No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,
Petitioner,
v.
WAGES AND WHITE LION INVESTMENTS, L.L.C.,
DBA TRITON DISTRIBUTION, ET AL.,
Respondents.

On Writ of Certiorari to
the United States Court of Appeals
for the Fifth Circuit

BRIEF FOR *AMICUS CURIAE* TAXPAYERS PROTECTION ALLIANCE IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*[1]

Across the United States, nearly 30 million adults report smoking cigarettes.[2] While the reasons for starting and continuing to smoke vary, many smokers are united in their desire to quit that dangerous habit. About two-thirds of adult American smokers report wanting to quit smoking over the past year, and more than half have actually tried to stop smoking.[3]

While there are multiple products on the market seeking to help smokers quit, few offer a relatively safe option that approximates the actual experience of smoking. E-cigarettes and other electronic nicotine delivery system ("ENDS") products are rare exit ramps from cigarette smoking that deal with the behavioral hurdles to quitting as well as the chemical hurdles. Prestigious health organizations such as Public Health England have concluded that e-cigarettes are 95 percent safer than their conventional

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[1] This brief was not authored in whole or in part by counsel for any party and no person or entity other than *amicus curiae* or its counsel has made a monetary contribution toward the brief's preparation or submission.

[2] Ctrs. for Disease Control & Prevention, *Adult Smoking Cessation—United States, 2022* (July 25, 2024), https://tinyurl.com/2j4thare.

[3] *Ibid.*

counterparts,[4] while randomized control trials confirm the efficacy of e-cigarettes as a quit-smoking aid.[5]

Despite this research, the Food and Drug Administration ("FDA") is doing everything in its power to undermine the use of e-cigarettes as a smoking-cessation pathway. Under the expansively claimed authority of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, ("TCA"), FDA asserts carte blanche to invent new and indeterminate standards to evaluate e-cigarette products and determine whether they will be left on the market. That open-ended delegation of legislative authority permits FDA to determine whether permitting the product would be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

The exceedingly vague language of the TCA, and FDA's arbitrary application of that language, deprives producers of e-cigarettes and related products anything close to reasonable notice as to which products are to be proscribed and denies consumers of multiple choices as to what types of e-cigarette products will best assist them in quitting their use of more dangerous conventional cigarettes.

This case illustrates the costly consequences of sweeping and arbitrary federal actions encouraged by vague and malleable statutes, and is, therefore, of great interest to *amicus curiae* the Taxpayers

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[4] Pub. Health Eng., *PHE publishes independent expert e-cigarettes evidence review* (Feb. 6, 2018), https://tinyurl.com/w2cxb73v.

[5] Peter Hajek et al., *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy,* 380 New Eng. J. Med. 629 (2019), https://tinyurl.com/mryfy44b.

Protection Alliance ("TPA"). TPA is a nonprofit 501(c)(4) Virginia non-stock corporation founded in 2011 as a taxpayer advocacy and education group with a focus on defending free enterprise and championing reduced taxation and limited government principles. TPA furthers its mission through its website, the preparation and dissemination of articles, analyses, and opinion pieces, and through broadcast television, social media, video, and congressional testimony.

Since its founding, TPA has warned policymakers about the growth of the administrative state and the correspondingly large tax bills required to underwrite regulatory enforcement. This tax-and-regulate feedback loop is at its worst when overbroad laws and arbitrary agency actions create a costly, unpredictable, and overreaching enforcement regime. TPA submits this brief to expand upon the multiple legal and policy problems with a flawed system that harms taxpayers and hinders smokers trying to kick their deadly habit.

SUMMARY OF ARGUMENT

Amicus agrees with Respondents that the Fifth Circuit correctly held that FDA acted arbitrarily and capriciously in denying Respondents the ability to market their products. This brief focuses on the vague underlying statute that improperly encouraged such arbitrary and capricious conduct.

