IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Case No. 25-mc-00063-SKC

IN RE: DEPARTMENT OF JUSTICE ADMINISTRATIVE SUBPOENA NO. 25-1431-030

GOVERNMENT'S OPPOSITION TO CHILDREN'S HOSPITAL COLORADO MOTION TO QUASH

The United States (the "Government") recognizes that the investigation concerns potential misconduct undertaken in the context of a politically sensitive subject matter, but that fact does not in any way make the subpoena invalid or unenforceable. Indeed, Children's Hospital Colorado ("CHC") does not make a showing that the administrative subpoena in question is procedurally defective, and it does not identify a lawful basis to avoid complying with a valid subpoena. This Court should overrule CHC's meritless objections and enforce the subpoena.

BACKGROUND

The Government is conducting an investigation into, among other things, whether off-label promotion and/or unlawful dispensing of puberty blockers and cross-sex hormones for use by minors violated federal law, including the Federal Food, Drug, and Cosmetic Act ("FDCA"). Declaration of Lisa K. Hsiao ("Hsiao Decl.") ¶ 6 (attached as Ex. A). Because public or private insurance plans were presented with claims related to off-label use of these medications, such a violation of the FDCA could constitute a "federal health care offense" as defined by 18 U.S.C. § 24.

CHC acknowledges that it provides extensive gender-related care to minors, including the off-label use of puberty blockers and cross-sex hormones that are one of the foci of the investigation. CHC Memorandum ("Memo.") at 4. Puberty blockers are administered off-label

for treating gender dysphoria because they are not approved by FDA for that specific use. *United States v. Skrmetti*, 605 U.S. __, 145 S. Ct. 1816, 1841 (June 18, 2025) (Thomas, J., concurring).

The instant subpoena to CHC was duly issued in July 2025 and served on CHC. The return date specified in the subpoena was set as August 7, 2025. CHC has not complied with the subpoena and has filed this Motion to Quash the subpoena.

ARGUMENT

The Government's burden to show that an administrative subpoena should be enforced "is a slight one," and the burden of a subpoena recipient to avoid enforcement "is a heavy one." *United States v. Balanced Fin. Mgmt., Inc.*, 769 F.2d 1440, 1444 (10th Cir. 1985).[1] Administrative subpoenas will generally be enforced if "the inquiry is within the [statutory] authority of the agency," "sufficiently limited in scope, relevant in purpose, and specific in directive so that compliance will not be unreasonably burdensome." *United States v. Wilson*, 98 F.4th 1204, 1221 (10th Cir. 2024).

The Supreme Court, for its part, has stated that enforcing an administrative subpoena—a creature of statute—should not involve examining the merits of the investigation or scrutinizing the Government's decision to institute such an investigation. *See United States v. Powell*, 379 U.S. 48, 56 (1964) ("There is no intimation in the legislative history that Congress intended the courts to oversee the [Government's] determinations to investigate."). Instead, the Court looks to the language of the statute to determine that the subpoena should be enforced. *Id*. And as long as "[t]he evidence sought by the subpoena [is] not plainly incompetent or irrelevant to any lawful purpose," it is "the duty of the District Court" to enforce the administrative subpoena. *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943).

CHC's motion invites this Court to ignore these well-established and unambiguous precedents because, at base, the subpoena at issue in this matter involves a controversial topic over which there are many high-profile political debates. Conspicuously absent from the

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[1] Internal citations and quotations omitted throughout.

controlling precedent above, however, is any suggestion that a district court should quash an administrative subpoena because the underlying conduct involves politically sensitive subject matters or because the subpoena recipient has political disagreements with the Executive Branch.

CHC is correct that gender-related care for minors is an area in which the United States has made strong statements. However, CHC is incorrect that the Executive Branch's position as to gender-related medical treatments for minors provides a legal basis to quash this subpoena. Indeed, while CHC's motion raises a number of issues that sound in public policy, states' rights, and politics, the motion does not meaningfully tie those objections to a statutory basis to quash an administrative subpoena properly issued under 18 U.S.C. § 3486.

I. The Subpoena Is Valid and Enforceable

a. *"Articulable Suspicion" Is Not a Requirement*

CHC's first and primary argument to this Court is misleading and wrong. Relying on an entirely inapplicable case, CHC argues that (i) the Government needs "articulable suspicion" of wrongdoing before this Court enforces any administrative subpoena, (ii) the Government cannot articulate such suspicion here, and therefore (iii) the subpoena should be quashed. Memo. at 9 (*citing In re Sealed Case (Administrative Subpoena)*, 42 F.3d 1412 (D.C. Cir. 1994)). But that is not the applicable legal standard.

