No. 21-13088

United States Court of Appeals for the Eleventh Circuit

SWISHER INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellees.

On Appeal from an Order of the
United States District Court for the Middle District of Florida,
Case No. 3:21-cv-00764 (Hon. Brian J. Davis)

BRIEF OF PUBLIC HEALTH AND MEDICAL ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a) and 11th Cir. R. 26.1-1 through 26.1-3, *amici curiae* are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

I hereby certify that, to the best of my knowledge, the Certificate of Interested Persons filed by Appellees on November 8, 2021 is complete.

Dated: November 15, 2021

s/ Sara A. Lawson
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Amici medical and public health organizations submit this brief in support of Appellees and urge the Court to affirm the district court's denial of the motion for preliminary injunction brought by Swisher International, Inc. ("Swisher").

STATEMENT OF INTEREST OF AMICI CURIAE

Amici are the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative. *Amici* are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year.

Amici have a strong interest in ensuring that cigars introduced to the market since the enactment of the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 et. seq. (2009) ("TCA") do not increase the risk to public health and especially to children, which can only be assured by subjecting these products to the same premarket review requirements and standards that the TCA applies to cigarettes and other tobacco products. *Amici* seek to protect the public from the serious, adverse health effects of cigars, given the severe risk of disease from smoking cigars; their addictiveness; cigar manufacturers' growing use of marketing strategies that appeal to young people; and persistently high rates of cigar smoking by young people. Accordingly, *amici* oppose Swisher's request to

enjoin enforcement of the premarket review requirements of the TCA because such an injunction would prolong the period during which Swisher's highly addictive and toxic flavored cigars remain on the market—with their adverse effects on public health—without completion of the required regulatory review by the United States Food & Drug Administration ("FDA").

Amici also have a special interest in this case because they are plaintiffs in *American Academy of Pediatrics v. FDA* ("*AAP*"), in which they obtained a federal court order (1) vacating the FDA's 2017 Guidance suspending the operation of premarket review for cigars for several years, (2) establishing new deadlines for submission of premarket applications, and (3) limiting the time period that new cigars may remain on the market without the required premarket orders. 379 F. Supp. 3d 461 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). *Amici* have a strong interest in opposing the relief sought by Swisher here, as it would improperly undermine the *AAP* order.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

Amici represent that no party or party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money intended to fund preparing or submitting this brief, and no person—other than *amici*, their members,

or their counsel—contributed money that was intended to fund preparing or submitting this brief. The parties have consented to the filing of this brief.

STATEMENT OF THE ISSUES

1. Whether the district court properly denied Swisher's motion for a preliminary injunction?

2. Whether Swisher is unlikely to succeed on the merits because its request for indefinite relief from the TCA's premarket review requirements would undermine the order of a coordinate federal court?

3. Whether Swisher's requested preliminary injunction would be contrary to the public interest because it would allow the continued sale of its unauthorized, addictive, and toxic cigars, which primarily come in flavors attractive to youth?

SUMMARY OF THE ARGUMENT

In this litigation, Swisher appeals the district court's denial of its emergency motion for a preliminary injunction that would prevent the FDA from enforcing the premarket review provisions of the TCA. The core of its claim for injunctive relief is that, having filed its substantial equivalence reports shortly before the September 9, 2020 filing deadline, and with no decision as yet from the FDA determining whether substantial equivalence has been demonstrated, Swisher could conceivably face enforcement against its unauthorized products. Swisher also makes various claims about the Deeming Rule itself.

As argued more fully below and in the Government's brief, Swisher's claims do not meet the standards for the "extraordinary remedy" of a preliminary injunction. *Brown v. U.S. Dept. of Health & Human Servs.*, 4 F.4th 1220, 1224 (11th Cir. 2021) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)). To avoid duplication of the Government's brief, *amici* focus on two of the flaws in Swisher's arguments. First, Swisher has no likelihood of success on the merits because its requested injunction, which seeks to preclude enforcement of the law, would give it indefinite relief from the TCA. This is contrary to the statute itself and would undermine the order of the *AAP* court. Second, the "balance of harms" and "public interest" factors weigh heavily against any injunction, because the harm to the public interest in the form of numerous well-established deleterious effects on public health, particularly to children and teens, from the continued proliferation of Swisher's flavored cigars that have not completed FDA substantial equivalence review, far outweighs any harm to Swisher—which, in any event, is largely of its own making.

STATUTORY AND REGULATORY BACKGROUND

As the Supreme Court has observed, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). In 2009, Congress responded to this threat by enacting the TCA to

give broad authority to the FDA to regulate tobacco products and curb the predatory conduct of the tobacco industry.

