The Honorable John H. Chun

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: SUBPOENA DUCES TECUM NO. 25-1431-016	Case No.: 2:25-MC-00041-JHC FILED UNDER SEAL GOVERNMENT'S MOTION TO ALTER OR AMEND THE JUDGMENT NOTICE ON MOTION CALENDAR: October 22, 2025

The Government respectfully moves under Federal Rules of Civil Procedure 59(e) and 60(b)(1) and (6) to alter or amend the Court's judgment. The Court made three groups of manifest errors in its recent opinion quashing the subpoena,[1] each of which provides an independent basis to deny SCH's motion to quash: *First*, the Court manifestly erred by determining that the Government is not conducting an investigation of federal health care offenses at SCH. *Second*, the Court manifestly erred by shifting and heightening the burden of proof on the Government, the non-movant, and by failing to provide the Government an opportunity to make a showing of predication for the investigation under the Court's new framework—a showing the Government can amply make, as demonstrated by this filing. *Third*, the Court manifestly erred by discounting the Attorney General's stated purpose in conducting a

[1] The Government does not move to alter or amend the Court's ruling on SCH's motion to seal.

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P.O. Box 386
Washington, DC 20044
(202) 353-4218

lawful investigation.

ARGUMENT

"Since specific grounds for a motion to amend or alter are not listed in Rule 59(e), the district court enjoys considerable discretion in granting or denying the motion." *Allstate Ins. Co. v. Herron*, 634 F.3d 1101, 1111 (9th Cir. 2011). Generally, there are "four basic grounds upon which a Rule 59(e) motion may be granted: (1) if such motion is necessary to correct manifest errors of law or fact upon which the judgment rests; (2) if such motion is necessary to present newly discovered or previously unavailable evidence; (3) if such motion is necessary to prevent manifest injustice; or (4) if the amendment is justified by an intervening change in controlling law." *Id.*

Rule 60(b) allows relief from a court's judgment on a number of grounds including error, mistake, and surprise. *Fuller v. M.G. Jewelry*, 950 F.2d 1437, 1442 (9th Cir. 1991). Although the grant of Rule 60(b) relief is rare and exceptional, the rule is remedial in nature, and when appropriate it must be liberally applied. *Cmty. Dental Servs. v. Tani*, 282 F.3d 1164, 1169 (9th Cir. 2002).

1. The Court Manifestly Erred When It Incorrectly Determined That the Attorney General Is Not Conducting a Federal Health Care Offense Investigation

The Court made manifest factual errors in determining that the Attorney General is not conducting a federal health care offense investigation, Opinion at 22, and that the "only" thing DOJ provided shedding light on this investigation was the Hsiao declaration, *id.* at 14. These rulings are manifestly erroneous because they conflict with the evidence and fail to consider contrary information in the record. These are the types of obvious errors that should be corrected on a Rule 59(e) motion. *Kaufmann v. Kijakazi*, 32 F.4th 843, 851 (9th Cir. 2022).

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P.O. Box 386
Washington, DC 20044
(202) 353-4218

The Court initially laid out several pieces of information indicating that the Attorney General has personally directed a lawful investigation into federal health care offenses. Opinion at 3. And yet, in the analysis section of its opinion, the Court made a contrary factual conclusion that DOJ is *not* actually attempting to investigate federal health care offenses, describing DOJ's showing as "threadbare" because the "only" material DOJ put forth was the Hsiao affidavit. Opinion at 14.

With respect, the Government believes the Court misapprehended the record. The existence of a federal health care offense investigation that the Attorney General personally ordered does not seem to be in meaningful dispute, and the Government does not believe that SCH made even a cursory showing that this investigation does not exist. In contrast, the Government made a sufficient showing based on the face of the subpoena and the other information before the Court that the investigation exists and that the subpoena is procedurally proper. *United States v. Golden Valley Elec. Ass'n*, 689 F.3d 1108, 1114 (9th Cir. 2012) (holding that a DEA supervisor's signature on an administrative subpoena as well as the subpoena's issuance was enough to show that procedural requirements had been met).

