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

COMBINED REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS ASSOCIATION FOR MOLECULAR PATHOLOGY AND DR. MICHAEL LAPOSATA'S MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO THE FEDERAL DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

FDA claims "this is an ordinary case of federal regulation pursuant to unambiguous Congressional authorization." FDA Br. at 3-4. But there is nothing ordinary about the challenged regulation or FDA's approach to statutory interpretation. As our opening brief emphasized, the Agency's Final Rule explicitly threatens tens of thousands of clinical laboratories and their medical professionals with criminal prosecution for providing the same kinds of essential healthcare services they have used to serve patients for decades; will impose tens of billions of dollars in burdensome, duplicative, and unnecessary regulatory mandates; and, most important, will prevent patients from accessing ***both*** tens of thousands of indisputably safe and effective LDTs that currently are used hundreds of millions times per year ***and*** tens of thousands of future LDTs that could be used to help diagnose, manage, or prevent serious diseases and develop future therapies.

As FDA's brief now underscores, the Final Rule will unleash these harms based not on a credible analysis of the statute's whole text, but instead by cherry-picking the broadest-imaginable definitions of two words ("apparatus" and "contrivance") that Congress first included in the FDCA some 85 years ago and construing them in a way that conceivably could criminalize every surgical procedure in America; rendering the statute's "commercial distribution" requirement a nullity; neutering the special protections Congress has provided health care practitioners for decades; and misrepresenting the scope and effect of CLIA—the comprehensive statutory regime Congress designed specifically for the purpose of ensuring the validity and reliability of the laboratory procedures over which FDA now claims authority. That is no way to interpret the law, and in accordance with binding precedent, this Court should vacate FDA's unlawful power grab before it takes effect on May 6, 2025. *See Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 779-80 (5th Cir. 2024) (citing *inter alia Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374-75 (5th Cir. 2022) ("Vacatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation.")).

ARGUMENT

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

FDA's Final Rule raises a classic "major question" that requires a clear and unambiguous textual basis in the FDCA to be sustained—not merely a textually plausible one. AMP Br. at 25-28. That is so because its assertion of vast regulatory authority over LDTs (1) "claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,'" *Util. Air Reg. Group v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)); (2) Congress repeatedly has declined to grant FDA power over LDTs, whether in whole or part, *W. Virginia v. EPA*, 597 U.S. 697, 731 (2022) (citing *Brown & Williamson*, 529 U.S. at 144; *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 760 (2021); *FTC v. Bunte Bros., Inc*., 312 U.S. 349, 352 (1941)); and (3) the Final Rule would compel "billions of dollars in spending each year" by the parties FDA now intends to regulate for the first time. *King v. Burwell*, 576 U.S. 473, 485 (2015). FDA's responses are unavailing.

It first asserts that FDA impliedly "has claimed"—though never exercised—authority over LDT procedures "continuously since 1977." FDA Br. at 43. That assertion is dubious at best and would not avoid major-questions review even if it were indisputable. Far from regulating laboratory procedures, FDA's 1977 rules clarified that "clinical laboratories" ***are exempt*** from the MDA's core registration and 510(k) obligations. FDA, *Establishment Registration & Premarket Notification Procedures*, 42 Fed. Reg. 42,520, 42,528 (1977) (21 C.F.R. § 807.65(i)). That exemption remains on the books today, and its origins are telling. Though FDA initially had proposed to exempt laboratories by listing them in a proviso for parties "who ***manufacture or otherwise alter devices*** solely for use in their practice," FDA, *Establishment Registration & Premarket Notification Procedures*, 41 Fed. Reg. 37,458, 37,463-64 (1976) (proposed 21 C.F.R.

§ 807.65(d)),[1] its final rule transferred the clinical-laboratory exemption to a new section for entities "whose major responsibility is ***to render a service [to patients or doctors] with a device or the benefits to be derived from the use of a device***." 42 Fed. Reg. at 42,528. As the accompanying Preamble explained, this change was no mere housekeeping edit: FDA moved the exemption precisely because it recognized that laboratories do not manufacture new devices but instead "***provide a service resulting from the use of a device***," *id*. at 42,521—an explanation that wholly undermines FDA's attempt to backdate its current assertion of authority over LDT services.

Nor would it matter if FDA had claimed in 1977 that leveraging extant devices to perform laboratory procedures is akin to manufacturing a new device. As FDA now concedes, its claim that LDTs are newly manufactured "devices" is based not on the ***1976*** MDA but instead on words in the ***1938*** statute. FDA Br. at 19 (discussing "apparatus" and "contrivance"); *id*. at 21 ("[T]he present definition of 'device' is the same in most relevant respects as [that of] the original 1938 FDCA."); *see also* AMP Br. at 28-29 (highlighting this issue). So rather than this case implicating a 21-year gap between the 1976 MDA and what the Proposed Rule identified as FDA's first formal assertion of potential authority over LDTs in 1997, AR7132 (citing FDA, *Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents* (the "ASR Rule"), 62 Fed. Reg. 62,243 (1997)), FDA in fact failed to suggest it might have such authority for either ***39 years*** (if the 1977 rule counts) or ***59 years*** (if the ASR Rule is the starting point, as FDA previously said).[2] That is major-questions territory any way you slice it, and the fact that FDA may

[1] All emphases are added unless otherwise noted.

