ECRONICON OPEN ACCESS

EC PULMONOLOGY AND RESPIRATORY MEDICINE

Research Article

Tobacco, Vaping, and E-Cigarette Regulation in the United States: A Pulmonary-Policy Literature Review

Ved Kartik[1] and Alok S Shah[2]*

[1]*Flintridge Preparatory School - La Canada Flintridge, California, USA*

[2]*Pulmonary Department, University of Chicago, USA*

***Corresponding Author:** Alok S Shah, Pulmonary Department, University of Chicago, USA.

Received: July 14, 2026; **Published:** July 28, 2026

Abstract

Combustible tobacco remains the leading cause of preventable death in the United States, killing approximately 480,000 Americans annually. The emergence of electronic nicotine delivery systems (ENDS) introduced two concurrent public health challenges: potential harm reduction for adult smokers on one hand, and a youth nicotine-initiation crisis on the other. The 2019 EVALI outbreak (2,807 hospitalizations, 68 deaths by February 2020 [60]) forced both dimensions into acute regulatory focus. This narrative literature review traces the science-to-policy pipeline connecting pulmonary evidence on tobacco and vaping products to federal and state regulatory action in the United States, drawing on peer-reviewed research, CDC surveillance data, FDA regulatory documents, and case law from 2009 through 2026. Three specific evidence-to-policy fractures emerge. First, EVALI was caused by vitamin E acetate in illicit THC products, yet the regulatory response primarily targeted legal nicotine ENDS, a jurisdictional mismatch that remains unresolved. Second, the evidence that non-tobacco flavors drive youth e-cigarette initiation is strong, yet enforcement against the unauthorized disposable products that dominate the youth market has been weak. Third, the FDA's population-level regulatory standard requires a single authorization decision per product for a problem that involves two distinct populations (adults who benefit from switching and youth who are harmed by initiating), producing structural policy paralysis. U.S. tobacco and vaping regulation is scientifically defensible in principle but administratively overwhelmed in practice.

Keywords: *E-Cigarette; Vaping; EVALI; Tobacco Regulation; FDA; PMTA; Flavor Ban; Pulmonary Health*

Introduction

Combustible tobacco use remains the single largest preventable cause of death in the United States. The 2014 Surgeon General's report documented that cigarette smoking has caused more than 20 million premature deaths since 1964, with causal links to COPD, lung cancer, ischemic heart disease, and stroke forming the scientific foundation of U.S. tobacco regulation [1].

Electronic nicotine delivery systems entered the U.S. market around 2007, initially positioned as harm-reduction tools for adult smokers. The introduction of nicotine-salt formulations and pod-style devices accelerated youth uptake [2], and by 2019 the National Youth Tobacco Survey documented record-high youth e-cigarette prevalence [3]. The tension between ENDS as cessation aid and ENDS as gateway product became the defining debate in U.S. tobacco policy.

This debate was overtaken in August 2019, when state health departments identified clusters of severe acute lung injury associated with vaping product use [4]. By February 2020, 2,807 hospitalized EVALI cases had been documented across all 50 states, with 68 deaths [5,60]. Vitamin E acetate in illicit THC cartridges was identified as the primary causative agent [6,7]. EVALI compressed years of regulatory inertia into months of emergency action.

This review traces the science-to-policy pipeline from clinical evidence through federal statute to state-level implementation, arguing that the U.S. regulatory response to vaping has been reactive, fragmented, and lagging behind the pulmonary evidence base.

Methods and Results

This narrative literature review draws on PubMed, Embase, Google Scholar, Westlaw, and primary regulatory sources (FDA.gov, CDC.gov). Search terms combined "e-cigarette", "ENDS", "vaping", and "EVALI" with "regulation", "FDA", "flavor ban", "PMTA", "pulmonary", and "respiratory". Inclusion criteria encompassed peer-reviewed pulmonary and tobacco-control research, CDC MMWR surveillance reports, FDA guidance documents and Federal Register entries, federal and state statutes, and federal court opinions. The date range spans June 2009 (enactment of the Tobacco Control Act) through 2026.

Initial database searches yielded 847 records across PubMed (312), Embase (198), Google Scholar (264), and Westlaw/regulatory sources (73). After removal of 203 duplicates, 644 unique records underwent title and abstract screening against the inclusion criteria. Of these, 142 proceeded to full-text review, and 61 were included in the final synthesis based on relevance to the science-to-policy argument, methodological rigor, and recency. Grey literature (government reports, policy commentaries, legal analyses) was included where it provided primary-source documentation of regulatory actions or legal proceedings not available in peer-reviewed form. When evidence types disagreed (e.g. randomized trial efficacy versus real-world observational data), both perspectives are presented and the methodological basis for each is stated. Longitudinal nationally representative data (e.g. PATH Study) was weighted more heavily than single-site cross-sectional analyses. Risk of bias in individual studies was assessed qualitatively based on study design, sample representativeness, and potential for confounding; no formal risk-of-bias scoring tool (e.g. Cochrane Risk of Bias tool) was applied, consistent with the narrative review approach.

