

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 21-60766
consolidated with
No. 21-60800

WAGES AND WHITE LION INVESTMENTS, LLC, doing business as
TRITON DISTRIBUTION,

Petitioner,

vs.

UNITED STATES FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order by the
United States Food & Drug Administration

**BRIEF OF VAPOR TECHNOLOGY ASSOCIATION AS *AMICUS*
CURIAE IN SUPPORT OF PETITIONERS' PETITION FOR
REHEARING *EN BANC***

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CERTIFICATE OF INTERESTED PERSONS

Nos. 21-60766 and 21-60800

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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INTEREST OF THE AMICUS CURIAE

The *Amicus Curiae*¹ Vapor Technology Association (VTA) is a national non-profit industry trade association whose members are dedicated to developing and selling high quality vapor products that provide adult consumers with an alternative to combustible cigarettes. VTA's membership includes manufacturers of vapor devices and e-liquids, distributors, suppliers, and brick-and-mortar vape shop retailers that all either manufacture and/or sell a variety of vapor products, including open-system vaping products. Since its founding, the VTA has been engaged on the critical issues confronting the vapor industry, advocating for rational science-based regulations.

INTRODUCTION

The questions presented by Petitioners merit consideration by the Fifth Circuit *en banc* because they are of exceptional importance. The need to eliminate the scourge that cigarette smoking has caused to

¹ Pursuant to Federal Rule of Appellate Procedure 29(a)(2), counsel for *Amicus Curiae* state that Petitioner and Respondent have all articulated their consent to the filing of the subject brief. Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for *Amicus Curiae* states that no counsel for any party authored this brief in whole or in part and that no party nor their counsel made a monetary contribution toward its preparation.

Americans cannot be overstated. Cigarettes are the only product sold in the U.S. that, when used as intended, cause disease and or death to the consumers using the product. According to the CDC, 1,300 Americans die every day from smoking, equating to almost 480,000 Americans dying annually.² That is a COVID scale event every two years. As recently explained by FDA, “The Surgeon General has reported that about 30 individuals will suffer from at least one smoking-related disease for every person that dies from smoking each year.” HHS, Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 86, May 4, 2022, at 26482.

ARGUMENT

I. THE MAJORITY RULING DIRECTLY THREATENS THE AVAILABILITY OF FLAVORED VAPING ALTERNATIVES FOR ADULTS WHO ARE DESPERATELY TRYING TO QUIT SMOKING.

A. If the Majority’s Ruling and FDA’s Arbitrary Actions Against Flavored ENDS Products is Allowed to Stand, Businesses, Workers, and States Treasuries Will Suffer Negative Economic Impacts.

² CDC, Smoking & Tobacco Use, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (last accessed 9/8/2022).

If the Majority decision is not revisited *en banc* and reversed, and FDA's actions left unchecked, FDA will be free to change its policies and requirements without any serious consideration to stakeholders' reliance interests. Consideration of Petitioners' petition is of exceptional importance since enforcement of the Majority panel's ruling will dramatically and adversely affect the independent vapor products industry, and related industries, in the states covered by the Fifth Circuit.

Economists at John Dunham & Associates have been studying the economics of the vapor industry for years. Recently, Dunham examined the potential economic impact of the Majority decision that would allow FDA to eliminate the sale of flavored vaping products in the Fifth Circuit unless, of course, applicants were fortunate enough to foresee and implement FDA's unstated requirements. Dunham's multi-faceted analysis should be deeply concerning. To begin, not only will 1,038 small businesses close but the economic impact on the U.S. and the states of the Fifth Circuit will exceed \$1 billion. Dunham, John, *The Economic Impact of a Ban on Flavor Vapor Products in the States of*

Louisiana, Mississippi and Texas, September 8, 2022, at Appendix 1, pp. 4-5 (App. 1).

Dunham examined the economic impact in the Fifth Circuit’s geographic footprint if a *de facto* flavor ban for open-system products – i.e., the type of products sold by Petitioners and covered in the PMTAs at issue – resulted from FDA’s issuance of marketing denial orders for all such products. Dunham found that the removal of all flavored open-system vaping products from the 5th Circuit would result in the loss of 6,660 full time equivalent jobs in the states of Louisiana, Mississippi and Texas, and the elimination of \$140.8 million in wages and benefits paid to these workers. App. 1, p. 4. In addition, the overall “economic loss to the three states would be about \$1.3 billion.” *Id.*

Further, Dunham found that if FDA’s justification for denying the sale of flavored vaping products is extended to all device types, an extension which is rationally predictable from FDA’s post-hoc justifications for its denials, it would result in the loss of 10,340 jobs in the states of Louisiana, Mississippi and Texas and the elimination of \$482.6 million in wages and benefits paid to these workers. The overall

economic output of these three states would be reduced by nearly \$2.0 billion. *Id.*, p. 3.

Finally, both the federal government and the states comprising the 5th Circuit would suffer from lost tax revenue through “reductions in income taxes, profits taxes, social security payments, and even property taxes.” *Id.* Dunham reports that the federal government would lose approximately \$116 million in tax revenue from the states of Louisiana, Mississippi and Texas together. *Id.*, p. 5. Further, the state treasuries of Louisiana, Mississippi, and Texas would lose \$13.5 million, \$10.1 million, and \$73.4 million respectively. *Id.*

B. Leading Tobacco Control Experts Warn About Decreasing Adult Access to Flavored E-Cigarettes and Question US Regulators’ Exclusive Focus on Youth.

In September 2021, fifteen of the past presidents of the staunchly anti-tobacco Society for Research on Nicotine and Tobacco (SRNT), published an analytical essay in which they explain, “Many, including this article’s authors, believe that vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking’s toll.” David J. K. Balfour, et al. “Balancing Consideration of the Risks and Benefits of E-Cigarettes”, *Amer. Jrnl. Pub. Health*, 111,

no. 9 (September 1, 2021), pp. 1662. Specifically, these anti-tobacco experts warn that current U.S. policy, including efforts to restrict flavored vaping products, is disregarding the needs of the adult smoker.