[2] This distinguishes *Mayfield v. Dep't of Labor*, 117 F.4th 611 (5th Cir. 2024), where DOL in ***1940*** implemented the ***1938*** Fair Labor Standards Act *via* a salary test it contemporaneously sourced in the law's terms. *Id*. at 615 ("DOL has long justified its rules on the ground that the terms used in (Continued…)

have "claimed this authority" since 1977 or 1997—all while shielding that "claim" from challenge by never enforcing it against LDT service providers—does not immunize it from challenge now. *Cf.* FDA Br. at 43. After all, there is no principle of "entrenched executive error" by which an agency can exercise "a sort of 30-year adverse possession that insulates disregard of statutory text from judicial review. [That idea] deservedly has no precedent in our jurisprudence." *Rapanos v. United States*, 547 U.S. 715, 752 (2006) (plurality); *see also Summit Petroleum Corp. v. EPA*, 690 F.3d 733, 746 (6th Cir. 2012) ("[A]n agency may not insulate itself from correction merely because it has not been corrected soon enough, for a longstanding error is still an error.").

FDA next claims this case does not involve a major economic question or impose sufficient costs to trigger major-questions review. FDA Br. at 46-47. It is wrong on both scores. Though it tries to trivialize the Final Rule as affecting just "one subset … of one subset … of one subset of the medical products over which FDA has jurisdiction," FDA Br. at 46, it ignores the Agency's prior estimate that this particular "subset" is used to perform up to ***1.65 billion procedures*** each year—or nearly five per year for every man, woman, and child in America. AMP Br. at 27 (citing AR7557-58). Even if that estimate were off by a factor of five, the Final Rule thus would have the potential to directly impact medical care for ***every single American, every single year, in perpetuity***—making it hard to imagine how FDA can say with a straight face that this case differs from *Utility Air* because it lacks potential to affect "'every household in the land,'" FDA Br. at 46 (quoting 573 U.S. at 311), or *Alabama Association of Realtors*, where the CDC temporarily "claimed the power to halt all residential evictions," *id.* at 46-47 (citing 594 U.S. at 764)—a

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the EAP Exemption connote a particular status and prestige that is inconsistent with low salaries."); *id.* at 617 ("DOL asserts an authority that it has asserted continuously since 1938.").

striking power, but one that might have affected only "between 6 and 17 million tenants at risk." 594 U.S. at 764.[3]

FDA fares no better with respect to the Final Rule's costs. It previously estimated that subjecting LDTs to the FDCA would impose ***up to $113.86 billion in one-time costs*** and another ***$14.31 billion in annually recurring costs***, AR7615; *see also* AR7617 (projecting annualized costs of up to ***$19.45 billion per year***), which is orders of magnitude greater than the $472 million in *Mayfield*. 117 F.4th at 616. FDA now downplays the Final Rule's impact by claiming it ultimately was "projected to cost private parties an average of $1.17 billion per year"[4] and arguing that for major-questions purposes "courts should look to the costs of 'the promulgated rule' rather than 'the economic impact that could result from the broadest possible rule that is consistent with [the] asserted authority.'" FDA Br. at 47 n.20 (citing AR440 and quoting *Mayfield*, 117 F.4th at 616 n.3). That methodology is at odds with the major-questions doctrine's rationale, AMP Br. at 27 & n.4 (quoting *W. Virginia*, 597 U.S. at 721)), but even it cannot salvage this rule: As our brief stressed, FDA slashed the rule's projected costs only by announcing a series of non-binding "enforcement discretion" policies (1) that are not set forth in the actual regulation (because FDA now admits there is "no provision of the FDCA that the agency could have invoked to do so," FDA Br. at 48), and (2) that FDA repeatedly threatened to modify, eliminate, or ignore at will. AMP Br. at 20-21, 39-40 (collecting AR citations). Indeed, its brief reiterates those threats. FDA Br. at 10.

[3] *Mayfield* again is no help to FDA; that rule affected just 1.2 million workers. 117 F.4th at 617.

[4] That's not quite right. $1.17 billion was ***one*** of FDA's cost estimates, but in light of its admitted uncertainty about how many LDTs and laboratories the Final Rule would affect, it elsewhere estimated that the new regulation could impose up to ***$3.22 billion per year in total annualized costs***, AR440, and in still other places that it could impose up to ***$4.54 billion in annual recurring costs alone***. AR387. Given its admitted uncertainties and the internal inconsistencies in its projections, FDA hardly can take credit for the lowest possible number.

The Final Rule thus will impose the full measure of its initially projected costs such "flimsy assurances" and "phantom guarantees" hardly can be relied upon, AMP Br. at 40; Kaul Decl. ¶ 18 (AMP Compl. Ex. 2)); Konnick Decl. ¶ 12 (AMP Compl. Ex. 3); Laposata Decl. ¶ 10 (AMP Compl. Ex. 1)—a point FDA now concedes by simply ignoring it.

