IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

No. 21-60766

OPPOSITION TO PETITIONER'S EMERGENCY MOTION FOR A STAY PENDING REVIEW

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INTRODUCTION

Finding that the use of tobacco products by youth "is a pediatric disease of considerable proportions," Congress in the Family Smoking Prevention and Tobacco Control Act (TCA) gave the Food and Drug Administration (FDA) authority to regulate cigarettes and other tobacco products. TCA, Pub. L. No. 111-31, div. A, § 2(1), (15), 123 Stat. 1776, 1777 (2009). Among other provisions, the TCA prohibited the marketing of any new tobacco product (defined as a product not on the market as of February 15, 2007) unless and until FDA authorizes its marketing. 21 U.S.C. § 387j(a)(1)-(2).

The statute provides that FDA "shall deny" a manufacturer's marketing application unless the agency finds that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). The statute specifies that, in making this determination, FDA must evaluate "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start." *Id*. § 387j(c)(4). Because

"[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products," TCA § 2(4), 123 Stat. at 1777, the statute in practice requires FDA, among other things, to weigh the risk that a new tobacco product will be attractive to youth against the product's potential for helping adults who smoke combustible cigarettes switch to a less dangerous alternative.

In this case, FDA applied that standard in evaluating petitioner's application to market certain flavored "electronic nicotine delivery system" (ENDS) products—specifically, various nicotine-containing "e-liquids" used in what are colloquially known as "e-cigarettes." In denying the application, FDA explained that there is an epidemic of e-cigarette use by children and adolescents, and that the epidemic is fueled by the availability of flavors such as candy and fruit, which are used to initiate approximately 90% of underage users. In light of the clear evidence that flavored e-cigarettes attract youth to an addictive product, FDA determined that the TCA's public-health standard would be satisfied only by robust and reliable evidence of countervailing benefits. FDA concluded that petitioner had not presented such reliable evidence.

Petitioner now asks this Court to "stay" FDA's denial of its request for marketing authorization on a theory that a "stay" of the denial would permit it to lawfully market its unapproved flavored e-cigarette products. That request reflects a basic misunderstanding of the statutory scheme. The Tobacco Control Act prohibits the marketing of new tobacco products, unless and until petitioner obtains FDA authorization. A stay of FDA's denial order would not make petitioner's products lawful to market. And a court could not properly compel FDA to authorize petitioner's products, just as a court could not properly compel FDA to approve a new drug under the parallel provisions of the Federal Food, Drug, and Cosmetic Act.

Petitioner is entitled to seek judicial review of the FDA denial order, and, if petitioner were to prevail, FDA would reconsider the application in accordance with this Court's opinion. But such an order would not be tantamount to a directive to authorize a new tobacco product. In any event, FDA properly denied petitioner's application because petitioner failed to adequately substantiate its claim that its flavored products would help "smokers' transition from smoking to vaping" and help "vapers maintain smoking abstinence," A296, so as to outweigh the documented risks that such products present to youth.

STATEMENT

I. The Tobacco Control Act's Regulation Of New Tobacco Products

The Family Smoking Prevention and Tobacco Control Act established a comprehensive scheme for the regulation of tobacco products. *See* TCA, 123 Stat. 1776. Among other requirements, Congress made it unlawful for a manufacturer to introduce in interstate commerce any "new tobacco product" unless the manufacturer obtains premarket authorization from FDA. 21 U.S.C. § 387j(a)(1)-(2). The statute defines a "new tobacco product" as a tobacco product that was not commercially marketed in the United States as of February 15, 2007, or that was modified after that date. *Id.* § 387j(a)(1).[1] It is not controverted that petitioner's products are "new tobacco products" within the meaning of the statute.

In barring the marketing of new tobacco products absent FDA authorization, Congress was aware of the risk that manufacturers would design new products attractive to children and adolescents. Congress found that the use of tobacco products "is a pediatric disease of

[1] The TCA provides a separate premarket authorization pathway for tobacco products that are substantially equivalent to products that were commercially marketed in the United States as of February 15, 2007. *See* 21 U.S.C. § 387j(a)(2)(A)(i)(I). That pathway is not at issue here.

considerable proportions," TCA § 2(1), 123 Stat. at 1777, and that the marketing and promotion of tobacco products "have been especially directed to attract young persons," TCA § 2(15), 123 Stat. at 1777. In hearings on the TCA, Senator Merkley addressed attempts to capture the underage audience for smokeless tobacco—efforts that swept even further than the cigarette advertising campaigns targeted at children and adolescents. He explained that "tobacco companies are marketing tobacco candy to our children" and designing products to resemble cell phones and other objects "so that teachers can't recognize that these are smokeless tobacco products in their students' pockets." 155 Cong. Rec. S5999 (daily ed. June 3, 2009).