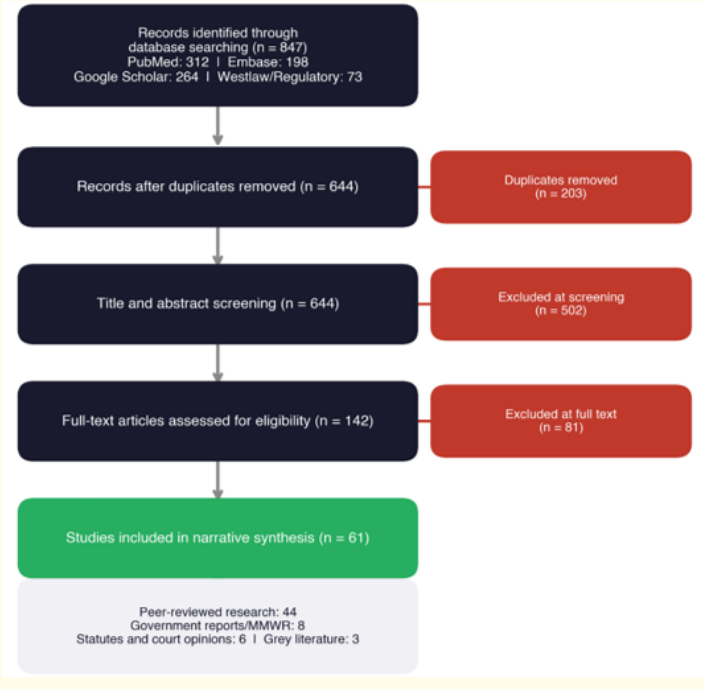

Figure 1

This review was not registered with PROSPERO or conducted under PRISMA or Cochrane systematic review protocols. PRISMA 2020 is a reporting guideline designed for systematic reviews that evaluate the effects of specific interventions, requiring a structured PICO-format question, predetermined eligibility criteria, and a standardized screening flow diagram. Cochrane protocols similarly require a defined health intervention, formal quality-assessment tools (MECIR standards), and adherence to a single answerable clinical question. The present review does not meet these criteria: its central question is whether U.S. regulatory architecture matches the pulmonary evidence base, not whether a specific intervention produces a measurable clinical effect. Furthermore, this review integrates evidence types that no single systematic framework can accommodate, including clinical studies, epidemiological cohorts, toxicological analyses, federal statutes, administrative rules, and court opinions. The narrative approach was therefore selected as the methodologically appropriate design for this interdisciplinary scope. Although this review cites Cochrane systematic reviews (e.g. [21]) as high-quality evidence sources within its synthesis, the use of such sources does not require the review itself to follow Cochrane methodology, just as citing a randomized trial does not require the citing paper to be a randomized trial.

The pulmonary evidence base

EVALI: The acute crisis

The EVALI outbreak resulted in 2,807 hospitalizations and 68 deaths by February 2020 [5,60]. Patients presented with bilateral ground-glass opacities, lipid-laden macrophages on bronchoalveolar lavage (BAL), and hypoxemia, with a median age of 24 among nonfatal hospitalized cases but 51 among fatal cases [4,8]. Fatal cases were ninefold more likely than nonfatal cases to have preexisting COPD [8].

The causation of EVALI by vitamin E acetate (VEA) rests on three independent evidence lines. Blount., *et al*. [6] detected VEA in 94% of EVALI patients' BAL fluid but in none of 99 healthy comparators. Bhat., *et al*. [7] demonstrated that inhaled VEA produced EVALI-like pathology in a murine model, while propylene glycol-vegetable glycerin controls did not. Taylor., *et al*. [9] reported that Minnesota law enforcement seizures contained no VEA in 2018 illicit THC cartridges but VEA in all 2019 cartridges, a temporal alignment with outbreak onset. Epidemiological data confirmed that 82% of patients reported THC-containing product use from informal sources [5,10].

King., *et al*. [11] distinguished EVALI from the concurrent youth nicotine-vaping epidemic as two separate crises requiring distinct policy tools, a distinction central to evaluating the regulatory response that followed.