The fact that the Final Rule ultimately will affect medical care for virtually every American—not just by causing "the loss of access to safe and effective IVDs" now and in the future, AR8, but by imposing "prohibitive" costs that FDA admits will cause laboratories "to exit the market [and] reduce operations" or never "enter the market" to begin with, AR414—in turn explains why Congress has devoted so much political capital to this issue. AMP Br. at 27-28; AMP Compl. ¶¶ 78-89. FDA derides this extensive legislative record as "a scattering of purported examples," FDA Br. at 44, and dismisses its relevance because "in none of these cases did Congress consider and reject the [exact] same 'program' as the Final Rule—clarifying that FDA's existing device authorities apply to laboratory-made IVD test systems on the same terms as IVD test systems made by non-laboratory manufacturers." *Id*. at 45-46. But it cites no authority for the proposition that proposed legislation counts only if it mirrors every jot and tittle of the challenged rule, and there is none. Instead, this legislative record matters for major-questions purposes since "it [is] telling when Congress has considered and rejected bills authorizing ***something akin to the agency's proposed course of action***. That too may be a sign that an agency is attempting to work around the legislative process to resolve for itself a question of great political significance." *W. Virginia*, 597 U.S. at 743 (Gorsuch, J., concurring; cleaned up and collecting cases). This is a major-questions case subject to the doctrine's clear-statement rule, and as we detail below, FDA has not remotely met its burden of justifying the Final Rule.

II. The Final Rule Conflicts with the FDCA's Device Definition, Commercial Distribution Requirement, and Practice of Medicine Exemption.

A. LDTs Are Not Devices.

Consistent with FDA's 1977 rulemaking, plaintiffs' briefs explained that each term in the FDCA's "device" definition commonly and in its most contextually appropriate sense refers to tangible goods, not intangible services performed using one or more previously manufactured devices—whether individually or, as in nearly all medical procedures, in tandem. AMP Br. at 28-30; ACLA Br. at 25-29. Rather than engage these arguments directly, FDA tries to rewrite the statute. It first asserts that FDA claimed power over the broad class of "*In vitro* diagnostic [IVD] products" in a 1973 regulation that defined such products to include "IVD test ***systems***." FDA Br. at 18 (partly quoting 21 C.F.R. § 809.3(a); emphasis in original); *see also id*. at 22 (again emphasizing that the 1973 rule "include[d] ***systems***"). It then argues that LDTs are such "systems," *id*. at 19, and concludes by claiming that the MDA "incorporated each of the terms that had defined FDA's pre-1976 jurisdiction into an expanded definition of 'device.'" *Id*. at 23.

Not so. Congress certainly was aware of FDA's 1973 regulation and indeed referenced it in the MDA's amended device definition. But it did so ***only in part***: While the original 1938 definition had included "instruments, apparatus[es], and contrivances, including their components, parts, and accessories," Pub. L. No. 75-717, § 201(h), 52 Stat. 1040, 1041 (1938), the 1976 MDA amended that definition to include "an instrument, apparatus, implement, machine, contrivance, implant, ***in vitro reagent***, or other similar or related article." 21 U.S.C. § 321(h)(1). Its reference to "in vitro reagent[s]" plainly was borrowed from FDA's 1973 regulation, which had defined "IVD products" to include "***reagents***, instruments, ***and systems***." 21 C.F.R. § 809.3(a). Yet despite adding "***in vitro reagent[s]***" to the statute—along with "implement," "machine," and "implant"—Congress conspicuously did not include "***system[s]***" when it passed the MDA. That failure

forecloses both FDA's assertion that the MDA "incorporated ***each*** of the terms" from FDA's 1973 regulation, FDA Br. at 23, and the Agency's attempt to bootstrap its pre-MDA rule into the MDA. After all, "when Congress knows how to say something but chooses not to, its silence is controlling." *In re Guillen*, 972 F.3d 1221, 1226 (11th Cir. 2020) (quotations omitted).[5]

That leaves FDA to argue that the words "apparatus" or "contrivance" conceivably could be construed as any "set of materials or equipment designed for a particular use" or even as any "artificial arrangement" or "thing contrived." FDA Br. at 19. But those are not the only, most common, or most contextually appropriate meanings. *See* AMP Br. at 29 (quoting the definitions FDA relied upon below and explaining that FDA's interpretation would violate the *noscitur a sociis* canon). And we stressed that FDA's preferred definitions of those terms are so limitless that virtually no medical procedure in America could evade FDA's reach. *Id*.; *see also* AMP Compl. ¶ 135 (analogizing the design of an LDT procedure to "a surgeon's selection and use of scalpels, scissors, forceps, needles, and sutures" and explaining that virtually any surgical procedure could be considered a crime if such choices were akin to manufacturing a new device).

FDA now tries to mitigate this concern by distinguishing the design of a procedure from its execution: "[T]he ***performance*** of an IVD test according to its manufacturer's instructions takes place subsequent to the process of designing and developing a ***test system*** intended for a particular use." FDA Br. at 28-29 (emphases in original). But that is no answer. A surgeon also designs the procedure before performing it, just like the doctors who design and perform LDTs in accordance

[5] FDA knows this is a problem, so it invokes a committee report to claim Congress intended to include "in vitro diagnostic products" in the statute's new device definition. FDA Br. at 20 (quoting S. REP. NO. 94-33 at 17 (1975)). But those are not the words the MDA actually used, and "legislative history is not the law. It is the business of Congress to sum up its own debates in its legislation, and once it enacts a statute we do not inquire what the legislature meant; we ask only what the statute means." *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 523 (2018) (quotations omitted).

with CLIA. They assess the patient's needs; determine the technique required to address those needs; choose the specific collection of technologies and instruments to be used and the sequence in which to deploy them; and then perform the as-designed technique to meet the procedure's objective. In FDA's words, the outcome of the surgeon's "design specifications and step-by-step instructions" in order "to produce a … result" is "attributable to the system as a whole rather than any individual components," *id*. at 29, and as our Complaint and Declarations detailed, that precisely mirrors the development and execution of LDT procedures in clinical laboratories. AMP Compl. ¶¶ 104-21. FDA's putative distinction of a surgery from an LDT procedure is no distinction at all, and even if its handful of dictionary definitions were broad enough to effectively criminalize basic surgical procedures, that cannot possibly justify the vast authority it now claims. *Malacara v. Garber*, 353 F.3d 393, 400 (5th Cir. 2003) ("Laws cannot be interpreted by snatching single words out of statutory sentences and matching [them] up against one of the many definitions of that word found in the advocate's dictionary of choice.") (internal quotation omitted).