In light of the risks posed by new tobacco products, which stem in significant part from initiating use by children and adolescents, Congress provided that FDA "shall deny" a manufacturer's application "if, upon the basis of the information submitted to [FDA] as part of the application and any other information before [FDA] with respect to such tobacco product," the agency "finds that . . . there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). The statute thus puts the burden

on the manufacturer to provide evidence that would justify a finding that the product satisfies this "public health" standard. In determining whether the application meets that standard, FDA must evaluate "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account both the "likelihood that existing users of tobacco products will stop using such products," and the "likelihood that those who do not use tobacco products will start." *Id.* § 387j(c)(4).

II. Electronic Nicotine Delivery Systems (ENDS)

"Electronic nicotine delivery systems"—which are colloquially known as "e-cigarettes"—include a wide variety of products. Their common feature is that they deliver nicotine, which is "among the most addictive substances used by humans," "by vaporizing a liquid that includes other chemicals and flavorings." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). "The device heats the liquid until it generates an aerosol—or 'vapor'—that can be inhaled." *Id.* Some such devices are designed to look like cigarettes, while others are designed to look like everyday objects such as pens or computer flash drives. *Id.* at 273 n.1.

In 2016, FDA exercised its statutory authority to deem e-cigarettes and other products that are made or derived from tobacco to be subject to the TCA's requirements. 81 Fed. Reg. 28,974 (May 10, 2016); *see Nicopure*, 944 F.3d at 273. By statute, any deemed tobacco products that met the Act's definition of a "new tobacco product" could not lawfully be marketed without FDA premarket authorization after the rule's effective date of August 8, 2016. In the final rule, FDA announced that, for e-cigarettes already on the market as of the rule's effective date, the agency generally would not take enforcement action based on a product's lack of premarket authorization for a two-to-three-year period while manufacturers prepared, and FDA reviewed, applications. 81 Fed. Reg. at 28,978. In 2017 guidance, FDA extended this enforcement period until 2022. *See American Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 468 (D. Md. 2019).

From 2017 to 2018, however, underage use of e-cigarettes skyrocketed: the number of high-school-age children reporting use of e-cigarettes rose by more than 75%, and use among middle-school-age children increased nearly 50%. *See American Acad. of Pediatrics*, 379 F. Supp. 3d at 467 (citing Alex M. Azar & Scott Gottlieb, *We Cannot Let E-Cigarettes Become an On-Ramp for Teenage Addiction*, Wash. Post, Oct. 11, 2018). In

light of this epidemic of underage usage, FDA reconsidered its 2017 guidance. *See In re Cigar Ass'n*, 812 F. App'x 128, 134 (4th Cir. 2020). And, in an action brought by public-health groups, a district court ruled that FDA's "across-the-board suspension of the Tobacco Control Act's premarket approval process" in the 2017 guidance was contrary to the statute and defeated its purpose by allowing unapproved tobacco products to be sold "at a time when minors' use of tobacco products like e-cigarettes is at an epidemic level and rising." *American Acad. of Pediatrics*, 379 F. Supp. 3d at 492. The court directed FDA to require manufacturers to submit applications for premarket authorization by May 2020—a date subsequently extended to September 2020 as a result of the COVID-19 pandemic—and provided that products for which timely applications had been submitted "may remain on the market without being subject to FDA enforcement action for a period not to exceed one year." *American Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). The court later clarified that FDA was permitted to take enforcement action during the application review period. Order, *American Acad. of Pediatrics*, No. 18-883 (D. Md. Aug. 12, 2019), Dkt. No. 132. FDA issued new enforcement

guidance in 2020 consistent with the district court's order and its own review. *See In re Cigar Ass'n*, 812 F. App'x at 134; FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry* (Apr. 2020).[2]

III. FDA's Denial Of Petitioner's Application To Market Flavored E-Cigarette Products

Petitioner submitted an application for premarket review of hundreds of flavored e-liquids, including "Mother's Milk and Cookies," "Strawberry Astronaut," and "Crème Brulee." A5-6. After weighing the evidence regarding the potential "risks and benefits to the population as a whole, including users and nonusers of the tobacco product," 21 U.S.C. § 387j(c)(4), FDA concluded that petitioner had not carried its burden of demonstrating that the marketing of its flavored e-cigarette products was appropriate for the protection of the public health.

