UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.* Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	Case No. 4:24-CV-824-SDJ
AMERICAN CLINICAL LABORATORIES, ASSOCIATION, *et al.* Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	Case No. 4:24-CV-479-SDJ

MOTION FOR SUMMARY JUDGMENT AND INCORPORATED MEMORANDUM OF POINTS AND AUTHORITIES BY PLAINTIFFS ASSOCIATION FOR MOLECULAR PATHOLOGY AND DR. MICHAEL LAPOSATA

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INTRODUCTION

This case challenges a historically unprecedented power grab that will jeopardize the health of hundreds of millions of Americans and—by FDA's own admission—impose tens of billions of dollars in new regulatory mandates by subjecting tens of thousands of laboratory developed test procedures ("LDTs") to FDA regulation for the first time. As a direct result of FDA's overreach, thousands of laboratory professionals—including world-renowned pathologist Michael Laposata, M.D., Ph.D. and the many other doctors and doctoral scientists who belong to Plaintiff Association for Molecular Pathology ("AMP")—now face the risk of arrest and prosecution for helping to diagnose and treat patients using the same kinds of robustly validated laboratory procedures they lawfully have developed and used to serve patients for decades. Indeed, the challenged Final Rule declares their practice of medicine "illegal" and repeatedly asserts that FDA not only can "pursue enforcement action … at any time" but "intends to do so." AR10.

That calculated threat will have precisely the chilling effect FDA intended, with disastrous results for Plaintiffs and patients alike. Given the risk of prosecution and admittedly "prohibitive" cost of compliance, AR414, the Final Rule already has led many AMP members to suspend work on new LDTs that could be used to help diagnose serious disease and inform treatment options. Smaller laboratories concededly will be forced "to exit the market, reduce operations, sell the business, be subject to acquisitions by larger firms or not enter the market," AR414, leading to job losses in the pathology profession, causing future doctors to choose other fields of practice, exacerbating the current shortage of pathologists in the U.S., and decreasing access to healthcare services in rural, isolated, and poor communities. Innovation will grind to a halt as laboratory services become "concentrated in a few large laboratories." AR285. And patients will pay the price, not only because the Final Rule's massive compliance costs likely will lead to price increases for laboratory procedures, *id*., but because many patients will face prolonged suffering—and some

will die—from conditions that could have been prevented, diagnosed, and/or treated sooner or better by LDTs that will be discontinued or never be developed. It is imperative that this Court act to prevent the catastrophic consequences that FDA's patently unlawful Final Rule will unleash.

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For nearly 50 years, Congress has distinguished between (1) mass-produced, tangible devices that are commercially distributed for third-party use (*e.g.*, implantable devices, surgical tools, and imaging machines) and (2) laboratory services, like the custom LDTs that highly trained healthcare professionals develop and perform within a federally licensed or accredited laboratory (*e.g.*, the specific sequence of processes used to detect a disease-associated biomarker).

The former generally are subject to FDA regulation under the federal Food, Drug, and Cosmetic Act ("FDCA"), which Congress augmented in 1976 after thousands of women were injured by an implantable intrauterine contraceptive device during what became known as the Dalkon Shield Crisis. To prevent similar harms from recurring, the 1976 Medical Device Amendments ("MDA") generally subject ***tangible medical devices*** to FDA's premarket review before they can be released "into interstate commerce for commercial distribution," 21 U.S.C. § 360(k), and to postmarket controls. *Infra* at 6-8. Not surprisingly, these requirements are strict, inflexible, and designed for mass-manufactured commodities that are distributed by the thousands or millions. They also are costly to fulfill, heavily bureaucratized, and plagued by delays.

In 1988, by contrast, Congress confirmed that ***intangible laboratory procedures*** are outside the MDA's scope. Though it declared that "the need for accuracy and reliability of [laboratory] test results is obvious" and found that the "present system for regulating the vast clinical laboratory industry … cannot begin to provide the necessary assurances of quality," S. REP. No. 100-561, at 3 (1988)—a statement that would have made no sense if Congress already

had subjected laboratory procedures to the MDA in order to provide such assurances—Congress chose ***not*** to subject LDTs to the FDCA. It instead passed the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Building on a 1967 predecessor statute that principally had been administered by what is now the Centers for Medicare & Medicaid Services ("CMS")—***not FDA***—CLIA amended the Public Health Service Act ("PHSA")—***not the FDCA***—to establish a uniform system of federal licensure for each laboratory that "examin[es] materials derived from the human body for the purpose of … diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 U.S.C § 263a(a). It ordered the issuance of new "standards to assure consistent performance … of ***valid and reliable*** laboratory examinations and other procedures." *Id*. § 263a(f)(1).[1] It required laboratories to implement "a quality assurance and quality control program [that is] adequate and appropriate for [ensuring] the ***validity and reliability*** of the[ir] examinations and other procedures." *Id*. § 263a(f)(1)(A). Unlike the FDCA, CLIA set strict qualification requirements for the personnel who develop and perform these procedures, *id*. § 263a(f)(1)(C); ordered laboratories to pass routine "proficiency testing" in order to ensure "acceptable performance … for all examinations and procedures," *id*. §§ 263a(f)(1)(D)-(f)(3)(B); and even gave CMS authority to impose any "other requirements [it] determines necessary to assure consistent performance … of ***accurate and reliable*** laboratory examinations and procedures." *Id*. § 263a(f)(1)(E). Finally, CLIA recognized the dynamic clinical context in which laboratories operate by directing CMS to use "flexibility" when "developing the standards to be issued." *Id*. § 263a(f)(2).

[1] Unless otherwise noted, all emphases are added.

Some 40 years after Congress chose to subject LDTs to CLIA's carefully tailored, laboratory-specific regulations—rather than the FDCA's requirements for mass-produced, commercially distributed devices—FDA's unelected bureaucrats now claim Congress made the wrong choice. And after 20 years of trying and failing to convince Congress to grant FDA regulatory authority over LDTs, *see infra* at 16-17, the Agency now has seized that authority for itself by issuing a Final Rule that will subject LDTs to costly, duplicative, and highly intrusive FDA regulation for the first time in American history. AR1-160.

Though FDA's Final Rule grudgingly admits that CLIA charged CMS with regulatory authority over laboratory procedures, it relies on admittedly unverified and "largely anecdotal" evidence, AR36, to assert that "CLIA does not provide sufficient assurances of safety and effectiveness for … LDTs." AR131. While Congress required "proficiency testing" to ensure "acceptable performance … for all examinations and procedures" laboratories perform, 42 U.S.C. §§ 263a(f)(1)(D)-(f)(3)(B), the Final Rule declares that "proficiency testing data, as standalone or comparative results, do not support [LDT] validation and performance." AR38. And despite conceding that "under CLIA, laboratories should already have some processes in place for detecting problems with their [LDTs]," AR22—*i.e.*, the very "quality assurance and quality control program[s]" CLIA ordered, 42 U.S.C. § 263a(f)(1)(A)—the Final Rule assails those programs simply because CMS's regulations do not precisely mirror FDA's device requirements. AR24.

FDA's explicit rejection of Congress's policy choices is neither appropriate nor lawful. "After all, agencies have only those powers given to them by Congress and enabling legislation is generally not an open book to which the agency may add pages and change the plot line." *Career Colls. & Sch. of Tex. v. U.S. Dept. of Educ.*, 98 F.4th 220, 243 (5th Cir. 2024) (quotations omitted). That principle carries added force in cases like this one, where an agency seeks to impose vast new

regulatory mandates by belatedly asserting power under decades-old legislation—especially when, as here, Congress repeatedly has considered, and repeatedly declined to grant, the asserted powers in the interim. *West Virginia v. EPA*, 597 U.S. 697, 724-25 (2022) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy, we typically greet its announcement with a measure of skepticism.") (citing *Util. Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014); internal quotation omitted).

FDA's rejection of these principles cannot stand. Like everyone else, the Agency is free to express disagreement with Congress's choices and continue lobbying Congress for the regulatory authority it craves. But it cannot lawfully seize power by the stroke of its own pen, and its violation of these fundamental precepts of administrative law cries out for judicial intervention. The Final Rule should be vacated and Defendants promptly enjoined from taking any action to enforce it.

STATEMENT OF THE ISSUE

Does FDA's Final Rule titled *Medical Devices; Laboratory Developed Tests*, AR1-160, violate the Administrative Procedure Act by subjecting LDTs to FDA regulation as "devices"?

LEGAL BACKGROUND AND STATEMENT OF UNDISPUTED FACTS

A. The FDCA's Regulatory Framework for Medical Devices

1. The 1938 FDCA and 1976 Medical Device Amendments

Congress first authorized FDA to regulate "device[s]" in 1938 (the "1938 Act"), Pub. L. No. 75-717, 52 Stat. 1040, and defined those products as tangible "instruments, apparatus[es], and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man … or (2) to affect the structure or any function of the body." *Id.* § 201(h), 52 Stat. at 1041. Unlike the 1938 Act's companion provisions for "drugs," however, Congress did not authorize FDA premarket review of such devices, much less require premarket approval—only to inspect manufacturing facilities,

id. § 704, and take postmarket enforcement action against adulterated or misbranded devices. *Id*. §§ 301-304; *cf. id*. § 505(a), 52 Stat. at 1052 (requiring premarket approval prior for drugs).