B. LDTs Are Not Commercially Distributed.

Even if FDA were correct that LDT procedures clearly are devices, the FDCA's commercial-distribution requirement forecloses the Final Rule's assertion of authority. AMP Br. at 32-35. FDA initially claims that our commercial-distribution "argument's major premise is false" because "a device may fall outside the scope of certain provisions without divesting FDA of jurisdiction altogether." FDA Br. at 31. But FDA never denies that ***each*** of the MDA's registration, listing, and premarket review provisions requires commercial distribution, AMP Br. at 33 (collecting citations); it identifies no material requirements of the FDCA that are not derivative of those provisions and their embedded commercial-distribution requirements; and it ignores the fact that the commercial-distribution requirement is powerful evidence that "devices"

must be things that can be "distributed," not intangible procedures that by definition never leave the laboratory. *See, e.g.*, *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."); *BP Am., Inc. v. FERC*, 52 4th 204, 215 (5th Cir. 2022) ("[I]n interpreting statutes, it is seldom appropriate to seize on single words or phrases; instead, statutory interpretation requires consideration of the statutory scheme as an integrated whole.").

When FDA does turn to the meaning of "commercial distribution," it attempts to split the phrase in half: first claiming "there are such things as 'commercial services'" and then quoting a dictionary definition for the proposition that "[d]istribution" allegedly is "'supplying something' for sale." FDA Br. at 32. This divide-and-conquer approach to the unified phrase "commercial distribution" is unavailing. Plaintiffs do not contend that LDT "services" cannot be offered on a "commercial" basis, but instead that—when paired with the term "distribution"—the contextually appropriate meaning of this phrase references "the exchange or buying and selling ***of commodities*** especially ***on a large scale*** and ***involving transportation from place to place***." AMP Br. at 33-34 (quoting WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED, Merriam-Webster (2002)). FDA's references accord. *See* CAMBRIDGE DICTIONARY, *Commercial*, https://perma.cc/XH6M-Q72J ("buying and selling ***things***"); MERIAM-WEBSTER, *Commercial*, https://perma.cc/B6RA-6Q6P ("designed for a large market" and providing the example "***in commercial quantities***").[6] So does common sense: No ordinary person would say that

[6] FDA claims the FDCA "does not condition FDA's authority on production of a minimum number of devices," FDA Br. at 28, but the statutory provision FDA invokes only underscores that "commercial distribution" contemplates mass-produced commodities: That provision defines a (Continued…)

"commercial services" performed in a single location—*e.g.*, a personal-training session, a massage, or a medical procedure—are being "distributed." Indeed, FDA's partly quoted definition of "distribution" only underscores the Agency's departure from this common-sense observation: Rather than meaning "'supplying something' for sale," FDA Br. at 32, the actual definition FDA cites repeatedly underscores that "distribution" typically entails the transfer of tangible items from person to person and/or place to place at scale: "***to give something out to several people, or to spread or supply something***," as in "The company aims eventually to distribute (= supply for sale) ***its products throughout China***," "***Food and clothing*** are being distributed ***among/to the flood victims***," and "The Scottish company aims to be distributing ***to retailers within the US and Canada***." CAMBRIDGE DICTIONARY, *Distribute*, https://perma.cc/3H75-25B6.[7]

That leaves FDA to once again assert that a committee report passingly equated "commercial distribution" with "the phrase 'on the market' used in its 'popular' sense." FDA Br. at 32 (quoting AR53 (itself quoting H.R. REP. 94-583, at 53 (1976)). But again, legislative history cannot override the plain meaning of the statute's words, *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."), and it is not clear how replacing "commercial distribution" with "on the market" helps FDA in any

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"custom device" as one that "is ***not generally available*** in the United States ***in finished form*** … for commercial distribution." 21 U.S.C. § 360j(b)(1)(C).

[7] Again, this is exact the distinction FDA's ASR Rule drew by distinguishing "ASR's ***that move in commerce***" from LDTs that are "***developed in-house … and used exclusively by that laboratory***." 62 Fed. Reg. at 62,249. And it is consistent with FDA's initial 1977 regulations, which—for instance—defined a device "distributor" as "any person who furthers the marketing of a device ***from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user***," 42 Fed. Reg. at 42,527, and applied its rules to repackagers who act "in furtherance of the ***distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer***." *Id*. at 42,526.

event. It never identifies what the "popular sense" of "on the market" meant in 1976—for instance, by pointing to contemporaneous usage suggesting that an ordinary person would have used the phrase "on the market" to refer to performing a procedure that does not entail an "'exchange[] in title [that] tend[s] to be followed by actual movement of goods.'" AMP Br. at 35 (quoting WEBSTER'S). That surely was not FDA's contemporaneous understanding; in 1978, FDA explained that commercial distribution entails an "order to purchase the device [resulting] in ***a contract of sale for the device*** in the United States, generally ***with delivery to occur*** immediately or at a promised future date." FDA, *Compliance Policy Guide* § 300.600, https://tinyurl.com/CPG300-600. And to the extent FDA means to imply that a device is "on the market" merely if available for use in exchange for a payment in U.S. dollars, it would render the "commercial distribution" requirement a nullity: The statute ***separately*** requires that a covered device be intended for "introduction or delivery … into interstate commerce," not just that it be placed into "commercial distribution." 21 U.S.C. § 360(k) (registration required before "the introduction or delivery for introduction into interstate commerce ***for commercial distribution*** of a device intended for human use"). FDA's attempt to substitute legislative history for actual law thus provides no support for the Final Rule's vast new regulatory mandates—let alone the requisite clear statement in this major-questions case.

