IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Case No. 25-mc-00063-SKC-CYC

In Re: Department Of Justice Administrative Subpoena No. 25-1431-030

UNITED STATES' NOTICE OF SUPPLEMENTAL AUTHORITY

Pursuant to Civ. Practice Standard 10.1(d), the United States of America respectfully submits this Notice of Supplemental Authority to identify new authority relevant to the United States' Opposition to Children's Hospital Colorado's Motion to Quash Subpoena (ECF 10).

On December 18, 2025, the nation's highest-ranking health official, the United States Secretary of Health and Human Services ("HHS"), together with the Commissioner of the United States Food and Drug Administration ("FDA"), the Director of the National Institutes of Health ("NIH"), the Administrator of the Centers for Medicare and Medicaid Services ("CMS"), and the Assistant HHS Secretary for Health announced the HHS Secretary's issuance of a formal declaration regarding "Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents." U.S. SEC'Y OF HEALTH & HUM. SERVS., DECLARATION ON PEDIATRIC SEX-REJECTING PROCEDURES (Dec. 18,

2025), https://www.hhs.gov/sites/default/files/declaration-pediatric-sex-rejecting-procedures.pdf ("HHS Declaration") (attached as Exh. A).

The HHS Declaration (supported by the accompanying Public Health Message from the Assistant HHS Secretary for Health (the highest-ranking officer of the United States Public Health Service), U.S. DEP'T OF HEALTH & HUM. SERVS., EVIDENCE-BASED CARE FOR CHILDREN AND ADOLESCENTS WITH GENDER DYSPHORIA (Dec. 18, 2025), https://health.gov/sites/oash/files/Message_Pediatric_Gender_Dysphoria_Treatment.pdf (attached as Exh. B)), expressly states:

> **Sex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors, and therefore, fail to meet professional recognized standards of health care. For the purposes of this declaration, "sex-rejecting procedures" means pharmaceutical or surgical interventions, including puberty blockers, cross-sex hormones, and surgeries such as mastectomies, vaginoplasties, and other procedures, that attempt to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex.**

HHS Declaration at 9 (emphasis in original).

The Secretary's Declaration is relevant to the propriety of the administrative subpoena to Children's Hospital Colorado to investigate whether the promotion, marketing, labeling, sale, and distribution of puberty blockers and cross-sex hormones to treat gender dysphoria and related disorders could violate the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*) and related federal

statutes—including whether claims about the safety, effectiveness, risks, and benefits of these drugs for such treatment may be false or misleading.

No portion of this filing was drafted by artificial intelligence.

Dated this 22nd day of December, 2025.

Respectfully submitted,

FOR THE UNITED STATES OF AMERICA

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of December, 2025, I filed the foregoing Notice of Supplemental Authority with the Clerk of Court using the CM/ECF system, and separately emailed to counsel for Children's Hospital Colorado at:

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Dated this 22nd day of December 2025.

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