In enacting the TCA, Congress found that the "lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease." H. R. REP. NO. 111-58, pt. 1, at 4 (2009). To combat that harmful activity, Congress established a premarket review framework to ensure that the FDA evaluated new tobacco products before they entered the market. As a general matter, Congress allowed a manufacturer to market a "new" tobacco product (i.e., a product introduced into commerce after February 15, 2007, the "grandfather date") only if it can demonstrate that the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). No cigar can possibly meet this "public health" standard since, as FDA has stated, "[c]igars are associated with significant risk and provide no public health benefit."[1]

To bring a new cigar to market lawfully, a cigar manufacturer must pursue an alternative pathway by submitting a report demonstrating that the new product is "substantially equivalent" to a product on the market as of the grandfather date—

[1] FDA, Draft Guidance, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, at 16 (Mar. 2019), https://www.regulations.gov/document/FDA-2019-D-0661-0003.

i.e., that it has the "same characteristics" as a product on the market before that date—or does not "raise different questions of public health." 21 U.S.C. § 387j(a)(2) & (a)(3). Generally speaking, any new cigar product on the market without an FDA order establishing its "substantial equivalence" is adulterated and subject to FDA enforcement.[2] Thus, the "substantial equivalence" pathway ensures that the FDA has the information needed, and the opportunity, to evaluate proposed changes in cigar products that increase their appeal, addictiveness or toxicity, or that otherwise raise "different questions of public health." As the D.C. Circuit observed in *Nicopure Labs, LLC. v. FDA*, "Congress ... took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health." 944 F.3d 267, 271 (D.C. Cir. 2019). As explained more fully below, because of their appeal to young people, flavored cigars of the kind marketed by Swisher, that were introduced after February 15, 2007,[3] are unlikely to be found

[2] The statute also provides for exemptions from the substantial equivalence requirement for "minor modifications" of tobacco products through the addition or deletion of a tobacco additive. 21 U.S.C. § 387e(j)(3).

[3] Swisher makes contradictory assertions with respect to the portion of its cigar products that are considered new products under the TCA (i.e., those introduced after February 15, 2007) and thus subject to the TCA's premarket review requirements. *Compare, e.g.*, Pl.-Appellant Opening Brief ("Brief") at 7 ("The bulk of Swisher's affected cigars were already on the market—often for decades—before 2007."), *with* Brief at 26 ("Nearly all of Swisher's cigar products are potentially subject to FDA enforcement….").

substantially equivalent to grandfathered products. They clearly raise "different questions of public health."

The TCA gave the FDA initial regulatory authority over cigarettes and certain other tobacco products; it also gave the agency the authority to extend its jurisdiction over all tobacco products, including cigars, by issuing a rule "deeming" them subject to its authority. That occurred by virtue of the issuance of the final Deeming Rule, effective in August 2016. *See* 81 Fed. Reg. 28, 974 (May 10, 2016). As a result of the Deeming Rule, new cigar products became subject to FDA enforcement as "adulterated products" because they lacked FDA orders finding them "substantially equivalent" to grandfathered products. There is no right under the TCA for a new product to be on the market without a marketing order; the newly-deemed products (primarily cigars and e-cigarettes) are on the market only through the enforcement forbearance of the FDA.[4]

[4] Swisher's assertion that FDA's failure to act on Swisher's substantial equivalence applications is a "de facto ban" on its cigars "through sheer lethargy" (Brief at 37-38) is deeply misleading. Congress prohibited the FDA from categorically banning *"all cigars"*—not from keeping one particular manufacturer's products (or a subset thereof) off the market. 21 U.S.C. § 387g(d)(3)(A) (emphasis added). No enforcement action based on a new Swisher cigar being on the market without the required marketing order would amount to a "ban" on Swisher's cigars; it merely means that Swisher has not yet met the standards set out in the statute for the particular new product to be marketed without increasing the public health risk posed by tobacco products. Such an enforcement action would also not affect Swisher's "grandfathered" cigars, i.e., those on the market as of Feb. 15, 2007.

In the Deeming Rule, the FDA provided cigar manufacturers eighteen months from the effective date of the Rule (August 8, 2016) to file their substantial equivalence reports, i.e., until February 8, 2018, and allowed any product for which a report was submitted to remain on the market for one year thereafter. 81 Fed. Reg. at 29,011. Most of that eighteen-month compliance period had run by the time the FDA, in August 2017, issued its Guidance purporting to extend the compliance period for cigars to 2021 and change the one-year post-filing grace period to an indefinite exemption. *See* Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, 82 Fed. Reg. 37,459 (Aug. 10, 2017).