C. The Final Rule Conflicts with the Practice of Medicine Exemption.

Finally, FDA's Final Rule is incompatible with what commonly is called the FDCA's practice-of-medicine exemption.[8] This venerable protection "expressly shields [d]octors from

[8] We acknowledge Amicus College of American Pathologists' concern about using the shorthand phrase "practice of medicine" in light of its perception of the term's potential implications for state licensing and federal reimbursement decisions. *See* CAP Br. at 13. The Court of course is free to (Continued…)

certain kinds of FDA meddling," *Apter v. HHS*, 80 F.4th 579, 592 (5th Cir. 2023), through two sets of provisions: one that specifically exempts "practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice," 21 U.S.C. § 360(g)(2); *id.* § 360i(c)(1), and one that more generally bars FDA from "construe[ing]" anything in the FDCA "to 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. Together, these provisions bar FDA from "intruding upon decisions statutorily committed to the discretion of health care professionals," including by "us[ing] a device for some other purpose than that for which it has been approved by the FDA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). As we previously explained, the Final Rule violates these important limitations by narrowing § 360(g)'s protections so far as to neuter this protective shield—including by insisting that the institutions and entities with whom protected health care practitioners like Dr. Laposata and AMP's other health care professionals are affiliated can be held liable where these protected individuals use previously manufactured devices to develop and perform LDTs. AMP Compl. ¶¶ 143-46; AMP Br. at 35-37.

Neither of FDA's responses is persuasive. It first contends that § 360's protections apply only to health care practitioners in their individual capacities—and therefore offer no protection for their affiliated "corporations, partnerships, or other entities"—simply because § 360 uses the possessive pronouns "his" and "their." FDA Br. at 33. But FDA does not even attempt to explain what purpose these protections would serve if the entities who employ protected health care

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use any term it prefers; what matters is that the Final Rule conflicts with the statutory provisions that commonly used phrase encapsulates.

practitioners—including even a solo practitioner's LLC—could be held liable when a protected party engages in the conduct these longstanding protections are designed to shield. And there is none: As our brief explained, no employer would permit their health care practitioners to engage in otherwise-protected conduct if the employer could face criminal charges. AMP Br. at 36. It is axiomatic that courts "should not lightly conclude that Congress enacted a self-defeating statute," *Quarles v. United States*, 587 U.S. 645, 654 (2019) (collecting cases), and that rule has added force here given Congress's admonition that "nothing in [the FDCA]"—let alone its mere possessive pronouns—"shall be construed to limit ***or interfere with*** the authority of a health care practitioner to prescribe or administer any legally marketed device … within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396.

FDA's other argument fares no better. In an effort to salvage at least some part of the Final Rule, it claims the practice of medicine exemption does not extend to the statute's *de novo* classification and PMA requirements even though they are inextricably tied to the provisions from which health care practitioners are exempt: section 510(k); 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). FDA responds by reading these authorities at their narrowest, but that misses the point: They evince the interdependent nature of the MDA's premarket pathways and the practice-of-medicine exemptions. FDA Br. at 35. The result of FDA's approach is predictable: It makes hash of the statutory regime.

Its dismissal of 21 U.S.C. § 360e provides a telling illustration. Section 360e governs the PMA process, first providing that a class III device generally requires a PMA, 21 U.S.C. § 360e(a), and then detailing the PMA application requirements, *id*. § 360e(c), and the procedures and approval standards for PMAs. *Id*. § 360e(d). Of special relevance here, it also requires FDA to

withdraw a PMA approval if, *inter alia*, the PMA's sponsor either (1) "has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under [*id*. §] 360i(a)" or (2) "has not complied with the requirements of [*id*. §] 360." *Id*. § 360e(e). These provisions necessarily imply that PMA sponsors must be subject to both (1) the recordkeeping requirements in § 360i(a) and (2) the other requirements of § 360. Yet as FDA concedes, § 360i(c) in fact "expressly exempts practitioners who meet the statutory criteria from adverse event reporting requirements under Section 360i(a)," FDA Br. at 34-35, and "section 360(g)(2) expressly exempts practitioners who meet the statutory criteria from the FDCA's registration requirements [in *id*.] §§ 360(b)-(f) [and] (j)." *Id*. at 34.

That is a sure sign Congress did not subject practitioners to the PMA process. FDA breezily dismisses this observation by saying "a person cannot fail to comply with requirements from which they are exempt," *id*. at 35, but that is non-responsive: Accepting FDA's position would mean that once FDA issues a PMA to a health care practitioner, it ***could not*** withdraw that approval even if the practitioner engages in conduct that ***would require*** FDA to withdraw any other PMA approval. That is nonsensical, *United Sav. Ass'n*, 484 U.S. at 371 ("Statutory construction … is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified [where] only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law."), and the Court should reject FDA's attempts to eviscerate both the scope and utility of the statute's longstanding protections for health care practitioners.

