NO. 24-60272

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

NICQUID, L.L.C.; WOOD CREEK VAPORY,

Petitioners,

v.

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

On Petition for Review from the Food and Drug Administration (Agency No. PM0003712PD1)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING PETITIONERS AND VACATUR

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September 5, 2024

CERTIFICATE OF INTERESTED PERSONS

I certify that the following listed persons and entities have an interest in this case's outcome as described in the fourth sentence of Fifth Circuit Rule 28.2.1. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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September 5, 2024

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. Consistent with its free-market mission, WLF believes that the best way to limit smoking's adverse health effects is to provide smokers with less-harmful alternatives to combustible tobacco. So it has often filed briefs and regulatory comments about the Food and Drug Administration's regulation of modified-risk tobacco products. *See, e.g.*, WLF Comment, *In re Modified Risk Tobacco Product Application for iQOS System* (FDA-2017-D-3001); *In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020) (per curiam).

If this Court denies the petition for review, millions of Americans would lack access to popular combustible tobacco alternatives. This would lead to more preventable diseases and deaths. As agencies cannot bar such lawful products from interstate commerce without providing

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* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to WLF's filing this brief.

due process and following the Administrative Procedure Act, this Court should vacate the denial order.

INTRODUCTION

The Supreme Court has long recognized the importance of fair notice under the Due Process Clause. Fundamental fairness requires that citizens "be informed as to what the State commands or forbids." *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939). In other words, the fair notice requirement is "the first essential of due process of law." *Connally v. Gen. Const. Co.*, 269 U.S. 385, 391 (1926) (*citing Int'l Harvester Co. of Am. v. Kentucky*, 234 U.S. 216, 221 (1914)).

The right to fair notice is often at issue when courts confront vague statutes. The Supreme Court has struck down statutes and regulations because parties cannot tell whether their conduct would violate a statute or regulation by reading its text. *See, e.g.*, *Johnson v. United States*, 576 U.S. 591, 595-605 (2015). Vagueness, however, is not the only basis for finding that an agency's action violates due process. Agencies can also violate due process by giving inadequate notice to regulated parties.

Agencies sometimes fail to give adequate notice by not complying with the APA's notice-and-comment rulemaking process. But they can also violate regulated parties' due-process rights by issuing a "new interpretation" "that creates 'unfair surprise' to regulated parties." *Kisor v. Wilkie*, 588 U.S. 558, 579 (2019) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007)).

That is what happened here. For years, FDA told electronic nicotine delivery system (ENDS) manufacturers that they need provide only certain data to obtain approval for their products. But when faced with a court-imposed deadline to act on applications, FDA denied almost every one for following its prior guidance. Rather than take FDA at its word, companies were told they should have assumed that FDA would change its mind and decide that companies must present evidence that FDA had assured them was unnecessary.

Moving the goalposts is the antithesis of due process of law. When applications were due, regulated parties lacked notice of the information FDA later decided was crucial for approval. Companies spent millions of dollars on research studies for their applications. That money went down

the drain when FDA did an about-face and rejected those studies as inadequate.

The APA protects parties' due-process rights by requiring courts to set aside agency actions like FDA's here. Allowing FDA to issue form denials to almost every company that complied with its prior guidance would invite other agencies to follow suit. The APA also cabins agencies' discretion by requiring courts to set aside arbitrary or capricious actions. FDA's actions here are quintessential examples of arbitrary decisions. Rather than rely on relevant science, FDA relied on unrelated findings to deny NicQuid's applications. Because FDA pulled a bait-and-switch, this Court should grant the petition.

STATEMENT

The Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, grants FDA authority to regulate cigarettes and other tobacco products. Among the TCA's goals is to provide FDA with "new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." 21 U.S.C. § 387

note § 4. To accomplish this goal, Congress gave FDA authority to address tobacco products' harms.

The TCA requires FDA to determine whether a product introduced to the market after 2007 would be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). If the answer is no, then the product may not be marketed. To ensure compliance with this provision, manufacturers must submit a premarket approval application before marketing a new tobacco product. *See id.* § 387j(a), (b).

