No. 25-10681, 25-10697, 25-10783

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

NOVO NORDISK INC,

Plaintiff-Appellant,

v.

WELLHEALTH INC., LIVE WELL DRUGSTORE, LLC, WELLS PHARMACY NETWORK, LLC,

Defendants-Appellees

BRIEF FOR THE ALLIANCE FOR PHARMACY COMPOUNDING AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES URGING AFFIRMANCE

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No. 25-10681, 25-10697, 25-10783
Novo Nordisk Inc. v. WellHealth Inc. (No. 25-10681); *Live Well Drugstore, LLC* (No. 25-10697); *Wells Pharmacy Network, LLC* (No. 25-10783*)*

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

1. Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1-1, *Amicus Curiae* the Alliance for Pharmacy Compounding furnishes the following trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of this appeal:

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No. 25-10681, 25-10697, 25-10783

Novo Nordisk Inc. v. WellHealth Inc. (No. 25-10681); *Live Well Drugstore, LLC* (No. 25-10697); *Wells Pharmacy Network, LLC* (No. 25-10783*)*

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2. Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1-1, counsel for Amicus Alliance for Pharmacy Compounding notifies this Court that the Alliance for Pharmacy Compounding is a Texas non-stock corporation and has no parent corporations nor one that owns 10% or more of its stock.

/s/Randall Nice
Randall Nice
Counsel for Amicus Alliance for Pharmacy Compounding

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STATEMENT OF IDENTIFICATION

Amicus curiae Alliance for Pharmacy Compounding ("APC") is a Texas Non-Profit Corporation. As a non-profit trade association, APC represents compounding pharmacists and technicians in both state-licensed pharmacies acting under authority of Section 503A of the Food, Drug & Cosmetic Act of 1938 ("FDCA") and Outsourcing Facilities acting under the authority of Section 503B of the FDCA. APC also represents compounding pharmacy stakeholders including prescribers, educators, patients, and pharmacy suppliers. Including APC partner organizations, APC represents approximately 150,000 patients, compounding professionals, prescribers, and others.

APC is concerned about pharmaceutical manufacturers inappropriately using state unfair trade laws to stifle compounding practices, prioritizing profits over patient access to important medications. Here, Appellant is attempting to use state unfair trade practice claims to prohibit compounding of in-demand drugs by alleging state laws require Food and Drug Administration ("FDA") approval for compounded drugs. These allegations ignore provisions of the FDCA that allow compounding pharmacies and outsourcing facilities to compound drugs under certain conditions. It also ignores the express intent of Congress that the FDA have sole authority in enforcing the FDCA. Amicus has a strong interest in ensuring that the Court has an accurate understanding of the historical context of compounding, the dangers of inconsistent regulations and enforcement, and the protections afforded to the practice of compounding by the FDCA.

APC files this brief pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure upon the accompanying Motion for Leave to File Amicus Brief.

No party's counsel authored this brief in whole or in part. No party or its counsel contributed financial support intended to fund the preparation or submission of this brief.

STATEMENT OF THE ISSUES

Whether the FDCA preempts claims brought under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") and premised on violations of the Florida Drug and Cosmetic Act ("DCA"), where those state-law claims are based on the FDCA.

SUMMARY OF ARGUMENT

This Court should affirm the district courts' orders because they appropriately protect the FDCA's compounding provisions by limiting enforcement of the FDCA to the FDA, as intended by Congress. The regulations governing the ingredients and products of pharmacy compounding are extensive and part of a meticulously devised regulatory framework. Further, the ability of pharmacies to compound in-shortage drugs, and to customize drugs for patients, is an important part of the national public health system. As such, Congress enacted a ban on enforcement of these regulations by parties other than the

United States. To allow state regulations and private parties to intrude into this framework would upset the carefully crafted regulatory balance set out by Congress and the FDA.

Enforcement of the FDCA is limited, by statute, to the federal government. This Court should not permit an end-run around the ban on extraneous enforcement of the FDCA through state laws. Instead, state regulations should be limited by the states' traditional role as regulators of the pharmacy profession. The extensive federal regulations governing compounding do not leave room for meddling by the states and private actors. Accordingly, this Court should affirm the decisions below and deny Appellant's efforts to use state laws to prohibit compounding.