That changed in 1976, when Congress responded to the Dalkon Shield Crisis by granting FDA authority to subject devices to premarket review and postmarket controls for the first time. Pub. L. No. 94-295, 90 Stat. 539. Yet even as the MDA broadened the "device" definition to include ***the individual reagents*** used in many test procedures, it continued to make clear that only tangible goods qualified: It defined a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article … intended for use in the diagnosis[,] cure, mitigation, treatment, or prevention of disease ... and which is not dependent upon being metabolized." 21 U.S.C. § 321(h)(1) (enumerations omitted). As detailed *infra*, the MDA then required premarket review for ***certain*** such devices in ***certain*** circumstances.

2. Premarket Requirements for Commercially Distributed Devices

Before most new devices can be "introduc[ed] or deliver[ed] for introduction into interstate commerce ***for commercial distribution***," the MDA requires FDA to issue (1) a clearance based on substantial equivalence (a "510(k) clearance"), (2) a de novo classification, or (3) a premarket approval ("PMA"). *Id*. § 360(k); *id*. § 360c(c)(2)(C)(ii) (classification based on "introduction into interstate commerce ***for commercial distribution*** before May 28, 1976"); *id*. § 360c(f)(1) (virtually identical); *id*. § 360e(b)(1) (same). The required form of premarket review in turn depends on the device's risk classification. *Id*. § 360c(a)(1). Class I devices are considered low risk, *id*. § 360c(a)(1)(A); Class II devices are moderate risk, *id*. § 360c(a)(1)(B); and Class III devices are the highest risk and require a PMA. *Id*. § 360c(a)(1)(C).

To obtain 510(k) clearance for lower-risk devices, applicants must submit a notification to FDA establishing that the proposed device is "substantially equivalent" to a previously marketed

predicate device—meaning they have the same intended use and either (1) share the same technological features or (2) differ in ways that do not raise different safety and effectiveness concerns. *Id*. § 360c(i). FDA typically requires non-clinical studies for this purpose and sometimes requires pre-clinical and/or clinical studies. 21 C.F.R. § 807.87(f)-(g). If FDA finds the proposed device is "not substantially equivalent" to its predicate, it is placed in Class III and the applicant must seek either de novo classification or pursue a full PMA. 21 U.S.C. § 360c(f).

De novo classification requests and PMAs are onerous. The former often require data from preclinical studies and/or human clinical studies and an analysis of the device's expected benefit-risk profile. *Id*. § 360c(a)(2). If FDA denies a de novo classification request on the merits, a PMA is required. *Id.* § 360c(f). That is the most burdensome premarket pathway—typically requiring both preclinical and clinical studies; detailed information regarding the design of the device and all its components, its manufacturing process, and its proposed labeling; and a benefit-risk analysis. *Id*. §§ 360e(c)(1), 360c(a)(2). FDA also typically conducts preapproval inspections of the manufacturer and clinical study sites before PMA approval. 21 C.F.R. § 814.44(e)(1)(iii).

Regardless of pathway, conducting the necessary studies and preparing these submissions is costly. FDA itself under-estimates that preparing and submitting a single submission costs up to $530,410 for a 510(k) or de novo application and $9.29 million for a PMA application. AR378-386; *but see* J. Makower *et al*., *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, at 7 (2010) (estimating the average cost to bring a product from concept to clearance is $31 million for a 510(k) and $94 million for a PMA). The total cost of subjecting LDTs to premarket review thus will be extraordinary: Once the Final Rule is fully effective, FDA estimates that complying with the MDA premarket requirements alone will

cost up to ***$4.21 billion per year***—though that substantially underestimates the true cost for the reasons detailed below. AR387 (derived from Table 36); AR404; *but see infra* at 20-21, 39-40.

3. Postmarket Requirements for Commercially Distributed Devices

Once 510(k) clearance or de novo classification is granted, any "change or modification … that could significantly affect the safety or effectiveness of the device" requires a new 510(k) or de novo application. 21 C.F.R. § 807.81(a)(3). A wide array of changes, including many that commonly are made in laboratories, trigger these requirements. AR2109; *see also* AR20 & n.36. Once FDA has approved a PMA, its sponsor must submit a PMA supplement before making "any change … that affects safety or effectiveness" regardless of its significance and a new PMA may be required for significant changes. 21 U.S.C. § 360e(d)(5)(B)(i).

FDA also subjects most devices to postmarket controls. "General controls" include requirements for registration and listing; malfunction and adverse event reporting (commonly called "medical device reporting" or "MDR"); correction, removal, and recall; labeling; and compliance with FDA's quality system regulation ("QSR"). 21 C.F.R. Parts 801, 803, 806, 807, 820. "Special controls" are tailored to specific device types and can include performance standards, postmarket surveillance, patient registries, data requirements, and compliance with other guidelines. In the LDT context, complying with these requirements will require extraordinary expense: FDA originally estimated that subjecting LDTs to these requirements would require up to ***$450 million in one-time costs*** and ***$2.025 billion in annual recurring costs***, AR2030 (derived from Table 31), though—through the sleight of hand we detail *infra* at 20-21, 39-40—it later reduced those estimates to up to ***$85 million in one-time costs*** and ***$327 million in annual recurring costs***. *See* AR386-87 (derived from Table 36).

4. The Practice-of-Medicine Exemption

Finally, the FDCA makes clear that FDA may not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396; *see also Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 395 (D.C. Cir. 2021) ("Section 396 constrains the FDA's authority by prohibiting it from regulating the practice of medicine."). Consistent with this broad "practice-of-medicine exemption," the MDA specifically exempts from the statute's core device requirements any "practitioners licensed by law to prescribe or administer … devices and who manufacture, prepare, propagate, compound, or process … devices solely for use in the course of their professional practice." 21 U.S.C. § 360(g)(2).

B. CLIA's Regulatory Framework for LDTs

Since 1967, LDTs—which are neither tangible goods nor commercially distributed for third-party use, but instead are multi-step, protocol-based procedures developed and performed by highly trained professionals within a laboratory—have been subject to a distinct regulatory regime: CLIA, which balances stringent quality and performance standards with the "flexibility" laboratories need to meet and adapt to urgent or unique patient needs. 42 U.S.C. § 263a(f)(2).

1. The 1967 CLIA and its 1988 Amendments

Though FDA has regulated devices since the 1938 Act, Congress did not authorize federal regulation of laboratory processes until it passed CLIA in 1967. Pub. L. No. 90-174, § 5(a), 81 Stat. 536. That law barred most laboratories from "solicit[ing] or accept[ing] in interstate commerce … any specimen for laboratory examination or other laboratory procedures, unless there

is in effect a [federal] license." *Id*.[2] Licensing in turn required HHS to find "that such laboratory will be operated in accordance with standards found necessary by [HHS]," *id*. at 536, and the 1967 CLIA required HHS to issue standards for quality control; records, equipment, and facilities; personnel qualifications; and proficiency testing. *Id*. at 537. HHS delegated these responsibilities to CMS's predecessor, the Health Care Financing Administration.

By 1988, Congress found that CLIA's initial framework was failing because it "offers a patchwork of inconsistent and overlapping standards that leaves some laboratories trying to comply with multiple layers of regulation … while others are free of any regulatory oversight." S. REP. No. 100-561, at 3. But instead of transferring laboratory oversight to FDA, Congress chose to strengthen CLIA. ***First***, it broadened CMS's authority to require certification before laboratories "solicit or accept" any specimen for examination, even if it never crosses state lines. 42 U.S.C. § 263a(b). ***Second***, it broadened CMS's mandate to "assure consistent performance … of ***valid and reliable*** laboratory examinations and other procedures," *id*. § 263a(f)(1), and ordered CMS to enhance its quality control standards to ensure they are "appropriate ***for the validity and reliability*** of the laboratory examinations." *Id*. § 263a(f)(1)(A). ***Finally***, the 1988 CLIA ordered CMS to impose new personnel qualifications based on "the type of examinations and procedures being performed," *id*. § 263a(f)(1)(C); required enhanced proficiency testing, *id.* § 263a(f)(3); and empowered CMS to impose any "other requirements [it] determines necessary to assure … ***accurate and reliable*** laboratory examinations and procedures." *Id*. § 263a(f)(1)(E).

[2] CLIA defined "interstate commerce" as "trade, traffic, commerce, transportation, transmission, or communication ***between any State*** … ***and any place outside thereof***." 81 Stat. at 536.