“To date, the singular focus of US policies on decreasing youth vaping may well have reduced vaping’s potential contribution to reducing adult smoking. Those policies include ... **decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation**, and convincing the public—including smokers—that vaping is as dangerous as smoking.”

Id. at 1666 (emphasis supplied). To correct the imbalanced approach, these anti-tobacco experts recommend limiting the "retail sale of flavored e-cigarettes to adult-only outlets such as vape shops" which is precisely how Petitioners' limit their sales. *Id.* To clarify their concerns, they also note that the “potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks of youth,” and explain that the actual risk to youth is not what is popularly believed. *Id.* at 1666 (“Vaping may addict some youths to nicotine, but many fewer than popularly believed.”)

C. Actual FDA Data Reveal that The Majority Ruling Completely Misapprehends the Relationship Between Petitioners’ Device Type and Youth Sales, and That Petitioners’ Selected Sales Channels Have the Fewest Reported Violations.

The Majority opinion misapprehends the fundamental differences between open and closed systems and the supposed risk to youth. The Majority reasoned:

But in reality, Petitioners fault FDA for refusing to turn a blind eye to all the evidence that has emerged since 2019. Particularly, after FDA increased enforcement actions against closed-system devices, the youth-smoking epidemic did not end; instead, youth smokers migrated to other device types with flavored e-liquids: “[W]hen FDA changed its enforcement policy to prioritize pod-based flavored ENDS, which were most appealing to youth at the time, we subsequently observed a substantial rise in use of disposable flavored ENDS—a ten-fold increase (from 2.4% to 26.5%) among high school current e-cigarette users.”

Wages & White Lion Inv., LLC v. FDA, 41 F.4th 427, 437, (5th Cir. 2022).

The relevant “reality” here is that, respectfully, the Majority blindly accepted FDA’s observation of a “ten-fold” rise in the use of flavored disposables which had nothing to do with open systems. To wit, disposables are the *ultimate* closed-system in that they mimic the closed-system device characteristics that FDA used to justify the cartridge-based flavor ban,³ and still FDA inexplicably exempted

³ “Of particular concern are the design features that appear to make the cartridge-based products so popular with young people. Attributes typically present in cartridge-based products include a relatively small size that allows for easy scalability, and intuitive and convenient features that facilitate ease of use, including draw activation, prefilled cartridges or pods, and USB rechargeability.” *See*, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, January 2020, pp. 15-16.

disposables from its closed-system flavor ban. In a letter to FDA sent contemporaneously with FDA's mass denials of flavored ENDS PMTA's, VTA explained the impropriety of this rationale:

Open-system devices share none of the design features that FDA relied upon in removing closed-system device flavors from the market. [...] Moreover, any suggestion that FDA is concerned that youth *might* simply switch to open-system flavored ENDS,... is speculative and unscientific. FDA could not have been surprised that youth matriculated to closed-system *disposables* since disposables share the exact same design features as the other flavored closed-systems that FDA banned last year. In fact, disposables are easier to use, easier to conceal, easier to use discreetly, are more intuitive, and are more convenient than pods/cartridges. Since the exact opposite is true for open-system flavors, FDA's experience with disposables offers no justification, much less empirical data, for any concern that youth would take up open-systems if and when FDA eliminates the flavored closed-system disposable exemption it created.

VTA Letter to FDA Center for Tobacco Products Director Mitchell Zeller, September 14, 2021, p. 2, Appendix 2.

Further, VTA has conducted a detailed analysis of FDA's publicly available data regarding youth sales violations between January 1, 2020, and June 30, 2022, which reveals striking facts. Initially, it is noteworthy that the FDA conducted over 110,000 retail inspections in which *no youth sales or other violations* were cited. See, FDA, Compliance Check Inspections of Tobacco Product Retailers,

https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm. And, of all the inspections conducted, only 4.57% resulted in a violation that involved a vapor product of any device type or flavor. *Id.* By comparison, the rate of youth sales violations for combustible cigarettes and cigars was 110% higher than the rate of youth vape sales violations. Moreover, in the first six months of 2022, FDA's data reveals that there has been a 78% increase in the number of youth sales violations for combustible tobacco products (cigars and cigarettes) and a 17% *decrease* in the number of youth vape sale violations. *Id.*

More importantly, FDA's retailer compliance database reveals that of all retailers cited, only 3.61% of all youth vapor sales violations occurred in true brick-and-mortar vape shops – stores which do not also sell combustible tobacco products – which is precisely where the Petitioners' products are sold. *Id.* VTA's analysis further found that of all youth sales violations since January of 2020, nearly 80% occurred occur in non-age restricted stores —such as convenience stores— through which Petitioners' products are *not* being sold. *Id.*

Finally, contrary to FDA's belief about flavors being the real issue, FDA's own data reveals that the majority of youth sales violations

between January 1, 2020 and June 30, 2022 – about 60% – involved the sale of traditional tobacco flavors (i.e., tobacco, menthol and mint) while less than 40% involved other flavors. Hence, FDA’s real-world data makes clear that youth violations have been occurring more with combustible tobacco products and significantly more with traditional tobacco flavors and not with the non-tobacco flavors like those sold by Petitioners in adult-only vape stores. These facts, coupled with the fact that FDA admittedly disregarded Petitioners’ marketing and sales limitations plans, which involved exclusive sale through adult-only vape shops, require *en banc* consideration.

CONCLUSION

For the foregoing reasons, the Vapor Technology Association respectfully requests that the Court grant Petitioners’ Petition for Rehearing *en banc*.

Dated: September 8, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the type-volume requirement set forth in the Federal Rule of Appellate Procedure. The word count feature found in Microsoft Word reports that this document contains less than 1950 words, excluding the items exempted by Federal Rule of Appellate Procedure 32(f).

