IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Case No. 25-mc-63-SKC-CYC

In re: Department of Justice Administrative Subpoena No. 25-1431-030

REPLY IN SUPPORT OF CHILDREN'S HOSPITAL COLORADO'S MOTION TO QUASH SUBPOENA

ORAL ARGUMENT REQUESTED
PURSUANT TO D.C.COLO. UNIFORM CIV. PRAC. STANDARDS OF THE U.S. MAGISTRATE JUDGES § V(3)

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The government concedes that it has no articulable suspicion or evidence of wrongdoing by Children's Hospital, Dkt. 10 ("Opp.") at 3–5; its investigation lacks a factual basis other than a Supreme Court concurrence that bears no relation to Children's Hospital, *id*. at 4–5; the provision of gender-affirming care to minors is lawful under Colorado and federal law, *id*. at 9; and the Subpoena was issued pursuant to the Bondi Memo, *id*. at 6–7, which was promulgated to execute two now-enjoined presidential Executive Orders that were found to be motivated by purposeful discrimination against transgender people. This Court needs nothing more to conclude that the Subpoena lacks a proper purpose, as the District of Massachusetts did when assessing an identical subpoena on a similar record. *See In Re: Admin. Subpoena No. 25-1431-019*, 2025 WL 2607784 (D. Mass. Sept. 9, 2025) (attached as Ex. 1) ("BCH Order"). As in that case, the Subpoena here should be quashed in full.

The government counters that this Court lacks authority to scrutinize its motives. Opp. at 4–5. But under well-established authority, its investigation must "be conducted pursuant to a legitimate purpose" and any use of a subpoena to "harass," "pressure," or pursue any other motive lacking "good faith[,]" constitutes an "abuse" of the "court's process" and is subject to judicial examination. *See United States v. Powell*, 379 U.S. 48, 57–58 (1964) (cited in Opp. at 2). The government further claims Children's Hospital hasn't shown that the DOJ is investigating it "pretextually" or "in a manner inconsistent with the law." Opp. at 6. But that

argument overlooks the record Children's Hospital submitted with its motion. And on that unrebutted record, this Court can and should conclude that the DOJ issued a burdensome, suspicion-free subpoena to "harass" and improperly "pressure" Children's Hospital into stopping its provision of care that is safe, effective, and lawful in Colorado.

The government's attempt to justify its authority to issue the Subpoena only compounds its problems. It claims an Assistant Attorney General was delegated authority to use HIPAA subpoenas to investigate certain violations of the Food, Drug, and Cosmetic Act ("FDCA"), but declines to attach the pertinent order, and asks this Court instead to take the government's word for it.

Finally, the Subpoena is plainly overbroad. The government claims it is investigating drug manufacturers (not hospitals) for potential FDCA violations related to the unlawful promotion of off-label uses of certain drugs, Opp. at 6–7, but never explains how that could possibly justify seeking pediatric medical records (much less social security numbers) from thousands of transgender children—an already marginalized population whose psychological, familial, and social histories are among the most sensitive records Children's Hospital keeps. The government also concedes that a HIPAA subpoena cannot be used to investigate a potential False Claims Act violation—notwithstanding that 10 of the 15 document requests are directed to that topic and thus should be summarily quashed. For these reasons and those below, the Subpoena should be quashed in full.

I. ARGUMENT

A. The Subpoena should be quashed in its entirety.

1. The DOJ admits it is engaged in a fishing expedition.

The government admits but shrugs off the fact that it lacks any articulable suspicion or evidence of wrongdoing by anyone at Children's Hospital, Opp. at 3–4, claiming it has unfettered authority to enforce a burdensome subpoena even if it simply "wants assurance" that Children's Hospital isn't violating the law. *Id.* at 3 (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950)). But *Morton Salt*, upon which the government relies, doesn't support giving the government carte blanche to enforce suspicion-free subpoenas regardless of the consequences, as the government suggests. On the contrary, it denigrates "fishing expeditions," *Morton Salt.* 338 U.S. at 641–42; recognizes that an "arbitrary" subpoena is "unlawful," *id.* at 654; and states that "a governmental investigation into corporate matters may be of such a sweeping nature and so unrelated to the matter properly under inquiry as to exceed the investigatory power," *id.* at 652.

That is what we have here. In fact, the government admits it is conducting a fishing expedition. *See* Opp. at 3–5, 10 (conceding lack of suspicion and stating Children's Hospital could be "a witness" for all the government knows). The District of Massachusetts recently struck down an identical subpoena to Boston Children's Hospital in part for this reason. *See* BCH Order at *6 ("[The government] cannot use its subpoena power to go on a fishing expedition."). Under

Morton Salt and its progeny, the sweeping Subpoena at issue here cannot be enforced. 338 U.S. at 652; *see also In re Sealed Case (Admin. Subpoena)*, 42 F.3d 1412, 1418 (D.C. Cir. 1994) (quashing subpoena because government sought "unfettered authority to cast about for potential wrongdoing"); *United States v. Theodore*, 479 F.2d 749, 754 (4th Cir. 1973) ("The Government cannot go on a fishing expedition . . . and if its purpose is a rambling exploration of a third party's files, it will not be enforced") (citations omitted).