2. CMS's Implementation of the 1988 CLIA

CMS's post-1988 CLIA regulations divide laboratory procedures into three categories based on complexity—waived, moderate, and high—and that categorization dictates the applicable requirements. 42 C.F.R. § 493.25. The Final Rule effectively defines LDTs as high complexity procedures, AR4, so we focus on those requirements here.

a. Certification of Laboratories Performing LDTs

Laboratories seeking to develop and perform LDTs must first apply to CMS or to an HHS-approved accreditation program for a "certificate of registration" allowing them to operate. 42 C.F.R. § 493.25(a); *id*. § 493.45(a)(1).[3] This application must "[d]escribe the characteristics of the laboratory operation and the examinations and other test procedures performed," *id*. § 493.43(c), and applicants must agree to "make [all] records available … to HHS," *id*. § 493.43(d), and then "[b]e inspected" before the registration expires. *Id*. §§ 493.45(c)(2)-(e)(1). If the laboratory passes inspection, CMS issues a "certificate of compliance" authorizing it to perform the particular LDTs and other procedures reviewed during the application process. *Id*. § 493.49(a). Once certified, laboratories must notify HHS of "any deletions or changes in test methodologies for any test or examination," *id*. § 493.51(c), and "permit announced or unannounced inspections" to "determine compliance." *Id*. § 493.49(b)(2)(i)-(iv). Noncompliance can lead to revocation of the laboratory's certificate and denial of reimbursement under Medicare and Medicaid. *Id*. § 493.49(c). These certificates are valid for up to two years, *id*. § 493.49(d), and laboratories must seek renewal at least nine months before expiration. *Id*. § 493.49(g).

[3] Third-party accreditation standards must be "equal to, or more stringent than" CMS certification, so we focus only on the latter—which create the proverbial "floor." 42 C.F.R. § 493.551(a).

Taken together, these requirements thereby mandate that, across a certification or accreditation cycle, CMS or the HHS-approved accrediting organization must: (1) evaluate and certify every LDT that is developed and performed by a given laboratory, any changes made to any previously certified LDT, and any new LDTs that have been developed and are being performed since initial certification; (2) have access to all records relating to each LDT that has been developed or modified; and (3) regularly inspect every laboratory that performs LDTs.

b. Quality Assurance and Quality Control Requirements for LDTs

CMS regulations also establish strict requirements to ensure the accuracy, quality, validity, and reliability of every laboratory procedure performed, including each individual LDT. 42 C.F.R. Subpart K (42 C.F.R. §§ 493.1200-1299). These requirements obligate every certified laboratory to "establish and maintain written policies and procedures" for a quality system, *id*. § 493.1200(a), and to engage in "***continuous improvement of the laboratory's performance and services***." *Id*. § 493.1200(b). In contrast to FDA's quality requirements—which are designed to keep mass-marketed devices static and then monitor them for adverse events after launch—CLIA's regulations thus seek to ensure that laboratories continually improve their test procedures.

To do so, CMS's quality regulations ***first*** ensure that the processes and methods for every LDT (whether new or modified) are documented, followed, and monitored. *Id*. § 493.1251(a). These protocols must detail each LDT's requirements for the "[s]tep-by-step performance of the procedure, including test calculations and interpretation of results," the "[p]reparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing," the "[l]imitations in the test methodology, including interfering substances," "[p]ertinent literature references" to support the LDT, and the process for "reporting patient results including … the protocol for reporting imminently life-threatening results, or panic, or alert values." *Id*.

§ 493.1251(b). Any "changes in procedures must be approved, signed, and dated by the current laboratory director before use." *Id*. § 493.1251(d).

Second, CMS's regulations expressly authorize laboratories to both "modif[y] an FDA-cleared or approved test system" and "introduce[] a test system not subject to FDA clearance or approval (including methods developed in-house [*i.e*., an LDT]," *id*. § 493.1253—provisos that would make no sense if LDTs were (and since 1976 have been) subject to mandatory FDA premarket review under the MDA. ***Finally***, CMS's quality regulations provide detailed quality standards for particular types of procedures and establish protocols for identifying and correcting errors. *Id*. §§ 493.1261-78. These provisions not only contemplate but require the prompt implementation of corrective actions—including modifications to established processes and procedures—not, in contrast to the MDA, the mere disclosure of issues to regulatory authorities.

c. Proficiency Testing Requirements

CMS's regulations further subject any laboratory performing LDTs to "proficiency testing … for each specialty, subspecialty, and analyte or test in which the laboratory is certified." 42 C.F.R. § 493.803(a). Proficiency testing entails the regular and rigorous evaluation of laboratory performance by an HHS-approved proficiency testing provider. 42 U.S.C. § 263a(f)(3)(A). Those providers must regularly provide each certified laboratory with samples that "mimic actual patient specimens" and have been prepared "for each specialty, subspecialty, and analyte or test for which [the laboratory] provides testing." 42 C.F.R. § 493.901(c)(1)(ii). The laboratory "must examine or test" samples "in the same manner as it tests patient specimens," *id*. § 493.801(b), using the same "personnel who routinely perform the testing [and] the laboratory's routine methods." *Id*. § 493.801(b)(1). The proficiency testing provider then must "evaluate and score the testing results,

and identify performance problems," *id*. §§ 493.901(b), 493.901(c)(2), and report the laboratory's performance to both HHS and the laboratory. *Id*. §§ 493.901(a)(1), 493.901(b).

Laboratories that fail proficiency testing face severe consequences. CMS not only can bar them from performing a particular LDT or type of LDT, but can suspend, limit, or revoke their certification; bar them from receiving federal payments; impose civil penalties; and initiate civil or criminal enforcement actions. *Id*. § 493.803 (requiring successful completion); *id*. §§ 493.1800-50 (penalties). Importantly, there is no comparable system for ongoing, proactive performance testing of FDA-regulated devices; proficiency testing is unique to laboratory procedures.

d. Personnel Requirements

Finally, CLIA imposes strict requirements for personnel performing procedures in high-complexity laboratories. 42 U.S.C. § 263a(f)(1)(C). ***First***, each laboratory must have a "laboratory director" who is (1) a Board-certified doctor licensed to practice medicine; (2) a doctor licensed to practice medicine with extensive laboratory training or experience overseeing high complexity testing; or (3) a chemical, physical, biological, or clinical laboratory doctoral scientist certified by an HHS-approved Board. *Id*. § 493.1443(b)(1)-(3). These highly qualified doctors and Board-certified doctoral scientists in turn are charged with both legal and practical responsibility for everything that happens within the laboratory. *Id.* § 493.1445(e) (detailing these responsibilities).

Second, laboratories must employ a "technical supervisor" who is responsible for selecting appropriate test methods and procedures and ensuring "the precision and accuracy of each test and test system." *Id*. § 493.1451(b)(1)-(2). They also are responsible for resolving and remediating problems, *id*. § 493.1451(b)(5), assuring employee training and education, *id*. § 493.1451(b)(7), and evaluating personnel competency. *Id*. § 493.1451(b)(8). Depending on the particular specialties and subspecialties of services performed in the laboratory, they must hold either an

M.D. or Ph.D. and be (1) Board-certified or (2) have fulfilled a combination of educational, experiential, and training criteria. *Id*. § 493.1449.

Third, laboratories performing LDTs must have a "clinical consultant" who is "qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care." *Id*. § 493.1455; *see id*. 493.1457(a)-(d). The clinical consultant must be a licensed doctor and meet the additional qualifications of a laboratory director. *Id*. § 493.1455. As with proficiency testing, these personnel requirements are unique to the laboratory context; medical device manufacturers need not meet any such criteria. *Cf.* 21 C.F.R. § 820.25.

C. FDA's Belated Assertion of Authority Over LDTs

For decades after the MDA's 1976 enactment, FDA did not formally express its belief that LDTs might be subject to the Agency's device authorities and it took no action against high-complexity laboratories developing LDTs under CLIA. Even as Congress recognized in 1988 that federal laboratory regulation was falling short, it did not identify FDA as a source of laboratory regulation—finding instead that laboratories were regulated only "under two programs. [CLIA] requires that all laboratories which send specimens in interstate commerce be subject to regulation by the Federal government. [And] the Social Security Act requires that laboratories serving as providers in the Medicare program be subject to quality standards established by [HHS]." H.R. REP. No. 100-899, at 11 (1988). Needless to say, Congress's failure to identify FDA as an existing (or even potential) regulator of laboratory procedures would have been a puzzling omission if the MDA actually had charged FDA with authority for regulating LDTs more than a decade earlier.

Indeed, even FDA admits that it did not formally assert that it might have authority to regulate LDTs as devices until it issued a tangentially related final rule in November 1997—21 years after the MDA's passage and nine years after the 1988 CLIA. AR7132 (citing FDA, Analyte

Specific Reagents—Final Rule (the "ASR Rule"), 62 Fed. Reg. 62,243 (1997)). Yet even then, FDA's assertion of possible regulatory authority over LDTs was both unsupported by any statutory analysis and directly at odds with its current position. That rule rejected suggestions that analyte specific reagents ("ASR") should be regulated as high-risk devices simply because they can be used in connection with the performance of LDTs. *Id*. at 62,249. Though the ASR Rule passingly asserted FDA's "belie[f] that clinical laboratories that develop [LDTs] are acting as manufacturers of medical devices," *id*., it concluded "that CLIA regulated laboratories … have demonstrated expertise and ability to use ASR's in test procedures and analyses" and found both "that ***the use of in-house developed tests [i.e., LDTs] has contributed to enhanced standards of medical care*** in many circumstances and that significant regulatory changes in this area ***could have negative effects on the public health***." *Id*. It also distinguished commercially distributed ASRs at issue from the LDTs in connection with which they can be used, noting that FDA's regulatory authority was focused on "the classification and regulation of ASR's ***that move in commerce***, not tests developed ***in-house by clinical laboratories … and used exclusively by that laboratory***." *Id*.