The provisions of the TCA focusing on the marketing approval of "tobacco products" such as e-cigarettes are unconstitutionally vague because they fail to give regulated parties proper notice of which products are permitted. Laws that fail to "give a person of ordinary intelligence fair notice" that his contemplated conduct is forbidden raise basic due

process concerns and are not constitutionally permitted. *FCC* v. *Fox TV Stations, Inc.*, 567 U.S. 239, 253 (2012) (quoting *United States* v. *Williams*, 553 U.S. 285, 304 (2008)). The TCA's open-ended and indeterminate "standard" of whether a product is "appropriate for the protection of the public health" ("APPH") is impossibly vague, lacking in legal guidance, and fails this basic test of due process. 21 U.S.C. § 387j(c)(2)(A). Public health is an all-encompassing term that implicates a wide range of physical and psychological conditions. The TCA might as well have granted authority to regulate for the public benefit, general welfare, or used any other equally indeterminate choice of words often seen to describe legislative authority.

Even assuming that "public health" has a marginally narrower meaning than "general welfare," it still encompasses a dizzying array of competing and disparate considerations. The complex relationship between cigarette and e-cigarette use affects not only lung cancer and heart disease, but also other illnesses such as obesity, depression, Parkinson's disease, and gout. The "protection of the public health" also encompasses second-order effects of prohibition and illicit use stemming from restrictive policies. Regulators focused on different competing aspects of public health ranging from attracting youth consumption to fostering a potentially dangerous black market in vapes could easily come to wildly different conclusions, reflecting the indeterminateness and legislative discretion inherent in the APPH standard.

Such vague legislative language undermines the rule of law and guarantees that agencies will act

arbitrarily (or legislatively) when regulating under the statute. Neither form of agency behavior is consistent with due process and separation of power requirements.

Apart from the vague and indeterminate overall nature of the TCA's APPH standard, FDA failed to comply with even the least vague part of that standard. For example, the agency is required to assess the "increased or decreased likelihood that existing users of tobacco products will stop using such products [i.e., cigarettes]" by allowing the relevant e-cigarette product on the market. 21 U.S.C. § 387j(c)(4)(A). Yet without meaningful evidence, FDA set a default assumption that tobacco-flavored ENDS products are as effective as other flavored ENDS products, notwithstanding a significant adult consumer preference for such other flavored products. It then put the burden on applicants to disprove that assumption and overcome the presumed harm of flavored ENDS products attracting more youth consumption. But such thumbs on the scale do not amount to a genuine consideration of the likelihood of increased or decreased consumption of tobacco products, much less a rigorous one.

And apart from such first-order effects, FDA failed to consider many second-order effects, including the overall lack of e-cigarette products on the market, the dearth of open-system ENDS products that appeal almost exclusively to former smokers, or the impact of its market restrictions on the supply chain for important smoking cessation tools and the danger of illicit and unregulated product substitution. FDA also did not consider whether adding variety to an artificially narrowed market would give adult smokers

more choices suited to their individual tastes, making it more likely they will find products that sustainably help them transition and stay away from combustible cigarettes. FDA's truncated review of product applications, and demand for flavor-by-flavor analysis, ignored these many APPH considerations and thus was arbitrary and capricious.

ARGUMENT

I. The APPH Standard of the Tobacco Control Act Is Unconstitutionally Vague and Invites Arbitrary Enforcement.

Statutes such as the TCA, which use vague and overbroad language to set legal standards for the public to follow or to empower agency action suffer from two interrelated flaws: they are vague to the point of indeterminateness and they improperly delegate legislative authority to executive actors. In this instance the TCA does both. The APPH standard is so indeterminate that it is impossible for the public to know or reasonably predict what products will satisfy the test and as a result it delegates broad legislative authority to FDA without adequate Congressional direction or guardrails.

Where the language of a statute "either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application," that statute "violates the first essential of due process of law" and cannot withstand constitutional scrutiny. *Connally* v. *General Constr. Co.*, 269 U.S. 385, 391 (1926). Whether the statute regulates economic behavior or imposes criminal liability (or, as here, does a bit of both), basic due process principles applicable to all laws require that they be intelligible. See *A.B. Small*

Co. v. *American Sugar Ref. Co.*, 267 U.S. 233, 239 (1925) (When "the exaction of obedience to a rule or standard [is] so vague and indefinite as really to be no rule or standard at all," it is unconstitutional both in "civil proceedings" and in "criminal prosecutions."); *Interstate Circuit, Inc.* v. *City of Dallas*, 390 U.S. 676, 685 (1968) (laws are unconstitutionally vague when the listed decision-making factors are broad words or phrases that "encourage erratic administration"); *National Endowment for the Arts* v. *Finley,* 524 U.S. 569, 588 (1998) ("undeniably opaque" regulations "raise substantial vagueness concerns").[6]

