

FDA Approves More Than 1200 Combustibles and 900 New Cigarettes

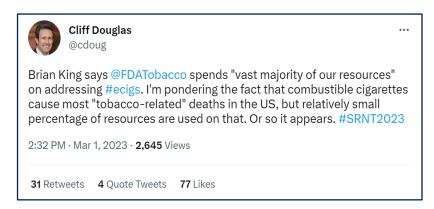
Vapor Technology Association March 2023

vaportechnology.org

While the FDA rejects thousands of less harmful vaping product applications, it approves the sale of more than 1,200 combustible tobacco products in contradiction of its mission.

The Director of the FDA's Center for Tobacco Products (CTP), Brian King, told the Associated Press in September of last year that:

"We do know that e-cigarettes – as a general class — have markedly less risk than a combustible cigarette product."¹ Yet, in a recent speech to the Society of Research on Nicotine & Tobacco on March 1, 2023, Director King explained that the FDA has spent the "vast majority of our resources" on e-cigarettes.



Without question, the vast majority of resources have been spent on (1) FDA's youth ecigarette "education" campaigns warning of the dangers of e-cigarettes, a campaign which FDA has admitted has negatively impacted adults' perceptions of e-cigarettes, and (2) FDA's review and rejection of 99% of the applications submitted for e-cigarette marketing approval.

FDA Commissioner Robert Califf recently said in a March 6, 2023 <u>Wall Street Journal</u> interview, "There aren't many people who argue in favor of combustible tobacco ... Well, I mean, we always start from the presumption that combustible tobacco is the most dangerous part of this. And we need to get rid of that as much as we possibly can. It's written into the mission of the FDA."

¹ Perrone, Matt, Insider Q&A: FDA official on vaping's "promise or peril", 9/26/22, AP News, <u>https://bit.ly/3ERVE9h</u>



Who would promote combustibles? Apparently, the FDA.

While FDA has spent the "vast majority" of its resources on e-cigarettes and denying 99% of all applications from hundreds of companies seeking to market the very products which Dr. King admitted have "markedly less risk than a combustible cigarette product," this begs the question of what FDA has been doing with its remaining resources to address combustible tobacco products which Commissioner Califf says are the "most dangerous"?

To find out, VTA recently conducted an analysis of FDA data and the answer is, frankly, disturbing. Based on VTA's review of all marketing authorizations made by the FDA over the last five years, we learned that FDA has authorized combustible tobacco products at a dangerously high rate.

VTA found that, in the last five years, while the FDA has approved only a handful of ecigarettes in tobacco flavor only, it has at the same time accelerated the introduction of 1,213 new combustible tobacco products into the U.S. market.

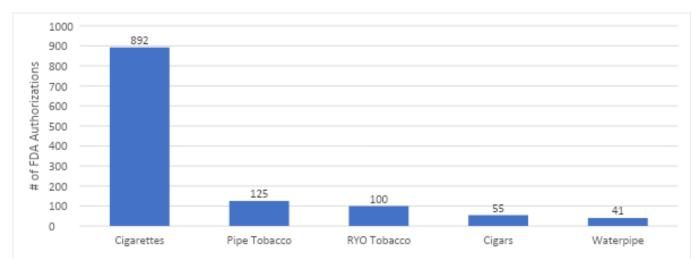
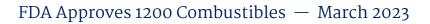


Figure 1 FDA Approvals of Combustible Tobacco Products 2018 –2022

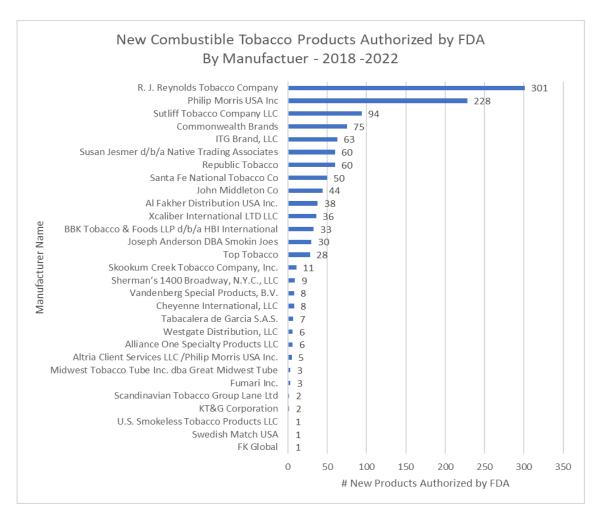
Source: Vapor Technology Association analysis of <u>FDA Tobacco Products Marketing Orders</u>, last accessed 3/16/23; content current as of 2/23/23.





Of these 1,213 new combustible tobacco products, the FDA has approved for sale 892 new cigarette products amounting to a whopping 74% of all the new combustible tobacco products FDA has allowed to be marketed.

To make matters worse, FDA allowed every one of these combustible products to be expedited to the market with only 90-days' notice and without any demonstration that these new combustible tobacco products are appropriate for the protection of public health – because, of course, such products could never meet that same standard applied only to the new and innovative less harmful products. Moreover, all the new combustible products approved were not subject to any robust scientific review and more than half of the new cigarettes authorized by FDA were *exempted* from providing any scientific evidence at all.



Source: Vapor Technology Association analysis of <u>FDA Tobacco Products Marketing Orders</u>, (last accessed 3/16/23; content current as of 2/23/23)



Big Questions

What about health equity?

While FDA repeatedly lauds its top priority of health equity and has launched its "Next Legends" educational campaign to "educate Native American Youth About Harms of Vaping through Culturally Specific Ads," 71 of the 892 (8%) of all the new commercial tobacco cigarettes it has accelerated to the market are for Native American manufacturers serving the Native American population.

What about flavors?

While FDA has completely refused to authorize any e-cigarette products in any flavor other than tobacco, FDA has authorized dozens of new combustible tobacco products with flavors such as vanilla crème, watermelon, cherry, English toffee, whiskey, coffee, French vanilla and, yes, mango.

What about the mission?

The FDA Commissioner said getting rid of combustible tobacco products "is written into the mission of the FDA." That's an odd statement given the FDA is approving combustible tobacco products over less harmful vaping products at a rate of 45:1. Not sure how that advances the FDA's mission. Perhaps the FDA can explain it, because we cannot.

FDA likely would claim that it is just following the law. But, while it now is asking Congress for more power and hundreds of millions of dollars to continue to "address" e-cigarettes, the real question is why does FDA continue to slam the front door shut on less harmful vaping and modern oral nicotine products while it ushers nearly 900 deadly cigarettes, and other combustible tobacco products, to market through the side door?

FDA's continued refusal to accept known scientific truths about vaping and modern oral nicotine will only ensure that cigarettes remain ubiquitous and dominant in the U.S.



About VTA

The Vapor Technology Association is the U.S. industry trade association whose members are dedicated to innovating and selling high-quality vapor and modern oral nicotine products that provide adult smokers with a better alternative to combustible cigarettes. VTA represents the industry-leading manufacturers of vapor devices, e-liquids, and flavorings, as well as the distributors and retailers, including hardworking American mom-and-pop brick-and-mortar retail store owners.

Sign up for the monthly VTA Insider and stay informed of critical issues impacting the vaping industry and nicotine products.

Subscribe to VTA Insider