IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

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

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

UNITED STATES' OBJECTIONS TO MAGISTRATE RECOMMENDATION

Pursuant to 28 U.S.C. § 636 and Local Civil Practice Standard 72.3, the United States of America hereby submits its Objections to the Magistrate Judge's Recommendation (hereinafter, "R&R"), ECF 35.

Objection 1. The R&R's discussion regarding the scope and relevance of the subpoena (ECF 35 at 6–8, 13–14) is factually erroneous and legally incorrect. It faults the Government for failing to explain or justify things that its briefing *did* explain and then treats those perceived deficiencies as dispositive, improperly imposing on the Government a burden that, as a respondent to a motion to quash at the outset of a pre-indictment investigation, it does not have.

The R&R criticizes the subpoena's call for communications related to the use of puberty blockers and hormones used in the treatment of gender dysphoria, "not just those used 'off-label.'" ECF 35 at 7. That criticism is flatly wrong. No drugs are FDA-approved for the treatment of gender dysphoria—none—a fact the Government explained in its answering brief. ECF 10 at 1–2. Thus, *every* use of a drug to treat gender dysphoria is "off-label" by definition. *Id*. The subpoena therefore does exactly what

the R&R erroneously says it does not: it squarely targets off-label use. Its requests for patient information expressly and repeatedly limit the scope to off-label uses. ECF 1-4 at 6. ("All documents relating to informed consent … for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about ***off-label use*** (*i.e.* uses not approved by the United States Food and Drug Administration.)") (emphasis added). Thus, the patient records for minors being prescribed such drugs, and petitioner's communications in specifications 7 through 9 — are explicitly limited to the drugs' use "for gender-related care" (*id.* at 6) — that is, off-label uses.

The R&R's relevance analysis is premised on an impermissible elevation of the Government's burden at the pre-indictment, investigative stage. By rejecting relevance unless the Government justifies, *ex ante*, how particular categories of documents demonstrate a direct nexus to a FDCA violation, ECF 35 at 8–9, the R&R transforms the reasonable-relevance inquiry into a merits determination that exceeds the narrow role of judicial review applicable to administrative subpoenas. The proper question is not whether the requested materials will themselves establish a violation of federal law, but rather whether the requested materials might merely assist in an FDCA investigation involving potentially misbranded, adulterated, and/or unapproved new drugs.[1] Stated differently, the question is simply whether the

[1] Under the FDCA, drug approval is indication-specific. Even though a drug is approved for a particular use, it may constitute an unapproved new drug for any other use. The introduction or delivery for introduction into interstate commerce—or the causing thereof—of an unapproved new drug is unlawful. 21 C.F.R. § 310.3(h); 21 U.S.C. §§ 331(d), 355(a).

subpoena "touches a matter under investigation." *Sandsend Fin. Consultants, Ltd. v. Fed. Home Loan Bank Bd.*, 878 F.2d 875, 882 (5th Cir. 1989); ECF 10 at 10.

Under the R&R's logic, the Government would have lacked authority to subpoena clinicians to identify the roughly 20,000 Americans who took thalidomide—an unapproved new drug distributed through physicians to pregnant women that infamously caused catastrophic birth defects. That conclusion is fundamentally inconsistent with the FDCA, which Congress intended "to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer," that is, the patient. *United States v. Sullivan*, 332 U.S. 689, 696 (1948); *United States v. 4 Devices, Labeled in Part "Color-Therm"*, 176 F.2d 652, 654 (10th Cir. 1949) (holding devices became unlawfully misbranded at point of delivery to consumer because false and misleading written instructions accompanied and explained devices, notwithstanding instructions' lack of physical attachment to device or interstate shipment). Investigating potential FDCA violations, therefore, necessarily involves inquiring into the conditions, patterns, and consequences of the potentially misbranded and unapproved drugs' distribution, including how they reach vulnerable patients—the "ultimate consumer"—and whether any written information "supplement[ing] or explain[ing]" those drugs provided to those patients at or near the point of delivery was false or misleading. *Kordel v. United States*, 335 U.S. 345, 350 (1948) (holding drugs are misbranded where consumer is provided written material that "supplements or

explains" drug that is false or misleading, regardless of material's physical attachment to drug or its container).

The R&R goes further by rejecting the relevance of the subpoena's requests for information that would shed light on potential FDCA violations premised on the promotional activities of the drugs' manufacturers—an avenue of liability that the R&R itself acknowledges may exist. ECF 35 at 7. Despite recognizing that theory, the R&R fails to meaningfully analyze whether the subpoenaed documents might bear some relevance to it. That omission is significant because "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); ECF 10 at 10.