2. The Subpoena lacks a proper purpose.

The government further insists this Court is prohibited from assessing the "motives" underlying its investigation. Opp. at 4–5. That is wrong. The Tenth Circuit consistently applies the *Powell* framework requiring that investigations "be conducted pursuant to a legitimate purpose" and subpoenas not be used to "harass" recipients or otherwise "abuse" the court's process. *Powell*, 379 U.S. at 57–58; *see also, e.g., Standing Akimbo, LLC v. United States*, 955 F.3d 1146, 1154 (10th Cir. 2020) (applying *Powell*).

As to the government's purpose, the government claims Children's Hospital is seeking to quash on the ground that "the underlying conduct involves politically sensitive subject matter." Opp. at 3. But that's a strawman. So, the government says Children's Hospital hasn't shown it is being investigated "pretextually" or "in a manner inconsistent with the law." *Id.* at 6.

But at bottom, the government offers nothing to rebut the record revealing the clear sequence of events that demonstrate the Administration's campaign to denigrate transgender people and eliminate gender-affirming care. *See* Dkt. 1 ("Mot.") at 3–8. Nor does the government contest that the Administration boasted about its success in coercing hospitals into eliminating gender-affirming care based in part *on subpoenas like the one at issue*. *See* Dkt. 1-14. And the government admits the Subpoena was issued pursuant to the Bondi Memo, Opp. at 6–7, which baselessly denigrated gender-affirming care as "mutilation," and was promulgated to execute upon Executive Orders that were found to be motivated by discriminatory animus. Indeed, the government baldly and wrongly contends that it would be *proper* if its purpose were to end gender-affirming care in Colorado. Opp. at 7; *see also* BCH Order at *6 (rejecting government's argument).

In short, the opposition does nothing to disturb the conclusion that the Subpoena is designed to "harass" and "pressure" Children's Hospital into eliminating gender-affirming care for transgender youth. That is precisely the conclusion the District of Massachusetts reached when assessing an identical Subpoena to Boston Children's Hospital. BCH Order at *5 ("The Government has not submitted any affidavits or other evidence to show proper purpose."); *id.* at *7 ("It is abundantly clear that the true purpose of issuing the subpoena is to interfere with the Commonwealth of Massachusetts' right to protect [gender-affirming care]

within its borders, to harass and intimidate BCH to stop providing such care, and to dissuade patients from seeking such care.").

The government's claim that it was directed to conduct "appropriate investigations," Opp. at 6, does not change the calculus. The EOs at issue were struck down in part because the "savings" clauses did not sanitize the obvious discriminatory intent. *See, e.g., Washington v. Trump*, 768 F. Supp. 3d 1239, 1278 (W.D. Wash. 2025). Finally, the government provides no authority for its suggestion that a Supreme Court concurrence can factually predicate a sweeping, suspicion-free subpoena. And if anything, *United States v. Skrmetti* confirms that the government must defer to the sound discretion of *states* when it comes to regulating the provision of gender-affirming care to minors. 145 S. Ct. 1816, 1836–37 (2025) (states are entitled to "wide discretion" to regulate the provision of gender-affirming medical care to minors). In Colorado, such care is lawful and covered by the Medicaid program. The government has provided no valid justification for its harassing subpoena. It lacks a proper purpose and should be quashed in full.

3. <u>The Subpoena is procedurally improper.</u>

The government's attempt to explain its authority to issue the Subpoena in the first place only reinforces its defects. The government insists the Subpoena was lawfully authorized based on authority delegated by the Attorney General to the Assistant Attorney General for the Civil Division, but refuses to provide the proof,

asking Children's Hospital and this Court instead to take the government's word for it. *See* Dkt. 10-1 ¶ 5.[1] The government also makes no attempt to argue that it can use a HIPAA subpoena to pursue the Attorney General's directive to investigate potential violations of the False Claims Act ("FCA"). Nor could it, as the FCA is not among the defined set of statutes the government can investigate using a 3486 subpoena, Mot. at 12, and it wouldn't make sense to do so in this context in Colorado in any event because gender-affirming care is lawful in Colorado.

The government's declaration and brief are informative in one respect: they claim the Subpoena was issued solely to investigate "violations of the FDCA," Dkt. 10-1 ¶ 5; specifically, whether drug "manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of [puberty blockers or hormones]," or "unlawful[ly] promot[ed] off-label uses of [such drugs for] gender-related treatment of minors," Opp. at 7. This theory, if true, would invalidate two-thirds of the Subpoena requests—numbers 1-6 (relating to personnel files and use of diagnosis codes) and 11-15 (patient medical records)—because none of those requests bear any relation to the purported misbranding or unlawful promotion justification and, if anything, appear to relate to potential False Claims Act violations for which the Subpoena is an improper investigatory tool.