ARGUMENT

The three district courts below appropriately held that efforts to use state law claims to prevent compounding were preempted by the FDCA. Compounded drugs are not "FDA approved," but the FDCA expressly allows compounding—without FDA approval—when certain exceptions are met, such as patient-specific customization or addressing a national drug shortage. Allowing manufacturers to invoke state laws that require FDA approval for all drugs would effectively undermine this critical public health safeguard. Moreover, enforcement of the FDCA lies exclusively with the federal government, not private parties through state-law claims. Accordingly, this Court should affirm the decision below.

I. COMPOUNDING PLAYS A VITAL ROLE IN PROTECTING PATIENT ACCESS TO MEDICATIONS.

Compounding is a traditional component of the practice of pharmacy involving "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002). Compounding also includes providing patients with essentially copies of FDA-approved drugs when the FDA determines there is a shortage of the drug. *See* FDA, *Compounding when Drugs are on FDA's Drug Shortages List* https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list (Aug. 8, 2025). Drug compounding—the creation of medicines for patients whose clinical needs cannot be met by FDA-approved products or when an FDA-approved product is subject to a national shortage—has long been a part of modern pharmacy practice. *See* Carvalho M, Almeida IF. *The Role of Pharmaceutical Compounding in Promoting Medication Adherence.* PHARMACEUTICALS (BASEL), Sep. 15, 2022, at 2. Today, "compounded medicines represent between 1% to 3% of pharmaceutical prescriptions and their use is growing." *Id*.

The science and art of compounding medications can be linked to the origins of pharmacy itself. The first documented chemical processes can be traced as far back as the time of the ancient Egyptians. Metwaly, AM, *Traditional ancient Egyptian medicine: A review*, Saudi J Biol Sci. 2021 Oct; 28(10): 5823–5832. Drug compounding is "taught as part of the standard curriculum at most pharmacy schools" and is "typically used to prepare

medications that are not commercially available." *Thompson*, 535 U.S. at 361. Drugs that are not commercially available generally fall into one of two categories: 1) FDA-approved drugs that are in shortage; and 2) customized formulations for a particular patient.

A. Compounding Plays a Critical Role in Mitigating National Drug Shortages.

Compounders serve an important role in the nation's health care system by alleviating national shortages of drugs. A pharmacy may compound an FDA-approved drug that is not commercially available. 21 USC § 353a(b)(1)(D). A drug is not "commercially available" when 1) the drug has been discontinued and is no longer marketed; or 2) the drug product appears on the FDA's drug shortage list. *Id*; FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry* 5 (2018). There are many reasons a drug may be in shortage or discontinued: the drug is not profitable, the market is too small to continue operations, or a natural disaster damages the manufacturing capabilities of a pharmaceutical supplier. *C.f.*, Gegory Muraski, *UMD Experts: Pharma Facilities Sit in Path of Tornadoes, Other Weather Disasters*, Maryland Today (Sept. 6, 2023), https://today.umd.edu/umd-experts-pharma-facilities-sit-in-path-of-tornadoes-other-weather-disasters (estimating that 42% of FDA-registered manufacturing facilities are in high-risk areas for tornadoes).

Compounders have frequently mitigated national drug shortages. In November of 2022, the FDA announced an "acute shortage" of amoxicillin and "an urgent need to

increase the supply" of the medicine. FDA, *Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act* 1 (2022). Compounding pharmacies helped alleviate this shortage by compounding more of the life-saving medication. *See* Christine Blank, *Compounding Pharmacies to Help Alleviate Amoxicillin Shortage*, Managed Healthcare Executive (Nov. 21, 2022) https://www.managedhealthcareexecutive.com/view/compounding-pharmacies-to-help-alleviate-amoxicillin-shortage. Likewise, during the Covid pandemic of 2020, the FDA reported 86 drug shortages, including those related to ventilator use. James Broughel, *Allowing Compounding Pharmacies to Address Drug Shortages*, Mercatus Center at George Mason University (Nov. 1, 2021) https://www.mercatus.org/research/policy-briefs/allowing-compounding-pharmacies-address-drug-shortages. Compounders provided crucial stop gaps when the public health system was strained by these shortages. *Id*.

