EXHIBIT A

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

SWISHER INTERNATIONAL, INC., Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 3:21-cv-764

BRIEF *AMICUS CURIAE* OF PUBLIC HEALTH GROUPS

Amici submit this Brief in opposition to the motion for preliminary injunction brought by Plaintiff Swisher International, Inc. ("Swisher").

STATEMENT OF IDENTITY AND 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) (the "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 the motion for injunctive relief by Plaintiff Swisher against 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 the 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 the Plaintiff here, which would improperly undercut the *AAP* order.

STATUTORY AND REGULATORY BACKGROUND AND SUMMARY OF ARGUMENT

As the Supreme Court has observed, "[T]obacco 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, "Cigars are associated with significant risk and provide no public health benefit."[1]

[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.

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—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." *Id.* § 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 recently 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 at 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,[3] that were introduced after February 15, 2007, are unlikely to be found substantially equivalent to grandfathered products. They clearly raise "different questions of public health."

[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 concedes that "many" of its substantial equivalence reports were required "because the cigars contained modified flavoring ingredients that were not present in any of the predicate cigars that were on the market prior to February 2007." Johnson-Malden Decl. ¶ 40.

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.[4] 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.[5]

In the Deeming Rule itself, the FDA provided cigar manufacturers 18 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

[4] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Final Rule), 81 Fed. Reg. 28,974 (May 10, 2016).

[5] Swisher's repeated assertion that FDA seeks to "ban" its cigars (*e.g.*, Pl.'s Mot. for Emerg. Prelim. Inj. ("Mot.") at 21) is deeply misleading. Congress prohibited the FDA from categorically banning *"all cigars"*—not from taking action with the effect of 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 amounts 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. Moreover, such an enforcement action would have no effect on Swisher's "grandfathered" cigars; i.e., those on the market as of Feb. 15, 2007. Swisher claims that the "bulk" of its cigars "were *already* on the market – often for decades – prior to 2007 . . . ." Mot. at 5 (citing Johnson-Malden Decl. ¶13) (emphasis in original).

thereafter. 81 Fed. Reg. at 29,011. Most of that 18-month compliance period had run by the time 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.[6]

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, ECF No. 182 (D. Md. Apr. 22, 2020). The court's remedial order also reinstated the Deeming Rule's provision under which 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, may remain on the market only until September 9, 2021 without being subject to FDA enforcement.

[6] *See* FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017); 82 Fed. Reg. 37,459 (Aug. 10, 2017).

In this litigation, Plaintiff Swisher seeks an emergency preliminary injunction against enforcement of 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, with no decision as yet from the FDA determining whether substantial equivalence has been demonstrated, "[t]hrough no fault of its own" Swisher finds itself "threatened [with] enforcement." Pl.'s Mot. for Emerg. Prelim. Inj. ("Mot.") at 2. Swisher makes various claims against the Deeming Rule itself, as well as against any enforcement of the premarket review provisions as to Swisher.

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. Secretary, 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 arguments, *amici* will focus on just two of the many flaws in Plaintiff's arguments.[7] First, Swisher has no likelihood of success on the merits because its requested injunction against enforcement of the law would give it indefinite relief from the TCA, which 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 health harms to the public, and particularly children and teens, from the

[7] *Amici* reserve the right to seek leave to file a brief addressing the remaining arguments at a later stage of the case, such as summary judgment.

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.

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.

In Part II(C) of its Motion, Swisher contends that the FDA impermissibly made a "sudden threat to ban Swisher's cigars" and that future enforcement would violate the Due Process Clause due to the FDA's prior forbearance from enforcement. Mot. at 22-23. To convey fully the flaws in this argument, a short discussion of the *AAP* litigation may be helpful.

As noted above, in 2017, FDA issued a guidance document purporting to give all cigars and e-cigarettes a blanket exemption from the TCA's authorization requirements for several years and then indefinitely thereafter. In response to a suit filed by *amici*, Judge Paul Grimm of the U.S. District Court for the District of Maryland found that this "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. This unlawful suspension of the TCA provided tobacco manufacturers such as Swisher "a holiday from meeting the obligations of the law." *Id.* at 493. Judge Grimm vacated the unlawful guidance document,

making clear that, while FDA had case-by-case enforcement discretion regarding violations of the Act, it could not immunize all violators altogether.[8] As discussed above, Judge Grimm's remedial order 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 (now September 9, 2021). *See* 399 F. Supp. 3d at 487. Under the order, the FDA may exempt new products from the Act's filing requirements only "for good cause on a case-by-case basis." *Id.*