III. The Final Rule Conflicts with CLIA.

To the extent there is any remaining doubt about the FDCA's application to LDTs, CLIA resolves it. As we have emphasized, FDA did not expressly indicate that LDTs might be subject to the ***1938 FDCA***'s general medical-device definition until ***the 1990s***. AMP Br. at 15-16, 28-29;

see also supra at 2-4, 7-8. In the intervening 60 years, however, Congress expressly subjected LDTs to a dedicated statutory regime, passing CLIA in 1967 and then strengthening it in 1988 for the specific purpose of regulating "the vast clinical laboratory industry [in order] to provide the necessary assurances of quality" and to ensure the "accuracy and reliability of test results" that are used "in the diagnosis, prevention, or treatment of disease" and on which countless "clinical decisions rest." S. REP. No. 100-561, at 3 (1988); *see also* 42 U.S.C. § 263a(f)(1). Those laws would have been all-but-unnecessary if the FDCA already granted FDA plenary authority over LDTs, *see Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 35 (2003) ("A statutory interpretation that renders another statute superfluous is of course to be avoided."), and it otherwise is well-settled that "[s]pecific terms prevail over the general in the same or another statute which otherwise might be controlling," *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932), especially when "the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand." *Brown & Williamson*, 529 U.S. at 143. FDA's brief does not overcome these bedrock interpretive canons.

It begins with the surprising assertion that CLIA and the FDCA do not actually overlap—claiming they "on their face … regulate different things," with the former focusing on "whether a laboratory and its personnel meet CLIA requirements" and the latter on "the tests themselves to ensure that they have appropriate assurance of safety and effectiveness for their intended use." FDA Br. at 36. But that is plainly incorrect: CLIA directly regulates "the tests themselves" through the myriad quality assurance, quality control, and proficiency testing requirements our opening brief addressed at length and FDA's brief entirely ignores. AMP Br. at 12-14 (detailing how CMS implements CLIA's mandates that laboratories (1) "maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory

examinations and other procedures," 42 U.S.C. § 263a(f)(1)***(A)***, and (2) further subject LDTs to proficiency testing, *id*. §§ 263a(f)(1)***(D)***, (f)(3)). And FDA's claim would be silly even if it weren't plainly erroneous. CLIA subclauses 263a(f)(1)***(B)*** and ***(C)*** do not impose "laboratory" and "personnel" requirements for their own sake, but instead for the textually manifest purpose of ensuring that all "laboratory examinations and other procedures"—*i.e*., "the tests themselves," FDA Br. at 36—are "valid and reliable" for their intended uses. 42 U.S.C. § 263a***(f)(1)***.

The fact that CLIA does so ***in part*** by regulating the "laboratory and its personnel" hardly means it is not regulating "the tests themselves." It just means Congress chose to ensure the validity and reliability of the LDTs that highly trained, well-credentialed doctors develop and perform within their laboratories by imposing different requirements than the FDCA applies to medical devices—which, in stark contrast to LDTs, are intended for third-party use and can be developed by almost any Harry, mass-manufactured by nearly any Dick, and commercially distributed to virtually any Tom, as FDA's Proposed Rule recognized in distinguishing LDTs from FDA-regulated home-test kits. *See* AR7139 (explaining that LDTs involve "the participation of medical professionals to help determine whether a particular test [i]s appropriate, counsel patients on the significance and limitations of a test, assist in interpreting results, assess how the results fit in the overall clinical picture, and consider next steps" and that "without this expert intermediary, there is a heightened need for FDA oversight"). Against this backdrop, the fact that CLIA's regulation of LDTs and the FDCA's regulation of medical devices differ in some respects and overlap in others only underscores the bizarre nature of FDA's suggestion that Congress subjected LDTs (and LDTs alone) to distinct regulatory schemes administered by distinct regulators—as though LDTs, rather than commercially distributed medical devices like pacemakers, brain implants, and surgical robots, pose unique dangers that no other FDA-regulated product does.

All but conceding the point, FDA ultimately tries to rationalize the overlapping regulation of doctor-developed-and-deployed LDTs that never leave the clinical laboratory by asserting that CLIA and the FDCA regulate different aspects of "the tests themselves," with CMS's regulations being solely "focused on ***analytical*** validity," FDA Br. at 36 (emphasis modified), and FDA's regulations on "***clinical*** validity." *Id*. at 37 (same). But it simply is not true that CMS focuses only on "analytical" validity while FDA focuses on "clinical" validity. Both regulators do both things. Start with FDA: As it eventually concedes, the Agency in fact regulates analytical validity and not just clinical validity. FDA Br. at 36. FDA tries to wave this problem away by asserting that "FDA's review of analytical validity … is more in-depth and more comprehensive than [CMS's]," *id*., but that self-serving say-so just means (1) that CLIA's analytical-validity requirements are redundant, *but see Dastar*, 539 U.S. at 35 ("A statutory interpretation that renders another statute superfluous is of course to be avoided."), or (2) that CMS is not adequately discharging its duty to ensure that LDTs are "valid and reliable," 42 U.S.C. § 263a(f)(1), "accurate and reliable," *id.* § 263a(f)(1)(E), and demonstrate "acceptable performance." *Id*. § 263a(f)(3)(B). We of course disagree, but that's beside the point: Even if FDA were right that CMS is falling short, that would not license FDA to seize CMS's statutory authority by administrative fiat. *Career Colls. & Sch. of Tex. v. U.S. Dept. of Educ*., 98 F.4th 220, 243 (5th Cir. 2024) ("[E]nabling legislation is generally not an open book to which the agency may add pages and change the plot."); *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).

