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VIA ECF

Ms. Patricia S. Connor
Clerk of the Court
United States Court of Appeals for the Fourth Circuit
1100 East Main Street, Suite 501
Richmond, VA 23219

RE: *American Academy of Pediatrics v. FDA*, No. 19-2130

Dear Ms. Connor:

Appellants Cigar Association of America, the Premium Cigar Association, and Cigar Rights of America (hereinafter “Cigar Appellants”) respectfully submit this response to the Food & Drug Administration’s (“FDA”) March 30, 2020 letter to this Court.

Cigar Appellants fully support any FDA action to extend by 120 days the deadline for the filing of substantial equivalence reports, in light of the public health emergency prompted by the COVID-19 virus. Indeed, they have petitioned the Government directly to provide similar relief.

While supporting the FDA’s proposed end result, Cigar Appellants are concerned with the time-consuming and unnecessary process proposed by the FDA for accomplishing this objective. The FDA invokes the five-step judicial process of Fed. R. Civ. P. 62.1, which would require an indicative order from the District Court, followed by a motion for limited remand in this Court, followed by a Fourth Circuit remand order, followed by a Rule 60(b) motion in the District Court, and finally a District Court order. The District Court has suggested it will accept briefs on phase 1 of this process—making an indicative ruling—until April 30, just 12 days before the deadline. District Court ECF No. 176 (Apr. 1, 2020). In light of the looming deadline and the strains of the COVID-19 emergency on businesses and government agencies alike, the time this process would take is prejudicial.

This Court, which retains jurisdiction over this matter, instead should issue a brief order recognizing that the case at bar does not restrict the Government from extending deadlines to address the COVID-19 emergency. Section 319 of the Public Health Service Act authorizes the Secretary of the Department of Health and Human Services (“HHS”), when he has declared a public health emergency, to extend “deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary” and to “waive . . . any sanctions otherwise

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applicable to such failure to comply.” 42 U.S.C. § 247d(d).¹ To do so, he need only determine that “individuals or public or private entities are unable to comply with” the relevant deadline “wholly or partially as a result of a public health emergency” declared by the Secretary. *Id.* The Act establishes the Secretary’s authority to act “notwithstanding any other provision of law.” *Id.*

HHS Secretary Alex Azar declared a public health emergency stemming from COVID-19 on January 31, 2020. The substantial equivalence report deadline concerns “reports” “to the Secretary” under a “law administered by the Secretary.” *Id.*; *see also* Family Smoking Prevention and Tobacco Control Act § 905(j)(1) (21 U.S.C. § 387e(j)(1)) (requiring substantial equivalence reports to be submitted “to the Secretary”); *id.* § 910(a)(2)(A)(i) (21 U.S.C. § 387j(a)(2)(A)(i)) (determining substantial equivalence assigned to the Secretary). The Secretary taking action under the Public Health Service Act would in no way conflict with the decisions below, which reversed an August 2017 extension that was not based on the Public Health Service Act and did not purport to restrict the government’s response to a public health emergency.

Cigar Appellants also take issue with the FDA’s statement that the COVID-19 crisis, and the agency’s plan for relief, do not “affect any of the arguments presented in these appeals.” First, the FDA’s filing makes clear that Cigar Appellants should be permitted to intervene in this case. Such an intervention would have been timely in January 2020, at the time of the first filing in any court where the Government stated it would no longer aggressively pursue an appeal of the decisions below. To the extent that the FDA believes that the orders below somehow constrain the agency’s ability to extend regulatory deadlines for cigar manufacturers due to the COVID-19 crisis, this intervening event provides additional and timely grounds for intervention.

Second, the FDA’s proposed course of action demonstrates that the District Court’s orders should be vacated. The District Court’s orders were based entirely on the FDA’s failure to take action against any e-cigarettes, which the District Court contended were causing an epidemic of youth usage with unknown health effects. Consolidated Opening Br. of Appellants and Intervenors-Appellants, at 42-44, ECF 71 (Jan. 23, 2020). On January 2, 2020, that underlying condition entirely changed: The FDA banned many e-cigarettes from the market until they obtained FDA approval and exercised its own discretion to require premarket submissions for those e-cigarettes that remained by May 12, 2020. *Id.* If the Vapor Appellants’ appeal is moot,

¹ FDA regulations similarly authorize the FDA “at any time [to] stay or extend the effective date of an action” and, in some circumstances requires, such a stay. 21 C.F.R. § 10.35(a), (e). All of the circumstances for a mandatory stay are met here, as the COVID-19 crisis has made compliance on May 12, 2020 impossible; the cigar industry will suffer irreparable harm; there are ample “public policy grounds” to keep employees in their homes rather than scrambling to prepare substantial equivalence reports; the delay—especially with regard to cigars—is not outweighed by other public health concerns; and litigation is pending challenging the substantial equivalence process that was brought “in good faith” and that is “not frivolous.” *Id.* at § 10.35(e).

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no court has ever considered whether the orders should remain in place for cigars alone. Yet, the District Court's orders are, at least in the FDA's view, unnecessarily tying the government's hands in responding to a national health crisis. Vacatur is particularly appropriate here, as both the Vapor and Cigar Appellants have not caused the mootness and "ought not in fairness be forced to acquiesce in the judgment." *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 25 (1994).

The Cigar Appellants request that this Court issue an order clarifying that the HHS Secretary and FDA Commissioner are not foreclosed from extending the May 12, 2020 deadline for substantial equivalence submissions as a result of the COVID-19 public health emergency. When proceeding to the merits, the Court should vacate the District Court's orders in light of mootness and intervening changed circumstances, including the agency's actions against e-cigarettes and the COVID-19 crisis.

Respectfully submitted,

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