But dubious assertions of authority often lead regulators down a slippery slope. And despite its modest beginning and embedded limitations, FDA's bald assertion that LDTs might be subject to regulation as medical devices quickly assumed a life of its own. Within a year of the ASR Rule, FDA had declared that any LDT "***using an ASR*** falls within the definition of device" regardless of "whether the [LDT itself] is in interstate commerce ***for commercial distribution***." AR2819-20.

D. Congress's Refusals to Grant FDA Regulatory Authority Over LDTs

Even then, however, FDA took no enforcement action against LDTs for nearly another decade. That changed in the mid-2000's—some ***three decades*** after the 1976 MDA's enactment and nearly ***two decades*** after the 1988 CLIA—when FDA informed certain laboratories "that their

in-house tests were medical devices and that they must comply with the [FDCA] or stop offering their tests." Citizen Petition, Docket No. FDA-2006-P-0149, at 3 (Sept. 28, 2006). Many of the LDTs FDA first targeted involved processes for analyzing genetic information—which of course has come to play a critical role in modern medicine. That quickly got Congress's attention, and since then Congress repeatedly has considered and rejected an array of bills that would do what neither CLIA nor the FDCA has ever done: grant FDA authority to regulate LDTs.

In 2007, for instance, Congress considered—but failed to pass—legislation that would have amended the FDCA to provide expressly that "[a]ny [LDT] shall be deemed to be a device under [FDCA] section 201(h)," Laboratory Test Improvement Act, S. 736, 110th Cong. § 3 (2007), and to subject LDTs to the FDCA's premarket review requirements. *Id*. §§ 5-7. And in 2020, Congress took up legislation that likewise would have subjected LDTs to FDA's regulatory authority under the FDCA—this time under a new regulatory category called "in vitro clinical tests." *See* Verifying Accurate Leading-Edge IVCT Development Act, H.R. 6102, 116th Cong. § 3 (2020). It too failed to pass, as have subsequent versions of that bill that were introduced in 2021 (H.R. 4128, 117th Cong.), 2022 (S. 4348, 117th Cong.), and 2023 (H.R. 2369, 118th Cong.). All told, Congress since 2006 now has considered at least a dozen separate bills addressing FDA's authority over LDTs and—despite decades of intense lobbying by FDA—has refused to pass a single one. *See* Compl. ¶¶ 78-89 (detailing the complete legislative record).

E. Defendants' Continued Defiance

FDA's increasingly strident approach to LDT regulation not only has faced resistance in Congress; even HHS previously condemned FDA's overreach. In 2020, FDA publicly threatened laboratories that had been performing COVID-related LDTs following the Agency's ill-fated decision to authorize a flawed COVID test kit developed by the Centers for Disease Control and

Prevention ("CDC") in its CLIA-***non***compliant facilities. *See* Compl. Exh. 6 (the "Charrow Memorandum"), at 1-2 (June 22, 2020). In response, HHS's General Counsel concluded that while ***in vitro reagents*** are devices, that "does not necessarily lead to the conclusion that ***LDTs*** fall within FDA's jurisdiction." *Id*. at 6. To the contrary, it found that "even assuming that LDTs are medical devices" and that this dubious interpretation might be upheld under the now-overruled doctrine of "*Chevron* deference," *id*., LDTs do not meet the additional preconditions to the MDA's application and subjecting LDTs to the MDA would be "inconsistent with [CMS's] CLIA rule[s] and the legislative history surrounding the 1988 amendments." *See id*. at 8-13. In a transparently political decision, however, Defendant Becerra revoked the Charrow Memo in 2021—pointedly emphasizing that it reflected "a policy established during the previous administration." AR8186.

1. The Proposed Rule

On October 3, 2023, FDA formally proposed to begin regulating LDTs by amending its current definition of "in vitro diagnostic product" ("IVD") to include all "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions … ***including when the manufacturer of these products is a laboratory.***" AR7125-26. The Preamble explained that this new language "reflect[ed] FDA's longstanding view that LDTs are devices [because] the [FDCA] does not differentiate between entities manufacturing the device. In other words, whether an IVD is a device does not depend on where or by whom the IVD is manufactured." AR7134. The Proposed Rule further asserted that developing and performing an LDT is tantamount to "manufacturing" a new device and made clear that FDA intended to subject LDTs to the FDCA's full panoply of pre- and postmarket requirements. AR7135-36.

The Proposed Rule sought to justify this approach by asserting that FDA's concerns with LDTs "have grown in recent years" and claiming "the situation is getting worse." AR7127. But to

support those dire claims, the Proposed Rule relied almost entirely on anecdotal evidence, including unverified news reports; litigation "complaints, adverse event reports, and other allegations identifying problems with [LDTs]" which FDA conceded it "ha[d] not confirmed," AR7127-28 & n.10; a handful of unreliable, small-scale studies purporting to show "high variability in performance" among certain LDTs—including one from which several of its original co-authors withdrew because of its flawed methods and data misrepresentation, *see* Comment of AMP, FDA2177-6150 at 12-14 (discussing these issues); and an undisclosed number of submissions for emergency-use COVID tests—hardly a representative context—that, just like the CDC's ***FDA-cleared*** COVID test, appeared to perform poorly. AR7128.

Despite this wafer-thin justification, the accompanying regulatory impact analysis made clear that FDA's proposal would have a staggering economic impact. It estimated the Proposed Rule would apply to as many as ***160,800 current LDTs*** and that up to ***15,552 additional LDTs per year*** would become subject to FDA's mandates, AR2020-21 (Table 24), at an estimated cost of up to ***$113.86 billion in one-time compliance costs*** and up to ***$14.31 billion in annual recurring costs***. AR2030 (Table 31). It further conceded that roughly half the affected LDTs are performed by "small businesses," AR2055, and that these entities "are more likely to reduce operations or exit the market than large laboratories," with the ultimate effect of "driving production concentration to a few large laboratories," "increas[ing] the risk of supply chain contractions, risking shortages for certain … LDTs and therefore affecting prices and access." AR2033-34.

2. The Final Rule

FDA received thousands of comments on the Proposed Rule, including more than 150 separate comments filed by AMP itself, individual AMP members, and by groups, entities, and organizations to which AMP or its individual members belong (collectively, the "AMP Comments"). *See* Compl. ¶ 97 (summarizing the AMP Comments). FDA was not swayed. It issued

the Final Rule on May 6, 2024 without modification, AR27, and the accompanying Preamble then rejected the myriad challenges that AMP and its members had raised. *See* AR26-148.

In an effort to reduce the Final Rule's cost projections, however, the Final Rule's Preamble outlined several "enforcement discretion policies" that FDA claimed would exempt certain LDTs from immediate regulation. AR9-10. Most notably, the Preamble stated that FDA would "generally not enforce premarket review and [most quality system] requirements … for currently marketed … LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified [only] in certain limited ways." AR10. It also outlined several other putative "enforcement discretion" categories. AR9-10. Even so, the Preamble repeatedly declared that FDA could modify these non-binding policies at any time. *See, e.g.*, AR105 ("As with any enforcement discretion policy, this policy is subject to change."). And it repeatedly threatened to take enforcement action against laboratories and laboratory professionals who develop and perform even those LDTs which fall squarely within these non-binding enforcement discretion policies. AR10 ("Regardless of the … enforcement discretion policies for certain [LDTs] discussed below, FDA retains discretion to pursue enforcement action for violations of the [FDCA] at any time, and intends to do so when appropriate."); AR16 ("[R]egardless of this or any other enforcement discretion policy, FDA retains discretion to pursue enforcement action at any time against violative [LDTs]."); AR19 (identical); AR22 (identical); *see also* AR12 (substantially similar).

As a result of these illusory enforcement discretion policies, the Final Rule's regulatory impact analysis magically reduced the estimated compliance burden to ***up to $85 million in one-time regulatory costs*** (a ***99.9% decrease*** from the ***up to $113.86 billion*** previously estimated) and ***up to $4.54 billion in annual recurring costs*** (from the ***up to $14.31 billion*** previously estimated). AR386-87; *see also* AR275 ("[W]e adjusted our estimate to reflect the enforcement discretion

policies in the [Final Rule]."). On July 12, 2024, the House Committee on Appropriations responded to the Final Rule by declaring that it is "a significant shift in the way LDTs are regulated and changes expectations for patients, doctors, and laboratories.… The Committee directs the FDA to suspend its efforts to implement the rule and continue working with Congress to modernize the regulatory approach for LDTs." H.R. REP. No. 118-583, at 88 (2024). FDA has not responded.