Amici challenged this 2017 Guidance, which the U.S. District Court for the District of Maryland vacated. *AAP*, 379 F. Supp. 3d at 498. In July 2019, the court reset the lapsed February 8, 2018 deadline to May 12, 2020—giving manufacturers another 10 months to prepare, which was several months more than the cigar manufacturers had remaining when the 2017 Guidance was issued. *AAP*, 399 F. Supp. 3d at 487. The court later extended that deadline to September 9, 2020 as a result of the COVID-19 pandemic. *AAP*, No. 8:18-cv-883-PGW, Dkt. No. 182 (D. Md. Apr. 22, 2020). The court's remedial order also reinstated the Deeming Rule's provision that new products for which applications were timely filed could only "remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the

application." *AAP*, 399 F. Supp. 3d at 487. Given that the deadline for timely applications was September 9, 2020, cigars and other deemed products, like e-cigarettes, that lack the required premarket orders could remain on the market only until September 9, 2021 without being subject to FDA enforcement.

ARGUMENT

I. Swisher Cannot Demonstrate a Likelihood of Success on the Merits Because Its Requested Injunction Would Give It Indefinite Relief from the TCA, Undermining the Order of a Coordinate Federal Court.

Swisher's requested injunction—to indefinitely suspend FDA enforcement with respect to its tobacco products—is merely an attempted end-run around the *AAP* order. As the *AAP* court found, the FDA cannot lawfully suspend enforcement of the TCA. Neither can injunctive relief granted to Swisher.

In *AAP*, *amici* filed suit in the United States District Court for the District of Maryland challenging the FDA's 2017 guidance that purported to give all e-cigarettes and cigars a blanket exemption from the TCA's authorization requirements for several years and then indefinitely thereafter until FDA ruled on their premarket or substantial equivalence applications. The court held that the FDA's action was unlawful, as an "across-the-board suspension of the Tobacco Control Act's premarket approval process" was "inconsistent with the" Act because it "h[e]ld in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers…." *AAP*, 379 F. Supp.

3d at 492-93. The court concluded that the FDA's 2017 guidance provided tobacco manufacturers, such as Swisher, "a holiday from meeting the obligations of the law," which the FDA could not lawfully do. *Id.* at 493. The Court thus vacated the FDA's unlawful guidance, making clear that, while FDA had case-by-case enforcement discretion regarding violations of the Act, it could not immunize all violators altogether.[5]

The Court thus reinstated the Deeming Rule's provision of a date certain for the cigar makers' "holiday" from the premarket review requirements of the TCA to come to an end, ultimately September 9, 2021. *See AAP*, 399 F. Supp. 3d at 487; *AAP*, No. 8:18-cv-883-PGW, Dkt. No. 182. The FDA may now exempt new products from the Act's filing requirements only "for good cause on a case-by-case basis." *AAP*, 399 F. Supp. 3d at 487.

Swisher's requested relief—"an order forbidding the FDA from enforcing the TCA against Swisher's cigars for the duration of this case," Brief at 39—represents a collateral attack on the *AAP* decision. The district court in this case recognized as much. *See* ECF 48 at 13 ("If anything affected Swisher's rights, it was the decision

[5] Swisher's depiction of the *AAP* holding is misleading by omission. Swisher repeatedly describes the opinion as merely "vacat[ing] the August 2017 guidance for lack of notice and comment…." Brief at 31; *see also id.* at 9, 49. This ignores the additional holding that the holiday provided by the FDA—the holiday Swisher would have this Court extend—is "inconsistent with the Tobacco Control Act and in excess of [FDA's] statutory authority…." *AAP*, 379 F. Supp. 3d at 494.

in *AAP* to vacate the FDA's guidance that gave Swisher exactly what it now asks this Court to do.").[6]

What Swisher calls FDA's "threats of enforcement" are nothing more than the FDA's recognition of the law and the District of Maryland's holding in the *AAP* case: anybody selling new tobacco products without a marketing or substantial equivalence order is acting unlawfully. The only "threat" Swisher describes is the agency's statement that products that are not authorized by September 9, 2021 and remain on the market "risk FDA enforcement per FDA's guidance…." Brief at 22 (citing Transcript at 20, *Deemed Product Review: A Conversation with the Center for Tobacco Products Office of Science* (June 11, 2021), https://www.fda.gov/media/150275 /download). Far from being a "threat," this statement merely acknowledges the plain meaning of the TCA as Congress wrote it, which the *AAP* court also recognized: "[a]n order . . . *is required*" before a product may be lawfully marketed. 21 U.S.C. § 387j(a)(2)(A) (emphasis added); *see also Nicopure*, 944 F.3d at 281 ("The premarket approval requirement is in the Act. It was Congress, not the FDA, that imposed it on new tobacco products . . . ."). An agency does not act unlawfully by recognizing clear and settled law and the dictates of a standing court order.

[6] Citations in the form "ECF X at Y" refer to the district court docket entry X at page Y.

