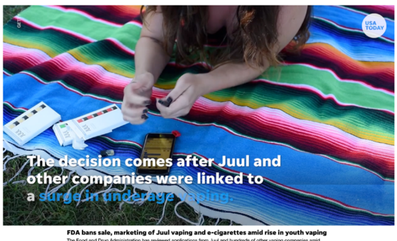
Hey Ken, we are FDA critics too, and would have gladly explained how this headline is bunk. But we never heard from you and zero harm reduction advocates are cited in this piece.

HEALTH

After pausing Juul ban, FDA focuses on synthetic nicotine vapes that critics say lure kids

Experts say FDA has been too soft on vaping companies that push flavored synthetic nicotine to skirt federal regulations.



FDA bans sale, marketing of Juul vaping and e-cigarettes amid rise in youth vaping

The Food and Drug Administration has reviewed applications from Juul and hundreds of other vaping companies amid calls to crack down on youth vaping. Ariana Figge, USA TODAY

Ken Alltucker
USA TODAY

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What epidemic? Vaping among young people has declined by 60% in the last 2 years. Only 3% of high schoolers reported vaping daily.

Anti-tobacco groups and lawmakers have raised questions over the agency's efforts to rein in synthetic nicotine products, often disposable and sold in flavors favored by underage vapers. The focus on this increasingly popular form of vaping comes after the FDA halted its ban on Juul this month for additional review.

What the media omits is that the agency is hellbent on wiping out virtually all products that are used by adults to quit smoking. It's already banned 99.999% of the open system vaping products on the market, and now it wants to wipe out the only other product vape shops have turned to for their survival.

CTFK doesn't really care about stopping youth vaping - it wants to ban ALL vaping, thus driving Americans back to deadly cigarettes.

"FDA has continually been too slow to act and too tentative in its actions," said Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, a nonprofit that works to reduce tobacco use. "The failure of FDA to act decisively is the reason that the youth e-cigarette epidemic grew out of control and continues today."

Apparently outlawing 99.999% of products is "too tentative" for Mr. Myers.

Pro-vaping experts warned the FDA for years leading up to the PMTA process that its regulatory approach would create black and gray markets. Those experts submitted comments directly to the FDA telling them that synthetics would be used if they didn't approve traditional vaping products for adult consumption. They ignored our guidance and now the entire vaping market is in regulatory limbo as it awaits more harebrained rulings.

In an effort to skirt FDA regulations, experts say, vaping companies began selling nicotine made in a lab rather than from tobacco. A law passed by Congress gave makers of synthetic nicotine products until May 14 to apply to market these products. Companies that failed to get authorization by July 13 are selling the products illegally, according to the FDA.

60 days. That's how long Congress gave synthetic nicotine companies to prepare their PMTA applications, which require expensive and time-consuming research. Most labs have a 6-month waiting period and take 12 to 24 months to produce results. The deck has been stacked against companies who were expected to produce results out of thin air.

In a letter to the FDA, AVM pleaded with the agency to use its enforcement discretion to allow companies to continue selling their products to adults who rely on vaping to stay off cigarettes. We were ignored.

FDA Commissioner Robert Califf said in a Twitter post that all non-authorized products are illegal and subject to enforcement. The FDA warned two manufacturers last week that they were illegally marketing such products. Letters also went out to another 107 retailers warning about unlawfully selling the products.

What authorization? The FDA has issued no authorizations to any products that submitted PMTAs by the deadline. That's because it appears the FDA is way over its head and lacks the knowledge to properly review these applications. It also shows how undue political pressure is forcing the agency to rush through a process that will inevitably put the lives of millions of former cigarette users at risk.

That the FDA should remove "most products" is taken as a given in most media reports. Instead of creating a regulated market for adults to continue using the vaping devices that help them quit smoking, the media and their activist allies believe complete prohibition is the only solution.

But the FDA has not yet removed most products despite calls to do so from anti-tobacco groups and some lawmakers. Robin Koval, CEO and president of Truth Initiative, a public health organization funded by a 1998 settlement between states and the tobacco industry, called on the agency to "immediately remove all synthetic nicotine products" from the market.

Who believe they know better than the millions of Americans who use vaping to quit smoking.

U.S. Sens. Dick Durbin, D-Ill., and Susan Collins, R-Maine, said in a letter last week that the agency's failure to vet and remove non-authorized products could have "grave consequences for the health of children across America."

Based on ridiculous timelines and unachievable standards!

The FDA said it has received applications for about 1 million synthetic nicotine products and will soon issue "refuse to accept" letters for those that don't past muster. The agency typically sends letters to get companies to comply and follows with fines, formal orders, seizures or court injunctions.

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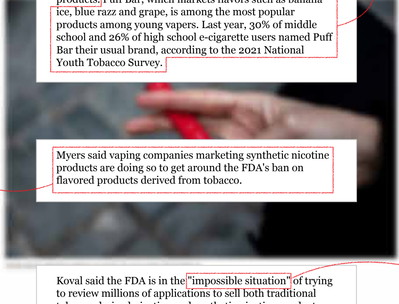
Anti-tobacco groups say companies marketing synthetic nicotine products are enticing young vapers with flavored products. Puff Bar, which markets flavors such as banana ice, blue razz and grape, is among the most popular products among young vapers. Last year, 30% of middle school and 26% of high school e-cigarette users named Puff Bar their usual brand, according to the 2021 National Youth Tobacco Survey.

Based on CDC data, only 0.81% of high schoolers vape daily and prefer Puff Bar.

The FDA already had a thin legal leg to stand on when it issued its Deeming Rule, giving itself the authority to regulate vaping products which contain no tobacco. The idea that the TOBACCO Control Act gives the agency power to regular non-tobacco derived products is absurd! That doesn't matter to Myers and his crusade.



Myers said vaping companies marketing synthetic nicotine products are doing so to get around the FDA's ban on flavored products derived from tobacco.

Koval said the FDA is in the "impossible situation" of trying to review millions of applications to sell both traditional tobacco-derived nicotine and synthetic nicotine products. In 2020, the FDA required all e-cigarette and vaping companies to submit applications to continue marketing products and banned fruit- and mint-flavored juice pods in nicotine derived from tobacco.

Understatement of the year.

She urged the agency to prioritize reviews of e-cigarette companies that sell the most products and are popular among kids. She added the FDA should remove from the market all non-authorized e-cigarettes, even those whose manufacturers have submitted applications for which the agency has not completed reviews.

Let's just forget about the thousands of vape shop owners and manufacturers who will forgo their livelihoods while awaiting action from an agency that is incapable of properly reviewing product applications.

Fixed it for you:

"Time is of the essence as every day of delay results in thousands of adults being forced back to using cigarettes as more vaping products are banned by the FDA based on its unscientific and political process."

"Time is of the essence as every day of delay results in hundreds of new products flooding the market, more young people taking their first hit and smokers uncertain whether these products will truly help or are even safe to use," Koval said in a statement.