Parameter	Value	Data Source
Total hospitalizations	2,807	CDC, Feb 2020 [60]
Total deaths	68	CDC, Feb 2020 [60]
Median age (nonfatal cases)	24 years	Layden et al., NEJM [4]
Median age (fatal cases)	51 years	Werner et al., NEJM [8]
Male sex (hospitalized)	66%	Krishnasamy et al., MMWR [5]
VEA in EVALI BAL fluid	94% (48/51 patients)	Blount et al., NEJM [6]
VEA in healthy comparators	0% (0/99 controls)	Blount et al., NEJM [6]
THC product use among cases	82%	Krishnasamy et al., MMWR [5]
COPD risk (fatal vs. nonfatal)	9-fold higher in fatal cases	Werner et al., NEJM [8]
National surveillance status	Transitioned to passive, Feb 2020	Krishnasamy et al., PHR [42]

Figure 2

Chronic respiratory effects of ENDS

A growing body of evidence links e-cigarette use to chronic respiratory effects, maturing from cross-sectional observations to longitudinal nationally representative analyses. McConnell., *et al*. [12] found nearly twofold increased odds of bronchitis symptoms among adolescent e-cigarette users (OR = 1.85; 95% CI 1.37-2.49), with a dose-response relationship persisting in never-cigarette-smokers. Chaffee., *et al*. [13] pooled four cohorts (N = 10,483) and confirmed the association (summary OR = 1.56 for bronchitis symptoms; 1.68 for shortness of breath), with no modification by device type.

Longitudinal evidence strengthened causal inference. Xie., *et al*. [14], using PATH Study data from young adults with no baseline respiratory disease, found that e-cigarette use predicted symptom development approximately 12 months later. Karey., *et al*. [52] confirmed this in 15,291 adults from PATH Waves 4 and 5. Owusu., *et al*. [15] extended the longitudinal evidence to youth, reporting that exclusive ENDS use (IRR = 1.49), exclusive cigarette use (IRR = 1.85), and dual use (IRR = 2.70) all predicted physician-diagnosed respiratory illness. This finding demonstrates that dual use is additive, not offsetting.

Biological plausibility is supported by Bircan., *et al*. [16], who found elevated odds of asthma and COPD among never-cigarette-smokers using BRFSS data; Boas., *et al*. [53], who documented elevated inflammatory biomarkers in young e-cigarette users; and Erythropel., *et al*. [17], who identified novel flavorant-propylene glycol adducts with inhalation toxicity unknown when the products reached the market [17,50]. The chronic-effects literature remains immature (most follow-up is two years or less), but the convergence of cross-sectional, longitudinal, mechanistic, and international evidence [18,54] supports a causal interpretation.