Nor is FDA correct that CMS's authority somehow is limited to assessing analytical validity. Rather than address CLIA's language, FDA's claim instead relies almost entirely on a set of unsigned "FAQs" that CMS uploaded to the Internet in 2013. FDA Br. at 36-38 (invoking CMS,

LDT and CLIA FAQs (Oct. 22, 2013), https://perma.cc/X3DE-G5H9). There's a reason FDA runs from the actual law: CLIA's plain text forecloses its claim. Far from limiting CMS to considering "analytical validity," CLIA instead directs CMS to ensure that all laboratory procedures are "***valid and reliable***"—full stop. 42 U.S.C. § 263a(f)(1); *see also id*. § 263a(f)(1)(A) ("validity and reliability"); *id*. § 263(a)(1)(E) ("accurate and reliable"). No test is "reliable" if it cannot be relied upon for its intended use. And while the word "analytical" does not appear anywhere in § 263a, *but see Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 439 (2019) ("[J]ust as we cannot properly expand [a statute] beyond what its terms permit, we cannot arbitrarily constrict it either by adding limitations found nowhere in its terms.") (emphases omitted); *Wheeler v. Pilgrim's Pride Corp.*, 536 F.3d 455, 459 (5th Cir. 2008) ("Under well-settled principles, we must refrain from reading additional terms … into [a statute]."), the words "clinical relevance" do. 42 U.S.C. § 263a(f)(3)(B); *but see U.S. Dep't of Treasury v. Fabe*, 508 U.S. 491, 504 n.6 (1993) ("By ignoring this word, the dissent overlooks another maxim of statutory construction: that a court should give effect, if possible, to every clause and word of a statute.") (quotations omitted).

Yet even if FDA were correct that ***CLIA*** somehow were limited to analytical validity, FDA still would be wrong that ***CMS*** bears no responsibility for ensuring that LDTs are clinically valid. As both our Complaint and brief observed, CLIA is not the only relevant law: Congress also charged CMS with regulating LDTs under provisions of the Social Security Act that it administers side-by-side with CLIA. AMP Compl. ¶ 45; AMP Br. at 15. Those laws bar CMS from making payments for any "items or services" that "are not reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. 1395y(a)(1)(A); *see also* 42 C.F.R. §§ 410.32, 411.15(k), and CMS enforces this prohibition in part by using expert Medicare Administrative Contractors ("MACs") to determine whether a given item or service is "***[s]afe and effective***," "[f]urnished in

accordance with accepted standards of medical practice ***for the diagnosis or treatment of the patient's condition***," and "***meets … the patient's medical need***," CMS, *Medicare Program Integrity Manual* § 13.5.4, based on a review of "the ***scientific evidence supporting the clinical indications*** for the item or service." *Id*. § 13.5.3.[9] FDA's claim that CMS does not evaluate the clinical validity of LDTs is thus demonstrably false, and its attempt to create daylight between CMS's LDT-specific authority under its governing statutes and FDA's authority under the FDCA's generic device provisions is meritless as a matter of law and fact.

Faced with all of this, FDA ultimately tries to reframe plaintiffs' challenge as claiming that CLIA effectuated an "implied repeal" of the FDCA. FDA Br. at 39; *see also id*. at 36 (asserting that plaintiffs are arguing "that CLIA somehow 'displaced' the FDCA's plain meaning") (quoting *Dept. of Agric. v. Kirtz*, 601 U.S. 42, 63-64 (2024)). But no plaintiff is arguing that CLIA displaced or impliedly repealed the FDCA. As they have for decades, both laws "can coexist harmoniously," FDA Br. at 40 (quoting *Kirtz*, 601 U.S. at 63), by simply recognizing that they regulate different things: tangible devices that are commercially distributed for third-party use (the FDCA), on the one hand, and internal laboratory processes and procedures (CLIA), on the other. Plaintiffs'

[9] Of special relevance to AMP, many MACs use a dedicated program (called "MolDX®") that covers reimbursement for both FDA-approved and FDA-cleared molecular diagnostic tests and LDTs. CMS, *Medicare Coverage Database—MolDX: Molecular Diagnostic Tests (MDT)* (Aug. 26, 2024), https://tinyurl.com/CMS-MolDX. That program expressly requires laboratories to prove their LDTs' clinical validity and clinical utility: "MolDX® will only cover and reimburse tests that demonstrate analytical ***and clinical validity***, ***and clinical utility*** at a level that meets the Medicare reasonable and necessary requirement." *Id*.; *see also* Palmetto GBA, *MolDX: Technical Assessment* (June 23, 2023), https://tinyurl.com/MolDX-TA ("[T]he assay must demonstrate ***clinical utility (CU)*** … and meet analytical and ***clinical validity*** (AV/CV) standards. In addition to these categories of evidence, CMS has directed MolDX to follow the ACCE criteria developed by the [CDC]."); CDC, *ACCE Model for Evaluating Genetic Tests* (Dec. 2010), https://tinyurl.com/CDC-ACCEModel ("The ACCE model process is [designed to] address disorder, testing, and clinical scenarios, as well as analytic ***and clinical validity, clinical utility***, and associated ethical, legal, and social issues.").

argument instead proceeds from the general/specific canon—which FDA's brief never addresses and which in fact derives from "the principle … that the two provisions are ***not*** in conflict, but ***can exist in harmony*** [because t]he specific provision does not negate the general one entirely, but only in its application to the situation that the specific provision covers," A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts*, at 185 (2012)—and the rule that "the implication of a later enactment … will often change the meaning that otherwise would be given to an earlier provision … because a law is to be construed as a whole (including later-added and later-revised provisions), and because laws *in pari materia* (including later-enacted laws) are to be interpreted together." *Id*. at 330; *see also D. Ginsberg & Sons, Inc.*, 285 U.S. at 208; *Brown & Williamson*, 529 U.S. at 143.