For seven years, the TCA did not cover ENDS products. But then FDA deemed ENDS tobacco products to be covered under the TCA. *See* 21 C.F.R. § 1100.2. This meant that at least 25,000 ENDS products on the market at the time would become illegal overnight. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 498 (6th Cir. 2020). It also would require ENDS manufacturers to seek premarket approval without direction about what evidence was needed to obtain premarket approval.

So at the same time FDA deemed ENDS products covered by the TCA, it promised not to start enforcement actions against ENDS manufacturers until it developed rules for the premarket applications—by 2018. *Deeming Tobacco Products To Be Subject to the Federal Food,*

Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,977-78 (May 10, 2016). FDA first extended its amnesty to 2022, but then changed the deadline to 2021 for ENDS products with flavors other than tobacco, menthol, or mint.

In 2019, FDA reassured ENDS manufacturers seeking premarket approval that it "underst[ood] that limited data may exist from scientific studies and analyses." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry*, 12 (June 2019). Thus, manufacturers need not "conduct long-term studies to support an application." *Id.* at 13. Later that year, FDA repeated that it did not think studies lasting six months or more were needed for ENDS manufacturers seeking premarket approval. *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566, 50,619 (Sept. 25, 2019).

Activists eventually sued FDA for extending the application deadlines. Because it expected only 6,800 applications, FDA consented to a ten-month deadline for receiving applications and a one-year period for

FDA to review the applications. The United States District Court for the District of Maryland ordered FDA to comply with those deadlines. *See Vapor Tech.*, 977 F.3d at 499-500. Because of COVID-19, the court later extended the application deadline by four months. *See id.*

FDA told ENDS manufacturers that their applications could include data "from a variety of sources" and that conducting new nonclinical or clinical studies was unnecessary. Joint Appendix at 34, *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022) (21-2077); *see* Iilun Murphy, *Premarket Tobacco Product Application Content Overview*, 26 (Oct. 23, 2018), https://perma.cc/2JF4-J3ZR. Many ENDS manufacturers relied on that guidance. They were later surprised to receive FDA's marketing denial orders faulting them for not conducting a randomized controlled trial or longitudinal cohort study to contrast flavored ENDS products with an appropriate comparator tobacco-flavored ENDS.

NicQuid timely filed its applications for its ENDS products. Following FDA guidance, the applications included results from a focus group study and a cross-sectional perception and intent study. They also included a marketing plan that had what FDA told NicQuid were adequate measures to prevent youth vaping. FDA denied NicQuid's

applications because the applications lacked a randomized controlled trial or longitudinal cohort study showing that non-tobacco flavored vaping products were more successful at helping smokers quit than tobacco-flavored vaping products. This Court stayed the denial order pending disposition of this petition for review.

SUMMARY OF ARGUMENT

I. The Fifth Amendment guarantees due process of law. At the heart of this due-process guarantee is the right to know what conduct is prohibited. The Supreme Court has long applied this principle in many contexts and continues to do so today.

FDA denied NicQuid and other ENDS manufacturers of fair notice of what it required for them to continue marketing and selling their products. In fact, FDA pulled a bait-and-switch. It told manufacturers what information must be included in applications. Then, after the deadline for submitting applications passed, FDA did an about-face and told manufacturers that its instructions were wrong. It then denied NicQuid's applications because of these alleged shortcomings. This exemplifies a due-process violation.

II. FDA's denial order will be used for decades in administrative law textbooks as the epitome of arbitrary and capricious agency action. FDA ignored all the evidence NicQuid presented because it didn't like the result of those studies, then faulted NicQuid for failing to provide evidence that FDA had said was unnecessary. This arbitrary and capricious process doesn't even consider FDA's about-face caused by congressional pressure. So even if the order did not deprive NicQuid of due process, it must be vacated under the APA.

ARGUMENT

I. FDA'S DENIAL ORDER DEPRIVED NICQUID OF DUE PROCESS OF LAW BY NOT GIVING FAIR NOTICE OF THE APPLICATION REQUIREMENTS.

Fair notice of what the law requires is at the core of the Due Process Clause. *City of Chicago v. Morales*, 527 U.S. 41, 58 (1999) (citing *Lanzetta*, 306 U.S. at 453); *see Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 374 (5th Cir. 2024) (en banc) (citations omitted). The Supreme Court has long recognized the importance of fair notice to due process. Almost 100 years ago, it described the fair notice requirement as "the first essential of due process of law." *Gen. Const. Co.*, 269 U.S. at 391 (citing *Int'l Harvester Co. of Am.*, 234 U.S. at 221).

