In The
United States Court of Appeals
For the Fourth Circuit

No. 19-2130
(8:18-cv-00883-PWG)

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs – Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants, and

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

Intervenors-Appellants.

In re: CIGAR ASSOCIATION OF AMERICA, et al.,

Appellants

PLAINTIFFS-APPELLEES' RESPONSE TO DEFENDANTS-APPELLANTS' MOTION FOR REMAND AFTER INDICATIVE RULING BY THE DISTRICT COURT

In response to the Court's April 6, 2020 Notice, Plaintiffs-Appellees state that they do not oppose the Government's Motion for Remand After an Indicative Ruling by the District Court. For the reasons stated in the District Court, Plaintiffs-Appellees disagree with the length and breadth of FDA's proposed extension on policy grounds, but do not oppose its request given the current extraordinary circumstances. *See* D. Ct. Dkt. No. 177.

As they did in response to the Government's notice that it was seeking an indicative ruling, the Cigar Associations use the motion to remand as a pretext to make new arguments about issues that were squarely presented in the principal briefing. The proper time to address the cases raised in Plaintiffs' brief was in the Cigar Associations' reply, not in *seriatim* filings well after the close of briefing and oral argument. Moreover, the Cigar Associations' rearguard arguments do not even address the denial of their motion to intervene, the threshold issue that precedes the subjects they now raise. If the Court affirms the denial of the Cigar Associations' motion to intervene, it need not consider the Cigar Associations' response at all.

To the extent the Cigar Associations' untimely arguments require a response, it bears noting that they misrepresent *Center for Science in the Public Interest v. Regan*, 727 F.2d 1161 (D.C. Cir. 1984), and the state of the law. In *Regan*, the district court had vacated a rule known as "No. 94" that had unlawfully rescinded an earlier rule known as "No. 66." *Id.* at 1163. One portion of the district court decision "required No. 66 to be made effective within one year." *Id.* at 1164. Subsequently, the agency *lawfully* rescinded No. 66. *Id.* at 1163-64. Because the agency no longer had any "obligation … to reinstitute No. 66," the *Regan* court vacated that limited portion of the district court's decision "to make it clear that the [agency] is under no present obligation to make No. 66 effective." *Id.* at 1165.

This portion of *Regan* has little if any relevance to the issues before this Court. The analogue to No. 66 in this case is the Deeming Rule, which FDA has most certainly not rescinded. The relevant portion of *Regan* is its rejection of intervenors-appellants' arguments for vacating the entire ruling below. *Id.* at 1165-66. As the *Regan* court explained, "review was prevented, not by 'happenstance,' but by the deliberate action of the losing party before the district court, the

[agency]," leaving "no reason for this Court to take *any* action whatsoever with respect to the remainder of the district court decision." *Id.* at 1165. Intervenors "cannot accomplish through a motion to vacate that which they could not achieve through a direct appeal." *Id.*; *see also, e.g.*, *Lamprecht v. FCC*, 958 F.2d 382, 389 (D.C. Cir. 1992) (intervenors "may only join issue on a matter that has been brought before the court by another party. They cannot expand the proceedings." (citation omitted)).

The Cigar Associations also criticize *Regan* because it was decided before *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994). But of course, they cite no cases suggesting that *U.S. Bancorp* overruled *Regan*; to the contrary, it is clear that *Regan* correctly anticipated it. *Compare Regan*, 727 F.2d at 1165 (vacatur inappropriate where review prevented "by the deliberate action of the losing party before the district court"), *with U.S. Bancorp*, 513 U.S. at 25 (vacatur inappropriate where "the losing party has voluntarily forfeited his legal remedy …, thereby surrendering his claim to the equitable remedy of vacatur").

As for the E-Cigarette Associations, while they have not yet filed their response to the Government's motion to remand, they will presumably assert the same after-the-fact arguments they made in their response to the Government's notice that it intended to seek an indicative ruling. *See* ECF 155. These arguments add nothing to the E-Cigarette Associations' arguments during briefing and oral argument, and should be rejected for the same reasons.

Most importantly, as explained at oral argument (approx. 38:30-40:20), the relief the E-Cigarette Associations are seeking—issuance of future guidance through notice-and-comment rulemaking—already occurred, as the E-Cigarette Associations have pointed to no way in which FDA violated the requirements of 5 U.S.C. § 553. *See* 84 Fed. Reg. 9345 (Mar. 14, 2019). Because the only relief the E-Cigarette Associations request is an action FDA has already taken, there is no "effectual relief" this Court can award them and their appeal is moot. *Incumaa v. Ozmint*, 507 F.3d 281, 286 (4th Cir. 2007).

Respectfully submitted,

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