No. 25-7384

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

U.S. DEPARTMENT OF JUSTICE,

Respondent-Appellant,

v.

QUEERDOC, PLLC,

Movant-Appellee.

On Appeal from the United States District Court
for the Western District of Washington

BRIEF FOR APPELLANT

BRETT A. SHUMATE
Assistant Attorney General

YAAKOV M. ROTH
Principal Deputy Assistant Attorney General

BRAD HINSHELWOOD
Attorney, Appellate Staff

ABIGAIL STOUT
Counsel to the Assistant Attorney General
Civil Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-7830

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases:

Statutes:

Rules and Regulations:

Other:

INTRODUCTION

Congress routinely authorizes federal agencies to issue subpoenas to investigate potential violations of federal law. An agency granted such power "may take steps to inform itself as to whether there is probable violation of the law," and in exercising its investigatory powers, the agency is "analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can 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). Judicial review of such subpoenas is correspondingly "quite narrow," asking only whether authority to investigate has been granted, whether the applicable procedural requirements have been followed, and whether the evidence sought is relevant to the investigation. *United States v. Golden Valley Elec. Ass'n*, 689 F.3d 1108, 1113 (9th Cir. 2012).

The Department of Justice has been clear and transparent that it has made it a priority to investigate potential violations of the Federal Food, Drug, and Cosmetic Act and other federal health care offenses in connection with the provision of so-called "gender affirming care" to minors. The Department has substantial basis to suspect that various actors involved in this industry (ranging from drug companies to clinics to insurance companies) have engaged in federal criminal activity, including misbranding drugs for off-label uses and filing deceptive insurance claims. Those serious concerns warrant factual investigation. It is the proper role and responsibility of the Department of Justice to conduct that investigation.

As part of that investigation, the Department of Justice issued a subpoena to QueerDoc, PLLC, a telemedicine clinic that specializes in treating children and adolescents who are diagnosed with gender dysphoria, and which the Department suspects has been engaged in potential federal misconduct. This is the type of subpoena that the Department issues all the time in the health care space—seeking records so it can duly investigate potential federal offenses. Enforcing this subpoena should have been mundane and routine, but instead the district court quashed the subpoena on its face, denouncing the entire investigation as bad faith and pretextual, and effectively shielded the entire industry from federal due diligence.

The district court's opinion is indefensible, and its order should be reversed. The court did not dispute that the subpoena satisfies the usual factors for assessing whether a subpoena is lawful, including that the Department has statutory authority to issue the subpoena and the information sought would be relevant to the investigation. It instead quashed the subpoena based on its sweeping conclusion that the subpoena was issued for an "improper purpose." But there was simply no basis for the court to reach that conclusion; each of its reasons is fundamentally flawed.

The district court principally inferred an improper purpose from the fact that the President and other officials in his administration have expressed opposition to the administration of puberty blockers and cross-sex hormones to minors with gender dysphoria. The court believed that the subpoena was therefore necessarily an effort to "end" certain practices under the guise of "merely investigating" them. ER-017. But

that simply does not follow. To be sure, the President has serious moral and policy objections to the practice of subjecting minors to these interventions with "sometimes irreversible" consequences, *United States v. Skrmetti*, 605 U.S. 495, 503 (2025); *id.* at 534-35 (Thomas, J., concurring), but the current investigations seek only to enforce existing federal statutes against the industry. That is plainly permissible. Just as an administration skeptical of cryptocurrency could prioritize investigations into money-laundering by crypto actors, or an administration opposed to sports gambling could choose to prioritize investigations into whether gambling operations are complying with all regulatory requirements, an administration that is dubious of making permanent changes to children's bodies in the guise of "medical care" is entitled to prioritize investigations into whether industry actors engaged in that activity are violating federal law. That does not amount to bad faith or pretext. To hold otherwise would immunize any industry or practice that an administration opposes as a policy matter, even if criminal activity is underway. That sweeping logic is unprecedented and unsustainable.

The district court also inferred improper purpose from a supposed "mismatch" between the subject of the investigation (namely, misbranding and false claims) and QueerDoc's role in the industry (namely, prescribing drugs). ER-017. That reflects a basic misapprehension of how federal health care offenses are investigated. Even setting aside concerns specific to QueerDoc, patient records and communications between prescribers and drug companies or insurers are a core part of any such

investigation, regardless of whether the prescriber is suspected of independent wrongdoing. An investigation cannot be artificially cabined to a single actor in a complex supply chain or industry.

Finally, the court thought that certain subpoena requests were overbroad, and again inferred an illicit purpose. They were not overbroad; it is typical practice for investigators to seek a broad set of records and materials. But if the court had concerns about the breadth of the subpoena, then it should have considered whether to narrow it—not quashed it entirely on grounds that would appear to foreclose the Department from issuing *any* subpoena.

The safety and propriety of gender-related interventions for minors is a topic of "fierce scientific and policy debates," one that the President and his administration have not hesitated to address. *Skrmetti*, 605 U.S. at 525. But that political backdrop does not excuse participants in this industry from complying with the same federal health care laws as everyone else. And it certainly should not shield them from ordinary criminal investigations or duly authorized subpoenas. This Court should reverse the order below.

STATEMENT OF JURISDICTION

The district court granted QueerDoc's motion to quash on October 27, 2025. The government filed a timely notice of appeal on November 21, 2025. *See* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether the district court erred in quashing a subpoena to QueerDoc expressly authorized by 18 U.S.C. § 3486 on the basis that the Department of Justice ostensibly issued the subpoena for an "improper purpose."

PERTINENT STATUTES

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory Background

1. The Federal Food, Drug, and Cosmetic Act

In 1938, Congress passed, and President Franklin D. Roosevelt signed into law, the Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDCA's "overriding purpose [is] to protect the public health." *United States v. Article of Drug*, 394 U.S. 784, 798 (1969). Because the FDCA's purpose should "infuse construction of the" FDCA, *United States v. Dotterweich*, 320 U.S. 277, 280 (1943), courts give the FDCA a "liberal construction" that furthers protection of the public health, including criminal enforcement, *Article of Drug*, 394 U.S. at 798; *see also United States v. Park*, 421 U.S. 658, 672 (1975) (explaining that the FDCA imposes a "positive duty to seek out and remedy violations when they occur").

The FDCA regulates the development, manufacturing, and distribution of drugs in the United States. Before any "new drug" may enter interstate commerce, the manufacturer must demonstrate to the United States Food and Drug Administration

("FDA") that the drug is both safe and effective for each of its intended uses. 21 U.S.C. §§ 331(d), 355(a). The introduction of an unapproved new drug into interstate commerce violates the FDCA. 21 U.S.C. § 331(d).