The fair notice requirement is not limited to statutes or formal regulations. Agencies may not "depart from a prior policy sub silentio or simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see Menkes v. Dep't of Homeland Sec.*, 486 F.3d 1307, 1310, 1314 (D.C. Cir. 2007). That is because due-process principles require agencies to "provide regulated parties fair warning" of what the agency "prohibits or requires" before taking adverse action. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (quotation omitted).

Fair notice bars agencies from announcing positions and then springing an "unfair surprise" by penalizing regulated parties for their "good-faith reliance" on the agency's representations. *Christopher*, 567 U.S. at 156-57 (quotation omitted); *see Wages & White Lion*, 90 F.4th at 381. This principle applies to both formal and informal guidance. *See Morton v. Ruiz*, 415 U.S. 199, 235 (1974); *PHH Corp. v. CFPB*, 839 F.3d 1, 48 (D.C. Cir. 2016), *reinstated in relevant part*, 881 F.3d 75, 83 (D.C. Cir. 2018) (en banc).

FDA's denial order flouts this well-settled rule. It faults NicQuid for not conducting a "randomized controlled trial[,] longitudinal cohort

study," or similarly "reliabl[e] and robust[]" study "over time" comparing the effectiveness of "flavored" vs. "[t]obacco-flavored" products in promoting smoking cessation. Record Excerpts 140. And FDA now treats "cross-sectional surveys, consumer perception studies, and general scientific literature" as unreliable on this score. *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657, 666 (9th Cir. 2023).

But any shortcomings in NicQuid's applications resulted from FDA's own instructions to applicants. It continually reassured manufacturers that it "did not expect that applicants would need to conduct" longitudinal studies. *Liquid Labs LLC v. FDA*, 52 F.4th 533, 540 (3d Cir. 2022) (cleaned up). FDA also disavowed requiring longitudinal studies, including "randomized controlled clinical trials." *E.g.*, 84 Fed. Reg. at 50,619.

These statements alone are bad enough. Yet they only scratch the surface of FDA's bait-and-switch approach here. Its prior instructions also explicitly encouraged submission of the very evidence it later rejected. FDA "support[ed] the use of different types of studies, methods, instruments and analyses" from various sources. *See* Letter from Mary Kushman, Lead Toxicologist, FDA to Bidi Vapor LLC, USA (May 8,

2020). As to cessation, FDA offered "[e]xamples of information that FDA recommend[ed]" as evidence of "likelihood of . . . cessation." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* ("2016 guidance"), 36 (May 2016). This included studies that FDA now considers unreliable—"[p]ublished literature" and "observational studies (perception, actual use, or both) examining cessation behaviors." *Id.* at 37.

As to flavored products, FDA asked manufacturers to "describe consumer perceptions among current ENDS users and other tobacco users for appeal." 2016 guidance, *supra* at 40. It even told manufacturers to supply "published reports and data on consumer perceptions," including "data [they] collect[ed] on consumer perceptions" to gauge "intentions to use the product." *Id.* at 36. "Then FDA flip-flopped." *Wages & White Lion*, 90 F.4th at 377.

FDA's flip-flop creates obvious unfair surprises. FDA issued guidance to "assist persons submitting [applications] for [ENDS]" products, "to improve the efficiency of application submission and review." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems*, cover (Mar. 2023). FDA expressly sought to

"enable ENDS manufacturers to consider and strengthen their applications based on the final PMTA for ENDS guidance." Decl. of Mitchell Zeller, Dir., Ctr. For Tobacco Prods., FDA, ¶ 13, *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019) (No. 18-cv-883).

NicQuid spent $1,000,000 submitting studies that followed FDA's guidance. *See* Stay App'x A100. FDA cannot then penalize NicQuid—by denying its applications—for faithfully adhering to FDA's instructions. FDA's technical review acknowledged that FDA moved the evidentiary goalposts, based on what FDA "learned" from "review[ing applications] for flavored ENDS so far." Record Excerpts 86. But if FDA wanted to change its evidentiary requirements based on its deepened understanding of the appropriate for the protection of public health evaluation, it should have acknowledged that shift before the application deadline and offered a "detailed justification." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Fox Television*, 556 U.S. at 515).