Even if the out-of-circuit case CHC cites actually held what CHC represents to this Court, it would be flatly contradicted by the Supreme Court's very clear holding, in an administrative subpoena matter, that an agency may "investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950). Administrative subpoenas simply do not require an agency to possess articulable suspicion of misconduct on the part of the subpoena recipient. *See United States v. Colo. Dep't of Lab. & Emp.*, No. 23-cv-1968, 2023 U.S. Dist. LEXIS 212449, at *6 (D. Colo. Nov. 29, 2023); *CFPB v. Ctr. for Excellence in Higher Educ.*, No. 19-cv-877, 2022 U.S. Dist. LEXIS 128191, at *10 (D. Utah Apr. 19, 2022).

CHC's basis for this incorrect argument is a D.C. Circuit case from 1994 considering subpoenas issued by the Resolution Trust Corporation ("RTC") in the aftermath of the savings-and-loan crisis of the late 1980s. *See In re Sealed Case*, 42 F.3d 1412. There, the D.C. Circuit fashioned a special rule requiring "articulable suspicion" in instances where RTC subpoenaed the *personal* financial records of former savings-and-loan executives for the purpose of assessing the ability to pay civil penalties (rather than assessing liability). The court interpreted that subpoena statute, 12 U.S.C. § 1820(c), to require "articulable suspicion" before the agency "may subpoena personal financial information for the purpose of determining an individual's ability to pay a civil penalty." *Id.* This made sense because, among other things, personal financial records that were irrelevant to liability were not generally within the subject matter that the RTC was assigned to investigate.

The RTC's subpoenas investigating the savings-and-loan crisis do not remotely relate the subpoena at issue here, and CHC has not even attempted to explain why a similar rule should apply in these circumstances or to a Section 3486 subpoena. Here, CHC is a large, regulated healthcare institution that admits in its motion to engaging in exactly the practices that are under investigation—the provision of powerful drugs given off-label to minors in potential contravention of federal law. In addition, the statute at issue here generally forbids the Government from using the subpoenaed records to investigate individual patients. In the absence of any case law applying an "articulable suspicion" standard in a context outside the savings-and-loan crisis of almost forty years ago, the Court should decline CHC's invitation to adopt such a standard here.

b. *The Subpoena Was Not Issued for an "Improper Purpose"*

Throughout its motion, CHC mischaracterizes the instant federal health care offense investigation as an improper federal Government effort to eliminate gender-related care and asserts that the subpoena should be quashed on that basis. But CHC gets the law on administrative subpoenas entirely backward by suggesting that this Court should undertake a plenary, free-wheeling inquiry into the purported motives behind the subpoena. Memo. at 10.

The law is clear that the Court's role in this proceeding is "strictly limited," and that DOJ's power to issue this administrative subpoena "is a broad-ranging one which courts are reluctant to trammel." *Enterra Energy, LLC v. SEC*, No. 08-mc-11, 2008 U.S. Dist. LEXIS 22727, at *7–*8 (N.D. Okla. Mar. 21, 2008).

CHC contends that this Court should assume an improper purpose because DOJ has declined to offer a factual basis for its investigation. But CHC fails to cite a single case in support of this proposition. That failure is unsurprising. As the Eighth Circuit has explained when evaluating an 18 U.S.C. § 3486 subpoena, there is "no legal authority for requiring the Government to justify its administrative subpoenas by revealing . . . any [] facts revealing the motives behind a lawful investigation." *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 818 (8th Cir. 2012). After all, an agency "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *Morton*, 338 U.S. at 632.

Indeed, CHC's argument invites this Court to do exactly what other courts have said is impermissible in an administrative subpoena enforcement matter: to litigate the Executive Branch's discretionary decision to investigate a matter and adjudicate the merits of a potential future enforcement action. Contrary to CHC's suggestions, the Supreme Court has held repeatedly that enforcement of administrative subpoenas "must not be limited by forecasts of the probable result of the investigation." *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 216 (1946).

