No. 24A_____

In the Supreme Court of the United States

JOHNNY COPPER, L.L.C.,
APPLICANT

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.
RESPONDENTS

EMERGENCY APPLICATION FOR A STAY OF AGENCY ORDER PENDING THE DISPOSITION BY THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT OF A PETITION FOR REVIEW

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Applicant is Johnny Copper, L.L.C.

Respondents are the United States Food and Drug Administration, Commissioner, U.S. Food and Drug Administration, U.S. Department of Health and Human Services, and the Secretary, U.S. Department of Health and Human Services.

RELATED PROCEEDINGS

United States Court of Appeals (11th Cir.):

Johnny Copper, L.L.C.. v. *FDA*, No. 24-13302, ECF #21 (Jan. 13, 2025)

CORPORATE DISCLOSURE STATEMENT

In accordance with said SUP. CT. R. 29.6, the Applicant, Johnny Copper, L.L.C., certifies that it is not a corporation and neither has a parent corporation and nor is ten percent (10%) or more of their stock owned by a publicly held corporation.

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To the Honorable Clarence Thomas, Associate Justice of the United States Supreme Court and Circuit Justice for the Eleventh Circuit:

In accordance with SUP. CT. R. 22 and 23 and the All Writs Act, 28 U.S.C. § 1651, the Applicant, Johnny Copper, L.L.C. (Johnny Copper), respectfully files this application for an immediate stay of the September 13, 2024 Marketing Denial Order (MDO), App., *infra*., 3a-11a, issued by the Respondent, United States Food and Drug Administration's (FDA) with respect to its Premarket Tobacco Product Application (PMTA). Johnny Copper seeks such stay pending the disposition of its petition for review filed on October 12, 2024 in the United States Court of Appeals for the Eleventh Circuit. On January 13, 2025, a divided motion panel of that Court denied a stay pending review (App., *infra*., 1a-2a).

INTRODUCTION

This case represents another chapter in the vaping industry's ongoing battle against FDA over the marketing of its stakeholders' products. The Court is well aware of the circumstances underlying this battle based upon its pending consideration of the merits in *FDA v. Wages and White Lion Investments, L.L.C.*, No. 23-1038 (*Wages*)[1] and *FDA v. R.J. Reynolds Vapor Co.*, No. 23-1187 (*Reynolds*).[2]

Johnny Copper's appeal in the Eleventh Circuit presents the same issues which this Court is presently considering in *Wages* and *Reynolds*. This case, however, differs from *Wages* and *Reynolds* in that it challenges the constitutionality of both FDA's regulatory authority over vaping products and the structure of the regulatory framework set forth in the Family Smoking Prevention and Tobacco Control Act (TCA), PUB. L. 111–31, codified as 21 U.S.C. §§ 301, *et seq*. Specifically, Johnny Copper presents two distinct constitutional arguments below not asserted in either *Wages* or *Reynolds*:

> (1) the TCA's "deeming" provision, 21 U.S.C. § 387a(b), is unconstitutional because Congress disregarded this Court's major question doctrine holding in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) when delegating authority which permitted FDA to "deem" which tobacco products, save four specific product subsets, it would regulate; and
>
> (2) the "appropriate for the protection of public health" standard set forth in 21 U.S.C. § 387j is unconstitutionally vague given the broad expanse of what constitutes the "public health" in the absence of limiting congressional guidance.

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[1] The Fifth Circuit ruling in *Wages* was published as *Wages and White Lion Invs., LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024).

[2] *Reynolds* is not to be confused with another Fifth Circuit ruling published as *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023), discussed *infra*.

Johnny Copper further presents three non-constitutional arguments, two of which the parties addressed in *Wages*. To avoid needless overlap, Johnny Copper is only relying herein upon the one non-common argument.

Johnny Copper filed a petition for review in the Eleventh Circuit, App., *supra.*, 59a-75a, and sought a stay pending review. A divided Eleventh Circuit motion panel denied Johnny Copper a stay pending review in a two-page unpublished order which simply recited *Nken v. Holder*, 566 U.S.C 418 (2009) as the basis for its denial (App, *infra.*, 1a-2a). The dissenting judge would have granted a stay based upon *Wages*. *Ibid*. at 2a.

This Court should grant a stay of the subject MDO pending the Eleventh Circuit's adjudication of Johnny Copper's petition for review.

JURISDICTION

The Circuit Justice has jurisdiction over this application pursuant to 28 U.S.C. § 1254(1) and has authority to grant Johnny Copper relief under 21 U.S.C. § 387*l*(b) and the All Writs Act, 28 U.S.C. § 1651(a).

STATEMENT

1. Johnny Copper will avoid taking the Court down the well-worn path of the history of vaping products and will isolate any discussion herein of how FDA has unlawfully attempted to ban vaping products to the constitutional and lone non-constitutional issue. Those other issues have been briefed sufficiently in both *Wages* and *Reynolds*.