In reviewing petitioner's application and those of other manufacturers, FDA focused on the particular health risks that these products present for children and adolescents. FDA explained that "use of

[2] https://go.usa.gov/xMsKh.

tobacco products, no matter what type, is almost always started and established during adolescence when the developing brain is most vulnerable to nicotine addiction," and that "almost 90 percent of adult daily smokers started smoking by the age of 18." A39. In contrast, a person who reaches "the age of 26 without ever starting to use cigarettes will most likely never become a daily smoker." A40. Accordingly, "preventing tobacco use initiation in young people is a central priority for protecting population health." A40.

FDA explained that the appeal of flavored e-cigarettes to youth is well established, and that "the preference for use of flavored [e-cigarettes] among youth is consistently demonstrated across large, national surveys and longitudinal cohort studies." A41. FDA observed that "fruit was the most commonly used flavor type among youth" across all e-cigarette product types, with 81.7% of youth users of such products stating a preference for fruit flavors. A41.

Given the substantial risk that flavored e-cigarettes pose for youth, FDA determined that robust and reliable evidence of a countervailing public-health benefit was needed to support a finding that the marketing of such products is appropriate for the protection of the public health. A45.

FDA denied petitioner's application because the evidence did not adequately substantiate petitioner's claim that its flavored products would help adult smokers stop or reduce smoking or do so more effectively than tobacco-flavored e-cigarettes, which are far less attractive to youth. A48.

ARGUMENT

I. Petitioner's Motion Rests On The Incorrect Premise That A "Stay" Of FDA's Denial Order Would Allow Petitioner To Lawfully Market Its Products.

Petitioner's stay motion rests on a fundamental misunderstanding of the statutory scheme that governs new tobacco products. Petitioner's asserted irreparable harm—the inability to market its products lawfully—flows from the Tobacco Control Act itself. A "stay" of the FDA denial order would not make petitioner's products lawful to market.

Congress barred the marketing of new tobacco products unless and until they receive FDA authorization. 21 U.S.C. § 387j(a)(1)-(2). And Congress provided that FDA "shall deny" an application for authorization to market a new tobacco product if FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A).

Thus, absent such a public-health finding by the agency, the TCA makes the marketing of a new tobacco product unlawful.

In this respect, the statutory provisions that govern new tobacco products parallel the statutory provisions that govern the marketing of new drugs. Under the Federal Food, Drug, and Cosmetic Act, it is unlawful for a manufacturer to market any "new drug" without FDA approval. 21 U.S.C. §§ 331(d), 355(a). A court could set aside the denial of a new drug application if, for example, FDA failed to consider relevant evidence critical to an evaluation. But by setting aside a denial, a court would not thereby authorize the marketing of a drug that FDA has not found to be safe and effective. Instead, it would remand to the agency to undertake further review in light of the court's decision.

That is equally the case for new tobacco products. If the Court ultimately concludes that FDA failed to consider relevant evidence or otherwise erred, the Court could remand to FDA for further consideration consistent with the Court's decision. But such arguments provide no support for the emergency relief sought here. FDA has not found that petitioner's products meet the statutory requirements for lawful marketing,

and petitioner has no entitlement to market its flavored e-cigarettes in the absence of that determination.

Petitioner underscores its misunderstanding of the statute when it asserts that, in denying its application, FDA "declared the vast majority of Triton's products illegal under the TCA effective immediately." Mot. 21. FDA's denial order did not change the status of petitioner's products. Petitioner had no right to market its products lawfully before FDA denied its application. For that reason, a "stay" of FDA's order denying the request for marketing authorization would not alter the legal status of petitioner's flavored e-cigarettes and permit their marketing.

The fact that petitioner has profited from the unlawful marketing of these products in the past does not establish a right to continued profits during the pendency of these proceedings. Petitioner's claim of irreparable injury rests entirely on the fact that it took advantage of the period between the deeming rule's effective date and the date on which FDA made the public-health determination at issue here. Petitioner was aware at all times that the statute made the lawfulness of its continued marketing dependent on FDA authorization. Moreover, as discussed above, even assuming that petitioner could persuade the Court after merits briefing that FDA failed to

fully consider some significant aspect of its application, petitioner would be entitled to a remand, not to an injunction requiring FDA to treat its flavored e-cigarettes as if they were authorized products. Such an injunction would be flatly at odds with Congress's decision to prohibit the marketing of new tobacco products without FDA authorization.