A drug manufacturer obtains FDA approval for a new drug through a new drug application ("NDA") that demonstrates its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). When FDA approves a drug, it approves it as safe and effective for particular use(s) in the NDA. *See* 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. In addition, for prescription drugs, FDA must also approve the drug's labeling, which specifies, among other things, FDA-approved uses and adequate directions for those uses. 21 U.S.C. §§ 352(f)(1), 355; *see* 21 C.F.R. §§ 201.5, 201.55-201.57, 201.100. Because a drug that is safe and effective for one use may be neither safe nor effective for others, FDA approval extends only to the uses specified in a drug's approved application and labeling. 21 U.S.C. § 355(d).

The FDCA generally prohibits "misbranding" a drug. *See* 21 U.S.C. § 352; *id.* § 331(a), (b), (c), (k). A drug may be misbranded if, *inter alia*, its labeling is false or misleading, *id.* § 352(a), or if its labeling does not bear adequate directions for use, *id.* § 352(f)(1). Under the FDCA, drug labeling is broadly defined to include any "written, printed, or graphic matter . . . accompanying" the drug. 21 U.S.C. § 321(m). The term "accompanying" includes materials that are separate from but related to the drug and any material that supplements, explains, or is designed for use with the drug. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345 (1948); *United*

States v. Urbutiet, 335 U.S. 355 (1948); *United States v. 47 Bottles*, 320 F.2d 564, 569 (3d Cir. 1963). Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

Given the FDCA's protective purpose, misdemeanor violations of the FDCA are punishable on a strict liability basis, without any proof of criminal intent. *See* 21 U.S.C. § 331, § 333(a)(1); *Park*, 421 U.S. at 672-73; *United States v. Wiesenfield Warehouse Co.*, 376 U.S. 86, 91 (1964). Where a violator has an intent to defraud or mislead, an FDCA violation may be punishable as a felony. 21 U.S.C. § 333(a)(2).

2. The Health Insurance Portability & Accountability Act of 1996 and HIPAA Subpoenas

In 1996, Congress passed, and President Clinton signed into law, the Health Insurance Portability and Accountability Act ("HIPAA"). As relevant here, the statute permits the Attorney General to issue a subpoena—often referred to as a "HIPAA subpoena"— to investigate federal health care offenses. 18 U.S.C. § 3486(a)(1)(A)(i)(I). A federal health care offense includes a "violation of, or a criminal conspiracy to violate," 21 U.S.C. § 331, "if the violation or conspiracy relates to a health care benefit program." 18 U.S.C. § 24(a)(2). And a "health care benefit program" is "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." *Id.* § 24(b). The Department of

Justice is therefore expressly empowered to use a HIPAA subpoena to investigate violations of the FDCA and related conspiracies, if the violation or conspiracy relates to products or services that might ultimately be paid for by a private or public health insurance program.

B. Factual Background

1. Off-Label Provision of Puberty Blockers and Cross-Sex Hormones to Treat Gender Dysphoria

This case involves a HIPAA subpoena that the Department of Justice issued in connection with an investigation into the provision of certain prescription drugs to minors with gender dysphoria. *See* ER-021. These include prescription drugs that suppress the production of sex hormones to delay puberty (commonly referred to as "puberty blockers") and cross-sex hormones meant to induce physical changes to the child's secondary sexual characteristics to resemble those typically seen in the opposite sex and less like the individual's biological sex. *See Skrmetti*, 605 U.S. at 503-04 (describing use of these drugs). Although these drugs are approved by FDA for some uses, FDA has not determined that any of these drugs are safe or effective for the treatment of gender dysphoria, nor has FDA approved any of these prescription drugs for the treatment of gender dysphoria or any other psychiatric disorder.

The use of these drugs in the treatment of gender dysphoria in minors is highly controversial—the subject of "fierce scientific and policy debates." *Skrmetti*, 605 U.S. at 525. As the Supreme Court recently explained, "health authorities in a number of

European countries have raised significant concerns regarding the potential harms associated with using puberty blockers and hormones to treat transgender minors," and "more than 20 States have enacted laws banning the provision of sex transition treatments to minors." *Id.* at 504-05; *see also id.* at 533-35 (Thomas, J., concurring).

Shortly after entering office, President Trump issued several Executive Orders weighing in on these and related issues. Executive Order 14,168 establishes a policy "to recognize two sexes, male and female," and states that a contrary "gender ideology" is harmful and that the two "sexes are not changeable and are grounded in fundamental and incontrovertible reality." *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615, § 2 (Jan. 20, 2025). Executive Order 14,187 establishes a federal policy not to "fund, sponsor, promote, assist, or support the so called 'transition' of a child from one sex to another." *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771, § 1 (Jan. 28, 2025).

Since issuing those orders, the White House has praised certain hospitals' decisions to "downsize or eliminate their so-called 'gender-affirming care' programs," explaining that the latter executive order was "already having its intended effect—preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child's sex." Article, *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), https://www.whitehouse.gov/articles/2025/02/president-trump-is-delivering-on-his-

commitment-to-protect-our-kids/; *see* Article, *The White House, President Trump Promised to End Child Sexual Mutilation – and He Delivered*, (July 25, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/ (similar).

2. The Department of Justice's FDCA Investigation

The Department of Justice has taken steps to investigate potential violations of the FDCA in connection with the provision of puberty blockers and cross-sex hormones to minors. In April, the Attorney General directed the Department "to investigate and hold accountable medical providers and pharmaceutical companies that mislead the public about the long-term side effects of chemical and surgical mutilations." ER-051 ("Bondi Memo"). The Attorney General did not purport to declare any conduct unlawful or to change the laws that apply to this industry. Rather, the Bondi Memo directed the Department to "undertake appropriate investigations of any violations of the Food, Drug and Cosmetic Act by manufacturers and distributors engaged in misbranding by making" purported "false claims about the on- or off-label use of puberty blockers, sex hormones," and similar drugs. ER-051.

In June, Assistant Attorney General for the Civil Division Brett Shumate issued a memorandum stating that "[t]he Civil Division will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities . . . [including] possible violations of the [FDCA] and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-

called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs." ER-055-56 ("Shumate Memo"). This memo too simply expressed an intention to investigate potential violations of existing federal statutes.

Based on information from whistleblowers and experts, there may be violations of federal law associated with gender-related treatments for minors. *See* ER-069. For example, the intentional use of incorrect diagnoses codes to fraudulently secure insurance coverage for gender-related treatments could be evidence of an intent to defraud or mislead that could, when combined with other prohibited conduct, support a felony violation of the FDCA. Similarly, misleading patients and their parents about the risks and benefits of the use of puberty blockers or cross-sex hormones (the drugs at the center of the investigation) as a treatment for gender dysphoria could also be evidence of felony intent. If such false and misleading statements took written form, such statements would misbrand the drug at issue. *See* 21 U.S.C. § 352(a) (drug is misbranded if its labeling is false or misleading in any particular). And any marketing or promotion of these drugs for gender dysphoria would be evidence of an intended use that has not been approved by FDA, rendering such drugs "unapproved new drugs" whose introduction into commerce is forbidden by the FDCA. *See* 21 U.S.C. § 331(d).