Furthermore, even after this Court's narrowing of agency interpretive discretion in *Loper Bright Enterprises, Inc.* v. *Raimondo,* 144 S. Ct. 2244 (2024), sometimes even the judicially determined meaning of a statute may be too indeterminate to provide any substantive standards against which to measure agency action. In such instances, the statute is not only vague as to the guidance it gives members of the public, it is also an improper delegation of legislative authority in that it authorizes the agency to make judgments properly reserved to and required of Congress. See *Whitman* v. *American Trucking Ass'ns, Inc.,* 531 U.S. 457, 472 (2001) ("[A]n agency can[not] cure an unlawful delegation of legislative power by adopting in its discretion a limiting construction of the statute.").

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[6] See *United States* v. *Davis*, 588 U.S. 445, 448 (2019) ("When Congress passes a vague law, the role of courts under our Constitution is not to fashion a new, clearer law to take its place, but to treat the law as a nullity and invite Congress to try again.").

A. The APPH Standard's Broad Language Fails to Give Proper Notice to Regulated Parties.

The provision in the TCA applying the "appropriate for the protection of the public health" ("APPH") standard to premarket tobacco product applications ("PMTAs"), 21 U.S.C. § 387j(c)(2)(A), is a particularly stark example of a vague and improper delegation of authority. It delegates virtually all material policy choices to FDA using language that provides few substantive limits, whether interpreted by the agency or the courts.

The term "public health" is broadly defined by the Merriam-Webster Dictionary as, "the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science."[7] And Black's Law Dictionary goes broader still, defining public health as "the health of the community at large" or, more narrowly, "the methods of maintaining the health of the community, as by preventive medicine and organized care for the sick."[8] The considerations that factor into such a broad policy area are likely endless.

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[7] *Public Health,* Merriam-Webster Dictionary, https://tinyurl.com/7mtz87ms (last visited Oct. 14, 2024); see also *Public Health,* Encyclopaedia Britannica ("the art and science of preventing disease, prolonging life, and promoting physical and mental health, sanitation, personal hygiene, control of infectious diseases, and organization of health services"), https://tinyurl.com/3tvk3cem (last visited Oct. 14, 2024).

[8] *Health,* Black's Law Dictionary (12th ed. 2024) (including "public health" as a sub-definition).

And while the statute requires FDA to consider certain factors when analyzing what would be appropriate for public health, including the impact of a new product on the consumption patterns of existing or potential users, 21 U.S.C. § 387j(c)(4)(A)-(B), those factors are just a small component of a broader, holistic, and open-ended assessment of public health.

B. FDA Cannot Conceivably Account for All Public-Health-Related Factors.

The APPH inquiry set forth in the statute contains no limits on the varied aspects of public health to be considered beyond the two mandatory considerations relating to the likely effect on tobacco product use by existing or new users. 21 U.S.C. § 387j(c)(4)(A) & (B). It contains no indication of how the apples and oranges of different public health considerations are to be weighed, and, indeed, seemingly contains few limits on what evidence or speculation FDA may use to *reject* a new product.[9] The list of public health considerations is thus infinitely malleable and entirely subject to cherry-picking by the agency with no guidance as to how one factor will weigh against any of the others.

Even considering the direct consequences of tobacco use, for example, generates an extensive list of possible harms to be considered, including (among other conditions): various cancers, heart disease, stroke, diabetes, emphysema, chronic bronchitis,

[9] While the statute requires a decision based on "well-controlled investigations," it offers no clarification of the public health variables to be examined by said investigations. 21 U.S.C. § 387j(c)(5)(A). And FDA does not seem to think that requirement applies to its assumptions about youth smoking or the default adequacy of tobacco-flavored products.