What Swisher calls FDA's "threats of enforcement" are nothing more than FDA's recognition of what Judge Grimm held: 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, "[I]f products are not authorized by September 9th of 2021 and [remain on] the market at that time, they risk FDA enforcement." Mot. at 9-10 (citing Transcript at 37, *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 is merely an acknowledgement of the plain meaning of the TCA as Congress wrote it: "[a]n order . . . *is required*" before a product may be marketed lawfully. 21 U.S.C. § 387j(a)(2)(A) (emphasis added);

[8] Swisher's depiction of the *AAP* holding is misleading by omission. Swisher repeatedly describes Judge Grimm's opinion as merely "vacat[ing] that guidance for lack of notice and comment." Mot. at 23; *see also id.* at 7, 18. This conceals that Judge Grimm explicitly found the holiday provided by FDA—the holiday Swisher would have this Court extend—to be "inconsistent with the Tobacco Control Act and in excess of [FDA's] statutory authority…." *AAP*, 379 F. Supp. 3d at 494.

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 . . . ."). It is also an acknowledgment of Judge Grimm's order establishing that tobacco products cannot indefinitely stay on the market without the required marketing orders. An agency does not act unlawfully by recognizing clear and settled law and the dictates of a standing court order.

Swisher is tellingly vague about what it thinks the FDA should have done instead of confirming its obligations as to applications that are not authorized by September 9, 2021. On the one hand, Swisher could be saying that the FDA was required to ensure the entire cigar industry that it would not enforce the TCA against them. This would plainly be impermissible, as courts have repeatedly held. *See Nicopure*, 944 F.3d at 281; *AAP*, 379 F. Supp. 3d at 492-93.

On the other hand, Swisher could be suggesting that the FDA was required to tell Swisher in particular that it would not enforce the statute against them. This runs up against 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). And Swisher is certainly not entitled to an injunction against FDA enforcement after September 9, when another federal court has expressly ordered that cigars on the market after that date without the required marketing orders are subject to potential FDA enforcement.

Indeed, a previous attempt by Swisher's leadership to enjoin FDA enforcement of the premarket review requirements was rejected by the U.S.

District Court for the District of Columbia. In that case, the Cigar Association of America, a trade association chaired by Swisher's President and CEO,[9] sought an injunction against enforcement of those requirements pending appeal of a decision granting summary judgment against various attacks against the 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.

Cigar Ass'n of Am. v. FDA, No. 16-cv-1460, 2020 WL 5231335 at *1 (D.D.C. Sept. 2, 2020) (citation omitted). These same reasons counsel against the injunction sought by Swisher.

In an attempt to bolster its argument, Swisher points to *PHH Corporation v. Consumer Financial Protection Bureau*, 839 F.3d 1 (D.C. Cir. 2016). Far from helping 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*."

[9] *See Welcome to the Cigar Association of America*, CIGAR ASS'N AM., https://www.cigarassociation.org/welcome/ (last accessed Aug. 14, 2021).

Id. at 46 (emphasis added). This holding was entirely about "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 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).

The situation here is markedly different from that in *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, but 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 could 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.[10] 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,[11] 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.[12]

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[10] *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.

[11] 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.

[12] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142 (proposed Apr. 25, 2014).

Although Plaintiff contends that it "diligently submitted" its substantial equivalence reports (Mot. at 13), its Complaint (¶ 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 premarket provisions of the TCA, four years after the FDA formally proposed to issue a rule extending its jurisdiction over cigars, and *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 understanding that "virtually all of its cigars qualify as new tobacco products … subject to the Act's premarket review provisions." Johnson-Malden Decl. ¶¶ 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, "[A]s 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…."[13]

[13] 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),

As Judge Grimm observed, "[M]anufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence 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. Cigar manufacturers made the same protestations about needing more guidance from the FDA that Swisher makes here, which Judge Grimm found "disingenuous[]." *AAP*, 399 F. Supp. 3d at 485.

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, "[T]he 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: "Thus, the record offers little assurance that, in the absence of a deadline for filing, the Industry 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, 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

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https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

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. 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, a result profoundly contrary to the public interest.

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)(l). In response, 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, "After 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."[14] Today, cigar manufacturers produce flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade.[15]

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, "It 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.[16] *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."[17]

As the cigar industry shifted toward the youth market, cigar sales skyrocketed. By 2019, cigar consumption was up 118% from 2000, while

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[14] 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.

[15] *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.

[16] *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/.