This document complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32 because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Century Schoolbook, size 14 font.

/s/ Anthony L. Abboud
Anthony L. Abboud

CERTIFICATE OF CONFERENCE

I hereby certify under Federal Rule of Appellate Procedure 29(a)(2) that on September 6, 2022, I contacted counsel for both the Petitioner and the Respondent by electronic mail seeking consent to file the subject amicus brief of the Vapor Technology Association and that counsel for both Petitioner and Respondent articulated their consent on September 6 and 7, 2022, respectively.

/s/ Anthony L. Abboud
Anthony L. Abboud

CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2022, a true and correct copy of the foregoing Brief of the Vapor Technology Association as *Amicus Curiae* in Support of Petitioners' Petition for Rehearing *En Banc* was filed with the Clerk's Office for the United States Court of Appeals for the Fifth Circuit using the CM/ECF system and served via electronic mail via the Court's ECM/ECF system. Participants in this case are registered ECM/ECF users, and service will be effected via the ECM/ECF system.

/s/ Anthony L. Abboud
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APPENDIX

1. Dunham, John, *The Economic Impact of a Ban on Flavor Vapor Products in the States of Louisiana, Mississippi and Texas*, September 8, 2022.
2. VTA Letter to FDA Center for Tobacco Products Director Mitchell Zeller, September 14, 2021.

APPENDIX 1

The Economic Impact of a Ban on Flavored Vapor Products in the States of Louisiana, Mississippi and Texas

Prepared for the Vapor Technology Association

By

John Dunham & Associates



September 8, 2022

The Economic Impact of a Ban on Flavored Vapor Products in the States of Louisiana, Mississippi and Texas

John Dunham & Associates (JDA) has examined the economic impact of a ban on flavored vapor products on the economy of the states of Louisiana, Mississippi, and Texas. Such a ban would have a devastating effect on the vapor sector in each of those state’s economies, while at the same time benefitting vapor suppliers in surrounding states.

Based on this analysis:

A flavor ban in these three states would be the loss of 12,430 FTE positions across the entire US economy. The overall cost to the US economy would be \$2.4 billion.

Almost 11,300 FTE positions would be lost in Louisiana, Mississippi and Texas. The economies of these three states would be over \$2.2 billion smaller than they would be if flavored and menthol vapor products continue to be sold.

A ban on just non-menthol flavored products in these three states would be the loss of nearly 11,350 FTE positions across the entire US economy. The overall cost to the US economy would be \$2.2 billion.

Looking at the three states alone, the total loss in jobs would be 10,340 FTE positions, with a loss of \$2.0 billion to the state economies.

A ban on flavored open-system (liquids) products in these three states would be the loss of just over 2,950 FTE positions across the US economy. The overall cost to the US economy would be about \$745.7 million.

The economies of these three states would lose just over 6,660 jobs, with an economic loss of about \$1.3 billion.

Table 1 below estimates the extreme case where all flavored and menthol vapor products (both open and closed systems) are banned in each of the three states, and then in combination across all states in the US.

Table 1
Impact of a ban on flavored and menthol vapor products

United States					
Current	Direct	Supplier	Induced	Total	
Current Jobs	66,357	28,089	39,109	133,555	
Current Wages	\$ 2,741,178,172	\$ 2,018,272,890	\$ 2,243,795,420	\$ 7,003,246,482	
Current Output	\$ 8,087,437,404	\$ 6,879,165,257	\$ 7,124,241,153	\$ 22,090,843,815	
With Proposal	Direct	Supplier	Induced	Total	
New Jobs	60,241	25,390	35,494	121,125	
New Wages	\$ 2,509,711,979	\$ 1,824,510,257	\$ 2,050,706,028	\$ 6,384,928,264	
New Output	\$ 7,395,150,577	\$ 5,816,491,597	\$ 6,454,063,779	\$ 19,665,705,953	
Change	Direct	Supplier	Induced	Total	
Jobs Change	(6,116)	(2,699)	(3,614)	(12,429)	
Wages Change	\$ (231,466,193)	\$ (193,762,632)	\$ (193,089,392)	\$ (618,318,218)	
Output Change	\$ (692,286,828)	\$ (1,062,673,660)	\$ (670,177,374)	\$ (2,425,137,862)	

Louisiana					
Current	Direct	Supplier	Induced	Total	
Current Jobs	823	328	418	1,569	
Current Wages	\$ 27,297,416	\$ 22,498,047	\$ 19,729,544	\$ 69,525,007	
Current Output	\$ 84,372,711	\$ 184,209,915	\$ 81,652,096	\$ 350,234,722	
With Proposal	Direct	Supplier	Induced	Total	
New Jobs	80	32	62	173	
New Wages	\$ 5,213,994	\$ 2,177,119	\$ 2,928,445	\$ 10,319,558	
New Output	\$ 8,164,682	\$ 17,825,851	\$ 12,119,575	\$ 38,110,108	
Change	Direct	Supplier	Induced	Total	
Jobs Change	(743)	(296)	(356)	(1,395)	
Wages Change	\$ (22,083,422)	\$ (20,320,928)	\$ (16,801,099)	\$ (59,205,449)	
Output Change	\$ (76,208,030)	\$ (166,384,065)	\$ (69,532,520)	\$ (312,124,615)	

Mississippi					
Current	Direct	Supplier	Induced	Total	
Current Jobs	737	230	305	1,273	
Current Wages	\$ 17,508,176	\$ 10,575,581	\$ 11,293,456	\$ 39,377,214	
Current Output	\$ 55,665,722	\$ 47,017,594	\$ 43,756,630	\$ 146,439,946	
With Proposal	Direct	Supplier	Induced	Total	
New Jobs	62	19	36	118	
New Wages	\$ 2,445,077	\$ 894,710	\$ 1,343,045	\$ 4,682,831	
New Output	\$ 4,709,402	\$ 3,977,758	\$ 5,203,642	\$ 13,890,802	
Change	Direct	Supplier	Induced	Total	
Jobs Change	(675)	(211)	(269)	(1,155)	
Wages Change	\$ (15,063,099)	\$ (9,680,871)	\$ (9,950,412)	\$ (34,694,383)	
Output Change	\$ (50,956,319)	\$ (43,039,836)	\$ (38,552,988)	\$ (132,549,144)	