Even if the Court were to examine the subpoena in light of CHC's accusation of a purported "improper purpose," CHC has not met its "extraordinarily heavy burden" to prove that such an improper purpose exists. *United States v. Kis*, 658 F.2d 526, 537 (7th Cir. 1981). The courts that have allowed a limited evaluation of the Government's motivations in administrative subpoena proceedings have described the relevant inquiry as whether the movant has demonstrated that the investigation is being conducted for an undisclosed, nefarious purpose, or whether the subpoena is not actually attempting to obtain evidence in furtherance of an

investigation of potential federal offenses. *See Solis v. Forever 21, Inc.*, No. 12-09188, 2013 U.S. Dist. LEXIS 64462, *6 (C.D. Cal. Mar. 7, 2013) (collecting cases).

CHC has not met the heavy burden imposed by this standard. CHC's political concerns with Executive Branch officials amount to "speculation" and "assertion[s]" that the subpoena is improper but offer little more.[2] *Id*. Nothing CHC presents alters the fact that the Government is attempting to investigate federal health care offenses using a congressionally authorized subpoena power. If the subpoena uncovers violations of federal law in the delivery of gender-related care to minors, and if the Government addresses this misconduct, "this is not an improper use of the subpoena power . . . [r]ather, it is a desired result." *Forever 21, Inc.*, 2013 U.S. Dist. LEXIS 64462, at *19.

Moreover, none of the Government's statements on this topic evince a desire to investigate CHC pretextually *for an undisclosed, nefarious reason* or to take actions against CHC in a manner *inconsistent with the law*—which would be necessary to show "bad faith" in this context.[3] *See United States Immigr. & Customs Enf't v. Gomez*, 445 F. Supp. 3d 1213, 1216 (D. Colo. 2020) (subpoena ordered enforced because recipient did not show that subpoena was "pretext for some unstated, nefarious, legally inappropriate reason"). While CHC makes much of certain executive orders and memos with respect to gender-related medical treatments on minors, the actual direction from the Attorney General to conduct this investigation is direct and clear: it authorizes only "appropriate" investigations of potential (i) FDCA violations in relation to

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[2] Similarly, CHC's request for some sort of evidentiary hearing or discovery into the Government's investigation fails under the relevant law, which requires "extraordinary circumstances" to authorize discovery. *United States v. Markwood*, 48 F.3d 969, 982 (6th Cir. 1995). CHC does not mention the extraordinary circumstances test or attempt to meet it, nor does CHC articulate what it hopes to discern from such evidence. "[A]s a general matter, a defendant is not entitled to engage in counter-discovery to find grounds for resisting a subpoena." *Id*. (collecting cases).

[3] The Supreme Court has cautioned against "reviewing a Presidential directive . . . by reference to extrinsic statements." *Trump v. Hawaii*, 585 U.S. 667, 702 (2018).

"manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of" or unlawful "promotion of off-label uses of" certain drugs used in gender-related treatments of minors; and (ii) "false claims submitted to federal health care programs." Gray Decl. Ex. 8 at 4. These statements reflect the Executive Branch's view that certain conduct in this general area may be illegal, that it should be investigated, and that those who committed crimes should be punished.

The Executive Branch's interest in ensuring that the provision of certain medications is carried out without running afoul of federal law is entirely unremarkable. Just as federal officials may prioritize scrutinizing the fentanyl distribution chain—many parts of which are legal because fentanyl is an FDA-approved medication—to stem opioid overdoses, federal officials may prioritize ensuring that gender-related health care to minors is being delivered in a way that does not violate federal law. Indeed, CHC's argument boils down to a basic non-sequitur: (1) the President wants to use existing federal law to curtail the practice of gender-related medical treatments on minors; (2) this is an improper purpose because CHC believes such treatments should be legal; and (3) the subpoena therefore must lack a legitimate purpose. CHC Memo. at 11.

But even accepting CHC's incorrect premise that the sole purpose of this specific investigation is somehow to end the provision of gender-related treatments—and not the stated purpose of investigating potential violations of federal law in the provision of such treatments—that still could not constitute the "nefarious purpose" CHC is required to demonstrate. Indeed, the United States Supreme Court just months ago explicitly held that banning gender-related pharmaceutical and surgical treatments of minors outright is a rational Governmental purpose, particularly in light of the profound health risks, unknown long-term effects, and inability of minors to fully appreciate such potential risks and unknowns. *Skrmetti*, 145 S. Ct. at 1835-36 (explaining that considering those concerns, Tennessee's law is "plainly rationally related to these findings and the State's objective of protecting minors' health and welfare.").