F. Relevant Factual Background

It would be hard to overstate the importance of professionally trained molecular pathologists—who hold an M.D. or Ph.D. and often both—to the delivery of modern healthcare services. These highly trained experts develop, refine, perform, and/or interpret the laboratory procedures used to help screen and diagnose patients, select appropriate treatments, monitor disease progression, and offer individual risk assessments. *See* Dec. of K. Kaul (the "Kaul Dec.," filed as Compl. Ex. 2), at ¶¶ 6-9; Dec. of E. Konnick (the "Konnick Dec.," filed as Compl. Ex. 3), at ¶¶ 5-9; Dec. of M. Laposata (the "Laposata Dec.," filed as Compl. Ex. 1), at ¶ 6-8. While some such procedures are well-established, standardized, and supported by robust market demand—such that a mass-marketed IVD test kit is available for use—science and medicine are constantly evolving and commercially distributed IVD kits often rely on outdated information or are not appropriate, available, affordable, or applicable to a patient's condition or current medical needs. Kaul Dec. ¶ 6; Konnick Dec. ¶ 7; Laposata Dec. ¶ 7-8.

These gaps put patients at risk—particularly in rural, isolated, poor, and underserved communities, where reduced access to medical care delays diagnosis and treatment even when tests are available. These gaps also can compromise both the development of new therapies and their utility, particularly when new and clinically relevant biomarkers are identified in academic, medical, and scientific literature and through government-supported clinical research. Kaul Dec.

¶ 13; Konnick Dec. ¶ 7; Laposata Dec. ¶ 14-15. Keytruda® (pembrolizumab) is an excellent example. That blockbuster immunotherapy drug is particularly effective in treating cancerous tumors with mismatch repair deficiency ("dMMR tumors"), and FDA first approved Keytruda® to treat any dMMR tumor in May 2017. But there was no FDA-approved IVD for diagnosing dMMR tumors at that time. Instead, and as FDA expressly acknowledged, the clinical trials supporting Keytruda's broad indication for treating any dMMR tumor therefore enrolled patients based ***entirely on LDT results***. FDA, *FDA grants accelerated approval to pembrolizumab for first tissue/site agnostic indication*, https://tinyurl.com/PembroPR (May 30, 2017).

Without those LDTs, Keytruda could not have been approved for its dMMR indication when FDA did so. And without such LDTs, it would have taken years for doctors to prescribe Keytruda® even after approval, because FDA did not approve the first IVD specifically labeled for determining patient eligibility for pembrolizumab until April 2021—some four years later. Since around 3% of all cancerous tumors exhibit dMMR, Y. Kang *et al*., *A scoping review and meta-analysis on the prevalence of pan-tumour biomarkers (dMMR, MSI, high TMB) in different solid tumours*, 12 SCI. REPORTS 20495, at 5-6 & Table 1 (2022), hundreds of thousands of cancer patients would have been denied this essential therapy but for the LDTs that ***first*** enabled Keytruda®'s approval for treating dMMR tumors and ***then*** empowered doctors to begin prescribing Keytruda® for dMMR tumors. There are countless other examples where LDTs have enabled life-saving medical interventions. K. Kaul *et al*., *The Case for Laboratory Developed Procedures: Quality and Positive Impact on Patient Care*, 4 ACAD. PATHOL. 1 (2017).

As the Keytruda® case study illustrates, these gaps are where pathologists—like Dr. Laposata and the roughly 3000 molecular laboratory professionals who are members of AMP—shine. For AMP members, developing a new LDT typically begins after a patient's attending

physician or laboratory leadership identifies a clinical need for assessing whether patients present a clinically relevant biomarker (*e.g.*, dMMR). The pathologist and his or her team then begin identifying the appropriate analytical methods and materials needed to test for the biomarker. Kaul Dec. ¶ 7; Konnick Dec. ¶ 8. For molecular pathology, these LDTs are developed exclusively within a high-complexity clinical laboratory certified or accredited under CLIA and whose operations therefore must be controlled by a doctor. Kaul Dec. ¶ 9; Laposata Dec. ¶ 6.

These laboratories typically have the instrumentation needed to perform an array of well-established analytical methods, so the molecular pathologist's first step is to determine which method is best-suited for detecting the finding(s) of interest given the clinical context. Konnick Dec. ¶ 8; Kaul Dec. ¶ 7. At that point, the pathologist can begin identifying the commercial reagents, probes, primers, and/or other materials needed to execute that method. In genetic testing, for example, these materials are used to extract DNA and/or RNA from a sample (*e.g.*, a tissue biopsy) and then execute a series of controlled processes to evaluate that material using a commercially available platform. Konnick Dec. ¶¶ 8-9; Kaul Dec. ¶ 7. The materials used in a molecular pathology laboratory are manufactured by third parties and purchased commercially; molecular pathologists are not ***manufacturing*** new machines or implements or ***formulating*** their own reagents and accessories, Konnick Dec. ¶ 8, but instead are ***developing and executing a well-validated process*** leveraging well-established, pre-existing platforms and products. Kaul Dec. ¶ 7.

The final step in LDT development is to enable the analysis of results. In the sequencing context, for instance, this step requires developing algorithms that align sequence reads with a reference genome for comparative purposes—*i.e.*, to identify the presence or absence of a clinically relevant biomarker. Konnick Dec. ¶¶ 8-9. Needless to say, every LDT and its specifications must be robustly validated prior to use, as required by CLIA, HHS-approved

laboratory accrediting agencies, and/or applicable state regulatory regimes. Konnick Dec. ¶ 9; Kaul Dec. ¶ 8. Full validation reports and records are produced and maintained by the laboratory, where they remain available for inspection pursuant to CLIA at any time. Kaul Dec. ¶ 8.

LDT development culminates in the production of a written protocol and supporting documentation that detail each material used to perform the LDT and the precise sequence of processes for performing the LDT and reporting results. *Id.* at ¶ 9. As a result, the embodiment of an LDT is a written protocol for a procedure that is intended to be performed entirely within the developing laboratory by highly trained professionals working with and under the supervision of a doctor—not a tangible, mass-produced good that is distributed beyond the developing laboratory for third-party use outside the developer's direct supervision and control. *Id.*

Once executed, the output of a validated LDT is a report delivered to the healthcare provider who ordered the analysis. *Id.* at ¶ 5. These reports require extensive scientific and medical knowledge, experience, and training both to produce and interpret—which is why CLIA requires every high complexity laboratory to, among other things, employ a clinical consultant, *see supra* 15—and it is not uncommon for molecular pathologists to spend considerable time discussing the report, the underlying LDT, and its particular characteristics and limitations with the patient's care team before a formal diagnosis is made and a therapeutic course selected. Kaul Dec. ¶ 5; Laposata Dec. ¶¶ 6, 11. This typically does not and cannot happen with third-party-manufactured, commercially distributed IVD kits—for which only limited information is available to clinicians because of the products' opaque and proprietary characteristics and because there is no relationship between the kit's producer and the healthcare professionals using it.

Molecular pathologists also work continually to improve and optimize their LDTs based on ongoing research and clinical feedback, new scientific discoveries, clinical needs, and

technological advances. Kaul Dec. ¶ 10; Laposata Dec. ¶ 10. This innovation, flexibility, and customization—which, to reiterate, is both allowed and encouraged by CMS's regulations, *see supra* at 12-13—is essential for addressing the complex and evolving landscape of science and medicine. Kaul Dec. ¶ 10. Of course, no substantial change can be made to an LDT without the LDT being revalidated and its protocol updated to reflect and document the change. *Id.* ¶ 9.

Once an LDT has been developed and validated for performance, molecular pathologists and their colleagues collaborate closely with treating physicians. *Id.* at ¶ 5; Laposata Dec. ¶ 11. Before ordering an LDT, treating physicians commonly contact the clinical director, technical supervisor, or clinical consultant to better understand the options and procedures for analyzing a patient specimen. Kaul Dec. ¶ 5. And after an LDT is performed, attending physicians frequently contact the clinical director, technical supervisor, or clinical consultant to better understand how to interpret the LDT's results within the patient's clinical context. *Id.*

ARGUMENT

I. The FDCA Does Not Authorize FDA to Regulate LDTs as Medical Devices.

A. This Is a Quintessential "Major Questions" Case.

Courts reviewing agency action must "exercise their independent judgment in deciding whether an agency has acted within its statutory authority" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). In doing so, courts "use every tool at their disposal to determine the best reading of the statute." *Id*. at 2266. Here, the question to be resolved using those tools is narrow: This Court need decide only whether the FDCA ***clearly and unambiguously*** authorizes FDA to regulate LDTs. That is so because this case triggers the "major questions doctrine," under which "courts 'expect Congress to speak clearly if it wishes to assign to an agency

decisions of vast economic and political significance.'" *West Virginia*, 597 U.S. at 716 (quoting *Utility Air*, 573 U.S. at 324); *see also Alabama Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2021).