Texas					
Current	Direct	Supplier	Induced	Total	
Current Jobs	4,784	2,234	3,000	10,019	
Current Wages	\$ 188,394,068	\$ 166,603,274	\$ 165,218,946	\$ 520,216,288	
Current Output	\$ 562,217,429	\$ 903,136,474	\$ 564,136,506	\$ 2,029,490,409	
With Proposal	Direct	Supplier	Induced	Total	
New Jobs	526	246	500	1,271	
New Wages	\$ 40,821,906	\$ 18,313,659	\$ 27,522,222	\$ 86,657,787	
New Output	\$ 61,801,055	\$ 99,276,158	\$ 93,974,030	\$ 255,051,243	
Change	Direct	Supplier	Induced	Total	
Jobs Change	(4,258)	(1,989)	(2,501)	(8,747)	
Wages Change	\$ (147,572,161)	\$ (148,289,615)	\$ (137,696,724)	\$ (433,558,501)	
Output Change	\$ (500,416,375)	\$ (803,860,316)	\$ (470,162,475)	\$ (1,774,439,166)	

As the table shows, the overall cost of the ban in these three states would be the loss of 12,430 FTE positions across the entire US economy.¹ These jobs would have paid \$618.3 million in wages and benefits. The overall cost to the US economy would be \$2.4 billion. These losses reflect the impact of increased cross-border sales from states where flavored vapor products are not banned; in addition, they also account for lost sales that had previously been purchased by consumers in other states from outlets in the three states considering a ban.

Looking at the three states in a vacuum, the total loss in jobs would be almost 11,300 FTE positions, paying \$527.5 million in wages and benefits. The economies of these three states would be over \$2.2 billion smaller than they would be if flavored and menthol vapor products continue to be sold.²

A ban on these products in Louisiana, Mississippi and Texas would encourage consumers to react in some combination of four different ways. Some, though likely very few, would stop consuming any vapor products. A larger percentage would switch from flavored vapor products to unflavored (or *tobacco flavored*) products. Some consumers would stop vaping and return to smoking combustible cigarettes or begin to consumer other flavored products such as cigars or moist snuff. Finally, the models and data from other states that have banned these products suggest that many consumers would simply turn to sources outside of the jurisdiction of the three states. These could be other states, Federal jurisdictions such as military bases, or simply purchase their products on-line.³

The impacts would be similarly substantial if just flavored products (not including menthol) were banned across the three jurisdictions. Table 2 on the following page outlines these impacts.

As the table below shows, the overall cost of the ban on just non-menthol flavored products in these three states would be the loss of nearly 11,350 FTE positions across the entire US economy. These jobs would have paid almost \$563.7 million in wages and benefits. The overall cost to the US economy would be \$2.2 billion. Looking at the three states alone, the total loss in jobs would be 10,340 FTE positions, paying about \$482.6 million in wages and benefits. The cost to the economies of these three states would be about \$2.0 billion.⁴

Table 2
Impact of a ban on flavored vapor products (except for menthol)

United States						Louisiana					
Current	Direct	Supplier	Induced	Total		Current	Direct	Supplier	Induced	Total	
Current Jobs	66,357	28,089	39,109	133,555		Current Jobs	823	328	418	1,569	
Current Wages	\$ 2,741,178,172	\$ 2,018,272,890	\$ 2,243,795,420	\$ 7,003,246,482		Current Wages	\$ 27,297,416	\$ 22,498,047	\$ 19,729,544	\$ 69,525,007	
Current Output	\$ 8,087,437,404	\$ 6,879,165,257	\$ 7,124,241,153	\$ 22,090,843,815		Current Output	\$ 84,372,711	\$ 184,209,915	\$ 81,652,096	\$ 350,234,722	
With Proposal	Direct	Supplier	Induced	Total		With Proposal	Direct	Supplier	Induced	Total	
New Jobs	60,772	25,624	35,813	122,209		New Jobs	143	57	92	292	
New Wages	\$ 2,530,407,835	\$ 1,841,361,151	\$ 2,067,789,934	\$ 6,439,558,920		New Wages	\$ 7,092,063	\$ 3,900,403	\$ 4,355,343	\$ 15,347,810	
New Output	\$ 7,455,513,909	\$ 5,907,906,548	\$ 6,513,106,608	\$ 19,876,527,065		New Output	\$ 14,627,385	\$ 31,935,792	\$ 18,024,893	\$ 64,588,070	
Change	Direct	Supplier	Induced	Total		Change	Direct	Supplier	Induced	Total	
Jobs Change	(5,585)	(2,465)	(3,296)	(11,346)		Jobs Change	(680)	(271)	(326)	(1,277)	
Wages Change	\$ (210,770,337)	\$ (176,911,739)	\$ (176,005,486)	\$ (563,687,562)		Wages Change	\$ (20,205,353)	\$ (18,597,644)	\$ (15,374,201)	\$ (54,177,198)	
Output Change	\$ (631,923,495)	\$ (971,258,710)	\$ (611,134,545)	\$ (2,214,316,750)		Output Change	\$ (69,745,327)	\$ (152,274,124)	\$ (63,627,203)	\$ (285,646,653)	
Mississippi						Texas					
Current	Direct	Supplier	Induced	Total		Current	Direct	Supplier	Induced	Total	
Current Jobs	737	230	305	1,273		Current Jobs	4,784	2,234	3,000	10,019	
Current Wages	\$ 17,508,176	\$ 10,575,581	\$ 11,293,456	\$ 39,377,214		Current Wages	\$ 188,394,068	\$ 166,603,274	\$ 165,218,946	\$ 520,216,288	
Current Output	\$ 55,665,722	\$ 47,017,594	\$ 43,756,630	\$ 146,439,946		Current Output	\$ 562,217,429	\$ 903,136,474	\$ 564,136,506	\$ 2,029,490,409	
With Proposal	Direct	Supplier	Induced	Total		With Proposal	Direct	Supplier	Induced	Total	
New Jobs	120	37	59	216		New Jobs	887	414	712	2,014	
New Wages	\$ 3,724,032	\$ 1,715,415	\$ 2,187,391	\$ 7,626,838		New Wages	\$ 53,383,238	\$ 30,893,659	\$ 39,223,223	\$ 123,500,120	
New Output	\$ 9,029,273	\$ 7,626,501	\$ 8,475,072	\$ 25,130,847		New Output	\$ 104,253,374	\$ 167,470,840	\$ 133,926,845	\$ 405,651,060	
Change	Direct	Supplier	Induced	Total		Change	Direct	Supplier	Induced	Total	
Jobs Change	(618)	(193)	(246)	(1,057)		Jobs Change	(3,897)	(1,820)	(2,288)	(8,005)	
Wages Change	\$ (13,784,145)	\$ (8,860,166)	\$ (9,106,066)	\$ (31,750,376)		Wages Change	\$ (135,010,830)	\$ (135,709,615)	\$ (125,995,722)	\$ (396,716,167)	
Output Change	\$ (46,636,449)	\$ (39,391,092)	\$ (35,281,558)	\$ (121,309,099)		Output Change	\$ (457,964,055)	\$ (735,665,634)	\$ (430,209,660)	\$ (1,623,839,349)	

