[PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 21-13340

BIDI VAPOR LLC,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,
ACTING COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003460

No. 21-13387

DIAMOND VAPOR LLC,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003472

No. 21-13438

JOHNNY COPPER, L.L.C.,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003757

No. 21-13454

VAPOR UNLIMITED LLC,

Petitioner.

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003581

No. 21-13521

UNION STREET BRANDS L.L.C.,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003525

No. 21-13522

POP VAPOR CO. LLC,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petitions for Review of a Decision of the
Food and Drug Administration
Agency No. PM0002546

Before WILLIAM PRYOR, Chief Judge, ROSENBAUM, and BRASHER, Circuit Judges.

WILLIAM PRYOR, Chief Judge:

These petitions for review concern whether it was arbitrary and capricious for the Food and Drug Administration to issue marketing denial orders to six tobacco companies for their electronic nicotine-delivery systems without considering the companies' marketing and sales-access-restriction plans designed to minimize youth exposure and access. The Administration refused to consider the marketing and sales-access-restriction plans based on both its need for efficiency and its experience that marketing and sales-access restrictions do not sufficiently reduce youth use of electronic nicotine products. Because "agency action is lawful only if it rests 'on a consideration of the relevant factors,'" *Michigan v. Env't Prot. Agency*, 135. S. Ct. 2699, 2706 (2015) (quoting *Motor Vehicle Mfrs. Ass'n U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)), and the Administration failed to consider the relevant marketing and sales-access-restrictions plans, the marketing denial orders were arbitrary and capricious. So, we grant the petitions for review, set aside the marketing denial orders, and remand to the Administration.

I. BACKGROUND

The Tobacco Control Act of 2009 prohibits manufacturers from selling any "new tobacco product" without approval from the Food and Drug Administration. *See* 21 U.S.C. § 387j. Any tobacco

product that was not on the market as of February 15, 2007, is a "new tobacco product." *Id.* § 387j(a)(1). The Act instructs the Administration to deny applications for new tobacco products if, based on the information before it, the Administration finds "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), (2)(A). Whether a new product is "appropriate for the protection of the public health" is determined by evaluating "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." *Id.* § 387j(c)(4). To make this determination, the Administration must consider 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 using such products." *Id.*

In 2016, the Administration deemed that electronic nicotine-delivery systems using nicotine derived from tobacco—including e-liquids and e-cigarettes—were "tobacco products" within the Administration's regulatory authority. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,028 (May 10, 2016) (hereinafter *Deeming Rule*). The Administration defines e-cigarettes as "electronic device[s] that deliver[] e-liquid in aerosol form into the mouth and lungs when inhaled." U.S. FOOD & DRUG ADMIN., PREMARKET TOBACCO PRODUCT APPLICATIONS FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS: GUIDANCE FOR INDUSTRY 6 (2019) (hereinafter *2019 Guidance*). E-liquids are defined to "include liquid nicotine, nicotine-

containing liquids," and other liquids "that are intended or reasonably expected to be used with or for the human consumption of a tobacco product." *Id.*

There are two categories of e-cigarettes: open and closed. Open e-cigarettes are typically larger and require the user to re-fill a tank with e-liquid. *Id.* Closed e-cigarettes tend to be smaller and are either entirely disposable or use disposable, pre-filled cartridges. *Id.*

Because many electronic nicotine-delivery systems were already on the market by 2016, the Administration decided to stagger its evaluation of the products and allow the products to stay on the market in the interim. *Deeming Rule*, 81 Fed. Reg. at 29,009–10. The Administration explained that as it gained more experience regulating electronic nicotine-delivery systems, it expected to provide more guidance to manufacturers as to what information would be required in the premarket authorization applications to show that a product was "appropriate for the protection of [the] public health." *See id.* at 28,997. The original application deadline for flavored electronic nicotine-delivery systems was September 2018, but "a series of schedule changes implemented by the [Administration] and federal courts" moved the final deadline to September 9, 2020. *Breeze Smoke, LLC v. U.S. Food & Drug Admin.*, 18 F.4th 499, 504 (6th Cir. 2021); *accord* Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization (Revised), 85 Fed. Reg. 23,973, 23,974 (Apr. 30, 2020).

Before the September 2020 application deadline, the Administration issued nonbinding guidance, hosted public meetings, and published a proposed rule to explain to manufacturers what evidence would be required in their applications. The Administration repeatedly represented to tobacco companies that marketing and sales-access-restriction plans were relevant to its determination of whether their products were "appropriate for the protection of the public health." *See* 21 U.S.C. § 387j(c)(4). For example, at a public meeting in 2018, an Administration representative stated that one of the considerations the Administration "ha[d] used in deciding whether a [tobacco] product [wa]s appropriate for the protection of the public health" was whether "the marketing of the new [product] [would] affect the likelihood of nonuser uptake, cessation rates[,] or other significant shifts in user demographics in a manner to decrease morbidity and mortality from tobacco product use." IILUN MURPHY, PREMARKET TOBACCO PRODUCT APPLICATION CONTENT OVERVIEW, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2018), https://www.fda.gov/media/117507/download.

The Administration repeated this advice when it published final guidance on premarket authorization applications for electronic nicotine-delivery-system products in June 2019. *See 2019 Guidance*, *supra*. The Administration recommended companies include any applicable "restrictions on the sales and distribution" of their products in their applications "to help support a showing that the marketing of the product would be [appropriate for the protection of the public health]." *Id.* at 20–21; *accord id.* at 12.

The Administration communicated its expectation that companies submit marketing and sales-access-restriction plans in a proposed rule published in September 2019. The proposed rule included a requirement for applicants to submit marketing plans, including "[a]ny means by which youth-access or youth-exposure to the products' labeling, advertising, marketing, and promotion would be limited." Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566, 50,643 (proposed Sept. 25, 2019) (to be codified at 21 C.F.R. pt. 1114). The proposed rule explained that the information in an applicant's marketing plan "is critical to [the Administration's] determination of the likelihood of changes in tobacco product use behavior." *Id.* at 50,581; *accord id.* (stating that the Administration "*will review* the marketing plan to evaluate potential youth access to, and youth exposure to the labeling, advertising, marketing, or promotion of, a new tobacco product" (emphasis added)). As an example, the proposed rule stated that "heavy use of online social media to promote a tobacco product without access restrictions, as opposed to actions such as paper mailings directed only to current smokers of legal age, indicates the potential for youth to be exposed to the promotion of the product." *Id.*

In April 2020, the Administration published a guidance document about its enforcement priorities and "current thinking" on electronic nicotine-delivery systems, which detailed the most-current data on youth electronic nicotine-delivery-systems use, the enforcement measures employed by the Administration in its attempt

to curb minor use, and the considerations of the Administration going forward. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (REVISED): GUIDANCE FOR INDUSTRY 2–3 (Apr. 2020) (hereinafter *2020 Guidance*). The 2020 Guidance stated that, since 2017, the Administration had seen "an alarming increase in the use of [electronic nicotine-delivery systems] by middle and high school students." *Id.* at 6. The 2020 Guidance explained that, in response, the Administration increased enforcement against and sent warning letters to manufacturers and retailers who marketed or sold products to youth. *Id.* at 6–7. Guidance also explained that certain kinds of marketing—such as making products "resemble kid-friendly foods and drinks" or "ordinary items that may not draw the attention of adults"—"can increase youth appeal." *Id.* at 25–26; *see also id.* at 25–27 (identifying cartoon figures and entertainment media popular with children as marketing tools that increase popularity with minors). And the Guidance stated that 71 percent of current youth users reported using the products "because they come in flavors [they] like." *Id.* at 14 (internal quotation marks omitted).

The 2020 Guidance also expressed the Administration's position that "age verification alone is not sufficient to address [the youth-use] issue" and that "many youth obtain their [products] from friends or sources in their social networks." *Id.* at 44–45. The Administration stated that the policy outlined in the 2020 Guidance

"[wa]s a more appropriate means to combat youth use of, and access to, these products." *Id.* at 44. And in response to these data, the Administration explained its rationale for treating flavored, cartridge-based electronic nicotine-delivery systems different from other electronic-nicotine-delivery systems.

With respect to flavored, cartridge-based systems, the Administration explained that "focusing on how the product was sold would not appropriately address youth use of the products that are most popular among youth." *Id.* at 21. The Administration reasoned that "[t]hese products are produced on a large scale, are easy to conceal, can be used discretely, and are not the products typically produced in vape shops that mix nicotine with e-liquid flavors." *Id.* And "[g]iven the urgent need to address the dramatic rise in youth use," the 2020 Guidance explained the Administration's decision to "prioritize[] enforcement with respect to any flavored, cartridge-based [electronic nicotine-delivery system] products . . . without regard to the location or method of sale." *Id.*

But with respect to other electronic nicotine-delivery systems, the Administration explained that it "intend[ed] to prioritize enforcement for lack of marketing authorization for any" electronic nicotine-delivery system products "when the manufacturer has not taken or is not taking adequate measures to prevent minors' access to these products." *Id.* To that end, the Guidance listed "factors the [Administration] intend[ed] to consider" when deciding if a manufacturer had taken adequate precautions to avoid youth use for these other products. *Id.* at 22. Those factors included

"[w]hether the manufacturer ha[d] implemented adequate programs to monitor retailer compliance with age-verification and sales restrictions" such as hotlines for reporting noncompliant sales and mystery shopper programs; "ha[d] established and enforce[d] penalties against retailers that fail to comply with age-verification and sales restrictions"; was "us[ing] adequate age-verification technology" for online sales, such as "an independent, third-party age- and identity-verification service that compares customer information against third-party data sources, such as public records"; and was "limit[ing] . . . the quantity of . . . products that a customer may purchase within a given period of time." *Id.*

On July 9, 2021, the Administration circulated an internal memorandum instructing staff on how to evaluate the remaining applications not yet in substantive scientific review. The memorandum explained that the "Office of Science ha[d] been tasked with developing a new plan to effectively manage the remaining non-tobacco flavored [product applications] not in . . . substantive scientific review . . . in order to take final action on as many applications as possible by September 10, 2021." The Administration's "objective [wa]s to address these applications by applying a standard for evidence necessary to demonstrate an incremental benefit to adult smokers of non-tobacco flavored [electronic nicotine-delivery systems] products." To do so, the Administration adopted a "fatal flaw" approach: "the evidence necessary for this evaluation would be provided by either a randomized controlled trial . . . or a longitudinal cohort study" and "[t]he absence of these types of

studies [wa]s considered a fatal flaw, meaning any application lacking this evidence w[ould] likely receive a marketing denial order."