II. Petitioner's Objections To FDA's Denial Order Misunderstand The Governing Statute And The Extent To Which Petitioner Failed To Provide Reliable Evidence Satisfying The Public-Health Standard For Approval Of New Tobacco Products.

A. In applying the TCA's public-health standard to petitioner's application to market flavored e-cigarette products, FDA explained that evidence of the role of flavored products in youth initiation is incontrovertible and that the resulting nicotine addiction has lifelong consequences. In 2020, for example, approximately 19.6% of U.S. high school students and 4.7% of middle school students—approximately 3.6 million students—were current users of e-cigarettes, making e-cigarettes "the most widely used tobacco product among youth by far." A40.

Of the 3 million high school students who reported current e-cigarette use, the vast majority (84.7%) use flavored products. A40. Studies also consistently demonstrate that the overwhelming number of

children and young adults are initiated into use of e-cigarettes by flavored products. For example, in a 2016-2017 study, 93.2% of youth and 83.7% of young adults reported that their first e-cigarette had been a flavored product. A40. Of youth currently using e-cigarettes, "71% reported using [e-cigarettes] 'because they come in flavors I like.'" A41.

The appeal of flavored products to children and adolescents is of exceptional importance because this age group is particularly vulnerable to nicotine addiction, which often persists into adulthood. *See* A42 (explaining that "[y]outh and young adult brains are more vulnerable to nicotine's effects than the adult brain due to ongoing neural development"). If young people can avoid tobacco use in that critical period, the chances of addiction drop dramatically. *See* A39 (noting that almost 90% of adult daily smokers started smoking by the age of 18).

As FDA explained, "as the known risks increase, so too does the burden of demonstrating a substantial enough benefit." A44. Because the risk that flavored e-cigarettes pose for youth initiation and use is clearly documented, "an applicant would have to show that the significant risk to youth could be overcome by likely benefits substantial enough such that the net impact to public health would be positive." A44. FDA also

explained that, because "tobacco-flavored" e-cigarettes "may offer the same type of public health benefit as flavored" e-cigarettes—"i.e., increased switching and/or significant reduction in smoking"—"but do not pose the same degree of risk of youth uptake," it was appropriate to consider whether "the flavored products have an added benefit relative to that of tobacco-flavored [e-cigarettes] in facilitating smokers completely switching away from or significantly reducing their smoking." A37.

B. Petitioner does not dispute the extent of underage use of e-cigarettes generally or the extent to which their popularity has been driven by flavored products. Petitioner argues, however, that it was arbitrary and capricious for FDA to conclude that its submissions failed to demonstrate that the marketing of its flavored e-cigarettes would be appropriate for the protection of the public health. Even a cursory review of the materials on which petitioner relies makes clear that this assertion is meritless.

Petitioner notes, for example, that youth have favored cartridge-type e-cigarettes because they are easy to conceal and can be used discreetly. Mot. 16; A297. Petitioner urges that its products do not provide this attraction because they are "bottled e-liquids for use in open-system

devices, not the closed-system cartridges that are popular with youth." Mot. 16. However, petitioner offers no response to FDA's conclusion that, while "there is variability in the popularity of device types," "the role of flavor is consistent" "in increasing the appeal of tobacco products to youth" across all product types. A41; *see* A37 n.ii (explaining that FDA's assessment of flavored e-cigarettes encompasses both open- and closed-system devices). FDA also explained that user trends among youth are highly variable. For example, when FDA "changed its enforcement policy to prioritize pod-based flavored [e-cigarettes], which were most appealing to youth at the time, we subsequently observed a substantial rise in use of disposable flavored [e-cigarettes]—a ten-fold increase (from 2.4% to 26.5%) among high school current e-cigarette users." A42 (footnote omitted).

Petitioner's insistence that its products do not present a meaningful risk of youth initiation because they are not marketed towards or accessible by youth echoes familiar tobacco-industry claims. Few manufacturers of e-cigarettes or other tobacco products would claim that they are marketing to youth, and many impose access restrictions of the type cited by petitioner. However, as FDA explained when it denied petitioner's application, the agency is "not aware of access restrictions that, to date,

have been successful in sufficiently decreasing the ability of youth to obtain and use" e-cigarettes. A45 n.xix. The 2018 FDA press release on which petitioner relies (Mot. 22) predated that finding by several years and, in any event, emphasized that FDA would take whatever steps necessary to reduce youth use of e-cigarettes, which remain "the most widely used tobacco product among youth by far," A40.