2. Johnny Copper has manufactured open-system vaping products since 2015 to provide a less harmful alternative to smokers while ensuring that its products do not get into the hands of minors. App., *supra.*, at 76a; 79a-82a. Johnny

Copper filed its Pre-Market Tobacco Product Application (PMTA) on September 9, 2020 covering 154 flavored open-system vaping products. *Ibid*. at 6a; 85a. Its PMTA totaled more than 300,000 pages (66 GB); included over 53 scientific studies; and a comprehensive consumer survey. *Ibid*. at 85a; 129a-131a. In total, this represented an investment of several thousand hours and in excess of $100,000.00. *Ibid*. at 80a-81a.

3. For instance, Johnny Copper's consumer study revealed that:

- 66.2 percent were over the age of 34;
- 97.9 percent were former smokers;
- Only 7.7 percent used both vaping devices and cigarettes;
- 52.3 percent who smoked in the past were able to stop immediately after using vaping products;
- Only 5.1 percent reported that they were still smoking and almost all reported their goal was to stop;
- 74.9 percent reported their goal was to stop using all tobacco products;
- 91.8 percent stated that vaping products helped them avoid smoking;
- 96.4 percent used non-tobacco-flavored vaping products;
- 73.8 percent had used other means of cessation in the past, such as *Chantix*®;
- 98.1 percent stated that they either only used "open-system" vaping devices or used both open and closed systems.

App., *supra*., at 83a; 120a-127a.

4. Johnny Copper has also taken aggressive steps to prevent youth access, as evidenced by the extensive plan which detailed its marketing and access

restrictions, including those which FDA said in its pre-PMTA representations were "adequate measures." App., *supra.*, at 79a-82a; 84a-85a; 95a-101a.

5. On September 7, 2021, FDA issued an MDO with respect to Johnny Copper's vaping products. App., *supra.*, at 12a-14a. Johnny Copper challenged the MDO and on August 23, 2022, the Eleventh Circuit issued its opinion in *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022) which vacated the FDA's September 2021 MDO.

6. On August 2, 2024, FDA rescinded its September 2021 MDO, App., supra., at 13a-16a, then on September 13, 2024, issued Johnny Copper a new MDO with respect to the same vaping products based upon a "targeted review," *ibid.*, at 3a-11a; 21a-22a, instead of the full and individualized scientific review required by 21 U.S.C. § 387j(c).

7. On October 12, 2024, Johnny Copper timely filed a Petition in the Eleventh Circuit to review the September 2024 MDO. On October 23, 2024, Johnny Copper filed a Motion in the Eleventh Circuit to stay the September 2024 MDO pending review. Therein, Johnny Copper asserted that: (a) FDA was acting pursuant to an unconstitutional delegation of legislative authority; (b) the TCA's "appropriate for the protection of public health" (APPH) standard is unconstitutional; (c) FDA unlawfully instituted a de facto ban on non-tobacco flavored products; (d) FDA ignored key elements of the APPH standard when reviewing its PMTA; and (e) FDA ignored its fair notice obligations.

8. On January 13, 2025, a divided Eleventh Circuit motion panel issued a two-page order which denied Johnny Copper's Motion (App., *supra.* 1a-2a). The Eleventh Circuit's order did not illuminate the factual or legal basis for the denial

other than a bare recitation of *Nken*, *supra*. without an explanation of how or why Johnny Copper did not satisfy its requirements. The dissenting judge, however, would have granted Johnny Copper's Motion based upon *Wages* (App., *supra*. 2a).

ARGUMENT

The Administrative Procedure Act (APA), 5 U.S.C. §§ 500, *et seq*., applies when a court reviews an MDO challenge, including motions for interim relief. 21 U.S.C. 387*l*(b); 5 U.S.C. §§705- 706. *Nken, supra.,* dictates that interim relief is warranted upon showing: (i) a substantial likelihood of success on the merits; (ii) irreparable injury absent relief; (iii) the injury outweighs any harm to the opponent; and (iv) granting relief will not disserve the public interest. 556 U.S. at 435. The last two factors "merge" in cases against the government. *Ibid*. This Court applies a nearly identical test when considering the propriety of an injunction against the government. *See Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010) (*per curiam*). A stay pending review is functionally an injunction. In a "close case" this Court "balance[s] the equities and weigh the relative harms." *Ibid*. Those factors overwhelmingly support a stay here.

I. JOHNNY COPPER IS LIKELY TO SUCCEED

Johnny Copper is likely to succeed on the merits because FDA's regulatory regime is unconstitutional and violates several key APA principles. The APA instructs courts to hold unlawful and set aside agency actions which are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" "**contrary to constitutional right, power, privilege, or immunity**;"

"in excess of statutory authority," "without observance of procedure required by law," or "unsupported by substantial evidence" (emphasis added). 5 U.S.C. §§706(2)(A) - (E). Johnny Copper demonstrated below a threshold showing that the TCA's "deeming" provision and "APPH" standard are unconstitutional. Johnny Copper further demonstrated below that FDA has unlawfully implemented a *de facto* ban on flavored vaping products in disregard of the TCA's prescribed manner of adopting a tobacco product standard.