These are not mere technical violations. Bypassing the drug approval process carries real health consequences for children. After surveying the evidence, the United States Department of Health and Human Services ("HHS") has identified harms

associated with these drugs—including infertility and sterility, impaired bone density development, cardiovascular and metabolic disease, psychiatric conditions, and others—and determined that "[a]vailable evidence cannot support determinations regarding the effectiveness of these medical interventions for improving mental health or alleviating gender dysphoria symptoms in children and adolescents." Admiral Brian Christine, *Evidence-Based Care for Children and Adolescents with Gender Dysphoria* ("HHS Statement"), DEPARTMENT OF HEALTH AND HUMAN SERVICES at 1 (Dec. 18, 2025) https://health.gov/sites/oash/files/Message_Pediatric_Gender_Dysphoria_Treatment.pdf. And the HHS Secretary, after conducting a comprehensive evidence review, concluded that "[s]ex-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." *Declaration of the Secretary of the Department of Health and Human Services Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents* ("HHS Secretary Declaration"), THE SECRETARY OF HEALTH AND HUMAN SERVICES at 9 (Dec. 18, 2025) https://www.hhs.gov/sites/default/files/declaration-pediatric-sex-rejecting-procedures.pdf.

3. The Subpoena to QueerDoc

QueerDoc is a telemedicine clinic that explicitly holds itself out in marketing and promotional materials—including through its website—as specializing in the

treatment of children and adolescents who suffer from gender dysphoria, including by providing puberty blockers and cross-sex hormones to minors for these unapproved uses. Portions of QueerDoc's website may qualify as drug labeling, especially the pages that provide written explanation of how the drugs work, what the risks and benefits are, and how they are used—that is, information that supplements and explains the drugs. *See* QueerDoc, *Puberty Blockers FAQ* ("Puberty Blockers FAQ") https://queerdoc.com/puberty-blockers-faq/ (last visited Dec. 19, 2025); ER-069. The website is also replete with potentially false or misleading claims about the drugs that may render them misbranded. For example, QueerDoc's Youth Gender Care webpage states that "[p]uberty blockers are an option to put a 'pause button' on puberty and are completely reversible," QueerDoc, *Youth Gender Care* ("Youth Gender Care") https://queerdoc.com/adolescent-gender-care/ (last visited Dec. 19, 2025)—an assertion which is potentially misleading based on HHS's determination and other clinical sources that have stated that some effects are permanent, *see*, *e.g.*, HHS Statement at 3 (identifying "substantial risks associated with irreversible medical interventions").

Publicly available information also suggests that QueerDoc may have an intent to defraud and mislead or may have engaged in misconduct related to its provision of FDA-regulated drugs. QueerDoc's website explicitly states—as a matter of practice—that it uses false diagnosis codes when prescribing for the unapproved use of treating gender dysphoria in order to disguise the true purpose of the prescription. *See*

QueerDoc, *Pharmacy Options* ("Pharmacy Options") https://queerdoc.com/pharmacy-options/ (last visited Dec. 19, 2025). And according to a 2024 news report, QueerDoc's principal "consider[s] [the QueerDoc] practice a form of civil disobedience" and "feel[s] compelled to defy anti-trans laws" by providing care even in states that have enacted laws making the provision of such care unlawful. Emma Davis, *Death Threats, Legal Risk and Backlogs Weigh on Clinicians Treating Trans Minors*, NBC News (Aug. 28, 2024), https://www.nbcnews.com/nbc-out/out-news/trans-minors-treatment-clinicians-laws-bans-rcna164515.

The Civil Division issued a HIPAA subpoena to QueerDoc in June 2025. It included fifteen document requests and sought information to investigate "[f]ederal health care offenses as defined in 18 U.S.C. § 24(a)." ER-021. The subpoena seeks documents and data relating to QueerDoc's provision of gender-related medical treatment, including medical records for patients prescribed puberty blockers or hormone therapy and documents relating to billing or coding practices, or insurance claims, for gender-related care. ER-027-28. It also seeks "communications with pharmaceutical manufacturers regarding the use of puberty blockers or hormones in connection with gender affirming care for minor patients." ER-028.

QueerDoc is not the only subpoena recipient. The Department of Justice has "sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children." Press Release, U.S. Dep't of Just., Off. of Pub. Affairs, *Department of Justice Subpoenas Doctors and Clinics Involved in Performing*

Transgender Medical Procedures on Children (July 9, 2025) https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical.

C. Procedural Background

On July 8, QueerDoc moved to quash the government's subpoena. Citing the executive orders, the Bondi Memo, the Shumate Memo, and the White House's public statements, QueerDoc chiefly asserted that the subpoena should be quashed because it was issued for an "improper purpose," namely as a pretextual means to stop particular medical treatment, rather than to investigate federal health care offenses. ER-304-07. QueerDoc also argued that the subpoena was overbroad and unduly burdensome. ER-084-87.

After briefing, QueerDoc filed a Notice of Supplemental Authority that suggested the government may need "an affidavit[] or other evidence to show proper purpose." ER-058. Although the government disagrees with the suggestion, it responded by filing a declaration from a Department of Justice attorney. ER-062 ("Gordus Declaration"). The Gordus Declaration explains why the administrative subpoena was issued pursuant to a proper investigation and how QueerDoc's provision of certain medications to treat gender dysphoria could violate the FDCA. It also explains how the information sought in the subpoena is relevant to the government's investigation, walking through each group of requests one by one. ER-070-72. The request related to personnel and corporate oversight seeks information to

identify, among other things, who had authority to direct prescribing, billing, or marketing practices to determine liability. ER-070-71. The requests related to billing, coding, and reimbursement practices "are necessary to determine whether the clinic disguised treatment for gender-related mental disorders as another, physical illness . . . to disguise or hide potential FDCA violations and potentially secure health care benefit program reimbursements through fraud." ER-070-71. The requests related to the practice's relationships with drug manufacturers, distributors, and pharmacies "seek[] evidence of an intent to market or promote drugs for unapproved uses in violation of the FDCA." ER-070-72. Finally, the requests related to clinical practices and drug safety will, among other things, "permit the United States to evaluate the scope of possible prescribing for unapproved uses (including the number and age range of patients treated), and consistency of diagnoses." ER-070-73.