These are just some examples of how, during a drug shortage, compounding pharmacies play a critical role in protecting patient care. Without access to compounded alternatives, patients may face treatment delays, suboptimal substitutions, or complete lack of therapy—each of which can have serious health consequences. In this way, compounding serves as a safety net within the healthcare system, maintaining access to vital medications and alleviating the strain shortages place on hospitals, providers, and patients.

B. Patients Rely on Customized, Compounded Medications for Treatment.

Customized medications also play an important role in our nation's health care system. Many patients' needs can be met with commercial medications approved by the FDA. However, prescribers—in their professional judgment—may find that an FDA-approved commercial drug is inappropriate, or even dangerous, for a particular patient. In these situations, pharmacists can compound a customized formulation that meets a patient's specific medical treatment needs that no commercially available drug can otherwise provide.

The FDA, and Congress, recognized the importance of the need for customized, compounded drugs:

> Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product.

FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry* 2 (2018); *see also* FDA, *Compounding and the FDA: Questions and Answers*, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (Nov. 15, 2024).

Compounding can also be used to improve medication adherence. Patients with multiple conditions may need to take numerous medications, requiring "complex and burdensome regimens." Taylor Ozzy, *The Role of Pharmacy Compounding in Enhancing Medication Compliance*, 16 J. Applied Pharm. 2 (2024). The burden on the patient can be reduced by having multiple medications compounded into a single dosage form for easier management. *Id*. Further, medications can be compounded into extended-release formulations to "maintain therapeutic drug levels over an extended period." *Id*.

Accordingly, Section 503A permits pharmacies to compound drug products customized for "an identified individual patient based on the receipt of a valid prescription." 21 USC § 353a(a). Compounding allows pharmacists to prepare essential medications in the appropriate dosage forms and strengths tailored to patients' needs, ensuring effective care.

Customized compounded medications are essential to the healthcare system because they provide individualized therapies that mass-produced drugs cannot. By tailoring medications to the patient, pharmacists ensure that treatment is both safe and effective, improving adherence and outcomes.

II. CONGRESS REGULATES COMPOUNDING THROUGH A COMPLEX SET OF STATUTES, REGULATIONS, AND AGENCY GUIDANCE.

The FDCA regulates drug manufacturing, marketing, and distribution. *See* 21 U.S.C. §§ 301-397. As part of this regulatory process, Congress invested the FDA with sole power

to enforce the FDCA. 21 U.S.C. § 337(a); *Thompson*, 535 U.S. at 361. The FDCA does not require compounded drugs to go through the same processes required of new, commercially manufactured drugs. *See generally*, 21 U.S.C. §§ 353a, 353b; 21 CFR § 216.23(d). Instead, Congress and the FDA have created a comprehensive regulatory framework informed by decades of experience and knowledge.

When first enacted in 1938, the FDCA did not address drug compounding, only commercial manufacturing. In 1992, the FDA issued a Compliance Policy Guide stating that the FDA would permit pharmacists to compound drugs in limited quantities. *Thompson*, 535 U.S. at 362. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), converting some of the Guidance policies into law. 64 Fed. Reg. 1207 (Jan. 8, 1999) (Rescinding the Compliance Policy Guide). The FDAMA amended the FDCA by adding 21 U.S.C. § 353a, an exemption to the FDCA's new drug approval process known as "Section 503A." 64 Fed. Reg. 1208. Section 503A exempts compounded drugs from the FDCA's new drug approval requirements provided certain conditions are met.

These conditions require that the compounded drug must be pursuant to a prescription for an identified patient and compounded in limited quantity by a licensed pharmacist in a state licensed pharmacy.[1] § 353a. Importantly, the drug must be

[1] Physicians are also permitted to compound under Section 503A. *Id*.

compounded with bulk drug substances that "comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph."[2] *Id*. If a monograph does not exist, the drug components must be components of drugs approved by the FDA. § 353a(b)(a)(A)(i)(l).

Congress has maintained a vigilant presence over compounding procedures and their regulations. In 2012, Congress recognized the need for regulations related to large scale compounding operations and passed the Drug Quality and Security Act of 2013 ("DQSA"). 21 U.S.C. § 353b *et seq*.; *See also Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1043 (9th Cir. 2022). The DQSA created a regulatory framework for "outsourcing facilities," 21 U.S.C. § 353b(a), also known as "503B facilities." 503B facilities register with the FDA and can compound large quantities of drugs without a patient-specific prescription. *Id*.

