UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Nos. 19-2130(L), 19- 2132, 19-2198, 19-2242

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs -Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants, and

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, et al.,

Intervenors-Appellants, and

CIGAR ASSOCIATION OF AMERICA, et al.,

Appellants.

On Appeal from the United States District Court
for the District of Maryland, No. 8:18-cv-883 (Grimm, J.)

CIGAR APPELLANTS' RESPONSE TO GOVERNMENT'S MOTION FOR REMAND AFTER INDICATIVE RULING BY THE DISTRICT COURT

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Appellants Cigar Association of America, the Premium Cigar Association, and Cigar Rights of America (hereinafter, the "Cigar Appellants") respectfully submit this response to the Government's Motion to Remand After Indicative Ruling by the District Court.

The Government proposes a cumbersome, multi-step process to modify the decisions below to address a public health emergency. The Government's proposal underscores that the decisions below have been completely overtaken by events, including the COVID-19 crisis and a January 2, 2020 agency decision to accelerate enforcement of the premarket review process against e-cigarettes. This Court should vacate the decisions below due to changed circumstances and mootness. This is the most straightforward, judicially efficient, and correct response to the intervening events presented to this Court.

If this Court were to vacate the decisions below, the parties could then determine whether further proceedings are necessary in light of the intervening January 2, 2020 enforcement decision regarding e-cigarettes and the COVID-19 public health emergency. Vacating the decisions below would clear this case from this Court's docket. And the case likely would not return to this Court, as the agency has decided to take prompt action against the e-cigarettes on which the rulings below focused and the District Court never suggested that its orders would be appropriate if a delayed compliance deadline had been set for cigars alone.

Urgent action is required to address the collision between the May 12, 2020 compliance deadline and the COVID-19 crisis. In the event that this Court is not prepared to vacate the decisions below in the near future, the Cigar Appellants do not oppose the Government's motion for a limited remand. In such circumstances, Cigar Appellants urge the Court to vacate the decisions as soon as is practicable, including during the limited remand.

Appellees have argued against the ordinary-course outcome of vacating the decisions below. Letter of Plaintiffs-Appellees, Dkt # 154 (Apr. 2, 2020). But Plaintiffs' mis-citation of a nearly 40-year-old D.C. Circuit case, *Center for Science in the Pub. Interest v. Regan*, 727 F.2d 1161 (D.C. Cir. 1984), actually demonstrates that at least the remedial order below should be vacated.

First, Plaintiffs argue that *Regan* "explicitly rejected" the Cigar Appellants "newfound interpretation of *U.S. Bancorp* [*Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18 (1994)]." Plaintiffs-Appellees Apr. 2 Letter at 1. *Regan* could not "explicitly reject[]" any interpretation of *Bonner Mall* because it *preceded* the Supreme Court's 1994 decision by a decade. *Bonner Mall* later held that a third-party that had nothing to do with the events that caused mootness "ought not in fairness be forced to acquiesce in the judgment." *Bonner Mall*, 513 U.S. at 25. That is precisely the case here. The Government's January 2, 2020 action mooted the Vapor appellants appeal in this case, and the industry appellants should not be forced

to live with the rulings below, simply because the Government took action to moot the case.

Second, the D.C. Circuit in *Regan* actually ***vacated*** a prospective remedial order that would no longer be reviewed due to mootness. The district court had overturned a Treasury Department action rescinding an existing rule. As here, the lower court then entered forward-looking orders for setting dates by which the original rule would go into effect. *Regan*, 727 F.2d at 1163. When intervening agency action mooted the appeal, the D.C. Circuit vacated the forward-looking remedial order, noting that such prospective injunctive relief "no longer has any prospective force" after the case had been mooted. *Id.* at 1165.

Bonner Mall teaches that the *merits and remedial* orders below should be vacated, because they affect third parties that did not cause the mootness and "ought not in fairness be forced to acquiesce in the judgment." *Bonner Mall*, 513 U.S. at 25. The D.C. Circuit's *Regan* decision—to the extent it remains good law—at least counsels in favor of vacating a prospective remedial order (the District Court's setting of a future regulatory deadline) when an intervening agency action has mooted the case.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 4, 2020, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Michael J. Edney
Michael J. Edney

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This response complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because it contains 659 words, excluding the parts of the motion exempted by Fed. R. App. P. 27(d)(2) and Fed. R. App. P. 32(f).

2. This motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Word in 14-point font.

/s/ Michael J. Edney
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