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April 2, 2020

VIA CM/ECF

Ms. Patricia S. Connor, Clerk
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(L) and consolidated cases (argued March 18, 2020 before Judges Agee, Thacker, and Rushing)

Dear Ms. Connor:

Vapor Appellants hereby respond to the Food and Drug Administration's (FDA) March 30, 2020 correspondence submitted in this appeal (Doc. #152). They agree a new date set at a minimum of 120 days from the current May 12, 2020 PMTA deadline is critically needed during this public health crisis. As we understand FDA's request, the District Court would simply be replacing the May 12, 2020 deadline set in the Remedies Order with a September 9, 2020 cutoff in response to the unprecedented coronavirus outbreak. This Court would then retain jurisdiction to decide all issues on appeal. Accordingly, Vapor Appellants will not oppose FDA's request provided that by doing so they do not waive or concede any arguments or rights, whether before this Court, the District Court, or FDA going forward.

However, we must make clear that, contrary to FDA's representations, the agency's request for a limited remand so the District Court can extend its own deadline does, in fact, *directly* impact the arguments presented on appeal by the Vapor Appellants. Specifically, FDA's request further demonstrates that the January 2020 Guidance ("Guidance") did *not* moot this appeal. FDA had to request that the Remedies Order be amended because it is that order, not the Guidance, that is ultimately dictating the deadline here. Indeed, only after the District Court grants FDA's request would the agency amend the Guidance to reflect, not surprisingly, the exact same September 9, 2020 date. Doc. 175-1 at 10. As such, the Guidance was not promulgated, as FDA claims, "independent" of the Remedies Order (Doc. 69 at 23); rather, it is nothing more than a rote memorialization of the District Court's remedy.

All of this means, therefore, that the Vapor Appellants' appeal is still very much alive and very much ripe. They are challenging the District Court's authority to set a PMTA deadline

instead of remanding that issue to FDA so that the agency can promulgate a new deadline through formal APA notice-and-comment rulemaking, consistent with the District Court's underlying Merits Decision. *See* Mem. Op. at 53 (App. 97) (holding a categorical PMTA deadline was subject to 5 U.S.C. § 553). Importantly, even if the District Court amends the Remedies Order (followed by a corresponding amendment by FDA to the Guidance), the legal error challenged on appeal would still not be corrected; namely, that a categorical deadline must be established under § 553, not by a district court or a mere confirming guidance document.

To be clear, Vapor Appellants are not asking that the 2017 guidance, which set an August 2022 deadline, be permanently restored. That guidance was vacated by the District Court in the Merits Decision, which Vapor Appellants have not appealed here. Indeed, Vapor Appellants' request for a remand is based on the holding set forth in the Merits Decision that an across-the-board deadline was a legislative rule requiring adherence to the APA. And that is also why it is irrelevant that the Guidance purportedly replaced the prior 2017 version. Rather, this appeal focuses on a different issue—*i.e.*, whether the District Court exceeded its authority when setting its own compliance policy in lieu of a remand to FDA so that the agency could establish a new deadline pursuant to the APA (not via an informal guidance document that simply parrots the Remedies Order). Accordingly, this Court would provide full relief to Vapor Appellants by granting such a remand so that FDA can set a deadline pursuant to § 553.

Sincerely,

Eric P. Gotting
Partner