Specifications 7 through 9 of the subpoena go squarely to the "off-label" promotion and marketing of puberty blockers and cross-sex hormones as a treatment for gender dysphoria despite their not being FDA-approved as a safe and effective treatment for that—or any other—mental condition. Indeed, the U.S. Department of Health and Human Services ("HHS") has affirmatively determined that such uses are neither safe nor effective and fail to meet professionally recognized standards of health care. *See* ECF 31 & accompanying exhibits. Especially against that backdrop, a pediatric hospital's communications about gender-related care with the manufacturers of such drugs are relevant to assessing whether unapproved uses were promoted or described in ways that were false and misleading. Subpoena requests 11 through 13 are likewise relevant to determine, *inter alia*, whether potentially false or

misleading promotional and marketing information was conveyed to the drug's ultimate consumer through the physician and/or materially influenced the physicians' decisions to administer potentially misbranded and unapproved drugs. The R&R entirely overlooks this theory of relevance in concluding that the subpoenaed materials could not reasonably bear on an FDCA investigation. ECF 35 at 8–9.

The R&R further errs by converting its scope analysis into a finding of pretext, concluding that the subpoena is not genuinely directed at FDCA violations but instead seeks information about the TRUE Center and its patients. ECF 35 at 13–14. It asserts the subpoena bears "little relation" to FDCA enforcement and reflects only "an idle hope" of uncovering relevant evidence. ECF 35 at 13. That conclusion fails to account for the reality that medical interventions for gender dysphoria in minors are almost exclusively pharmacological, *i.e.,* puberty blockers and cross-sex hormones, which are not approved under the FDCA for that use. When intended for that use, such drugs are therefore potentially misbranded and/or unapproved new drugs. Because those drugs are essentially the only means by which such interventions are provided, an investigation into medical gender-related care for minors necessarily involves examining their promotion, labeling, distribution, and delivery—core concerns of the FDCA. By treating "care" as something distinct from the drugs that are its *sine qua non,* the R&R manufactures an artificial basis for finding pretext.

Objection 2. Even if one were to credit the R&R's concerns regarding the subpoena's scope and relevance, ECF 35 at 6–9, those concerns at most support

narrowing or modifying distinct subpoena specifications, not the drastic step of quashing the entire subpoena. The R&R recommends complete quashal without accounting for the well-established remedial preference for narrowing or modifying requests. The R&R therefore errs by selecting across-the-board quashal without first assessing whether the perceived defects could be cured through reasonable modification. Once the R&R correctly found that the subpoena was within the Attorney General's statutory authority (ECF 35 at 5–6), any defects in scope or relevance should have been addressed through tailoring. *See Wiwa v. Royal Dutch Petroleum Co.*, 392 F.3d 812, 818 (5th Cir. 2004) ("Generally, modification of a subpoena is preferable to quashing it outright."); *Linder v. Nat'l Sec. Agency*, 94 F.3d 693, 698 (D.C. Cir. 1996) (same); *Garrity v. Governance Bd. of Carinos Charter Sch.*, No. CV 20-340 MV/KK, 2021 WL 3033278, at *3 (D.N.M. July 19, 2021). Indeed, the R&R's own analysis underscores the point. It faults the subpoena for allegedly creating a "dragnet" of patient information instead of imposing criteria tied to misbranding. ECF 35 at 6–7. But that criticism, even if correct, demonstrates why modification rather than quashal is the appropriate remedy. Because the law prefers modification over quashal, the R&R should have recommended narrowing the request to the criteria that itself identified, rather than extinguishing the subpoena altogether.

Objection 3. The R&R faults the government for failing to reveal insights into the "nature of any scheme that might be afoot." ECF 35 at 14. But 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." ECF 10 at 5, (citing *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 818 (8th Cir. 2012)). When Petitioner later cited new authority suggesting otherwise, the Government sought to provide the Court with just those details, ECF 18 & 18-1. The Court declined to consider it. ECF 32. Regardless of the Magistrate Judge's refusal to consider, this Court has the independent authority under Federal Rule of Civil Procedure 72(b)(3) to "receive further evidence" in its *de novo* review of the record. *Coon v. Trans Am. Fin. Servs.*, No. 24-4025-DDC-RES, 2024 WL 2091272, at *1 (D. Kan. May 9, 2024) (collecting cases). The Government again attaches the Hsiao Declaration and asks the Court to consider it as it reviews the record. ECF 18-1 at 47–62.

Objection 4. The R&R errs by effectively inverting the burden governing this proceeding. This action was brought by the subpoena recipient to quash an administrative subpoena—not by the Government seeking judicial enforcement. Yet the R&R imports "abuse of process" principles typically applied in *enforcement* actions and proceeds as though the Government has the burden to affirmatively establish the legitimacy of its investigation at the outset. *See, e.g.,* ECF 35 at 4 ("The government bears the initial burden of "making a prima facie showing of reasonable relevance."). But unlike the cases cited, the Government here is not the moving party, and it is not seeking judicial enforcement. *Powell* specifically says that the subpoena recipient bears the burden of showing an abuse of process even when the Government moves

to enforce, and the R&R erred by placing that burden on the Government throughout the entire proceeding. *United States v. Powell*, 379 U.S. 48, 58 (1964). The R&R does not identify what burden the hospital bore, nor does it explain how it carried that burden. Instead, the R&R concludes that Petitioner's evidence was of such "clarity" that it did not require testing. ECF 35 at 16. By resolving the motion to quash without identifying or applying the movant's burden, by taking the movant's evidence as essentially irrebuttable, and by requiring the non-movant to establish a prima facie case of propriety at the outset, the R&R effectively decided the case before the Government had an opportunity to litigate it.

