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July 13, 2023

VIA CM/ECF

David J. Smith
Clerk of the Court
United States Court of Appeals for the Eleventh Circuit
56 Forsyth Street, N.W.
Atlanta, Georgia 30303

Re: *Eknes-Tucker, et al.* v. *Governor of the State of Alabama, et al.*, No. 22-11707 (11th Cir.)—Intervenor-Appellee United States' Response to Defendants-Appellants' Notice of Supplemental Authority Under Federal Rule of Appellate Procedure 28(j)

Dear Mr. Smith:

The Sixth Circuit's order granting a stay in *L.W.* v. *Skrmetti* was decided quickly without full briefing, and the panel cautioned that its views were only "initial" and "may be wrong." Order 15.

The United States respectfully disagrees with the panel's "initial" view that Tennessee's ban does not discriminate based on sex. As Judge White in partial dissent explained, "the law discriminates based on sex because 'medical procedures that are permitted for a minor of one sex are prohibited for a minor of another sex.'" Order 16 (citation omitted). Importantly, the panel did *not* disagree that the ban discriminates against transgender minors but explained its view that heightened scrutiny does not apply to such discrimination. Order 12-13. The panel acknowledged that other courts have taken different approaches. Order 13-14, 16 & n.2. Among them is this Court, which has held that "discrimination against a transgender individual because of [] gender non-conformity is sex discrimination" under the Equal Protection Clause, triggering heightened scrutiny. *Glenn* v. *Brumby*, 663 F.3d 1312, 1317 (11th Cir. 2011).

The *L.W.* panel wrongly inferred that the absence of FDA approval for puberty blockers and hormone therapies to treat gender dysphoria means that "medical and regulatory authorities are not of one mind" about these treatments. Order 7, 9. But this absence implies no such conflict. FDA approval may not be obtained for reasons that have nothing to do with a medication's safety and efficacy for a particular use. For example, even where there is "substantial evidence of safety and efficacy" for a new use, "a sponsor may not seek FDA approval because doing so is not economically beneficial." U.S. Br. 42 (citing Doc. 62-2, at 10).

"Once the FDA has approved a medication" for one condition, "thereby agreeing that it is safe" and "effective for this intended use," the FDA agrees that "prescribers are generally free to prescribe it for other indications" when they judge it is medically appropriate. Doc. 62-2, at 8-9 (citing https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label). Off-label use of FDA-approved drugs is not uncommon, including in pediatrics. See U.S. Br. 42 (citing Tr. 240; Doc. 62-2, at 8-10).

Sincerely,

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Chief

s/ Barbara Schwabauer
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cc: Counsel of Record (via CM/ECF)