In major-question cases, even interpretations that have "textual plausibility" must yield when an agency claims authority to subject whole industries—here, thousands of laboratories and laboratory professionals—to new regulatory mandates to which they "had never before been subject." *West Virginia*, 597 U.S. at 722 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); citing *Utility Air*, 573 U.S. at 310, 324)). After all, "[e]xtraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle devices,'" *id*. at 723 (quoting *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001)), and courts generally "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." *Id*. (quotation omitted). Agency actions implicating a major question thus require "more than a merely plausible textual basis…. The agency instead must point to 'clear congressional authorization' for the power it claims." *Id*. at 723 (quoting *Utility Air*, 573 U. S. at 324).

Three distinct circumstances trigger this clear-statement rule: (1) where "an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,'" *Utility Air*, 573 U.S. at 324 (quoting *Brown & Williamson*, 529 U.S. at 159); (2) where Congress has considered but declined to grant the claimed authority, *West Virginia*, 597 U.S. at 731 (citing *Brown & Williamson*, 529 U.S. at 144; *Alabama Ass'n*, 594 U.S. at 760; *FTC v. Bunte Bros., Inc*., 312 U.S. 349, 352 (1941)); and (3) where new federal mandates would require "billions of dollars in spending each year" by the newly regulated parties. *King v. Burwell*, 576 U.S. 473, 485 (2015). This case doesn't check just one of those boxes; it checks them all.

The Final Rule seeks to enforce a 1976 statute—more on this later—that FDA did not first formally say empowered it to regulate LDTs until 1997. Yet FDA now claims that 50-year-old law gives it plenary authority over laboratory processes that it admits are a "ubiquitous" and "growing sector of" the healthcare system. 88 Fed. Reg. at 68,010 (estimating that "70 percent of medical decisions are based on laboratory test results"). The economic significance of that interpretation is hard to overstate. FDA itself estimated that enforcing its interpretation would affect ***1.65 billion medical procedures per year*** by subjecting ***tens of thousands*** of LDTs to FDA regulation, at a cost of ***up to $113.86 billion in one-time expenditures*** and another ***$14.31 billion in annually recurring costs***. AR7557-58, 7615-16. That would both impose an extraordinary economic burden on laboratories and represent a remarkable expansion of FDA's regulatory activity. AR7558 (Table 4) (noting that FDA reviews barely 4000 medical device applications in a typical year).[4]

This vast economic and regulatory impact in turn explains why Congress has devoted so much political capital to this issue over the past two decades. Again, it has considered a dozen bills addressing LDT regulation since 2006 but time and again has refused to grant FDA power to regulate LDTs. *Supra* at 16-17; *see also* Compl. ¶¶ 78-89 (detailing each of these bills). Instead, it repeatedly has condemned FDA's overreach. 21 U.S.C. § 371 (note) (2012) (barring FDA from even proposing non-binding guidance concerning LDTs without first notifying Congress); H.R. REP. No. 114-531 (2016), at 72-73 (expressly "direct[ing] the FDA to suspend further efforts to finalize the LDT guidance and continue working with Congress to pass legislation that addresses

[4] It is irrelevant that the Final Rule says FDA does not necessarily intend to apply its interpretation to all LDTs (while nonetheless reserving the power to do so whenever it pleases). The purpose of the economic-significance inquiry is to determine "whether Congress in fact meant to confer … such a sweeping and consequential authority," *West Virginia*, 597 U.S. at 721, and that logic applies regardless of whether an agency claims it might exercise limited "enforcement discretion."

a new pathway for regulation of LDTs"). Indeed, Congress just responded to the Final Rule by doing so again: "The Committee directs the FDA to suspend its efforts to implement the [Final Rule] and continue working with Congress to modernize the regulatory approach for LDTs." H.R. REP. No. 118-583, at 88.

The Final Rule thus has the "vast economic and political significance" that triggers the major questions doctrine, *West Virginia*, 597 U.S. at 716, and as detailed *infra*, the FDCA does not remotely grant the required "'clear congressional authorization' for the power [FDA] claims." *Id.* at 723 (quoting *Utility Air*, 573 U.S. at 324). Indeed, the Final Rule would not reflect the MDA's "single, best reading" even if this weren't a major questions case. *Loper Bright*, 144 S. Ct. at 2266.

B. LDTs Are Not "Devices," But Laboratory Procedures Subject to CLIA.

The Final Rule necessarily hinges on FDA's claim that LDTs are "devices," because the FDCA provisions FDA seeks to enforce apply only to "devices." *See, e.g.*, 21 U.S.C. § 360(k). But FDA admits there is a "lack of language in the [FDCA] specifically mentioning … LDTs," AR64, and LDTs otherwise fall outside the FDCA's enumerated categories—which include only tangible goods, not intangible procedures. 21 U.S.C. § 321(h)(1) ("an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article"). As ACLA's brief details, those terms all refer to material goods in their ordinary and contextually appropriate senses, ACLA Br. at 25-26 (collecting cases and dictionary definitions), and none encompasses an LDT—which is a process of discrete steps performed as a service. *Supra* at 21-25.

The Final Rule does not credibly argue otherwise. At most, it claims the terms "apparatus" and "contrivance" conceivably include intangible processes. AR46. As set forth *infra*, that claim is thin on its own terms, but it's worth pausing to note its problematic nature: Those terms first appeared in ***the 1938 FDCA***, 52 Stat. at 1041, leaving FDA to effectively argue it waited some ***60***

years before formally claiming that LDTs might be subject to the FDCA (in the 1997 ASR Rule) and ***85 years*** before sourcing its authority in those statutory terms (not until the 2024 Final Rule). That puts this case even beyond OSHA's attempt to source its 2021 COVID eviction moratorium in a 1944 statute. *See Ala. Realtors*, 594 U.S. at 760-61. And given the limitless breadth of FDA's cherry-picked definitions ("an artificial arrangement" or "something contrived for, or employed in contriving to effect a purpose," AR46 (quoting AR2989, AR2997)), it is hard to imagine ***anything*** that FDA might consider beyond its reach—including the many non-LDT laboratory processes that FDA has ***never*** sought to regulate and for which CLIA never would have been needed, whether in 1967, 1988, or today—if the FDCA since 1938 has meant what FDA now says.

Yet even on their own terms, FDA's definitions fall short. Its sources go on to identify the most common meaning of "contrivance" as "a thing contrived ***especially: a mechanical device***." AR2989. And its chosen definition of "apparatus" underscores that, in its relevant sense, it too refers to tangible objects—like "***an instrument or appliance*** designed for a specific operation [such as] ***an apparatus for measuring vision***," AR2997, or "***[t]he mechanical requisites*** employed in scientific experiments or investigations." AR2999. In any case, statutory interpretation "is a creature not of definitional possibilities but of statutory context," *Tex. Pipeline Ass'n v. FERC*, 661 F.3d 258, 264 (5th Cir. 2011) (quotation omitted), and the fact that every other term in the device definition refers to a material object is a powerful reason to construe these terms accordingly. *Dubin v. United States*, 599 U.S. 110, 124 (2023) ("Under the familiar interpretive canon *noscitur a sociis*, a word is known by the company it keeps.") (quotations omitted).

The rest of the statute confirms that devices are best understood as tangible objects, not procedures using such objects. *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988) (explaining that statutory meaning "is often clarified by the remainder of the

statutory scheme … because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law."). For instance, the FDCA and FDA's regulations are replete with requirements for device labels and packaging. 21 U.S.C. § 360(j)(1)(A)-(B) (requiring submission of device labels and labeling to FDA); *id*. § 321(a) (misbranding liability for "false or misleading" labeling); *id*. § 321(e)(2) (misbranding liability "unless [the device] label bears… its established name"); 21 C.F.R. § 801 *et seq*. (general labeling requirements for devices); *id*. § 809 *et seq*. (specific labeling requirements for IVDs); *id*. § 820.120-130 (quality regulations for device labeling and packaging); *id*. § 830 *et seq*. (requirements for Unique Device Identifiers on labels and packaging). And the FDCA in turn makes clear that a device "label" must be displayed "upon the immediate container." 21 U.S.C. § 321(k). These provisions make perfect sense in the context of tangible items that can be packaged and to which a label can be affixed. But they make no sense in the context of LDTs, which by their very nature cannot be labeled or packaged precisely because they are intangible laboratory procedures—not tangible goods. The same is true of FDA's recall authority, under which it can order a manufacturer to "replace the device with a like or equivalent device." 21 U.S.C. § 360h(b)(2). Again, that makes perfect sense in the context of material goods but has no plausible application in the context of an LDT procedure.

