



**COLLECTIVE PROGRESS & FUTURE SUSTAINABILITY
– KEY CONSIDERATIONS, SHARED PERSPECTIVES,
AND COMMON GROUND**

78th TSRC, Knoxville, TN
14-17 September 2025

Science and Policy: The Intersection of U.S. Regulation and Scientific Progress

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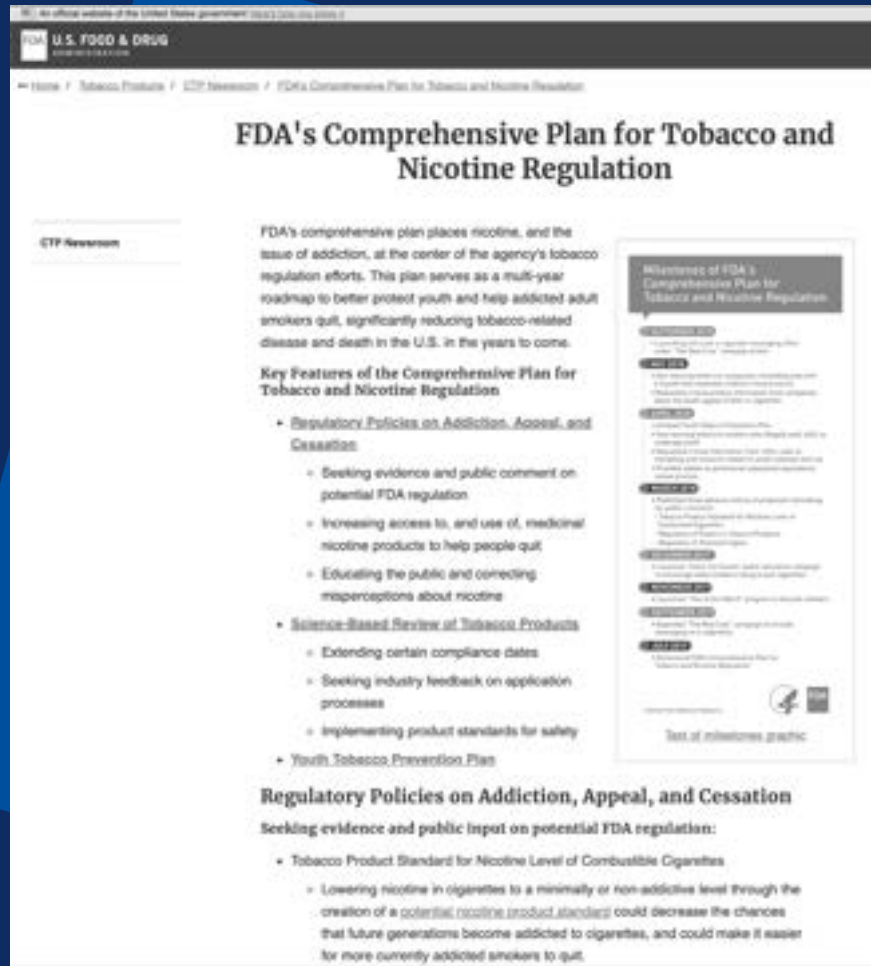
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Collective progress and future sustainability



