FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

QUEERDOC, PLLC, *Plaintiff - Appellee*, v. DOJ - UNITED STATES DEPARTMENT OF JUSTICE, *Defendant - Appellant*.	No. 25-7384 D.C. No. 2:25-mc-00042-JNW OPINION

Appeal from the United States District Court
for the Western District of Washington
Jamal N. Whitehead, District Judge, Presiding

Argued and Submitted March 6, 2026
Seattle, Washington

Filed August 14, 2026

Before: Richard A. Paez, Carlos T. Bea, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Bea;
Dissent by Judge Paez

SUMMARY*

Administrative Subpoena

The panel reversed the district court's order quashing in its entirety an administrative subpoena issued by the United States Department of Justice (DOJ) to QueerDoc pursuant to the Health Insurance Portability and Accountability Act (HIPAA), which authorizes the Attorney General or his designee to issue a subpoena in any investigation of a federal health care offense, and remanded for further proceedings.

QueerDoc is a telehealth provider of gender affirming care that treats patients, including minors, who suffer from gender dysphoria. Patients of QueerDoc may be diagnosed with gender dysphoria and prescribed puberty blockers and cross-sex hormones.

Following President Trump signing Executive Order 14,168, which declared that the United States "recognize[s] two sexes, male and female," and that "[t]hese sexes are not changeable[,]" and Executive Order 14,187, which declared that the federal government would not "fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another[,]" DOJ issued an administrative subpoena to QueerDoc ordering QueerDoc to produce various documents necessary for the investigation of potential violations of federal health care laws. The district court quashed the subpoena in its entirety, finding the subpoena unenforceable because DOJ had issued it for an

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

"improper purpose": to achieve the President's policy objective of "eliminating gender-affirming care."

The panel held that DOJ issued the administrative subpoena pursuant to statutory authority because 1) HIPAA permits investigations for potential violations of the Federal Food, Drug, and Cosmetic Act's misbranding prohibitions; 2) DOJ complied with HIPAA's procedural requirements; and 3) the subpoena requests were relevant to an authorized investigation under HIPAA.

The panel next held that QueerDoc did not meet its heavy burden of showing that the subpoena was issued for an improper purpose. Consistent with the presumption of regularity and the high standard required to quash an administrative subpoena on improper purpose grounds, the Executive Branch's public opposition to "gender-affirming care" is insufficient to show that an agency within the Executive Branch issued an otherwise permissible HIPAA subpoena in bad faith. The President may direct DOJ to exercise its statutory authority in a manner that aligns with his broader policy goals.

Because the district court decided only that the subpoena was motivated by an improper purpose and did not rule on QueerDoc's arguments that DOJ's subpoena is overbroad and poses an undue burden, the panel remanded for the district court to consider those issues the first instance.

Dissenting, Judge Paez wrote that the district court's finding that DOJ issued the subpoena to QueerDoc in bad faith was not clearly erroneous. Considering the information properly before the district court at the time it rendered its decision, the government failed to satisfy its prima facie burden of showing the information subpoenaed was relevant and material to its purported investigatory purpose. Even if

the government satisfied its prima facie burden, the district court's decision to quash the subpoena should be affirmed because ample evidence supports its finding that the subpoena was issued in bad faith.

COUNSEL

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OPINION

BEA, Circuit Judge:

As part of an ongoing investigation into potential violations of federal health care laws, the United States Department of Justice (DOJ) issued an administrative subpoena to QueerDoc pursuant to the Health Insurance Portability and Accountability Act (HIPAA). QueerDoc is an online medical clinic that treats patients, including minors, who suffer from gender dysphoria. An interested patient, after an introductory meeting and the completion of some online forms, can have a "medical visit" that consists of a videoconference with a licensed medical professional. After this virtual appointment, a patient may be diagnosed with gender dysphoria and prescribed puberty blockers and cross-sex hormones.

QueerDoc commenced this action by filing a motion to quash the subpoena in federal district court. The parties did not dispute that DOJ had statutory authority to issue the subpoena. However, the district court found the subpoena unenforceable because DOJ had issued it for an "improper purpose": to achieve the President's policy objective of "eliminating gender-affirming care." The district court thus quashed the subpoena in its entirety.

We hold that QueerDoc has not met its heavy burden of showing that the subpoena was issued for an improper purpose. Consistent with the presumption of regularity and the high standard required to quash an administrative subpoena on improper purpose grounds, the Executive Branch's public opposition to "gender-affirming care" is insufficient to show that an agency within the Executive Branch issued an otherwise permissible HIPAA subpoena in bad faith. The President may direct DOJ to exercise its statutory authority in a manner that aligns with his broader policy goals. Accordingly, we reverse the district court's order quashing the subpoena in its entirety and remand for further proceedings.

I

A

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorizes the Attorney General or his designee to issue a subpoena in "any investigation of . . . a Federal health care offense." 18 U.S.C. § 3486(a)(1)(A)(i)(I). "Federal health care offense," defined at 18 U.S.C. § 24(a), includes any prohibited acts under the Federal Food, Drug, and Cosmetic Act (FDCA) and related conspiracies. *See* 21 U.S.C. § 331.

The FDCA outlaws the introduction into interstate commerce of "any new drug" unless the Food and Drug Administration (FDA) has approved a new drug application (NDA) for that drug. 21 U.S.C. §§ 331(d), 355(a). The NDA must demonstrate that a drug is safe and effective for a certain range of uses; the FDA approves the drug only for those specified uses. *Id.* § 352(f); 21 C.F.R. § 201.5. The FDA also approves the drug's labeling, which specifies the approved uses and provides directions for administering the drug in accordance with those uses. 21 C.F.R. §§ 201.5, 201.55–201.57. Manufacturing, promoting, or labeling a drug for non-FDA-approved uses, known as "off-label uses," may violate the FDCA's prohibition on misbranding. *See* 21 U.S.C. §§ 352(a), (f), 355(a).

QueerDoc operates in this highly regulated industry. QueerDoc holds itself out as a "telehealth provider of gender affirming care" that offers services to patients, including minors, in ten states. A person who lives in one of these states and believes that he may suffer from gender dysphoria can go to QueerDoc's public website and register for a free fifteen-minute consultation regarding potential treatment plans. *See* QueerDoc, *Telemedicine Services*, https://perma.cc/EQW5-C7WT; QueerDoc, *Youth Gender Care*, https://perma.cc/23UZ-7YWE. Assuming the prospective patient wishes to proceed, he will upload various medical records and consent forms to QueerDoc's online "patient portal" and will then have an hour-long medical visit by videoconference with one of QueerDoc's licensed medical professionals. *See* QueerDoc, *Telemedicine Services*. After the visit, the doctor may render a diagnosis (here, of gender dysphoria), refer the patient to another clinic for testing or further treatment, and prescribe drugs for the patient. *See* QueerDoc, *Telemedicine Services*; QueerDoc,

Youth Gender Care; QueerDoc, *Our Pricing*, https://perma.cc/FZ7E-MTT2.

The drugs that QueerDoc prescribes to its patients fall within one of two categories: "puberty blockers" and "cross-sex hormones." The term "puberty blockers" refers to a set of prescription drugs that block the natural production of sex hormones, thereby suppressing the effects of normal puberty in an adolescent's body. Report, U.S. Dep't of Health and Human Services, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* ("HHS Report") at 116–17 (Nov. 19, 2025), https://perma.cc/ZMA3-YPQ2. The term "cross-sex hormones" refers to a set of prescription drugs intended to alter a person's secondary sexual characteristics so that they resemble those of the opposite sex (e.g., estrogen for males; testosterone for females). *Id.* at 123. Neither puberty blockers nor cross-sex hormones have been approved by the FDA for the purpose of treating gender dysphoria.[1] All use of these drugs to treat gender dysphoria is "off-label."

[1] The FDA has approved puberty blockers for other uses, including the treatment of central precocious puberty (CPP), a condition in which the pituitary gland is activated prematurely, sometimes during infancy or early childhood. *See* HHS Report, *supra*, at 115–16. CPP is associated with many "negative health outcomes," including decreased adult height. *Id*. Thus, puberty blockers are approved to treat CPP in youths but not to treat gender dysphoria. Moreover, because puberty blockers are administered to CPP patients differently from the way they are administered to patients with gender dysphoria, the side effects of the latter treatment are unknown. *See United States v. Skrmetti*, 605 U.S. 495, 533 (2025) (Thomas, J., concurring) ("To treat precocious puberty, puberty blockers are administered until the age appropriate for puberty; to treat gender dysphoria, however, puberty blockers are administered to stop puberty throughout the years it would normally occur.").

Although QueerDoc prescribes puberty blockers and cross-sex hormones, it does not manufacture or distribute these drugs. In addition to providing medical services, QueerDoc operates a public website that informs readers about various matters pertaining to "gender-affirming care." For example, two of QueerDoc's webpages provide written and visual instructions for injecting cross-sex hormones into one's own body. QueerDoc, *Tips for Less Painful Injections*, https://perma.cc/6TC5-T84R; QueerDoc, *Self-Injections*, https://perma.cc/3UTA-QKEQ. Other webpages provide links to pharmacies from which a person may obtain puberty blockers and cross-sex hormones and advise the reader on how to submit insurance claims for these drugs. QueerDoc, *Pharmacy Options*, https://perma.cc/XLL9-9286; QueerDoc, *Insurance Dictionary*, https://perma.cc/PRC8-KVKT. On another webpage, QueerDoc claims that the effects of puberty blockers are "completely reversible." QueerDoc, *Youth Gender Care*, https://perma.cc/23UZ-7YWE.

It is generally understood that the FDCA does not regulate core aspects of medical practice, such as a doctor's choice of which drug to prescribe to a patient. *See, e.g.*, U.S. Food and Drug Admin., *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) ("Congress did not intend the [FDA] to regulate or interfere with the practice of medicine."). State law and professional standards of practice regulate a doctor's ability to prescribe drugs for off-label uses. The FDCA, in contrast, regulates the labeling and branding of drugs and their distribution into the national market.

As relevant here, the FDCA prohibits the "misbranding" of a drug. 21 U.S.C. §§ 331(a)–(b), 352. One way to

"misbrand" a drug is to publish false or misleading labeling of that drug. *Id.* § 352(a). Under the FDCA, "labeling" includes all "labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). A piece of "labeling" may "accompany" a drug even if it is physically separated from the drug's container. *See Kordel v. United States*, 335 U.S. 345, 350 (1948) ("No physical attachment . . . is necessary."). The FDA has given "labeling" a broad definition that includes virtually any "printed, audio, or visual matter descriptive of a drug." 21 C.F.R. § 202.1(*l*)(2).

The off-label use of puberty blockers and cross-sex hormones to treat minors with gender dysphoria is the subject of "fierce scientific and policy debates," *United States v. Skrmetti*, 605 U.S. 495, 525 (2025), and reflects a "deep conflict over human nature." *State v. Loe*, 692 S.W.3d 215, 239 (Tex. 2024) (Blacklock, J., concurring). The Trump Administration has taken one side of this dispute. On January 20, 2025, President Trump signed Executive Order 14,168 (EO 14,168), which declared that the United States "recognize[s] two sexes, male and female," and "[t]hese sexes are not changeable." Exec. Order No. 14,168, 90 Fed. Reg. 8615, § 2 (Jan. 20, 2025). On January 28, 2025, President Trump signed Executive Order 14,187 (EO 14,187), which declared that the federal government would not "fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another." Exec. Order 14,187, 90 Fed. Reg. 8771, § 1 (Jan. 28, 2025). Section 8(c) of EO 14,187 directed DOJ to "prioritize investigations" into "violations of the [FDCA] by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation." *Id.* § 8(c). Section 11(b)

provided that EO 14,187 "shall be implemented consistent with applicable law." *Id.* § 11(b).

On April 22, 2025, then-Attorney General Pamela Bondi circulated to all DOJ employees a memorandum (the "Bondi Memo") to implement § 8(c) of EO 14,187. To that end, the Bondi Memo directed the Consumer Protection Branch, an office within the Civil Division of DOJ, to conduct "appropriate investigations of any violations of the [FDCA] by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition.'" The Bondi Memo took the position that "the promotion of off-label uses of hormones . . . run[s] afoul of the FDA's prohibitions on misbranding and mislabeling." The Bondi Memo stated a goal: to "bring [gender-affirming care] to an end."

On June 11, 2025, Brett Shumate, Assistant Attorney General for the Civil Division, circulated to all Civil Division employees a memorandum (the "Shumate Memo") that further refined the directives in EO 14,168, EO 14,187, and the Bondi Memo. Relevant here, the Shumate Memo directed the Civil Division to "prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities" for "possible violations of the [FDCA]."

B

1

On June 11, 2025, Assistant Attorney General Shumate served QueerDoc with the present subpoena. The subpoena

ordered QueerDoc to produce, no later than July 9, 2025, the following documents:

Request 1:	Personnel files for (i) QueerDoc executives; (ii) QueerDoc employees or contractors who are authorized to prescribe medications or perform medical evaluations; and (iii) QueerDoc employees or contractors who are engaged in billing activities.
Requests 2–6:	Documents relating to billing, coding, and reimbursement practices in the provision of "gender-related care" to minors, including billing records, insurance claims, internal protocols, and training materials.
Requests 7–9:	Communications between QueerDoc and drug manufacturers, salespeople, and pharmacies relating to the use of puberty blockers and hormones in minors for the purpose of "gender-related care."
Request 10:	Records of sponsorships or contracts between

	QueerDoc and any manufacturer of puberty blockers or hormones or any pharmacy that distributes these drugs.
Requests 11–13:	Patient records for any patient who was prescribed puberty blockers or hormone therapy, including medical records describing the basis for the prescription. For minor patients who were prescribed puberty blockers, documents relating to informed consent, patient intake, and parental authorization, including disclosures about off-label use of puberty blockers and the associated risks.
Requests 14–15:	Records of communications between QueerDoc and drug manufacturers, pharmacies, or government agencies relating to the safety of puberty blockers and hormones in the treatment of minors. Documents relating to any adverse effects or "unfavorable consequence[s]" of

> "gender-related care" in minor patients.

The subpoena stated that production of the documents was "necessary in the performance of the responsibility of the [DOJ] to investigate Federal health care offenses as defined in 18 U.S.C. § 24(a)."

On June 26, 2025, QueerDoc's counsel and three DOJ attorneys met by videoconference to discuss the subpoena. QueerDoc's counsel asked about the basis for DOJ's investigation of QueerDoc. One DOJ attorney referred to the directives contained in EO 14,168, EO 14,187, and the Bondi Memo, and explained that his office had been "tasked with investigating potential violations of the [FDCA]," but did not offer specific reasons for investigating QueerDoc other than its prominence as a provider of "gender-affirming care." DOJ stated that although it would require QueerDoc to begin production by July 9, it did not expect that production would be completed by that date.

2

On July 8, 2025, QueerDoc filed a motion to quash the subpoena in the United States District Court for the Western District of Washington pursuant to 18 U.S.C. § 3486(a)(5). *See* Motion to Quash Subpoena, No. 2:25-mc-00042-JNW (W.D. Wash., July 8, 2025), ECF Doc. 1. QueerDoc did not claim that DOJ lacked statutory authority to issue this subpoena. *See id.* at 9. QueerDoc instead argued that the subpoena was unenforceable, irrespective of statutory authority, because DOJ had issued it for an "improper purpose." *Id.* at 6–9. Alternatively, QueerDoc argued that the subpoena was invalid because its document requests

were "overbroad" and compliance with them would be "unduly burdensome." *Id.* at 9–12.

QueerDoc asserted that the "improper purpose" for this subpoena originated "[a]t the highest levels of government." *Id.* at 8. QueerDoc argued that the "true purpose" of § 8(c) of EO 14,187 was to "downsize or eliminate *all* gender-affirming care." *Id.* at 7 (emphasis in original) (internal quotation marks omitted). QueerDoc contended that because DOJ issued the subpoena to implement § 8(c) of EO 14,187, it had issued the subpoena to achieve the same goal as the Administration: to "end" the provision of gender-affirming care. *Id.* at 4, 8. Because "[e]nding gender affirming care" was not a "valid" purpose of a HIPAA subpoena, QueerDoc argued, this subpoena should be quashed. *Id.* at 6–9. QueerDoc did not contend that any of DOJ's investigators harbored illicit motives. Rather, QueerDoc asserted that the Administration's directives and public statements themselves were sufficient proof of improper purpose. *Id.* at 8–9 ("The Court can—and should—find improper purpose and bad faith from [the Administration's] statements alone.").

DOJ filed a response arguing that the Administration's "position as to gender-related medical treatments for minors" was not a valid reason to quash the subpoena. DOJ emphasized that a court's duty in a subpoena-enforcement proceeding is to ensure that the investigating agency has acted pursuant to statutory authority. Because it was undisputed that HIPAA authorized DOJ to issue the subpoena, DOJ argued that the district court should enforce it. *See* 18 U.S.C. § 3486(c).