Moreover, if this Court were to grant Swisher's requested relief, any similarly situated company would be eligible for the same relief, resulting in a massive and indefinite exemption from premarket review for large swaths of the cigar industry, if not the industry as a whole. Such an extra-statutory regulatory holiday would be plainly impermissible, as courts have repeatedly held. *See Nicopure*, 944 F.3d at 281; *AAP*, 379 F. Supp. 3d at 492-93. Swisher's request that the Court prohibit the FDA from enforcing the TCA with respect to its cigars also runs contrary to decades of well-settled law that "the decision to prosecute is . . . not readily susceptible to the kind of analysis the courts are competent to undertake." *Wayte v. United States*, 470 U.S. 598, 607 (1985).

Indeed, a previous attempt by Swisher's leadership to enjoin the FDA from enforcing the premarket review requirements was rejected by the U.S. District Court for the District of Columbia. *Cigar Ass'n of Am. v. FDA*, No. 16-cv-1460, 2020 WL 5231335 (D.D.C. Sept. 2, 2020). In that case, the Cigar Association of America, a trade association whose board of directors includes three Swisher executives,[7] sought an injunction to prevent enforcement of those requirements pending appeal of a decision granting summary judgment against various attacks against the

[7] *See CAA Board of Directors*, CIGAR ASS'N AM., https://www.cigarassociation.org/board-of-directors/ (last accessed Nov. 9, 2021).

Deeming Rule (including many of the arguments Swisher makes here). The court denied the injunction:

> The injunctive relief requested here would upset the *AAP* court's judgment without justification. It would, in the short term, exempt from the *AAP* court's order all newly deemed cigar and pipe tobacco products. Such collateral relief from another court's order is generally unwarranted…. It would be inequitable for this court to undo, even temporarily, the hard-fought victory achieved by the plaintiffs in *AAP*. The *AAP* plaintiffs' interests, avoiding an unnecessary conflict with the *AAP* court's decision, and the public's interest in enforcing the *AAP* court's remedial order, all counsel strongly against injunctive relief pending appeal.

Id. at *1. These same reasons counsel against the injunction sought by Swisher.

Swisher points to *PHH Corporation v. Consumer Financial Protection Bureau*, 839 F.3d 1 (D.C. Cir. 2016) to support its request for an injunction. But far from aiding Swisher, *PHH* illustrates its overreach. In *PHH*, an agency reversed a prior interpretation of a statute and sought to apply the new interpretation retroactively. *Id.* at 46-49. The D.C. Circuit held that this violated "[t]he Due Process Clause [which] limits the extent to which the Government may *retroactively* alter the legal consequences of an entity's or person's *past conduct*." *Id.* at 46 (emphasis added). *PHH* plainly turned on "anti-retroactivity principles," *id.* at 48—not *prospective* application. *See, e.g.*, *id.* at 47 ("An 'agency should not change an interpretation in an adjudicative proceeding where doing so would impose new liability on individuals for past actions which were taken in good-faith reliance on

agency pronouncements.'" (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156-57 (2012))). Indeed, *PHH* expressly distinguished the retroactive liability before it from the commonplace situation, such as the present case, of "expect[ing] regulated parties to conform their conduct to an agency's interpretations once the agency announces them." *Id.* (quoting *SmithKline*, 567 U.S. at 159).

This case is not *PHH*. FDA has not threatened to impose liability for the period in which Swisher was marketing its products pursuant to FDA's explicit promise of forbearance. It has merely declined to provide immunity for *future* marketing that is inconsistent with the plain requirements of the law and the order of a coordinate federal court. Swisher is arguing that it should be allowed to break the law *prospectively* with impunity—based in large part on prior assurances that were held unlawful by the Maryland District Court. This unprecedented claim should be rejected.

II. Any Harm to Swisher Is of its Own Making and Is Far Outweighed by Harm to the Public Interest if an Injunction Were to Extend Swisher's Regulatory "Holiday."

A. Swisher has had years of notice that its products would be subject to FDA enforcement, yet delayed filing the required reports.

As discussed above, the TCA gave the FDA regulatory authority over cigarettes and certain other tobacco products; it also gave the agency the authority

to extend its jurisdiction over all tobacco products, including cigars, by issuing a rule "deeming" them subject to its authority. In 2010, *over ten years ago,* cigar manufacturers, including Swisher, were put on notice that FDA planned to subject their products to the premarket review provisions of the TCA.[8] This intention was reiterated by the FDA in 2011, when the agency stated its intention to deem all "tobacco products," as defined by the TCA, subject to that Act,[9] and again in 2014 when FDA issued the proposed Deeming Rule making clear that the premarket review requirements would apply to all cigars under the proposal. *See* 79 Fed. Reg. 23,142 (Apr. 25, 2014).

Despite this notice, Swisher's Complaint (ECF 1 ¶ 78) reveals that it did not begin to develop a testing program to provide data for submission until 2018, even though, as late as August 2017, its applications were required to be submitted by February 2018. Thus, Swisher did not even begin to develop a testing program for its products until eight years after it knew it would eventually be subject to the

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[8] *See* Office of Information and Regulatory Affairs, Office of Management and Budget, *Unified Regulatory Calendar, Cigars Subject to the Family Smoking Prevention and Tobacco Control Act*, RIN No. 0910-AG38 (Spring 2010), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG38.