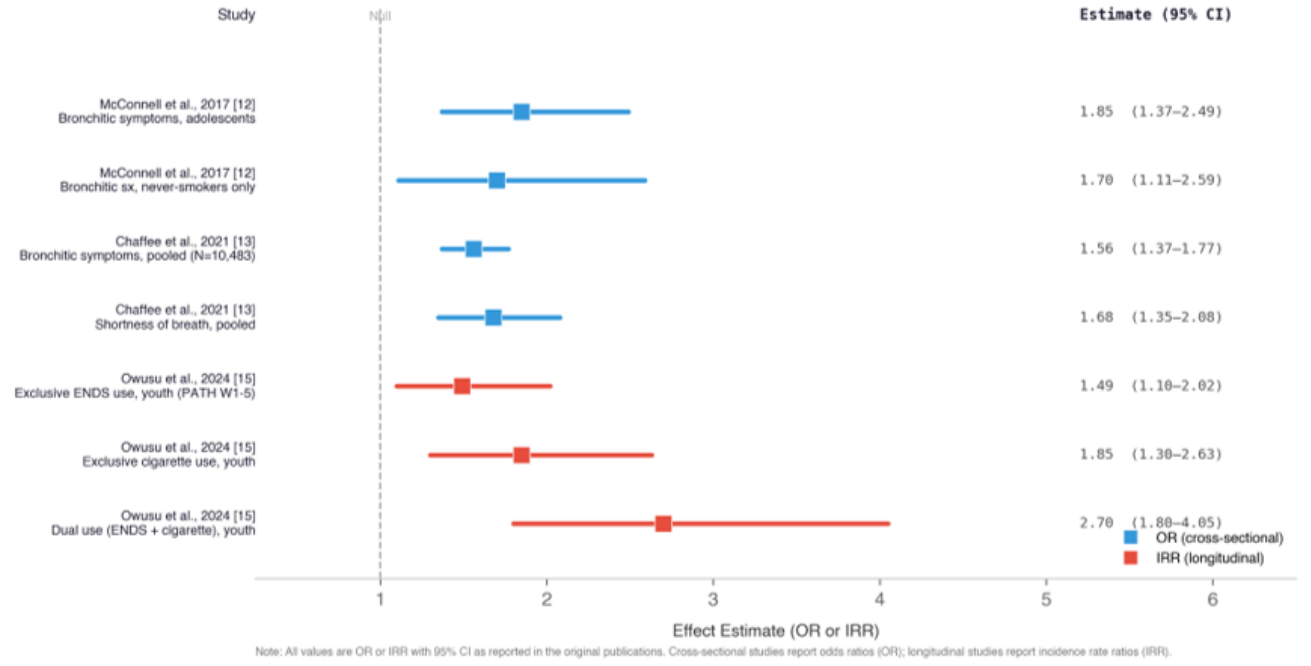

Figure 3

The harm-reduction counter-evidence

Substantial evidence supports nicotine e-cigarettes as effective cessation tools for adults. Hajek., *et al*. [19] found that e-cigarettes doubled one-year quit rates versus NRT (18.0% vs. 9.9%; RR = 1.83), though 80% of successful quitters were still vaping at 12 months. Auer., *et al*. [20] reported the largest cessation effect to date (28.9% vs. 16.3% abstinence at six months; RR = 1.77). The Cochrane Living Systematic Review [21] reports high-certainty evidence that nicotine e-cigarettes increase quit rates versus NRT (RR = 1.55; 95% CI 1.28 - 1.88). Rigotti [22] describes this evidence as reaching "a tipping point" for clinical-guideline incorporation.

However, Banks., *et al*. [23] argue that trial efficacy does not translate to real-world effectiveness, as most real-world users become dual users rather than complete switchers. Baenziger., *et al*. [24] found in an umbrella review that e-cigarette use among non-smokers is associated with subsequent combustible cigarette initiation. The NASEM 2018 report [25] judged the overall net population impact of e-cigarettes "currently unknown", an assessment that remains accurate in 2026.

The U.S. regulatory response

Federal architecture

The 2009 Tobacco Control Act (TCA) gave FDA authority over tobacco products, establishing the "appropriate for the protection of the public health" standard and banning characterizing flavors in cigarettes except tobacco and menthol [26]. The menthol exemption is widely regarded as a political compromise [27,28]. FDA's leadership framed the TCA as a public health regime rather than a product-safety regime [55]. The 2016 Deeming Rule [29] extended FDA authority to ENDS, requiring premarket authorization, but did not impose flavor restrictions or product standards for nicotine concentration or device safety.

The PMTA pathway has proven operationally overwhelmed. Approximately 6.7 million applications were received by the September 2020 deadline [30]. As of early 2026, FDA has authorized approximately 39 e-cigarette products (all tobacco- or menthol-flavored), while issuing over one million denial orders [31]. A 2023 HHS Inspector General audit documented inconsistent review standards and structural advantages for large manufacturers [30]. The unauthorized disposable brands dominating the youth market (Elf Bar, Breeze, Mr. Fog) are sold despite lacking PMTA authorization [3,31].

Enforcement, litigation, and FDA v. wages

In January 2020, FDA issued enforcement guidance targeting unauthorized flavored cartridge-based ENDS, excluding tobacco and menthol [32]. The guidance exempted disposable e-cigarettes, a loophole the market immediately exploited. Menthol sales rose [33], youth shifted to disposables [34], and total unit sales increased despite the restriction [35].

FDA subsequently issued over one million Marketing Denial Orders for flavored ENDS in 2021, triggering litigation that reached the Supreme Court. In FDA v. Wages and White Lion Investments, 604 U.S. 542 (2025), a unanimous Court held that FDA did not act arbitrarily in denying flavored-ENDS PMTAs [36]. The decision demonstrated continued judicial deference to agency operational judgments even after the Court weakened Chevron deference in Loper Bright Enterprises v. Raimondo, 603 U.S. ___ (2024) [57]. However, the products driving youth use (unauthorized disposables) were never in the PMTA system the Court validated [3].

State-level variation

Federal enforcement gaps drove a wave of state action. Massachusetts enacted the first comprehensive ban on all flavored tobacco products (including menthol) in June 2020; cigarette sales fell approximately 25% and menthol sales dropped 96% in the first year [37],