Two months after filing its response, and one month before the district court issued its order quashing the

subpoena, DOJ tried to supplement the record with a declaration from Allan Gordus, the Assistant Director of the Consumer Protection Branch (the "Gordus Declaration"). The Gordus Declaration explained DOJ's reasons for believing that QueerDoc may be engaged in the "misbranding" of puberty blockers and cross-sex hormones through false or misleading labeling. DOJ attempted to file the Gordus Declaration pursuant to a local rule that permits a party to "add an additional document in support of a previous filing." W.D. Wash. Loc. Civ. R. 7(m).

3

On October 27, 2025, the district court quashed the subpoena in its entirety on the ground that DOJ had issued it for an "improper purpose." *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1301–04 (W.D. Wash. 2025). The district court first analyzed the Administration's general policy on "gender-affirming care." *See id.* at 1302–03. Based on EO 14,168, EO 14,187, the Bondi Memo, the Shumate Memo, and public statements from the Administration, the district court found that "the Administration's explicit agenda" was to "downsize or eliminate all gender-affirming care." *Id.* at 1303 (internal quotation marks omitted). The district court concluded that this "agenda" was improper because its objective—"the elimination of medical care that Washington and other states explicitly protect"—was one that "the Administration cannot accomplish . . . ." *Id.* at 1301. The district court then imputed that improper purpose to DOJ's investigation of QueerDoc: Because DOJ "implemented [the Administration's] directives through [the issuance of] administrative subpoenas," the district court concluded that DOJ issued the subpoena to QueerDoc for an "improper purpose." *Id.* at 1302–04.

The district court also noted that the "mismatch" between QueerDoc's business activities and the stated purpose of the investigation demonstrated the subpoena's "pretextual nature." *Id.* at 1303. While acknowledging that "the government need not justify its decision to open an investigation" in the typical case, the district court subjected DOJ's reasoning to a "more muscular review." *Id.* at 1302. Turning to the sufficiency of DOJ's explanation, the district court found that DOJ's "inability to articulate why it is investigating QueerDoc" "confirm[ed]" that the subpoena was issued for the improper purpose of ending "gender-affirming care." *Id.* at 1303.

Because the district court quashed the subpoena in its entirety on improper purpose grounds, it did not reach QueerDoc's arguments regarding overbreadth and undue burden. *Id.* at 1304. The district court also suggested that DOJ had issued the subpoena under its valid HIPAA authority, although QueerDoc had not raised the issue of statutory authority in its motion to quash. *See QueerDoc*, 807 F. Supp. 3d at 1301 n.1. Finally, the district court struck the Gordus Declaration on the ground that it did not comply with Local Civil Rule 7(m). *See id.* at 1303 n.2. The district court noted that it would have quashed the subpoena even if it had considered the Gordus Declaration, which, in the court's view, "further demonstrate[d] the pretextual nature of the subpoena." *Id.*

This appeal followed.

II

We have jurisdiction pursuant to 28 U.S.C. § 1291. *In re Subpoena Duces Tecum*, 228 F.3d 341, 346–47 (4th Cir. 2000) (orders enforcing or quashing administrative subpoenas are "final" because "there is no ongoing judicial

proceeding that would be delayed by an appeal."); *see Cobbledick v. United States*, 309 U.S. 323, 330 (1940) (proceedings to enforce administrative subpoenas are "self-contained, so far as the judiciary is concerned[.]").

We review the district court's order quashing an administrative subpoena for abuse of discretion. *McLane Co. v. EEOC*, 581 U.S. 72, 75 (2017). We will uphold the district court's findings of fact unless they are "illogical, implausible, or without support in inferences that may be drawn from the record." *United States v. Hinkson*, 585 F.3d 1247, 1263 (9th Cir. 2009) (en banc). However, "the District Court's latitude does not extend to legal issues about what counts as an illicit motive," *United States v. Clarke*, 573 U.S. 248, 256 (2014), and we review such legal issues de novo. *Hinkson*, 585 F.3d at 1261–62.

III

We begin by describing a federal court's authority to enforce or quash an administrative subpoena before explaining why the district court exceeded its authority in this case.

A

An administrative agency's authority to issue subpoenas is created by statute. *Peters v. United States*, 853 F.2d 692, 696 (9th Cir. 1988). Just as Congress delegated to agencies the power to execute federal law in particular domains, Congress delegated to certain agencies the "power[] of original inquiry" to fulfill their statutory mandates. *United States v. Morton Salt Co.*, 338 U.S. 632, 642 (1950). As part of this scheme, Congress made federal courts the exclusive bodies that could enforce, modify, or quash administrative subpoenas. *In re Nat'l Sec. Letter*, 33 F.4th 1058, 1063 (9th

Cir. 2022) ("[W]hile an agency may issue a subpoena without prior judicial approval, it must invoke the aid of a federal court to enforce it."). The scope of a court's inquiry during a subpoena-enforcement proceeding, however, is "strictly limited." *FTC v. Texaco, Inc.*, 555 F.2d 862, 871–72 (D.C. Cir. 1977) (en banc). If enforcing a subpoena entailed rigorous, trial-like proceedings, "the investigative process [w]ould be completely disrupted," agencies would be "diverted from their legitimate duties," and the "injection of collateral issues . . . would make the investigation interminable." *Hannah v. Larche*, 363 U.S. 420, 443 (1960). Hence, these proceedings are "summary in nature." *United States v. Stuart*, 489 U.S. 353, 369 (1989).

The court's primary role is to ensure that the agency does not act "arbitrarily or in excess of [its] statutory authority." *Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 216 (1946). The agency bears the initial burden of showing that (1) Congress empowered the agency to issue investigatory subpoenas; (2) the agency followed applicable procedures; and (3) the subpoena sought evidence that could be relevant and material to a statutorily authorized investigation. *United States v. Golden Valley Elec. Ass'n*, 689 F.3d 1108, 1113 (9th Cir. 2012). An affidavit in which the investigating official declares a legitimate basis for the subpoena is sufficient to establish the agency's *prima facie* case for enforcement. *FDIC v. Garner*, 126 F.3d 1138, 1143 (9th Cir. 1997). Once the agency has established its *prima facie* case, the recipient is left with "few defenses" against enforcement. *United States v. Derr*, 968 F.2d 943, 945 (9th Cir. 1992).

One defense is that enforcement of the subpoena would be an "abusive use of the court's process" because, although the subpoena was authorized by statute, the agency issued it

for an "improper purpose" or in bad faith. *United States v. Powell*, 379 U.S. 48, 51, 58 (1964). An "abuse of process" would occur if a court enforced an administrative subpoena that the agency had "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.* at 58. A party that seeks to quash a subpoena on this basis bears a "heavy" burden to produce "specific facts and evidence to support his allegations of bad faith or improper purpose." *United States v. Jose*, 131 F.3d 1325, 1328 (9th Cir. 1997) (en banc) (citation and internal quotation marks omitted).

A federal court has the inherent power to ensure that its process is not abused by a government that acts from illicit motives. *See Powell*, 379 U.S. at 58 ("It is the court's process which is invoked to enforce the [subpoena], and a court may not permit its process to be abused."). The authority to quash an administrative subpoena when its enforcement would abuse the court's process derives from this inherent power. *SEC v. ESM Gov't Sec., Inc.*, 645 F.2d 310, 317 (5th Cir. Unit A 1981) ("The equitable powers of the courts of the United States . . . over their own process, to prevent abuse, oppression and injustice, are inherent. . . . The Supreme Court's directive[] in *Powell* . . . leave[s] no doubt that this power may be properly invoked in cases involving the enforcement of administrative subpoenas."); *see also Chapman v. Maren Elwood Coll.*, 225 F.2d 230, 234 (9th Cir. 1955) (explaining that a subpoena-enforcement proceeding is "equitable in character"). The prohibition against bad-faith subpoenas is also grounded in the Fourth Amendment's requirement that a subpoena be reasonable. *Golden Valley*, 689 F.3d at 1113. Whether the authority

rests on our inherent equitable power or on the Fourth Amendment, the inquiry remains the same.

The doctrine of "improper purpose" arose from the use of civil tax summonses by the Internal Revenue Service (IRS). In the term before it decided *United States v. Powell*, the Supreme Court noted that the recipient of an IRS civil tax summons could raise the defense that the IRS had issued the summons "for the improper purpose of obtaining evidence for use in a criminal prosecution." *Reisman v. Caplin*, 375 U.S. 440, 449 (1964). This defense came from the text of the Internal Revenue Code, which enumerated four valid purposes of a civil tax summons. *See id.* at 442 n.1. Moreover, there was a separate concern that if the IRS used its civil summons authority to obtain information to be used later in a criminal investigation, it would circumvent rules of criminal procedure intended to protect the rights of defendants. *See United States v. LaSalle Nat'l Bank*, 437 U.S. 298, 312 (1978). Therefore, the Supreme Court held that the IRS could not issue a civil summons if there was a "pending criminal charge" or if the IRS was conducting "an investigation solely for criminal purposes." *Donaldson v. United States*, 400 U.S. 517, 533 (1971). The Supreme Court later added that the IRS could not use its civil summons authority in "bad faith," which would occur if the IRS issued a summons to investigate potential tax violations after the IRS had referred those violations to DOJ for criminal prosecution. *LaSalle*, 437 U.S. at 311–13, 316.

Although the leading cases on "improper purpose" and "bad faith" involve the use of IRS civil tax summonses in connection with criminal investigations, the doctrine also applies to extreme cases of official misconduct. For example, it is improper to issue a subpoena solely for the benefit of a private party, rather than for a public-regarding

purpose. *See United States v. Cortese*, 614 F.2d 914, 921 (3d Cir. 1980) (if a private informant was "pursuing its own business purpose by giving the IRS data," and the "entire motivation" for the IRS investigation was this private party's information, an improper purpose may exist). An agency investigator may not issue a subpoena to satisfy a "personal vendetta." *EEOC v. First Ala. Bank of Birmingham*, 440 F. Supp. 1381, 1385 (N.D. Ala. 1977), *aff'd*, 611 F.2d 132 (5th Cir. 1980). Nor may a member of Congress direct an agency to pursue a "patently frivolous" investigation. *See SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 127–30 (3d Cir. 1981) (en banc); *but see United States v. Am. Target Advert., Inc.*, 257 F.3d 348, 355 (4th Cir. 2001) ("[Recipient] has demonstrated a fair degree of hostility directed toward it by Senator Pryor. But that is not enough."). Finally, a court may not enforce a subpoena based on evidence that the agency obtained through "fraud, deceit, or trickery," for when an agency "invokes the power of a court to gather the fruits of its deception . . . there is an abuse of process." *ESM*, 645 F.2d at 316–17.

There is no exhaustive list of "improper purposes." *LaSalle*, 437 U.S. at 318 n.20 ("Future cases may well reveal the need to prevent other forms of agency abuse of . . . judicial process."). As a corollary to a court's inherent authority to police the integrity of its processes, a court may recognize and proscribe novel "improper purposes" in the first instance. *See Wheeling-Pittsburgh*, 648 F.2d at 124 ("[Just] because the Supreme Court has never confronted allegations like the ones before us does not mean that the federal judiciary is powerless to structure relief . . . ."). But a court's exercise of this inherent authority must accord with the thick set of legal principles that limit judicial review of administrative subpoenas. *Cf. Armstrong v. Exceptional*

Child Care Ctr., Inc., 575 U.S. 320, 327–28 (2015) ("'Courts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law.'") (quoting *Hedges v. Dixon Cnty.*, 150 U.S. 182, 192 (1893)).

Our court has long respected those principles of judicial restraint. Applying them to the present case, we hold that the district court erred in finding that DOJ had issued the subpoena for an improper purpose.

B

We first turn to the requirement that DOJ issue an administrative subpoena pursuant to statutory authority. We conclude that DOJ did so here.

1

To establish its statutory authority, DOJ had to demonstrate the following: (1) Congress granted DOJ the authority to issue investigatory subpoenas; (2) DOJ followed the relevant procedural requirements; and (3) the evidence sought by the subpoena was relevant and material to a statutorily authorized investigation. *Golden Valley*, 689 F.3d at 1113. It satisfied each requirement.

First, Congress authorized DOJ to issue investigative subpoenas under HIPAA. 18 U.S.C. § 3486(a)(1)(A)–(B) ("In any investigation of . . . a Federal health care offense . . . the Attorney General . . . may issue in writing and cause to be served a subpoena requiring the production . . . of any records or other things relevant to the investigation . . . ."); *see also id.* § 24(a). Because HIPAA permits investigations for potential violations of the FDCA's misbranding prohibitions, DOJ properly issued its subpoena under HIPAA. *See* 21 U.S.C. §§ 331(a)–(c), 352(a), (f).

Second, DOJ complied with HIPAA's procedural requirements. *See* 18 U.S.C. §§ 3486(a)–(b). The subpoena's fifteen document requests and definitions adequately "describe[d] the objects" that QueerDoc was required to produce. *Id.* § 3486(a)(2). The subpoena "prescribe[d] a return date," required production at a location within 500 miles of where QueerDoc was served with the subpoena, was signed by the Attorney General's designee, and was served on QueerDoc's registered agent. *Id.* § 3486(a)–(b).

Third, the subpoena requests were relevant to an authorized investigation under HIPAA. 18 U.S.C. § 3486(a)(1)(B)(i). The question of an administrative subpoena's relevance is not one of evidentiary relevance. *Doe v. United States*, 253 F.3d 256, 266 (6th Cir. 2001) (analyzing a HIPAA subpoena). Instead, "[r]elevancy is determined in terms of the investigation," *Golden Valley*, 689 F.3d at 1113, and an agency "may define the boundary of its investigation quite generally," *CFPB v. Accrediting Council for Indep. Colls. & Schs.* (*ACICS*), 854 F.3d 683, 690 (D.C. Cir. 2017) (citation and internal quotation marks omitted). A HIPAA subpoena must be enforced unless the "evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose of the agency." *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076 (9th Cir. 2001) (citation, alterations, and internal quotation marks omitted).

DOJ's subpoena to QueerDoc clears this low bar. As DOJ explained in its briefing and in the Gordus Declaration, QueerDoc may itself be misbranding drugs in violation of

the FDCA.[2] Further, QueerDoc may possess information relevant to DOJ's broader investigation of manufacturers and distributors. *See* Opening Brief for Appellant 32–38; Reply Brief for Appellant 6–8; ER 62–73.

As the Gordus Declaration explains, DOJ has questions about whether QueerDoc is engaged in the misbranding of puberty blockers and cross-sex hormones. *See* ER 62–73.

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[2] In the district court, after briefing on QueerDoc's motion to quash was complete, QueerDoc filed a notice of supplemental authority concerning a recent district court decision that quashed an administrative subpoena. QueerDoc's filing indicated, among other things, that quashal had been proper in that separate case because the government had not filed any affidavits to show its proper purpose for issuing the subpoena, which sought information about a hospital's provision of gender-affirming care. In response to QueerDoc's filing, DOJ sought leave to file the Gordus Declaration. DOJ explained that "[b]ecause QueerDoc supplemented its original filing with additional authority to suggest the government issued the administrative subpoena for an improper purpose and may need 'an affidavit[] or other evidence to show proper purpose,' the United States asks this Court to permit the filing" of the Gordus Declaration. The Gordus Declaration did no more than expand upon DOJ's previously stated positions in response to QueerDoc's assertion that DOJ had to provide further information to justify the subpoena. The district court struck the Gordus Declaration. *QueerDoc*, 807 F. Supp. 3d at 1303 n.2. But it did so after imposing a "more muscular review" of DOJ's asserted purpose, *id.* at 1302, a standard that cannot be reconciled with our case law, which establishes that judicial review of an administrative subpoena is "quite narrow." *Golden Valley*, 689 F.3d at 1113 (citation omitted). Having imposed an improperly high standard, the district court should have permitted DOJ to meet that standard. Moreover, the district court itself considered the effect of the Gordus Declaration on the merits of the case, finding that the declaration "further demonstrate[d] the pretextual nature of the subpoena." *QueerDoc*, 807 F. Supp. 3d at 1303 n.2. Even if the district court did not err in striking the Gordus Declaration, we exercise our discretion to consider it. QueerDoc has long had notice of the declaration and an opportunity to respond to it, and the declaration merely expands on DOJ's previously stated positions.