Parkinson's disease, Alzheimer's disease, depression, severe manifestations of COVID-19, gout, hepatitis B and C infections, chronic obstructive pulmonary disease, asthma, macular degeneration, and numerous pregnancy complications.[10]

The strength of the causal relationship differs depending on users' interactions with different tobacco or ENDS products. For example, a cigarette smoker who switches to predominantly using e-cigarettes has a lower chance of developing various cancers, heart disease, and likely other adverse conditions.[11] And ENDS products significantly improve the chances of quitting relative to other forms of nicotine replacement. For example, a 2019 analysis in the peer-reviewed *New England Journal of Medicine* studied various cessation strategies and concluded, "the 1-year

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[10] See Susanna C. Larsson et al., *Appraising the causal role of smoking in multiple diseases: A systematic review and meta-analysis of Mendelian randomization studies*, 82 EBioMedicine 104154 (2022), https://tinyurl.com/24k69uja.

[11] See, *e.g.*, Ann McNeill et al., *E-cigarettes: an evidence update* 6, Pub. Health Eng. (Aug. 2015), https://tinyurl.com/bdmc4zbe ("using [e-cigarettes] is around 95% safer than smoking" and "could help reduce smoking related disease, death and health inequalities"); Pub. Health Eng., *supra* note 4 (vaping is "at least 95% less harmful" than smoking); David T. Levy et al., *Potential deaths averted in USA by replacing cigarettes with e-cigarettes*, 27 Tobacco Control 18, 18 (2018), https://tinyurl.com/mu5eza4s (concluding that, over a 10-year period, using e-cigarettes in place of tobacco cigarettes "yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario"); Josef Yayan et al., *Comparative systematic review on the safety of e-cigarettes and conventional cigarettes*, 185 Food Chem. Toxicol. 114507 (2024), https://tinyurl.com/24bd74wk (reviewing the literature and finding e-cigarettes to have less carcinogenic materials and to cause less severe respiratory effects than cigarettes).

abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group," a reduction of nearly half.[12] This high switching rate, coupled with the reduced risk of e-cigarettes, is obviously a critical part of any "public health" inquiry by FDA.

But the law fails to answer the key question of how to determine and weigh competing considerations related to public health. If some underaged users gain access to e-cigarettes, how does that weigh against the many adult users who might switch? Does the lower health impact of e-cigarette use offset the more severe consequences of reduced use of conventional cigarettes? Must we determine whether underaged users are also switching from worse alternatives such as combustible cigarettes (and hence their use is a net plus)? And how does any of this weigh relative to second- and third-order public health consequences?

Regarding such other consequences, any "public health" inquiry presumably requires a full accounting of the impacts of prohibition, including an increased black market in unregulated products. Although FDA has "authorized a handful of e-cigarettes," "nearly all other e-cigarettes [are] illegal."[13] Such products include those from leading brands such as Elf Bar, which are produced by Chinese manufacturers with little or no indication of product inputs.[14] Just as alcohol prohibition in the 1920s and 1930s resulted in

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[12] Hajek et al., *supra* note 5, at 629.

[13] Matthew Perrone, *US seizes more illegal e-cigarettes, but thousands of new ones are launching*, Associated Press (Dec. 30, 2023), https://tinyurl.com/3mc6ffza.

[14] *Ibid.*

consumption shifts toward illicit, less-safe product batches,[15] an overly strict regulatory structure surrounding ENDS products can have significant adverse public health consequences. The 2019 e-cigarette, or vaping, use-associated lung injury ("EVALI") outbreak, which resulted in approximately 70 deaths, was likely caused by vitamin E acetate being used as an additive in unapproved e-cigarette products.[16] Any supposed benefit of a denial in deterring e-cigarette use among young people thus must be offset by the potential continued use by young people of illegal and even less safe products. And, of course, young people who might otherwise vape could just as easily turn to traditional cigarettes, as they did for years before e-cigarettes became available.[17]

Furthermore, not all product substitutability occurs along the narrow spectrum of tobacco products. Cigarette users have responded to tax increases, restrictions, and bans by consuming more calories, contributing to a rise in obesity rates.[18] Obesity is

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[15] See generally Jeffrey A. Miron & Jeffrey Zwiebel, *Alcohol Consumption during Prohibition*, 81 Am. Econ. Rev. 242 (1991).

[16] Brian Soto et al., *The implications of Vitamin E acetate in E-cigarette, or vaping, product use-associated lung injury*, 18 Annals Thoracic Med. 1 (2023), https://tinyurl.com/bdf5zc8s.