Finally, we note that even if the device definition were broad enough to encompass LDTs—and it is not—FDA's choice to construe it as covering LDTs runs headlong into CLIA. Since 1967, Congress has maintained CLIA for the specific purpose of regulating laboratory procedures—including through registration, licensing, clearance, quality, inspection, testing, and personnel requirements that are specifically tailored to the laboratory context. *See supra* at 9-15. And when Congress decided the original CLIA was falling short in 1988, it not only strengthened CMS's oversight of LDTs in lieu of empowering FDA, but failed even to suggest that FDA might have a

role to play in regulating laboratory procedures—let alone suggest that the FDCA empowered FDA to do so in 1938 or 1976. That is a sure sign that Congress never intended FDA to regulate LDTs—which in turn is why CMS's post-1988 CLIA regulations expressly authorize CLIA-certified laboratories both to "modif[y] an FDA-cleared or approved test system" and to "introduce[] a test system ***not subject to FDA clearance or approval (including methods developed in-house…)***." 42 C.F.R. § 493.1253(b)(2).

The Final Rule thus not only needlessly duplicates CLIA by subjecting LDTs to overlapping standards administered by different agencies; it directly conflicts with CMS's longstanding recognition that LDTs are not subject to FDA clearance or approval, as the Charrow Memo recognized. *See* Charrow Memo at 16. Indeed, much of the Final Rule takes direct aim at CLIA—for instance, by challenging the adequacy of proficiency testing. AR38 (claiming that "proficiency testing data, as standalone or comparative results, do not support test validation and performance expectations" because it is "insufficiently challenging"). That is a strange criticism given that the FDCA includes no proficiency testing requirement for devices—whether sufficiently challenging or not. And in any event ***proficiency testing is the method Congress chose for LDTs***. 42 U.S.C. §§ 263a(f)(1)(D) & 263a(f)(3). If FDA now believes such testing is inadequate, it can ask Congress to amend CLIA or ask CMS to raise its standards. But FDA does not get to seize power just because it disagrees with Congress's choices. *Quarles v. St. Clair*, 711 F.2d 691, 708 n.60 (5th Cir. 1983) ("The role of the agencies remains basically to execute legislative policy; they are not more authorized than are the courts to rewrite acts of Congress.") (quotation omitted).

In any event, when distinct statutory regimes conceivably could apply to a single object, the usual rule is that the more specific law governs even absent a conflict. *See D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932) ("Specific terms prevail over the general in the same or

another statute which otherwise might be controlling."). The Supreme Court made this very point in its seminal major-questions case—when it rejected ***FDA's attempt*** to regulate tobacco. *Brown & Williamson*, 529 U.S. at 131. As the Court explained, "the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad, but the subsequent statutes more specifically address the topic at hand." *Id*. at 143. Citing Congress's repeated efforts to regulate tobacco outside the FDCA, it concluded that "Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA." *Id*. at 144; *see also Train v. Colorado Public Interest Research Group Inc.*, 426 U.S. 1, 23-25 (1976) (rejecting claims that EPA could regulate nuclear materials even though the Clean Water Act covers "radioactive materials" because nuclear materials are specifically regulated by the Atomic Energy Act). So too here: Again, Congress well knew of the need to ensure the quality and validity of LDTs in both 1967 and 1988, and it chose to do so through CLIA—not by empowering FDA to regulate LDTs under the FDCA. Far from providing "clear congressional authorization' for the power [FDA] claims," *West Virginia*, 597 U.S. at 723, the statutory text, context, and history foreclose it.

C. The Final Rule Conflicts with the Commercial Distribution Requirement and Practice of Medicine Exemption.

The fact that LDTs are not clearly "devices"—and if anything, clearly are not "devices"—is enough to condemn the Final Rule. But even if LDTs clearly were "devices," a definition alone cannot supply the clear statement required in major-question cases. *Utility Air*, 573 U.S. at 315-16, 319-21 (rejecting EPA's attempt to regulate greenhouse gases even though they fall within the definition of "air pollutant"); *Solid Waste Agency v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172-73 (2001) (rejecting the Army Corps of Engineers's attempt to regulate isolated wetlands even though they fall within the definition of "waters of the United States"); *see also N.C. Coastal*

Fisheries Reform Grp. v. Capt. Gaston LLC, 76 F.3d 291, 302 (4th Cir. 2023) ("[A]n expansive, vaguely worded definition is not akin to clear congressional authorization. So, in a major-questions case, more is required before holding that the agency has been granted the asserted power.").

That makes sense. Statutory definitions are not independently operative, but instead supply meaning to the statutory provisions establishing enforceable legal duties and rights. And when it comes to the FDCA's operative provisions, they not only fail to supply the requisite "'clear congressional authorization' for the power [FDA] claims," *West Virginia*, 597 U.S. at 723 (quoting *Utility Air*, 573 U. S. at 324), but foreclose it. Indeed, the Final Rule conflicts with both the MDA's commercial-distribution requirement and its crucial practice-of-medicine exemption.

As we emphasized earlier, the FDCA does not empower FDA to regulate "devices" in the abstract, but instead subjects devices to such regulation only if certain other conditions are satisfied. One of those conditions is the statute's commercial distribution requirement: Rather than subject every device to premarket review, the MDA repeatedly provides that such review applies only to devices that are or will be "introduc[ed] or deliver[ed] … into interstate commerce ***for commercial distribution***." 21 U.S.C. § 360(k); *id*. § 360c(c)(2)(C)(ii) (classification dependent on whether a given device was "introduced or delivered for introduction into interstate commerce ***for commercial distribution*** before May 28, 1976") (internal enumeration omitted); *id*. § 360c(f)(1) (virtually identical); *id*. § 360e(b)(1) (same); *id*. § 360e(i)(1) (same).

The statute does not define "commercial distribution," so courts must "look to the [phrase's] ordinary definition." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 284 (2011). That meaning is not hard to find: "Commerce" refers to "the exchange or buying and selling of ***commodities especially on a large scale and involving transportation from place to place***." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE,

UNABRIDGED, Merriam-Webster (2002). And in its most common and contextually appropriate sense, "distribution" refers to the "delivery" or "conveyance" of a good "from a main source" to another location. *Id*. Put those two concepts together—as the FDCA does through its repeated references to "commercial distribution"—and these mutually reinforcing definitions make clear that the law's premarket review requirements apply only where a commodity good is the subject of an exchange from one person or entity to another and from one place to another.

Once again, that makes perfect sense in the context of mass-produced devices, like the implantable IUD that caused the Dalkon Shield Crisis. For example, when a manufacturer creates a new syringe, that commodity good will be transferred in bulk from the manufacturer to its customers, from one place to others, as part of an ordinary business transaction. LDTs, by contrast, bear no resemblance to this archetype. They are not commodities, but medical procedures designed in a laboratory, for use only by that laboratory, and never leave that laboratory or its control. Kaul Dec. ¶ 9. There is no transfer of title. And neither the clinician nor the patient ever receives the LDT—only information generated from the professional service performed by and within the laboratory. Kaul Dec. ¶ 9. Indeed, this is precisely the distinction FDA itself drew in the ASR Rule—when it expressly distinguished "ASR's ***that move in commerce***" from "tests developed ***in-house*** … and ***used exclusively by that laboratory***." 62 Fed. Reg. at 62,249.

The Final Rule does not credibly refute this analysis, let alone justify abandoning the ASR Rule's recognition of its force. Instead, it relies on the MDA's legislative history to claim that "the phrase 'commercial distribution' means 'on the market.'" AR53 (quoting H.R. REP. No. 94-853, at 36 (1976)). But even if legislative history could override the plain meaning of "commercial distribution," *but see Ratzlaf v. United States*, 510 U.S. 135, 147-148 (1994) ("[We] do not resort to legislative history to cloud a statutory text that is clear."), FDA's invocation of a phrase that

does not appear in the statute only begs the question of what "on the market" means. The dictionary is no help: The "market" is "a sphere within which price-making forces operate ***and in which exchanges in title tend to be followed by actual movement of goods***," and placing a product "on the market" means to put an item "up for sale" or to make it "available for purchase" ***in that sphere***. Webster's Third New International Dictionary of the English Language, Unabridged, Merriam-Webster (2002). But again, title to the LDT never transfers and the LDT never moves; it stays in the laboratory for the laboratory's exclusive use under the supervision and direction of a doctor. Kaul Dec. ¶ 9. FDA's attempt to substitute this legislative history for the law's actual words thus provides no support for the Final Rule's vast new regulatory mandates.

The Final Rule also conflicts with the statute's practice-of-medicine exemption. As the Supreme Court long has recognized, "the FDCA expressly disclaims any intent to directly regulate the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) (citing 21 U.S.C. § 396); *see also Apter v. HHS*, 80 F.4th 579, 592 (5th Cir. 2023) ("[T]he [FDCA] expressly shields [d]octors from certain kinds of FDA meddling."). To that end, the MDA expressly exempts licensed practitioners—including Dr. Laposata and AMP's licensed providers—from its registration, recordkeeping, reporting, inspection, and listing requirements. 21 U.S.C. § 360(g)(2) ("The foregoing subsections … shall not apply to … practitioners licensed by law to prescribe or administer … devices and who manufacture, prepare, propagate, compound, or process … devices solely for use in the course of their professional practice."); *id*. § 360i(c)(1) (establishing a similar exemption from the MDA's recordkeeping and reporting requirements). By extension, the MDA exempts these professionals from its 510(k) requirements, which apply only to a "person who is required to register under this section," *id*. § 360(k), and, by further extension, from the de novo classification and PMA requirements—which are defined by cross-reference

back to section 510(k); to the statute's reporting, recordkeeping, and inspection requirements; or both. *Id*. §§ 360c(f)(2)(A)(i)-(ii), (f)(4), (f)(6)(C), (i)(E)(i)-(iii); *id*. § 360e(e)(1)(D).