Objection 5. The R&R's conclusion of improper purpose rests on a mistaken premise: that the Attorney General cannot both hold a policy view critical of medical interventions for children with gender dysphoria while also directing lawful investigations into potential violations of federal law arising from those practices. The law does not permit courts to engage in a searching, *de novo* inquiry into the Attorney General's subjective motivations. To the contrary, an administrative subpoena is not invalid merely because it may serve both legitimate and contested purposes: "It is not ... a ground to deny enforcement of a subpoena that ... is being employed for a wrongful purpose **if there is also a legitimate purpose for the subpoena**." *Lynn v. Biderman*, 536 F.2d 820, 826 (9th Cir. 1976) (emphasis added).

Powell, upon which the R&R relies for some propositions, specifically says that Congress did not "intend[] the courts to oversee the [Executive Branch's]

determinations to investigate." 379 U.S. at 56. The R&R erred by engaging in just such an inquiry and then quashing the subpoena based primarily on the results of that inquiry. Petitioner was required to show that the subpoena could not be lawful in *any* of its applications. *See Trump v. Hawaii*, 585 U.S. 667, 706 (2018) (rejecting suggestion of animus or improper purpose where government action at issue was "expressly premised on legitimate purposes"). Instead, it simply provided the Court with a handful of Executive Branch press releases with which it disagrees. The R&R's approach would shift the burden to the Government to prove the absence of any improper purpose whenever a subpoena is challenged. That is not what the law requires.

Objection 6. The R&R's overreliance on public statements of Executive Branch officials to infer improper purpose is erroneous and contrary to law. ECF 35 at 13. Its analysis reveals that its pretext finding depends almost entirely on statements of policy preference and enforcement priorities, rather than on any legal deficiency inherent in the subpoena itself. Under the R&R's reasoning, subpoenas in areas such as firearms regulation could be quashed whenever a political leader publicly expressed a desire to eliminate violence associated with otherwise lawful gun ownership. The Attorney General could not, for example, increase ATF enforcement of existing regulation of firearm dealers by exercising her statutorily authorized investigative powers without having those efforts deemed pretextual— simply because she publicly voiced policy objectives to restrict gun ownership. Moreover, this approach is indistinguishable from what *Trump v. Hawaii* says this Court may not do—infer

improper purpose from public statements of Executive Branch officials when the Government takes action authorized by statute and for which it articulates a facially legitimate and bona fide reason for doing so. 585 U.S. at 703, 706.

Objection 7. The R&R commits error by concluding that the subpoena is unauthorized because Congress has not expressly sanctioned investigations into gender-related medical treatments. ECF 35 at 21–22. Congress does not authorize investigations by naming particular targets or subjects; it enacts generally applicable laws and vests the Attorney General with authority to investigate and enforce them. Congress did not enact a statute specifically authorizing investigations into the prescription opioid epidemic, yet the Attorney General properly investigated healthcare practitioners, pharmacies, distributors, and pharmaceutical manufacturers for violating federal law. Congress has similarly authorized enforcement of federal healthcare laws here. The R&R's reasoning would improperly exempt an entire category of conduct from generally applicable laws. Similarly, the fact that gender-related care for minors is legal under Colorado law cannot be a reason to quash the subpoena, contrary to the R&R's suggestions. Prescribing scheduled opioids is also legal under Colorado law, but if a Colorado clinician misbrands or adulterates those drugs, prescribes them "without a legitimate medical purpose," or defrauds patients and/or Medicare in the course of such prescribing, the clinician would be subject to federal criminal investigation. 21 C.F.R. § 1306.04(a). So too here.

Dated this 20th day of January 2026.

Respectfully submitted,

FOR THE UNITED STATES OF AMERICA

BRETT SHUMATE
Assistant Attorney General

JORDAN C. CAMPBELL
Deputy Assistant Attorney General

LISA HSIAO
Acting Director

ROSS S. GOLDSTEIN
PATRICK RUNKLE
Assistant Directors

/s/ Scott B. Dahlquist
SCOTT B. DAHLQUIST
Trial Attorney

United States Department of Justice
Enforcement & Affirmative Litigation Branch
P.O. Box 386
Washington, DC 20044
Tel: 202-532-4602
Fax: 202-514-8742
scott.b.dahlquist@usdoj.gov

Attorneys for the United States of America

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of January 2026, filed the foregoing with the Clerk of Court using the CM/ECF system, and separately emailed to counsel for Children's Hospital Colorado at:

Elliot R. Peters
epeters@keker.com

Cody Gray
cgray@keker.com

Katherine S. Folly
kfolly@keker.com

Aseem Mehta
amehta@keker.com

KEKER, VAN NEST & PETERS LLP
633 Battery Street
San Francisco, CA 94111-1809
Telephone: 415-391-5400
Facsimile: 415-397-7188.

Dated this 20th day of January 2026.

/s/ *Scott B. Dahlquist*
Scott B. Dahlquist