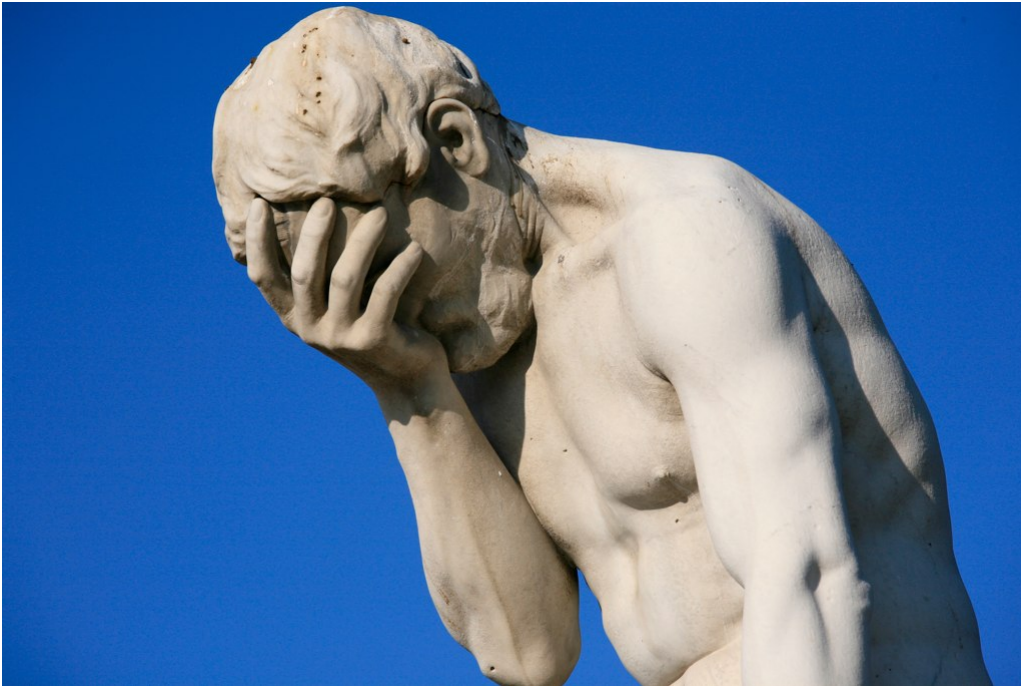


# The FDA forces Juul to pull the most successful anti-smoking product ever

written by Clive Bates | 23 June 2022



The U.S. Food and Drug Administration, the regulator of consumer tobacco and nicotine products in the United States has today denied applications from Juul Labs Inc. for its vaping products. FDA will require the company to pull its products from the market. This is an absolutely terrible decision with no basis in ethics, public health, or good regulatory practice.

The key extracts from FDA's announcement and my statement in response follow below.

# FDA Denies Authorization to Market JUUL Products

Currently Marketed JUUL Products Must Be Removed from the US Market



For Immediate Release: June 23, 2022

[FDA press notice](#)

## FDA's justification- key extracts

FDA's reasoning does not rely on youth vaping or the usual (unfounded) criticisms of Juul, but on a vague and generalised concern that they do not have enough evidence to do a toxicology assessment. They are not saying there is an actual problem, just that the evidence provided by Juul falls short of an unspecified standard.

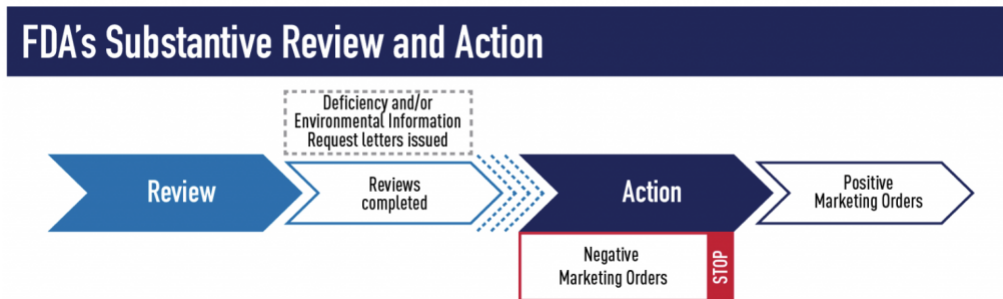
*After reviewing the company's [premarket tobacco product applications \(PMTAs\)](#), the FDA determined that the applications lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of the public health. In particular, some of the company's study findings raised concerns due to insufficient and conflicting data - including regarding genotoxicity and potentially harmful chemicals leaching from the company's proprietary e-liquid pods - that have not been adequately addressed and precluded the FDA from completing a full toxicological risk assessment of the products named in the company's applications.*

*To date, the FDA has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods. However, the MDOs issued today reflect FDA's determination that there is insufficient evidence to assess the potential toxicological risks of using the JUUL products. There is also no way to know the potential harms from using other authorized or unauthorized third-party e-liquid pods with the JUUL device or using JUULpods with a non-JUUL device. The FDA recommends against modifying or adding substances to tobacco products. JUUL users are encouraged to report*

any unexpected health problems or product problems to the FDA through the [Safety Reporting Portal](#) and to seek medical attention as necessary.

[FDA press release, 23 June 2022](#)

Note that FDA's review process involves sending a 'deficiency letter' to the applicant if it feels it has insufficient evidence to make a determination.



[FDA's explanation of the pre-market review process](#)

This is not meant to turn up as a nasty surprise at the decision point.