Petitioner's application also cites evidence that adults use flavored e-cigarettes, which no one disputes. But the cited evidence does not substantiate petitioner's claim that flavors play an important role in "helping vapers maintain smoking abstinence and preventing relapse to smoking." A296. Indeed, petitioner acknowledges that, in a 2015 survey of 20,000 e-cigarette users conducted by the Consumer Advocates for Smoke-Free Alternatives Association, nearly a third of the respondents reported that they "started out using tobacco or menthol flavors" when they began using e-cigarettes. A296. Contrary to petitioner's suggestion (A296), the fact that those users later switched to other flavors of e-cigarettes does not show that the users would have relapsed to smoking if the other flavors had been unavailable.

Likewise, the coalition survey that the application cites indicates that tobacco-flavored or mint/menthol-flavored e-cigarettes were among the top four flavor choices for approximately 60% of the 10,000 respondents. A296. Although petitioner argued that other flavors "could serve an important role in transitioning existing adult users away from more harmful, combustible cigarette products," A296, petitioner did not cite evidence substantiating its assumption that users of other flavors would smoke combustible cigarettes if those flavors were unavailable.

C. Petitioner's assertion that it was unfairly surprised by the evidentiary showing required to market a new tobacco product, Mot. 12-14, is meritless. The TCA requires FDA to deny an application unless the manufacturer demonstrates that marketing its new product is "appropriate for the protection of the public health," and the TCA directs FDA to make that finding based on "clinical investigations by experts qualified by training and experience to evaluate the tobacco product" or other "valid scientific evidence" that FDA determines is sufficient. 21 U.S.C. § 387j(c)(5)(A). FDA evaluated petitioner's application under that standard and determined that the evidence did not support the conclusion that the

marketing of petitioner's flavored products would be appropriate for the protection of the public health.

Contrary to petitioner's contention, FDA's 2019 guidance does not and could not relax the statute's requirements. As an initial matter, the guidance explicitly stated that it provides only nonbinding recommendations based on FDA's current thinking, and that FDA will apply the TCA's standard in the adjudication of applications for premarket authorization of particular products. A62. The cases on which petitioner relies are inapposite because they involved binding agency action.

Moreover, the guidance specifically cautions that "[n]onclinical studies alone are generally not sufficient to support a determination that permitting the marketing of a tobacco product would be appropriate for the protection of the public health." A73. It explains that, although a literature review may be sufficient to support authorization in some circumstances, there would have to be "an established body of evidence regarding the health impact (individual or population) of your product or a similar product that can be adequately bridged" for that to be the case. A107. The guidance notes that, because "limited data may exist from scientific studies and analyses," A73, FDA anticipates that "applicants will

conduct certain investigations themselves and submit their own research findings as a part of their" application, A73 n.22; A92. And the guidance explains that "[i]f an application includes, for example, information on other products (e.g., published literature, marketing information) with appropriate bridging studies, FDA intends to review that information to determine whether it is valid scientific evidence sufficient to demonstrate that the marketing of a product would" satisfy the TCA's standard. A73.

Consistent with the guidance, FDA determined that the literature on which petitioner relied to demonstrate a health benefit for adult smokers (A13 n.11) was insufficient because, "in contrast to the evidence related to youth initiation—which shows clear and consistent patterns of real-world use that support strong conclusions--the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive." A45. "In fact, the findings are quite mixed and as a result the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." A46. FDA thus concluded that the evidence did not demonstrate that petitioner's flavored products present a

health benefit for adult smokers that is sufficient to outweigh the attraction of such products for youth. A46-49.[3]

D.1. Petitioner's suggestion that FDA created a "double standard" in weighing the risks and benefits of a new tobacco product, Mot. 17, is likewise meritless. Petitioner emphasizes that FDA "relied on general, non-product specific evidence for its assertions of risk to youth." *Id*. But as FDA explained, the risk that flavored products pose for youth is well documented in national studies. A40-42. Petitioner does not take issue with the comprehensive youth studies that the agency discussed, and does not dispute that underage use of e-cigarettes is a serious public health problem or that underage users are attracted by—and predominantly use—flavored e-cigarettes. FDA explained why these risks extend to refillable tank-style products with which petitioner's e-liquids are used.