[9] Letter from Lawrence Deyton, Dir., FDA Ctr. for Tobacco Prods., & Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Stakeholders re: Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011), https://www.aaphp.org/Determination.

premarket provisions of the TCA, four years after the FDA formally proposed to issue a rule extending its jurisdiction over cigars, and likely *after* the deadline for substantial equivalence reports established by the final Deeming Rule.

Moreover, Swisher did not file its substantial equivalence reports until days before the September 9, 2020 deadline set by the Maryland federal court despite its supposed belief that "virtually all of its cigars qualify as new tobacco products… subject to the Act's premarket review provisions…." ECF 2-2 ¶¶ 13, 31. There is no reason Swisher, or any other cigar manufacturer, need have waited until September 2020 to file substantial equivalence reports. Indeed, the FDA had urged tobacco companies to make premarket filings of all kinds long before the deadlines set by the agency. As Acting FDA Commissioner Ned Sharpless stated in Fall 2019, "as I've said before, responsible manufacturers certainly don't need to wait to act. We encourage industry to use available FDA resources as a guide for their submissions to the agency…."[10]

As the AAP court observed, "manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence

[10] FDA News Release, *FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products* (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making." *AAP,* 379 F. Supp. 3d at 498.[11]

Indeed, the industry's failure to engage with the regulatory process was a central reason for the Maryland federal court to issue its remedial order in July 2019 establishing the original May 2020 application deadline. According to the court, "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings." *Id.* The court continued: "[t]hus, the record offers little assurance that, in the absence of a deadline for filing, the [i]ndustry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." *Id*. at 486.

Thus, contrary to the district court's dicta below that "enforcement [would] appear[] on its face, as unjust…," ECF 48 at 17, Swisher has escaped complying

[11] In *AAP*, the cigar manufacturers made the same protestations about needing more guidance from the FDA that Swisher makes here, which the court found "disingenuous[]" due, in part, to the "lengthy guidance documents" FDA had promulgated. *AAP,* 399 F. Supp. 3d at 485. The court credited FDA's statements that "it issued final guidance concerning the SE [substantial equivalence] process in January 2011, long before the deeming rule was finalized" as well as "three versions of a frequently asked questions document concerning the SE process, most recently in December 2016." *Id.*

with the TCA statutory requirements for years—during which time it profited handsomely at the expense of the health of the public, including children attracted to its flavored cigars. The dilemma Swisher and other tobacco companies face now is largely of their own making, a factor that tips the balance of the harms against the issuance of an injunction that would simply prolong the nearly decade-long regulatory "holiday" enjoyed by manufacturers of cigars and other deemed tobacco products.

B. By extending the regulatory "holiday" enjoyed by Swisher, the requested injunction would disserve the public interest through its adverse impact on public health.

Swisher and other cigar makers have used their years-long regulatory "holiday" to introduce scores of youth-friendly flavored products that have come to dominate the cigar market with significantly adverse consequences for public health, particularly for children and teens. While Swisher argues that "[t]his case is not about whether cigars are good or bad," Brief at 55, the fact that the injunction sought by Swisher would prolong the period during which Swisher's flavored products can continue to inflict grievous harm to public health without having completed the legally-required FDA review is certainly relevant—and profoundly contrary—to the public interest, a key factor in the preliminary injunction analysis. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) ("[C]ourts of equity should pay

particular regard for the public consequences in employing the extraordinary remedy of injunction.").

1. Since 2009, Swisher and other cigar makers have radically transformed the cigar market to appeal to children.

The TCA prohibited the marketing of flavored cigarettes other than menthol. 21 U.S.C. § 387g(a)(1). Tobacco manufacturers responded by dramatically increasing the production of small, flavored, cigarette-like cigars, transforming the cigar market. When the FDA recently indicated its intention to engage in rulemaking to issue a product standard prohibiting flavors in cigars, the agency observed that, "[a]fter the 2009 statutory ban on flavors in cigarettes other than menthol, use of flavored cigars increased dramatically, suggesting that the public health goals of the flavored cigarette ban may have been undermined by continued availability of these flavored cigars."[12] Today, cigar manufacturers produce flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade.[13]

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[12] FDA News Release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

[13] *See* CAMPAIGN FOR TOBACCO-FREE KIDS, NOT YOUR GRANDFATHER'S CIGAR: A NEW GENERATION OF CHEAP AND SWEET CIGARS THREATENS A NEW GENERATION OF KIDS, at 7 (Mar. 13, 2013), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf.