Compounding of drugs by 503B outsourcing facilities is governed by an extensive framework of laws, regulations, and standards. These requirements include restrictions on the use of bulk drug substances to those on the FDA drug shortage list or the FDA's list of bulk drug substances for which there is a clinical need. *Id*. Additionally, other ingredients

[2] A monograph is a written document that contains the attributes of FDA approved medicines, such as identity, strength, purity, and performance. United States Pharmacopoeia Convention, *An Overview of USP Monographs*, https://www.usp.org/about/public-policy/overview-of-monographs, (last visited Oct. 6, 2025).

must comply with the standards of an United States Pharmacopeia or National Formulary monograph and cannot appear on the FDA's list of drugs that have been withdrawn. *Id*. 503B facilities must comply with current good manufacturing practices (CGMP), which are extensive guidelines and standards to ensure the quality, safety, and efficiency of pharmaceuticals. *See* 21 U.S.C. § 351. The FDA continues to regulate the ingredients and bulk substances used in outsourcing facilities. *See e.g.*, FDA, FDA-2018-D-1067, *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (2019).

Congress, in collaboration with the FDA, has established a multifaceted regulatory framework to oversee pharmacy compounding. This intricate system encompasses a range of regulations aimed at ensuring the FDA's role when enforcing the FDCA versus the state's role in regulating the practice of medicine and pharmacy as it related to compounding medications. Through legislative initiatives and FDA guidelines, such as DQSA, FDAMA, and the Pharmacy Compounding Compliance Policy Guide, Congress and the FDA work in tandem to regulate pharmacy and outsourcing facility compounding. By implementing stringent standards for facilities, ingredients, labeling, and more, this regulatory framework aims to uphold the integrity of compounded medications while safeguarding public health.

III. THIS COURT SHOULD NOT ALLOW THE PRIVATE ENFORCEMENT OF THE FDCA.

State laws can regulate the profession of pharmacy, but they cannot intrude on the federal regulations governing the ingredients and products of compounding. As discussed above, Congress enacted a regulatory framework to ensure patients have access to medications unavailable through commercial manufacturers. Part of that framework includes only permitting the FDA to enforce the FDCA—and its regulation of compounding. The district courts below were correct to rule that Appellants attempt to use state law to enforce the FDCA was preempted.

A. Federal Regulation of the Nation's Health Care System Constrains State Authority.

The Supreme Court has acknowledged that states have "a compelling interest in the practice of professions within their boundaries, and . . . they have broad power to establish standards for licensing practitioners and regulating the practice of professions." *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 625 (1995) (quoting *Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 (1975)). However, under the Constitution's Supremacy Clause, state laws that interfere with or are contrary to federal law are preempted, even if the state law is firmly within a state's acknowledged power. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Courts will not permit state laws that "exert an extraneous pull on [a regulatory] scheme established by Congress." *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 353 (2001). Preemption occurs "where the scheme of federal regulation is sufficiently comprehensive to make reasonable inference that Congress left no room for supplementary state regulation." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 713 (1985) (internal quotation marks omitted). State laws cannot stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Nor can state laws contravene a federal law's objective and policies. *Id*.

B. State Laws Permitting Private Enforcement of the FDCA are Preempted.

Congress left no room for state or private interference with the FDCA. The desire of Congress to preempt state and private involvement in the FDCA is evidenced by the restriction on the Act's enforcement. *See* 21 U.S.C. § 337(a). Section 337(a) provides that "[a]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United Staes." The FDA uses this authority to "achieve a somewhat delicate balance of statutory objectives" and priorities. *Buckman*, 531 U.S. at 348.

Courts have consistently limited FDCA enforcement to the federal government. *See DiCroce v. McNeil Nutritionals, LLC,* 82 F.4th 35, 41 (1st Cir. 2023) (holding that violations of Massachusetts law prohibiting deceptive trade practices and false advertising

were preempted by FDCA); *Nexus Pharm., Inc.*, 48 F.4th at 1049-50 (holding that state laws prohibiting the sale of compounded, unapproved drugs were preempted by FDCA); *Loreto v. Procter & Gamble Co.*, 515 Fed.Appx. 576, 579 (6th Cir. 2013) (holding that action for mislabeled products was preempted by the FDCA); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2nd Cir. 1997) (upholding dismissal of Lanham Act and state unfair trade practice claims because plaintiff's "true goal is to privately enforce alleged violations of the FDCA.").