The information the Court has about this investigation is not "only" the Hsiao affidavit, as the Court erroneously found, but is also all of the information about the investigation that SCH attached to its opening brief, as well as the statements that the parties made in their filings.[2] Fed. R. Evid. 1101(d)(3) (stating that the Federal Rules of Evidence do not apply in

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[2] Unlike a typical administrative subpoena matter, in which the Government may need to explain an investigation to a Court because the investigation is arcane or non-public—or the subpoena recipient is a private individual whose relationship to the matter is unestablished or opaque—all of the facts and laws supporting this subpoena are public, obvious, and out in the open. To the extent the salient facts are not public, SCH itself put those facts in the record. The Court erred in expecting that this information needed to arrive in the form of a Government affidavit.

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"miscellaneous proceedings"). On the basic question of whether the Civil Division of the Department of Justice is investigating federal health care offenses, before the Court were the following:

- The Attorney General ordered the Civil Division's Consumer Protection Branch, of which the undersigned is an Assistant Director, to "undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act 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.'" Opinion at 3.
- The Assistant Attorney General issued a memorandum directing the Civil Division, of which the Consumer Protection Branch is a component, to "use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with [the Attorney General's directive]." *Id.*
- The Assistant Attorney General for the Civil Division possesses delegated authority from the Attorney General to issue the subpoena in question because it seeks evidence of federal health care offenses in the form of FDCA violations related to public or private insurance claims. Opinion at 8-9.
- The Assistant Attorney General issued the administrative subpoena in question to SCH as part of the investigation described above. Opinion at 4.
- The subpoena was procedurally proper. Opinion at 9.
- SCH is "the largest provider of pediatric [medical] services in the Pacific Northwest," has 3,100 child patients at its gender clinic, and had 525,000 total

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(202) 353-4218

patient visits last year. Declaration of Jeffrey G. Ojemann, MD at 2, 4.

- SCH prescribes and/or provides gender-related pharmaceuticals to children at its gender clinic. *Id.*
- Gender-related pharmaceuticals given to children are not FDA-approved for those purposes. Opinion at 19-20.
- Causing the distribution of unapproved new drugs can be an FDCA violation, which can be a federal health care offense. 21 U.S.C. § 331(d); Opinion at 8.

These undisputed facts paint a clear picture: the Attorney General has ordered an investigation of potential FDCA health care offense violations committed in the course of gender-related care for minors; SCH provides such care and uses federally-regulated drugs in an off-label manner while providing such care; and the Assistant Attorney General for the Civil Division used properly delegated authority to issue a procedurally proper subpoena in furtherance of this investigation. At the very least, SCH as the movant did not carry its "heavy" burden, Opinion at 6, to disprove *any* of the bulleted facts above, much less all of them. In fact, the Government here provided more information to the Court than the Ninth Circuit required in *Golden Valley* to demonstrate the existence of the investigation. 689 F.3d at 1114.

The investigation exists, and SCH is a proper entity to receive a subpoena. The Court's contrary conclusion, that "DOJ has not shown that it is investigating a federal healthcare offense," *e.g.*, Opinion at 23 n.8, is manifestly erroneous.

2. The Court Shifted the Burden to the Government, Heightened the Burden on the Government, and Failed to Provide the Government an Opportunity to Make a Showing Under the Court's New Standard

The Court committed manifest legal errors when it: (1) shifted the burden to the Government in a manner contrary to law; (2) heightened the burden on the Government in a

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Washington, DC 20044
(202) 353-4218

manner contrary to law; and (3) failed to provide the Government with a meaningful opportunity to meet the Court's newly announced standard.