As the FDA has found, young people are far more likely than older smokers to prefer flavored cigars. *See* 79 Fed. Reg. at 23,146 ("Research has shown that…sugar preference is strongest among youth and youth adults and declines with age."). As one cigar manufacturer has acknowledged, "[i]t is mainly new recruits to cigar smoking who take to the new flavors…," and it has long been the case that "new recruits" are disproportionately minors.[14] *See also* 79 Fed. Reg. at 23,155 ("Virtually all new users of most tobacco products are youth…."). The appeal of flavored cigars to youth is undeniable. Data from the 2013-2014 wave of the federal government's Population Assessment of Tobacco and Health ("PATH") study show that 73.8% of youth cigar smokers reported that they smoked cigars "because they come in flavors I like."[15]

As the cigar industry shifted toward the youth market, cigar sales skyrocketed. From 2000 to 2016, annual U.S. cigar consumption nearly doubled (from 6.2 to 12

[14] *See No. 2 worldwide in cigars*, SWEDISH MATCH (Mar. 7, 2007), https://www.swedishmatch.com/Media/Pressreleases-and-news/News/No-2-worldwide-in-cigars/.

[15] Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. AM. MED. ASS'N 1871, tbl.2 (2015), https://jamanetwork.com/journals/jama/fullarticle/2464690.

billion sticks), while cigarette use steadily declined.[16] The current cigar market overwhelmingly and increasingly consists of mass-produced, flavored products appealing primarily to youth. From 2008 to 2015, there was explosive growth in kid-friendly flavored cigars; the number of unique cigar flavor names more than doubled, from 108 to 250.[17] And sales reflected that growth: dollar sales of flavored cigar products increased by nearly 50% between 2008 and 2015, raising flavored cigars' share of the overall cigar market to 52.1% in 2015.[18] Data from the 2020 National Youth Tobacco Survey also reflects this growth: cigarillos, such as Swisher Sweets, were the most popular cigar type used by current youth cigar smokers (44.1%), and the majority of youth cigarillo smokers (57.6%) reported using flavored products.[19]

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[16] Julia Cen Chen-Sankey et al., *Cigar-Smoking Patterns by Race/Ethnicity and Cigar Type: A Nationally Representative Survey Among U.S. Adults*, 60 AM. J. PREVENTIVE MED. 87, 87 (2021), https://pubmed.ncbi.nlm.nih.gov/33341182/.

[17] Doris G. Gammon et al., *National and state patterns of concept-flavoured cigars sales, USA, 2012-2016*, 28 TOBACCO CONTROL 394, 394 (2019), https://pubmed.ncbi.nlm.nih.gov/30068564/.

[18] Cristine D. Delnevo et al., *Changes in the Mass Merchandise Cigar Market Since the Tobacco Control Act*, 3 (2 SUPP. 1) TOBACCO REG. SCI. S8, tbl.1 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351883/pdf/nihms852155.pdf.

[19] Tiffany A. Parms et al., *Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020*, AM. J. PREVENTIVE MED. 1, 3 tbl.1 (available online Sept. 5, 2021), https://www.sciencedirect.com/science/article/abs/pii/S0749379721004050.

Swisher in particular has led this market shift towards flavored products that appeal primarily to youth. Swisher Sweets, for example, is the third most popular cigar brand among youth ages 12 to 17 years.[20] A quick glance at the company's website reveals why: the majority of its products—and particularly its newer products—are flavored.[21] As Swisher's Chief Operations Officer stated in his declaration, "[a] substantial portion of [its 173 different types of] cigars have an identifiable characterizing flavor, such as cherry or vanilla, and are branded or marketed accordingly." ECF 2-1 ¶ 8; *see also* Brief at 37-38 ("[A] substantial portion of Swisher's cigars" are flavored). Just since 2018, Swisher has introduced flavored products with names like "Purple Swish," "Passion Fruit," "Coco Blue," and "Maui Pineapple"—all of which come in brightly-colored, kid-friendly packaging.[22]

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[20] Derived from Substance Abuse and Mental Health Services Administration's public online data analysis system. Substance Abuse & Mental Health Data Archive, *National Survey on Drug Use and Health, 2019*, https://bit.ly/30dv48R (Click "Run Crosstab" to generate table); *see also* Cristine D. Delnevo et al., *Preference for flavoured cigar brands among youth, young adults and adults in the USA*, 24 TOBACCO CONTROL 389, 392 tbl.3 (2015), https://pubmed.ncbi.nlm.nih.gov/24721967/ (finding that Swisher Sweets were the second most popular cigar brand among youth in 2010-2011, with 21% of 12-17 year-olds reporting it as their preferred cigar brand).

[21] *See, e.g.*, *Our Cigarillos*, SWISHER SWEETS, https://swishersweets.com/pages/our-cigarillos (last accessed Nov. 10, 2021).