CHC also does not offer the Court a coherent standard by which to judge whether a subpoena is issued for a "legitimate purpose" on a politically charged topic. CHC obviously believes that its provision of gender-related care for minors is "legitimate," and so CHC also believes the federal Government's investigations into federal health care offenses related to such practices must *ipso facto* be "illegitimate." But on that circular reasoning, any recipient of a subpoena could obtain quashal by asserting that it acted properly. CHC's standard appears to be that if it disagrees politically with the policy positions of the current administration and engages in conduct related to those policy positions, it should be entitled to quash subpoenas duly authorized by federal law and/or obtain discovery about the investigation. That is not the law. *See SEC v. McGoff*, 647 F.2d 185, 194 (D.C. Cir. 1981) (holding that allegation of political targeting by Carter Administration was not enough to authorize inquiry into agency's motives in issuing administrative subpoena).

c. *The Investigation Basis Is Legitimate*

Even if the Court considers the basis of the investigation, the Court need not look far to assure itself that the investigation is legitimate. As just one data point showing adequate predication for this investigation, Justice Thomas' recent concurrence in *Skrmetti* lays out numerous concerning pieces of evidence suggesting that the *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8 ("SOC 8"), published by the World Professional Association for Transgender Health ("WPATH") is based "on insufficient evidence and allows politics to influence its medical conclusions." *Skrmetti*, 145 S. Ct. at 1845–49.

Noting "the lack of consensus over the efficacy and ethics of pediatric sex-transition treatments," Justice Thomas detailed how gender-related care for minors in the United States has been littered with potential consumer-protection violations: false statements made to induce patient and parental consent to off-label drug use and other life-altering procedures; powerful pharmaceuticals casually being given off-label to very young minors, causing lifelong side effects; purported treatment guidelines based on false or insufficient evidence; and other alarming trends that the Executive Branch could reasonably believe deserve exploration. *Id.*

Furthermore, much of the data cited by Justice Thomas came to light in *Boe v. Marshall*, 22-cv-184 (M.D. Ala.), where WPATH undertook significant and ultimately unsuccessful efforts to block access to records showing SOC 8's development.[4] CHC does not even mention these issues, let alone seek to explain why the Government is not permitted to investigate them.

CHC also argues that Government enforcement in this area will purportedly chill the rights of Colorado residents and others to receive gender-related care under state law. The argument is meritless. If persons in Colorado committed federal health care offenses while delivering gender-related treatment for minors, federal Government enforcement of federal law against those persons would be fully consonant with the Supremacy Clause and would not infringe the rights of Colorado residents under state law—because they have no right under state law to violate federal law. *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993) ("Where [state law] conflicts with, or frustrates, federal law, the former must give way."). Moreover, CHC and any other person will be able to raise whichever colorable defenses they wish to in any enforcement action the Government may or may not ultimately bring in connection with the subpoena.

II. The Subpoena Is Procedurally Proper

CHC also argues that the subpoena was signed by the wrong person at the Department of Justice. CHC is incorrect. The subpoena was issued in the investigation of FDCA-related federal health care offenses. 18 U.S.C. § 3486(a)(1)(A)(i)(I). It was signed by an Assistant Attorney

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[4] For example, in denying an effort by WPATH to keep records of SOC 8's development from being publicly released, the district court observed that WPATH "touts its guidelines and standards of care for treating transgender children as the product of rigorous science and broad consensus. Given this wide acceptance of what WPATH claims to be reliable evidence, one would think it would be willing and eager to demonstrate as much. It is not." *Boe v. Marshall*, 22-cv-184 (M.D. Ala.), (ECF No, 754, *Memorandum Opinion and Order Granting Time Sensitive Motion for Relief*, June 9, 2025.)

General of the United States using authority delegated from the Attorney General,[5] it was served on CHC, and it called for the production of nonprivileged documents relevant to the investigation within 500 miles of CHC. 18 U.S.C. § 3486(a)(3). The subpoena is procedurally proper and should be enforced.

III. The Requests Seek Relevant Evidence and Are Not Unduly Burdensome

CHC objects to the breadth of the subpoena, but its arguments rest on misunderstandings of the law. Here, the Government has not made a decision as to whether CHC is a target—so whether CHC itself complied with all relevant laws is not relevant. CHC may be simply a witness to, for example, pharmaceutical companies promoting puberty blockers for off-label use. Or it may be a witness to whom other people or entities directed false statements on the topic of gender-related pharmaceuticals for minors. Or CHC personnel may have committed federal health care offenses without the knowledge of CHC management. CHC's motion does not discuss these obvious examples or explain why they are improper. Because CHC has failed to show such objectives are not "irrelevant to any lawful purpose," the subpoena must be enforced on these grounds alone. *Endicott Johnson Corp*, 317 U.S. at 509.