A. FDA IS ACTING PURSUANT TO AN UNCONSTITUTIONAL DELEGATION OF LEGISLATIVE AUTHORITY

In 1964, the Surgeon General issued its landmark report on the devasting health impacts of cigarettes and smoking.[3] Congress thereafter considered 75 smoking-related bills between 1965 and 1978,[4] even proposing to amend the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 301, *et seq.*, to grant FDA regulatory authority.[5] It instead enacted the first cigarette labeling act.[6] *Brown & Williamson,* 529 U.S. at 137-38.

In 1996, FDA invoked the FFDCA to regulate tobacco by classifying nicotine as a drug, and cigarettes as a drug delivery device. 61 FED. REG.

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[3] U.S. Dept. of Health, Educ., and Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*, 1964.

[4] Klebe, E.R., *Actions of the Congress and the Federal Government on Smoking and Health*, Congressional Research Serv., Report No. 79-219 (Sept. 26, 1979).

[5] *See* H.R. 2248, 89th Congress (1966).

[6] Klebe, *supra*.

44,619, *et. seq*. (Aug. 28, 1996). *Brown & Williamson* analyzed tobacco's historic and economic significance; observing it concerned a "significant portion" of the economy and a "unique place in American history and society." 529 U.S. at 159-60. This Court thus held in *Brown & Williamson* that the regulation of tobacco was a "major question" and FDA lacked regulatory authority absent Congress enacting specific enabling legislation. *Ibid.*, at 126.

Brown & Williamson conclusively bound Congress and FDA concerning the future regulation of tobacco products. Congress honored this Court's holding when crafting the TCA's regulatory framework based upon the extant "tobacco product" definition, 21 U.S.C. § 321(rr), and then applying that framework to four product subsets (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco),[7] *ibid.* at § 387a(b). Congress knew vaping products existed when debating the TCA;[8] excluded them; and never thereafter amended 21 U.S.C. § 387a(b) to include them. This was an unlawful delegation because it disregarded *Brown & Williamson's* major question holding.

Congress, however, veered from *Brown & Williamson's* mandate by delegating FDA with legislative authority to "deem" any additional tobacco products as being subject to its regulatory capture. 21 U.S.C. § 387a(b). In May

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[7] Such terms are defined respectively in 21 U.S.C. §§ 387(3), (4), (15) and (18).

[8] *See e.g.* 155 CONG. REC. No. 50 at H3802 - H3805 (daily ed. Mar. 24, 2009) (statement by Rep. Buyer); 155 CONG. REC. No. 82 at S6009 - S6012 (daily ed. Jun. 3, 2009) (statement by Sen. Burr).

2016, FDA invoked this deeming authority as to vaping products. 81 FED. REG. 28,974, *et seq*. (May 10, 2016).

Congress compounded this unlawful delegation by failing to "provide standards for when and how [FDA] was to exercise its discretion to deem[.]" *Nicopure Labs, LLC v. FDA*, 266 F. Supp.3d 360, 392 (D. D.C. 2017). FDA agreed:

> "Congress's choice of the deferential word 'deems' and the absence of any standard—beyond the requirement that the product meet the 'tobacco product' definition—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion."[9]

Id. The broad discretion which FDA claimed begs the question given *Brown & Williamson*'s clear mandate.

FDA's invocation of the full measure of the TCA's deeming authority defies science and logic *vis-à-vis* vaping products because scientists and the medical community concur that vaping products are magnitudes less harmful than cigarettes. On this point, a 2015 groundbreaking study by Public Health England, concurred upon by the British Royal College of Physicians, opined the vaping products are at least 95% less harmful than cigarettes and recommended their use by adult smokers.[10]

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[9] The lack of guiding standards also presents a non-delegation doctrine question. *See Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935); *J.W. Hampton, Jr. & Co. v. U.S.*, 276 U.S. 394, 409 (1928).

[10] *See e.g*., *McNeill, A., et. al., E-cigarettes: An Evidence Update*, Public Health England, 2015; Royal College of Physicians, E-cigarettes and Harm Reduction: An Evidence Review, Apr. 2024.

Here's why the TCA's deeming authority is unconstitutional. This Court dictated in *Brown & Williamson* that only Congress could construct the blueprint of any regulatory framework for tobacco products. Fundamental to crafting any regulatory framework is defining the scope of what is to be regulated. When it comes to tobacco products, the identification of the products to be regulated was at the core of Congress adhering to this Court's major question holding in *Brown & Williamson*, thus the congressional decision to delegate this core legislative authority to FDA to identify the tobacco products to be regulated violated *Brown & Williamson's* clear mandate and was unconstitutional.[11]

B. THE APPH STANDARD IS UNCONSTITUTIONALLY VAGUE AND HAS LED FDA TO IGNORE A CORE POLICY UNDERLYING THE TCA.

Second, but no less significant to Johnny Copper's arguments, is the fact that Congress predicates the market authorization of new tobacco products, including vaping products, upon an APPH standard which is

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[11] FDA will no doubt argue that Congress satisfied the major question mandate in 2022 by including vaping products in the Consolidated Appropriations Act, 2022, PUB. L. 117-103, div. P., tit. I, subtitle B, 136 STAT. 49, 789-92 (Mar. 15, 2022). All that Congress did in such enactment was amend the 21 U.S.C. § 321(rr) "tobacco product" to include products containing non-tobacco-derived nicotine and 21 U.S.C. § 387a(b) to add such products to the existing four product subsets. The enactment did not add any additional tobacco products or alter the Section 387a(b) deeming provision as to all other products.