[22] *Swisher Sweets Purple Swish*, CONVENIENCE STORE NEWS (Oct. 8, 2019), https://csnews.com/swisher-sweets-purple-swish; *Purple Swish*, SWISHER SWEETS,

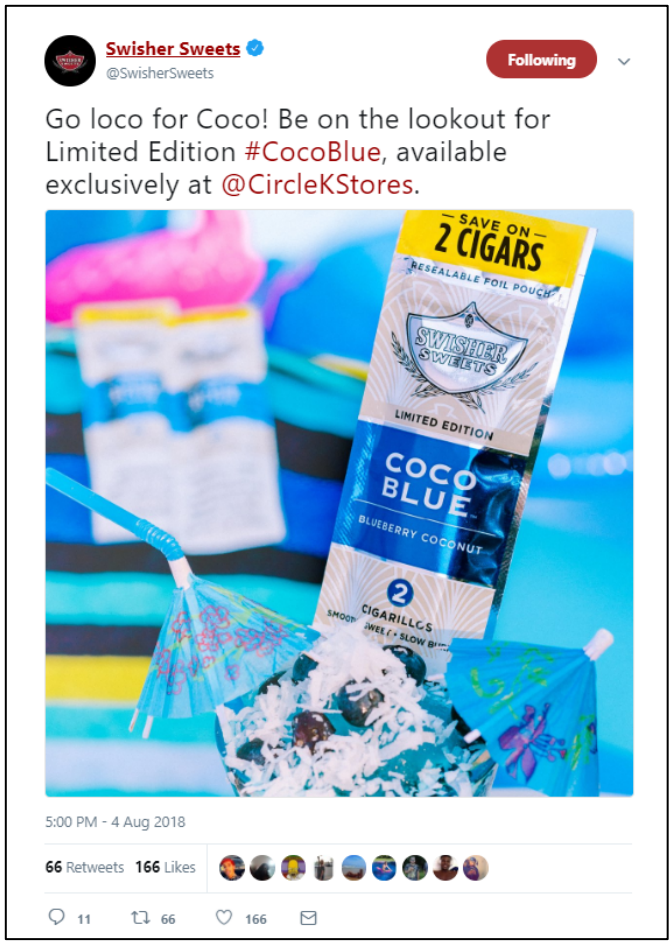

Figure 2: Swisher Sweets (@SwisherSweets), TWITTER (Aug. 4, 2018, 5:00 PM), https://twitter.com/SwisherSweets/status/1025894282803273730.

Figure 1: Swisher Sweets (@SwisherSweets), TWITTER (July 18, 2019, 12:01 PM), https://twitter.com/SwisherSweets/status/1151884758089117697.

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https://trade.swisher.com/purple-swish/(last accessed Nov. 9, 2021); Swisher Sweets (@SwisherSweets), TWITTER (July 18, 2019, 12:01 PM), https://twitter.com/SwisherSweets/status/1151884758089117697 (Passion Fruit); Swisher Sweets (@SwisherSweets), TWITTER (Aug. 4, 2018, 5:00 PM), https://twitter.com/SwisherSweets/status/1025894282803273730 (Coco Blue); Swisher Sweets (@SwisherSweets), TWITTER (Feb. 6, 2018, 6:18 AM), https://twitter.com/SwisherSweets/status/960880462506938369 (Maui Pineapple).

Figure 3: *Maui Pineapple,* SWISHER SWEETS, http://trade.swishersweets.com/maui-pineapple/ (last accessed Feb. 27, 2018).

Swisher has also targeted youth through event sponsorship, pricing practices, and advertising. In June 2019, for example, the company hosted the Swisher Sweets Summer Twist Yacht Party, an event featuring celebrities popular among youth and young adults.[23] The party attendees included former Disney Channel actress Bella Thorne, Chanel West Coast from MTV's *Ridiculousness* and Justina Valentine from MTV's *Wild N Out*.[24] Swisher also operates a so-called "Artist Project," in which it promotes its brand at concerts, sponsors musical artists, and holds pop-up music events in convenience stores that are promoted on its website and social media.[25]

[23] Swisher Sweets Artists Project, *Summer Twist Yacht Party*, YOUTUBE (June 29, 2019), https://www.youtube.com/watch?v=b-OK5PC2cPY.

[24] *Id.*

[25] *See, e.g.*, *Artist Project,* SWISHER SWEETS, https://ap.swishersweets.com/ (last accessed Nov. 9, 2021); Ollie Ganz et al., *Swisher Sweets 'Artist Project': using*

The price for Swisher products also varies among neighborhoods in a manner that encourages youth consumption. A study analyzing 2013 data from California found that Swisher Sweets cost significantly less in census tracts with higher proportions of school-aged youth and young adults.[26] Moreover, a survey of cigar advertisements at 530 California retailers selling tobacco near middle and high schools (median distance of 0.35 miles) found that one in five cigar ads were for Swisher Sweets.[27]

Figure 4: Swisher Sweets (@swishersweets), INSTAGRAM (June 22, 2019), https://www.instagram.com/p/By-60bEnU53/ (last accessed June 22, 2019).

musical events to promote cigars, 27 TOBACCO CONTROL e93 (2018), https://pubmed.ncbi.nlm.nih.gov/29439208.