On August 17, 2021, the Administration circulated another internal memorandum about the standard of review for non-tobacco-flavored products for "a streamlined scientific review." The memorandum reiterated that, "most likely," the evidence that would be necessary to meet the "high burden for applicants seeking to demonstrate a potential benefit to adult smokers that could justify th[e] risk" to youth would be a randomized controlled trial or a longitudinal cohort study. (Footnote omitted.) But the new memorandum also stated that the Administration "would also consider evidence from another study design, provided that it could reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing users of flavored products with those of tobacco-flavored products." The memorandum detailed the risks to youth and potential benefits to adults justifying this standard of review.

The August 17 memorandum also addressed the marketing and sales-access-restriction plans contained within many of the applications. It acknowledged that "[l]imiting youth access and exposure to marketing is a critical aspect of product regulation." But it explained that, although "[i]t is theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced," the Administration had not yet evaluated an application that had "proposed advertising and promotion restrictions that would

decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use." The Administration also stated that it was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use [electronic nicotine-delivery systems]," so "for the sake of efficiency, the evaluation of the marketing plans in applications w[ould] not occur at this stage of review." memorandum was rescinded one week later on August 25, 2021.

On August 26, 2021, the Administration announced that it had denied authorization for 55,000 flavored products from three manufacturers in its first adjudications for the applications that progressed to substantive scientific review. Press Release, U.S. Food & Drug Admin., FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health (Aug. 26, 2021), https://bit.ly/32ehP8C. The Administration explained that it denied the applications for "lack[] [of] sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products." *Id.* It explained that the agency received applications for 6.5 million products from over 500 companies, with one company accounting for 4.5 million of the applications. *Id.* It reiterated the evidentiary standard from the rescinded August 17 memorandum: that "evidence of benefits to adult smokers for such products would likely be in the form of a randomized

controlled trial or longitudinal cohort study, although the [Administration] does not foreclose the possibility that other types of evidence could be adequate if sufficiently robust and reliable." *Id.* The Administration explained that it issued marketing denial orders "[b]ecause this evidence was absent in th[o]se applications." *Id.* And the Administration stated that it would "continue to review other premarket tobacco applications for non-tobacco flavored [products] to determine whether there is sufficient product-specific scientific evidence of a benefit to adult smokers to overcome the risk posed to youth" and that "in the absence of this evidence, the agency intend[ed] to issue a[marketing denial order]." *Id.*

Petitioners are tobacco companies that manufacture electronic nicotine-delivery system products and applied for premarket authorization before the September 2020 deadline. Bidi Vapor LLC applied for premarket authorization for eleven electronic nicotine-delivery systems called "BIDI Sticks." BIDI Sticks are disposable, closed electronic nicotine-delivery systems pre-filled with flavored e-liquid. BIDI Sticks come in eleven flavors: one tobacco and ten non-tobacco flavors. Bidi's application included product information, scientific safety testing, literature reviews, consumer insight surveys, and details about the company's youth-access-prevention measures, distribution channels, and adult-focused marketing practices. Regarding its marketing and sales-access restrictions, Bidi stated in its application that the company's "marketing strategies target only existing adult vapor product users, including current adult smokers." Toward that end, Bidi discontinued

direct sales through its website, declines to advertise anywhere other than its age-gated website and adult-only brick-and-mortar stores, and monitors its limited distribution channels for compliance with its adult-only marketing and sales policies. Bidi requires all "downstream business partners to establish and publicize a hotline for anonymous reporting of non-compliant sales and [to] implement a policy of notifying the [Administration] of retailer violations." "Bidi . . . uses a state-of-the-art authentication system to ensure supply chain security and prevent counterfeit . . . products from getting in the hands of consumers . . . [and] to safeguard against procurement by minors." And Bidi renamed the flavors of its products "to more neutral names" that would be less attractive to youth.

Diamond Vapor LLC, Johnny Copper, L.L.C., Vapor Unlimited LLC, and Union Street Brands L.L.C. applied for premarket authorization for numerous e-liquids meant for use in open-tank devices. These tobacco companies submitted survey information from their customers about smoking cessation, literature reviews, scientific studies about switching to e-cigarettes, smoking cessation, and the role of flavors, and details about its marketing and youth-access-prevention plans. For example, Diamond uses technology for its online sales that relies on public records to verify a purchaser's age. Johnny Copper implemented "Trace/Verify technology" on all of its bottles of e-liquids, which involved placing a unique QR code on each bottle connected to the driver's license of

the purchaser so that authorities can identify the purchaser if the product is later found in the possession of a minor.

Pop Vapor Co. LLC applied for premarket authorization for 132 e-liquids and 18 disposable devices. In its application, Pop submitted a literature review, a marketing plan, proposed reseller requirements, and post-market surveillance plans. Pop uses age-verification technology that uses public records for its online sales, limits its "sales channels to online retail sites with adequate online age verification software," and uses only black-and-white labeling to "minimize the visual appeal of [its] products."

Between September 1 and September 16, 2021, the Administration issued nearly identical marketing denial orders to each of the tobacco companies for their non-tobacco flavored products. The orders stated that the "key basis for [the Administration's] determination" was that "[a]ll of [the applications] lack[ed] sufficient evidence demonstrating that [the] flavored [products] will provide a benefit to adult users that would be adequate to outweigh the risks to youth." Because the Administration did not find such evidence in the tobacco companies' applications, it could not "find that permitting the marketing of [the] new tobacco products would be appropriate for the protection of the public health" and did not conduct scientific review of "other aspects of the applications."

Alongside the orders, the Administration provided Technical Project Lead Reviews for each of the applications. The Reviews explained the scope of review: an evaluation as to "whether the subject [applications] contain[ed] evidence from a randomized

controlled trial, longitudinal cohort study, and/or other evidence regarding the impact of the new products on switching or cigarette reduction that could potentially demonstrate the added benefit to adult users of their flavored [products] over an appropriate comparator tobacco-flavored [product]." Because the applications did not include such evidence, the Administration issued marketing denial orders to each of the tobacco companies for all of their flavored products. The discussion sections of the Reviews were nearly identical to the rescinded August 17 memorandum. The Reviews also included the same footnote from the August 17 memorandum explaining that the Administration did not evaluate the marketing plans "for the sake of efficiency" because the Administration was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use [electronic nicotine-delivery systems]."

Finally, the record includes the forms that Administration staff used to evaluate the authorization applications. The forms had only three criteria: whether the application included a randomized controlled trial on new product use and smoking behavior, a longitudinal cohort study on the same, or other evidence related to the potential benefit to adults of flavored products compared to tobacco-flavored products. For each of the tobacco companies' applications, the checkboxes next to the randomized-controlled-trial and longitudinal-cohort-study criteria were marked "absent," and the "[o]ther evidence" criterion was marked "N/A."

After the tobacco companies had received marketing denial orders, the Administration published its Final Rule. Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300 (Oct. 5, 2021) (to be codified at 21 C.F.R. pt. 1100 *et seq.*). Section 1114.7(f)(2) of the Final Rule explicitly requires applications to contain a "Description of Marketing Plans," which must include a description of the companies' intended audience, its plan to target that audience in its labeling, advertising, and marketing, and a discussion of how access to the new products would be restricted with respect to youth. *See* 86 Fed. Reg. at 55,419–20 (to be codified at 21 C.F.R. § 1114.7(f)(2)). The explanation accompanying the Final Rule stated that information contained in marketing plans is "necessary for [the Administration] to properly evaluate the extent of youth exposure . . . and youth access to the product" and "is directly relevant to the . . . [Administration's] consideration of the likelihood that youth will use the tobacco product and its determination that permitting the product to be marketed would be [appropriate for the protection of the public health]." *Id.* at 55,324.

In response to the marketing denial orders, the tobacco companies each timely filed petitions for review. We stayed the marketing denial orders for Bidi Vapor, Diamond Vapor, Johnny Copper, and Vapor Unlimited. Some of the petitions were consolidated before oral argument, and we consolidate the remaining petitions for decision.

II. STANDARDS OF REVIEW

We "hold unlawful and set aside agency action[s]" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2), (2)(A); *VHV Jewelers, LLC v. Wolf*, 17 F.4th 109, 114 (11th Cir. 2021). We consider only "the basis articulated by the agency itself," not "appellate counsel's *post hoc* rationalizations." *State Farm*, 463 U.S. at 50; s*ee also Dep't Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) ("An agency must defend its actions based on the reasons it gave when it acted.").

III. DISCUSSION

The "arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). "It follows that agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan*, 135 S. Ct. at 2706 (quoting *State Farm*, 463 U.S. at 43). "Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem . . . ." *State Farm*, 463 U.S. at 43. To determine if an agency considered all the "relevant factors" and "important aspect[s] of the problem," a court may look to the language of the relevant statutes, *see, e.g.*, *Michigan*, 135 S. Ct. at 2706–08 (determining whether cost was a relevant factor by interpreting the statutory phrase "appropriate and necessary") (internal quotation marks omitted), regulations, *see, e.g.*, *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1122 (9th Cir. 2012) (determining whether "groundwater

withdrawals were a relevant factor" by looking to the Endangered Species Act regulations), the administrative record, *see, e.g.*, *id.* at 1123–24 (finding support in the record of "the possible impact of ground water withdrawal on surface water levels" and concluding that "therefore . . . the Biological Opinion should have addressed it") and even "beyond the administrative record," *id.* at 1123 n.14.