First, the Court erroneously shifted numerous burdens to the Government. The Government did not file a lawsuit or otherwise seek relief from this Court, and the Assistant Attorney General's subpoenas here do not need court approval to issue. So, although the Court correctly stated that SCH bears a "heavy" burden to show the subpoena should be quashed and that the Government did not bear a burden, Opinion at 6, the Court manifestly erred by shifting to the Government the very burdens that the Court said the Government does not have and that the case law does not require. To wit, the Court repeatedly found in its opinion (*e.g.*, Opinion at 20) that by not providing information showing specific cause to investigate SCH, the Government had not met a burden or made out a *prima facie* case. The Court did not logically identify how SCH had met its *prima facie* "heavy" burden to place those burdens on the Government in the first place, however.

SCH made one specific, non-politically charged challenge to the subpoena's procedural validity—whether the Assistant Attorney General of the Civil Division has authority to sign this subpoena—and the Government adequately answered it. Opinion at 8-9. But the rest of SCH's showing consisted of public statements by Executive Branch officials not specifically about SCH with which SCH obviously has political and legal disagreements. Because no case that the Government has found has held that such a situation can meet a subpoena recipient's heavy burden, it is unclear why those statements shifted the burden to the Government at all. It is even less clear why SCH's general showing that the Executive Branch wants to end pharmaceutical and medical gender-related care for minors shifted a burden to the Government to provide something akin to probable cause. Opinion at 20.

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(202) 353-4218

Second, the Court manifestly erred by applying a balancing test to decide the motion to quash. The Ninth Circuit has made very clear that procedurally proper administrative subpoenas "must be enforced" unless there is a "patent lack of jurisdiction" to investigate. *EEOC v. Fed. Express Corp.*, 558 F.3d 842, 851 n.3 (9th Cir. 2009) (collecting cases).

With respect to the Court, the test it applied—a balancing test that weighed SCH's purported privacy interests in its pre-existing business records against the Court's impressions of the Government's investigation—is unrecognizable in the field of administrative subpoena law and manifestly conflicts with the binding precedent quoted above. *Compare* Opinion at 23-24 ("[T]he core inquiry is one of balancing a public interest in allowing for agency investigations as authorized by Congress against private interests that, although not granted full Fourth Amendment protection, are nonetheless safeguarded.") *with Fed. Express Corp.*, 558 F.3d at 851 n.3 ("a procedurally sound subpoena must be enforced"). Because this was a procedurally proper subpoena, Opinion at 9, the result of this proceeding should have been simple under the governing case law: SCH's motion to quash should have been denied.

Just as erroneously, the Court decided that SCH could meet its "heavy" burden that the subpoena was outside the scope of DOJ's authority by a mere preponderance of the evidence in its opening brief—the exact opposite of a heightened burden. Opinion at 18. The Court's erroneous preponderance standard is inconsistent[3] with the Ninth Circuit's "repeated[]

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[3]The Court cited only *United States v. Gertner*, 65 F.3d 963, 967 (1st Cir. 1995), to support its adoption of the preponderance standard, which the Court states "other circuits appear to have recognized." Opinion at 18. Such reliance is misplaced. *Gertner* considers, but does not adopt, a preponderance of the evidence showing at the "third tier" of a proceeding to enforce an IRS summons, after the taxpayer already surmounted her heavy burdens. 65 F.3d at 966. We are not in the "third tier" of this proceeding, *Gertner* is a thirty-year-old case in a very different context, and the Ninth Circuit's statements about "heavy" burden and the "narrow" scope of judicial review since that case, including in *Crystal* and *Federal Express*, stand in contrast to this Court's application of a preponderance standard to SCH's opening brief.

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admonish[ions] that questions concerning the scope of an agency's [] authority [] are not to be resolved in subpoena enforcement proceedings" because "a procedurally sound subpoena must be enforced." *Fed. Express Corp.*, 558 F.3d at 851 n.3. The Court's ruling also conflicts with *United States v. La Salle Nat'l Bank*, 437 U.S. 298, 316 (1978), which held that a taxpayer has a "heavy" burden to prove that the IRS served a civil summons as pretext to support a criminal investigation. No fair reading of *La Salle National Bank* would suggest that SCH can avoid compliance by making a simple preponderance showing of pretext in its opening brief.