[26] Lisa Henriksen et al., *Neighborhood Variation in the Price of Cheap Tobacco Products in California: Results From Healthy Stores for a Healthy Community*, 19 NICOTINE & TOBACCO RES. 1330, 1334 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5896445/.

[27] Kymberle L. Sterling et al., *Flavors and Implied Reduced-Risk Descriptors in Cigar Ads at Stores Near Schools*, 23 NICOTINE & TOBACCO RES. 1895, 1897 (2021), https://pubmed.ncbi.nlm.nih.gov/34214176/.

The result of this proliferation of flavored cigars directed at the youth market has been predictable and troubling: "youth cigar use has not declined when compared to use of other tobacco products" since the passage of the TCA. 81 Fed. Reg. at 29,023. Cigar usage among all high school students now exceeds cigarette usage.[28] In December 2020, the Centers for Disease Control and Prevention reported that 770,000 high school students currently used cigars.[29] Black high schoolers smoke cigars at more than three times the rate of cigarettes, and an estimated 190,000 high school students who smoked cigars in 2019 did so frequently (20 of the preceding 30 days).[30] According to the 2019 National Survey on Drug Use and Health, more than 1,400 persons under the age of eighteen smoke their first cigar each day.[31] This trend also persists in the young adult population (18-25 year-olds),

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[28] Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Students—United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1881, 1883 (Dec. 18, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf.

[29] *Id.* at 1884 tbl.

[30] *See id.*; Teresa W. Wang, *Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. SURVEILLANCE SUMMARIES 1, 12 tbl.3 (Dec. 6, 2019), https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf.

[31] *Table 4.9A—Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, Prior to Age 21, and at Age 21 or Older: Numbers in Thousands, 2018 and 2019*, SUBSTANCE ABUSE AND MENTAL HEALTH

with cigars being the most common type of tobacco product initiated during young adulthood.[32]

2. Cigar smoking is a significant public health concern.

The evidence amassed and considered by the FDA for the Deeming Rule establishes unequivocally that cigar smoking presents a significant public health risk, both to minors and adults. As the FDA found, "[a]ll cigars pose serious negative health risks." 81 Fed. Reg. at 29,020. In 2010 alone, "regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older." *Id.*

"All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users," as well as "other adverse health effects, such as increased risk of heart and pulmonary disease," "a marked increase in risk for chronic obstructive pulmonary disease (COPD)," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke than nonsmokers." *Id.*

SERVICES ADMINISTRATION (SAMHSA) (2020), https://bit.ly/3c3Tqny. Cigars are defined as cigars, cigarillos, or little cigars.

[32] Cristine D. Delnevo et al., *The Effect of Cigarillo Packaging Characteristics on Young Adult Perceptions and Intentions: An Experimental Study*, 18 INT'L J. ENVTL. RES. & PUB. HEALTH 4330, 4330 (2021), https://pubmed.ncbi.nlm.nih.gov/33921793/ (citing 2019 National Survey on Drug Use and Health data). Since the minimum age for sale of tobacco products is now twenty-one under federal law, the young adult category now includes many underage consumers.

Use of cigars by young people raises unique public health concerns. As the FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, . . . [it] remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." *Id.* at 29,023 (emphasis in original); *see also id.* at 29,029 ("The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system."); *id.* at 29,033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

Cigars also can produce significantly more secondhand smoke than cigarettes, and cigar smoke causes negative health effects such as heart disease and lung cancer in nonsmokers. *Id.* at 29,022. In short, as the FDA stated in 2019, "[c]igars are associated with significant risk and provide no public health benefit."[33]

The injunction that Swisher seeks would extend the period during which its new flavored cigar products may remain on the market without marketing authorization —in contravention of the TCA—and continue to harm the public health, especially the health of children and teens. This adverse impact on the public interest thus substantially outweighs any injury to the company, particularly since

[33] FDA, Draft Guidance, *supra* note 1, at 16.

that injury was largely self-inflicted through Swisher's years of delay in submitting substantial equivalence reports to the FDA.

CONCLUSION

For these reasons, the court should affirm the district court's denial of Swisher's motion for a preliminary injunction.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the word limits set forth in Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(g)(1) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the word count feature in Microsoft Word reports that this document contains 6,382 words.

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Dated: November 15, 2021

s/ Sara A. Lawson
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CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on November 9, 2021, I contacted counsel for Appellant and Appellees by electronic mail and that Appellant and Appellees each consented to the filing of the brief of *amici curiae*.

Dated: November 15, 2021

s/ Sara A. Lawson
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CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

Dated: November 15, 2021

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