The Final Rule defies these critically important exceptions. Even though the FDCA defines the de novo classification and PMA requirements by reference back to section 510(k) and/or the reporting, recordkeeping, and inspection requirements from which licensed professionals are exempt, the Final Rule declares that otherwise exempted healthcare professionals are fully subject to the de novo and PMA pathways. AR62. It then effectively eliminates these professionals' antecedent exemption from the 510(k), registration, recordkeeping, reporting, full inspection, and listing requirements. *Id*. The Final Rule does so in three ways. ***First***, it asserts that ***the institutions and entities*** with which these otherwise-exempt individuals are affiliated can be held liable for these individuals' LDT-related activities even though Congress granted ***the individuals themselves*** immunity. *Id*. Indeed, the Final Rule claims FDA could "impose liability on a solo practitioner's personal service corporation" even if the practitioner herself cannot personally be held liable, simply because the statute uses "the possessive terms 'their' and 'his.'" *Id*. That is preposterous, and the liability risk created by FDA's absurdist interpretation inevitably will cause many institutions to bar licensed professionals from providing essential healthcare services that expressly were exempted from the FDCA precisely so that licensed professionals can provide them. *Id*.

Second, the Final Rule declares that the practice-of-medicine exemption does not apply when an otherwise-exempt professional works on an LDT in concert with anyone who is not themselves exempt. *See id*. ("[T]o the extent that comments are arguing that the exemptions apply" where "one individual is licensed to administer the device and others manufacture the device, FDA disagrees.") (internal parentheses omitted). Leaving aside the fact that professional laboratorians developing and performing an LDT are not "manufacturing" anything, that assertion conflicts with

CLIA's intentional allocation of distinct responsibilities to distinct laboratory professionals holding distinct qualifications precisely because high-quality laboratory work requires collective effort by different people with different skills—not a single woman or man acting alone. *See supra* at 14-15. Indeed, if FDA's position were correct and applied, for instance, to the surgical context, then FDA could target the scrub nurses, medical technicians, and other individuals who assist a surgeon simply because they are not themselves licensed to prescribe the myriad devices used during an operation. This cannot be the law; it would make it impossible to practice medicine in America, which is precisely what the practice-of-medicine exemption is designed to avoid.

Finally, the Final Rule declares that the practice-of-medicine exemption does not in any event apply to anything involving "commercial activity." *Id*. (quotation omitted). The Final Rule does not define that term (which appears nowhere in the statute's practice-of-medicine exemption), but it presumably would be triggered whenever an otherwise-exempt professional ultimately seeks payment—which of course is the case for virtually every medical procedure performed in the United States, whether in a laboratory or operating room. Together, these remarkable claims lay bare the breathtaking scope of the Final Rule's assertion of regulatory authority, which would eviscerate a crucial statutory exemption that has shielded the practice of medicine from FDA interference for decades and thereby violate FDA's duty "to give effect, if possible, to every clause and word of a statute, rather than to emasculate an entire section." *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (internal quotation and citation omitted).

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As we repeatedly have stressed, this is a major-questions case—where the Agency itself admits that billions of dollars, billions of procedures, and the health of hundreds of millions of Americans are at stake—and that means the Final Rule can only be upheld if the statute includes "clear congressional authorization for the power [FDA] claims." *West Virginia*, 597 U.S. at 723.

FDA has not remotely met its burden; instead, its interpretation time and again runs directly counter to both the FDCA's text, context, and structure and those of CLIA.

II. The Final Rule is Arbitrary and Capricious.

Even if FDA did have the legal authority to regulate LDTs as medical devices, its decision to do so is arbitrary and capricious. Agencies are required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. In reviewing that explanation, [courts] must consider whether the decision is based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations and citations omitted). Agency actions are by definition arbitrary and capricious if the Agency "failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." *Id*.

Despite its sweeping assertion of regulatory authority, the Final Rule all but admits that subjecting LDTs to the FDCA cannot rationally be justified by the poor-quality, mischaracterized, and admittedly "largely anecdotal" reports the Final Rule invokes. *See* AR36. Even taking that "evidence" at face value, FDA at most claims that in any given year, less than a handful of the tens of thousands of LDTs currently in use raise "concerns": Since 2008, FDA says it has identified just 52 total "concerns" with LDTs—or about 3 "concerns" per year—among the up to 160,800 LDTs it estimates are currently in use. That is an overall "concern" rate of just ***0.03% (and less than 0.02% when calculated annually)***. AR37 n.52. And for all the Agency's rhetoric about the supposedly "growing" number of allegedly "problematic LDTs," the Final Rule asserts only that FDA has "uncertainty," AR18, AR26, AR35, AR37, AR90, AR92, AR125—even as it concedes that applying the FDCA to LDTs "could lead to the ***loss of access to safe and effective IVDs on***

which patients currently rely," AR8, and will at a minimum impose ***billions of dollars per year*** in new regulatory mandates. AR386-87. That is why the Final Rule's non-binding Preamble ultimately announces an array of supposed "enforcement discretion policies" that—if they even could be taken seriously in the face of FDA's repeated threats to take enforcement action despite those policies, *see* AR10, AR12, AR16, AR19, AR22, AR105—would exempt tens of thousands of LDTs from the requirements FDA otherwise insists are necessary to protect the public. *See* AR9-10 (summarizing these non-binding policies).

Make no mistake: Plaintiffs believe that many of these enforcement discretion policies—and still others—are essential.[5] As the AMP Comments explained, fully subjecting LDTs to burdensome and duplicative FDA regulation will drive laboratories out of business and cause significant job losses in the pathology profession; stifle the development of new LDTs; subject those LDTs which are developed to lengthy delays while FDA struggles under a crush of new applications and inspections; thwart innovation and otherwise drive LDTs offline or into obsolence by barring modifications CLIA expressly allows; increase healthcare costs by forcing laboratories to raise prices; and, most important, prevent patients from accessing potentially tens of thousands of admittedly "safe and effective" LDTs, which ultimately will delay patient diagnoses or lead to misdiagnoses, prevent the timely initiation of treatment, and force millions of Americans to suffer from prolonged and advancing diseases, extended and ever-more-invasive medical treatments, and far worse clinical outcomes. Laposata Dec. ¶¶ 10-15; Kaul Dec. ¶¶ 14-22; Konnick Dec. ¶¶ 11-17.

[5] That said, FDA's categories are arbitrarily under- and over-inclusive. For example, in a classic case of "rules for thee but not for me," it exempts the federal government's largest healthcare providers from regulation. AR9 ("FDA intends to exercise enforcement discretion and generally not enforce requirements for LDTs manufactured and performed within the Veterans Health Administration (VHA) or the Department of Defense (DoD).").

Yet far from redeeming the Final Rule, FDA's admission that actually applying the FDCA to LDTs would wreak such havoc—and therefore must be accompanied by an array of "enforcement discretion policies"—serves only to condemn the Final Rule. A rational agency facing these consequences would thoroughly reconsider whether the statute sensibly could or should be interpreted in a way that would unleash those results—not manufacture a series of *ad hoc* exemptions that defy what it claims Congress compelled. And in the end, FDA's enforcement-discretion dodge is doomed to fail anyway. The Final Rule will impose ***all of these harms*** because no rational provider can rely on an "enforcement discretion policy" that is outlined only in a non-binding Preamble, remains "subject to change as circumstances warrant," AR105, and not only is accompanied by repeated threats "to pursue enforcement action … at any time" but a stark warning that FDA "intends to do so." AR10. And these flimsy assurances will provide ***none of the benefits*** FDA intended them to generate on paper—namely the tens of billions of dollars in supposed cost savings that FDA derives from offering these phantom guarantees.

Without belaboring the point, this is not the stuff of reasoned agency decision-making—let alone a justification sufficient to support what FDA concedes will be billions of dollars per year in new regulatory compliance costs even if the Agency's legally inoperative and expressly self-defeating regulatory Preamble could be taken seriously. Whether or not FDA has the authority to regulate LDTs under the FDCA (and it does not for the reasons argued *supra*), its Final Rule represents the height of arbitrary, capricious, and abusive agency action. It must be vacated.

CONCLUSION

For the foregoing reasons, the Court should enter summary judgment in favor of Plaintiffs, vacate the Final Rule, and enjoin Defendants from taking any action to enforce the Final Rule.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2024, a true and correct copy of this document was served electronically by the Court's CM/ECF system on all counsel of record.

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