IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN ACADEMY OF PEDIATRICS, et al.

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.

Defendants-Appellants,

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, et al.

Intervenors-Appellants, and

CIGAR ASSOCIATION OF AMERICA, et al.

Appellants.

Case No.: 19-2130(L) [consol. with Nos. 19-2132, 19-2198 & 19-2242]

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

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In response to this Court's April 6, 2020 Notice, Vapor Appellants agree that a new PMTA deadline set at a minimum of 120 days from the current May 12, 2020 deadline is critically needed due to the unprecedented coronavirus outbreak and that a limited remand should be granted consistent with the District Court's indicative ruling (ECF 179). Accordingly, Vapor Appellants do not oppose the Government's request provided that by doing so they do not waive or concede any arguments or rights, whether before this Court, the District Court, FDA, or any other governmental body going forward. It is also their understanding that this Court would then retain jurisdiction to decide all issues on appeal.

However, Vapor Appellants must also address several points made by the Cigar Appellants (Doc. 157) and Plaintiffs-Appellees (Doc. 159) in their respective Responses. *First*, Cigar Appellants discuss *Ctr. for Science in Pub. Interest v. Regan*, 727 F.2d 1161 (D.C. Cir. 1984) when arguing that the January 2020 Guidance moots this case. In doing so, they fail to acknowledge that *Regan* is entirely distinguishable and, in fact, clearly demonstrates why there is no mootness here. *See also* Doc. 124 at 13 n.7.

In that case, the lower court had largely set aside an attempted rescission by the Treasury Department of an alcohol labeling regulation because it was "inadequately explained" and thus violated the APA. 727 F.2d at 1166-67 n.6. The Treasury Department then promulgated a new rescission rule and argued that

the underlying challenge to the earlier attempt was moot. The D.C. Circuit agreed, in part, because the Treasury Department's new rule was based on a rulemaking rationale that was set out "in much greater detail." *Id.* The Court noted that an "agency is certainly acting within its authority when it attempts to offer a better explanation." *Id.* As such, the new rule presented a different case, as it was based on "reasoning not previously articulated by the agency as its policy." *Id.* at 1166. In other words, the agency tried to correct the problem challenged on appeal.

But that is not what happened here. FDA made no attempt to fix the APA shortcomings identified in the District Court's Merits Decision—i.e., that a categorical PMTA deadline was required to go through formal notice-and-comment rulemaking under 5 U.S.C. § 553. App. 97. Indeed, the January 2020 Guidance was adopted as interpretive guidance, not a legislative rule, which FDA repeatedly argues is not subject to judicial review because it is exempt from the APA. *See, e.g.*, Gov't Reply Br. (Doc. 123) at 8. As the Supreme Court later held in *Northeastern Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 661-62 (1993), a new regulation that replaces and repeals an old one does not moot a case where it fails to correct the problem raised on appeal. *See also* Doc. 124 at 13 n.6.[1]

[1] Indeed, the FDA cannot have it both ways. It cannot now moot a § 553 challenge through agency action that, in turn, is designed to avoid any further judicial

Second, all of this shows the absurdity of the Plaintiffs-Appellees' claim in its Response that the January 2020 Guidance somehow complied with § 553 and that Vapor Appellants have received the entirety of their requested relief. As we pointed out repeatedly in our underlying briefs and during oral argument, interpretive guidance, even one that is preceded by public comment, does not accord Vapor Appellants the same rights as a § 553 rulemaking. *See, e.g.*, Doc. 71 at 41-42, 46; Doc. 124 at 13-16; Doc. 56 at 2.

Under the Plaintiffs-Appellees' approach, not only can FDA freely disregard concerns expressed by stakeholders (and, in fact, the January 2020 Guidance does not address significant concerns that Vapor Appellants raised before the District Court and in their appellate briefs regarding the May 12, 2020 deadline—e.g., time required for long-term clinical studies, lack of FDA-approved testing protocols, etc.), FDA did so (as it now argues) without being subject to judicial review.[2]

As such, the January 2020 Guidance was published through a process that is fundamentally different than APA rulemaking and does not correct the unlawful

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scrutiny under the same provision. That is not mootness; rather, it is repeating the very same unlawful conduct that should be redressed on appeal.

[2] Indeed, Plaintiffs-Appellees are actually relying on a document that repeatedly says it "Contains Nonbinding Recommendations" and "does not establish any rights for any person and is not binding on FDA or the public." App. 189.

conduct alleged on appeal—i.e., the District Court's failure to remand this issue to FDA so that a new PMTA filing deadline can be promulgated under § 553, consistent with the District Court's findings in the Merits Decision.

Third, even assuming *arguendo* that the January 2020 Guidance moots the Vapor Appellants' appeal, this Court should not, as argued by Cigar Appellants, vacate the Merits Decision in addition to the Remedies Order. The Vapor Appellants have only challenged the District Court's imposition of a new PMTA deadline (i.e., the remedy). They have not appealed the Merits Decision or sought to permanently restore the now vacated 2017 Guidance; in fact, their challenge is based on the Merit Decision's holding that a categorical PMTA deadline must have complied with the APA's formal notice-and-comment procedures. Thus, the only decision that could be "mooted" here is the Remedies Order.

April 10, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2020, I filed the foregoing in the United States Court of Appeals for the Fourth Circuit via the CM/ECF system. I further certify that all parties are registered CM/ECF users, and that service will be accomplished via electronic filing.

/s/ *Eric P. Gotting*
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