

FDA BAN ON JUUL DEVICES: A WIN FOR TOBACCO CONTROL

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TOXINS IN JUUL PRODUCTS PUT PUBLIC HEALTH AT RISK

- On June 23rd, the Food and Drug Administration (FDA) issued a marketing denial order of the JUUL device and 4 types of JUUL pods containing nicotine concentrations of 5% and 3% (Virginia tobacco and menthol flavored)¹
- The FDA found issue with the genotoxicity and other harming chemicals leaching from the JUUL pods themselves
- A complete full risk assessment could not be completed as the FDA found a lack of evidence to suggest that the harmful chemicals found in JUUL products were not a risk to public health

FDA APPROVAL PROCESS FOR TOBACCO PRODUCTS

- Tobacco and nicotine products are regulated by the Federal Drug Administration (FDA). In July 2019, a Federal judge ordered that the FDA to require all e-cigarette products to submit Premarket Tobacco Product Applications (PMTA) so that the FDA could review the safety of the product, including whether the product is “appropriate for the protection of public health”.² The calculation for “protection of public health” could consider the following points:
 - Whether cigarette users actually switch to e-cigarettes (and thus avoiding the harm posed by regular cigarettes);³
 - Whether e-cigarette users might be related to former smokers from relapsing back to nicotine addiction;² and
 - Whether the product (JUUL) has toxins that may harm health
- Keeping in line with the criteria necessary of the PMTA, JUUL failed to provide reliable evidence that the toxins released by their products would not harm the general public (i.e., non-users)¹

FURTHER COMPREHENSIVE POLICY IS NEEDED

- Currently, the FDA has approved 23 ENDS products,¹ after determining these particular products benefit smokers who switch completely or significantly reduce their cigarette use, would outweigh the risk to youth, and the products’ aerosols are significantly less toxic than combustible cigarettes.³
- The FDA’s decision to ban JUUL is a critical step in reducing nicotine addiction, and can serve as a blueprint in banning other electronic nicotine delivery system (ENDS) products



REFERENCES

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