The district court granted QueerDoc's motion to quash, concluding that the government had issued the subpoena for an improper purpose—pretext to "end the very practice it claims to be merely investigating"—and citing the executive orders, memoranda, and public statements. ER-017. The district court also pointed to what it called a "mismatch" between DOJ's "stated investigation" ("manufacturers and distributors engaged in misbranding" and providers submitting false insurance claims) and QueerDoc's "actual operations" (prescribing medications). ER-017. Because QueerDoc is not manufacturing or distributing medications or submitting insurance claims, the district court posited that QueerDoc "cannot . . . commit the violations

being investigated." ER-017. The court also concluded that "the breadth of the subpoena supports" its ruling, claiming that certain requests "demand a staggering amount of personal health data" or were "facially overbroad." ER-018.

In a footnote, the district court struck the Gordus Declaration on procedural grounds. ER-018. The court noted that "even if [it] were to consider [the declaration, its] assertions about the scope of governmental resources devoted to this investigation would only further demonstrate the pretextual nature of the subpoena." ER-018.

SUMMARY OF ARGUMENT

This Court should reverse the district court's order quashing the subpoena. The QueerDoc subpoena is valid and was properly issued. The Department of Justice has statutory authority to investigate potential FDCA violations; the Department followed the relevant procedural requirements; and the subpoena seeks relevant information material to the investigation into whether drug companies, insurers, and clinics involved in the provision of "gender affirming care" to minors committed violations of federal health care offenses, including misbranding drugs. *See Golden Valley Elec. Ass'n*, 689 F.3d at 1113. Neither the district court nor QueerDoc has contested that these factors are satisfied. That alone is sufficient to require the enforcement of the subpoena.

The district court erred by concluding that the subpoena was nonetheless issued for an improper purpose. The law does not support a free-floating inquiry into subjective purpose; indeed, the government is not aware of any appellate decision that

upholds quashing an administrative subpoena on this basis. Nor, in any event, has QueerDoc carried the heavy burden that would be required to show such an improper purpose.

QueerDoc's principal theory—accepted by the district court—is that the current administration's opposition to certain medical interventions for minors with gender dysphoria renders pretextual any investigation into those practices. That is wrong and untenable. The federal health care laws apply to these entities just as much as they apply to everyone else, and the Department has a legitimate basis to inquire into potential violations. Nothing in the law supports the startling conclusion that any industry or practice that an administration opposes as a policy matter is somehow entitled to presumptive immunity from any criminal investigation. Nor do the district court's other rationales advance its holding: There is no "mismatch" between the investigation's purpose and QueerDoc's records. And the subpoena is not overbroad, which even if true would not support quashing it entirely.

Finally, at minimum, the district court erred by failing to give the Department a fair opportunity to meet the new, heightened standard that it created and imposed.

STANDARD OF REVIEW

This Court reviews a decision to quash an administrative subpoena for abuse of discretion. *McLane Co. v. EEOC* ("*McLane I*"), 581 U.S. 72, 75 (2017). As part of abuse-of-discretion review, this Court determines *de novo* whether the district court identified the correct legal rule. *United States v. Hinkson*, 585 F.3d 1247, 1261–62 (9th

Cir. 2009). A ruling "predicated on an erroneous view of the legal standard" is an abuse of discretion. *EEOC v. McLane Co.* ("*McLane II*"), 857 F.3d 813, 815 (9th Cir. 2017); *see also McLane I*, 581 U.S. at 81 n.3.

ARGUMENT

I. The QueerDoc subpoena is valid and was properly issued.

Congress has authorized federal agencies to issue administrative subpoenas in aid of their investigations. As the Supreme Court has explained, "[w]hen investigative and accusatory duties are delegated by statute to an administrative body, it … may take steps to inform itself as to whether there is probable violation of the law." *Morton Salt*, 338 U.S. at 642-43. In exercising investigatory powers, the agency is "analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *Id.*; *see also Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 216 (1946). Moreover, in seeking information through an administrative subpoena, the agency is not "limited by forecasts of the probable result of the investigation," *Walling*, 327 U.S. at 216 (quotation omitted), and need not make any threshold showing of probable cause, *United States v. Powell*, 379 U.S. 48, 56 (1964); *United States v. Doe*, 253 F.3d 256, 263 (6th Cir. 2001).

In line with these principles, this Court has long recognized that, in general, an administrative subpoena is valid so long as Congress has (1) granted the authority to investigate, (2) the relevant procedural requirements have been followed, and (3) the

evidence sought is relevant and material to the investigation. *Golden Valley Elec. Ass'n*, 689 F.3d at 1113.

Neither the district court nor QueerDoc seriously contested that the subpoena here satisfies these three requirements. *First*, the HIPAA statute expressly authorizes the Attorney General to issue subpoenas to investigate potential violations of federal health care offenses. 18 U.S.C. § 3486. Neither QueerDoc nor the district court disputed that the Attorney General (and the Assistant Attorney General of the Civil Division, through delegated authority) are authorized to issue a HIPAA subpoena pursuant to 18 U.S.C. § 3486. ER-014.

Second, neither QueerDoc nor the district court disputed that the government followed HIPAA's procedural requirements. The issuance of the subpoena was "procedurally sound": it was signed by the authorized official, properly served, and "calls for the production of documents relevant to an investigation within 500 miles of QueerDoc." ER-014.

Third, the information sought is relevant and material to the investigation. The "relevance requirement is not especially constraining, but is instead generously construed to afford the agency access to virtually any material that might cast light on the matter under investigation." *United States v. Exxon Mobil Corp.*, 943 F.3d 1283, 1287 (9th Cir. 2019) (quotations omitted; alterations adopted). The standard is low, and "[r]elevancy is determined in terms of the investigation rather than in terms of evidentiary evidence." *EEOC v. Fed. Exp. Corp.*, 558 F.3d 842, 854 (9th Cir. 2009).

The Government need only show that the documents it requests are broadly relevant to the purpose of an authorized investigation. *Reich v. Montana Sulphur & Chem. Co.*, 32 F.3d 440, 447 (9th Cir. 1994).

Here, the standard is easily satisfied. The Shumate Memo directed the Civil Division to use its authority to investigate potential "violations of the [FDCA] and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs." ER-056. The drugs—which are the focus of the investigation—are increasingly used in gender-related care for minors even though FDA has not determined that they are safe or effective for the treatment of gender dysphoria. Marketing or promoting these drugs as treating gender dysphoria in minors could therefore violate the FDCA's misbranding provisions.