QueerDoc's webpages promote the off-label use of these drugs, instruct users how to administer them, tell users where to obtain them, and claim that any effects are "completely reversible." QueerDoc, *Self-Injections*; QueerDoc, *Pharmacy Options*; QueerDoc, *Youth Gender Care*. According to DOJ, these statements may qualify as "labeling" of puberty blockers and cross-sex hormones under the FDA's broad definition of that term. *See* 21 C.F.R. § 202.1(*l*)(2). DOJ further maintains that promotion of a drug for off-label uses may violate the FDCA if that promotion constitutes "false or misleading" "labeling" of that drug. 21 U.S.C. §§ 331(a), 352(a). Finally, QueerDoc's website suggests that it may be engaged in fraudulent billing practices. *See* QueerDoc, *Pharmacy Options* ("We usually order prescriptions under the diagnosis of 'endocrine disorder' not 'gender dysphoria[.]'").[3]

Under this theory of the investigation, the personnel files and training materials sought in Request 1 are relevant because they may help DOJ identify the individuals responsible for any unlawful billing, prescribing, or labeling practices. Requests 2 through 6, which seek records of billing, coding, and reimbursement practices, are relevant to determining whether QueerDoc disguised treatment for gender dysphoria as treatment for another illness, which could demonstrate an "intent to defraud or mislead" under 21 U.S.C. § 333(a)(2). Requests 14 and 15, which seek communications with drug manufacturers and distributors about possible adverse effects of these drugs, are relevant to

[3] Endocrine disorders are conditions caused by imbalances in hormone levels or by the body's inability properly to utilize hormones. Common types include diabetes, thyroid diseases, and pituitary or adrenal disorders. Such disorders appear to be quite different from "gender dysphoria."

establishing conspiracy as well as intent and knowledge regarding the potential falsity of QueerDoc's statements. Further, the subpoena requests may be relevant because they could help DOJ determine whether QueerDoc's conduct falls within DOJ's regulatory jurisdiction. *Fed. Mar. Comm'n v. Port of Seattle*, 521 F.2d 431, 434 (9th Cir. 1975) ("[An] agency has the power to obtain the facts requisite to determining whether it has jurisdiction over the matter sought to be investigated.").

Other requests are relevant not because they concern QueerDoc's own potential FDCA violations, but because they seek information that QueerDoc may possess about other actors in DOJ's broader FDCA investigation, such as manufacturers and distributors of puberty blockers and cross-sex hormones. Drug manufacturers and distributors may violate the FDCA by shipping drugs into interstate commerce with the intent that they be used for an off-label purpose. *See* 21 U.S.C. §§ 352(a), (f)(1), 355(a). Communications between manufacturers and QueerDoc might produce evidence of a manufacturer's "knowledge" that puberty blockers are "offered or used" for an off-label purpose. 21 C.F.R. § 201.128. Promotional materials or communications with sales representatives may also be valuable evidence. *See, e.g.*, Press Release, U.S. Dep't of Justice, *Genzyme Corporation to Pay $32.5 Million to Resolve Criminal Liability Relating to Seprafilm* (Sep. 3, 2015), https://perma.cc/2V3Y-9SDG (conduct of "sales representatives" and distribution of "promotional material" relevant to misbranding charges under the FDCA). Requests 7 through 10, which seek records of communications with manufacturers and sales representatives regarding the use of puberty blockers or hormones, are thus relevant to an authorized HIPAA investigation. Requests 11 through 13,

which seek patient records, may produce evidence about the scale of any misconduct and about whether QueerDoc or another party concealed the risks or failed to warn about the potential adverse effects of "gender-affirming care."

Applying a greater degree of scrutiny to the relevance of each subpoena request would undermine Congress's decision to empower DOJ to investigate potential violations of federal health care laws. *See* 18 U.S.C. § 3486(a)(1). DOJ cannot know what information it may need to prove an eventual violation or which entities it may wish to prosecute. That is why it has the power to investigate. Hence, "[t]he initial determination of what information is reasonably relevant is left to the investigating agency." *In re Gimbel*, 77 F.3d 593, 601 (2d Cir. 1996). We defer to the agency's assessment of relevance and intervene only in the extreme case in which a subpoena seeks information that is "plainly incompetent or irrelevant to any lawful purpose" of the agency. *Port of Seattle*, 521 F.2d at 434 (quoting *Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943)). To require any higher quantum of proof would be illogical. It would tell an agency that it must prove what, at this stage, the agency can do no more than suspect.

DOJ met its slight burden of demonstrating relevance, as the district court suggested. *QueerDoc*, 807 F. Supp. 3d at 1301 n.1 (concluding that the subpoena "calls for the production of documents relevant to an investigation" under HIPAA). We therefore hold that DOJ issued the subpoena pursuant to statutory authority.

2

The counterarguments raised by QueerDoc and the dissent are unavailing. The gravamen of these arguments is that DOJ's investigation exceeds the substantive reach of the

FDCA. *See* Brief for Appellee 43–52; Dissent 62–64, 75–77. Such arguments are premature at this stage in the proceedings, so they do not support quashing the subpoena.

a

"[C]ourts must enforce administrative subpoenas unless 'the evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose of the agency.'" *Karuk Tribe*, 260 F.3d at 1076 (brackets and internal quotation marks omitted) (quoting *Port of Seattle*, 521 F.2d at 433–34). "Although a party may not avoid an administrative subpoena on the ground that it has a valid defense to a potential subsequent lawsuit, such a challenge may, in limited circumstances, be mounted when the defense raised is 'jurisdictional' in nature—i.e., when the agency lacks jurisdiction over the subject of the investigation." *Id.* at 1076–77. However, at the subpoena-enforcement stage, any "factual challenges based on a lack of statutory 'coverage' are clearly not permitted." *Id.* at 1077 (citation omitted).

QueerDoc argues that DOJ's investigation is infirm for several reasons: (1) the statements on its website do not constitute "labeling" under the FDCA; (2) the FDCA does not regulate the act of prescribing drugs for off-label uses; (3) applying the FDCA's "misbranding" prohibition to QueerDoc's statements on its website would violate its First Amendment right to freedom of speech; and (4) interpreting the FDCA to reach the prescribing of drugs for an off-label use would violate principles of federalism. These arguments all raise potential defenses to liability under the FDCA and are therefore unripe for decision at this early point in the investigation, when DOJ has not initiated any enforcement action against QueerDoc. *Karuk Tribe*, 260 F.3d at 1076; *see also EEOC v. Shell Oil Co.*, 466 U.S. 54, 72 n.26 (1984)

("[A]ny effort by the court to assess the likelihood that the [commission] would be able to prove the claims made in the charge would be reversible error.").

The contrary approach urged by QueerDoc and our dissenting colleague would require us to decide thorny questions of statutory and constitutional law at this preliminary stage in the proceedings. For instance, if an online medical clinic prescribes a drug to its patients and publishes articles on its website that instruct the public about using that drug, do those articles constitute "labeling" of the drug under the FDCA? *See* Brief for Appellee 43–45; Dissent 76–77. Such "novel and complex" questions are "especially ill-suited to a premature and absolute pronouncement" at the subpoena-enforcement stage. *EEOC v. Mar. Autowash, Inc.*, 820 F.3d 662, 667 (4th Cir. 2016) (Wilkinson, J.). Although these defenses may prevail if QueerDoc raises them in a later enforcement action, it is uncertain whether DOJ will ever bring such an action. A claim that depends on "contingent future events that may not occur as anticipated, or indeed may not occur at all" is "not ripe for adjudication." *Texas v. United States*, 523 U.S. 296, 300 (1998) (citations omitted).

b

We also reject the argument that the subpoena amounts to an unauthorized "fishing expedition." Brief for Appellee 52–55; *see* Dissent 63–64. Relying on our decision in *Peters v. United States*, QueerDoc contends that DOJ may not use a HIPAA subpoena to obtain information about third parties. 853 F.2d 692 (9th Cir. 1988). Thus, according to QueerDoc, the subpoena requests that seek information about drug manufacturers and distributors are statutorily invalid because they do not relate to an investigation of QueerDoc

itself. But QueerDoc overreads *Peters*. That decision did not establish a general prohibition against administrative subpoenas that sought information about persons other than the subpoena's recipient. Indeed, such a rule would contradict the recognized principle that an agency need not "charge first and investigate later." *Reich v. Mont. Sulphur & Chem. Co.*, 32 F.3d 440, 444 (9th Cir. 1994). Since *Peters*, we have upheld subpoenas that sought information about unidentified targets. *See, e.g.*, *Golden Valley*, 689 F.3d at 1115.

Rather, *Peters* involved a subpoena that was unenforceable because it furthered a "general investigation of unnamed individuals" and was therefore too indefinite. *See* 853 F.2d at 699–700. The subpoena in *Peters* did not specify which laws the agency suspected were being violated and did not name the parties under investigation. *See id.* at 694–96. Indefinite subpoenas, like the one in *Peters*, remain subject to quashal. But we are not faced with an "indefinite" subpoena here. DOJ's subpoena sought specific records (communications, billing, coding, and reimbursement practices) for specific patients (minors) for specific drugs (puberty blockers and cross-sex hormones) from a specific entity (QueerDoc) for an investigation of a specific set of FDCA violations (misbranding). Moreover, unlike the subpoena recipient in *Peters*, QueerDoc operates its business in the highly integrated pharmaceutical industry. DOJ must have some flexibility in subpoenaing downstream actors in such a complex supply chain to effectuate its investigation. *See Texaco*, 555 F.2d at 877 ("[A] wide range of investigation is necessary and appropriate where, as here, multifaceted activities are involved, and the precise character of possible violations cannot be known in advance.").

C

Because DOJ established its *prima facie* case for enforcement of the subpoena, QueerDoc bore a "heavy" burden to produce "specific facts and evidence to support [its] allegations of bad faith or improper purpose." *Jose*, 131 F.3d at 1328 (citation and internal quotation marks omitted). The district court found that QueerDoc had discharged its heavy burden. That was an error.

It is undisputed that the Administration opposes the provision of "gender-affirming care" to minors. *See* Opening Brief for Appellant 3 ("The President has serious moral and policy objections to the practice of subjecting minors to these interventions[.]"). Those views are not "improper." As QueerDoc's counsel conceded at oral argument, the President may have moral and political objections to gender-affirming care, wish to end it, and take steps to achieve that goal consistent with law. *See* Oral Argument at 18:18–18:52, *QueerDoc, PLLC v. U.S. Dep't of Just.* (No. 25-7384), https://perma.cc/4NRE-Z3CT.[4]

[4] The full exchange from oral argument is below:

> COUNSEL: These subpoenas were issued as part of the Administration's larger effort to end gender-affirming care.
>
> JUDGE BEA: Is that an improper motive for the Executive? To end gender-affirming care?
>
> COUNSEL: Your Honor, the Executive issued an Executive Order stating that they wanted to "end" gender-affirming care, calling it a "stain on the nation's history." That, in and of itself, is not improper—

The district court nonetheless inferred an improper purpose for DOJ's investigation because of the Administration's policy views and enforcement priorities. QueerDoc presented no evidence of any other improper purpose to the district court, such as a desire to benefit one of QueerDoc's market competitors or to settle some collateral dispute. *See* Motion to Quash, *supra*, at 8. On appeal, QueerDoc maintains that "the government's statements . . . alone" demonstrate improper purpose. Brief for Appellee 32. But there is nothing improper about a President having policy preferences and directing the Executive Branch to enforce federal law in a manner consistent with those preferences. Because QueerDoc provided no additional evidence of improper purpose and the district court overread the government's public statements in finding an improper purpose, we reverse.

1

First, the Administration's policy views and objectives were not themselves "improper."

The use of puberty blockers and cross-sex hormones on minors is the subject of "fierce scientific and policy debates." *Skrmetti*, 605 U.S. at 525. Many states have codified protections for "gender-affirming care." *See* Brief for State of Washington et al. as *Amici Curiae* 6–7 & n.8. These protections reflect the view of many leading medical associations that "hormones and puberty blockers are 'appropriate and medically necessary' to treat gender dysphoria." *Skrmetti*, 605 U.S. at 582 (Sotomayor, J.,

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JUDGE BEA: —not an improper motive, right?
COUNSEL: Certainly. The Administration can have that as a policy goal and can take steps to achieve that policy goal.

dissenting). In contrast, more than 20 states have banned or limited the provision of sex-transition treatments to minors. *Id.* at 504–05 (majority). Similarly, health authorities in many developed nations have limited the use of these treatments for minors, citing a lack of evidence supporting their efficacy. *See id.*; *see also* Pamela Paul, *As Kids, They Thought They Were Trans. They No Longer Do.*, N.Y. TIMES (Feb. 2, 2024), https://perma.cc/VG68-Q79G ("[In] Sweden, Norway, France, the Netherlands and Britain . . . medical professionals have recognized that early research on medical interventions for childhood gender dysphoria was either faulty or incomplete."). The efficacy and long-term risks of these treatments are uncertain.[5] The off-label use of puberty blockers to treat gender dysphoria may adversely affect a minor patient's bone density, brain development, and fertility; the off-label use of cross-sex hormones may harm a

[5] In March 2026, Finnish researchers published a study based on data from 2,100 Finns who sought care from a gender clinic between 1996 and 2019 before they reached age 23. *See* S.-M. Ruuska, K. Tuisku, T. Holttinen, and R. Kaltiala, *Psychiatric Morbidity Among Adolescents and Young Adults Who Contacted Specialised Gender Identity Services in Finland in 1996–2019*, 115 Acta Paediatrica 1545, 1545–53 (2026). The study found that among these youths—who showed sufficient signs of gender dysphoria to seek care from a gender clinic—those who underwent a medical gender transition were much *more* likely to seek specialist psychiatric care later. *See id*. at 1545 ("Among adolescents who underwent medical gender-reassignment, psychiatric morbidity increased markedly."). Among males in that group, 10 percent had sought specialist psychiatric care before treatment, whereas 61 percent did so after treatment. *Id*. Among females, the proportion rose from 22 percent to 55 percent. *Id*. As this study demonstrates, there is some disagreement among professionals as to whether gender-affirming care necessarily "improves mental health outcomes and reduces suicide risk in transgender youth." Brief for American Academy of Pediatrics as *Amicus Curiae* 8–11.

patient's sexual organs and increase his risk of cancer. *See Skrmetti*, 605 U.S. at 534–35 (Thomas, J., concurring).

The district court found that the Administration sought to "eliminate all gender-affirming care." *QueerDoc*, 807 F. Supp. 3d at 1303 (internal quotation marks and citation omitted). Although the subpoena here was validly based on an investigation of health care law violations, the goal of ending "gender-affirming care" is not in and of itself an "improper" policy objective. It is not so irrational or arbitrary as to be *ultra vires*. The Administration is entitled to adopt a position on either side of this "ongoing debate among medical experts," *Skrmetti*, 605 U.S. at 523, and to pursue policies consistent with that position. A district court has no warrant to override the President's judgment on a disputed matter of public policy. It is for the American people, through the democratic process, to decide whether a President's views on such topics and the policies that result from those views are "improper."

The district court nevertheless concluded, with little explanation, that the President's opposition to "gender-affirming care" was an improper objective. *See QueerDoc*, 807 F. Supp. 3d at 1301. The district court noted that "[a]lmost every court and medical organization to address the issue has recognized the benefit of providing gender affirming care to individuals suffering from gender dysphoria" and that "[s]everal states have codified protections for gender-affirming care." *Id.* (simplified). But the President is entitled to a contrary view in an unsettled scientific debate. Further, the Administration's policy need not be justified on "scientific" grounds alone. The Administration may also consider ethical and philosophical perspectives regarding the relationship between gender identity and biological sex. *See Skrmetti*, 605 U.S. at 540

(Thomas, J., concurring) ("Setting aside whether sex-transition treatments for children are *effective*, States may legitimately question whether they are *ethical*." (emphases in original)); *Loe*, 692 S.W.3d at 239 (Blacklock, J., concurring) (explaining that the debate around gender-affirming care for minors is not just a scientific question but also "one of philosophy, morality, even religion.").

Second, the Administration's directives to DOJ to carry out this policy did not render DOJ's subpoena "improper."

DOJ's actions are "entitled to a presumption of regularity." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971). This "long-standing" principle holds that "in the absence of clear evidence to the contrary," a court presumes that government officials "properly discharged their official duties." *Cruz v. Bondi*, 146 F.4th 730, 739 (9th Cir. 2025) (quoting *United States v. Chem. Found., Inc.*, 272 U.S. 1, 14–15 (1926)). Yet the district court inferred from the Administration's general opposition to gender-affirming care, along with its directives to DOJ to issue subpoenas to providers of such care, that DOJ had "issue[d] [the] subpoena *not* to investigate legal violations but to intimidate and coerce [QueerDoc] into abandoning lawful medical care." *QueerDoc*, 807 F. Supp. 3d at 1299 (emphasis in original). In doing so, the district court improperly disregarded the presumption of regularity.

Executive Order 14,187 directed DOJ to "prioritize investigations" into entities that may be "misleading the public about long-term side effects" of gender-affirming care. 90 Fed. Reg. 8771, § 8(c). The Order also stated that it "shall be implemented consistent with applicable law." *Id.* § 11(b). The Bondi Memo directed DOJ to conduct only "appropriate investigations" of potential FDCA violations.

To the extent that the directives ordered DOJ to end "gender-affirming care," they ordered DOJ to pursue that goal within the bounds of the law. They did not order DOJ to act *ultra vires*.