¹ The 2021 Economic Impact Study of the Vapor Industry, Prepared for: Vapor Technology Association, John Dunham & Associates, Inc., September 20th, 2021, at: <https://vaportechology.org/value-of-vapor/>

² Prepared for the Vapor Technology Association by John Dunham & Associates, 2022. See methodology section,

³ The lower impact in the three states suggest that many consumers who reside in other states currently purchase these flavored vapor products from sources in Louisiana, Mississippi and Texas. A ban would eliminate these sales as well.

⁴ Ibid.

These loses are slightly larger since there is still an option to switch to menthol product.

The vast majority of flavored products are what are called open-systems, which consist of refillable devices and liquids that are heated to produce vapor. Flavored open system products are still permitted by the Federal Government. The impacts would be smaller, although still substantial if flavored products were just banned for open system products across the three states.

Table 3 outlines the impact of such a ban in Louisiana, Mississippi and Texas. As the tables below show, the overall cost of the ban on flavored open-system (liquids) products in these three states would be the loss of just over 2,950 FTE positions across the US economy. These jobs would have paid \$140.8 million in wages and benefits. The overall cost to the economy would be about \$745.7 million. The economies of these three states would lose just over 6,660 jobs, paying nearly \$313.1 million in wages and benefits. The economic loss to the three states would be about \$1.3 billion. In this case, the losses in the three states where the products would be banned are greater than the national figure since many of the current in-state vapor product users would simply purchase their flavored products from other states or jurisdictions.

Table 3
Impact of a ban on flavored vapor products – open systems

United States				
Current	Direct	Supplier	Induced	Total
Current Jobs	66,326	28,075	39,091	133,493
Current Wages	\$ 2,739,921,859	\$ 2,017,477,748	\$ 2,242,928,356	\$ 7,000,327,963
Current Output	\$ 8,083,176,042	\$ 6,876,478,487	\$ 7,121,281,292	\$ 22,080,935,821
With Proposal	Direct	Supplier	Induced	Total
New Jobs	64,962	27,384	38,194	130,540
New Wages	\$ 2,689,182,799	\$ 1,968,065,636	\$ 2,202,236,392	\$ 6,859,484,827
New Output	\$ 7,933,553,112	\$ 6,451,907,536	\$ 6,949,782,128	\$ 21,335,242,776
Change	Direct	Supplier	Induced	Total
Jobs Change	(1,365)	(691)	(897)	(2,953)
Wages Change	\$ (50,739,061)	\$ (49,412,112)	\$ (40,691,964)	\$ (140,843,136)
Output Change	\$ (149,622,930)	\$ (424,570,951)	\$ (171,499,164)	\$ (745,693,045)

Louisiana				
Current	Direct	Supplier	Induced	Total
Current Jobs	823	328	418	1,569
Current Wages	\$ 27,297,416	\$ 22,498,047	\$ 19,729,544	\$ 69,525,007
Current Output	\$ 84,372,711	\$ 184,209,915	\$ 81,652,096	\$ 350,234,722
With Proposal	Direct	Supplier	Induced	Total
New Jobs	429	171	230	830
New Wages	\$ 15,618,115	\$ 11,737,539	\$ 10,838,630	\$ 38,194,284
New Output	\$ 44,018,398	\$ 96,104,834	\$ 44,856,425	\$ 184,979,658
Change	Direct	Supplier	Induced	Total
Jobs Change	(393)	(157)	(189)	(739)
Wages Change	\$ (11,679,301)	\$ (10,760,508)	\$ (8,890,914)	\$ (31,330,724)
Output Change	\$ (40,354,313)	\$ (88,105,081)	\$ (36,795,670)	\$ (165,255,064)

Mississippi				
Current	Direct	Supplier	Induced	Total
Current Jobs	737	230	305	1,273
Current Wages	\$ 17,508,176	\$ 10,575,581	\$ 11,293,456	\$ 39,377,214
Current Output	\$ 55,665,722	\$ 47,017,594	\$ 43,756,630	\$ 146,439,946
With Proposal	Direct	Supplier	Induced	Total
New Jobs	394	123	169	686
New Wages	\$ 9,854,640	\$ 5,654,848	\$ 6,236,905	\$ 21,746,393
New Output	\$ 29,764,910	\$ 25,140,686	\$ 24,164,962	\$ 79,070,558
Change	Direct	Supplier	Induced	Total
Jobs Change	(343)	(107)	(137)	(587)
Wages Change	\$ (7,653,537)	\$ (4,920,733)	\$ (5,056,551)	\$ (17,630,821)
Output Change	\$ (25,900,812)	\$ (21,876,908)	\$ (19,591,668)	\$ (67,369,388)