In addition to applying the wrong tests, the Court heightened the Government's burden in other significant ways: it read *United States v. Powell*, 379 U.S. 48, 56 (1964), to stand for the proposition that the Government's burden here is "heavier" than the Government's burden in *Powell*. Opinion at 14. The opposite is true, as Congress passed a law—discussed extensively in *Powell*—preventing "unnecessary" IRS summonses. 379 U.S. at 56. Section 3486 of Title 18 contains no such limitations, however, and under no circumstances is the Government's burden in this matter *heavier* than the burden in an IRS summons matter.

The Court misread *Powell* in another way. *Powell* noted that even in an IRS summons enforcement proceeding, the Court cannot be the arbiter of the Government's decision to launch an investigation. 379 U.S. at 56. But this Court's decision does exactly that by effectively vetoing the Attorney General's decision to launch this investigation based on the Court's assessment of its propriety. Neither SCH nor the Court explained how arguably making a showing on the *Powell* factors authorizes an inquiry that *Powell* itself said the Court should not undertake.

The Court also heightened the Government's burden by misreading *United States v. Goldman*, 637 F.2d 664 (9th Cir. 1980), and *In re Sealed Case*, 42 F.3d 1412 (D.C. Cir. 1994), at a critical juncture in its ruling, Opinion at 20-22, to establish a contrary-to-law rule that the

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(202) 353-4218

Government may not send a subpoena in the "idle hope" of obtaining documents or to discover "other wrongdoing, as yet unknown." These cases stand for no such general propositions and, if they did, they would conflict with Supreme Court precedent. The dispute in *Goldman* was not about the validity of the subpoena at all; instead, it was about the relevance of requests for documents predating the statute of limitations in an otherwise valid IRS subpoena. 637 F.2d at 666-67. And *In re Sealed Case* was about whether the Office of Thrift Supervision had statutory authority to subpoena the *personal* bank accounts of 1980s savings-and-loan executives whose accounts were not relevant to determining liability.

In contrast to the Court's misplaced reliance on the narrow relevance holdings of *Goldman* and *Sealed Case*, *United States v. Morton Salt Co.*, 338 U.S. 632, 642-43 (1950) (the Government "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not"), establishes that the Government is perfectly empowered to send subpoenas within its statutory authority in order to determine whether a federal health care offense may have been committed—as it has done here with SCH, which is a large, regulated healthcare provider that had 525,000 patient visits last year. The Court recognized this clear *Morton Salt* principle when stating the law early in its opinion, Opinion at 10-12, but inexplicably arrived at a conclusion that manifestly conflicts with it, Opinion at 20, by disallowing DOJ to investigate acknowledged articulable potential federal healthcare offenses plainly within its statutory authority.

Third, this Court manifestly erred by not allowing the Government to meet this Court's new standard that, in a subpoena enforcement matter, the Government must provide an "explanation for why [the subpoena recipient] is the target of its subpoena" that is based on more than "idle hope" or "speculation" and also articulates "specific[] . . . conduct involving [the subpoena recipient]." *Id.* The Government believes this is a probable cause standard, and the

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P.O. Box 386
Washington, DC 20044
(202) 353-4218

Government could not have anticipated that this Court would announce this novel standard given the case law's firm rejection of it. *Golden Valley*, 689 F.3d at 1115 ("The Supreme Court has refused to require that an agency have probable cause to justify issuance of a subpoena.").

Because the Court's standard was unexpected, the Government should have been—or now should be—given the opportunity to meet it, assuming that the Court will maintain its announced standard. Rule 60(b) relief is appropriate to allow a case to be decided on the merits, *In re Gilman*, 887 F.3d 956, 964 (9th Cir. 2018), and the Court's erroneous ruling deprived the Court of a chance to consider the substantive merits of the Government's investigation in the "third tier" of the proceeding. *Gertner*, 65 F.3d at 967. Here, the Court never reached the third tier; the Government is the non-movant and should have been given the same opportunity as any other litigant. *See FTC v. Gallo*, No. 653-73, 1973 U.S. Dist. LEXIS 11573, at *9 (D.D.C. Oct. 9, 1973) (ordering the Government to submit additional information about an administrative subpoena after the district court determined that the subpoena recipient had made an initial showing in its brief).