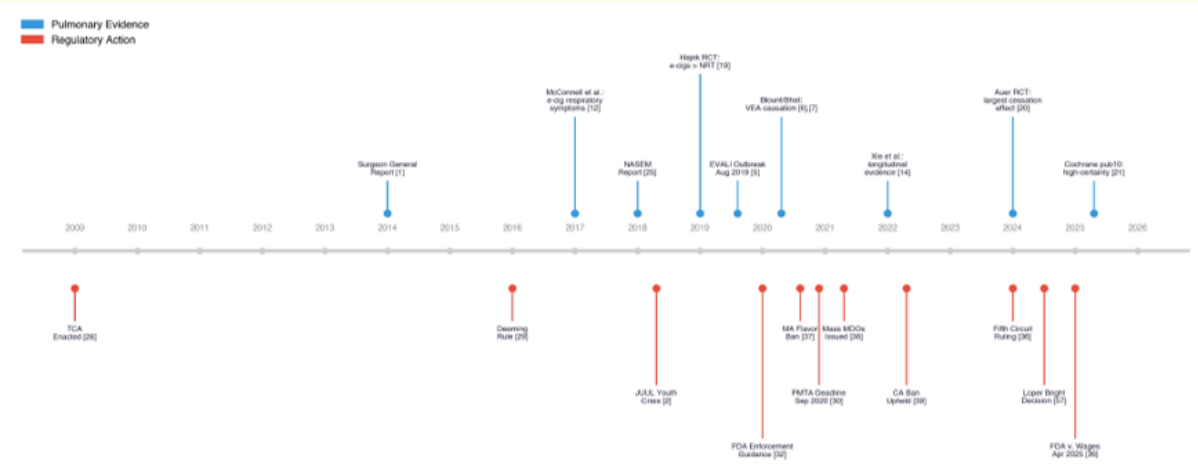

Figure 4

though spatial analysis identifies some cross-border redistribution [38]. California, New York, New Jersey, and Rhode Island followed with restrictions of varying scope [39,40]. Olson., *et al*. [56] documented that Minnesota flavor restrictions produced particularly large reductions among vulnerable youth populations.

More than ten states have enacted vapor product registries requiring ENDS manufacturers to certify FDA authorization as a condition of in-state sale [41], a creative federalism solution to FDA's enforcement gap. Not all state action has moved toward restriction: Ohio enacted statutory preemption of local flavor bans via its 2024 budget legislation [58], though the law was promptly held unconstitutional by state trial and appellate courts and is currently under review by the Ohio Supreme Court [61]. The Ohio saga illustrates that the regulatory patchwork is contested at every level, producing uneven and uncertain population protection.

Critical analysis

The EVALI mismatch

EVALI was caused by VEA in illicit THC cartridges [6,7,9]. The regulatory response (enforcement guidance, PMTA denials, state flavor bans) primarily targeted legal nicotine ENDS [32]. The youth vaping epidemic warranted its own response [11], but the public narrative fused the two crises, enabling regulators to leverage EVALI urgency for actions whose evidence base was the youth-initiation literature rather than the EVALI literature.

This mismatch is not entirely irrational but reflects a jurisdictional constraint: FDA's statutory tools (deeming, PMTA, enforcement guidance) apply to legal products, not illicit markets. A response proportionate to the EVALI evidence would have required interagency coordination with DEA and state cannabis regulators to target illicit THC cartridge supply chains, expansion of ingredient-disclosure authority for all inhalable consumer products, and continuation of active EVALI surveillance. Instead, the CDC transitioned active national EVALI surveillance to state-based passive monitoring in February 2020 [42]. The absence of reported EVALI cases since 2020 is consistent with either actual resolution or surveillance failure; without reactivated surveillance, the two cannot be distinguished.

The flavor ban paradox

The evidence for flavor-driven youth appeal is strong: Pepper., *et al*. [43] found 6.49 times greater interest in fruit versus tobacco flavors; 88% of youth e-cigarette users report flavored-product use [3]; systematic review confirms consistent effects across studies

[44]. Yet the top youth brands, specifically Elf Bar (36.1% of current users), Breeze (19.9%), and Mr. Fog (15.8%) [3], all lack PMTA authorization [31]. FDA v. Wages addressed whether FDA's denial process was proper [36], but the products driving youth use were never in the PMTA system.

The population-level trade-off

The third evidence-to-policy fracture is structural. The TCA's population-level standard requires a single authorization decision for products whose effects differ radically across the populations using them [26]. For adult smokers seeking to quit, high-certainty evidence supports cessation efficacy [21]. For nicotine-naive youth, longitudinal evidence links e-cigarette use to respiratory symptoms [14] and combustible cigarette initiation [24]. No product design simultaneously optimizes for both populations.

International comparators illustrate that different jurisdictions have resolved this tension by choosing different priorities, not by resolving the underlying dilemma. The UK endorsed regulated vaping for cessation [45] but now faces youth disposable-vaping rates exceeding U.S. levels [51], demonstrating that permissive adult access does not prevent youth uptake. Australia classified nicotine vaping as prescription-only [46] but has seen substantial illicit market growth, demonstrating that restrictive access without enforcement capacity produces its own failures. The U.S. has attempted to serve both populations through a single regulatory track and has achieved neither objective fully.

A potential structural remedy would split the PMTA pathway into two tracks: an adult-cessation track requiring randomized cessation-trial data, nicotine concentrations aligned with NRT equivalents, pharmacy or healthcare-professional distribution, and restrictions on youth-appealing marketing; and a consumer-retail track requiring demonstration that the product does not increase youth initiation, with comprehensive flavor restrictions, age-verification enforcement thresholds, and post-market surveillance obligations. Such a bifurcation would address the population-level trade-off explicitly rather than collapsing it into a single decision.