According to QueerDoc's declaration, DOJ's attorneys stated that they were investigating QueerDoc because of the directives contained in EO 14,168, EO 14,187, and the Bondi Memo. But the fact that DOJ acted pursuant to these high-level directives is not evidence that DOJ acted with an improper purpose, since a court has no warrant to presume that an agency carried out lawful directives in an unlawful manner. *See Ross and Morrison v. Reed*, 14 U.S. 482, 486 (1816) ("It is a general principle to presume that public officers act correctly until the contrary be shown."). Likewise, although DOJ officials did not give QueerDoc a detailed justification for their investigation, they provided QueerDoc with notice that their investigation related to possible FDCA violations. That answer did not demonstrate that DOJ was proceeding improperly. DOJ was not obligated to divulge confidential information about its investigation to QueerDoc, which was itself a subject of the investigation. *See United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 818 (8th Cir. 2012) (involving a HIPAA subpoena) ("[Recipient] cites no legal authority for requiring the Government to justify its administrative subpoenas by revealing the identity of any informants, the information those informants may have provided, or any other facts revealing the motives behind a lawful investigation."). Even the district court recognized this principle when it explained that "the government need not justify its decision to open an investigation." *QueerDoc*, 807 F. Supp. 3d at 1302.

The district court should not have inferred DOJ's bad faith from political advocacy statements made by government officials. *Cf. Mullin v. Doe*, No. 25-1083, 609 U.S. ____, 2026 WL 1825840, at *12 (U.S. June 25, 2026) ("Political discourse by prominent public figures is increasingly couched in terms that would have scandalized the public just a short time ago. . . . But whatever one may think of the cited statements, they are insufficient to show that the [government acted out of animus]."). Given our narrow review of administrative subpoenas and the heavy burden required to demonstrate an improper purpose, these public statements—coupled with important qualifying language and the presumption of regularity—cannot taint an otherwise valid government investigation. *See Golden Valley*, 689 F.3d at 1113; *Jose*, 131 F.3d at 1328. And QueerDoc presented no evidence of impropriety besides the Administration's public statements and directives. For instance, QueerDoc proffered no evidence that DOJ acted on behalf of one of QueerDoc's market competitors, that DOJ pursued a "claim it knows it cannot win" merely to satisfy an ill-disposed senator, or that one of DOJ's investigators issued the subpoena merely to settle a "personal vendetta" against QueerDoc. *See, e.g.*, *Cortese*, 614 F.2d at 921; *Wheeling-Pittsburgh*, 648 F.2d at 127; *First Ala. Bank of Birmingham*, 440 F. Supp. at 1385.

In sum, QueerDoc did not provide "specific evidence of improper intent," *Garner*, 126 F.3d at 1146, and therefore failed to carry its "heavy" burden to demonstrate that DOJ issued the subpoena for an improper purpose. *Jose*, 131 F.3d at 1328.

2

The district court's finding of improper purpose was erroneous. Equally misguided, however, was the district court's intrusion upon the President's core constitutional power to set law enforcement priorities and to order his subordinate officers to carry out these enforcement priorities.

To fulfill the President's duty to "take Care that the Laws be faithfully executed," U.S. Const. art. II, § 3, "the Executive Branch must prioritize its enforcement efforts." *United States v. Texas*, 599 U.S. 670, 679 (2023). The Executive Branch lacks the resources to investigate every potential violator of every law and must adapt its enforcement priorities to the "ever-shifting public-safety and public-welfare needs of the American people." *Id.* at 680. The Constitution therefore vests in the President the "'exclusive authority and absolute discretion' to decide which crimes to investigate and prosecute." *Trump v. United States*, 603 U.S. 593, 620 (2024) (quoting *United States v. Nixon*, 418 U.S. 683, 693 (1974)). Further, although the Constitution vests the entirety of the executive power in the President, U.S. Const. art. II, § 1, "the President alone and unaided could not execute the laws . . . [h]e must execute them by the assistance of subordinates." *Myers v. United States*, 272 U.S. 52, 117 (1926). "[B]y virtue of the general grant to him of the executive power," the President may exercise "administrative control" over executive officers, which includes the power to "supervise" executive officers and "guide their construction of the statutes under which they act." *Id.* at 135.

Here, the President established the Executive Branch's general policy of enforcing the FDCA against providers of

gender-affirming care in § 8(c) of EO 14,187. Subsequently, his subordinates implemented this policy at increasing levels of specificity through the Bondi Memo, the Shumate Memo, and, ultimately, the investigation of QueerDoc. Indeed, DOJ's attorneys told QueerDoc that this investigation proceeded because of the President's executive orders, the Bondi Memo, and the Shumate Memo. This sequence reflects the ordinary operation of the Executive Branch. The President sets broad policy that his subordinates implement at increasingly specific levels down the organizational hierarchy. *See Trump v. Slaughter*, No. 25-332, 609 U.S. ____, 2026 WL 1855612, at *7 (U.S. June 29, 2026) ("The Constitution . . . establish[ed] a hierarchy—a 'Chief Magistrate' with whom the buck stops, and below him various 'assistants or deputies' who 'derive their offices from his appointment' and remain 'subject to his superintendence.'" (quoting The Federalist No. 72, p. 436 (C. Rossiter ed. 1961) (A. Hamilton))).

Yet the district court found that the Administration's opposition to the general practice of gender-affirming care made any investigation that advanced this policy "pretextual" and "improper." *QueerDoc*, 807 F. Supp. 3d at 1303. The district court's reasoning would require subordinate executive officers either to act independently of and contrary to the President's policies or to refrain from acting altogether. Either course would undermine the President. Such reasoning would lead to a disordered government, in which the President could neither "supervise" executive officers nor "guide their construction of the statutes under which they act." *Myers*, 272 U.S. at 117, 135.

Further, if a President's stated policy views are evidence of improper purpose, as the district court held, the

administration of the federal government would crumble. Every President has law enforcement priorities, just as every President has signature policies (often, the former are components of the latter). Consider a hypothetical that the parties raised in their briefs: A President opposes online sports gambling platforms because he believes that they foster addiction and cause financial ruin, thereby harming the public welfare. This President uses his bully pulpit to advocate for comprehensive legislation that bans these platforms, but as the legislative process grinds along, he also uses existing tools of federal law to hold these platforms accountable. Would it be "improper" for an IRS agent to issue an otherwise valid civil tax summons to a gambling company? Would the FTC be unable to investigate that company for allegedly misleading gambling advertisements? The district court's reasoning, which contains no limiting principle, would deem such actions improper. That approach enables the federal judiciary to intrude on some of the President's fundamental prerogatives: his decisions about which policies to advance, how to allocate scarce law-enforcement resources, and how to articulate his policies to the public. That approach is clearly wrong and underscores the magnitude of the district court's error.

3

None of the counterarguments raised by the dissent, QueerDoc, the court below, or QueerDoc's *amici* gives us any reason to believe that an improper purpose exists here.

a

We reject the contention that DOJ's allegedly "post hoc" attempts to justify the subpoena illustrate the improper purpose for which it was issued. Brief for Appellee 37; Brief

for Former DOJ Attorneys as *Amici Curiae* 17–23; Dissent 73–78.

This argument invokes the "foundational principle of administrative law," which holds "that a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). But the rule against "post hoc justifications" does not apply in this case because DOJ's investigatory purpose as to QueerDoc has remained constant throughout: to investigate potential violations of the FDCA's misbranding provisions. Indeed, from EO 14,187 to the Shumate Memo, the government has consistently stated that its investigation involved possible "violations of the [FDCA] by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation," 90 Fed. Reg. 8771, § 8(c), including "doctors, hospitals, pharmaceutical companies, and other appropriate entities," ER 55–56 (Shumate Memo).

Moreover, an agency investigation is dynamic. The agency's reasons for issuing a subpoena to a party may change as its investigators acquire new information. Requiring an agency to justify itself at the outset and to adhere to that justification throughout the investigation would frustrate the agency's investigatory function. *United States v. Tan*, 16 F.4th 1346, 1352 (9th Cir. 2021) ("[Requiring] specificity ahead of time could hinder the investigation by . . . foreclosing the pursuit of new, relevant avenues of inquiry that come to light . . . ."). So, absent a clear statutory mandate, we do not require agencies to "charge first and investigate later." *Reich*, 32 F.3d at 444; *see also EPA v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 447 (9th Cir. 1988), *overruled on other grounds by McLane*,

581 U.S. at 80–81 ("EPA need not allege that it has a suspicion or has knowledge of any facts indicating that the law has been violated.").

HIPAA imposes no such mandate on DOJ. *See* 18 U.S.C. § 3486(a). HIPAA authorizes DOJ to issue investigative subpoenas to enforce a limited set of laws and to do so in accordance with specified procedures, but it does not require DOJ to issue a formal charge against a suspected wrongdoer as a predicate to exercising this power. *See id.* §§ 24(a), 3486. Congress included a pre-investigation charging requirement in other statutes, such as Title VII, which permits the EEOC to issue an investigatory subpoena only after a "sworn charge of discrimination" has been filed. *Univ. of Penn. v. EEOC*, 493 U.S. 182, 190 (1990). The absence of such a requirement under HIPAA reflects Congress's judgment about the proper balance between efficient agency investigations and the risk of governmental abuse in federal health care investigations. We have no warrant to amend HIPAA to add restrictions on DOJ's investigatory power. *Cf. Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 549 (1978) ("The court should . . . not stray beyond the judicial province . . . to impose upon the agency its own notion of which procedures are 'best' or most likely to further some vague, undefined public good.").

b

We also reject the contention that the purported breadth of the subpoena and its alleged incongruence ("mismatch") with DOJ's FDCA theory of investigation were probative of the agency's bad faith. *QueerDoc*, 807 F. Supp. 3d at 1303–04; Brief for Appellee 35; Dissent 80–85.

To the extent that any overbreadth or mismatch could help establish improper purpose in the abstract, these considerations do not support the district court's improper purpose determination in this case. There was no mismatch between the government's investigation and QueerDoc's activities. Hence, DOJ made out its *prima facie* case that the subpoena was statutorily authorized. *See Golden Valley*, 689 F.3d at 1113, 1115. QueerDoc need not be a manufacturer or distributor to receive the HIPAA subpoena at issue here. As DOJ explained in the Gordus Declaration, certain statements on QueerDoc's website may themselves violate the FDCA's misbranding provisions. *See* 21 U.S.C. § 352(a). Given the labyrinthine supply chains in the pharmaceutical industry and the corresponding complexity of federal health care investigations, DOJ must have the flexibility to seek information from ancillary entities, such as QueerDoc, that may possess relevant information that could help establish FDCA misbranding violations by upstream entities such as manufacturers and distributors.

Nor does the breadth of the subpoena's production requests suggest bad faith in this case. As explained above, the subpoena seeks information relevant to potential FDCA misbranding violations. That relevance is sufficient to establish DOJ's *prima facie* case for enforcing the subpoena. The dissent's principal concern is with the subpoena's requests for patient information, which make up only three of the fifteen document requests. *See* Dissent 80–82. But even if the subpoena is overbroad—an issue the district court did not reach and the parties briefed only minimally—the proper remedy would be to narrow it, not to quash it in its entirety, as the district court did here. *See Morton Salt*, 338 U.S. at 653–54; *In re Subpoena Duces Tecum*, 228 F.3d at 349.

c

We reject the argument, advanced by QueerDoc and its *amici*, that the Administration's policy was improper because it conflicts with Washington state law, which authorizes the provision of "gender-affirming care" to minors. *See* Brief for Appellee 42 ("DOJ issued this subpoena to end medical care that is lawful under the laws of numerous states."); *see also* Brief for Former DOJ Attorneys as *Amici Curiae* 19–20; Brief for State of Washington et al. as *Amici Curiae* 4–13. Whether an activity is authorized by state law is irrelevant to determining the lawful authority for a federal investigation, because federal law is supreme. U.S. Const. art. VI, cl. 2. The State of Washington cannot shield a resident company from having to comply with federal law.

QueerDoc and its *amici* might be understood to argue that DOJ's interference with lawful state activities suggests that DOJ exceeded its authority under the FDCA. Under this view, an interpretation of the FDCA that permits DOJ to encroach upon the practice of medicine might exceed Congress's enumerated powers. Whatever the merits of such arguments, they are "defense[s] to a potential subsequent lawsuit" and are thus premature at the subpoena-enforcement stage. *Karuk Tribe*, 260 F.3d at 1077–78 (citing *Endicott Johnson*, 317 U.S. at 509). Further, those arguments likely have no bearing on the "improper purpose" inquiry, which is distinct from the question of statutory authority. *See Miccosukee Tribe of Indians of Fla. v. United States*, 698 F.3d 1326, 1331–32 (11th Cir. 2012) (distinguishing a subpoena's "underlying validity" from whether the subpoena was issued for an improper purpose); *Mazurek v. United States*, 271 F.3d 226, 231 (5th Cir. 2001) ("Mazurek incorrectly conflates his challenge to [the

agency's statutory authority] and the alleged illegitimacy of the [agency's] investigation.").

d

We respectfully disagree with our dissenting colleague, who contends that we must be "highly deferential" to the district court's "factual determination" that DOJ issued the subpoena for an improper purpose. Dissent 66. The issue here is not one of fact. The district court conducted no evidentiary hearings and took no testimony. Instead, the district court relied on the Administration's public statements to infer an improper purpose on the part of DOJ. That did not amount to fact-finding but rather the drawing of legal conclusions from undisputed facts.

There is no dispute that the current Administration has a policy objective of ending gender-affirming care. *See* Opening Brief for Appellant 27 ("It is certainly uncontested that the President, the Attorney General, and others in the administration have expressed strong moral, ethical, and policy opposition to [gender-affirming care.]"). However, the questions before us on appeal are whether the Executive Branch's public-facing statements reflecting a general policy objective can establish an improper purpose, and further, whether the Executive Branch's policy statements can undermine an otherwise valid subpoena. It is simply of no moment that the district court found that DOJ acted for the purpose of ending gender-affirming care, because that finding was based on several misapprehensions about "what counts as an illicit motive" of the government, which are "legal issues" that we review de novo. *Clarke*, 573 U.S. at 256. For two reasons, the dissent errs in its resolution of these legal issues.

First, as discussed above, the Administration's general policy objective of ending gender-affirming care in a manner consistent with existing law is not an "improper purpose." *See supra* Part III(C)(1). It bears repeating that not even QueerDoc's counsel contends that this policy goal was improper. *See supra* note 4; Oral Argument at 18:18–18:52. Indeed, the dissent appears to concede this point, acknowledging that "the President may adopt a policy position on gender-affirming care[.]" Dissent 89. If this policy objective of the Executive Branch was proper, then it was proper for DOJ, as an agency within the Executive Branch, to use its authority under HIPAA to carry out this broader policy.

To avoid the difficult argument that the President's policy views were themselves "improper," the dissent attempts to distinguish DOJ's reasons for acting from the President's general policy positions. *See, e.g.*, Dissent 89 ("That the *President* can voice policy opposition to gender affirming care does not mean that the *DOJ* can weaponize its statutorily constrained subpoena authority . . . ." (emphases in original)). But as a conceptual matter, the dissent's proffered division between DOJ and the President is misguided. The Constitution vests the entirety of the executive power in the President. U.S. Const. art. II, § 1. DOJ, as an agency within the Executive Branch, thus exercises no executive power except that which the President has delegated to it. *See Slaughter*, 609 U.S. at ____, 2026 WL 1855612, at *21 (recognizing that "these officers exercise the *President's* power, not their own, and thus must be responsible to him" (emphasis in original)). The President's control over DOJ must be especially great, as DOJ is charged with the "investigation and prosecution of crimes," which "is a quintessentially executive function."

Morrison v. Olson, 487 U.S. 654, 706 (1988) (Scalia, J., dissenting). As the dissent concedes, the President's policy objective of ending gender-affirming care, consistent with applicable law, was not itself unlawful. *See* Dissent 89, 91. The dissent never explains why DOJ may not then act to achieve that policy objective pursuant to its investigatory authority under HIPAA.

Second, as explained above, nothing prevents DOJ from issuing an otherwise valid subpoena that is consistent with the President's policy agenda. Congress empowered DOJ to investigate violations of the health care laws. It is not the case that DOJ is unable to investigate an area simply because the President or other high-ranking officials have voiced policy opinions on the topic. With essentially no explanation, the district court deemed illegitimate the Administration's policy objections to gender-affirming care and then inferred that the subpoena to QueerDoc was based on this illegitimate purpose. That legal conclusion was incorrect. Regulated entities routinely receive subpoenas from government agencies that request information. QueerDoc, which operates in the highly regulated pharmaceutical industry, is no exception. We are hard-pressed to imagine that the dissent would conduct such an intrusive review of the government's purpose for issuing this subpoena but for the fact that this case involves gender-affirming care.

In a final effort to justify the district court's finding of improper purpose, the dissent argues that it is improper for DOJ to issue an administrative subpoena for the purpose of putting the subpoena's recipient out of business. *See* Dissent 89 (arguing that DOJ cannot "weaponize its statutorily constrained subpoena authority as a tool to put health care providers out of business."). But the fear that the costs of

compliance will force a party to shutter its business implicates the question of undue burden, not of improper purpose. QueerDoc has an interest in continuing to operate its business. That interest is adequately protected by the "undue burden" restriction on an agency's subpoena power, under which a court may modify the terms of a subpoena if "compliance threatens to unduly disrupt or seriously hinder normal operations of [the recipient's] business." *Texaco*, 555 F.2d at 882.