To decide if a new tobacco product is "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), the Tobacco Control Act requires the Administration to consider "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," and explicitly instructs the Administration to consider 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 using such products," *id.* § 387j(c)(4). The Administration's 2019 Guidance recommended that companies include any applicable "restrictions on the sales and distribution" of their products in their applications "to help support a showing that the marketing of the product would be [appropriate for the protection of the public health], *2019 Guidance*, *supra*, at 20–21, and the Administration's 2020 Guidance included marketing and sales-access-restriction plans in the "factors the [Administration] intend[ed] to consider" when deciding if a manufacturer had taken adequate precautions to avoid youth use, *2020 Guidance*, *supra*, at 22. Although there was not a final, published regulation in effect at the time the marketing denial orders were issued in September 2021, both the proposed rule published

in 2019 and the final rule published in October 2021 identify marketing and sales-access-restriction plans as "critical," "necessary," and "directly relevant" to its determination. *See* 84 Fed. Reg. at 50,581 (proposed rule describing applicants' marketing and sales-access-restriction plans as "*critical* to [the Administration's] determination of the likelihood of changes in tobacco product use behavior" (emphasis added)); 86 Fed. Reg. at 55,324 (to be codified at 21 C.F.R. § 1114.7(f)(2)) (final rule describing the required marketing plans as including "information *necessary* for [the Administration] to properly evaluate the extent of youth exposure . . . and youth access to the product" and "*directly relevant* to the . . . [Administration's] consideration of the likelihood that youth will use the tobacco product and its determination that permitting the product to be marketed would be [appropriate for the protection of the public health]" (emphases added)). And the record includes the companies' proposed marketing and sales-access restrictions that go to the heart of the Act's requirements and the Administration's concerns about youth access to the companies' products.

The marketing and sales-access-restriction plans in the tobacco companies' applications were relevant factors to the Administration's determination as to whether marketing the companies' products would be "appropriate for the protection of the public health." *See* 21 U.S.C. § 387j(c)(2)(A). The marketing and sales-access-restriction plans bear on the statutory requirement to consider the "likelihood that those who do not use tobacco products will start using such products." *See id.* § 387j(c)(4). The many guidance

documents recommending that the companies include their marketing and sales-access-restriction plans establish that the Administration recognized the plans to be relevant to its analysis. *See 2019 Guidance*, *supra*, at 12, 20–21; *2020 Guidance*, *supra*, at 22; *Ctr. for Biological Diversity*, 698 F.3d at 1122–24. Both the proposed rule and the final rule explicitly require applicants to submit detailed marketing and sales-access-restriction plans, and the explanations accompanying the proposed and final rules identify this information as "critical," "necessary," and "directly relevant" to the Administration's analysis. *See* 84 Fed. Reg. at 50,581; 21 C.F.R. § 1114.7(f)(2); 86 Fed. Reg. at 55,324. Although neither the proposed rule nor the final rule governed this matter when the marketing denial orders issued, together they confirm that the Administration has consistently recognized that the marketing and sales-access-restriction plans are relevant factors to the determination. And the record includes marketing and sales-access-restriction plans submitted by the companies that directly address an "important aspect of the problem"—youth access to the companies' products. *See State Farm*, 463 U.S. at 43; *Ctr. for Biological Diversity*, 698 F.3d at 1123–24.

Because the marketing and sales-access-restriction plans were relevant factors and addressed "an important aspect of the problem," *State Farm*, 463 U.S. at 43, it was arbitrary and capricious for the Administration not to consider them. The Administration explicitly stated in marketing denial orders and Technical Project Lead Reviews that it did not consider the marketing or sales-access-

restriction plans in the tobacco companies' applications. It is also unclear from the record before this Court what marketing plans or sales-access restrictions the Administration considered before making the decision to ignore the plans proposed by these six tobacco companies. The footnote explaining that the Administration did not consider the marketing plans because of its experience apparently was included in every Technical Project Lead report, as it appears in every report given to the six tobacco companies here and appears in the sample report provided on the Administration's website. *See* U.S. FOOD & DRUG ADMIN., TECHNICAL PROJECT LEAD (TPL) REVIEW OF PMTAS (Sept. 17, 2021) , https://www.fda.gov/media/152482/download. So, it is unclear which applications the Administration evaluated before making the decision not to consider any marketing or sales-access-restriction plans or which marketing and sales-access proposals were included in the applications allegedly evaluated.

The Administration offers its experience as its primary excuse for its refusal to consider the marketing and sales-access-restriction plans. The Administration cites its "extensive experience with sales[-]access and marketing restrictions" and repeats its explanation from the marketing denial orders that it was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use [e-cigarettes]." (Internal quotation marks omitted.) It asserts that the tobacco companies "did not purport to propose novel measures outside of [the Administration's] experience" and points to statements made in its

2020 Guidance about how sales-access restrictions on their own had failed to reduce youth use. *See 2020 Guidance*, *supra*, at 44–45. And it argues that it "reasonably determined that consideration of [the companies'] proposed advertising and sales[-]access restrictions would not tip the balance between adult benefits and youth risks and therefore would not alter [its] conclusion."

Experience fails as a justification for ignoring the marketing and sales-access-restrictions plans. Although "[a]gencies, the [Food and Drug Administration] among them, have expertise and experience in administering their statutes that no court can properly ignore," *see Judulang v. Holder*, 565 U.S. 42, 53 (2011), reviewing courts must ensure that an agency "consider[ed] . . . the relevant factors" and made no "clear error of judgment," *id.* (quoting *State Farm*, 463 U.S. at 43). The Administration ignored the marketing and sales-access-restriction plans because the Administration had not yet evaluated an application that had "proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use" and was "not aware of access restrictions that, to date, ha[d] been successful in sufficiently decreasing the ability of youth to obtain and use [electronic nicotine-delivery systems]." But this excuse is akin to a federal district court judge refusing to hear a convicted criminal defendant at sentencing about his reformation plans or the impact on his family because, in the judge's experience, he found that those things do not matter. Like the

federal judge considering the convicted criminal's pleas at sentencing, the Administration is not required to find the marketing and sales-access-restriction plans convincing or decide that this evidence tilts the scales—but it is required to *consider* it because it is a "relevant factor[]" and "important aspect of the problem." *See State Farm*, 463 U.S. at 43 (internal quotation marks omitted).

The Administration offered an additional excuse in the Technical Project Lead Reviews for refusing to consider the marketing and sales-access-restriction plans: efficiency. The Administration seems to have abandoned that argument on appeal. But to the extent that the Administration maintains that efficiency is an adequate excuse, it is not. By definition, the requirement that federal agencies consider all "relevant factors," *see Michigan*, 135 S. Ct. at 2706 (internal quotation marks omitted), prohibits agency shortcuts. If an agency could excuse considering all the relevant factors by appealing to efficiency, the requirement would cease to have any effect.

Finally, ignoring the marketing and sales-access-restriction plans was not harmless error. The Administrative Procedure Act instructs courts to take "due account . . . of the rule of prejudicial error" when reviewing agency decisions. *See* 5 U.S.C. § 706. The Administration argues that because the tobacco companies do not purport to have proposed marketing and sales-access-restriction plans different from the measures that the Administration had previously determined were inadequate to "counter-balance" the problem of youth use, no harm flowed from the failure to consider

this evidence. But an agency decision is harmless only "when a mistake of the administrative body is one that clearly had no bearing on the procedure used or the substance of the decision reached." *United States v. Schwarzbaum*, 24 F.4th 1355, 1366 (11th Cir. 2022) (internal quotation marks omitted). It is difficult to imagine how failure to consider a relevant factor would "clearly ha[ve] no bearing on the *procedure* used or substance of the decision reached." *See id.* (emphasis added).

But even assuming that failure to consider a relevant factor could be harmless error, it was not here. The 2020 Guidance did not state that existing marketing and sales-access-restriction plans were categorically ineffective for electronic nicotine-delivery systems other than flavored, cartridge-based products. *See 2020 Guidance*, *supra*, at 21–22, 44–45. *Contra Wages & White Lion Invs., L.L.C. v. Food & Drug Admin.*, No. 21-60766, slip op. at 20–21 (5th Cir. July 18, 2022); *Prohibition Juice Co. v. U.S. Food & Drug Admin.*, No. 21-1201, slip op. at 31 (D.C. Cir. July 26, 2022). And the tobacco companies submitted marketing and sales-access-restriction plans that conformed with the recommendations for their kinds of products in the 2020 Guidance, directly addressed the concerns of youth access and popularity, and included measures not specifically mentioned in the 2020 Guidance, such as Johnny Copper's "Trace/Verify technology" and Bidi's authentication system designed to prevent counterfeit products from becoming accessible to youth. Because "the [Administration] *may* reach a different result when it" considers the marketing and sales-access-restriction

plans, "we cannot say that the [Administration's] error was harmless." *See Schwarzbaum*, 24 F.4th at 1366 (internal quotation marks omitted); *see also Shinseki v. Sanders*, 556 U.S. 396, 410 (2009) ("To say that the claimant has the 'burden' of showing that an error was harmful is not to impose a complex system of 'burden shifting' rules or a particularly onerous requirement. . . . Often the circumstances of the case will make clear to the appellate judge that the ruling, if erroneous, was harmful and nothing further need be said.").

Our conclusion that it was arbitrary and capricious for the Administration to ignore the relevant marketing and sales-access-restriction plans does not mandate a different result on remand. We acknowledge the evidence in the record catalogued by the dissent of the serious risk to youth, and it may be that the Administration will conclude on remand that the marketing and sales-access-restriction plans submitted in the tobacco companies' applications do not outweigh those risks. We do not make a moral judgment—only a procedural one. Our review of the administrative orders is limited, and we decide only that the Administration must at least consider the relevant evidence before it, which includes the companies' marketing and sales-access-restriction plans.

The crux of our disagreement with the dissent is whether it is the role of this Court or of the Administration to consider the novel marketing and sales-access-restriction plans submitted by the tobacco companies. The dissent admits that the Administration "said that" marketing and sales-access restrictions "would be

relevant," *see* Dissenting Op. at 1, and that at least some of the tobacco companies submitted novel marketing and sales-access restrictions, *see id.* at 20. But the dissent concludes that "these plans . . . do nothing to change the attractiveness to kids of using flavored vaping products," as the Administration "has found that kids generally get their vaping products from friends and their social networks, not directly from retailers." *See id.* at 18–19. But this determination is not ours to make.