[3] In denying petitioner's application, FDA noted that, because the "behavior change of interest (switching or cigarette reduction) occurs over a period of time," studies designed to observe these behaviors may "follow participants over a period of six months or longer," but that "it is also possible that studies with a shorter duration would be adequately reliable." A47 n.xxiii. The 2019 guidance likewise notes that, "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application," A74, but does not rule out the possibility that such studies will be needed to demonstrate a health benefit for a type of product that is especially attractive to youth, such as flavored e-cigarettes.

A41-42. Thus, to demonstrate that its products should nevertheless be authorized, it was necessary for petitioner to provide reliable evidence that the products present significant countervailing public-health benefits, which petitioner failed to do.

2. There is likewise no merit to petitioner's assertion that FDA's scientific review of petitioner's application "consisted of only two 'check-the-box' forms." Mot. 8. The record shows that FDA reviewed petitioner's application not only for evidence from a randomized controlled trial or longitudinal cohort study, but also for "[o]ther evidence . . . related to potential benefit[s] to adults." A21, 29; *see also* A48. It was only after determining that petitioner's application lacked such evidence that FDA concluded petitioner had failed to demonstrate that its products would provide an adequate benefit that outweighs the risks to youth. *See* A21, 29, 48-49. Petitioner's observation that FDA has acted consistently in reviewing other manufacturers' similar applications to market flavored e-cigarette products, Mot. 8, is a hallmark of good government, not a reason to fault the agency.

3. Petitioner ultimately retreats to arguing that the Tobacco Control Act *prohibits* FDA from considering the extent to which products will likely

help adults to stop smoking combustible cigarettes and the comparative impact of different flavors. Mot. 18-22. That assertion is baseless. Congress tasked FDA with using its expertise to determine whether the marketing of a new product is "appropriate for the protection of the public health," taking into account (among other things) population-based risks and benefits. In applying that standard, it is appropriate for FDA to consider whether a product is likely to help adults stop smoking and whether it poses a greater risk to youth than other products with comparable benefits. Indeed, petitioner's own application sought to satisfy the statutory standard by urging, among other things, that "flavors are crucial to getting adult smokers to make the switch and stay away from combustible cigarettes," A295; that certain survey respondents "started out using tobacco or menthol flavors but now always or almost always use other flavors," A296; and that this change in preference "has powerful implications" for "the role of flavors in helping smokers' transition from smoking to vaping" and "helping vapers maintain smoking abstinence and preventing relapse to smoking," A296.

In the denial order before the Court, FDA correctly implemented Congress's directive to determine whether the marketing of a new tobacco

product is appropriate for the protection of the public health. As discussed above, FDA found that flavored e-cigarette products present a significantly greater risk of youth initiation and use than do tobacco-flavored e-cigarette products, and the agency therefore concluded that a greater showing of health benefits for adult users of conventional cigarettes will generally be necessary to support a finding that flavored e-cigarette products are appropriate for the protection of the public health. FDA also observed that, because tobacco-flavored e-cigarettes "may offer the same type of public health benefit as flavored" e-cigarettes, "i.e., increased switching and/or significant reduction in smoking, but do not pose the same degree of risk of youth uptake," it was appropriate to consider whether "the flavored products have an added benefit relative to that of tobacco-flavored [e-cigarettes] in facilitating smokers completely switching away from or significantly reducing their smoking." A37.

That analysis is consistent with the inquiry mandated by Congress, which instructed FDA to take into account the extent to which specific products are likely to affect the health of different populations of potential users. *See* 21 U.S.C. § 387j(c)(4). That a different TCA provision allows FDA to prohibit "'characterizing flavors' in combustible cigarettes,"

Mot. 19 (quoting 21 U.S.C. § 387g(a)(2)), has no bearing on whether the marketing of petitioner's new tobacco products would be appropriate for the protection of the public health. Likewise, the separate TCA provision regarding authorization of modified-risk products has no bearing on the determination at issue here. That provision applies when a manufacturer seeks to label or advertise its product with particular claims, which petitioner has not sought to do.

CONCLUSION

The Court should deny petitioner's motion for a stay.

Respectfully submitted,

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OCTOBER 2021

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion satisfies the type-volume limitation in Rule 27(d)(2)(A) because it contains 5,045 words. This motion was prepared using Book Antiqua, 14-point font, a proportionally-spaced typeface.

/s/ Lindsey Powell
Lindsey Powell