The significance of this definition change is shown by a real-time example. FDA has proposed to require cigarette manufacturers to reduce the nicotine quantity of their products. 90 FED. REG. 5,032 (Jan. 16, 2025). But for Congress expanding the "tobacco product" definition, cigarette manufacturers would be able to bypass FDA's proposed requirement by infusing cigarettes with non-tobacco derived nicotine.

unconstitutionally vague. The nature of such vagueness lies in the fact that the concept of "public health" is infinitely broad but lacks a clear congressional definition. FDA has used this vagueness as a weapon to turn the APPH into a moving target

So, what constitutes the "*public health*" for APPH purposes? For starters, Congress did not define the term in either the TCA or the FFDCA. This Court's jurisprudence thus looks to the ordinary meaning of the term. *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995). The Merriam-Webster Dictionary defines the term as being:

> "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."[12]

Black's Law Dictionary articulates a broader definition:

> "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."[13]

These definitions tell us what is intuitive: the factors comprising the concept of "public health" are virtually infinite. Yet, Congress did not set guardrails when articulating the APPH standard which cabins FDA's analysis of the varied aspects of the factors which touch upon the "public health" save the

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[12] *Public Health,* Merriam-Webster Dictionary,https://tinyurl.com/7mtz87ms;
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

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

limited considerations set forth in 21 U.S.C. § 387j(c)(4) (the respective likelihood that current tobacco users will stop and the likelihood that current non-users will not start).

The concept of "public health" involves an infinite variety of facts which are different and often competing. Yet, Congress failed to guide how FDA must consider and analyze these important factors, and the TCA contains few limits on what evidence satisfies the standard.[14] The virtually infinite list of possible public health considerations is also entirely subjective as to how FDA must weigh factors against each other. FDA has applied the "public health" concept as a moving target.

For instance, Congress did not articulate how FDA must weigh the youth use of vaping products against the fact they have been a godsend to many adult smokers. Congress also failed to delineate whether, or how, any lower health impacts of vaping products across all population demographics offset the more severe consequences of continued cigarettes use across the same demographics. Further, Congress did not specifically say whether FDA must consider any youth use of vaping products for smoking cessation as a mitigating factor.

The TCA's plain language suggests an affirmative response to the latter point since youths are part of the "population as a whole" and their use of

[14] The TCA requires "well-controlled investigations" but offers no clarification of the pertinent factors governing them. 21 U.S.C. § 387j(c)(5)(A).

vaping products to quit smoking is a 21 U.S.C. § 387j(c)(4)(A) factor (*i.e.* the APPH standard looks to the increased likelihood that a product will cause a current user to stop). The National Youth Tobacco Survey (NYTS) which measures youth tobacco use demonstrates that they do, in fact, use vaping products to quit smoking (*e.g.*, 2.5% of youths reported vaping to quit smoking in 2021).[15] Ironically and curiously, the NYTS stopped inquiring about such fact after 2021.

In FDA's eyes, however, there are no benefits whatsoever to youths using vaping products. Its answer to such use has been to mandate that vaping products intended for adult consumption prove they satisfy the APPH standard by conducting a long-term clinical test to demonstrate the comparative efficacy of non-flavored products versus tobacco-flavored products as a function of causing smoking cessation. *Wages* discussed such concept at length as did the parties' briefs therein. Such standard, to borrow the words of Winston Churchill, is like a "riddle wrapped in a mystery inside an enigma"[16] because FDA has never articulated its most basic parameters (like the number of adult smokers who must be converted by a product to be considered "effective"). The Solicitor General cannot now respond with an

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[15] Gentzke, A., *et al. Tobacco Product Use and Associated Factors Among Middle and High School Students* — National Youth Tobacco Survey, United States, 2021. MMWR SURVEILL. SUMM. 2022;71(No. SS-5):1–29, Table 6.

[16] Churchill, W., *The Russian Enigma* (BBC Broadcast Oct. 1, 1939), available at http://www.churchill-society-london.org.uk/RusnEnig.html

articulation of the answer with any measure of credibility because FDA has itself never done so. We thus have a requirement with no defined standard.

A regulatory structure which provides no "ascertainable standard" cannot survive constitutional scrutiny. *U.S.* v. *L. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921). A regulatory structure which lacks ascertainable standards fails the Constitution's requirement that Congress "suppl[y] an intelligible principle to guide the delegee's use of discretion." *Gundy* v. *United States*, 588 U.S. 128, 135-136 (2019). Congress authorized FDA to make regulatory determinations that effectively require omniscience by regulated parties without any guiding principles for balancing an almost unlimited array of competing variables. The APPH standard is unconstitutionally vague for this reason.