Lastly, we respectfully disagree with the dissent's suggestion that our decision undermines the separation of powers by rendering judicial review of administrative subpoenas "a hollow formality." *See* Dissent 95. Our decision lays down no novel principle. It reflects a straightforward application of our well-established law regarding the enforcement of agency subpoenas. The agency still bears the initial burden of demonstrating that it has issued a subpoena pursuant to statutory authority. *See supra* Part III(B). Even if the agency discharges this burden, a recipient remains protected against having to comply with unduly burdensome or overbroad subpoenas. *See infra* Part IV. Nor do we narrow or amend the legal standards that govern a court's "improper purpose" inquiry. *See, e.g.*, *Golden Valley*, 689 F.3d at 1113. We hold only that QueerDoc did not meet its "heavy" burden to demonstrate improper purpose in this case. *Jose*, 131 F.3d at 1328.[6]

[6] That longstanding, uncontroversial standard, which the dissent mentions once, is not fairly described as "hollow." Dissent 67, 95. Nor does it permit the so-called "potent" judicial review in the way that the dissent envisions it. Dissent 86, 88, 95 (citing *SEC v. Arthur Young & Co.*, 584 F.2d 1018, 1024 n.39 (D.C. Cir. 1978)). In *Arthur Young*, the D.C. Circuit explained in a footnote that "while the court's role in subpoena enforcement is narrow, within its confines it is potent." 584

At bottom, the dissent's argument rests on the supposition that the Administration's policy goal of ending gender-affirming care through the enforcement of existing federal law was improper, so any subpoena issued in that area is invalid even if it validly seeks to investigate potential violations of the health care laws. We cannot agree with a position that is so at odds with our circuit precedent, with the proper role of the federal judiciary within our constitutional system, and indeed with QueerDoc's own representations at oral argument. *See supra* note 4. It would be a stunning expansion of the judicial power to hold that the little-used authority to quash otherwise valid subpoenas in their entirety when they are issued for an "improper purpose"—an authority meant to police fraud on the court and other extreme abuses of official power—allows a federal court to strike down statutorily authorized subpoenas merely because the agency issued those subpoenas in service of a general policy that a judge deems "improper."

IV

Because the district court decided only that the subpoena was motivated by an improper purpose, it did not rule on

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F.2d at 1024 n.39 (internal citation omitted). That statement merely reflects the principle that courts retain the "duty not to rubber-stamp [an agency's subpoenas], but to adjudge their legitimacy." *ACICS*, 854 F.3d at 689. It does not permit the dissent's sweeping judicial review, for in most cases, "'when the information sought falls within the purview of the regulatory agency's authority,' judicial review of an administrative subpoena typically results in enforcement." *Id.* (quoting *FEC v. Machinists Non-Partisan Pol. League*, 655 F.2d 380, 385–86 (D.C. Cir. 1981)). Nor does the judicial review that courts exercise in this context detract from a subpoena recipient's "heavy" burden to show an improper purpose. *See id.* (recognizing that "[i]n *extraordinary circumstances*, a court also may inquire into allegations that an agency is using an administrative subpoena for an improper purpose" (emphasis added)).

QueerDoc's arguments that DOJ's subpoena is overbroad and poses an undue burden. We do not resolve these issues today. Instead, we remand them for the district court to consider in the first instance. But we offer the following guidance on remand.

First, the parties are expected to cooperate on remand to narrow or resolve any potential disagreements about the scope of discovery. Before the district court may grant relief from an overbroad or unduly burdensome subpoena, QueerDoc must make a "reasonable effort to reach [an] accommodation with the government." *Morton Salt*, 338 U.S. at 653; *see also In re Subpoena Duces Tecum*, 228 F.3d at 349 ("[B]efore a court will conclude that a subpoena is 'arbitrarily excessive,' it may expect the person served 'to have made reasonable efforts . . . to obtain reasonable conditions' from the government." (quoting *Morton Salt*, 338 U.S. at 653)); *Doe*, 253 F.3d at 268–69 (rejecting undue burden claim in part because the recipient "made no attempt to reach a reasonable accommodation with the government.").

Second, because DOJ's subpoena requests information that is relevant to an authorized HIPAA investigation, any determinations by the district court that limit the scope of DOJ's discovery will require proper legal and evidentiary support. *See Texaco*, 555 F.2d at 882 ("The burden of showing that the request is unreasonable . . . is not easily met where, as here, the agency inquiry is pursuant to a lawful purpose and the requested documents are relevant to that purpose.").

Because undue burden is evaluated and remedied on a request-by-request basis, QueerDoc must explain why compliance with each request would be burdensome.

QueerDoc's evidence of undue burden must consist of more than bare conclusory declarations. *See FTC v. Shaffner*, 626 F.2d 32, 38 (7th Cir. 1980) (rejecting undue burden when recipient made only the "conclusory allegation that compliance with the subpoena would 'severely interfere, disrupt and temporarily terminate [recipient's] legal practice.'"). Rather, QueerDoc must provide objective and specific evidence, such as "the number of files involved, the number of estimated work hours required to effect compliance, [or] the estimated costs of compliance." *Id.*

A subpoena request that requires production of a large volume of documents or a high proportion of the recipient's records does not necessarily constitute an undue burden. *See, e.g.*, *Garner*, 126 F.3d at 1145–46 (upholding a subpoena that required production of over one million documents); *NLRB v. G.H.R. Energy Corp.*, 707 F.2d 110, 114 (5th Cir. 1982) ("[T]he production of thousands of documents is also insufficient to establish burdensomeness."); *Walsh v. Alight Sols., LLC*, 44 F.4th 716, 726–27 (7th Cir. 2022) ("[L]arge production requests are not necessarily unduly burdensome."); *NLRB v. Carolina Food Processors*, 81 F.3d 507, 513 (4th Cir. 1996) (similar). Nor does a subpoena impose an undue burden just because compliance will be time- and resource-intensive. *See EEOC v. Citicorp Diners Club, Inc.*, 985 F.2d 1036, 1040 (10th Cir. 1993) (upholding a subpoena for which compliance required "two full-time employees working approximately six months").

Finally, the district court may entertain any objections specific to DOJ's requests for patient medical records if QueerDoc argues that compliance with these requests would raise concerns about patient privacy. The district court and the parties should also consider whether protective orders or

other devices should be used to ameliorate any concerns about privacy.

* * *

For the foregoing reasons, the district court erred in quashing the subpoena on the basis that it was issued for an "improper purpose." We reverse the district court's order quashing the subpoena and remand for further proceedings consistent with the above guidance.

REVERSED AND REMANDED.

PAEZ, Circuit Judge, dissenting:

As I see this case, the narrow question we must decide is whether the district court's finding that the Department of Justice ("DOJ") issued the subpoena to QueerDoc in bad faith was clearly erroneous. It was not. DOJ submitted essentially nothing in opposition to the motion to quash the subpoena. There is, however, a mountain of evidence that corroborates that DOJ used the threat of criminal investigation to pressure health care providers to stop offering gender-affirming care. The record amply supports the district court's finding that DOJ issued the subpoena as pretext for its real goal of eliminating gender-affirming care, not in good faith investigation of potential violations of the Federal Food, Drug, and Cosmetic Act ("FDCA").

In evading our highly deferential standard of review and the extensive record evidence to the contrary, the majority manufactures legal errors that will require federal courts to rubber stamp investigations initiated by the DOJ to harass opponents and chill disfavored causes, so long as the investigation serves the President's policy priorities. But the

President's authority to voice a policy position is far broader than the DOJ's statutorily constrained authority to issue subpoenas. Because the law does not permit the DOJ to initiate sham investigations—even if the President says to do so—I dissent.

I.

We review a district court's decision to quash an administrative subpoena for abuse of discretion. *McLane Co. v. EEOC*, 581 U.S. 72, 75 (2017). Whether the district court identified the correct legal rule is reviewed de novo. *United States v. Hinkson*, 585 F.3d 1247, 1261–62 (9th Cir. 2009). Part of the legal rule includes "what counts as an illicit motive." *United States v. Clarke*, 573 U.S. 248, 256 (2014).

But the agency's actual purpose in issuing a subpoena is a factual question subject to deferential clear error review. *Ponsford v. United States*, 771 F.2d 1305, 1307–08 (9th Cir. 1985).[1] Evaluating motive and purpose are "the 'kind of fact-intensive, close calls' better suited to resolution by the district court than the court of appeals." *McLane*, 581 U.S. at 81 (citations omitted). We may not reverse because we "would have weighed the evidence differently" had we "s[at] as the trier of fact" or because there was some "evidence to contradict this view." *Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985); *United States v. Ritchie*, 15 F.3d 592, 599 (6th Cir. 1994). Unless the district court's finding was "illogical, implausible, or without support in inferences that

[1] *Accord United States v. Gertner*, 65 F.3d 963, 970 (1st Cir. 1995); *La Mura v. United States*, 765 F.2d 974, 981 (11th Cir. 1985); *Groder v. United States*, 816 F.2d 139, 145 (4th Cir. 1987); *United States v. Ritchie*, 15 F.3d 592, 599 (6th Cir. 1994); *United States v. Krauth*, 769 F.2d 473, 478 (8th Cir. 1985).

may be drawn from the record," we must affirm. *Hinkson*, 585 F.3d at 1262.

The majority's suggestion that the district court's finding of DOJ's purpose in issuing the subpoena "is not one of fact" because the "district court relied solely on a cold record" is misguided. Majority 48; *Crittenden v. Chappell*, 804 F.3d 998, 1006 (9th Cir. 2015). We review factual findings for clear error "even when the district court's findings do not rest on credibility determinations, but are based instead on physical or documentary evidence or inferences from other facts." *Anderson*, 470 U.S. at 574.

"We may affirm a district court's judgment on any ground supported by the record, whether or not the decision of the district court relied on the same grounds." *Atel Fin. Corp. v. Quaker Coal Co*., 321 F.3d 924, 926 (9th Cir. 2003).

II.

An administrative agency seeking to enforce a subpoena bears the burden of establishing that (1) Congress has granted the agency the authority to investigate; (2) the agency has followed the procedural requirements; and (3) the evidence sought is relevant and material to the investigation. *United States v. Golden Valley Elec. Ass'n*, 689 F.3d 1108, 1113 (9th Cir. 2012). If the government establishes its prima facie case, the burden shifts to the recipient to challenge the subpoena on "any appropriate grounds." *United States v. Jose*, 131 F.3d 1325, 1328 (9th Cir. 1997) (en banc) (quoting *Reisman v. Caplin*, 375 U.S. 440, 449 (1964)).

The government fails on both fronts. I first address how the government failed to satisfy its prima facie burden to enforce the subpoena against QueerDoc. Even if it did,

QueerDoc has nonetheless satisfied its burden to quash the subpoena because it was issued for an improper purpose. Finally, I respond to the majority's contrary conclusions, which ignore the role of Congress in authorizing agency action and erroneously conflate the "purpose" of the President with the "purpose" of a subpoena.

A.

I start with the government's prima facie burden. An affidavit or declaration from the investigating agency explaining the purpose of the investigation may be sufficient to satisfy the agency's prima facie burden. *FDIC v. Garner*, 126 F.3d 1138, 1143 (9th Cir. 1997). Despite the majority's near-dispositive reliance on the declaration from Allan Gordus ("Gordus Declaration"), that declaration was not properly before the district court when it ruled on the motion to quash.

After QueerDoc moved to quash the subpoena, DOJ declined to submit *any* affidavit attesting to its investigatory purpose. While the motion was pending in the district court, multiple district courts granted analogous motions to quash. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *12–13 (W.D. Wash. Sept. 3, 2025). Before the district court ruled on the motion, DOJ filed a "praecipe" requesting leave to file the Gordus Declaration attesting to the purpose of the investigation. The district court granted QueerDoc's motion to strike the Gordus Declaration pursuant to the court's local rules. *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1303 n.2 (W.D. Wash. 2025); *see* W.D. Wash. Loc. Civ. R. 7(m). The government does not now contend that the district court abused its discretion in striking the Gordus

Declaration, *Bias v. Moynihan*, 508 F.3d 1212, 1223 (9th Cir. 2007), and we therefore may not substantively consider whether the Declaration satisfied the government's prima facie burden.

Pursuant to the Western District of Washington's Local Rule 7(m), "Praecipe," "[p]arties are expected to file accurate, complete documents, and the failure to do so may result in the court's refusal to consider later filed corrections or additions to the record." W.D. Wash. Loc. Civ. R. 7(m). A court may grant an exception where a party: (1) identifies an "error" in a filed document and seeks permission through a praecipe to file a "corrected document," or (2) seeks to file an additional document "in support of a previous filing," and "set[s] forth why the document was not included with the original filing and reference[s] the original filing by docket number" in the praecipe. *Id.* The district court struck the Gordus Declaration, explaining that under Rule 7(m), "a praecipe serves a narrow function: to correct clerical errors or, in limited circumstances, to add documents inadvertently omitted from an original filing," and is "not a vehicle for submitting new evidence or supplementing legal arguments after briefing has closed."[2] *QueerDoc*, 807 F. Supp. 3d at 1303 n.2.

District courts "have broad discretion in interpreting and applying their local rules." *Delange v. Dutra Const. Co.*, 183 F.3d 916, 919 n.2 (9th Cir. 1999) (quoting *Miranda v. Southern Pac. Transp.*, 710 F.2d 516, 521 (9th Cir. 1983)). "Only in rare cases will we question the exercise of

[2] As explained in Section III.A.2, the Gordus Declaration did not merely expand upon the government's prior positions, as the majority contends. Rather, the Gordus Declaration proffered investigatory theories, justifications, and facts not previously presented to the district court.

discretion in connection with the application of local rules." *Ghazali v. Moran*, 46 F.3d 52, 53 (9th Cir. 1995) (quoting *United States v. Warren*, 601 F.2d 471, 474 (9th Cir. 1979)). Neither the majority nor the government offer any persuasive reason for why this is a "rare case[]" in which the district court's application of its own local rules was an abuse of its "broad" discretion. *Id.; Delange*, 183 F.3d at 919 n.2 (quoting *Miranda,* 710 F.2d at 521).

Instead, the majority strains to rationalize its consideration of the Gordus Declaration, perhaps recognizing that without the Declaration, the government did not provide the district court with any evidence to satisfy its "burden." *Crystal v. United States,* 172 F.3d 1141, 1144 (9th Cir. 1999). Each disingenuous justification falls short.

First, the majority reasons, the government was not on notice that it had the burden to establish the purpose of the investigation until another district court quashed an analogous subpoena. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229. But we have long held that the government bears the "burden" of establishing that "the investigation will be conducted for a legitimate purpose" and that "the material being sought is relevant to that purpose," a burden that "may be satisfied by a declaration from the investigating agent." *Crystal*, 172 F.3d at 1143–44; *United States v. Dynavac, Inc*., 6 F.3d 1407, 1414 (9th Cir. 1993).

Next, the majority contends that the district court imposed an "improperly high standard" and should have allowed the government to satisfy that standard by filing the Declaration. Majority 27 n.2. Not so. The district court simply recognized that improper purpose analysis requires "more muscular review" than whether the government satisfied its prima facie burden, rejecting the government's

argument that courts may not consider whether the government acted in bad faith. *QueerDoc*, 807 F. Supp. 3d at 1302. The majority appears to agree with the district court that the improper purpose inquiry is at least more intrusive than the "slight burden of demonstrating relevance." Majority 30. In context, the district court's decision to impose greater scrutiny on the government's purpose, compared to the issue of relevance, is not inconsistent with our prior description that such scrutiny is, overall, "narrow." *Golden Valley*, 689 F.3d at 1113 (citation omitted).

Finally, the majority claims we have discretion to consider the Declaration "[e]ven if the district court did not err in striking [it]." Majority 27 n.2. The majority distorts the doctrine of forfeiture to reach its preferred result. We may have discretion to consider the antecedent question of whether the district court abused its discretion notwithstanding the government's failure to raise this issue on appeal. *See, e.g.*, *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 940 n.5 (9th Cir. 2008). But we do not have discretion to consider the Declaration itself absent a determination that the district court abused its discretion in striking it.

The Federal Rules of Appellate Procedure enable circuit courts to review stricken filings to determine whether the district court's decision to strike was erroneous. Fed. R. App. P. 10(a)(1). But we may not rely upon *correctly* stricken materials to upset a district court's ruling. Our review is "confined to the record that was *properly* before

the district court when it made its decision."[3] *Rios-Jimenez v. Principi*, 520 F.3d 31, 39 (1st Cir. 2008) (emphasis added); *see also Chelf v. Prudential Ins. Co. of Am.*, 31 F.4th 459, 464 n.2 (6th Cir. 2022) (rejecting request to review documents on appeal that the district court "declined to consider").