The Civil Division, in turn, issued a subpoena to QueerDoc—a telemedicine clinic that specializes in so-called gender transition for minors and prescribes the drugs that are the focus of the investigation. The subpoena seeks records related to billing, coding, reimbursement practices, clinical practices, and QueerDoc's relationships with drug manufacturers, among other things, to further its investigation into potential FDCA violations.[1] These types of records are relevant to determine whether QueerDoc or other actors intentionally used incorrect diagnosis codes to

[1] Although QueerDoc and the district court spend some time on breadth, they do not seriously contest relevance. *See* ER-084-87; ER-018-19.

fraudulently secure insurance coverage for gender-related treatments, misled or deceived patients and their parents about the risks of gender-related treatments, or engaged in false and misleading labeling that would render the drug misbranded—all potential violations of federal law. That is more than sufficient to satisfy the relevance prong. *Fed. Exp. Corp.*, 558 F.3d at 854 (explaining that "courts must enforce administrative subpoenas unless the evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose" (quotation omitted; alteration adopted)).

The QueerDoc subpoena thus meets all the essential criteria for a lawful subpoena. *See Reich*, 32 F.3d at 448. It seeks relevant information for a legitimate investigation into real misconduct that the Department of Justice is authorized to investigate and enforce. The district court should therefore have denied the motion to quash and instead permitted enforcement of the subpoena.

II. The district court erred in quashing the subpoena based on an ostensible improper subjective purpose.

Although the district court did not question the subpoena's compliance with these established criteria, it nevertheless quashed the subpoena. The district court held that the subpoena was issued for an "improper purpose"—specifically, the President's opposition to certain medical interventions in children. Citing statements made by the President and other administration officials and certain perceived deficiencies in the subpoena, the district court inferred that the subpoena was not genuinely intended to

expose federal misconduct, but rather "seeks to end the very practice it claims to be merely investigating." ER-017.

That holding is flawed on multiple levels. To start, there is no legal basis to quash a procedurally valid subpoena that seeks to investigate criminal wrongdoing by casting doubt on the government's subjective purpose for the investigation. Even if there were, neither QueerDoc nor the district court came anywhere close to showing such an improper purpose here. Instead, the district court conflated legitimate policy views with illicit animus, misunderstood how federal health care investigations work, and treated a run-of-the-mill breadth dispute into grounds for facially quashing an entire subpoena (if not an entire investigation). This decision cannot stand.

A. Courts cannot quash valid administrative subpoenas based on speculation about subjective purpose.

Neither the Supreme Court's nor this Court's caselaw supports the district court's sweeping approach to "improper purpose." In particular, this Court has made clear that an improper purpose is not sufficient to quash so long as there is also a valid purpose for the investigation. And no appellate court has, to our knowledge, ever upheld the quashing of an administrative subpoena on purpose grounds.

The Supreme Court has explained that, when called upon to enforce an administrative subpoena, a district court has the ability to ensure that "its process" is not "abused." *Powell*, 379 U.S. at 58. "Such an abuse would take place if the summons had been issued for an improper purpose, such as to harass the [recipient] or to put

pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Id.*

Given that the improper purpose inquiry asks whether an otherwise valid subpoena seeking evidence relevant to an investigation should nevertheless be quashed or denied enforcement, this Court has unsurprisingly recognized that the subpoena recipient would bear a "heavy" burden in proving the subpoena was issued pursuant to an improper purpose. *See Crystal v. United States*, 172 F.3d 1141, 1144 (9th Cir. 1999) (quotation omitted); *Reich*, 32 F.3d at 443-44, 448-49. And, importantly, this Court has clarified that "[i]t 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).

Although *Powell*'s dicta about improper purpose is over 60 years old, the district court did not cite any court of appeals decision concluding that an administrative subpoena was issued for an improper purpose. Rather, this Court has consistently rejected such claims. For example, this Court concluded that a subpoena was not issued for an improper purpose in the face of allegations that it constituted an improper attempt to circumvent the agency's enforcement provisions. *Chavez-Deremer v. Amazon.com Servs., LLC*, No. 24-3260, 2025 WL 2417398, at *2 (9th Cir. Aug. 21, 2025). Although the recipient argued that the agency should have brought an enforcement action—rather than use its investigative subpoena power—this Court

affirmed enforcement of the subpoena, recognizing that the statute granted the agency "a broad grant of investigatory power." *Id.*

In another instance, this Court enforced a subpoena despite allegations that the agency had "effectively used [a] voluntary disclosure program as a trap to lull taxpayers into compromising their constitutional rights." *Crystal*, 172 F.3d at 1142. Although the Court characterized the government's conduct as "careless," it concluded that the agency did not issue the summonses in bad faith or for an improper purpose. *Id.* 1152-153. *See also United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 819 (8th Cir. 2012); *United States v. Markwood*, 48 F.3d 969, 983-84 (6th Cir. 1995) (rejecting improper purpose argument and concluding that the movant's claimed "'evidence' of impropriety . . . [was] merely an assertion of impropriety, and [did] not amount to a substantial demonstration that the government [was] abusing the court's process").

The district court here made no finding—and QueerDoc presented no evidence—that the government issued the subpoena to harass QueerDoc, pressure QueerDoc to settle a collateral dispute, or for any other reason specific to QueerDoc that may constitute an improper purpose under *Powell* or this Court's caselaw. Even more fundamentally, the district court did not deny that, whatever its views of the subjective motive for the investigation, "there is also a legitimate purpose for the subpoena." *Lynn*, 536 F.2d at 826; *see also Jagers v. Fed. Crop Ins. Corp.*, 758 F.3d 1179, 1185-186 (10th Cir. 2014) (rejecting the argument that "the agency's subjective desire

to reach a particular result must necessarily invalidate the result, regardless of the objective evidence supporting the agency's conclusion"). Nor could it. It is public knowledge that clinics like QueerDoc prescribe puberty-blockers and other drugs for treating gender dysphoria, even though they have never been FDA-approved for that use. And QueerDoc's own website contains statements that could amount to misbranding or mislabeling. These indicators alone raise legitimate concerns about potential FDCA violations by clinics and drug companies, and thereby constitute a legitimate purpose for investigation.

Given the ample basis to investigate federal health care offenses by different actors involved in providing "gender-affirming care" to minors, there is no serious question that a "legitimate purpose" exists for the Department's subpoena and for its investigation more broadly. That should have been the end of the matter; there was no further occasion for the court to probe the Department's subjective motives for pursuing this facially valid investigation. *See Trump v. Hawaii*, 585 U.S. 667, 706 (2018) (rejecting the suggestion of animus or improper purpose where the government action at issue was "expressly premised on legitimate purposes").

B. The district court's inference of improper purpose is groundless.

Even assuming that courts may quash administrative subpoenas by finding an improper subjective purpose, the district court here had no sound basis to draw any

such inference. The court gave three reasons for its conclusion, but none of them withstands basic scrutiny.