Courts have also consistently blocked efforts by plaintiffs to evade Section 337(a) by dressing their FDCA claims as state law actions. In *Buckman*, the Court held that a state tort law relying on a fraud claim which "exist[ed] solely by virtue of the FDCA disclosure requirements" was preempted. 531 U.S. at 353. The Second Circuit acknowledged state law claims are invalid when they attempt to "privately enforce alleged violations of the FDCA." *PDK Labs, Inc.*, 103 F.3d at 1113. The Sixth Circuit also recognized that the desire of Congress to limit enforcement of the FDCA "is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." *Loreto*, 515 Fed.Appx. at 579.

Including Section 337(a) in the FDCA would be meaningless if plaintiffs can use state law claims to enforce or invalidate provisions of the FDCA. Here, Appellant is attempting the same end run around Section 337(a) by using state law claims that are premised on the FDCA. This is the same de-facto private enforcement of the FDCA that

has been rejected by most appellate courts. This Court should follow that precedent and uphold the desire of Congress to prevent private enforcement of the FDCA.

C. Permitting Private Enforcement of the FDCA Poses Serious Risks to the Nation's Health Care System.

Limiting private enforcement of the FDCA to the FDA protects public health by ensuring access to compounded medications. Without the legal protections afforded by Section 503A—and its consistent enforcement by the FDA—pharmaceutical manufacturers could use state law claims to bar compounders from preparing medications during national shortages. Likewise, lawsuits from pharmaceutical manufacturers could prevent pharmacies from providing essential therapies when commercial products are inadequate or unavailable. To deliver services to patients, compounders rely upon the FDA's consistent guidance and enforcement positions regarding the FDCA. This Court should not allow private actors to upset the FDA's "delicate balance of statutory objectives" and priorities. *See Buckman* 531 U.S. at 348.

All compounded drugs lack FDA approval by their nature; however, the FDCA permits the compounding of drugs pursuant to the exceptions in Sections 503A and 503B. Under the theories advanced by Appellant, pharmaceutical companies could bring lawsuits under state law against compounding pharmacies even if they comply with Sections 503A. This would be disastrous for public health if compounding pharmacies and outsourcing facilities were forced to stop compounding drugs during a national shortage. Likewise,

patients who rely upon customized medications face the prospect of being deprived of important drug therapies.

If this Court reverses the three district courts below, the ruling will become a potent weapon for pharmaceutical manufacturers who can now wield enforcement action previously reserved to the FDA. Courts recognize the burden litigation can place on defendants in civil actions. *C.f., Trevino v. Iden*, 79 F.4th 524, 530 (5th Cir. 2023). "Civil litigation in the federal courts is often an expensive affair, and each party, win or lose, generally bears many of its own litigation expenses, including attorney's fees that are subject to the so-called American Rule." *City of San Antonio, Texas v. Hotels.com, L. P.*, 593 U.S. 330, 332 (2021). These burdens are particularly troublesome for compounding pharmacies which are usually small businesses. *See* Donald R. Mattison et al., eds., *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use* 30 (The National Academies Press 2020) ("Compounding, particularly in smaller, independent community pharmacies, remains an important component of pharmacy practice"). Thus, faced with significant legal expenses, many pharmacies are likely to forgo compounding drugs in shortage or customizing medications.

Congress protected states' compelling interest in regulating the practice of professions when it required 503A compounding to occur in state licensed pharmacies by state licensed pharmacists. Any further effort by state laws that interfere with the FDCA

should be viewed with suspicion. Accordingly, this Court should leave the authority to enforce the FDCA where Congress intended: with the FDA.

CONCLUSION

Congress has enacted a complex regulatory structure to balance the important need for compounded drugs while ensuring the safety of the public. As part of that balance, Congress limited enforcement of the FDCA through Section 337(a). The attempt to circumvent Section 337(a) by bringing claims for violations of the FDCA under state law claims troubles amicus and its members. Accordingly, the APC joins Appellees in urging the Court to affirm the district courts' decisions.

Dated: October 6th, 2025
Scottsdale, Arizona.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7) because the brief contains 5,050 words, uses a monospaced typeface font and contains 746 lines of text, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the appellate CM/ECF system on October 6th, 2025.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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