert Califf, a professor of cardiology at Duke University School of Medicine and the FDA commissioner under Trump and former President Barack Obama. “The commissioner reports to the Secretary of Health and Human Services [HHS]

and the secretary reports to the president. FDA policies are de facto policies of the Executive Branch, so if the HHS secretary or president chooses to do so, they can intercede.”

Califf was one of seven former FDA commissioners who published an article in *Health Affairs* in January recommending that the FDA separate from HHS and become an independent federal agency.

Yet independence is exactly what members of a Senate committee expected last week when they held a hearing on Trump’s nominee for FDA commissioner, Stephen Hahn. He is a radiation oncologist and the chief executive officer at the University of Texas MD Anderson Cancer Center.

“Is the FDA under your leadership able and willing to take action which will protect our kids whether or not the White House wants you to take that action?” asked Senator Mitt Romney, a Utah Republican. Hahn said the policy was still under consideration and he did not have all the facts. “But I can tell you this for sure, sir, I will use science and data to guide the decisions if I’m fortunate enough to be confirmed”, Hahn said.

Hahn would be the first FDA commissioner in 30 years who has almost no previous government experience. He would succeed Scott Gottlieb, who championed a package of measures aimed at e-cigarettes, including lowering the nicotine content to minimally addictive or non-addictive levels, enforcing the ban on sales to minors, and supporting restrictions on sales of flavoured e-cigarettes to adults. Gottlieb resigned in April.

At the end of the White House meeting last week, Trump was asked if he would go back to his “initial instinct” in September to ban flavoured e-cigarettes. “We did have an instinct...” he replied. “It’s going to be very interesting. We’ll let you know pretty soon.”

Susan Jaffe