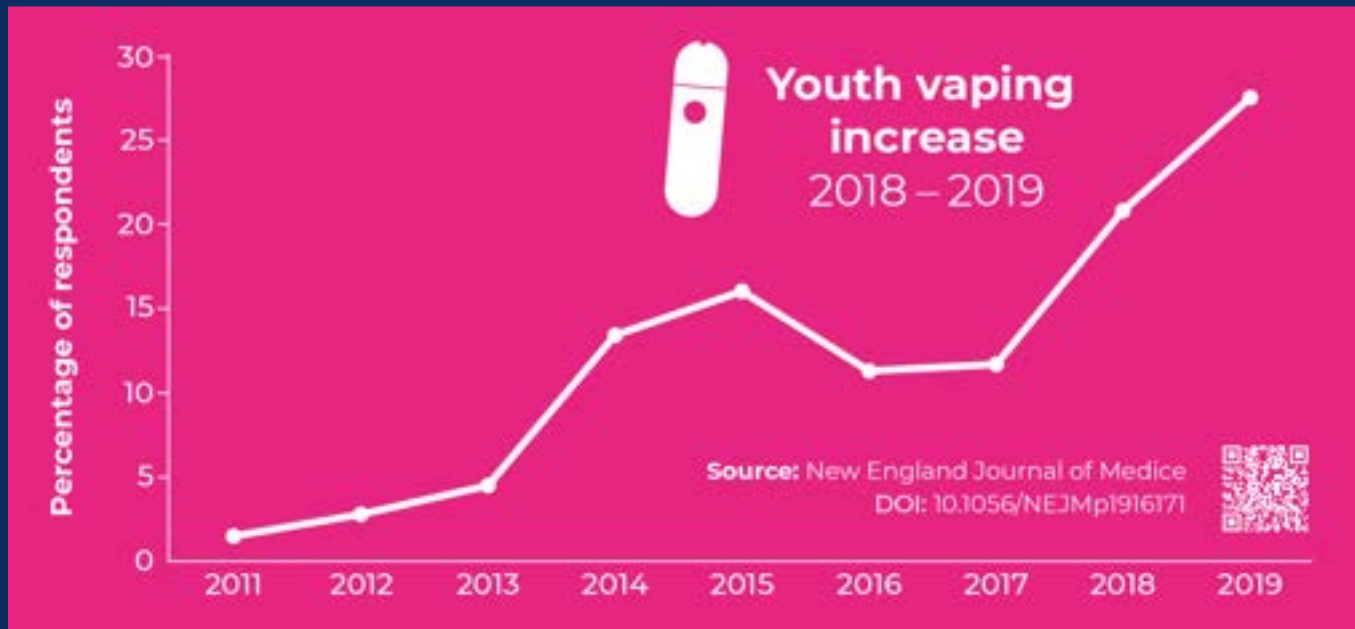
- Where we've been
- Where we are today
- A sustainable future

Work in (collective) progress



Comprehensive
Plan for Nicotine
and Tobacco
Regulation

Unexpected challenges to progress



EVALI

Background information: US CDC
DOI: 10.15585/mmwr.mm6903e2

Unexpected challenges to progress

Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.fda.gov/submit>. Alternatively, submit written comments to the Dockets Management Staff (CDR 3-302), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20851. All comments should be identified with docket number FDA-2019-0-0041.

For questions regarding this guidance, contact the Center for Tobacco Products at (Toll) 1-877-638-1373 (1-877-285-1373) Monday-Friday, 9 a.m. – 4 p.m. EE.

Additional copies are available online at <https://www.fda.gov/tobacco-products/industry-guidance/regulations-rule-making-and-enforcement>. You may send a e-mail request to smallbiz@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Dockets Control Center, 604g 75, Rm. 0331, 10803 New Hampshire Ave., Silver Spring, MD 20903-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

April 2020

* This is a revision to the first edition of this guidance, which issued in January 2020.

2020 FDA Guidance on
Flavors

Paving the way for

Illicit disposable vapor
product proliferation in US

Thousands of unauthorized vapes are
pouring into the US despite the FDA
crackdown on fruity flavors



[fda.gov/media/133880/
download?utm](https://www.fda.gov/media/133880/download?utm)