The Government is amply able to meet the Court's newly announced standard and address the Court's concerns, as demonstrated by the attached affidavit proffering previously undisclosed information to the Court. *See* Hsiao Declaration (attached). The affidavit sets out the legal and factual background to the Government's investigation as well as relevant facts about SCH and the drugs at issue. *Id.* And it describes how there is cause to investigate whether SCH and its associates are violating the FDCA—either directly or through a conspiracy with others (e.g., with pharmacies, drug manufacturers, and/or distributors)—with the intent to defraud and mislead. *Id.* at 10-13.

To highlight two of these items: *First*, through analysis of anonymized insurance industry claims data, the Government identified dozens of children at SCH or its affiliates since 2015

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Washington, DC 20044
(202) 353-4218

about whom the data shows were first diagnosed with central precocious puberty ("CPP") at age 10 or older, including numerous children who were first diagnosed with CPP between the ages of 14 and 18. *Id.* Because CPP only afflicts children aged 9 or younger, the Government is concerned that SCH incorrectly diagnosed certain children with CPP in order to mislead insurance companies or others into covering puberty blockers for older children with gender dysphoria. Misleading insurance companies or others about a patient's diagnosis in order to obtain payment for pharmaceuticals could form the basis of a federal healthcare offense.

Second, SCH participated in a 2022 study purportedly supporting the use of puberty blockers and cross-sex hormones in minors with gender dysphoria. *Id.* However, public critiques of this study suggest that the study and the press releases about it were possibly misleading and deceptive. *Id.* Making false or misleading statements in order to support the use of and billing for off-label pharmaceuticals could violate multiple federal health care statutes.

The declaration also describes how the requests in the investigative HIPAA subpoena issued to SCH are needed to further this investigation. *Id.* at 13-15.

3. The Court's Pretext Finding Is Manifestly Erroneous

Finally, the Court manifestly erred when it incorrectly assumed that the subpoena is "likely pretextual." Opinion at 19. In making that finding, the Court misread an Attorney General memo ordering this "appropriate" investigation as somehow actually directing DOJ to send pretextual subpoenas and not to perform a real investigation. Respectfully, the Attorney General did not order an unlawful investigation, there is not a single piece of record evidence indicating that she did so, and the Court's contrary conclusion is wrong factually and legally.

As expressed by the Attorney General and the President, the Executive Branch has a policy goal of ending gender-related pharmaceutical and surgical treatment of minors. The Executive Branch can choose to support that policy goal—a goal that the Supreme Court

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P.O. Box 386
Washington, DC 20044
(202) 353-4218

recognizes is rational, as detailed in *United States v. Skrmetti*, 605 U.S. __, 145 S. Ct. 1816, 1835-36 (June 18, 2025)—in a variety of ways. This includes, of course, by conducting lawful and appropriate investigations to determine if federal law has been violated by individuals engaging in potential misconduct connected to the provision of such treatments. Government officials, like all human beings, often have multiple valid reasons for performing actions: The Attorney General wants to investigate federal healthcare offenses (including those committed in connection with the provision of gender-related care to minors) at the same time she wants to curtail the practice of gender-related pharmaceutical and surgical care to minors overall. Nothing about that situation is improper, mutually exclusive, pretextual, or even remarkable—SCH did not even attempt to address why the Attorney General having both goals is impermissible.

A court may not reject an agency's stated reasons for acting simply because the agency might also have had other reasons. *See Jagers v. Federal Crop Ins. Corp.*, 758 F. 3d 1179, 1185–1186 (10th Cir. 2014) (rejecting argument that "the agency's subjective desire to reach a particular result must necessarily invalidate the result, regardless of the objective evidence supporting the agency's conclusion"). Relatedly, a court may not set aside an agency's policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities. *Sierra Club v. Costle*, 657 F. 2d 298, 408 (D.C. Cir. 1981).