This makes sense. Our job is to determine whether the district court erred based on the record appropriately before it at the time it rendered its decision. For example, if a district court properly excluded declarations on summary judgment, we could not rely upon the stricken declarations to find a genuine dispute of material fact and reverse the district court's decision granting summary judgment. *See Milczak v. Gen. Motors, LLC*, 102 F.4th 772, 781 (6th Cir. 2024). Likewise, if a district court properly excluded inadmissible evidence, we could not invoke that evidence as grounds for overturning the district court's decision. To do so would subvert our system of review.

B.

With the scope of the record clarified, this becomes an easy case. Considering the information properly before the district court at the time it rendered its decision, the government failed to satisfy its prima facie burden of

[3] Here, the district court docket literally reads:

> STRICKEN ~~GOVERNMENT'S PRAECIPE TO FILE ADDITIONAL DOCUMENT, filed by Defendant United States Department of Justice. (Attachments: # 1 Declaration of Government Attorney Allan Gordus, # 2 Exhibit 1 to Declaration of Allan Gordus, # 3 Exhibit 2 to Declaration of Allan Gordus, # 4 Exhibit 2 to Declaration of Allan Gordus (Folder 2), # 5 Exhibit 2 to Declaration of Allan Gordus (Folder 3))~~.

showing the information subpoenaed was relevant and material to its purported investigatory purpose. *See Reich v. Montana Sulphur & Chem. Co*., 32 F.3d 440, 447 (9th Cir. 1994) (explaining that the agency must show "that the documents it requests are relevant to the purpose of an authorized investigation"). Although the government's burden to establish relevance is "not great," *United States v. Goldman*, 637 F.2d 664, 667 (9th Cir. 1980), the agency may not engage in a "fishing expedition." *Peters v. United States*, 853 F.2d 692, 697 (9th Cir. 1988) (citation omitted); *In re Subpoena Duces Tecum*, 228 F.3d 341, 349 (4th Cir. 2000). That is, the government must establish a "realistic expectation rather than an idle hope that something may be discovered." *Goldman*, 637 F.2d at 667 (quoting *United States v. Harrington*, 388 F.2d 520, 524 (2d Cir. 1969)).

The government did not file any affidavits attesting to the relevance of its expansive production demands in responding to QueerDoc's motion to quash. *See Garner*, 126 F.3d at 1143. DOJ arguably offered one justification, stating that its requests for information about billing and coding "relate to how [QueerDoc's] providers billed for medical services to prescribe or deliver, *inter alia*, the pharmaceuticals in question." This purported justification, echoed by the majority, is insufficient to satisfy the government's prima facie burden. The FDCA regulates "misbranding" and "adulteration," not billing or coding. *See* 21 U.S.C. § 331(b). As the majority acknowledges, the FDCA does not regulate "a doctor's ability to prescribe drugs." Majority 11. Moreover, QueerDoc does not submit claims to "health care benefit program[s]." *See* 18 U.S.C. § 24(a)(2).

Nor did the June 11, 2025 memorandum issued by Assistant Attorney General for the Civil Division Brett

Shumate ("Shumate Memo") satisfy the government's prima facie burden under the FDCA. The Shumate Memo directed FDCA investigations into "*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." But QueerDoc is neither a drug manufacturer nor a pharmacy.

In sum, DOJ failed to satisfy its prima facie burden of establishing that the records subpoenaed were material and "relevant to the purpose of an authorized [FDCA] investigation." *Reich*, 32 F.3d at 447. At most, DOJ's sweeping demands for QueerDoc's records established only an "idle hope" of uncovering information relevant to its stated investigatory purpose. *Goldman*, 637 F.2d at 667 (citation omitted).

Given DOJ's failure to carry its burden, I would affirm the district court's quashal on this alternative ground. *See Perfect 10, Inc. v. Visa Int'l Serv. Ass'n*, 494 F.3d 788, 794 (9th Cir. 2007).

III.

Even assuming the government satisfied its prima facie burden, the district court's decision to quash the subpoena should be affirmed because ample evidence supports its finding that the subpoena was issued in bad faith.

"Subpoena enforcement power is not limitless." *FTC v. Ken Roberts Co.*, 276 F.3d 583, 586 (D.C. Cir. 2001). A court may not enforce an administrative subpoena where it "would be an abusive use of the court's process." *United States v. Powell*, 379 U.S. 48, 51 (1964). "Such an abuse would take place if the [subpoena] had been issued for an improper purpose," including "harass[ment]," "pressur[ing]

[the recipient] to settle a collateral dispute," or "any other purpose reflecting on the good faith of the particular investigation." *Id.* at 58.

"The authority of an administrative agency to issue subpoenas for investigatory purposes is created solely by statute." *United States ex rel. Richards v. De Leon Guerrero*, 4 F.3d 749, 753 (9th Cir. 1993) (quoting *Peters*, 853 F.2d at 696); *United States v. LaSalle Nat. Bank*, 437 U.S. 298, 316 n.18. Because an agency's subpoena power is authorized by statute, the issuance of a subpoena for a purpose other than the purpose authorized by Congress is improper. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 18 U.S.C. § 3486(a)(1)(A)(i)(I), authorizes subpoenas solely to investigate a "[f]ederal health care offense," which requires that a violation or conspiracy of the FDCA "relates to a health care benefit program." 18 U.S.C. § 24(a)(2). Neither the government nor the majority argues that all gender-affirming care violates the FDCA, so ending gender-affirming care cannot be an authorized investigative purpose. The "dispositive question" is whether the record shows that DOJ issued the subpoena in "honest[]" and "good faith" "pursuit of the congressionally authorized purpose[]" of investigating a federal health care offense. *LaSalle*, 437 U.S. at 316, 317 n. 19.

Importantly, a determination that the government satisfied its prima facie burden does not obviate the improper purpose inquiry. These are separate analytic steps. *See infra* Section III.A.4. When the government establishes that the information sought is relevant to an investigation into plausible federal health care offenses, but the subject of the subpoena establishes that this purpose was merely a pretext

for a different, impermissible goal, the district court may properly quash the subpoena.

Our inquiry at this stage is highly deferential. An agency's motive or purpose in issuing a subpoena is quintessentially a factual determination made by the district court and reviewed on appeal for clear error. Thus, if the district court's finding that DOJ issued the subpoena to "harass" QueerDoc or to "pressure" it to "settle a collateral dispute" (to put QueerDoc out of business or otherwise end its provision of gender-affirming care) is logical, plausible, and supported by the record, we must affirm.[4] *Powell*, 379 U.S. at 58; *Hinkson*, 585 F.3d at 1262. It plainly is.

A.

The record supports the district court's determination that it was "presented . . . with an explanation for agency action" that was "incongruent with what the record reveals about the agency's priorities." *Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019).

The burden of establishing improper purpose through "specific facts and evidence" of improper intent is generally

[4] Even if the issuance of a subpoena to end gender-affirming care did not squarely fall within the *Powell* examples, that does not foreclose an improper purpose. On this point, the majority and I are on common ground. "[A] court may recognize and proscribe novel 'improper purposes.'" Majority 24; *LaSalle*, 437 U.S. at 317 n.19 (explaining that *Powell* contains "examples" of improper purposes but is not an "exclusive statement about the meaning" of improper purpose); *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 124 (3d Cir. 1981) (en banc) ("[B]ecause the Supreme Court has never confronted allegations like the ones before us does not mean that the federal judiciary is powerless to structure relief when necessary."). An "unusual" unauthorized purpose is still improper. *Wheeling-Pittsburgh Steel Corp.*, 648 F.2d at 125.

"heavy," in no small part because DOJ investigations are confidential. *Jose*, 131 F.3d at 1328 (citation and internal quotation marks omitted); *LaSalle*, 437 U.S. at 316; U.S. Dept. Just., Justice Manual § 1-7.100; *id.* § 1-7.400. Those under investigation can ordinarily only speculate about an agency's motives, and speculation is insufficient to establish bad faith. *See, e.g., SEC v. McGoff*, 647 F. 2d 185, 193–94 (D.C. Cir. 1981); *Adamowicz v. United States*, 531 F.3d 151, 160 (2d Cir. 2008); *United States v. Am. Target Advert., Inc*., 257 F.3d 348, 355 (4th Cir. 2001). Consider the cases invoked by the majority. In *Jose*, the recipient made "only a bald assertion that he 'feel[s] that the underlying reason'" was improper and provided "no facts or evidence to support this allegation." 131 F.3d at 1328. Likewise, in *Garner,* the subpoena recipients failed to make "any specific allegations of bad faith or improper purpose." 126 F.3d at 1146. To the extent subpoena recipients obtain evidence of improper purpose, it is often limited to an individual employee's motivation, which does not amount to institutional bad faith. *See, e.g., United States v. Markwood*, 48 F.3d 969, 984 (6th Cir. 1995). By contrast, because DOJ initiated a remarkably public investigation, as described *infra* Section III.A.3, and announced its purpose, QueerDoc presents substantial evidence of DOJ's "institutional posture." *LaSalle*, 437 U.S. at 316.

Specifically, the government's (1) own statements of purpose, (2) shifting post-hoc rationalizations, (3) deviation from longstanding prosecutorial norms, and (4) intrusive informational demands provide ample support for the district court's finding that the "specific facts and evidence" in the record show DOJ "issued the subpoena first and searched for a justification second." *Jose*, 131 F.3d at 1328 (citation and internal quotation marks omitted); *QueerDoc*, 807 F. Supp.

3d at 1303. When confronted with the motion to quash, the district court properly considered the full record and determined that QueerDoc satisfied its burden to establish bad faith. *Jose*, 131 F.3d at 1328. The question on appeal is not how we would weigh the evidence de novo, but rather, whether the district court's finding was clearly erroneous. *Anderson*, 470 U.S. at 574.

I address each category of evidence in turn.

1. Statements of Purpose

An agency's "self-proclaimed practice" that deviates from the purported purpose of an investigation provides evidence of "pretext." *Gertner*, 65 F.3d at 969–70. Remarkably, the government repeatedly announced that it was investigating QueerDoc to end the provision of services that facilitate gender-affirming care.[5] The district court took the government at its word. We should have done the same.

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[5] Gender-affirming care includes "any single or combination of a number of social, psychological, behavio[]ral or medical (including hormonal treatment or surgery) interventions designed to support and affirm an individual's gender identity." World Health Org., *Gender Incongruence and Transgender Health in the ICD*, https://www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd [https://perma.cc/9KV3-QQWC]. The Administration has described gender-affirming care as care that supports the "so-called 'transition' of a child from one sex to another," and characterized such care as entailing "chemical and surgical mutilation." Exec. Order 14,187, 90 Fed. Reg. 8771, §§ 1–2 (Jan. 28, 2025).

This case involves a subset of gender-affirming care. Specifically, QueerDoc is a telehealth provider that prescribes puberty blockers and hormones to treat gender dysphoria. Puberty blockers stop the production of sex hormones, thereby delaying puberty, and hormones "help adolescents identified as female at birth look more masculine and

To be clear, at no point did the government claim that the mere provision of gender-affirming care constituted the relevant federal health care offense. Rather, the government first said that it wanted to end gender-affirming care, and then came up with possible ancillary federal health care offenses to investigate. If gender-affirming care is not itself a crime, and DOJ's purpose is to end gender-affirming care, then it must be the case that in issuing a subpoena to QueerDoc, DOJ was motivated by more than a proper law enforcement purpose.

On January 28, 2025, President Trump issued Executive Order 14,187, "Protecting Children from Chemical and Surgical Mutilation." Exec. Order 14,187, 90 Fed. Reg. 8771, § 1 (Jan. 28, 2025). The EO accuses medical providers of gender-affirming care of "maiming and sterilizing" children or engaging in "mutilation," and states that "[t]his dangerous trend will be a stain on our Nation's history, and it must end." *Id.* §§ 1–2. The EO directed the Attorney General to "prioritize enforcement of protections against female genital mutilation" and to "take appropriate action to end . . . violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation." *Id.* §§ 8(a), (c). On February 3, 2025, the White House stated that the "intended effect" of the EO was to "downsize or eliminate" gender-affirming care. White House, *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), https://www.whitehouse.gov/releases/2025/02/president-

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those identified as male at birth look more feminine." *United States v. Skrmetti*, 605 U.S. 495, 581 (2025) (Sotomayor, J., dissenting).

trump-is-delivering-on-his-commitment-to-protect-our-kids/ [https://perma.cc/9MSG-M6CL].

On April 22, 2025, then-Attorney General Pamela Bondi issued a memorandum ("Bondi Memo"), titled "Preventing the Mutilation of American Children." Bondi claimed a "radical ideological agenda . . . teaches children to deny biological reality" and described as "barbaric [the] practice of surgically and chemically maiming and sterilizing children." She promised to "act decisively to protect our children and hold accountable those who mutilate them under the guise of care." Accordingly, she directed the investigation of (1) "manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition,'" and (2) "false claims submitted to federal health care programs for any non-covered services related to radical gender experimentation." Bondi promised that "the Department of Justice will bring these practices [gender-affirming care] to an end."

On June 11, 2025, on his first day in office, Assistant Attorney General Brett Shumate of the Civil Division issued a memorandum reiterating the Attorney General's promises to "hold accountable those who mutilate" children and to "pursue investigations" related "to radical gender experimentation." The Memo stated that "[t]he Civil Division will use all available resources to prioritize investigations of doctors, hospitals, [and] pharmaceutical companies" that "advance the Administration's policy objectives," including pursuing "violations of the Food, Drug, and Cosmetic Act 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." The memorandum reiterated that DOJ would "aggressively pursue claims under the False Claims Act against health care providers that bill the federal government for impermissible services."

The same day, Assistant Attorney General Shumate served QueerDoc with a criminal administrative subpoena under HIPAA, 18 U.S.C. § 3486(a)(1)(A)(i)(I).

On July 8, 2025, QueerDoc filed a motion to seal the district court's docket. The next day, DOJ issued a public announcement that it had "sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children," and promised that "[m]edical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice." U.S. Dept. Just., *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 [https://perma.cc/S5YJ-QRY7].

That same day, at a Federal Trade Commission workshop titled "The Dangers of 'Gender-Affirming Care' for Minors," then-Chief of Staff Chad Mizelle stated that DOJ's goal was to "take down this multi-billion dollar industry," and that "[w]e are using all of the tools at the Department of Justice" to do so. Fed. Trade Comm'n, *The Dangers of "Gender-Affirming Care" for Minors* at 49 (Jul. 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-

Transcript.pdf [https://perma.cc/47J5-VQRZ]. In response to a participant's statement that investigations of false diagnosis codes might "stop [gender-affirming care] even in blue states," Deputy Assistant Attorney General Jordan Campbell said DOJ was "[w]orking on it." *Id.* at 29.

On July 25, 2025, the White House issued a statement lauding that President Trump had "delivered" on his promise to "end" gender-affirming care, and listing health systems that stopped providing such care following his Executive Orders. White House, *President Trump Promised to End Child Sexual Mutilation – and He Delivered* (July 25, 2025), https://www.whitehouse.gov/releases/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/ [https://perma.cc/8KK8-PXMD].

The district court properly concluded that these statements provided strong evidence of an improper "institutional posture." *LaSalle*, 437 U.S. at 316. The majority argues that whether statements by agency officials can establish bad faith is a legal question subject to de novo review. But this legal question has already been answered. Officials' statements are probative evidence of institutional motive. *See Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266, 268 (1977) (explaining that evaluating motive "demands" consideration of "circumstantial and direct evidence of intent," including "contemporary statements by members of the decisionmaking body"); *Gertner*, 65 F.3d at 969–70 (finding that "several public statements" by the agency contributed to a "sufficient evidentiary" showing of bad faith); *Mullin v. Doe*, 146 S. Ct. 2121, 2138–39 (2026) (applying *Arlington Heights* to consider whether statements by the President and the Secretary of Homeland Security established racial animus). The district court correctly concluded that these

statements provide strong circumstantial evidence that DOJ issued the subpoena to pressure QueerDoc to "settle a collateral dispute"—that is, to end its provision of gender-affirming care or shut down its business. *Powell*, 379 U.S. at 58.

2. Shifting Justifications

DOJ's shifting rationalizations support the district court's finding that the subpoena was not "honestly" issued in pursuit of a federal health care investigation. *LaSalle*, 437 U.S. at 316; *see Washington v. Garrett*, 10 F.3d 1421, 1434 (9th Cir. 1993) (explaining that "different justifications . . . suggest the possibility that . . . the official reasons [were not] the true reason[s]"); *EEOC v. Ethan Allen, Inc.*, 44 F.3d 116, 120 (2d Cir. 1994) (recognizing that a reasonable juror could find explanations "pretextual, developed over time to counter the evidence"). The record contradicts the majority's claim that DOJ's theory of liability "has remained constant." Majority 44.