[17] Apart from the vagueness and legislative discretion concerns, FDA's blithe assumption of net harm to young people who might be attracted to flavored products, while failing to consider such likely substitutions, demonstrates the arbitrary and capricious nature of its decisions. And it sets an artificial thumb on the scale against new product approvals without any of the rigorous scientific evidence it demands of manufacturers.

[18] Anindya Sen et al., *Obesity, smoking, and cigarette taxes: Evidence from the Canadian Community Health Surveys*, 97

regularly identified as a major impediment to public health, contributing to diseases such as atherosclerosis, stroke, diabetes, and Alzheimer's.[19] FDA, then, must add this inter-product substitutability to its long list of "public health" factors to evaluate and somehow weigh against its speculation regarding harm to youth.

If a statutory phrase provides no "ascertainable standard" and invites the "widest conceivable inquiry," the resulting regulatory structure cannot survive constitutional scrutiny. *United States* v. *L. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921). Permitting enforcement of such a statute "would be the exact equivalent of an effort to carry out a statute which in terms merely penalized and punished all acts detrimental to the public interest when unjust and unreasonable in the estimation of the court and the jury." *Ibid.* Such a standard falls far short of Congress's requirement to "suppl[y] an intelligible principle to guide the delegee's use of discretion" and makes it functionally impossible for courts to "figure out what task it delegates and what instructions it provides." *Gundy* v. *United States*, 588 U.S. 128, 135-136 (2019).

Yet here, Congress has authorized FDA to make a regulatory determination that effectively requires omniscience and provides no legislative measure of how to balance apples and oranges, data and

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Health Pol'y 180 (2010) ("a 10% increase in cigarette taxes is significantly correlated with a 4-5% increase in the percentage of obese population"), https://tinyurl.com/39p4rcx2.

[19] Ashley Selman et al., *The Role of Obesity and Diabetes in Dementia*, 23 Int'l J. Molecular Scis. 9267 (2022), https://tinyurl.com/4vru5fr7.

speculative inferences, or whatever else FDA throws into the "public health" mix. This "widest conceivable inquiry" is significantly wider than other congressional demands made of the agency and amounts to legislative license to go forth and do good.

II. FDA Acted Arbitrarily by Not Considering All Factors Related to Cigarette Use.

FDA also erred in its application of the TCA's clearest requirement, the requirement to examine the "increased or decreased likelihood that existing users of tobacco products will stop using such products." 21 U.S.C. § 387j(c)(4)(A).

Yet, FDA could not be bothered to comply with this straightforward statutory requirement. In its evaluation of Respondents' product, FDA explains that it reviews applications "for any acceptably strong evidence that the flavored products have an *added benefit* relative to that of tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their smoking."[20] This marginal analysis allows the agency to sidestep any evidentiary review of Respondents' products' ability to lead tobacco-users away from cigarettes and toward safer products. FDA reasons that, even if these products are useful substitutes for conventional tobacco products, that is irrelevant for the purpose of the analysis because "[already-allowed] tobacco-flavored ENDS may offer the same type of public health benefit as flavored ENDS, *i.e.*, increased switching and/or significant reduction in smoking, but

[20] Pet. App. 290a.

do not pose the same degree of risk of youth uptake."[21] But such speculation that mere tobacco-flavored products are enough to gain the smoking cessation benefits, much less enough for the varied population of adults trying to quit or to sustain having quit combustible cigarettes, is implausible on its face. Indeed, roughly 70% of adults using ENDS products report favoring non-tobacco flavored products. [22]

Additionally, narrowing the market availability of ENDS products introduces market fragility and likely higher prices. A broad market that consists of a variety of competitors producing close substitutes is less likely to face significant supply constraints. Yet the current regulatory landscape has led to a significantly narrowed field of producers and products. As of October 10, 2024, FDA has granted marketing authorizations to only three companies (NJOY LLC, R.J. Reynolds Vapor Company, and Logic Technology Development LLC) selling a total of eight "families" of e-cigarettes and compatible refill cartridges.[23]

While there is no way of divining the "right" number of competitors and products needed to adequately cater to industry demand, experience shows us that regulation-induced concentration in FDA-supervised industries leads to supply

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[21] *Id.* at 289a.