"[F]ederal appellate courts . . . are not factfinders," *Holsey v. Warden, Ga. Diagnostic Prison*, 694 F.3d 1230, 1259 (11th Cir. 2012), and "a remand is the proper course unless the record permits only one resolution of the factual issue," *Pullman-Standard v. Swint*, 456 U.S. 273, 292 (1982). Because it is outside of our competency to determine what interventions make flavored vapes more or less accessible to minors, remand to the Administration is the proper remedy. *See Schwarzbaum*, 24 F.4th at 1365 ("Remand is the appropriate remedy when an administrative agency makes an error of law, for it affords the agency an opportunity to receive and examine the evidence in light of the correct legal principle." (internal quotation marks omitted)); *Pres. Endangered Areas of Cobb's Hist., Inc. v. U.S. Army Corps of Eng'rs*, 87 F.3d 1242, 1246 (11th Cir. 1996) ("[I]f the agency has not considered all relevant factors . . . the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." (internal quotation marks omitted); *cf. United States v. Phifer*, 909 F.3d 372, 386 (11th Cir. 2018) (remanding to the district court to conduct an

evidentiary hearing to determine which definitions of a scientific term in a regulation "are generally accepted within the scientific community.").

We also disagree with our sister circuits' contrary decisions in *Wages & White Lion*, slip op. at 19–24, and *Prohibition Juice*, slip op. at 29–32. For starters, we are not persuaded by our sister circuits' readings of the 2020 Guidance. Both of our sister circuits read the 2020 Guidance to make categorical statements about the efficacy and relevance of marketing and sales-access restrictions with respect to flavored electronic nicotine-delivery systems. *See Wages & White Lion*, slip op. at 20 ("[The tobacco companies] should have known that marketing plans on their own are not particularly useful. [The Administration] explained as much in its 2020 Guidance, in which it noted that youth usage continued to rise *despite* [the Administration's] 2018 efforts to curb predatory marketing . . . ."); *Prohibition Juice*, slip op. at 31 ("Yet [the tobacco companies'] plans—to require customers' self-verification of age at the point of sale and to use what they characterize as less vibrant marketing unappealing to youth—track measures the [Administration] in its 2020 [G]uidance deemed inadequate to prevent or otherwise materially limit youth access to favored [products]."). To be sure, the 2020 Guidance states that "youth usage continued to rise *despite* [the Administration's] 2018 efforts to curb predatory marketing," *Wages & White Lion*, slip op. at 20 (citing *2020 Guidance*, *supra*, at 6–9), and that "age verification alone is not sufficient to address this issue," *2020 Guidance*, *supra*, at 44. But those

observations were not the end of the Administration's analysis; they were only the beginning.

As explained above, the Administration responded to these data by setting forth two frameworks. With respect to flavored, cartridge-based systems, the Administration determined that "focusing on how the product was sold would not appropriately address youth use of the products that are most popular among youth," as "[t]hese products are produced on a large scale, are easy to conceal, can be used discreetly, and are not the products typically produced in vape shops that mix nicotine with e-liquid flavors." *2020 Guidance*, *supra*, at 21. And "[g]iven the urgent need to address the dramatic rise in youth use," the 2020 Guidance "prioritize[d] enforcement with respect to any flavored, cartridge-based [electronic nicotine-delivery system] products . . . without regard to the location or method of sale." *Id.*

But with respect to other electronic nicotine-delivery systems, the Administration explained that it "intend[ed] to prioritize enforcement for lack of marketing authorization for any" electronic nicotine-delivery system products "*when the manufacturer has not taken or is not taking adequate measures to prevent minors' access to these products*." *Id.* (emphasis added). And "[i]n assessing whether a manufacturer is taking (or has taken) adequate measures to prevent minors' access," the Administration "intend[ed] to consider" "factors . . . includ[ing] . . . [w]hether the manufacturer ha[d] implemented adequate programs to monitor retailer compliance with age-verification and sales restrictions"

such as hotlines for reporting noncompliant sales and mystery shopper programs; "ha[d] established and enforce[d] penalties against retailers that fail to comply with age-verification and sales restrictions"; was "us[ing] adequate age-verification technology" for online sales, such as "an independent, third-party age- and identity-verification service that compares customer information against third-party data sources, such as public records"; and was "limit[ing] . . . the quantity of . . . products that a customer may purchase within a given period of time." *Id.* at 22.

So, the 2020 Guidance did not express a determination by the Administration that marketing and sales-access-restriction plans for flavored electronic nicotine-delivery systems are categorically ineffective. The 2020 Guidance provided that those measures were insufficient to curb youth use of flavored, cartridge-based products based on their nature and popularity. But with respect to other kinds of electronic nicotine-delivery systems, including the flavored but not cartridge-based products submitted by the tobacco companies here, the 2020 Guidance stated that the Administration intended to consider the companies' marketing and sales-access-restriction plans. And the Administration's responses to submitted comments about the failure of marketing and sales-access restrictions to prevent youth use, are, when read in context, about flavored, cartridge-based products, not all flavored electronic nicotine-delivery systems. *Compare id.* at 42 ("[The Administration] determined that focusing on how the product was sold would not be sufficient to address youth use of these products."), *with id.* at 21

("[The Administration] determined that focusing on how the product was sold would not appropriately address youth use of the products that are the most popular among youth—*i.e.*, flavored, cartridge-based products."), *and id.* ("[The Administration] intends to prioritize enforcement for lack of a marketing authorization for any other [electronic nicotine-delivery system] products (*i.e.*, any tobacco-, menthol-, or non-flavored [electronic nicotine-delivery system] products and any non-cartridge-based, flavored [electronic nicotine-delivery system] products) when the manufacturer has not taken or is not taking adequate measures to prevent minors' access to these products . . . ."). The 2020 Guidance did not absolve the Administration of the requirement to consider the tobacco companies' youth-prevention plans.

This appeal is also different from those before our sister circuits in several ways. First, our harmless-error standard is different from the standard imposed by the Fifth Circuit. *Compare Schwarzbaum*, 24 F.4th at 1366 ("An agency decision is harmless when a mistake of the administrative body is one that clearly had no bearing on the procedure used or the substance of decision reached." (internal quotation marks omitted)), *with Wages & White Lion*, slip op. at 23 ("The burden falls on [the tobacco companies] to show that they would have received authorization had [the Administration] considered these plans."). Second, the statements made before the Fifth Circuit at oral argument by the Administration that it "review[ed] . . . a summary of the marketing plans," *Wages & White Lion*, slip op. at 22, were not made before this Court. And

third, the concessions of harmless error made before the D.C. Circuit at oral argument by the tobacco companies, *see Prohibition Juice*, slip op. at 31, were not made here. *See id.* at 35–36 (Katsas, J., concurring) ("As [the majority opinion] persuasively demonstrates, the petitioners here made no serious argument that the [Administration's] failure to consider their marketing plans was prejudicial, as required for them to obtain relief under the [Administrative Procedure Act]. . . . In joining the Court's opinion, I do not understand it to foreclose the possibility of our finding prejudicial error in other cases where manufacturers press the prejudice point more forcefully.").

IV. CONCLUSION

The petitions for review are **GRANTED,** the orders of the Administration are **SET ASIDE**, and the matters are **REMANDED** to the Administration.

ROSENBAUM, Circuit Judge, Dissenting:

SPOILER ALERT: THIS OPINION CONTAINS SPOILERS ON HOW THE U.S. FOOD AND DRUG ADMINISTRATION ("FDA") WILL RESOLVE PETITIONER VAPING-PRODUCT[1] COMPANIES' PREMARKET TOBACCO PRODUCT APPLICATIONS ON REMAND FROM THIS APPEAL.

Then again, never mind. There's nothing to spoil here. Anyone who knows all the relevant facts necessarily already knows how this one ends. On remand, the FDA will deny Petitioner Companies' applications to sell their fruit-, mint-, and candy-flavored ("flavored") vaping products.[2] The record makes that clear. I would not waste everyone's time and money with a remand. The Majority faults the FDA for not considering the Companies' proposed restrictions on kids' use. And to be sure, the FDA said that factor would be relevant. But even assuming that the FDA erred when it didn't consider the Companies' proposed marketing and

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[1] The industry and the FDA refer to vaping products as electronic-nicotine-delivery-system ("ENDS") products. Because ENDS products are commonly known as "vaping products," that is the term I use in this dissent.

[2] To be clear, I use the term "flavored" to refer to vaping products with flavors like fruit, mint, and candy—in other words, nontraditional tobacco-product flavors. Vaping-product companies also make tobacco-flavored products. I do not include tobacco-flavored products in my defined term "flavored" vaping products. Rather, I refer to them distinctly as "tobacco-flavored."

access-restriction plans, the FDA's framework for evaluating premarket tobacco product applications leaves no room for doubt that the FDA will deny—in fact, under the Family Smoking Prevention and Tobacco Control Act, must deny—the applications on remand. To paraphrase the Borg,[3] then, remand is futile.

Here's how we know: The FDA has established that the sale of flavored (as opposed to tobacco-flavored) vaping products amplifies the risk that kids will start vaping and—because vaping has been shown to be a gateway to smoking combustible cigarettes—smoking. Yet at the same time, there's no reliable evidence that flavored vaping products offer any real advantage over tobacco-flavored vaping products in helping existing smokers quit or reduce their habits. Nor, despite years of trying (and consideration of various creative programs), has the FDA been able to identify any marketing or access restrictions that work in a meaningful way to prevent kids from obtaining flavored vaping products in the first place. In fact, the FDA has concluded that access restrictions at points of sale do not work because most kids get their vaping products through friends or their social networks.