Here's why the vagueness of the APPH standard and FDA's flawed implementation matter. FDA has not only implemented the APPH standard in a manner which lacks clarity and transparency, it has essentially thrown out the baby with the bathwater by ignoring the adverse public health consequences of its policy. One adverse consequence is the black market which always follows a prohibitive policy. Prohibition was health-driven policy which history shows resulted in a proliferation of mass quantities of illicit, less-safe alcohol products,[17] say nothing about the bootleggers who peddled them.

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[17] Miron, J., *et al., Alcohol Consumption during Prohibition*, 81 AM. ECON. Rev. 242 (1991).

History is repeating itself, and not in a good way, because FDA's policies regarding flavored open-system vaping products has resulted in Chinese manufacturers quickly filling the market with a virtually limitless array of disposable vaping devices.[18] The bootleggers this time are Chinese instead of Italian or Irish; same game, different players. Worse, FDA has no clue who these manufacturers are, what kind of quality controls they utilize, or the conditions under which they manufacture products—all things which domestic vape product manufacturers have had to disclose as part of their PMTAs. It can hardly be debated these are critical facets of any public health inquiry when considering whether (and how) to allow the marketing of vaping products.

FDA's myopic fixation with youth use of vaping products has caused it to adopt policies which produce another adverse consequence—one which directly contradicts the mandate Congress gave when adopting the TCA. Smoking cessation was one of the key congressional goals underlying the TCA. *See* TCA § 2(34), 123 STAT. 1776, 1779 (Jun. 22, 2009). ("Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely").

Yet, one of the adverse consequences of FDA's fixation with flavored vaping products has been the counterproductive result of increased smoking.

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[18] Matsakis, L., *The US Is Being Flooded by Chinese Vapes*, Wired, Jun. 25, 2024.

A January 2024 Yale School of Public Health study demonstrated that increased cigarette sales, particularly among brands preferred by youth, occurred in jurisdictions which banned flavored vaping products.[19] A December 2024 study by the same group of scientists considered a cross-sectional analysis of behavioral risk data for more than 242,000 adult participants between age 18 to 29, derived from 2018 and 2023, and concluded that restrictions on flavored vaping products resulted in increased smoking.[20] FDA's fixation with keeping vaping products out of the hands of youths has resulted in increased smoking (or at least an increased likelihood of it) by youths. The impact of FDA's policy has produced a result that runs directly contrary to Congress's intent to reduce smoking—a result which directly flies in the face of any understanding of "public health."

C. FDA UNLAWFULLY INSTITUTED A *DE FACTO* BAN ON NON-TOBACCO FLAVORED PRODUCTS

Aside from the above constitutional defects, FDA has chosen to regulate flavored vaping products in a manner which directly contradicts the TCA's plan language and straight forward tobacco product standard requriements. Congress articulated clear and unambiguous requirements which FDA must follow as a predicate to adopting tobacco product standards. 21 U.S.C. § 387g.

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[19] Friedman, A.*, et. al., E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales* (Jan. 29, 2024).

[20] Friedman A., *et. al*., Flavored E-Cigarette Sales Restrictions and Young Adult Tobacco Use, JAMA HEALTH FORUM, 2024:5(12) (Dec. 27, 2024).

Therein, Congress enacted the cornerstone product standard when adopting the TCA by banning the inclusion of non-menthol flavors in cigarettes, *ibid.*, at § 387g(a)(1), and authorized FDA to create additional product standards, but only through an APA notice-and-comment rulemaking process, *ibid.*, at § 387g(c).

1. FDA'S COMPARATIVE EFFICACY STANDARD IS A DISGUISED TOBACCO PRODUCT STANDARD.

The TCA provides that a tobacco product standard concerns a product's "components, ingredients [or] additives." 21 U.S.C. § 387g(a)(4)(B)(i). The TCA then defines the term "additive" in pertinent part to mean:

> "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding)…."

Ibid., at § 387(1). Given these statutory provisions, the regulation of flavorings in vaping products is a quintessential tobacco product standard which requires notice-and-comment rulemaking. 21 U.S.C. §387g(a)(1)-(4); *Wages*, at 384 n.5; *Reynolds*, 65 F.4th at 192.

Congress set forth the procedure for adopting a tobacco product standard in 21 U.S.C. § 387g(c) by requiring that FDA:

> "publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any product standard,"

21 U.S.C. § 387g(c)(1). Congress therein also set forth the technical

requirements of such notice, *ibid*., at § 387g(c)(2). This is the same general notice-and-comment rulemaking procedure which the APA requires. *See* 5 U.S.C. § 553.

The Fifth Circuit found in both *Wages* and *Reynolds* that FDA's implementation of its comparative efficacy standard through the PMTA adjudication process was tantamount to the creation of a "tobacco product standard." Both *Wages* and *Reynolds* found that FDA implemented an unlawful *de facto* ban[21] on non-tobacco flavored vaping products by failing to comply with the TCA's notice-and-comment procedures. *Wages*, 90 F.4th at 384, n. 5; *Reynolds*, 65 F.4th at 189.