This Court also believed that other healthcare entities choosing to end gender-related pharmaceutical and surgical treatment of minors was evidence of the lack of merit in this investigation. Opinion at 21. But if the Government sends ten subpoenas to entities engaging in a questionable practice that might be illegal under federal law, and nine of them stop the practice, that is in no way evidence that the subpoena to the tenth entity is unenforceable. The federal government often sends subpoenas investigating practices that may or may not violate federal

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P.O. Box 386
Washington, DC 20044
(202) 353-4218

law, and there is the obvious possibility that an entity receiving such a subpoena will curtail the challenged practice before any enforcement action is litigated. Other courts have recognized this phenomenon and have correctly found it unremarkable. *Solis v. Forever 21, Inc.*, No. 12-09188, 2013 U.S. Dist. LEXIS 64462, at *21 (C.D. Cal. Mar. 7, 2013). The Court manifestly erred in not explaining why other entities' choices to change their practices—the Court's list included entities that did not even receive a subpoena as part of this investigation at all, Opinion at 21—shed any light whatsoever on the enforceability of *this subpoena* to SCH.

Furthermore, instead of attaching the presumption of regularity and propriety that it must to the Attorney General and Assistant Attorney General's actions, *Banks v. Dretke*, 540 U.S. 668, 696 (2004), the Court assumed that the Attorney General or the Assistant Attorney General gave orders and signed subpoenas in the pursuit of a nonexistent or pretextual investigation. In order to have done so, of course, these officials would not only need have lied in their official memos about the "appropriate[ness]" and existence of the investigation, but they would also need to disbelieve their own justifications for these actions—that is, that at least some aspects of pharmaceutical and surgical gender-related care for minors likely violate federal law. But SCH did not ask the Court for such findings, did not present any evidence in support of them, and the Court did not make them.

Instead, SCH and the Court *credited* the Attorney General's statements that she wants to end pharmaceutical and surgical gender-related treatments for kids as accurately reflecting her state of mind, but then inexplicably *discredited* her order of an "appropriate" investigation into federal health care offenses as being pretextual and then *ignored* her explanation of how off-label uses of pharmaceuticals and misrepresentations about their effects could violate federal health care law. The Court did not explain why it chose to credit one part of the Attorney General's statement and reject or ignore the others. This was manifest error and should be corrected.

United States Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
(202) 353-4218

CONCLUSION

The Government respectfully requests that the Court amend its opinion and deny SCH's motion to quash.

Dated: October 1, 2025.

BRETT A. SHUMATE
Assistant Attorney General

JORDAN C. CAMPBELL
Deputy Assistant Attorney General

LISA K. HSIAO
Acting Director
Consumer Protection Branch

/s/ Patrick R. Runkle
ROSS S. GOLDSTEIN
PATRICK R. RUNKLE (PA #207360)
Assistant Directors
SCOTT DAHLQUIST
Trial Attorney

U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
Tel: (202) 353-4218
patrick.r.runkle@usdoj.gov

I certify that this memorandum contains 4,085 words, in compliance with the Local Civil Rules.

CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2025, I served the foregoing Motion via electronic mail pursuant to Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure to the following counsel of record, who has consented in writing to electronic service:

Jeffrey B. Coopersmith
CORR CRONIN LLP
1015 Second Avenue, Floor 10
Seattle, WA 98104
jcoopersmith@corrcronin.com

David M. Zinn
Christopher N. Manning
Jennifer G. Wicht
Amy M. Saharia
Patrick C. Hynds
Dana B.Kinel
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
dzinn@wc.com
cmanning@wc.com
jwicht@wc.com
asaharia@wc.com
phynds@wc.com
dkinel@wc.com

Dated this 1st day of October, 2025.

/s/ Patrick R. Runkle
PATRICK R. RUNKLE

United States Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
(202) 353-4218