Dimension	United States	United Kingdom	Australia
Regulatory model	PMTA premarket authorization	Retail availability with age restrictions	Prescription-only (TGO 110, 2021)
Adult cessation support	Limited: only tobacco/ menthol flavors authorized	NHS-endorsed for smoking cessation	Available via medical prescription
Youth access restriction	Enforcement gaps for disposables	Age verification and marketing restrictions	Prescription requirement
Illicit market control	Weak against unauthorized imports	Growing disposable vaping problem	Substantial illicit market growth
Outcome (as of 2025)	Neither full cessation nor youth protection	Youth vaping rates exceed U.S. levels	Low compliance with Rx model

Figure 5

Emerging frontiers

Nicotine pouches grew over 300-fold in unit sales between 2016 and 2020 [47]; 1.8% of U.S. students currently use pouches, with ZYN holding 69% of youth market share [48]. Manufacturers initially exploited a synthetic-nicotine loophole to evade regulation [49], closed by the Consolidated Appropriations Act of 2022 [59] but with nascent enforcement. No pulmonary evidence on pouch safety exists. Novel e-liquid toxicology continues to emerge, with flavorant-propylene glycol adducts showing cytotoxicity to respiratory epithelial cells [17,50].

Discussion

The United States has constructed a tobacco regulatory architecture that is scientifically defensible in principle but administratively overwhelmed in practice. The TCA's population-level standard is sound, and FDA v. Wages confirms its legal foundation [36]. Yet the PMTA pathway cannot keep pace with the market: unauthorized disposables drive youth use outside the system the Court validated [3,31].

For the pulmonary community, three implications emerge. Clinicians should screen for vaping history in all patients with acute respiratory symptoms, including those outside the traditional EVALI demographic [8]. Engagement with state-level policy is a high-impact advocacy opportunity, as comprehensive flavor bans have produced the most measurable reductions in youth exposure [37]. Research priorities include long-term follow-up of EVALI survivors, standardized ENDS emissions testing, and spirometric cohort studies in youth e-cigarette users.

The late-2020s tobacco-control challenge is a translation deficit: the gap between evidence generation and policy implementation. Empirically, this deficit manifests in three measurable ways: delayed policy response to accumulated evidence (the chronic-effects literature of 2017-2024 preceded effective enforcement by years), jurisdictional mismatches between regulatory authority and actual harm sources (EVALI originated in an illicit market that FDA's tools cannot reach), and decommissioning of active surveillance despite unresolved questions about ongoing incidence (national EVALI surveillance was transitioned to passive state-based monitoring in February 2020). These are not knowledge failures but institutional-capacity failures, and addressing them will require structural reform rather than additional evidence generation.

Limitations of the Study

This narrative review has several limitations. Literature selection reflects the authors' judgment rather than a reproducible screening protocol; approximately 200 sources were screened, with 58 included based on relevance and rigor. The analysis is English-language only and U.S.-centric, with illustrative international comparisons. The regulatory landscape is evolving rapidly: FDA v. Wages was decided during this review's preparation, and the Court's remand on the harmless-error question means the case is not fully resolved even in 2026. The chronic-effects literature on ENDS remains immature, with most studies reporting two years or less of follow-up. The youth-vaping decline documented in the 2023-2024 NYTS data [3] partially complicates the "regulation is failing" framing, though the persistence of unauthorized products and flavor use among current users suggests the decline reflects factors beyond regulatory effectiveness alone.

Conclusion

The pulmonary evidence base on vaping has matured substantially: EVALI causation by VEA is established [6,7]; chronic respiratory associations are replicated across longitudinal nationally representative studies [14,15]; and cessation efficacy is supported by high-certainty evidence [21]. The regulatory response, while upheld judicially [36], remains structurally mismatched to the products driving harm. Unauthorized disposables dominate the youth market outside the PMTA system [3]. Active national EVALI surveillance was transitioned to passive monitoring [42]. Nicotine pouches have entered the market with no pulmonary evidence base [47].

The pulmonary community is not a bystander in this process: it generates the clinical evidence that anchors regulatory decisions, treats patients affected by products the regulatory system has not adequately constrained, and possesses the professional credibility to advocate for the structural reforms that the current system requires.

Conflict of Interest Statement

The authors declare no conflicts of interest.

Funding Support

No funding was received for this work.

Bibliography

1. U.S. Department of Health and Human Services, The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. DHHS, CDC (2014).

2. JL Barrington-Trimis and AM Leventhal. "Adolescents' use of 'pod mod' e-cigarettes - urgent concerns". *New England Journal of Medicine* 379.12 (2018): 1099-1102.

3. A Jamal., *et al*. "Tobacco product use among middle and high school students - NYTS, United States, 2024". *Morbidity and Mortality Weekly Report* 73.41 (2024): 917-924.

4. JE Layden., *et al*. "Pulmonary illness related to e-cigarette use in Illinois and Wisconsin - final report". *New England Journal of Medicine* 382.10 (2020): 903-916.