FDA's 2020 enforcement priorities guidance confirmed this interpretation and understanding of 21 U.S.C. § 387g when acknowledging that "restricting or eliminating" flavors is a "product standard."[22] FDA further confirmed such interpretation and understanding in its 2022 proposed product standard which sought to ban menthol as a flavoring in cigarettes[23] and in its current

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[21] FDA's proposed nicotine content rule will itself be tantamount to a *de facto* ban on cigarettes which contradicts the TCA's mandate that FDA "continue to permit the sale of tobacco products to adults…." See TCA, §3(7), 21 U.S.C. § 387 note, 123 STAT. at 1782.

[22] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry* at 34 (Apr. 2020)

[23] FDA, *Tobacco Product Standard for Menthol in Cigarettes*, 87 FED. REG. 26,454, 26,456 (May 4, 2022).

proposed product standard to limit the nicotine content of cigarettes.[24] FDA's proposed menthol cigarette rule and nicotine content rule both acknowledge its authority to regulate the inclusion or exclusion of an ingredient in tobacco products derives from the product standard provisions set forth in 21 U.S.C. § 387g.[25] It is undisputed that FDA has not sought to promulgate a tobacco product standard relating to flavored vaping products through the TCA's notice-and-comment rulemaking process.

The Fifth Circuit determined that FDA's comparative efficacy standard was a substantive rule because it "turns on whether [the agency] intends to bind *itself* to a particular legal position." *Reynolds*, 65 F.4th at 189. The court found that such standard bound FDA's staff when reviewing flavored vaping products PMTAs and applied the standard as binding, impacting the rights of thousands of applicants. *Ibid.* at 192-94. FDA, without a doubt, applied this same unlawful and *ultra vires* process when adjudicating Johnny Copper's PMTA. That should end the dispute about the impropriety of FDA's failure to adhere to Congress's clear directions in 21 U.S.C. § 387g.

Yet, FDA's comparative efficacy standard appears to be another one of its moving targets. On January 16, 2025, FDA authorized the marketing of 20

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[24] FDA, *Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products*, 90 FED. REG. 5,032 (Jan. 16, 2025).

[25] 87 FED. REG. at 26,456; 90 FED. REG. at 5,035.

flavored nicotine pouch products.[26] Yet, the Technical Project Lead document[27] which accompanied FDA's marketing order omits any mention of it applying the same comparative efficacy standard to the nicotine pouch products as it required of Johnny Copper and all other manufacturers of flavored vaping products. Furthermore, FDA's Technical Project Lead document for the subject flavored nicotine pouches also evidences another FDA moving target with respect to the sufficiency of marketing plans. Therein, FDA professed that:

> "[b]efore determining that permitting the marketing of a new tobacco product would be APPH, FDA also considers the potential impact of marketing restrictions and other mitigation efforts that aim to reduce the risk of youth initiation and tobacco use. Marketing restrictions include advertising and promotion restrictions intended to limit youth exposure to and appeal of tobacco product marketing (e.g., measures such as limiting advertising to platforms that are predominantly used by adults and using advertising content and methods that are not known to resonate with youth, or even eliminating advertising in certain media channels altogether) and sales access restrictions intended to restrict youth access to tobacco products (e.g., measures such as selling products only in face-to-face interactions, in adult-only facilities, or via websites that require robust age verification)."[28]

Yet, Johnny Copper's marketing plan evidenced the same elements. App., *supra.*, 95a-101a. Actually, Johnny Cooper's marketing plan included elements (like *Trace/Verify* technology) which exceeded what FDA asked as

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[26] *See* FDA, *FDA Authorizes Marketing of 20 ZYN Nicotine Pouch Products after Extensive Scientific Review* (Jan. 16, 2025).

[27] FDA, Technical Project Lead (TPL) Review of PMTAS (Swedish Match USA Inc). https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted.pdf

[28] *Ibid.*, at 5.

noted by the Eleventh Circuit in *Bidi,* 47 F.4th at 1205. FDA pulled a bait-and-switch by proclaiming the elements of the nicotine pouch marketing plan was adequate while blithely disregarding the elements of Johnny Copper's marketing plan because it presumed that:

> "[t]hus far, FDA's experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH."

Ibid., at 20a-21a. FDA is clearly treating novel flavored tobacco products on a disparate basis. FDA cannot square this disparate treatment in the respective explanations articulated in its Technical Project Lead documents.

2. FDA HAS ROOTED ITS COMPARATIVE EFFICACY STANDARD UPON *SEC V. CHENERY CORP*.

FDA has thumbed its nose at the TCA's legal requirements by unlawfully enforcing its comparative efficacy standard through the PMTA adjudication process, ostensibly relying upon *SEC v. Chenery Corp.*, 332 U.S. 194 (1947). *Chenery*, as the Court knows, countenances agencies regulating through *ad hoc* adjudications. FDA's application of *Chenery* has resulted in the enforcement of a blanket product standard which ensured that all vaping product manufacturers have received an MDO for their non- tobacco flavored products. *Reynolds*, at 192; *Wages*, at 384 n.5 ("FDA unquestionably failed to follow §387g's notice-and-comment obligations before imposing its *de facto* ban on flavored e-cigarettes").