To the extent the government claims the Subpoena's purpose is to investigate the foregoing FDCA misbranding violations, the incongruence between that

[1] Children's Hospital requested a copy of the referenced order prior to filing this action but never received it. *See* Dkt. 1-8 (Gray Decl., Ex. 5).

justification and the majority (10 of 15) of the requests shows the justification is a pretext. Indeed, it appears to be a post-hoc rationalization, given the Subpoena was actually issued to intimidate Children's Hospital into foregoing gender-affirming care, as the Administration itself has boasted. *See supra*. Recent reporting buttresses this conclusion: the career official originally in charge of the Consumer Protection Branch declined to sign the subpoenas; "raised serious concerns about collecting children's health data and whether it was necessary to advance the investigation"; and "argued it's not illegal under the Federal Food, Drug, and Cosmetic Act for physicians to prescribe puberty blockers and related treatment for children who wish to undergo a transition." *See* Ben Penn and Ian Lopez, *Justice Dept. Expands Gender Care Probe as Hospital Fights*, Bloomberg Law (Aug. 20, 2025), available at http://bit.ly/4ntsVdX.

The government, in short, has not shown that the Subpoena was lawfully authorized. It should be quashed in its entirety, or, at the very least, on this record, Children's Hospital is entitled to an evidentiary hearing to discern the government's authority and purpose for the Subpoena. *See United States v. Clarke*, 573 U.S. 248, 254 (2014) (evidentiary hearing is appropriate where recipient can point "to specific facts or circumstances plausibly raising an inference of bad faith").

B. The Subpoena is overbroad and unduly burdensome.

The government claims its Subpoena is not overbroad because Children's Hospital provides "the type of pharmaceuticals under investigation" and the

requests supposedly "relate[] to the provision of those drugs and services." Opp. at 10. The government also purports to dismiss in a single sentence any claim that its Subpoena is unduly burdensome, arguing that Children's Hospital should have to comply because it is "large" and "regulated." Opp. at 12.

These arguments fail. As to breadth, the government claims it is investigating drug manufacturers (not hospitals) for potential FDCA violations related to the *unlawful promotion* of off-label uses of certain drugs, Opp. at 6–7, but never explains how that could possibly justify seeking patient files, addresses, social security numbers, billing records, or parent/guardian information, among other things, from thousands of pediatric, transgender patients—a highly marginalized population whose psychological, familial, and social histories are among the most sensitive records Children's Hospital keeps.

Nor does the government explain how any "unlawful dispensing of puberty blockers and cross-sex hormones for use by minors," Opp. at 1, could even fit within the FDCA, which prohibits drug manufacturers from adulterating or misbranding their products, *see* 21 U.S.C. § 331, and does not regulate the presentation of claims to health insurers. Moreover, according to the Bondi Memo, any "unlawful dispensing" theory is predicated on a violation of the False Claims Act (not the FDCA) through the use of false diagnosis codes, *see* Dkt. 1-8 at 4; the DOJ lacks authority to investigate that theory through a HIPAA subpoena, *see supra*; and it wouldn't make sense to do so in this context in any event because doctors can

lawfully code for gender-affirming care in Colorado. Tellingly, the government never addresses the argument that providers in Colorado would have no reason to engage in deceptive coding or billing. *See* Mot. at 3–4, 8, 10–11. And the government cannot dispute that the drugs at issue are FDA approved, may lawfully be dispensed pursuant to a prescription, and are lawful to use off-label in Colorado to provide gender-affirming care to minors.

Mindful of the above, the Subpoena is plainly overbroad at least as to requests 1-6 (relating to personnel files, billing records, and use of diagnosis codes) and 11-15 (patient medical records), which, if anything, are directed to potential violations of the False Claims Act—not the FDCA—and should be summarily quashed. As to burden, the government cannot enforce an "unreasonably burdensome" subpoena, *United States v. Wilson*, 98 F.4th 1204, 1221 (10th Cir. 2024), there are obvious overbreadth issues here, and the record on burden is unrebutted, Dkt. 1-15 ¶¶ 37–39 (compliance would take thousands of hours).

In sum, the government has come nowhere close to sufficiently explaining how the extraordinary burden and scope of the Subpoena are justified given the intrusive nature of the requests, its admitted speculation (at best) about potential wrongdoing, and the clear irrelevance of the requests to the hypothetical crimes the government has hypothesized could theoretically have been committed by others.

II. CONCLUSION

The Subpoena should be quashed in its entirety.

CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2025, I filed the foregoing with the Clerk of Court using the CM/ECF system, which caused the foregoing to be sent to:

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Respectfully submitted,

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/s/ Cody Gray
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