5. VP Krishnasamy., *et al*. "Update: characteristics of a nationwide outbreak of EVALI - United States, August 2019-January 2020". *Morbidity and Mortality Weekly Report* 69.3 (2020): 90-94.

6. BC Blount., *et al*. "Vitamin E acetate in bronchoalveolar-lavage fluid associated with EVALI". *New England Journal of Medicine* 382.8 (2020): 697-705.

7. TA Bhat., *et al*. "An animal model of inhaled vitamin E acetate and EVALI-like lung injury". *New England Journal of Medicine* 382.12 (2020): 1175-1177.

8. AK Werner., *et al*. "Hospitalizations and deaths associated with EVALI". *New England Journal of Medicine* 382.17 (2020): 1589-1598.

9. J Taylor., *et al*. "Characteristics of e-cigarette products used by patients with associated lung injury and products seized by law enforcement - Minnesota, 2018 and 2019". *Morbidity and Mortality Weekly Report* 68.47 (2019): 1096-1100.

10. I Ghinai., *et al*. "E-cigarette product use among persons with associated lung injury - Illinois and Wisconsin, April-September 2019". *Morbidity and Mortality Weekly Report* 68.39 (2019): 865-869.

11. BA King., *et al*. "The EVALI and youth vaping epidemics - implications for public health". *New England Journal of Medicine* 382.8 (2020): 689-691.

12. R McConnell., *et al*. "Electronic cigarette use and respiratory symptoms in adolescents". *American Journal of Respiratory and Critical Care Medicine* 195.8 (2017): 1043-1049.

13. BW Chaffee., *et al*. "E-cigarette use and adverse respiratory symptoms among adolescents and young adults in the United States". *Preventive Medicine* 153 (2021): 106766.

14. W Xie., *et al*. "Association of electronic cigarette use with respiratory symptom development among U.S. young adults". *American Journal of Respiratory and Critical Care Medicine* 205.11 (2022): 1320-1329.

15. D Owusu., *et al*. "ENDS, cigarettes, and respiratory illness: longitudinal associations among U.S. youth". *American Journal of Preventive Medicine* 66.4 (2024): 636-645.

16. E Bircan., *et al*. "Electronic cigarette use and its association with asthma, COPD and asthma-COPD overlap syndrome among never cigarette smokers". *Tobacco Induced Diseases* 19 (2021): 23.

17. HC Erythropel., *et al*. "Formation of flavorant-propylene glycol adducts with novel toxicological properties in chemically unstable e-cigarette liquids". *Nicotine and Tobacco Research* 21.9 (2019): 1248-1258.

18. TA Wills., *et al*. "E-cigarette use and respiratory disorders: an integrative review of converging evidence". *European Respiratory Journal* 57.1 (2021): 1901815.

19. P Hajek., *et al*. "A randomized trial of e-cigarettes versus nicotine-replacement therapy". *New England Journal of Medicine* 380.7 (2019): 629-637.

20. R Auer., *et al*. "Electronic nicotine-delivery systems for smoking cessation". *New England Journal of Medicine* 390.7 (2024): 601-610.

21. N Lindson., *et al*. "Electronic cigarettes for smoking cessation". *Cochrane Database of Systematic Reviews* 1.1 (2025): CD010216.

22. NA Rigotti. "Electronic cigarettes for smoking cessation - have we reached a tipping point?". *New England Journal of Medicine* 390.7 (2024): 664-665.

23. E Banks., *et al*. "Electronic cigarettes and health outcomes: epidemiological and public health challenges". *International Journal of Epidemiology* 52.4 (2023): 984-992.

24. ON Baenziger., *et al*. "E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers: umbrella review, systematic review and meta-analysis". *BMJ Open* 11.3 (2021): e045603.

25. National Academies of Sciences, Engineering, and Medicine, Public Health Consequences of E-Cigarettes. Washington, DC: The National Academies Press (2018).

26. U.S. Congress, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

27. SA Glantz and DW Bareham. "Compromise or capitulation? US FDA jurisdiction over tobacco products". *PLOS Medicine* 6.7 (2009): e1000118.

28. DG Aaron. "The FDA as gatekeeper and the menthol exemption". *American Journal of Public Health* 110.6 (2020): 775-776.

29. U.S. FDA. "Deeming tobacco products to be subject to the FD&C Act; final rule". *Federal Register* 81.90 (2016): 28973-29106.

30. U.S. HHS, Office of Inspector General. "FDA has improved its premarket review of new tobacco products, but more could be done to address application backlog". OIG Report OEI-01-20-00240 (2023).

31. U.S. FDA. "Premarket tobacco product marketing granted orders". FDA Center for Tobacco Products (2026).

32. U.S. FDA. "Enforcement priorities for ENDS and other deemed products on the market without premarket authorization" (2020).