Initially, DOJ stated only that it had initiated the investigation pursuant to the Executive Orders and the Bondi Memo. The Bondi Memo asserted that "manufacturers and distributors" of medications could be engaged in "misbranding" under the FDCA by making "false claims about the on or off-label use" of gender affirming drugs. But QueerDoc is neither a manufacturer nor distributor of drugs. The Shumate Memo stated that DOJ would pursue *FDCA* investigations into "pharmaceutical companies" that manufacture hormones and puberty blockers and "dealers such as online pharmacies" that sell such drugs. By contrast, with respect to providers, the Shumate Memo said only that DOJ would pursue "claims under the *False Claims Act*" for those "that bill the federal government for impermissible

services." But DOJ did not issue the subpoena to pursue a False Claims Act investigation, and QueerDoc "does not participate in federal insurance programs or submit insurance claims." *QueerDoc,* 807 F. Supp. 3d at 1298.

When QueerDoc asked if "specific concerns" prompted DOJ's investigation, a DOJ attorney offered only that QueerDoc was being investigated because it was a "prominent" provider of gender-affirming care: "[T]hat's the extent of it." *See Gertner*, 65 F.3d at 970 (finding that a "generic affidavit, devoid of particularization, suggests that the [agency] never really suspected the [subpoena recipient] of any questionable activity"). Nevertheless, DOJ attorneys were instructed to make "frequent and extensive reports" to "senior leadership." That is, despite the absence of particular information prompting the investigation, it was apparently an agency priority.

QueerDoc filed a motion to quash the subpoena on July 8, 2025. DOJ did not file any affidavits regarding investigatory purpose with its responsive briefing. In September 2025, district courts in Massachusetts and Washington quashed analogous DOJ subpoenas on relevance and improper purpose grounds. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239; *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *12–13.[6]

[6] At least seven courts have quashed, recommended quashal, or modified these subpoenas. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239; *In re Subpoena Duces Tecum No. 25-1431-016,* 2025 WL 3562151, at *12–13; *In re DOJ Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *11 (D. Colo. Jan. 5, 2026); *In re Children's Nat'l Hosp.*, 2026 WL 160792, at *9 (D. Md. Jan. 21, 2026); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 580 (E.D. Pa. 2025); *In re 2025*

The government then pivoted. On September 26, 2025—two months after the close of briefing—the government filed a declaration offering new justifications for its investigation. The Gordus Declaration posited that (1) any evidence of fraudulent billing could establish intent under the *FDCA* (not the False Claims Act), and (2) that QueerDoc could be liable for misbranding under the FDCA for "caus[ing] the distribution of" an "approved drug for an unapproved use" or for having "false and misleading" information on its website that "may legally qualify as drug labeling under the FDCA."

On appeal, DOJ again tries motley legal theories on for size. For one, DOJ avers, the QueerDoc subpoena may instead aid in investigating potential FDCA violations by unnamed *manufacturers and distributors*. Why, then, would DOJ's press release announce only the issuance of subpoenas to "doctors and clinics" that "mutilated children," not to manufacturers or distributors—if the latter are the ones suspected of violating the law? U.S. Dept. Just., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children* (July 9, 2025). And how are children's names, dates of birth, social security numbers and addresses relevant to *this* purpose?

Alternatively, DOJ contends, it may be investigating purportedly fraudulent billing statements. But the FDCA regulates "misbranding" and "adulteration." *See* 21 U.S.C.

UPMC Subpoena, 2025 WL 3724705, at *3 (W.D. Pa. Dec. 24, 2025); *In re Admin. Subpoena 25 1431 032 to R.I. Hosp.*, 2026 WL 1392565, at *10 (D.R.I. May 14, 2026). The "uniformity of judicial expression in the district courts is significant and impressive." *McComb v. Hunt Foods, Inc.*, 167 F.2d 905, 908 (9th Cir. 1948).

§§ 331(a)–(c). It does not regulate billing or coding. This rationale provides no help to the majority.

Finally, DOJ suggests that QueerDoc itself may be liable for misbranding under the FDCA. The government acknowledges that the FDCA only "regulates the development, manufacturing, and distribution of drugs." It "does not go further by regulating a doctor's practice of medicine," which is reserved to the states. *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 534 (6th Cir. 2021); *United States v. Skrmetti*, 605 U.S. 495, 524 (2025) (explaining that states retain "wide discretion" to regulate "areas where there is medical and scientific uncertainty" (citation omitted)). This includes a provider's decision to prescribe medication for off-label uses. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("'[O]ff-label' usage . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit . . . the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient.").

Notwithstanding these principles, DOJ argues that QueerDoc's webpage describing puberty blockers as "reversible" may constitute false or misleading "labeling" of a drug, and subject QueerDoc to liability for "misbranding" under the FDCA. 21 U.S.C. §§ 331(a)–(b), 352(a). And the majority adds a new proposal for the government to add to its "labeling" theory: Perhaps webpages that provide patients guidance for self-administering injections, informational graphics depicting cartoon unicorns, and "tips" to facilitate "less ouch" injections, such as purchasing "calming aromatherapy" and "[h]olding a pet or emotional support animal," constitute "labeling" of a drug. QueerDoc,

Less Ouch! Tips for Less Painful Injections, https://queerdoc.com/tips-for-less-painful-injections/ [https://perma.cc/6TC5-T84R]; QueerDoc, *Self-Injections*, https://queerdoc.com/self-injections/ [https://perma.cc/3UTA-QKEQ]. But to constitute "labeling" of a drug, written material must appear "upon any [drug] or any of its containers or wrappers," or "accompany[]" the drug. *See* 21 U.S.C. § 321(m).

The theory that a health care provider's website is "labeling" that "accompan[ies]" a drug is not persuasive. *Id.* QueerDoc's website is not "distributed to consumers as part of an integrated distribution program." *Alberty Food Prods. Co. v. United States*, 185 F.2d 321, 325 (9th Cir. 1950) (concluding newspaper advertisements did not accompany a drug). Nor does it share "a common origin" with a drug. *Kordel v. United States*, 335 U.S. 345, 348 (1948). At its core, this theory is not credible because QueerDoc's website relates to the provision of medical care (which is reserved to the states), not to the commercial manufacturing or distribution of drugs (which is covered by the FDCA).[7]

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To the majority, it does not matter that DOJ's investigatory targets and justifications changed after issuing

[7] While a party "may not avoid an administrative subpoena on the ground that it has a valid defense to a potential subsequent lawsuit," that does not "mean that under no circumstances may the court inquire into the underlying reasons for the examination." *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076–77 (9th Cir. 2001); *Powell*, 379 U.S. at 58. Rather, the "specific sequence of events" preceding and following the issuance of the subpoena, including the government's shifting and thin theories of liability, may provide "circumstantial . . . evidence" of bad faith. *Arlington Heights*, 429 U.S. at 266–67.

the subpoena, because "an agency investigation is dynamic." Majority 44. It certainly matters. A fundamental principle of administrative law is that courts may not uphold agency actions based on "post hoc rationalizations," theories developed to "defend[] in court the agency's acts." *FTC v. Atl. Richfield Co.*, 567 F.2d 96, 100 (D.C. Cir. 1977); *Gonzalez v. Reno*, 212 F.3d 1338, 1350 (11th Cir. 2000); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). The majority does just that by adopting investigative theories first articulated in the properly stricken Gordus Declaration—all while bafflingly claiming that the "government's investigatory purpose has remained constant." Majority 44.

Even if we could ignore this "foundational principle of administrative law," *Michigan v. EPA*, 576 U.S. 743, 758 (2015), DOJ does not claim that it has "acquire[d] new information" that caused it to change investigatory targets, legal theories, and justifications. Majority 44. In law, as in life, "the simplest explanation is generally the best." *Apache Stronghold v. United States*, 101 F.4th 1036, 1082 (9th Cir. 2024) (en banc) (Bea, J., concurring in part and dissenting in part). Here, the record suggests that after multiple courts quashed DOJ's subpoenas as having been issued to intimidate providers of gender-affirming care, DOJ adopted new post-hoc rationalizations to "counter the evidence" and save its improper investigation. *Ethan Allen, Inc.*, 44 F.3d at 120.

3. Deviation from Prosecutorial Norms

DOJ's approach to this investigation runs counter to longstanding agency policies and norms that prioritize confidentiality. "Departures from the normal procedural

sequence" provide "circumstantial . . . evidence" of bad faith. *Arlington Heights*, 429 U.S. at 266–67.

The day after QueerDoc filed a motion to seal proceedings to protect the integrity of the investigation and the "safety of the providers associated with QueerDoc [and] their patients," DOJ publicly announced that it had issued subpoenas to more than twenty providers of gender-affirming care. U.S. Dept. Just., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children* (July 9, 2025).

This represents a significant departure from agency norms that prioritize confidentiality. The DOJ's investigative work "involves non-public, sensitive matters." Justice Manual, § 1-7.100. DOJ's manual explains that it generally "will not confirm the existence of or otherwise comment about ongoing investigations," or "comment on [their] nature or progress before charges are publicly filed." *Id.* at §§ 1-7.100, 7.400. This norm makes sense. When investigatory subjects and witnesses are put on notice of an ongoing investigation, it becomes more difficult to obtain the evidence necessary to identify and prosecute violations of the law. *See* Brief for Former U.S. DOJ Attorneys as *Amicus Curiae* 29. In addition to potentially "jeopardiz[ing] an investigation," publicizing an investigation also risks "put[ting] a witness or law enforcement officer in danger; . . . prejudic[ing] the rights of a defendant; or unfairly damag[ing] the reputation of a person." Justice Manual § 1-7.100. Confidentiality thus promotes effective enforcement of the law.

DOJ abandoned these longstanding norms in this case. DOJ did not wait for "charges [to be] publicly filed" to

disclose the existence and nature of its investigation. *Id.* § 1-7.400. Instead, just a month after serving a subpoena on QueerDoc, DOJ publicly announced its investigations into providers of gender-affirming care—and opposed QueerDoc's motion to seal the district court's docket. DOJ's departure from confidentiality norms key to an investigation's success (in DOJ's own telling) provides circumstantial evidence that its goal was not to "honestly" pursue potential FDCA violations. *LaSalle*, 437 U.S. at 316.

4. Subpoena Breadth

The subpoena's expansive scope supports the district court's finding that the government acted in bad faith. *See Media Matters for Am. v. FTC*, No. 25-5302, 2025 WL 2988966, at *7 (D.C. Cir. Oct. 23, 2025) (holding that the "broad scope" of a civil investigative demand provides "relevant evidence of pretext"). While the government's demand for intrusive identifying information bears little on its purported purpose of investigating federal health care offenses, it effectively serves the goal of intimidating patients and providers.

The subpoena requires disclosure of thousands of intrusive patient and employee records.[8] Requests 11 and 12 seek patient data and records for every patient prescribed

[8] The subpoena ordered QueerDoc to produce fifteen categories of documents, including "[c]omplete personnel files for each employee, contractor, or affiliate," "[a]ll documents . . . concerning the use of . . . diagnosis codes," "[a]ll communications with public or private health care benefit programs or plans regarding" coding, "[a]ny training materials . . . relating to billing or coding practices for gender-related care," "[a]ll documents relating to contracts" with manufacturers or pharmacies of puberty blockers or hormones, and "[a]ll documents relating to any adverse event . . . in a minor patient with regard to gender-related care."

puberty blockers or hormone therapy, including "[d]ocuments sufficient to identify each patient." QueerDoc must produce patients' "name[s], date[s] of birth, social security number[s], address[es], and parent/guardian information." On appeal, the government doubles down on its "need" for patients' identifying information, but it is unclear what information would not be obtainable from anonymized records. Indeed, a district court recently found that DOJ has agreed to anonymized data in several jurisdictions. *In re Admin. Subpoena 25 1431 032 to R.I. Hosp.*, 2026 WL 1392565, at *3.

So too, the subpoena seeks identifying information on QueerDoc's *adult* patients, although DOJ claims it is only investigating the provision of gender-affirming care to *minors*. *See United States v. Henry*, 491 F.2d 702, 705 (6th Cir. 1974) (finding pretext determination "buttressed by" the subpoena's demand of records that "could not apply" to the stated investigatory purpose but "could be useful" for the improper purpose).

In contrast to legitimate law enforcement, it is obvious how DOJ's intrusive demands "could be useful" to the improper purpose of eliminating gender-affirming care. *Henry,* 491 F.2d at 705. For one, disclosure of patients' names and personally identifying information intimidates current patients and deters prospective patients from seeking care. Patients may choose to forgo care rather than risk public intolerance, hostility, or violence. Access to gender-affirming care "can be a question of life or death," as untreated gender dysphoria can cause "depression, eating disorders, substance abuse, self-harm, and suicidality."[9]

[9] The majority identifies a recent Finnish study, not briefed by the parties and not raised by amici curiae, and suggests that its findings evince

Skrmetti, 605 U.S. at 581 (Sotomayor, J., dissenting) (citing E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, 23 Int'l J. Transgender Health S1, S62 (2022)).

The subpoenas also chill the provision of gender-affirming care by intimidating providers who offer such care. The financial cost of litigation and the operational burden of compliance with expansive production demands may put providers out of business. *See United States v. Samuels, Kramer & Co.*, 712 F.2d 1342, 1347–48 (9th Cir. 1983) (requiring an evidentiary hearing on improper purpose in light of evidence government may have issued subpoena in part to "close [recipient's business] down"). And the

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professional disagreement with previous research finding that "gender-affirming care improves mental health outcomes and reduces suicide risk in transgender youth." Majority 36 n.5; *see* Brief for American Academy of Pediatrics as *Amicus Curiae* 8–11 (canvassing research). As a threshold matter, it is not our role to parse the merits of quantitative research neither raised before the district court nor briefed on appeal. Assuming we were tasked with evaluating this study, since the study's publication, wide-ranging critiques have emerged about its methodology. Among the notable critiques, a group of professors wrote that the data "cannot be used to draw conclusions about mental health after [gender-affirming care], nor can they be used to compare those who accessed [gender-affirming care] and those who did not," and requested a reanalysis and re-review of the data based on the study's "misrepresentation of data, misrepresentation of findings, and inappropriate controls." E. Kale Edmiston et al., *Concerns Regarding Data Modelling and Interpretation in Ruuska et al*., Acta Paediatrica: Reader's Forum 1–2 (May 30, 2026), https://doi.org/10.1111/apa.70617. Likewise, based on the study's alleged methodological flaws, an open letter signed by nearly fifty academics, researchers, practitioners, and advocates urged "prompt editorial reconsideration" of the study to "ensure scientific soundness." *See* David R. Banos et al., *Letter of Concern About Ruuska et al. From 4 April 2026*, Acta Paediatrica: Reader's Forum 1–4 (May 22, 2026), https://doi.org/10.1111/apa.70620.

industry-wide threat of criminal investigation pressures providers to stop offering such care, even if they are not yet investigatory targets. Unsurprisingly, these threats have proven effective at achieving the "intended effect" of chilling gender-affirming care. *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025). Since the Executive Orders, "more than 40 hospitals nationwide have paused or ceased to offer some type of gender-affirming care" to minors. Theresa Gaffney, *Amid Federal Pressure, More Hospitals Stop Gender-Affirming Care for Minors*, STAT News (Feb. 5, 2026), https://www.statnews.com/2026/02/05/hospitals-stop-gender-care-minors-trump-administration-pressure/ [https://perma.cc/UD9V-LBV3].

This case is no different. Dr. Crystal Beal, Chief Executive Officer of QueerDoc, attested that "full compliance" with the subpoena, including reviewing and producing patient records, personnel files, and other documents, and ensuring conformity with state privacy laws, would "seriously threaten QueerDoc's ability to remain in business." QueerDoc is a small telehealth provider. Apart from Dr. Beal, QueerDoc has only one other employee. Because QueerDoc does not have an information technology department to manage document production, Dr. Beal would have to hire a discovery vendor. QueerDoc would also have to "invest additional resources into legal resources." And Dr. Beal would have to shift from "providing healthcare services to patients" to "managing document productions."

*

The majority responds that the subpoena's expansive scope does not show bad faith, because the information sought may be relevant to DOJ's investigation. But a

subpoena recipient may move to quash a subpoena *either* because the information is irrelevant to the purported investigation *or* because the subpoena was issued for an improper purpose. *See Crystal*, 172 F.3d at 1144 (describing the "burden" shift after "the government has established the *Powell* elements"). That is, a subpoena recipient who moves to quash a subpoena may prevail by establishing that the information sought is irrelevant, notwithstanding the agency's demonstrated good faith. Or a subpoena recipient may show that a subpoena was issued in bad faith, although it clears the prima facie relevance bar. *See Gertner*, 65 F.3d at 968–71 (affirming improper purpose determination notwithstanding a sufficient relevance showing).

The majority similarly reasons that "fear that the costs of compliance will force a party to shutter its business implicates the question of undue burden, not of improper purpose." Majority 50–51. QueerDoc could certainly seek to narrow the subpoena because compliance would unduly burden its business operations. But this simply presents a different question from whether the subpoena was issued *for the purpose* of putting QueerDoc out of business—and under our precedent, warrants a different remedy. That is, a subpoena recipient may obtain an order narrowing a subpoena because compliance would be unduly burdensome, although the agency issued the subpoena in good faith pursuit of its statutorily authorized purpose. Or a district court may properly quash a subpoena on improper purpose grounds after finding that the agency issued the subpoena for the purpose of shutting down a business, regardless of whether the subpoena in fact imposed a legally sufficient undue burden. *See Samuels, Kramer & Co.*, 712 F.2d at 1347–48.