Indeed, "the measure of relevance used in subpoena enforcement actions is quite broad." *United States v. Fla. Azalea Specialists*, 19 F.3d 620, 624 (11th Cir. 1994); *Sandsend Fin. Consultants, Ltd. v. Fed. Home Loan Bank Bd.*, 878 F.2d 875, 882 (5th Cir. 1989) (administrative subpoena will survive relevance challenge so long as it "touches a matter under investigation"). Because CHC is an acknowledged provider of the type of off-label pharmaceuticals under investigation, the individual requests—which seek records related to the provision of those drugs and services—are also valid under the statute. The fact that CHC thinks its provision of gender-

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[5] There is a delegation of authority from the Attorney General to the Assistant Attorney General of the Civil Division to issue HIPAA subpoenas in criminal investigations involving violations of the FDCA related to federal health care benefit programs. Hsiao Decl. ¶ 5.

related care is appropriate, CHC Memo. at 14–15, is simply not a defense to producing records to the Government; the Government need not take CHC's word that it is not violating the law.

CHC specifically objects to the Government's requests for records of services provided to patients and identifying information of patients and providers. CHC Memo. at 13–14. First, as a legal matter, 18 U.S.C. § 3486 subpoenas are colloquially referred to as "HIPAA subpoenas" not because they are used to investigate HIPAA violations *per se*, but rather because Congress enacted the provision as part of HIPAA specifically to allow the Government to obtain HIPAA-protected health information of patients in health care investigations. It is hard to understand how the Government's request for patient files is improper, CHC Memo. at 14, when the statute at issue was passed in order to allow the Government to obtain these specific items. Congress already struck the appropriate balance in this statute and specifically contemplated the Government obtaining medical records of the type requested here. *In re Subpoena Duces Tecum*, 228 F.3d 341, 351 (4th Cir. 2000) (reversing quashal of § 3486 subpoena and ordering the production of medical records).

Indeed, the Fourth Circuit has already rejected an argument indistinguishable from CHC's argument here and held that the Government's interest in obtaining patient files using a Section 3486 subpoena outweighs patient privacy concerns, because the disclosure to the Government of patient records is not "meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care." *In re Subpoena Duces Tecum*, 228 F.3d at 351.

The Fourth Circuit also held that privacy concerns about patient records were unfounded because this statute already provides privacy protection for patient information. *Id*. ("[The Government's] interest outweighs the privacy rights of those whose records were turned over to the Government, particularly in light of the limitation placed on uses of subpoenaed information by § 3486."). To wit, the statute requires the Government to return records if the investigation does not ripen into an enforcement action. 18 U.S.C. § 3486(a)(8). More relevant to CHC's objections, the statute generally prohibits the Government from using or disclosing "health

information about an individual" that is obtained via this subpoena, and it further generally prohibits the Government from using protected health information about a patient against that patient. 18 U.S.C. § 3486(e). Finally, the statute makes people and entities responding to these types of subpoenas immune from civil liability for responding in good faith. 18 U.S.C. § 3486(d). Patient health information is frequently sought and obtained in federal health care offense investigations—in fact, it is difficult or impossible to investigate the provision of health care services to patients if the Government cannot obtain information about the provision of health care services to patients.

CHC also objects to the requests for communications about diagnosis codes and communications with third parties about pharmaceuticals. CHC Memo. at 14–15. However, these requests are also reasonably relevant to the Government's investigation. *Enterra Energy,* 2008 U.S. Dist. LEXIS 22727, at *8 ("For purposes of an administrative subpoena, the question of relevancy is a broad one."). The use of false or masked diagnosis codes to cause insurance companies to cover gender-related off-label pharmaceuticals they might not otherwise cover is part of the investigation, and could constitute an FDCA health care offense—that is, a prohibited act under 21 U.S.C. § 331 with an intent to defraud or mislead. Also, communications with pharmaceutical companies about the off-label use of the powerful and potentially harmful drugs that CHC gives to minors are a core interest of the investigation, also could constitute FDCA offenses, and obviously pass the relaxed relevance test for administrative subpoenas.

As to burden, the idea that a large, regulated hospital with thousands of patients cannot expend the resources to locate and produce relevant documents is absurd, and CHC's arguments simply do not make out an undue burden under administrative subpoena law. *See FTC v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977) ("Some burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest.").

CONCLUSION

The Government respectfully requests that the Court overrule CHC's objections and compel CHC to comply with the subpoena.

Dated this 29th day of August 2025.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 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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