Further reading:
tinyurl.com/bdenrhs6

Unexpected challenges to progress



American Academy of
Pediatrics vs FDA



<https://tinyurl.com/2ew4de2p>



Continued lack of clarity
on 'APPH' from FDA

Today — a shifting product regulatory landscape



Vuse Alto Marketing Granted Order



NJOY Marketing Granted Order

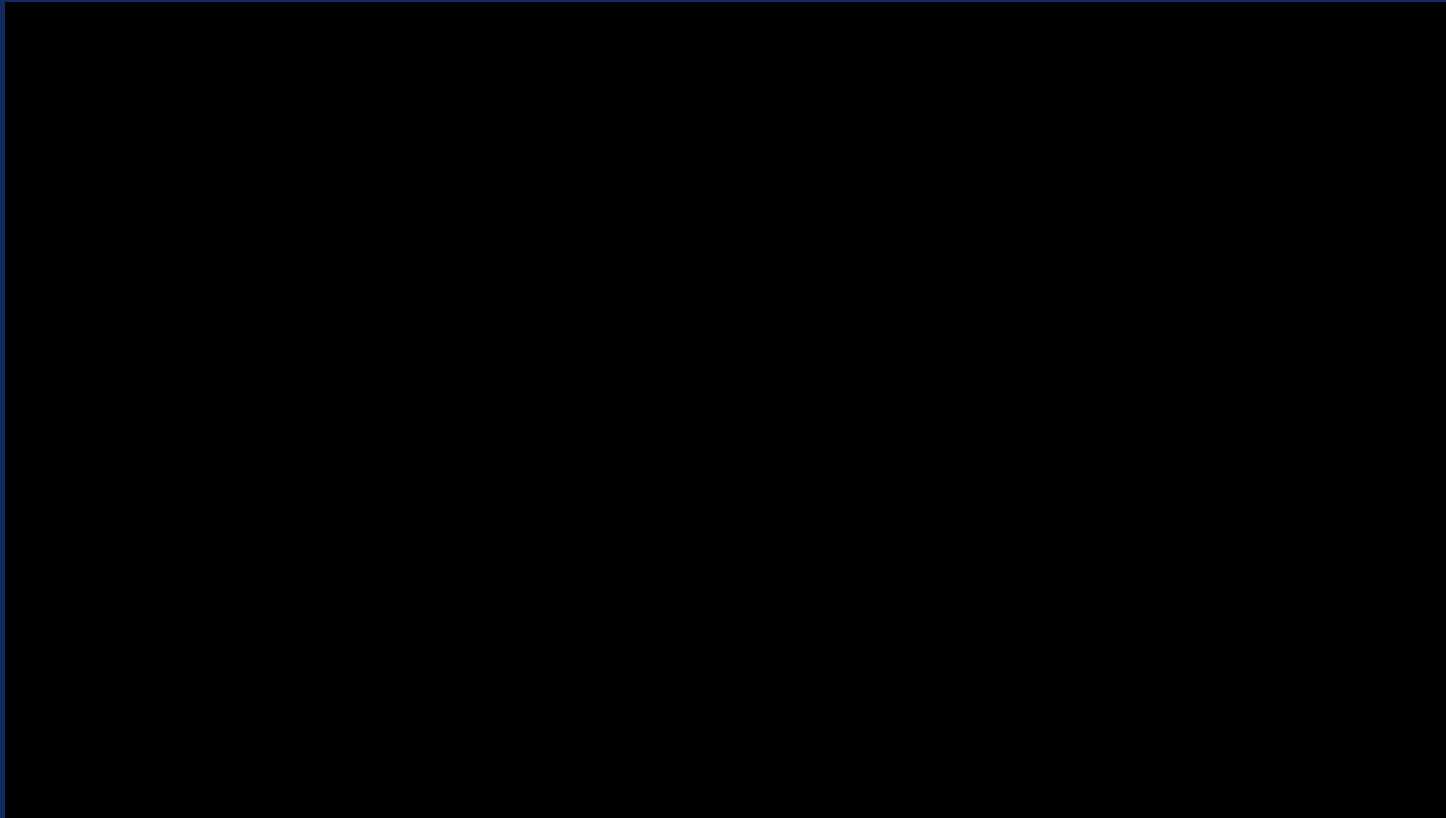


JUUL
Marketing
Granted Order



ZYN
Marketing
Granted Order

Emphasis on THR



Clip from
Jovem Pan News
Published July 25, 2025

Address illicit enforcement



- ✓ Illegal vapor products seized at ports
- ✓ DOJ/FDA Joint-Task Force
- ✓ Congress recommends \$200 million of FDA user fees be dedicated to enforcement
- ✓ US Postal Service halts shipments
- ✓ HHS, CBP Seize \$86.5 million worth of illegal e-Cigarettes (4.7 million units) in largest-ever operation – Sep 10, 2025