[22] Ping Du et al., *Changes in Flavor Preference in a Cohort of Long-Term Electronic Cigarette Users*, 17 Annals Am. Thoracic Soc'y 573, 575 tbl. 1 (2020), https://tinyurl.com/5f6kytwk.

[23] FDA, *Searchable Tobacco Products Database*, https://tinyurl.com/fxxwpbd6 (last visited Oct. 10, 2024).

shortfalls.[24] FDA's current approach fails to take into account the indirect public health consequences of industry concentration, lack of supply-chain resilience, and higher prices.

Furthermore, Respondents' products would significantly increase supply in the submarket for open-system e-cigarettes. As University of California toxicologist Gideon St. Helen explains, there are significant differences between closed-system e-cigarettes, "which are designed to allow minimal user modification of component parts and contents, [and] open systems [which] allow users to readily manipulate various settings (*e.g.*, power and temperature) and parts (atomizer heads/coils), and allow infinite iterations of e-liquids to be vaped through refillable tanks."[25]

The available evidence suggests that former smokers prefer open-system to closed-system products. A review of the empirical literature, for example, found that "open systems were more likely to be used by former smokers than current smokers and

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[24] See Scott Lincicome et al., *Formula for a Crisis* (Jan. 11, 2023) (onerous FDA regulation has led to a 3-4 supplier market, resulting in significant supply constraints when even a single manufacturer's operations are disrupted), https://tinyurl.com/54k57r7u; accord Andrés M. Patiño et al., *Facing the Shortage of IV Fluids—A Hospital-Based Oral Rehydration Strategy*, 378 New Eng. J. Med. 1475, 1475 (2018) ("Most of the IV fluid used in the United States is produced by only three manufacturers, so availability is vulnerable to even small fluctuations in supply.")

[25] Gideon St. Helen, *A ban targeting only open-system e-cigarettes is unlikely to prevent a future EVALI-like outbreak among e-cigarette users*, 116 Addiction 995, 996 (2021), https://tinyurl.com/4d47y8rt.

were more likely to be used daily than closed systems."[26] Subsequent survey evidence of e-cigarette users has yielded similar results.[27] Additionally, youth users of vaping products tend to prefer closed-system products to open-system products. According to the CDC's National Youth Tobacco Survey, in 2023, among U.S. middle and high school students who were currently using e-cigarettes, only 5.9 percent reported using a "tank or mod system" (*i.e.*, open systems) compared with 60.7 percent who reported using disposable (*i.e.*, closed) systems.[28]

Currently, all e-cigarette products with FDA-authorized marketing are closed-system products. Approval of open-system products could therefore induce significant switching behavior for the population of cigarette smokers who prefer them, while having minimal impact on young people who prefer smaller and more concealable closed systems. By ignoring the importance of the open-vs.-closed system dichotomy for usage patterns and switching

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[26] Samane Zare et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoSONE e0194145 (2018), https://tinyurl.com/3heswa68.

[27] See Anna Tillery et al., *Characterization of e-cigarette users according to device type, use behaviors, and self-reported health outcomes: Findings from the EMIT study*, 21 Tobacco Induced Diseases 159 (Dec. 2023), https://tinyurl.com/3y7n7shf (finding "significant differences between user demographics, e-cigarette preferences, device characteristics, and use behaviors by user group").

[28] Jan Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, CDC (Nov. 3, 2023), https://tinyurl.com/3u67weac.

behaviors, FDA again acted arbitrarily in evaluating one of the few express elements of the APPH standard.

Adult switching behavior is driven, at least in part, by having adequate product choice to accommodate different or evolving tastes among those seeking to quit smoking. FDA's refusal to conduct a more comprehensive analysis, and insistence on unrealistic flavor-by-flavor proof to offset speculative claims of harm to youth from flavored products, is an arbitrary and capricious application of its legal duties.

CONCLUSION

The APPH standard, which allows FDA unchecked discretion to determine what products protect the complex policy field of public health, is a significant affront to due process and separation of powers. FDA's arbitrary and capricious enforcement of even the more intelligible elements of the TCA amply illustrates those problems. For the forgoing reasons and the reasons discussed in Respondents' brief, the judgment of the Fifth Circuit should be affirmed.

Respectfully submitted,

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