Texas				
Current	Direct	Supplier	Induced	Total
Current Jobs	4,784	2,234	3,000	10,019
Current Wages	\$ 188,394,068	\$ 166,603,274	\$ 165,218,946	\$ 520,216,288
Current Output	\$ 562,217,429	\$ 903,136,474	\$ 564,136,506	\$ 2,029,490,409
With Proposal	Direct	Supplier	Induced	Total
New Jobs	2,185	1,021	1,477	4,683
New Wages	\$ 98,647,234	\$ 76,107,009	\$ 81,332,192	\$ 256,086,435
New Output	\$ 256,829,810	\$ 412,567,019	\$ 277,707,004	\$ 947,103,834
Change	Direct	Supplier	Induced	Total
Jobs Change	(2,598)	(1,214)	(1,523)	(5,336)
Wages Change	\$ (89,746,834)	\$ (90,496,264)	\$ (83,886,754)	\$ (264,129,852)
Output Change	\$ (305,387,619)	\$ (490,569,454)	\$ (286,429,501)	\$ (1,082,386,575)

Flavored closed system vapor products are, in many cases, already banned at the Federal level, meaning that a statewide or local ban would likely have a small impact.

Not only would these bans lead to losses in employment, but taxes at both the state and federal levels would fall as well. Lost job and corporate activity would lead to reductions in taxes paid by businesses and workers. This includes reductions in income taxes, profits taxes, social security payments, and even property taxes. Table 4 on the following page outlines the estimated tax losses resulting from the bans examined in this report.

It should be noted that the analysis of the open-system flavor ban does not include offsetting revenues from additional closed-system sales. As people in these three states no longer have access to flavored open-system vapor products, some would shift to purchasing closed system products.

While large national companies and integrated tobacco companies that also produce vapor products will not be impacted significantly by the proposed flavor bans, smaller companies, including adult-only vapor retailers in the three states will bear most of the brunt of the economic losses. In Louisiana there are approximately 141 specialty vape shops, there are

125 in Mississippi, and 772 in Texas. It is likely that all of these small businesses would have to close following a ban on flavored vapor products.

Table 4
Estimated fiscal impact of various ban scenarios

Flavored and Menthol both Open, and Closed-System

	Federal Taxes		State Taxes	
United States	\$	(49,046,914)	\$	(41,737,426)
Louisiana	\$	(3,199,321)	\$	(3,611,987)
Mississippi	\$	(4,235,680)	\$	(5,615,511)
Texas	\$	(35,904,274)	\$	(27,347,555)

Flavor only (Not Menthol) both Open and Closed-System

	Federal Taxes		State Taxes	
United States	\$	(48,960,098)	\$	(41,649,807)
Louisiana	\$	(3,422,306)	\$	(3,863,734)
Mississippi	\$	(4,128,982)	\$	(5,474,053)
Texas	\$	(36,064,080)	\$	(27,469,277)

Flavored (Not Menthol) Open-System Only

	Federal Taxes		State Taxes	
United States	\$	(72,469,833)	\$	(59,208,962)
Louisiana	\$	(11,951,241)	\$	(13,492,779)
Mississippi	\$	(7,640,792)	\$	(10,129,884)
Texas	\$	(96,325,258)	\$	(73,368,991)

Demand Model Methodology

JDA's Regulatory Assessment Model (RAM) is an updated version of a multi-market demand model first developed by the American Economics Group (AEG) under contract with Philip Morris. It was completely rebuilt by Dr. Hyeyeon Park in 2001, and its structure was updated by JDA in 2019. The model was presented to the National Conference of State Legislatures, Senior Fiscal Analysts Seminar in Portland Maine, on September 4, 1999, where it was well received. In fact, at that time many state fiscal analysts asked if the model could be made available to them as a forecasting tool. The results from the model were also presented to the Tax Foundation Excise Tax Seminar, held in Jacksonville, Florida, on January 12, 2001, as part of a larger discussion on the economic impact of tobacco taxes.

Since then, the RAM model has been modified to work with nearly any product or market. It is designed to measure product sales in a multi-state market structure with differential pricing. The general methodology is a two-stage estimation of the demand equation linked to a non-linear programming model of import and export patterns. Data for the model comes from the 2021 Economic Impact Model of the Vapor Industry, as well as from the US Census Bureau, the Bureau of Economic Analysis, US Department of Labor and JDA research. Caliper Corporation was used to estimated distances between states.

Estimates on what sales should be in each state are developed first. In this case, both demand and prices come directly from the Impact model. If cross-border sales were observable, the calculations would be complete; however, since they are not, the model must estimate them through non-linear programming techniques that solve the 51 demand functions simultaneously. The model adjusts the cross-price elasticities between states to balance the actual sales with expected demand.

Demand elasticities are calculated using a logarithmic demand curve with a base of -0.671 which is an average for vapor products.⁵

⁵ See: Gallaway, Michael, et. al., *Short-run and long-run industry-level estimates of US Armington elasticities*, *North American Journal of Economics and Finance*, March 2003.

Once the linear program model balances, the model can be *shocked* with either new prices or demand values. By rebalancing the model following the shock, it is possible to calculate demand response estimates across all states (as well as cross-border sales changes).

Revenue and job impacts can then be estimated through linear extrapolation.

Explanation of Economic Impact Terms

Direct Impact Categories:

The direct impacts of this study were divided up into the categories of the vapor industry. The vapor industry (as defined in this study) includes manufacturers of E-liquids, coils, box mods and other vape products, wholesalers, and retailers that sell vapor products such as; vape shops, convenience stores, supermarkets, gasoline stations, pharmacies and drug stores, warehouse clubs and supercenters, and discount tobacco stores.