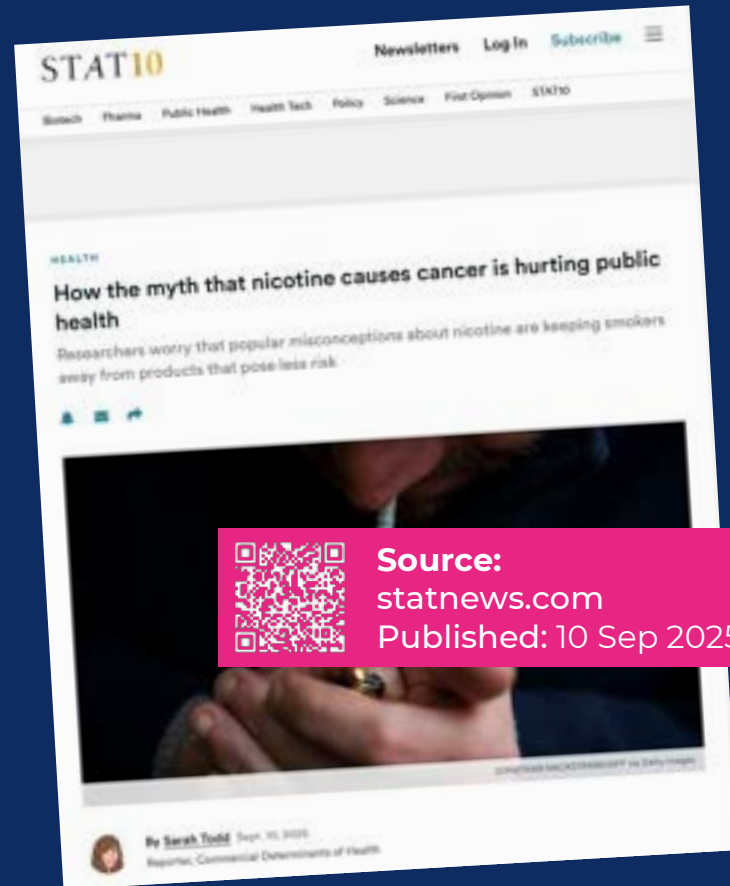
World Vape Show in Miami, FL (Sep 4–5) postponed due to customers having trouble importing products in the U.S.

Expedited pathway for nicotine pouch authorization (?)



- Rumored launch of fast-track pilot for nicotine pouches specifically for four tobacco firms
- Targeting December 2025 to complete premarket reviews
- Streamlined and reduced reviews — focused only on information essential to start the scientific review of nicotine pouches i.e., core product characterization, manufacturing consistency and stability, and abuse-liability data
- More frequent communication between agency and applicants
 - Contrast with previous multi-year process (five years for ZYN)
 - Pilot represents major acceleration in regulatory decision-making

Media correcting nicotine misperceptions



- STAT News article explicitly separates nicotine from combustion harm
 - Highlights FDA-authorized alternatives
- Vox, Health Affairs, New Yorker — all seeing more nuanced coverage of 'risk continuum'
- Media tone beginning to reflect scientific consensus (Gottlieb NEJM 2017, DOI: 10.1056/NEJMp1707409)

New opportunity for more accurate and balanced messaging?

What could solidify a sustainable change?



- Ongoing acknowledgement of THR and the importance of non-combustible products
- Continued enforcement of illicit products
- Establishment of pilot review program and extension to other non-combustible product categories
- Establishment of guidance and/or regulations for expedited review pathways
- Product standards
- Collaboration



END

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