1. The district court principally reasoned that policy statements and press releases from the President and the Attorney General criticizing gender interventions for minors demonstrated an improper purpose to "end" these practices under the guise of "merely investigating" them. ER-017. That is an indefensible and untenable logical leap.

It is certainly uncontested that the President, the Attorney General, and others in the administration have expressed strong moral, ethical, and policy opposition to the practice of irreversibly altering minors' bodies as a way to address diagnoses of gender dysphoria. The administration believes these interventions are untested, unsafe, unnecessary, and unethical—concerns that are gaining traction within the medical community in the United States and abroad. *See* HHS Statement at 1-3; HHS Secretary Declaration at 1-9; *Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Nov. 19, 2025) https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf. At the same time, the executive orders, Bondi Memo, and Shumate Memo do not purport to declare those interventions categorically unlawful, or to change federal law in any respect. They merely direct investigations (and, if appropriate, enforcement actions) designed to enforce existing federal health care laws against entities in this industry. There is nothing bad faith or pretextual about that. The government is simply

prioritizing enforcement of federal law in an industry of special concern for policy reasons.

The district court's conflation of policy opposition with improper purpose is misguided. An administration's policy statements on a particular topic have never amounted to an improper reason to issue a subpoena or further an investigation into whether a particular federal law has been violated. *Cf. Trump*, 585 U.S. at 706-07. Such logic would immunize from investigation any industry or practice that an administration is opposed to as a policy matter. According to the district court's reasoning, an administration's "explicit agenda" on a particular policy necessarily renders any investigation that touches on that policy as pretextual. ER-017. The logic of the district court's ruling would prevent government investigations into anything touching on gender-related treatment—effectively immunizing *illegal* conduct in this space.

That approach would have startling consequences. Consider an administration that publicly advocated for a federal ban on sports gambling, while simultaneously seeking to ensure that the industry, where lawful, carried out its activities in a manner consistent with existing federal law. On the district court's logic, tax or other investigatory subpoenas to sports gambling operations and related businesses could be quashed based on the administration's "explicit agenda" of seeking to "end" such gambling. ER-017. Similarly, an administration that pursued or supported new legislation that would ban or limit practices of large technology or social media

companies could see subpoenas related to ensuring that those practices comply with existing law quashed on the same basis. Or consider an administration that advocates for new gun control measures, while also heightening its enforcement of existing regulations against firearm dealers. On the district court's logic, those investigations would have to be quashed based on improper purpose.

The list could go on. But the central point is that the government's opposition to a particular industry or practice does not immunize it from scrutiny to ensure that it is being carried out in a lawful manner. Just as sports gambling companies would not be immunized from scrutiny if a future administration sought to ban them, actors engaged in the sorts of activities at issue here are not immunized from compliance with existing federal law—or from a response to an otherwise-lawful subpoena designed to ascertain if violations of existing federal law have occurred.

Indeed, at bottom, the district court's rationale is simply an attack on the core executive power to exercise enforcement discretion in prioritizing what misconduct to investigate. Under Article II, the Executive Branch possesses authority to decide "how to prioritize and how aggressively to pursue legal actions against defendants who violate the law." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021). And "[t]he Executive Branch—not the Judiciary—makes arrests and prosecutes offenses on behalf of the United States." *United States v. Texas*, 599 U.S. 670, 679 (2023). "The power to decide when to investigate, and when to prosecute, lies at the core of the Executive's duty to see to the faithful execution of the laws," *Community for Creative*

Non-Violence v. Pierce, 786 F.2d 1199, 1201 (D.C. Cir. 1986), and "the Government's enforcement priorities" are a legitimate consideration in decisions about whether to prosecute, *Wayte v. United States*, 470 U.S. 598, 607 (1985). *See also United States v. Nixon*, 418 U.S. 683, 693 (1974); *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (decisions about enforcement of "the Nation's criminal laws" lie within the "special province of the Executive" (quotation omitted)). The Executive Branch has "exclusive authority and absolute discretion" to decide which crimes to investigate and prosecute. *Nixon*, 418 U.S. at 693; *see also Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (explaining that investigative and prosecutorial decision-making is "the special province of the Executive Branch").

Under those established principles, the Department of Justice is entitled to prioritize financial crimes, immigration offenses, or health care fraud—and it can also choose to prioritize the investigation and enforcement of those offenses in particular sectors, or in relation to particular activities (such as gambling operations, firearm dealers, or telemedicine clinics). It is axiomatic that government resources are limited, that different administrations have different priorities, and accordingly, that administrations allocate resources differently to align with their policy priorities.

Here, at most, the district court's logic could support an inference that the Department is focusing on misconduct by drug companies, insurers, and medical clinics engaged in providing "gender-affirming care" to minors because of the administration's broader policy concerns with that activity. Even if so, that is entirely

permissible, and certainly not an "improper purpose" sufficient to quash a subpoena. Nothing in *Powell* or this Court's cases suggests otherwise.

Finally, the district court's rationale makes no sense on its own terms, since the subpoenas do not and cannot "end" the interventions the administration opposes. The court framed the question before it as whether the Department of Justice "may use its administrative subpoena power to achieve what the Administration cannot accomplish through legislation." ER-013-14. But subpoenas merely seek information so the Department can investigate—and, if appropriate, prosecute—federal criminal offenses that nobody disputes may occur in connection with puberty blockers and cross-sex hormones. The Department does not contend that the act of writing a prescription for an off-label use would, in and of itself, give rise to FDCA liability. But it is beyond question that such drugs may be misbranded in violation of federal law.

Ensuring that such violations have not occurred with respect to those drugs is plainly a legitimate purpose, and that is precisely what the Bondi and Shumate memoranda direct be investigated: potential FDCA violations "by manufacturers and distributors engaged in misbranding by making" purported "false claims about the on- or off-label use of puberty blockers, sex hormones," and similar drugs, ER-051, and investigations of "doctors, hospitals, pharmaceutical companies, and other appropriate entities . . . [including] possible violations of the [FDCA] and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-

called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs," ER-055-56.

2. The district court also pointed to the supposed "mismatch" between the Department of Justice's "stated investigation" and "QueerDoc's actual operations" to support its improper purpose conclusion. ER-017. The court suggested that the government "issued the subpoena first and searched for a justification second," and that QueerDoc was not a proper subpoena target because it is not a manufacturer or distributor of drugs or a direct submitter of insurance claims. ER-017. That reasoning fundamentally misunderstands both the subpoena standard and how federal health care investigations work in practice.