What is Meant by the Term Direct Impact?

Direct Impacts are those jobs, wages or economic output solely attributable to the industry defined for the study; in this case manufacturers of E-liquids, coils, box mods and other vape products, wholesalers, and retailers that sell vapor products such as; vape shops, convenience stores, supermarkets, gasoline stations, pharmacies and drug stores, warehouse clubs and supercenters, and discount tobacco stores. These are the jobs that one can count. If one were to go to a manufacturing facility and count the number of people working there, that would be the direct employment (although there may be many more people working than there are jobs since many people work only part time). JDA uses direct employment at manufacturing facilities, offices, retail locations and other sites that are defined to be part of the industry to calculate all of the other effects presented in the study. For example, if a company facility employs 500 people, JDA then uses the IMPLAN model to calculate how much in wages and output those 500 employees create.

What is Meant by the Term Indirect?

Indirect is the term used in economic impact studies to define those effects that result from firms in the defined (or Direct) industry purchasing goods and services from other industries. JDA defines these as Supplier Impacts in its models. For example, when an e-liquid manufacturer pays rent on its warehouse to their landlord, or when they hire a trucking company to deliver products, or purchasing vapor products from a lab or warehouse, they are creating indirect effects in the real estate sector or trucking sector of the economy.

In the case of wholesalers, retailers and others that handle products through a supply chain, the value of the goods moving through a warehouse or a store are not counted as indirect impacts; only those goods and services used to provide the wholesale or retail service are included. When a wholesaler pays an electric bill for its facility, or a retailer buys paper for its store, indirect impact is created. Whereas, when a vapor product wholesaler buys e-liquid from a manufacturer, this transaction is not considered in the supplier impact.

What is Meant by the Term Induced?

Induced effects are the response by the economy that occur through re-spending of income received by payments made to employees and business owners measured in the direct and supplier parts of the economy. When people work for a retail location selling vapor products or for firms that supply goods and services to the industry, they receive wages and other payments. This money is recirculated through their household spending inducing further local economic activity. Economists call these induced impacts the multiplier effect of an activity or industry.

Examples of induced effects are the jobs created in a diner located outside of a vape component factory or retail store where people purchase sandwiches for lunch, or at the gas station where they purchase fuel for their commute, or even in neighborhoods, where workers purchase houses, go to restaurants or visit the movie theater.

What Specifically Do You Mean When You Say a Job?

Jobs are a measure of the annual average of monthly jobs in each industry as defined by the Quarterly Census of Employment and Wages put out by the Bureau of Labor Statistics. Jobs in our models are derived independently and do

not match jobs reported by government entities in that the model defines the industry differently, and because it includes proprietors and other employees not eligible for unemployment benefits, and data from more firms and facilities than are surveyed by the government. Jobs are measured in full-time equivalent units.

What is Meant by The Term Economic Output or Economic Impact?

JDA uses output in its models as a general measurement of economic impact because it is the broadest and most comparative measure. Output can basically be considered similar to final sales; however, it differs due to the fact that it also includes adjustments in inventories and does not include certain taxes. In general, output represents the value of industry production for the model year calculated in terms of producer prices. Output differs depending on the industry being measured. In the case of the vapor industry, output is similar to gross sales for vapor product manufacturers. For retailers and wholesalers, output does not represent sales, but rather is similar to the accounting measure of gross margin. Simply put, output in the case of retailing can be seen as total sales revenue minus the cost of goods sold. This is similar to the wholesale or retail markup on a product.

What is Meant by the Term Taxes Paid?

This economic impact study measures the Vapor Industry's total tax contributions. The model includes information on income received by the Federal, state and local governments, and produces estimates for the following taxes at the Federal level: Corporate income; payroll, personal income, estate and gift, and excise taxes, customs duties; and fines, fees, etc. State and local tax revenues include estimates of: Corporate profits, property, sales, severance, estate and gift and personal income taxes; licenses and fees and certain payroll taxes.

The model was built prior to the enactment of the Tax Cuts and Jobs Act, and represent taxes paid during the model year.

APPENDIX 2

September 14, 2021

VIA ELECTRONIC MAIL

Mitch Zeller, Director
Center for Tobacco Products
Document Control Center (DCC)
9200 Corporate Blvd., Room 020J
Rockville, MD 20850

Re: FDA's New Standard & Requirements for Evaluating Flavored ENDS PMTAs

Dear Director Zeller:

I write on behalf of the Vapor Technology Association (VTA) and the open-system industry that is selling e-liquids and devices to adult consumers, particularly adult smokers attempting to quit cigarettes. Our member companies, and many other similarly situated companies, have filed substantial PMTAs for open-system flavored ENDS products after investing heavily in the statutorily required components of a PMTA, including HPHC testing, and other research such as stability testing, toxicological testing, perception surveys, and likelihood of use research to support their applications. Surely, you must recognize that FDA received numerous applications filed in good faith and containing robust and reliable data, research and information from open-system device and e-liquid companies, and that these applicants' PMTAs were filed with the assistance of recognized expert consultants, scientists, toxicologists, and laboratories with a long history of working with the FDA.

As you know, we have previously raised and discussed our many concerns with you regarding the opacity of the PMTA process, the repeatedly shifting deadlines, and the lack of articulation of what FDA requires in an application. Of course, we recognize that you have published non-binding guidance and a draft PMTA rule. And we appreciate (and have participated in) the stakeholder meetings and informational sessions. We have offered numerous recommendations via comments on how FDA could appropriately and judiciously apply the PMTA process and achieve the objectives of the Deeming Regulation without eliminating a major segment of the vapor industry, i.e., those selling open-system devices and e-liquids.