So the FDA has stated that applications that don't reliably establish that flavored vaping products impart an advantage over tobacco-flavored vaping products in decreasing smoking among

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[3] *See* https://nerdist.com/article/star-trek-history-of-the-borg/ (last visited Aug. 10, 2022).

existing smokers, or that don't include marketing plans and access restrictions for kids that significantly cut off all avenues for kids to obtain these products will be denied because they are not appropriate for the protection of the public health. And the Tobacco Control Act requires the FDA to deny any application that is not appropriate for the protection of the public health.

Here, none of the Companies' applications include reliable evidence that flavored vaping products offer an advantage over tobacco-flavored vaping products in decreasing smoking among existing smokers. And while some applications suggest some new ways to reduce kids' access to flavored products, none contain marketing and access plans that provide new methods (that the FDA has not already considered and found wanting) that significantly decrease kids' access to their flavored products through all avenues kids use to obtain the products. But the FDA's evidence shows that when companies apply pressure to one aspect of the current access system, youth simply flock to other avenues to obtain flavored vaping products. So the FDA has made it clear that applications like the ones here—which fail to offer new plans that significantly curtail youth access across all avenues of obtaining flavored products—cannot be appropriate for the protection of the public health and must be denied.

When, as here, the outcome on agency remand is "not seriously contestable," remanding "would be an idle and useless formality." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6

(1969) (plurality opinion). The Administrative Procedure Act authorizes the denial of a petition for review under these circumstances because any error the agency may have committed is then, by definition, harmless. And as the Supreme Court has expressly explained—and contrary to the Majority Opinion's contention—"the ruling in [*SEC v. Chenery Corp.*, 318 U.S. 80 (1943),] [does] not require[] [us] to remand in futility." *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 756 n.7 (1986), *overruled on other grounds by Planned Parenthood of Se. Penn. v. Casey,* 505 U.S. 833 (1992).

I see no point in sending these petitions back for the FDA to do what everyone paying attention here knows that, under the framework the FDA has established for evaluating whether a new flavored vaping product is appropriate for the protection of the public health, the FDA will and must do: deny the applications. Engaging in this futile activity only delays the inevitable—and in the process imposes unnecessary time, effort, and financial costs on all involved. I therefore respectfully dissent.

I divide my discussion into two parts. In Section I, I set forth the facts in the administrative record that show that the FDA will deny these applications on remand. In Section II, I explain why, assuming without deciding that the FDA erred in denying the applications without reviewing the marketing and access plans, remand is not appropriate.

I.

A. The Regulatory Framework

Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Act") in 2009. In so doing, Congress wanted to be sure its intent in passing the law was clear. So as part of the legislation and so no confusion could exist, Congress made legislative findings of fact. Foremost among those factual findings, Congress determined that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions . . . ." 21 U.S.C. § 387 Findings at ¶ (1). It followed up, noting that "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products." *Id.* ¶ (4); *see also id.* ¶ (31) ("An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18.").[4]

Besides these findings, Congress attributed the problem of underage use of tobacco products largely to the tobacco industry's marketing practices. Recounting that, in 2005, manufacturers "spent more than $13 [billion]" on advertising, marketing, and

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[4] Among other evidence, the FDA conducted a study in 1996 and found that, at that time, 82% of all adults who had ever smoked had their first cigarette before they turned 18. *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 272 (D.C. Cir. 2019) (citing Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996)).

promotion of their products, Congress found that these efforts were "especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." *Id.* ¶¶ (16), (15); *see also id.* ¶ (31) ("Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products."). For these reasons, Congress concluded that "[i]t [was] in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry." *Id.* ¶ (29).

Because the window for starting to use tobacco products is open widest for younger users, Congress reasoned, if that window were closed, many would-be younger users would never begin using tobacco products. Indeed, Congress theorized that even if better control of access to tobacco products for youth reduced the products' use by minors by only 50%, that would "sav[e] over [3 million] of them from premature death due to tobacco-induced disease." *Id.* ¶ (14). And at least as of the time Congress enacted the Act, it figured that cutting minors' use of tobacco products in half "would also result in approximately [$75 billion] in savings attributable to reduced health care costs." *Id.* No doubt that figure is considerably higher now.

Congress also expressly identified the problem that "products that purport to reduce the risks to the public of tobacco use" but actually do not, present to creating new tobacco-product users. *Id.* ¶ (37).

To address these problems, through the Act, Congress required manufacturers to submit all new tobacco products for FDA review and approval before they could be marketed in interstate commerce. *See* 21 U.S.C. § 387j. The Act imposes strict limitations on new tobacco products the FDA can approve for marketing. More specifically, the Act prohibits the FDA from approving any such application when "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). And it defines this standard as requiring a showing "with respect to the risks and benefits to the population as a whole, including users and nonusers" of the new product. *Id.* § 387j(c)(4). That showing must account for both "the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.*

Put simply, for a new product to be appropriate for the protection of the public health (and therefore even be eligible to obtain FDA approval), the Act requires the applicant to show that, on balance, the new product will result in more existing product users (like smokers) stopping or meaningfully drawing back their usage than existing nonusers becoming users. On its face, this equation prioritizes Congress's concern to shut down tobacco-product usage as a "pediatric disease of considerable proportions."

Enter vaping products. Believe it or not, Joseph Robinson filed a patent for the first e-cigarette design nearly a century ago—in 1927.[5] But it wasn't until the 2000s that vaping products began to be sold in the United States and hit the bigtime here.[6]

Under the authority the Act gave it, the FDA issued a final rule, effective August 2016, in which it deemed vaping products to be "tobacco products." *See* Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at C.F.R. pts. 1100, 1140, 1143) ("Deeming Rule").[7] As a result, products that were not on the market as of February 15, 2007, became subject to the Act. *See id.* at 28,978. But in exercising its discretion, the FDA announced that it wouldn't enforce the Act against those vaping products for certain

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[5] Hilary Brueck, Insider, *The Wild History of Vaping, From a 1927 'Electric Vaporizer' to Today's Mysterious Lung Injury Crisis* (Nov. 12, 2019), *available at* https://www.insider.com/history-of-vaping-who-invented-e-cigs-2019-10#in-1927-joseph-robinson-dreamed-up-what-might-be-the-very-first-electric-vaporizer-a-device-he-said-was-for-medicinal-compounds-2 (last visited Aug. 16, 2022).

[6] *See id.*

[7] That final rule is not at issue, and our sister circuits that have considered the issue have upheld the rule. *See*, *e.g.*, *Nicopure Labs*, 944 F.3d at 293 (upholding final rule against challenges under the Administrative Procedure Act and the First Amendment); *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436 (5th Cir. 2020) (upholding final rule against nondelegation-doctrine challenge).

delineated periods to allow for the development of more information about the products. *See id.*

Ultimately, companies wound up having until September 9, 2020, to submit their applications for premarket review of their vaping products and establish that the marketing of those products was "appropriate for the protection of the public health." *Breeze Smoke, LLC v. U.S. Food & Drug Admin.*, 18 F.4th 499, 504 (6th Cir. 2021); *accord* Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization (Revised), 85 Fed. Reg. 23,973, 23,974 (Apr. 30, 2020) ("2020 Guidance").

B. The Underage Vaping Problem

In the meantime, though, the FDA learned a lot more about vaping. It turns out that vaping dishes out a double-whammy of detrimental health effects on kids who engage in it: (1) vaping itself has been associated with direct and profound health consequences, including, among others, "the development of acute or chronic lung injuries" and even death (not to mention battery explosions from vaping products),[8] and (2) those who vape are substantially

[8] And nicotine in vaping products can permanently harm developing adolescent brains and can "induce short and long-term deficits in attention, learning, and memory." Bidi Vapor Technical Project Lead Rev. ("Bidi TPL"), at 8; Diamond Vapor Technical Project Lead Rev. ("Diamond TPL"), at 8; Johnny Copper Technical Project Lead Rev. ("Johnny Copper TPL"), at 8; Vapor Unlimited Technical Project Lead Rev. ("Unlimited TPL"), at 8; Union Street

more likely to become smokers of combustible cigarettes, which in turn inflict significant adverse health consequences of their own. 2020 Guidance at 9, 13, 29; *see also* Bidi TPL[9] at 8 ("A 2017 systematic review and meta-analysis that summarized nine prospective cohort studies found significantly higher odds of smoking initiation . . . among youth who had used [vaping products] a[s] compared to youth who had not . . . . The 2018 NASEM report concluded that there is substantial evidence that [vaping-product] use increases risk of ever using combusted tobacco cigarettes among youth and young adults."); 9 ("Two studies found associations between [vaping] and self-reported history of asthma, chronic bronchitis, emphysema, or chronic obstructive pulmonary disease . . . ."); *see also* Diamond TPL at 8–9; Johnny Copper TPL at 8–9; Unlimited TPL at 8–9; Union TPL at 8–9; Pop TPL at 8–9.

Flavored vaping products in particular play an outsized role in the problem of kids' vaping. In fact, among kids between the ages of 12 and 17 who have reported vaping, nearly all—93.2%—have said that they had their first vaping experience with a flavored product. 2020 Guidance at 14. Perhaps that's no surprise, given that many companies (including some Petitioners here) name their flavors things like Rainbow Nerds, Captain Loopy, Berry Gogurt,

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Technical Project Lead Rev. ("Union TPL"), at 8; Pop Vapor Technical Project Lead Rev. ("Pop TPL"), at 8.

[9] "TPL" is short for "technical project lead review," which is what the FDA calls its evaluation of a premarket tobacco application.

Nanner Puddin, Scrumdiddlyumptious, Teacher's Pet, Cap'n Crunk, and Blue Razz Cotton Candy[10]—which seem designed to appeal to kids. Not only do most kids have their first vaping experience with flavored products, but flavored vaping products remain "extraordinar[ily] popular[]" with kids even after that first introduction. 2020 Guidance at 13–14. Indeed, kids "overwhelmingly" use flavored vaping products, *id.* at 24, and are "more likely to use flavored [vaping products] than adult [vapers are]," Bidi TPL at 12; Diamond TPL at 12; Johnny Copper TPL at 12; Unlimited TPL at 12; Union TPL at 12; Pop TPL at 9.