Starting with the standard, no probable cause or reasonable suspicion is required to issue or enforce a subpoena. *See Powell*, 379 U.S. at 57; *Golden Valley Elec. Ass'n*, 689 F.3d at 1115 ("The Supreme Court has refused to require that an agency have probable cause to justify issuance of a subpoena."). And the Department of Justice is not required to articulate the particulars or details of its investigation strategy in order to issue a subpoena and collect information—which may or may not result in the bringing of charges against QueerDoc or anyone else.

Turning to the practicalities of investigations in this space, when the Department investigates a federal health care offense, it seeks information from each entity in the relevant system or supply chain to investigate and determine if federal offenses have been committed (and by whom). An investigation into potential

misconduct by an insurance company, for example, will often require records from doctors or pharmacies; an investigation into drug companies may require records of communications between those companies and third parties; and so on. In an integrated industry, it is fanciful to believe that any serious investigation could be conducted without seeking information from entities beyond the target.

Here, QueerDoc, as a prominent telemedicine clinic and prescription provider, is indisputably an entity with information relevant to the Department's investigation. Information from QueerDoc's patient records may show whether certain drugs are being used for off-label purposes, and how those treatments are being described for purposes of insurance claims. Communications between QueerDoc and drug companies may show whether the drug companies are misbranding the drugs or are participating in a conspiracy to do so. The fact that QueerDoc is not itself either a manufacturer or distributor of these drugs obviously does not mean that it lacks information that is relevant to investigating the companies that do.

Moreover, though nothing more is needed on this score, public materials show that QueerDoc itself is a legitimate target for investigation in its own right, given its own public statements about its conduct. Although QueerDoc is a clinic, not a drug company, its own website describes puberty blockers as "an option to put a 'pause button' on puberty and are completely reversible." Youth Gender Care. Those statements might themselves qualify as false and misleading labeling that render the drugs misbranded. The QueerDoc website further admits that it "usually order[s]

prescriptions under the diagnosis of 'endocrine disorder' not 'gender dysphoria,'" potentially to deceive insurance plans that "automatically reject payment for 'gender-incongruent' treatments." Pharmacy Options. That is certainly an adequate and reasonable basis to initiate an investigation into potential FDCA violations.

The district court appeared to believe that the government had to make a higher showing of misconduct up front, before issuing a subpoena. That is legally backwards. The Supreme Court and Ninth Circuit have explicitly rejected the notion that the government is required to "charge first and investigate later." *Reich*, 32 F.3d at 444. In *Reich*, the movant argued that "[b]ecause OSHA could not identify any regulations which might be being violated, its investigation amounted to a fishing trip in the hopes of finding violations." *Id.* This Court squarely rebuffed the argument, explaining that "it reverses the investigatory process long since approved by the Supreme Court by requiring OSHA to charge first and investigate later." *Id.*

"The power of an agency to investigate 'is more analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'" *Id.* at 444-45 (quoting *Morton Salt,* 338 U.S. at 642-43). "For an agency to subpoena corporate records, '[i]t is not necessary . . . that a specific charge or complaint of violation of law be pending or that the order be made pursuant to one. It is enough that the investigation be for a lawfully authorized purpose, within the power of Congress to command.'" *Id.* at 445 (quoting *Walling,* 327

U.S. at 208–09); *see also Endicott Johnson Corp. v. Perkins,* 317 U.S. 501, 508–09 (1943) (reversing the district court for having insisted that Secretary of Labor establish other elements of violation before issuing subpoena); *EPA v. Alyeska Pipeline Serv. Co.,* 836 F.2d 443, 447 (9th Cir. 1988), *abrogated on other grounds* ("An administrative agency, unlike parties relying on the judicial discovery process, need not first allege a violation of the law before it can investigate."). It is enough that the investigation was initiated for a lawfully authorized purpose—here, investigating potential FDCA violations.

3. Finally, the district court asserted that the breadth of the subpoena supported its conclusion as to improper purpose, highlighting six of the subpoena's thirteen requests and concluding without analysis that three "have little to do with investigating violations of FDCA" and three others are "facially overbroad" because they seek "QueerDoc's communications with manufacturers, sales representatives, marketing departments, and medical science liaisons regarding the treatment of gender dysphoria and the use of puberty blockers or hormones generally, not just those used 'off-label.'" ER-018-19.

That assertion likewise has no purchase in the improper purpose analysis. To start, there is no obvious reason why the overbreadth of a subpoena would suggest an improper subjective purpose, as opposed to a legitimate purpose to sweep broadly and avoid missing something important. The district court did not claim, let alone substantiate, that the Department intends to use the overbroad information for some

other, impermissible end. The mere fact that a subpoena seeks a broad swathe of information is not a basis to infer an improper purpose.

In all events, the subpoena is not overbroad. As noted, the district court did not hold—and QueerDoc did not contend—that the subpoena failed to meet the threshold requirement that the information sought is relevant and material to the investigation. *Golden Valley Elec. Ass'n*, 689 F.3d at 1113. And even under that inquiry, a subpoena "need not request only evidence that is specifically relevant to proving [the potential federal violation]; the requested information need only be relevant and material *to the investigation*" more broadly. *Fed. Exp. Corp.*, 558 F.3d at 855 (quotation omitted). In *Federal Express*, for example, this Court concluded that a subpoena was not overbroad where it requested information company-wide, even though the investigation was supported only by an individual charge of discrimination. *Id.*

Here, each of the six requests that the district court criticized actually has a manifestly valid investigatory purpose. Requests seven through nine seek information related to the practice's relationships with drug manufacturers, sales representatives, marketing departments, distributors, and pharmacies. ER-028. These requests seek evidence of intent to market or promote drugs for unapproved uses in violation of the FDCA. If QueerDoc, or one of its affiliated health care providers, received promotional materials, scientific exchange information, or payments to encourage the prescribing of puberty blockers or cross-sex hormones, such information could support a FDCA theory (including conspiracy) involving the illegal misbranding of

drugs or the illegal distribution of misbranded drugs or unapproved new drugs. Similarly, information regarding financial arrangements (e.g., consulting agreements, sponsorships, or speaking honoraria) may suggest improper influence to reinforce a showing of intent to misbrand the drugs, including an intent to defraud or mislead.

The district court called these requests "facially overbroad" because they seek communications "regarding the treatment of gender dysphoria and the use of puberty blockers or hormones generally, not just those used 'off-label.'" ER-018-19. Not so. Receiving all communications establishes a baseline and provides information to analyze the potential differences in behavior or operations when the drugs are prescribed for their approved uses versus an off-label use—an important comparison point when trying to establish intent.