33. MC Diaz., *et al*. "Menthol e-cigarette sales rise following 2020 FDA guidance". *Tobacco Control* 30.6 (2021): 700-703.

34. G Kong., *et al*. "E-cigarette devices, brands, and flavors attract youth: informing FDA's policies". *Addictive Behaviors* 119 (2021): 106935.

35. FRM Ali., *et al*. "E-cigarette unit sales by product and flavor type, United States, 2020-2022". *Morbidity and Mortality Weekly Report* 72.25 (2023): 672-677.

36. FDA v. Wages and White Lion Investments, 604 U.S. 542 (2025).

37. M Kingsley., *et al*. "Impact of Massachusetts' statewide sales restriction on flavored and menthol tobacco products". *American Journal of Public Health* 112.8 (2022): 1147-1150.

38. S Asare., *et al*. "Spatial analysis of changes in cigarette sales following the Massachusetts menthol flavor ban". *JAMA Network Open* 5.9 (2022): e2232103.

39. AC Liber., *et al*. "Early evidence of flavored tobacco product restrictions in Massachusetts and New York State". *Tobacco Induced Diseases* 21 (2023): 140.

40. MF Pesko., *et al*. "The impact of two state-level approaches to restricting flavored tobacco products". *BMC Public Health* 22.1 (2022): 1786.

41. Public Health Law Center. "State e-cigarette registry bills and what to make of them". Mitchell Hamline School of Law (2024).

42. VP Krishnasamy., *et al*. "EVALI: looking back, moving forward". *Public Health Reports* 136.1 (2021): 3-6.

43. JK Pepper., *et al*. "Adolescents' interest in trying flavoured e-cigarettes". *Tobacco Control* 25.2 (2016): ii62-ii66.

44. C Meernik., *et al*. "Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review". *BMJ Open* 9.10 (2019): e031598.

45. A McNeill., *et al*. "Nicotine vaping in England: an evidence update including health risks and perceptions, 2022". OHID, UK (2022).

46. Australian Government. "Therapeutic Goods (Standard for Vaping Goods) (TGO 110) Order 2021". TGA (2021).

47. KL Marynak., *et al*. "Nicotine pouch unit sales in the US, 2016-2020". *The Journal of the American Medical Association* 326.6 (2021): 566-568.

48. E Park-Lee., *et al*. "E-cigarette and nicotine pouch use among middle and high school students - United States, 2024". *Morbidity and Mortality Weekly Report* 73.35 (2024): 774-778.

49. MO Robichaud., *et al*. "Tobacco companies introduce 'tobacco-free' nicotine pouches". *Tobacco Control* 29.e1 (2020): e145-e146.

50. SV Jabba., *et al*. "Chemical adducts of reactive flavor aldehydes formed in e-cigarette liquids are cytotoxic and inhibit mitochondrial function in respiratory epithelial cells". *Nicotine and Tobacco Research* 22.1 (2020): S25-S34.

51. D Hammond and JL Reid. "Trends in vaping and nicotine product use among youth in Canada, England and the USA, 2017-2022". *Tobacco Control* 34.1 (2025): 115-118.

52. E Karey., *et al*. "Longitudinal association between e-cigarette use and respiratory symptoms among US adults: findings from the PATH Study Waves 4-5". *PLOS ONE* 19.2 (2024): e0299834.

53. Z Boas., *et al*. "Activation of inflammation in healthy young adult smokers and e-cigarette users". *JAMA Cardiology* 2.3 (2017): 278-284.

54. Y Wang., *et al*. "Impact of electronic cigarette usage on the onset of respiratory symptoms and COPD among Chinese adults". *Scientific Reports* 14 (2024): 5598.

55. L Deyton., *et al*. "Tobacco product regulation - a public health approach". *New England Journal of Medicine* 362.19 (2010): 1753-1756.

56. LT Olson., *et al*. "Youth tobacco use before and after local sales restrictions on flavored and menthol tobacco products in Minnesota". *Journal of Adolescent Health* 70.6 (2022): 978-984.

57. Loper Bright Enterprises v. Raimondo, 603 U.S. ___ (2024).

58. Ohio H.B. 33, 135th Gen. Assemb., Reg. Sess. (Ohio 2023) (tobacco flavor preemption provisions, effective 2024).

59. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, §111, 136 Stat. 49.

60. CDC. "Outbreak of lung injury associated with the use of e-cigarette, or vaping, products". CDC.gov.Online. (Final case count: 2,807 hospitalizations, 68 deaths as of Feb. 18, 2020).

61. City of Columbus *et al*. v. State of Ohio, Franklin County Common Pleas (2024); affirmed, Ohio 10th Dist. Ct. App. (2025). (Holding Ohio H.B. 33 tobacco preemption provisions unconstitutional; appeal to Ohio Supreme Court pending).

Volume 15 Issue 8 August 2026