## My statement in response

*It looks like the FDA searched for a pretext for denying Juul's products and this is the best they could come up with. I doubt the FDA will be able to justify this on appeal or in court. But for now, it sends an extremely negative signal to America's 34 million smokers and millions of vapers. More smokers will be deterred from switching, some vapers may relapse, and the cigarette trade will prosper.*

*FDA seems to be relying on vague and generalised concerns about Juul toxicology evidence, but it offers no basis for concern about a real health risk or it would have mentioned it. FDA even admits it has no evidence of an immediate hazard. This is another case of FDA arbitrarily raising a previously invisible regulatory hurdle. A problem like this, if it was real, should have been addressed in FDA's deficiency letter to Juul clarifying what other data it needed to complete its assessment. No-one should have had a surprise like this.*

*We know Juul spent \$100 million on its PMTA and I think we can be pretty confident it did a thorough job on toxicology. Also, it seems the FDA now wants*

*Juul to be responsible for third-party or bootleg Juul products, how can that be right? Control over third parties and illegal products is FDA's job, not Juul's.*

*This is also the same FDA that recently authorised the highly-toxic 22nd Century low nicotine cigarette as somehow appropriate for the protection of public health. FDA even permits this cigarette manufacturer to make [absurd health claims](#) about it. The whole regulatory process is becoming surreal now. No-one could make a vape product even remotely as toxic as a cigarette, but guess which one got the green light.*

*FDA has made its statement gratuitous alarming, name dropping words like "genotoxicity" and "leaching" as if these are actual problems with Juul, which they are not. Then FDA gives advice to Juul customers to phone in adverse effects. There is no reason to do this for Juul any more than any other product. In my view, FDA reveals is indulging in a calculated smear and unwarranted attack on the company.*

*The last thing that FDA seems to care about is the three million American adults who use Juul products and are mostly very happy that they don't smoke or are heading that way as a result. The interests of these people are treated as irrelevant collateral damage in some pointless war that FDA and tobacco control activists are fighting against Juul.*

*We have to remember that while FDA is forcing Juul to pull the most successful anti-smoking device ever made, there are 3,000 cigarette products out in the market largely untouched by FDA regulation and steadily killing 480,000 Americans annually.*

*Clive Bates, Counterfactual Consulting, independent public health and sustainability advocate and former Director, Action on Smoking and Health (UK). 23 June 2022*

## **Statement by Juul Labs Inc.**

Juul politely indicates it does not accept this decision and will do whatever it takes to fight it via the FDA or in court.

*We respectfully disagree with the FDA's findings and decision and continue to*

*believe we have provided sufficient information and data based on high-quality research to address all issues raised by the agency.*

*In our applications, which we submitted over two years ago, we believe that we appropriately characterized the toxicological profile of JUUL products, including comparisons to combustible cigarettes and other vapor products, and believe this data, along with the totality of the evidence, meets the statutory standard of being “appropriate for the protection of the public health.”*

*We intend to seek a stay and are exploring all of our options under the FDA’s regulations and the law, including appealing the decision and engaging with our regulator. We remain committed to doing all in our power to continue serving the millions of American adult smokers who have successfully used our products to transition away from combustible cigarettes, which remain available on market shelves nationwide.*

[Joe Murillo, Chief Regulatory Officer at Juul Labs, 23 June 2022](#)

## **Low politics**

Look on in horror as Representative Raja Krishnamoorthy boasts about how he swayed FDA Commissioner Robert Califf to stick the knife into Juul.

*“Better to remain silent and be thought a fool than to speak out and remove all doubt.” Abe Lincoln*[@CongressmanRaja](#) *explains his success in capturing*[@DrCaliff\\_FDA](#) *to attack*[@JUULvapor](#) *with wholly baseless reasoning ... grateful anti-vaping activists look on.* [pic.twitter.com/omqhjRDTwp](#)

— Clive Bates (@Clive\_Bates) [June 28, 2022](#)

A Congressman make foolish boasts in front of admiring activists

Krishnamoorthy provides completely absurd activist talking points that bear no relation to FDA's stated reasons for trying to destroy Juul. *But then FDA's real reasons may also bear no relation to its stated reasons.*

## Legal action

Juul has, of course, challenged this arbitrary, capricious and vindictive mobbed-up attack in court.

David Abrams, Scott Ballin, Martin Jarvis, David Sweanor and I filed an *amici curiae* brief in support of Juul's motion for a stay pending substantive review on public health grounds: see our [public health amicus brief](#)

See more legal documents in the [Papers and Letters section](#) of this site.

## Other well-founded writing

- Jim McDonald, [Toxic Politics: FDA's Flimsy JUUL Denial Will Send Many to Cigarettes](#), Vaping 360
- Alex Norcia, [Juul ordered off the US vape market by the FDA](#), Filter
- Jacob Grier, [Why banning Juul won't save lives](#), Slate
- Tim Andrews, [FDA's war on nicotine puts ideology over science](#), Washington Times
- Guy Bentley, [The FDA's Juul ban makes a mockery of public health](#), New York Daily News
- Guy Bentley, [In a Surprise Move, the FDA denies approval for Juul tobacco and menthol vapes](#), Reason
- Lindsey Stroud, [FDA bows to pressure, not science, in issuing denials to JUUL](#), Independent Women's Forum
- Michelle Minton, [FDA's Juul Ban Part of Deadly War on Nicotine](#), Competitive Enterprise Institute (and [Washington Times](#))
- Alex Milliken, [The FDA should exercise discretion in its enforcement and allow e-cigarettes](#), National Taxpayers Union
- Heartland Institute, [Food and Drug Administration's war on Juul Is asinine](#), Red State
- Yaël Ossowski, [FDA's Juul crackdown is the latest blow in the irrational war on nicotine](#), Consumer Choice Center