FDA thus unquestionably used the PMTA adjudication process to issue blanket MDOs to all non-tobacco and non-menthol open-system vaping products analyzed to date and has merely approved four NJOY® menthol-flavored, closed-system products,[29] which represent a mere 0.000333% of all MDO'd vaping products. This is what it intuitively looks like—a *de facto* ban on all non-tobacco flavored vaping products absent an adherence to the TCA's straight forward requirements.

3. FDA CANNOT RELY UPON *CHENERY*.

Any reliance by FDA upon *Chenery* is not well grounded.[30] *Chenery* blessed the concept of agencies making law on "case-by-case" basis, 332 U.S. at 203, but did not grant unrestricted *carte blanche* to implement broad policy initiatives through *ad hoc* regulatory adjudications. This is evident from *Chenery's* admonition that agencies should effectuate their statutory commands through prospective rulemaking "as much as possible." *Ibid.*, at 202. On this point, the TCA plainly requires that FDA adhere to a notice-and-comment rulemaking process when adopting a tobacco product standard, 21

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[29] FDA, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review* (Jun. 21, 2024).

[30] In fact, the future viability of *Chenery* was recently questioned with respect to the authority of agencies to make retroactive ad hoc adjudications in the context of *Wages*. *See* Ben, L., *et. al., The Future of Chenery II: Potential Implications from FDA v. Wages and White Lion, L.L.C.*, COLUMBIA BUS. L. REV. (Dec. 3, 2024). https://journals.library.columbia.edu/index.php/CBLR/announcement/view/741

U.S.C §§ 387g(a)(4)(B)(i) and 387(1), and that requirement plainly applies to the regulation of "flavorings," *ibid*. at § §387g(a)(1)-(4); *Wages*, at 384, n.5; *Reynolds*, at 192.

FDA's refusal to adhere to the TCA's mandatory rulemaking process should end the inquiry. Yet, this Court's *Chenery* jurisprudence holds than an agency's development of policy through adjudications rather than formal rulemaking "may affect the degree of deference" to be afforded. *Gonzalez v. Reno*, 212 F.3d 1338, 1350 (11th Cir. 2000). *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024), however, changed the Court's deference calculus by requiring an analysis of the "thoroughness of the agency's reasoning." Any deference concerning *ad hoc* adjudications post-*Loper* should be applied based upon what *Chenery* admonishes—adhering to statutory rulemaking processes when implementing broad policy initiatives unless a given circumstance falls within one of its limited exceptions.

4. FDA CANNOT INVOKE ANY OF *CHENERY'S* EXCEPTIONS.

In this instance, FDA's comparative efficacy standard is not saved by the elements of *Chenery's* narrow "specialized problem" exception to the general rulemaking requirement. This narrow exception allows an agency to regulate by *ad hoc* adjudication if it: (1) lacks "sufficient experience," (2) "could not reasonably foresee" the subject issue, or (3) is dealing with circumstances "so specialized and varying in nature" that it is "impossible" to capture such circumstances with a general rule. 332 U.S. at 202–03. FDA cannot pigeonhole

itself into one of these special circumstances *vis-à-vis* any perceived youth risks of flavored vaping products which it has articulated in the many MDO challenges since 2021 as the basis for its *ad hoc* adjudications.

i. THE SUFFICIENT EXPERIENCE EXCEPTION DOES NOT APPLY.

FDA cannot plausibly argue that it lacks "sufficient experience" in dealing with flavored vaping products since they have been marketed since 2006 in the United States.[31] FDA's experience with vaping products goes back as far as April 2009 based upon *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

FDA was further aware of the alleged risks of flavored vaping products in April 2014 when proposing the Deeming Rule.[32] FDA made references on no less than 5 pages of its proposed Deeming Rule to express concerns about the perceived youth risks of flavored vaping products.[33] FDA thus had experience with flavored vaping products and any associated risks for nearly 5 years prior to adopting its comparative efficacy standard.

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[31] Fadus, M., *The Rise of E-Cigarettes, Pod Mod Devices, and JUUL Among Youth: Factors Influencing Use, Health Implications, and Downstream Effects*, *Drug Alcohol Depend.*, 201:85-93 (Aug. 1, 2019).

[32] FDA, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 FED. REG. 23,142, *et. seq*. (Apr. 25, 2014).

[33] *See e.g., ibid.*, at 23,144, 23,146 - 23,148 and 23,157.

ii. THE LACK OF REASONABLE FORESEEABILITY EXCEPTION DOES NOT APPLY.