As the problem with youth vaping began to come into focus in 2018, the FDA tried to solve it with a two-pronged approach: (1) regulatory actions against manufacturers and retailers who marketed and sold to kids and (2) direct enlistment of vaping-product manufacturers to reduce youth interest and access. 2020 Guidance at 6–7. To accomplish the second part of this approach, the FDA asked manufacturers to submit plans to "address minors' access to and use of [their] products." *Id.* at 7.

As directed, manufacturers responded by introducing various programs intended to safeguard against underage use of their products. *See id.* As a sampling, they tried things like mystery shopper programs that monitored retailer compliance with age-

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[10] Readers may notice that some of these names seem to allude to—or outright invoke—breakfast cereals, snacks, and candies marketed to kids.

verification and sales restrictions, contractual penalties for retailers who sold vaping products to kids, age-verification and identity-verification services for sales over websites, and limiting single-purchase quantities. *Id.*

Nothing worked. And here's why, in large part: as the FDA explained in its 2020 Guidance, "many [kids] obtain their [vaping products] from friends or sources in their social networks." *Id.* at 44–45. So "age verification," "focusing on how the product [is] sold, . . . legal prohibitions, and . . . voluntary actions by some manufacturers" are "not sufficient to address youth use of these products, given the many sources of products available for youth access." *Id.* That's an important point: the FDA announced in its 2020 Guidance that it had concluded, after studying the problem for years, that sales-access restrictions and marketing plans just aren't enough to protect against youth use.[11]

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[11] The FDA reiterated this point at oral argument: its 2020 Guidance concludes that sales-access restrictions and marketing plans aren't sufficient to protect youth. Oral Argument, Case No. 21-13522, at 22:49–23:12. As the FDA emphasized, "The problem here is that when you limit who you can sell e-cigarettes to—for instance, only sell them to adults with very good ID—the problem is that kids often get e-cigarettes from friends or family, and so limiting just who you sell an e-cigarette to is not going to be enough to mitigate that substantial risk to kids from flavored e-cigarettes." *Id.* at 22:08–22:28. The FDA then confirmed, "FDA's saying that sales-access restrictions and advertising restrictions, although they certainly can be helpful, they themselves are not sufficient to mitigate the substantial risk to kids when you have this scientific consensus on a substantial risk to kids, and you have a lack of a showing

Indeed, despite companies' marketing and access-restriction efforts in response to the FDA's attempts to stem the underage-vaping problem, underage vaping instead accelerated. *See id.* at 8. By 2019, youth vaping had hit the highest levels recorded until then. *Id.* Between 2017 and 2019, vaping more than doubled among middle-school and high-school students, reaching levels of 10.5% of middle-school students and 27.5%—more than a quarter—of all high-school students. *Id.* at 12. In absolute numbers, that's more than 5 million kids. *Id.*

To state the obvious, youth vaping had reached crisis proportions. And the FDA came to the well-supported conclusion that marketing plans and access restrictions alone were not solving the problem.

But it wasn't all bad news. It turns out that vaping products may help existing smokers to quit or switch to vaping, which is less detrimental than smoking. *See* Bidi TPL at 10; Diamond TPL at 10; Johnny Copper TPL at 10; Unlimited TPL at 10; Union TPL at 10; Pop TPL at 10; *see also* FDA Technical Project Lead Rev. for Apps. Submitted by R.J. Reynolds Vapor Co. (Oct. 12, 2021) ("R.J. Reynolds TPL"), at 4. And in the existing-smoker population, "the most preferred flavor . . . [is] the tobacco . . . flavor compared to

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of a benefit, marketing plans, including sales-access restrictions and advertising restrictions, they can't close the gap." *Id.* at 22:49–23:12.

non-tobacco flavors (e.g., mint, nectar, and tropical)." R.J. Reynolds TPL at 4.

It's just that studies don't reveal significant added benefits that flavored products offer over tobacco-flavored products in this regard. *See* 2020 Guidance at 38; *see also* Bidi TPL at 11 ("[T]he evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive.[] In fact, the findings are quite mixed and as a result the literature does not establish that flavors differentially promote switching amongst [vaping product] users in general."); Diamond TPL at 11; Johnny Copper TPL at 11; Unlimited TPL at 11; Union TPL at 11; Pop TPL at 11–12; *see also* R.J. Reynolds TPL at 20 ("[F]indings from the applicant's likelihood-of-use study suggest that current established cigarette smokers are more likely to prefer original (tobacco) flavor relative to other flavors . . . ."). In other words, the FDA was aware of no reliable evidence showing that existing smokers who used vaping products to quit or reduce their smoking would decide not to use vaping products in that way if manufacturers sold only tobacco-flavored vaping products.

Yet while the evidence did not show that the flavored vaping products made any significant difference to whether existing smokers would quit, those products played the starring role in introducing a whole new generation to the dangers of vaping and smoking. *See* 2020 Guidance at 14; *see also* R.J. Reynolds TPL at 4 ("Existing evidence consistently indicates that use of tobacco-flavored [vaping

products] is less common compared to . . . flavored [vaping products] among youth."), 17 (noting that research showed that "the prevalence of tobacco flavor was 2.9% among 10th and 12th graders"[12]). And on top of that—and despite the manufacturers' repeated and concentrated efforts—no manufacturer to that point had devised a marketing or sales-access plan that slashed youth vaping.

C. The FDA's Denial of the Petitioners' Applications

To sum up, the FDA tried to address the underage vaping problem by cutting it off at what it originally believed to be the source: manufacturers and retailers of vaping products. But the FDA discovered that access restrictions do not work because kids often get their vaping products from friends and through their social networks—not directly from manufacturers or retailers.

For this reason, the FDA recognized that the very existence of flavored vaping products themselves is the problem when it comes to kids' use: as long as the products exist, kids will get their hands on them. So without an effective means of making the products significantly less attractive to kids, no sales-access restrictions or marketing plans matter. Indeed, the FDA's efforts to solve the problem of kids' use by securing the cooperation of the

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[12] Ninth- and eleventh-graders were not included in the survey. *See* https://nida.nih.gov/research-topics/related-topics/trends-statistics/infographics/monitoring-future-2020-survey-results (last visited Aug. 10, 2022).

manufacturing companies failed. But in the meantime, the FDA learned that flavored vaping products in particular are what kids find attractive about vaping and that no reliable evidence to date shows that those products offer any significant advantage over tobacco-flavored vaping products when it comes to cessation or meaningful reduction of existing smokers' smoking.

So after a few years of learning these things the hard way, by the time the September 2020 deadline for filing applications for premarket approval for the marketing of vaping products came around, the FDA found itself left with a no-brainer under the Act's appropriate-for-the-protection-of-the-public-health standard. On one side of the equation, flavored vaping products overwhelmingly inspired a new generation to take up vaping and (and then smoking). And on the other side, the companies that sought approval of those flavored products could not establish any significant benefit over tobacco-flavored vaping products in helping existing smokers quit or meaningfully reduce their smoking. Given that situation, the plain text of the Act required the FDA to conclude that—barring some new evidence that meaningfully altered either (or both) of these circumstances—flavored vaping products were not appropriate for the protection of the public health. After all, they did not come close to having a net positive effect on the public health. Just the opposite.

That brings us to the Companies' applications for premarketing approval. Only those aspects of these applications that

concern flavored vaping products are at issue. The Companies' applications included marketing and sales-access restriction plans. Those plans identified some strategies aimed at reducing youth use, such as eliminating kid-friendly advertising and labeling, using age-gated websites to sell the Companies' vaping products, and limiting the quantity of vaping products that one person could purchase at a time. Bidi Vapor's marketing plan also showed it had ceased selling its vaping products directly to consumers online through its website. And Johnny Copper's showed it planned to implement a program called "Trace/Verify" to identify the adult purchaser of its vaping product if that product ended up in the hands of a kid. In other words, all the Companies' applications included only marketing and sales-access restrictions plans—the same types of plans that the FDA had already announced in its 2020 Guidance were not enough to mitigate the dangers that flavored vaping products present to kids.

So not surprisingly, the FDA denied the Companies' applications, despite their inclusion of these marketing and access-restriction strategies. When it denied the applications, the FDA noted in the TPLs for each Company that "[l]imiting youth access and exposure to marketing is a critical aspect of product regulation." Bidi TPL at 11 n.xix; Diamond TPL at 11 n.xix; Johnny TPL at 11 n.xix; Unlimited TPL at 11 n.xix; Union TPL at 11 n.xix; Pop TPL at 9 n.xxii.

Yet, the FDA observed, in its extensive experience reviewing marketing plans and access restrictions, it had yet to see anything that worked to decrease the allure of vaping to kids and kids' access to vaping products "such that the risk for youth initiation would be reduced." *Id.* And given "the substantial concerns, and supporting evidence" about kids' pervasive use of flavored vaping products, the FDA reasoned that, without any reliable evidence "to address and counter-balance" that problem (meaning kids would not use the flavored vaping products under review or the products would provide a meaningful enough (or even any) proven advantage over tobacco-flavored vaping products in helping existing smokers quit so as to "counter-balance" kids' use), the Companies' marketing and sales-access-restriction plans, in the real world, could never be enough. *Id.* [13] So, the FDA opined, there was no point in reviewing them.

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[13] The complete text of the footnote that the FDA included in each TPL providing this information stated,

> Limiting youth access and exposure to marketing is a critical aspect of product regulation. It is theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced. However, to date, none of the ENDS PMTAs that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use. Similarly, we are not aware of

Assuming without deciding that the FDA erred in not evaluating the Companies' marketing and sales-access-restriction plans, then, the question we must consider is whether the FDA's review of these things in the Companies' applications could possibly matter to the FDA's new decision if we remand.

We know the answer to that: It couldn't. The record unmistakably shows the futility in remanding.

