

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: 2025 UPMC SUBPOENA

MISCELLANEOUS ACTION

Case No. 2:25-mc-1069-CB

NOTICE OF SUPPLEMENTAL AUTHORITY

The United States of America respectfully submits this Notice of Supplemental Authority in support of its Opposition to Plaintiffs' Motion to Quash the subpoena that the United States issued to UPMC under 18 U.S.C. § 3486 in the furtherance of its investigation of federal healthcare offenses.

Plaintiffs assert that the use of the drugs at issue—puberty blockers and powerful cross-sex hormones—as a treatment for minors suffering from gender dysphoria and related psychiatric disorders is “associated with reductions in suicide attempts” and “decreased rates of depression and anxiety.” ECF 2 at 3. Also according to Plaintiffs, because the medical care UPMC provided was legitimate, the Government’s subpoena cannot be justified and instead reflects an improper effort to “threaten providers” and “intimidate families.” *Id.* at 1.

Recent developments refute Plaintiffs’ arguments. On December 18, 2025, the United States Secretary of Health and Human Services (“HHS”), the nation’s highest-ranking health official, 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 (the highest-ranking officer of the United States Public Health Service) announced the

HHS Secretary's issuance of a formal declaration regarding "Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures and Adolescents." U.S. SEC'Y OF HEALTH & HUMAN SERVS., DECL. ON PEDIATRIC SEX-REJECTING PROCEDURES (Dec. 18, 2025), <https://www.hhs.gov/sites/default/files/declaration-pediatric-sex-rejecting-procedures.pdf> (attached as Ex. A).

The Secretary's Declaration (supported by the accompanying Public Health Message from the Assistant Secretary for Health, *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 Ex. B)), expressly states that federal health authorities have determined that the treatments that Plaintiffs seek to shield from investigation are neither safe nor effective and categorically fail to meet professionally recognized standards of medical care:

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).

HHS has determined that puberty blockers and cross-sex hormones should not be used to treat gender dysphoria and related disorders in minors. Because the Declaration reflects the determination that such use is outside the professional practice of medicine, the Declaration refutes Plaintiffs' arguments that the intent of the Government's investigation is to end legitimate medical care while "threaten[ing]" and "intimidat[ing]" people. The Declaration also bears

directly on whether the Government may reasonably subpoena UPMC to investigate whether the promotion, marketing, labeling, sale, and distribution of drugs in pursuit of illegitimate uses violates 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, or appropriateness of these drugs for such treatment may be false or misleading.

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 December 22, 2025, I served the foregoing Notice of Supplemental Authority via ECF to counsel of record.

Dated this 22nd day of December 2025.

/s/ *Patrick Runkle*
PATRICK RUNKLE