Requests eleven through thirteen seek information relating to patient-level clinical practices and drug safety. ER-028-29. The district court's sole comment about these requests is that they seek a "staggering amount of personal health data related to QueerDoc's patients." ER-018. But this observation does not justify or provide a reason to quash the subpoena. These three requests would provide information about patient-level practices and drug safety to permit the government to evaluate the scope of possible prescribing for unapproved uses (including the number and age range of patients treated) and consistency of diagnoses. It also establishes the scope of interstate distribution and the scale of potential FDCA violations. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate

whether diagnoses were miscoded, which can prove fraudulent intent. Documentation of clinical justification, informed consent, and disclosure is important to assessing whether QueerDoc (or potential co-conspirators) concealed or downplayed risks associated with the unapproved use of the drugs. The absence of or minimization of such warnings could establish an intent to mislead. Patient charts also typically capture adverse outcomes, side effects, and complications of drug use.

Reviewing patient records may also reveal systematic use of the same masking codes, fraudulent informed consent documents, or other possible criminal conduct—enabling investigators to distinguish between mere errors and an institutionalized practice. Receiving patient records including patient identities could also provide essential investigative leads. Parents could be witnesses about what disclosures were made, and patients (depending on age and circumstances) could provide information about the informed consent process, side effects, or potentially false or misleading information about the drugs conveyed during treatment. Health benefit programs tied to identified patients could provide additional evidence on potential illegal distribution of the drugs for unapproved uses. All of this information is relevant for the government's legitimate FDCA investigation.

Finally, even assuming some aspects of the subpoena are overbroad, that overbreadth would not be a ground for quashing the *entire* subpoena, including requests as to which the district court made no assertion of overbreadth. At most, overbreadth could be a basis for narrowing or tailoring a subpoena based on a specific

showing of undue burden. *See, e.g.*, *Golden Valley Elec. Ass'n*, 689 F.3d at 1115-116 (discussing overbreadth arguments in administrative subpoena context). Those concerns thus could not support the district court's order here, particularly where the court did not address QueerDoc's undue burden contentions.

* * *

Quashing an administrative subpoena on its face due to "improper purpose" is an extraordinary step for a federal court to take. And it is a particularly unjustified step when the subpoena is unquestionably procedurally valid and seeks information that is indisputably relevant to potential criminal wrongdoing. The district court's order has effectively immunized an entire class of actors from federal criminal liability simply because the President has voiced legitimate ethical and policy opposition to their conduct. That is not consistent with the law. If any actors are ultimately charged with violating existing law, they will have every opportunity to rebut the charges, consistent with due process and the presumption of innocence. But they cannot stop an investigation before it even begins, merely by invoking the "fierce scientific and policy debates" over their conduct. *Skrmetti*, 605 U.S. at 525.

III. At minimum, the district court should have given the government an opportunity to satisfy its new, heightened standard.

For all the reasons set forth above, the district court legally erred by quashing the subpoena, and essentially imposed on the government a heightened standard that is contrary to established precedent. At minimum, however, if the district court was

going to adopt and apply what amounts to such a heightened standard, then it should have given the government an opportunity to satisfy that new standard through the submission of additional factual materials. Yet the district court struck the Gordus Declaration as noncompliant with Local Civil Rule 7(m).[2] ER-018. Regardless of the procedural mechanism, however, the district court should have given the government some opportunity to respond to QueerDoc's new argument that an affidavit was required and, more important, to the novel burden and standard that the district court articulated.

By failing to afford that opportunity, the district court has left the government in an untenable position. In theory, the Department of Justice could simply issue a new subpoena to QueerDoc, and (if challenged) defend using new evidence showing the *bona fides* of the investigation and validity of the subpoena's purpose. But the district court's sweeping reasoning appears to foreclose any subpoena and, indeed, perhaps any investigation at all.

Accordingly, if this Court does not reverse the decision below outright and permit enforcement of the subpoena, it should at minimum vacate and remand with

[2] Local Rule 7(m) addresses two circumstances. First, "[i]n the event an error is discovered," the rule allows a party to file "a praecipe requesting that the court consider a corrected document." Separately, a party may seek "to add an additional document in support of a previous filing" so long as the "praecipe . . . set[s] forth why the document was not included with the original filing and reference the original filing by docket number." The government invoked the latter aspect of the rule here.

instructions to allow the government to supplement the record in an effort to meet the district court's new, heightened standard for subpoena enforcement.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's order.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

YAAKOV M. ROTH
Principal Deputy Assistant Attorney General

BRAD HINSHELWOOD
Attorney, Appellate Staff

/s/ Abigail Stout
ABIGAIL STOUT
Counsel to the Assistant Attorney General
(202) 514-7830
Civil Division
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530

December 2025

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, Appellant states that they know of no related case pending in this Court.

/s/ Abigail Stout
Abigail Stout

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 9,738 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

/s/ Abigail Stout
Abigail Stout

CERTIFICATE OF SERVICE

I hereby certify that on December 19, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Abigail Stout
Abigail Stout

ADDENDUM

TABLE OF CONTENTS

18 U.S.C. § 24 – Definitions relating to Federal health care offense

(a) As used in this title, the term "Federal health care offense" means a violation of, or a criminal conspiracy to violate—

(1) section 669, 1035, 1347, or 1518 of this title or section 1128B of the Social Security Act (42 U.S.C. 1320a–7b); or

(2) section 287, 371, 664, 666, 1001, 1027, 1341, 1343, 1349, or 1954 of this title section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), or section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131), or section 411, 518, or 511 of the Employee Retirement Income Security Act of 1974,[1] if the violation or conspiracy relates to a health care benefit program.

(b) As used in this title, the term "health care benefit program" means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

Health Insurance Portability & Accountability Act of 1996

18 U.S.C. § 3486 – Administrative subpoenas

(a) AUTHORIZATION.—

(1)

(A) In any investigation of—

(i)

(I) a Federal health care offense; or (II) a Federal offense involving the sexual exploitation or abuse of children, the Attorney General;

Federal Food, Drug, and Cosmetic Act

21 U.S.C. § 331 – Prohibited Acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355,[1] 360bbb–3, or 364c of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb–3, 364a, 373, 374(a), 379aa, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc–1(i), 360e(f), 360i, 360bbb–3, 364a, 364g, 379aa, 379aa–1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 2223 [2] of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco

product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..1This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. § 333 – Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,[1] if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

21 U.S.C. § 352 – Misbranded drugs and devices

(a) FALSE OR MISLEADING LABEL

(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42. The requirements set forth in section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

. . .

(f) DIRECTIONS FOR USE AND WARNINGS ON LABEL

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

21 U.S.C. § 355 – New Drugs

(a) NECESSITY OF EFFECTIVE APPROVAL OF APPLICATION

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

. . .

(d) GROUNDS FOR REFUSING APPLICATION; APPROVAL OF APPLICATION; "SUBSTANTIAL EVIDENCE" DEFINED

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient

information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.