We know this because, as the FDA recounted in its 2020 Guidance, the FDA's experience already shows that nearly all the marketing plans and access restrictions the Companies submitted have a proven track record of failing to make any significant headway in the reduction of kids' use of flavored vaping products. For example, FDA's 2020 Guidance explained that it had already issued warning letters to retailers using kid-friendly advertising—but stopping that advertising wasn't enough to eliminate kids' interest in vaping. The Guidance also specifically referenced age-gating websites and limiting the quantity of vaping products sold to a single customer as "potential safeguards" that FDA thought, in 2018, could help. But by 2020, the data revealed that these types of fixes

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> access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS. Accordingly, for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review, and we have not evaluated any marketing plans submitted with these applications.

were not effective in preventing the real-world problem of keeping kids from obtaining vaping products.

As for any novel access-restriction plans the Companies submitted, there were only two among all the Companies' plans: Bidi proposed not to sell its products online at all, and Johnny Copper proposed its "Trace/Verify" strategy. But these plans—admirable as they may be—do nothing to change the attractiveness to kids of using flavored vaping products. And as the FDA has established its framework for evaluation of the premarket applications, that's where the heart of the problem lies, since the FDA has found that kids generally get their vaping products from friends and their social networks, not directly from retailers. It is that finding that, in the absence of evidence showing that flavored vaping products significantly contribute to smoking cessation among existing smokers—drives the conclusion that the marketing of flavored vaping products is necessarily not appropriate for the protection of the public health. So there can be no question that, on remand, the FDA will again deny the Companies' applications. Indeed, the TCA requires it to do so.

II.

Given that we know the FDA will again deny these applications on remand, we must consider whether we must remand them to the FDA, anyway. We need not. And on this record, we should not. Remanding here ensures wasted time, energy, and money.

The Administrative Procedure Act requires courts to "du[ly] account" for "the rule of prejudicial error" when considering whether to remand matters to the deciding agency. 5 U.S.C. § 706. In other words, if it's clear from the record that correcting the FDA's error would not change the outcome of the Companies' applications, the error did not result in "prejudicial error," and remand is not warranted.

As I've explained, that's precisely the case here. Remand is futile.

The Majority Opinion relies on *United States v. Schwarzbaum*, 24 F.4th 1355, 1367 (11th Cir. 2022), to reach the opposite conclusion. But *Schwarzbaum* itself acknowledged that the remand rule from *Chenery*, 318 U.S. 80, "does not require courts to remand in futility." 24 F.4th at 1367 (quoting *Ridgewood Health Care Ctr., Inc. v. NLRB*, 8 F.4th 1263, 1276 (11th Cir. 2021)). Judge Posner, relying on the words of Judge Friendly, has explained why: "*Chenery* was intended only to establish the important point that a reviewing court could not affirm an agency on a principle the agency might not embrace." *Illinois v. ICC*, 722 F.2d 1341, 1349 (7th Cir. 1983) (internal quotation marks omitted). As Judge Posner and Judge Friendly have further noted, *Chenery* was "not [intended] to require the tedious process of administrative adjudication and judicial review to be needlessly dragged out while court and agency engage in a nigh endless game of battledore and shuttlecock with respect to subsidiary findings." *Id.*

The Majority Opinion disagrees. *See* Maj. Op. at 27–28. It asserts that this dissent makes "fact[ual] find[ings]" and suggests I engage in a "moral judgment." *Id.* at 30, 29.

But as the administrative record reflects, that's just not accurate. Rather, as I've shown above, the administrative record itself unambiguously reveals that, as of the time the FDA denied the Companies' petitions, it had concluded that (1) eliminating advertising and labeling overtly to attract kids didn't stop kids' demand for and access to vaping products; (2) strategies like age-gating websites and monitoring retailers' sales also didn't cease the youth-vaping problem because kids get their vaping products from older friends and through their social networks (not through buying them online or at a store), anyway; and (3) it was primarily the flavoring itself in the vaping products that attracted kids. In the FDA's own words from its 2020 Guidance "age verification," "focusing on how the product [is] sold, . . . legal prohibitions, and . . . voluntary actions by some manufacturers" are just "***not sufficient*** to address youth use of these products, given the many sources of products available for youth access." 2020 Guidance at 44–45 (emphasis added). It's hard to imagine the FDA could have been any clearer.

All these things will still be true on remand. And as I've discussed, nothing in the Companies' petitions neutralizes or meaningfully otherwise addresses these problems. So the FDA's conclusions about the source of the youth vaping problem and the inefficacy of marketing and sales-access-restriction plans in resolving this

problem *necessarily require* the FDA to deny the Companies' marketing applications, as currently composed, on remand. When, as here, "only one conclusion [by the agency] would be supportable," we have recognized that remand is futile. *Schwarzbaum*, 24 F.4th at 1367. And when the FDA does what we know it will—indeed, must—do, the Companies will be back here again on appeal, and we will have no choice but to deny their petitions then.

Put simply, the FDA's analysis of the problem up through its denial of the Companies' applications—an analysis that is entirely unaffected by anything in the Companies' marketing and access-restriction plans[14]—leaves no doubt that remand is an exercise in futility. And it's not because the FDA has supposedly changed its analysis or because I have allegedly made factual findings. Rather, remand is futile *because of* the FDA's analysis of the problem of kids' use of flavored vaping products and *because of* the FDA's

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[14] To illustrate just how little effect the marketing plans will have on FDA's analysis on remand, I've attached as an appendix two of the "plans" that FDA will now have to review. One is Union Street's "Youth Prevention Policy," a five-page document that suggests youth-prevention strategies such as "check[ing] for proof of age for any customer who is attempting to purchase vapor products." The other is Pop Vapor's "Marketing Plan," which, in all of four pages, states its position that its "products should only be sold to, and used by, adults age 21 and older." It's not that these statements take a position contrary to the FDA's view that vaping products are dangerous for kids. But these "marketing plans" aren't exactly groundbreaking. And on this record, it's clear that they aren't capable of changing FDA's mind about the dangers of youth use of and access to vaping products.

findings of fact about the inefficacy of marketing plans and sales-access restrictions, and its related findings of fact about where kids get their products from.

So it's wrong to describe my analysis as "fact[-]find[ing]" or some type of "moral judgment." Maj. Op. at 30, 29. Rather, my analysis is a straight-forward application of the administrative record here. And that administrative record belies all the mischaracterizations of this dissent that the Majority Opinion engages in.

I am also not the first to conclude that remand of applications for flavored vaping products is futile. Both the Fifth and the District of Columbia Circuits have likewise held that remand to the FDA under circumstances like these is not appropriate under the Administrative Procedure Act's harmless-error provision. *See Wages & White Lion Invs., L.L.C. v. FDA*, ___ F.4th ___, No. 21-60766, 2022 WL 2799797, *11 (5th Cir. July 18, 2022); *Prohibition Juice Co. v. FDA*, ___ F.4th ___, No. 21-1201, 2022 WL 2920823, *12-14 (D.C. Cir. July 26, 2022); *see also id.* at 15 (Katsas, J., concurring). For good reason.

We should not engage in what we all know will be an exercise in futility. On this record, the Majority Opinion's decision to remand when it's clear that the FDA's decisional framework requires denial of the Companies' applications unnecessarily clogs the administrative process and increases the costs to all concerned. I respectfully dissent.

APPENDIX

Youth Prevention Policy for Union Street Brands LLC

Union Street is committed to doing our part in preventing underage use of ENDS products in our local and worldwide communities. As this Youth Prevention Policy will demonstrate, we have implemented thorough methods of preventing youth access to Union Street's e-liquid products.

I. Vapor Sales Policy and Procedure

Union Street has spent a significant amount of time and resources to ensure that the company is doing everything it can to prevent youth access to our products. Union Street prohibits entry of minors into our locations. We require ID verification for all purchases. All employees undergo thorough training on our age verification procedures.

Each employee has a moral, ethical and legal responsibility to refuse to sell vapor products to anyone under the age of 21. Vapor products must not be sold to anyone under the age of 21. We require all employees to check for proof of age for any customer who is attempting to purchase vapor products.

a. Verify the customer's age before selling vapor products.

The customer must have an acceptable and valid Driver's License, Non Driver ID, or Commercial Driver's License to purchase tobacco products. All wholesale customers must provide valid identification including but not limited to photo identification and tax identification documentation.

b. Other points

It is illegal for a minor to purchase vapor products for anyone for any reason. A minor may not purchase these products for a parent. It is illegal for an adult to purchase these products for a minor. Never sell vapor products to anyone if you have reason to believe they are going to give them to someone under the age of 21. Remember, no one under 21 may possess vapor products of any kind.

c. Training

Upon beginning employment, all employees will receive training to ensure that they understand all state laws and company policies regarding the prohibition against selling tobacco products to minors.

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II. Online E-Commerce Age-Restrictions

Online sales are restricted to adults following age verification through independent, third-party agencies using public records databases. Union Street e-commerce platform (www.mamaseliquid.com) utilizes third-party age verification technology through AgeChecker.net.

a. Age Restriction. Company product sales must comply with all county, city, and state age restriction laws for e-vapor product purchase.

b. Age Verification. Online company product sales are restricted to adults age verified by independent third-party companies using public records databases.

c. Attempt to match the name, address and date of birth provided by the customer to information contained in records in a database of individuals whose age has been verified to be 21 years or older by reference to an appropriate database of government records kept by the distributor, a direct marketing firm, or any other entity.

d. Verify that the billing address on the check or credit card offered for payment by the purchaser matches the address listed in the database.

e. If unable to verify that the purchaser is 21 years of age through the above, require the customer or recipient to submit an age-verification kit consisting of an attestation signed by the customer that he or she is 21 years of age or older and a copy of a valid form of government identification.

f. Verify that the billing address on the check or credit card provided by the consumer matches the address listed in the form of government identification.

g. Deliver only to the purchaser or recipient's verified billing address on the check or credit card used for payment. Delivery to a post office box address is prohibited.