Through it all, FDA never suggested that it was going to demand product-specific randomized clinical testing or longitudinal cohort studies as the standard for proving that flavored ENDS products help adults quit smoking. Yet, FDA's recent public statements associated with the FDA's issuance of Marketing Denial Orders (MDOs) on flavored ENDS, and the MDOs themselves, are clearly articulating a new standard for Pre-Market Tobacco Application (PMTA) review of flavored ENDS products. Not only does FDA's standard retroactively introduce a new product-specific testing requirement, FDA has made that testing requirement a *prerequisite* without which a flavored ENDS PMTA will be rejected.

To evaluate whether a flavored ENDS product is appropriate for the protection of public health, FDA's new standard appears to be based on a premise that is unfounded in science: that *all* flavored ENDS products, regardless of the flavor and device type, are attractive to youth. If that

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were the true, FDA would never have limited its flavor ban last year only to closed-system *Pods* and *cartridges*, its rationale for which could not have been clearer: it was these closed-system products – particularly JUUL’s products – that were driving the usage rates amongst youth and “of particular concern” were the design characteristics, not simply the presence of flavors:

“Data from the 2019 NYTS also indicate that youth overwhelmingly prefer cartridge-based ENDS products, and we have found that these products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale.... Most youth who were currently e-cigarette users reported a cartridge-based e-cigarette as their usual brand.... Of particular concern are the design features that appear to make the cartridge-based products so popular with young people. Attributes typically present in cartridge-based products include a relatively small size that allows for easy scalability, and intuitive and convenient features that facilitate ease of use, including draw activation, prefilled cartridges or pods, and USB rechargeability.”

See, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, January 2020, pp. 15-16.

Open-system devices share none of the design features that FDA relied upon in removing closed-system device flavors from the market. So, if FDA is in possession of new data which proves that America’s youth are using large, complex, cumbersome, inconvenient, impossible to conceal, hard to use discreetly, difficult to access open-systems at any material rate, we would greatly appreciate that data being disclosed publicly. We also note that youth vaping of nicotine in the U.S. has plummeted more than 25% in the latest 2020 NYTS survey making the continued justifications of an “epidemic” entirely misplaced. Moreover, we would not be surprised if the 2021 NYTS survey shows a continuing decline in youth use of ENDS or flavored ENDS generally, and no material use of open system ENDS. Without data, FDA’s generalized statement that all flavored ENDS are attractive to youth is simply untethered from fact.

Moreover, any suggestion that FDA is concerned that youth *might* simply switch to open-system flavored ENDS, as they did to disposables after the pod/cartridge ban, is speculative and unscientific. FDA could not have been surprised that youth matriculated to closed-system *disposables* since disposables share the exact same design features as the other flavored closed-systems that FDA banned last year. In fact, disposables are easier to use, easier to conceal, easier to use discreetly, are more intuitive, and are more convenient than pods/cartridges. Since the exact opposite is true for open-system flavors, FDA’s experience with disposables offers no justification, much less empirical data, for any concern that youth would take up open-systems if and when FDA eliminates the flavored closed-system disposable exemption it created. *Id.* at p. 9, fn. 20.

FDA’s decision to retroactively impose a prerequisite testing requirement, suggests that it is also ignoring the applicant’s data that would otherwise prove the age cohorts who use the applicant’s specific products and the applicant’s history of no or limited youth usage. Our concern is that FDA is ignoring relevant product specific data on youth, but is requiring product specific randomized clinical testing or longitudinal cohort studies proving the benefit to adults, while also requiring that such evidence must be robust enough to overcome the Agency’s generalized presumption regarding youth.

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One would think that the materially important prerequisite of product-specific randomized clinical testing or longitudinal cohort studies would have been clearly articulated by FDA long before the applications were due and, certainly, if there was any intervening reason to require such testing (which there was not), long before this month when numerous denials were issued without giving companies, via a deficiency letter, any opportunity to even attempt to comply.

Objectively, the only thing that has changed recently (other than the material decline in youth vaping rates) is the cacophony from Congress and special interest groups who have made it their mission to harangue the FDA publicly at hastily called hearings with an expressly stated intent to interfere with FDA's regulatory process. These same individuals and groups have turned up the pressure on FDA, demanding that FDA ignore the science altogether by banning all flavors outright or by rejecting certain PMTAs regardless of the science submitted with that PMTA.

However, companies which have invested heavily in the FDA's articulated regulatory process have done so in good faith expecting FDA to resist political pressures and dedicate itself to the science. These companies expected that FDA would fairly and consistently apply the standards that it has presented to the industry for the past two years and not move the proverbial goal posts at the last minute, just to end the game quickly. These companies also expected that FDA would at some point give *at least equal weight* in its balancing test to the millions of adult smokers, who are actually dying from smoking cigarettes, as it gives to the perceived and still attenuating risk to youth who experiment with vaping.

FDA's recent actions and inactions are inconsistent with FDA's own guidance, with FDA's draft rule, and with FDA's specific public and private statements to companies who are attempting to comply with the PMTA process in good faith. While FDA may have other unarticulated reasons for denying the applications that it has recently rejected, FDA's dramatic shift in denying outright open-system flavored ENDS applications for lack of product-specific testing suggests that FDA has made a policy decision to remove all flavored ENDS products from the market one application at a time without a full review of the PMTA itself.

At the same time, despite providing detailed information at a June 2021 presentation to all stakeholders on how FDA was prioritizing its PMTA review on JUUL's and the Big Tobacco companies' PMTAs and would be render its decisions by September 9, 2021, and despite the Acting Commissioner testifying before Congress to the same, the Agency has failed to render any decisions on these closed-system products (whether or not flavored). Yet, these are the decisions that FDA said would have the greatest impact on public health given these products' dominance of the marketplace. The fact that FDA has changed its focus to the categorical denial of open-systems is now gravely concerning on many levels and we respectfully request a meeting with you to discuss our concerns.

Respectfully submitted on behalf of,

VAPOR TECHNOLOGY ASSOCIATION



Tony Abboud
Executive Director