[17] 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).

cigarette consumption declined 49% from 2000 levels.[18] 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.[19] And sales reflected that growth: dollar sales of flavored cigar products increased by nearly 50% between 2008 and 2015, increasing flavored cigars' share of the overall cigar market to 52.1% in 2015.[20]

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.[21] A quick glance at the company's website reveals why: the majority of its products—and particularly its newer products—are flavored.[22] 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." Caldropoli Decl. ¶ 8. Just since 2018, Swisher has

[18] Derived from Alcohol and Tobacco Tax and Trade Bureau ("TTB"), Tobacco Statistics, https://www.ttb.gov/tobacco/tobacco-statistics.
[19] Doris G. Gammon et al., *National and state patterns of concept-flavoured cigars sales, USA, 2012-2016*, 28 TOBACCO CONTROL 394, 394 (2019).
[20] Cristine D. Delnevo et al., *Changes in the Mass Merchandise Cigar Market Since the Tobacco Control Act*, 3 (2 SUPPL. 1) TOBACCO REG. SCI. S8, tbl.2 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351883/pdf/nihms852155.pdf.
[21] 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://pdas.samhsa.gov/#/survey/NSDUH-2019-DS0001/crosstab/?column=CATAG2&filter=CGR30BR2%21%3D9993%2C9991&results_received=true&row=CGR30BR2&run_chisq=false&weight=ANALWT_C (Click "Run Crosstab" to generate table).
[22] *See, e.g.*, *Our Cigarillos*, SWISHER SWEETS, https://swishersweets.com/pages/our-cigarillos (last accessed Aug. 13, 2021).

introduced flavored products with names like "Purple Swish," "Passion Fruit," "Sweet Cream," "Coco Blue," and "Maui Pineapple."[23]

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

Figure 2: *Maui Pineapple*, SWISHER SWEETS, http://trade.swishersweets.com/maui-pineapple/.

[23] *Swisher Sweets Purple Swish*, CONVENIENCE STORE NEWS (Oct. 8, 2019), https://csnews.com/swisher-sweets-purple-swish; Swisher Sweets, *Purple Swish*, https://trade.swisher.com/purple-swish/ (last accessed Aug. 16, 2021); Swisher Sweets (@SwisherSweets), TWITTER (July 18, 2019, 12:01 PM), https://twitter.com/SwisherSweets/status/1151884758089117697 (Passion Fruit); Angel Abcede, *Swisher Introduces Sweet Cream*, CSP DAILY NEWS (Jan. 29, 2019), https://www.cspdailynews.com/tobacco/swisher-introduces-sweet-cream; 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).

Swisher has also targeted youth through event sponsorship and pricing practices. 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.[24] 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*.[25] 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.[26] Moreover, the price variation of Swisher among neighborhoods 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.[27]

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

[24] Swisher Sweets (@swishersweets), INSTAGRAM (June 22, 2019), https://www.instagram.com/p/By-qpUvAfEh/?utm_medium=copy_link; https://www.instagram.com/p/ BzBG8ulgof7/?utm_medium=copy_link; https://www.instagram.com/p/By-60bEnU53/?utm_medium=copy_link.
[25] *Id.*
[26] *See, e.g.*, *Artist Project*, SWISHER SWEETS, https://ap.swishersweets.com/(last accessed Aug. 16, 2021); Ollie Ganz et al., *Swisher Sweets 'Artist Project': using musical events to promote cigars*, 27 TOBACCO CONTROL e93 (2018).
[27] 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, 1333 (2017).

cigarette usage.[28] In December 2020, the Centers for Disease Control and Prevention reported that more than 700,000 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 preceding 30 days).[30] According to the 2019 National Survey on Drug Use and Health, more than 1,400 persons under the age of 18 smoke their first cigar each day.[31]

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, "All 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

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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.1 (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 SERVICES ADMINISTRATION (SAMHSA) (2020), https://www.samhsa.gov/data/sites/default/files/reports/rpt29394/NSDUHDetailedTabs2019/NSDUHDetTabsSect4pe2019.htm. Cigars are defined as cigars, cigarillos, or little cigars.

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.*

Use of cigars by young people raises particular 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; *see also* NAT'L CANCER INST., CIGARS: HEALTH EFFECTS AND TRENDS., at iii (1998). In short, as the FDA stated in 2019, "Cigars are associated with significant risk and provide no public health benefit."[32]

Therefore, because the requested injunction would extend the period during which Swisher's new flavored cigar products will continue to harm the

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

public health, and particularly children and teens, its adverse impact on the public interest substantially outweighs any injury to the company, particularly since 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 deny Swisher's motion for a preliminary injunction.

Respectfully submitted,

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