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III. Child Resistant Packaging

Union Street's open-system e-liquid products will use child resistant packaging in compliance with the Child Nicotine Poisoning Prevention Act of 2015. Union Street Utilizes the following Child Resistant Packaging:

Package Types:

30ml - Glass Dropper Bottle with child resistant 20/400 cap-closure and tamper evident seal. *The 30ml Bottle 20/400 Closure fulfills the requirements for a Poison Prevention Package as per the current Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.*

60ml - Chubby Gorilla CGUB1-60MLV3 PET plastic bottles with Child Resistant Cap (CRC) child resistant cap and tamper evident seal/bands. Include flow restriction tips. *CGUB1-60MLV3 models were tested using the PPPA standards and they meet effectiveness specifications (16 CFR 1700.15(b)) when tested by 16 CFR1700.20 methods. These models were also tested using the Child Nicotine Poisoning Prevention Act (CNPPA) protocols set forth by CPSC and all meet the requirements for nicotine flow restriction.*

IV. Appropriate Marketing and Packaging

1. As a member of the Vapor Technology Association (VTA), Smoke Free Alternatives Trade Association (SFATA), and Florida Smoke Free Association (FSFA), we adhere to their strict marketing guidelines. VTA Marketing Standards for Membership are based on the following core principles:

   a. VTA is committed to educating and informing its members on the best ways to comply with applicable laws and regulations governing electronic cigarettes, vaporizers and related electronic nicotine delivery systems ("Vapor Products"), which laws include, but are not limited to, the Federal Food Drug & Cosmetic Act (21 USC Ch. 9 et seq.) as modified by the Family Smoking Prevention and Tobacco Control Act and 21 CFR Parts 1100, 1140 and 1143 (Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, May 10, 2016) (the "Tobacco Control Act")and the Child Nicotine Poisoning Prevention Act of 2015, 15 U.S.C. §§ 1471, et seq.

   b. Vapor Products are for adults only and should not be intentionally marketed to, sold to or used by those who have not attained the age of 21 years (or the appropriate age restriction within the subject territory) ("Minors").

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   c. VTA Members' marketing activities must refrain from knowingly marketing Vapor Products to Minors, which is strictly prohibited.

2. Our social media accounts are age restricted to 21+, meaning that no one under the age of 21 can view them.

3. Our website utilizes an age gate which requires users to confirm they are of legal vaping age (21+) before viewing the site.

4. Our packaging is never labeled in a way that is misleading or resembles copyright protected or kid-friendly food products.

5. Our vapor products do not include content which is directed towards Minors.

6. Our marketing of vapor products is not directed at Minors and no channel of marketing is employed if more than 15% of its audience is Minors. This restriction includes, but is not necessarily limited to, TV, print and radio advertising, as well as event marketing or sponsorships. Our advertising is limited to radio stations whose target market is age 25 and up. *(Note: Union Street does not utilize TV, print, or radio advertising.)*

7. Our vapor products do not use in commerce names, imagery or designs that intentionally mimic, play upon, invoke or otherwise infringe upon existing trademarks, trade names or trade dress, particularly if they are associated with products that are or were primarily marketed to Minors.

8. Our vapor products are not portrayed as any sort of smoking cessation device or as a product which may be used to help quit smoking.

9. Our vapor products are not marketed as providing a therapeutic value, as being safe or healthy for consumers, or as products which do not produce secondhand health effects.

10. Our vapor products are not marketed or sold using modified risk descriptors or claims (e.g., "light," "low," and/or "mild"). Our vapor products are not marketed as (a) having no ash or smoke, (b) having no tar, (c) being less harmful, (d) posing a lower risk of disease or (e) as containing reduced or zero levels of harmful ingredients.

11. We accurately represent the ingredients contained in our Vapor Products and, in particular, the ingredients contained in any e-liquid. We do not deceive the consumer regarding the contents of our vapor products.

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12. We ensure that all product sampling is restricted to adults and follow all applicable laws.

13. We do not use health professionals to market or otherwise endorse our vapor products, directly or indirectly.

14. Our marketing is directed towards those who are current users of tobacco products and are never designed to encourage non-tobacco users to start using Vapor Products.

V. Conclusion

Union Street's goal in its efforts is to provide adult consumers who would otherwise be smoking combustible cigarettes with an alternative source of nicotine, while preventing minors from accessing vapor products. To that end, Union Street has implemented robust youth prevention methods for its operations including preventing entry of minors into its manufacturing location, and third party age-verification technology.

Union Street's consumer survey data demonstrates that the company's safeguards and stringent age-verification protocols have made the company successful in its mission of providing quality products to an older adult consumer base of former combustible tobacco smokers. Furthermore, Union Street's consumer demographic and age data shows that this Youth Prevention Policy is successful in its effort to prevent underage use of Union Street's products.

[Pop Vapor Marketing Plan]

Marketing Plan

Our company is committed to responsible labeling, advertising, marketing, promotion and honest consumer-directed activities. The goal of our marketing initiative includes alignment of our product with federal, state, and local standards. Our strategic plan encompasses the following core values and principles:

1) Our company only markets and sells our products to legal adult tobacco product users.
2) Our company is honest about our products, including providing information on potential health risks.
3) Our company respects the law and views compliance with the law as a minimum standard that we must constantly meet and exceed.
4) Our company follows a strict standardized ethical code, with some local adaptation

Market Program

After receiving premarket submission clearance from the FDA, our company proposes to implement a strategic approach to our marketing plan. The purpose for advertising and promoting our product is to (a) provide information to tobacco consumers regarding product choice, (b) capture brand share from competitors, and (c) promote brand awareness.

Target Market

Our intended target audience for our marketing is adult smokers over the age of 21. Specific demographic characteristics for focus include individuals aged 25-44 years old, and current smokers who are interested in smoking cessation.

Advertising and Media Outreach

Planned Media and PR Distribution Channels

- Our marketing tactics include the use of US-based social media channels (Instagram, Facebook), magazine advertisements, and radio announcements. All media channels will include statements that our products are intended for ADULT USE only.
- We do not use knowingly use earned media to promote our products.
- We grow our brand organically with quality products and superior customer service.

Partnerships and Sponsors

- We do engage with partners and influencer marketing to advertise and promote our products. Our influencers regularly reinforce the use of our products as an ADULT USE, 21+ product.

JA308

Global Media Channels/Affiliates

- We maintain relationships we have with our wholesalers, distributors, and industry affiliates.

Marketing Budget

- We have not dedicated a budget for media buys, marketing, and promotional activities.

Marketing Timeline

- We do not have a specific marketing timeline for our marketing activities
- Our marketing timeline consists of consistent consumer engagement via social media posts

Consumer Engagements/Sampling

- We do not have plans to participate in consumer engagements, including events at specific direct-to-consumer tradeshows only

Product Samples

- Our company is not engaging in end user promotion with sampling.
- Our company only provides product sampling, in limited quantities, to verified businesses who responsibly sell tobacco products through adult only sales channels.

Company Marketing Standards

Our company recognizes our responsibility to provide conscientious communication to consumers and the public. As part of a sound ongoing marketing campaign, we have implemented specific rules and principles to guide our PR, advertising and promotional efforts.

Quality Content Standard

- Our company will employ carefully curated processes to provide relevant, credible, and diligent content.
- Our company prohibits the use of imagery or design that might perceived as violation or infringement of trademark and/or trade dress.

Accurate and Non-Misleading standard

- Our marketing campaign will ensure that our brand and specific content conveys an accurate and non-misleading impression of the promoted product.
- All statements and content will comply with applicable laws.

JA309

- Our marketing campaign will include clear messaging detailing, including the risks associated with our product
- Our company will refrain from misleading and/or unauthorized claims about our products. All claims including customer reviews, social media posts, testimonials, and marketing made on any forum will always be substantiated, credible, authentic, and backed by reputable sources.
- Our company does not make any disease, health, safety, or modified risk claims about our products.
- Our company does not make smoking cessation claims about our products.

Labeling and Product Warnings Standard

- Our company is dedicated to diligent labeling that is not false or misleading.
- Our product will bear its established name prominently, adequate directions for use, and adequate warnings that are necessary for the protection of users

Our product warnings include:

- FDA Nicotine Warning Statement: "**WARNING: This product contains nicotine. Nicotine is an addictive chemical.**"
- California Proposition 65: [redacted] WARNING: This product can expose you to chemicals including formaldehyde, which is known to the State of California to cause cancer, and nicotine, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.
- "WARNING: Contains nicotine, which can be poisonous. Avoid contact with skin and eyes. Do not drink. Keep out of reach of children and pets. In case of accidental contact, seek medical help. For use only in e-cigarettes or vaporizers by persons of legal age (at least 18). THIS IS NOT A FOOD."
- NOT FOR SALE TO PERSONS UNDER LEGAL SMOKING AGE.
- KEEP AWAY FROM CHILDREN AND PETS.

Preventing Youth Access and Appeal Standard

- Our products should only be sold to, and used by, adults age 21 and older.
- To prevent the sale and distribution of our products to young people and ensure appropriate marketing for the protection of the public health, we have adopted the following policies and practices:
  - Our company complies with the local, state, and federal age restrictions
  - Our company's online sales are restricted to adults only following age verification through independent, third-party agencies using public records databases.
  - Our company educates and supports our distributors, wholesalers, and retailers to ensure that they have appropriate systems in place for age verification for in-person and online sales.

JA310

  - Our company PR and marketing campaign will comply with all applicable promotion and advertising restrictions, with an emphasis on reducing exposure of our promotional content to children and adolescents.

- Our company PR and marketing campaign will comply with all applicable promotion and advertising restrictions, with an emphasis on reducing exposure of our promotional content to children and adolescents.
  - To further these efforts to limit access and reduce youth interest in our product, we have taken the additional following steps:
    - Converted to using only a plain black and white label and external packaging to minimize the visual appeal of our products
    - Prohibited the use of youth appealing content for product naming and labeling. Our company will not use images or names such as candy, candy flavors or other child/teen content and imagery.
    - Emphasized the barring of underage sales in our marketing and promotion strategy
    - Restricted social media marketing and ensure all content intended for the US market is age-restricted
      - Limiting social media marketing to only utilizing age-appropriate influencers to promote our brand
      - Excluded the use of images/pictures appealing to youth
    - Limited our sales channels to online retail sites with adequate online age verification software

Overall, our company is committed to responsible marketing and industry-leading consumer engagement. We will continue to comply and collaborate with federal and state agencies in order to ensure the communication of our products is appropriate for the protection of public health.

JA311