The APA forbids FDA from imposing new requirements on regulated parties after it is too late for them to comply. As the new requirements were "a substantive rule," *R.J. Reynolds Vapor Co. v. FDA*,

65 F.4th 182, 193 (5th Cir. 2023) (citation omitted), they violated NicQuid's due-process rights. *See Wages & White Lion*, 90 F.4th at 388 (FDA "did not give manufacturers fair notice of the rules."). And because the APA bars such due-process violations, this Court should grant the petition for review.

II. FDA'S DENIAL ORDER WAS ARBITRARY AND CAPRICIOUS.

Agencies must "articulate a satisfactory explanation for [their] action[s]." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 682 (2020) (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)). FDA claims that it weighed the risks of youth usage against the benefits of flavored ENDS products' reducing or eliminating adult smoking. But it never actually weighed the costs and benefits because it disregarded key evidence.

FDA's conclusions about the risks of youth usage undergird its whole approach. FDA continues to view youth usage as a substantial threat, citing general studies about youths' using closed-system products—small, highly portable, and often disposable devices. It also purports to rely on scientific literature and consumer studies showing

that flavors appeal more to youth than do tobacco-flavored or unflavored products.

WLF opposes youths' using ENDS products. NicQuid similarly condemns youths' using ENDS. *See* Record Excerpts 114. But FDA refused to consider evidence that its general risk assessment does not apply to NicQuid's products. NicQuid sells bottled e-liquid products used in tanks. Stay App'x A086. As former FDA commissioner Dr. Scott Gottlieb confirmed, "kids just don't like those big open-tank contraptions." Nicholas Florko, *Former FDA Commissioner Calls for a Full Ban on Pod-Based E-Cigarettes*, Stat (Nov. 12, 2019), https://perma.cc/WRW6-ST8C.

FDA "did not . . . assess" the "aspects of the applications" that showed that youth are unlikely to use NicQuid's products. Record Excerpts 140. Rather, it concluded that "across . . . different device types, the role of flavor is consistent." Record Excerpts 55 (cleaned up). This was another abrupt change in course. In 2020, FDA found that youths "overwhelmingly prefer cartridge-based ENDS products" because of their concealability, high nicotine content, and ease of use. *Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed*

Products on the Market Without Premarket Authorization; Guidance for Industry; Availability, 85 Fed. Reg. 720, 722 (Jan. 7, 2020); *see also Wages & White Lion*, 90 F.4th at 367 ("cartridge-based products [are] popular with young people" because of their "relatively small size that allows for easy concealability" (quotation omitted)). These characteristics are noticeably missing from NicQuid's products. Yet FDA painted with a broad brush to conclude that flavor drove youth ENDS usage. Although that may be true within a given ENDS product type, FDA could not cite any evidence about the effect of flavor across all product types. The evidence shows that those who use NicQuid's products are over 45. Record Excerpts 148. Although this may sound youthful to octogenarians, it is not the vulnerable youth that FDA was worried about.

The Centers for Disease Control and Prevention's most recent data confirms that FDA missed the mark on youth ENDS use. It shows that youth use of tank-based ENDS compatible with NicQuid's bottled e-liquids had decreased in recent years, despite the removal of flavored cartridge-based products from the market. *Compare* Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Weekly Report 1310, 1310-12

(2020) (youths' use of ENDS dropped from 27.5% to 19.6%, of which only 14.8% used a tank system) *with* Eunice Park-Lee et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 Morbidity & Mortality Weekly Report 1387, 1387-88 (2021) (youths' use of ENDS dropped from 19.6% to 11.3%, of which only 7.5% reported using a tank system).

This data shows that the percentage of youths who used a tank system after flavor-based cartridge ENDS were taken off shelves in 2020 decreased—not increased—by almost 50%. This would make no sense if FDA's assumption that flavor drives everything for youths was correct. Under FDA's reasoning, youths would have substituted tank-based systems for the cartridge systems once the cartridges exited the market. Because the exact opposite occurred, it further exposes FDA's conclusion that flavors drive youth initiation across ENDS device types as lacking a rational basis in the data and FDA's overall decision as arbitrary and capricious.