FDA can also not say that it failed to perceive the foreseeability of any youth risk issue prior to reviewing flavored vaping product PMTAs. After all, FDA professed in 2014 that flavored tobacco poses risks to youths when proposing the Deeming Rule.[34] FDA even proposed a solution in the Deeming Rule—banning the introduction of characterizing flavors to all tobacco products.[35] The Office of Management and Budget, however, struck such ban from the final Deeming Rule as part of its Congressionally-mandated fiscal review.[36]

FDA knows, based upon its prior unsuccessful attempt to implement a ban on the addition of characterizing flavors as a product standard through the rulemaking process that it must adhere to the TCA's rulemaking process as a predicate to adopting a tobacco product standard which regulates flavored vaping products. FDA is thus attempting to do indirectly through *ad hoc* PMTA adjudications what it has been unable to accomplish directly through the TCA's prescribed rulemaking process.

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[34] *Ibid.*

[35] *See* OMB Mark-Up - FDA-2014-N-0189-83193, OMB Docket No. 2014-850 at 167 – 180. https://www.dropbox.com/scl/fi/tz9sh8gxum121vbxdxei8/OMB-Mark-Up-FDA-2014-N-0189-83193_content.pdf?rlkey=25gjsy0zexq8fme3w3q9ce8os&dl=0.

[36] *Ibid.*

iii. THE SPECIALIZED CIRCUMSTANCES EXCEPTION DOES NOT APPLY.

Finally, FDA cannot be heard to say that the perceived youth risk issue *vis-à-vis* flavored vaping products is "so specialized and varying in nature" that it is "impossible" to capture such risk through the traditional rulemaking process. FDA's attempt to do so in the proposed Deeming Rule, its attempt to ban menthol cigarettes, and its current attempt to limit nicotine levels in cigarettes completely obliterate any argument that the specialized circumstances exception could apply. FDA cannot seek shelter in *Chenery's* safe harbor exception to avoid the TCA's clear and unambiguous rulemaking requirement.

II. THE REMAINING *NKEN* FACTORS SUPPORT A STAY

Johnny Copper has demonstrated a substantial likelihood of success on the above constitutional and non-constitutional issues, and the remaining *Nken* factors support a stay, considering the final two factors merge in this instance.

First, Johnny Copper will be irreparably harmed if the MDO is not stayed pending review. Constitutional deprivations constitute a *per se* irreparable harm, *Elrod v. Burns*, 427 U.S. 347, 373 (1976), and a "substantial financial injury" may be "sufficient to show irreparable injury," especially against the government which is immune from monetary damages due. *Reynolds, supra.*, at 194. Moreover, requiring that a party continue to comply with "an agency order later held invalid almost *always* produces irreparable harm of

nonrecoverable compliance costs." *Florida v. HHS*, 19 F.4th 1271 (11th Cir. 2021).

Below, Johnny Copper filed a detailed declaration of its owner, App., *supra*., at 86a, which highlighted the lost business damages and harm to its goodwill and reputation which would ensue from the MDO (*e.g.*, losing sales of over $500,000.00 annually and having to significantly downsize its operations). Those financial damages will be irreparable because Johnny Copper cannot look to FDA for compensation should the Eleventh Circuit vacate the MDO after considering the merits. Further, Johnny Copper demonstrated below, and demonstrates here, that issuing a stay will harm neither FDA nor the public interest. As the Fifth Circuit noted in *Reynolds*, "it is of the highest public importance" that agencies comply with the law. 65 F.4th at 191-92. Johnny Copper has clearly demonstrated FDA's regulatory regime is unconstitutional and contrary to the APA and TCA.

Moreover, maintaining the status quo is "an important consideration." *Reynolds*, 65 F.4th at 191-92. Johnny Copper's products were being sold several years before the PMTA deadline. FDA allowed them to remain on the market, by its own enforcement discretion policy, for at least a year after the PMTA deadline before issuing its initial MDO. The Eleventh Circuit stayed enforcement of the initial MDO pending review in *Bidi* and FDA then waited nearly 2 years after *Bidi* vacated that initial MDO to re-adjudicate Johnny Copper's PMTA. A brief delay while the Eleventh Circuit considers the propriety of the second MDO will not harm either FDA or the public given the above circumstances. In fact, allowing Johnny Copper to continuing to serve

its adult customers' demand for reduced-harm products in the interim will serve the public interest given the showing below that such products have helped them avoid much riskier cigarettes. Finally, there is no risk to youth as FDA's data show they are not using its products.

CONCLUSION

Johnny Copper has presented a compelling case in the above arguments which evident both a substantial likelihood of success on the merits and equities which warrant a stay pending review. FDA's regulatory process is predicated upon an inherent unconstitutional delegation of a core legislative power and an unconstitutionally vague marketing review standard. FDA has then compounded these infirmities by implementing the PMTA review process in a manner which directly contradicts the tobacco product standard requirements which Congress could not have stated any more succinctly. The result of allowing these infirmities to fester pending the Eleventh Circuit's review of Johnny Copper's petition for review cannot be justified and must be stayed. Johnny Copper thus prays that the Court grant the requested relief.

Respectfully submitted.

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