Thus, even assuming the government carried its prima facie burden, the district court did not err in concluding that the subpoena's intrusive and expansive scope supported its bad faith finding.

* *

The district court's finding that DOJ issued the subpoena to chill QueerDoc's provision of gender-affirming care is logical, plausible, and supported by the record, which is all that clear error review requires. *Hinkson,* 585 F.3d at 1262.

The majority should have ended its inquiry here.

IV.

The district court's finding that DOJ acted for the purpose of ending gender-affirming care was not "based on several [legal] misapprehensions." Majority 48. The majority invents purported legal errors based on the misguided view that courts are powerless to constrain agency overreach if doing so would "intrude" on the President's policy priorities. This misunderstands the relationship between the executive, judicial, and legislative branches in the investigative subpoena context. "Subpoena enforcement power is not limitless." *Ken Roberts Co*., 276 F.3d at 586. Agencies must operate within the bounds of the law enacted by Congress, and courts have a "duty not to rubber-stamp" administrative subpoenas "but to adjudge their legitimacy." *CFPB v. Accrediting Council for Indep. Colls & Schs.*, 854 F.3d 683, 689 (D.C. Cir. 2017). The district court's decision respects this balance of powers. The majority's opinion undermines it.

A.

The checks and balances built into the § 3486 subpoena authority constrain executive power. True, the Executive Branch has "discretion" to prioritize "legal actions against defendants who violate the law." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021). But the administrative subpoena power is not a discretionary executive function; it is a congressionally authorized power, limited by statute and subject to judicial review that is "narrow," but "potent." *SEC v. Arthur Young & Co*., 584 F.2d 1018, 1024 n.39 (D.C. Cir. 1978). Where Congress has provided authority to issue subpoenas for a particular purpose, neither the President nor the DOJ has the authority to stray from that purpose.

First, "[t]he authority of an administrative agency to issue subpoenas for investigatory purposes is created solely by statute." *United States ex rel. Richards*, 4 F.3d at 753 (quoting *Peters*, 853 F.2d at 696); *LaSalle,* 437 U.S. at 317 n.18. Rather than sanction "unconstrained investigative authority," Congress, in the context of this case, authorized the use of subpoenas solely for the purpose of investigating "[f]ederal health care offense[s]." *EEOC v. Shell Oil Co.*, 466 U.S. 54, 65 (1984); 18 U.S.C. § 3486(a)(1)(A)(i)(I). Thus, our task is simply to determine whether the district court's finding that DOJ issued the subpoena for a purpose not authorized by Congress was clearly erroneous. *LaSalle,* 437 U.S. at 317 n.18. Again, the district court had ample evidence to conclude that when DOJ issued its subpoena, it did so not for the purpose of investigating a crime, but to run QueerDoc out of business.

In an apparent effort to avoid the clear error standard of review for factual findings, the majority recasts the issue before us as "what counts as an illicit motive," a legal

question subject to de novo review. *Clarke*, 573 U.S. at 256. But the "illicit motive[s]" at issue in this case are well-established. *Id.* Because DOJ "does not enjoy inherent authority to summon production of the private papers of citizens" and may "exercise only that authority granted by Congress," the issuance of a subpoena for a purpose other than its statutorily authorized purpose is improper. *LaSalle*, 437 U.S. at 317 n.18. That is, if DOJ issued the subpoena not in "honest[]" and "good faith" investigation of a federal health care offense, as § 3486 requires, but to "harass" QueerDoc or to "pressure" it to "settle a collateral dispute" (to shut down its business or end its provision of gender-affirming care), it acted pursuant to an improper purpose. *Id.* at 316, 317 n. 19; *Powell*, 379 U.S. at 58. The district court thus applied the "correct legal standard." *Clarke*, 573 U.S. at 256.

Second, federal courts have a duty to ensure agencies do not exceed their statutory authority in issuing subpoenas. Agencies are expected to pursue "earnest and eager action" in enforcement proceedings. *United States v. Morton Salt Co.*, 338 U.S. 632, 640 (1950). But "judicial review is provided" to protect against "harsh and overzealous action" or "mistaken or arbitrary orders." *Id.*

"[W]hile the courts' role in subpoena enforcement may be a strictly limited one, it is neither minor nor ministerial." *Ken Roberts Co.*, 276 F.3d at 587 (citation and internal quotation marks omitted). In subpoena enforcement proceedings, courts may review only whether the agency satisfied its prima facie burden, and if so, whether the subpoena recipient satisfied its burden to show the subpoena was issued in bad faith, poses an undue burden, or is overbroad. *See Golden Valley Elec. Ass'n*, 689 F.3d at 1113. These are "narrow" inquiries; but "the court's role . . . within

its confines [] is potent." *Arthur Young & Co.*, 584 F.2d at 1024 n.39. That is, district courts have a duty to carefully weigh evidence suggesting an investigation is pretextual, rather than simply accepting at face value an agency's claim that it acted in good faith. The district court properly examined a "narrow" question—whether the subpoena was issued in bad faith—and engaged in "potent" review within its confines, examining all relevant evidence of DOJ's intent. *Id.*

Potent review of whether an agency acted in bad faith reflects fidelity to our constitutional order. For one, the "integrity of the judicial process" is at stake. *Wheeling-Pittsburgh Steel Corp.*, 648 F.2d at 125. Administrative subpoenas are not self-enforcing. Rather, "[i]t is the court's process which is invoked to enforce the administrative [subpoena] and a court may not permit its process to be abused." *Powell*, 379 U.S. at 58.

The integrity of the legislative process is also at stake. The judiciary's "duty to police the boundary between the Legislature and the Executive is as critical as our duty to respect that between the Judiciary and the Executive." *City of Arlington v. FCC*, 569 U.S. 290, 327 (2013) (Roberts, C.J., dissenting). Where an agency exceeds its statutory authority in issuing a subpoena, courts have a "duty not to rubber-stamp" the agency's demand for production of documents, but to instead "stand guard" against "abuses of their subpoena-enforcement processes." *Accrediting Council*, 854 F.3d at 689; *Arthur Young & Co.*, 584 F.2d at 1024.

The majority abdicates this core judicial duty. In the name of executive power, and based on a "fundamental misunderstanding about the authority of the [DOJ]," the

majority "thwart[s]" Congress's clear limitations on the HIPAA subpoena power, sanctions agency abuse of court process, and abandons our role in maintaining the separation of powers. *LaSalle*, 437 U.S. at 317 n.18; *Shell Oil Co.*, 466 U.S. at 65; *see Morrison v. Olson*, 487 U.S. 654, 693 (1988) (quoting *Buckley v. Valeo*, 424 U.S. 1, 122 (1976)) ("[T]he system of separated powers and checks and balances established in the Constitution was regarded by the Framers as 'a self-executing safeguard against the encroachment or aggrandizement of one branch at the expense of the other.'"); 1 B. Montesquieu, *The Spirit of the Laws* 161 (Thomas Nugent transl., J. Prichard ed. 1914) ("To prevent this abuse, it is necessary from the very nature of things that power should be a check to power.").

B.

The majority's primary rejoinder is that the President's policy goal of ending gender-affirming care is not itself improper. True, the President may adopt a policy position on gender-affirming care, even if that position is unsupported by scientific evidence.[10] But that is not the legal question before us. That the *President* can voice policy opposition to gender-affirming care does not mean that the *DOJ* can weaponize its statutorily constrained subpoena authority as a tool to put health care providers out of business. The crux of the majority's confusion lies here. It uses one word to refer to two distinct ideas. As QueerDoc's

[10] "[T]he American Academy of Pediatrics, American Medical Association, American Psychiatric Association, American Psychological Association, and American Academy of Child Adolescent Psychiatry all agree that hormones and puberty blockers are 'appropriate and medically necessary' to treat gender dysphoria." *Skrmetti*, 605 U.S. at 582 (Sotomayor, J., dissenting) (citation omitted).

counsel acknowledged at oral argument, the President has a "purpose," which the federal courts do not sit to review. *See* Oral Argument at 18:18–18:52, *QueerDoc, PLLC v. U.S. Dep't of Just.* (No. 25-7384). But the subpoena is also issued for a "purpose," and that purpose is subject to congressional limitation and judicial review.

The majority claims that the President's Article II removal power, *Trump v. Slaughter*, No. 25-332, 609 U.S. ____, 2026 WL 1855612, at *6 (U.S. June 29, 2026), eliminates the "division between DOJ and the President." Majority 49. This odd position reveals a "fundamental misunderstanding about the authority of the [DOJ]." *LaSalle*, 437 U.S. at 317 n.18. Because the individuals within the Executive Branch are legally distinct, whether an executive official's action is lawful depends on who takes the action. For example, where an executive agency has the power to conduct formal adjudications, the President cannot *himself* legally wield that authority. *Myers v. United States*, 272 U.S. 52, 135 (1926) (explaining that notwithstanding Article II, there are duties the President "cannot in a particular case properly influence or control"). Or order an agency adjudicator to rule against a specific party. *Portland Audubon Soc. v. Endangered Species Comm.*, 984 F.2d 1534, 1545 (9th Cir. 1993) ("[S]trongly disagree[ing]" with the argument that the "President's broader policy role" permits such influence). Nor are executive agency officials entitled to presidential immunity for official acts. *Harlow v. Fitzgerald,* 457 U.S. 800, 809 (1982) (concluding it would be "untenable to hold absolute immunity an incident of the office of every Presidential subordinate"). In other words, the President is not an agency, *Franklin v. Massachusetts*, 505 U.S. 788, 796

(1992), and an agency is not legally synonymous with the presidency.

As this unbroken line of cases makes clear, under our constitutional order, whether an action is lawful depends on who did it, what they did, and why. In this case, it is the law enacted by Congress—HIPAA—that dictates the legality of DOJ's subpoena. Clearly, Congress's authorization of *DOJ* to issue subpoenas to investigate federal health care offenses does not permit the *President* to demand private citizens' documents. As much as my colleagues wish to avoid it, the converse is also true. That the *President* may lawfully voice policy opposition to a practice does not mean the *DOJ* can exceed its statutory authority and issue pretextual subpoenas to put a company out of business. Perhaps (barring other lawful constraints) DOJ could merely parrot the President's position that gender-affirming care should end, but that does not mean that DOJ could take the separate action of issuing subpoenas for that purpose, and thus violate the conditions on the subpoena power that Congress prescribed.

The majority claims I "never explain[]" why DOJ may not issue a subpoena for the purpose of ending gender-affirming care, if the President may voice policy opposition to such care. Majority 50. I will repeat myself for the majority's benefit: the law Congress enacted does not allow DOJ to issue a subpoena in order to harass a practitioner or to put a provider out of business, and our precedent prohibits agencies from pursuing bad faith, pretextual investigations. *See Powell*, 379 U.S. at 58. As judges, our duty is to follow the law, not ignore it.

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There is no question that the President has discretion to "decide which crimes to investigate and prosecute."

Majority 41 (quoting *Trump v. United States*, 603 U.S. 593, 620 (2024)). As a corollary, the majority reasons that any subpoena that is consistent with a President's policy priorities cannot be issued in bad faith. Otherwise, such a finding of bad faith would interfere with the President's ability to advance his policy priorities, direct his subordinates, and investigate regulated industries.

This misses the mark. In isolation, an agency's consistency with presidential priorities is not dispositive of whether it acted in good faith. This case is not about whether DOJ may investigate a regulated industry if the President has voiced policy opposition to that industry. No one contends such an industry is immune from investigation. Nor did the district court quash the subpoena because it was merely *consistent* with the President's priorities. Instead, the district court quashed the subpoena because it found extensive evidence, *see supra* Section III.A, satisfying QueerDoc's burden, that DOJ's stated, statutorily authorized purpose for its investigation was not in fact its "honest[]" objective. *LaSalle*, 437 U.S. at 316.

Consider the majority's hypothetical. A future President could advocate for legislation to ban online sports betting platforms. And the Federal Trade Commission ("FTC") could properly initiate investigations into suspected anticompetitive conduct by online sports betting platforms, which could violate the Federal Trade Commission Act ("FTC Act"). *See* 15 U.S.C. § 46. But that is not what happened in this case. Imagine instead that the FTC announced that it would use the threat of criminal prosecution to "end" the online sports betting industry by putting individual firms out of business, initiating investigations with the aim of imposing heavy legal fees, and only coming up with possible violations of the FTC Act after

the fact. The former scenario reflects "the ordinary operation of the Executive Branch." Majority 42. The latter evinces bad faith.

The majority's holding to the contrary has no limiting principle. If mere consistency with the President's policy priorities were to insulate subpoenas from judicial review of whether the agency acted pretextually, the statutory constraints imposed by Congress would be meaningless. After all, "[t]he President sets broad policy that his subordinates implement at increasingly specific levels." Majority 42. An agency could thus *always* invoke consistency with presidential priorities to immunize a subpoena from judicial review—even one brazenly issued in bad faith. HIPAA does not license such unfettered authority.

C.

DOJ officials' public statements put my colleagues in a bind. To rule in favor of the government, the majority is forced to hold that the district court erred in considering statements by agency officials in determining whether the subpoena was issued for a pretextual reason. But the "dispositive question" is whether the agency acted in bad faith—and bad faith turns on intent. *LaSalle*, 437 U.S. at 317 n.19. Accordingly, district courts must "inquire into the underlying reasons" motivating an administrative subpoena. *Powell*, 379 U.S. at 58; *Goldman*, 637 F.2d at 666. Statements by officials about DOJ's objectives provide strong evidence of institutional purpose. *See Arlington Heights*, 429 U.S. at 266, 268 (evaluating motive "demands" consideration of "evidence of intent as may be available," including "contemporary statements by members of the decisionmaking body"); *Gertner*, 65 F.3d at 969–70; *Mullin*, 146 S. Ct. at 2138–39. It is blackletter law that across varied

contexts, to "evaluat[e] purpose," courts routinely and "regularly take into account the statements of governmental officials." *Freedom From Religion Found., Inc. v. Chino Valley Unified Sch. Dist. Bd. of Educ.*, 896 F.3d 1132, 1149 (9th Cir. 2018).

The majority also argues that the district court disregarded the presumption of regularity in finding DOJ acted in bad faith. True, courts presume that government officials "properly discharge[] their official duties." *Cruz v. Bondi*, 146 F.4th 730, 739 (9th Cir. 2025) (quoting *United States v. Chem. Found., Inc.*, 272 U.S. 1, 15 (1926)). But there is "[n]o doubt" that the presumption "is subject to be rebutted." *R.H. Stearns Co. v. United States,* 291 U.S. 54, 63 (1934). That is, the presumption applies "in the *absence* of clear evidence to the contrary." *Cruz,* 146 F.4th at 739 (quoting *Chem. Found.*, *Inc.*, 272 U.S. at 14–15) (emphasis added). As described above, QueerDoc has presented ample evidence "to the contrary." *Id.* We need not assume that DOJ is acting in good faith to investigate crimes when it has told us that it is acting with the intent to end an industry.

Finally, the majority suggests that the government's perfunctory acknowledgement of the law is sufficient to overcome QueerDoc's evidence of bad faith. Specifically, the majority observes that the Executive Order states that it "shall be implemented consistent with applicable law" and the Bondi Memo authorizes only "appropriate investigations." In the majority's view, the fact that the government said it would follow the law should end our inquiry.

This ipse dixit reasoning would eliminate judicial review of whether a subpoena was issued for an improper purpose. In practice, a statement by a government official that the

agency would follow the law would *always* defeat a motion to quash, regardless how flagrant the evidence of pretext. But a district court's role is to serve as an "independent reviewing authority," not "a 'rubber stamp' for agency demands for the production of information." *Wearly v. FTC*, 616 F.2d 662, 665 (3d Cir. 1980); *Markwood*, 48 F.3d at 979. I cannot join the majority in turning "potent" judicial review of institutional bad faith into a hollow formality. *Arthur Young & Co.*, 584 F.2d at 1024 n.39.

V.

It is hard to imagine clearer evidence that DOJ issued the subpoena to QueerDoc in bad faith. "We as the judiciary should not pretend to be blind to what the American public can easily observe for themselves." *Nat'l TPS All. v. Noem*, 166 F.4th 739, 782 (9th Cir. 2026) (Mendoza, J., concurring); *accord Dep't of Com.*, 588 U.S. at 785 ("[W]e are not required to exhibit a naiveté from which ordinary citizens are free." (quotation marks and citation omitted)). The majority does just that in rejecting the district court's well-supported finding in favor of unfettered subpoena power that is divorced from our precedent, unmoored from the law Congress enacted, and a threat to the separation of powers. I am doubtful the majority would so contort the governing law and our precedent if this case did not promise to impede access to gender-affirming care. Because neither the President nor the DOJ have the authority to rewrite § 3486, and because judicial review is not a rubber stamp for agency overreach, I dissent.