FDA also ignored evidence showing NicQuid's successful efforts to prevent youth access. NicQuid's applications detailed its thorough

auditing and age-verification measures and marketing strategy that targeted only adults. Record Excerpts 115. These efforts led to no recorded instance of a minor buying NicQuid's products. Record Excerpts 148. But FDA acknowledged not evaluating any of this evidence. Instead, citing other applications, FDA claimed to be unaware of access restrictions that successfully prevent youth from obtaining ENDS. Yet FDA had earlier confirmed that age-verification protections like NicQuid's "would protect kids" by "preventing access to flavored" products. FDA, *Statement from Comm'r Scott Gottlieb, M.D., on proposed new Steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes* (Nov. 15, 2018), https://perma.cc/HQ8W-PFSN. Ignoring this contrary evidence was arbitrary and capricious. *See Roe v. Dep't of Def.*, 947 F.3d 207, 225 (4th Cir. 2020); *Clark County v. FAA*, 522 F.3d 437, 442-43 (D.C. Cir. 2008).

This Court's en banc decision in *Wages & White Lion* is not the only one to recognize FDA's errors. In another case, FDA "refused to consider the marketing and sales-access-restriction plans" showing that the applicant could limit youth use of the ENDS products. *Bidi Vapor LLC v.*

FDA, 47 F.4th 1191, 1195 (11th Cir. 2022). Chief Judge Pryor, writing for the court, correctly found this action to be "arbitrary and capricious." *Id.*

FDA also concluded that, to overcome the perceived high risk of youth usage, NicQuid must produce especially rigorous evidence of countervailing benefits to adult smokers. *See Lotus*, 73 F.4th at 672; *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022). Thus, if FDA miscalculated the risks of youth usage, it also mis-calibrated the evidentiary standard for judging benefits to adult smokers.

Even so, FDA's sky-high evidentiary mandate for showing benefits for smokers is arbitrary. FDA demands product-specific studies contrasting the appeal of flavored vs. tobacco-flavored products. Yet, as discussed above, FDA saw no need for such specifics in asserting risks to youth. In fact, it found that it need not consider more specific studies. The reason for this disparity was simple: the product-specific studies for youth usage did not support FDA's position but the broad studies did.

Similarly, to show that adult smokers reduce or stop smoking, FDA declared all "cross-sectional surveys, consumer perception studies, and general scientific literature" surveys inherently unreliable. *Lotus*, 73 F.4th at 666. Yet FDA had earlier called these very same studies the best

available evidence of youth usage. FDA thinks that product-specific features drive adult cessation but not youth initiation. This "self-contradictory, wandering logic does not constitute an adequate explanation." *Del. Dep't of Nat. Res. & Env't Control v. EPA*, 785 F.3d 1, 16 (D.C. Cir. 2015) (quotation omitted).

FDA also failed to "adequately consider the impact of" its extraordinarily specific evidentiary standard. *See Ackerman v. U.S. Dep't of Agric.*, 995 F.3d 528, 533-34 (6th Cir. 2021). FDA ignored the consequences of employing a rationale that apparently rejects all flavored ENDS products for insufficient evidence using cookie-cutter reasoning. Those denials are forcing an exodus of products from the market—products that FDA acknowledges former smokers rely on to stop smoking. *See* FDA, *FDA Issues Decisions on Additional E-Cigarette Products*, PR Newswire (Mar. 24, 2022), https://perma.cc/TG5A-AHYH. FDA had cautioned that this "public health outcome" was to be "avoided if at all possible" because of the "serious" risk that former adult smokers would switch back to cigarettes. Zeller Decl., *supra* ¶¶ 12, 15. FDA likewise failed to consider that its denials could cause ENDS users to turn to the illicit market—another problem FDA previously recognized.

See 81 Fed. Reg. at 29,007. Now, FDA says nothing about what will happen to millions of former smokers. FDA's erratic regulatory approach was therefore arbitrary and capricious.

CONCLUSION

This Court should grant the petition and vacate FDA's denial order.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,776 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

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September 5, 2024

CERTIFICATE OF SERVICE

I hereby certify that, on September 5, 2024, I served all counsel of record via the Court's CM/ECF system.

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September 5, 2024