FDA's invocation of *Kirtz* does not undermine these venerable principles. That case arose after the Rural Housing Service ("RHS") sought to evade liability under the ***1996*** Fair Credit Reporting Act's ("FCRA") ***specific cause of action*** for borrowers harmed by a lender's failure to investigate disputed credit records. *Kirtz*, 601 U.S. at 46-47 (citing 15 U.S.C. § 1681s-2(b)). In a last-ditch argument the Court conceded it had no need to address, *id*. at 51, the government asserted that FCRA did not clearly waive RHS's sovereign immunity—despite authorizing suit against "any governmental agency," *id*. at 50 (quoting 15 U.S.C. § 1681a(b); ellipses omitted)—because the ***1974*** Privacy Act included a ***general cause of action*** that conceivably could apply where a federal agency intentionally or willfully fails to correct its internal credit records. *Id*. at 63 (citing 5 U.S.C. § 552a(g) & 31 U.S.C. § 3711(e)).

The Court rejected that claim, holding that the Privacy Act could not possibly be construed as undermining FCRA's waiver of sovereign immunity given the government's concession "that, the Privacy Act notwithstanding, it ***is*** subject to and liable under at least some provisions of the

FCRA." *Id*. (emphasis original). And while the Court went on to observe in passing that "juggl[ing] multiple and sometimes overlapping legal obligations [is not] an unusual feature of contemporary American life," *id*., it had no occasion to consider the specific/general canon or the later-enacted-statute canon because the government had been arguing precisely the opposite of what those canons teach: Again, its claim was that the ***1974*** Privacy Act's ***general cause of action*** somehow undermined the ***1996*** FCRA's ***specific cause of action***. To the extent *Kirtz* has any bearing here, it therefore only undermines the government's claim that ***the general device provisions of the 1938 FDCA*** render superfluous the ***laboratory-specific regulatory regime*** Congress enacted in ***the 1967 and 1988 versions of CLIA***—and not least because Congress made clear when it passed the 1988 CLIA that it did not view the FDCA as having any relevance to the regulation of LDTs. AMP Br. at 15 (quoting H.R. REP. No. 100-899, at 11 (1988)); *see also* S. REP. No. 100-561, at 3.

FDA offers two final retorts. It first claims that "Congress does not need to name-check its earlier work in order to avoid repealing it by implication." FDA Br. at 39 (citing *Kirtz*, 601 U.S. at 63-64). But again, plaintiffs aren't making an implied-repeal argument, and *Kirtz* in any event didn't address clear and repeated statements by Congress that its earlier legislation had no bearing on the issues addressed by the later legislation—let alone after conducting multiple hearings where it received testimony from the relevant federal agency. *See, e.g.*, H.R. REP. No. 100-899, at 19 (documenting at least 3 House hearings where HHS testified); *see also* S. REP. No. 100-561, at 3-4, 5, 21 (referencing information provided by HHS).

That leaves FDA to once again argue that there is no tension between the FDCA and CLIA that would implicate the various reconciliation canons, even though CMS's longstanding implementing regulations expressly authorize laboratories to "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)." 21 C.F.R. § 493.1253(b)(2). FDA claims this regulation merely reflects that there might be "devices that do not require premarket authorization based on classification or an exemption from 510(k) requirements." FDA Br. at 40. But that assertion is impossible to reconcile with the regulatory proviso permitting laboratories to make FDA-uncleared and FDA-unapproved modifications to devices that were "FDA-cleared or approved" in the first instance. 21 C.F.R. § 493.1253(b)(2). And it ignores that CMS's regulation expressly defines "a test system not subject to FDA clearance or approval" as "including methods developed in-house," *id*.—***not*** merely as methods which were not subject to FDA clearance or approval in the first instance.

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At bottom, the Final Rule not only is inconsistent with the text, structure, and history of the FDCA, but fundamentally irreconcilable with CLIA. FDA therefore has not met its burden of establishing "clear congressional authorization for the power it claims," *W. Virginia*, 597 U.S. at 723, and indeed, its position would not reflect the law's "single, best meaning" even if this weren't a major questions case. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024). Binding precedent thus requires vacatur of the Final Rule. *Franciscan All.*, 47 F.4th at 374-75.

IV. The Final Rule Is Arbitrary and Capricious.

Even if FDA did have the legal authority to regulate LDTs as medical devices, its Final Rule must be vacated because it is arbitrary and capricious. As our opening brief detailed, FDA's assertion of vast new regulatory authority threatens to impose ***hundreds of billions of dollars*** in new mandates that will drive innumerable laboratories out of business; lead to significant job losses; overwhelm FDA with a deluge of new applications and inspectional requirements; increase costs for all laboratory procedures; and, most important, deprive patients of access to tens of

thousands of LDTs that FDA admits are safe and effective and thwart future innovation, all of which will lead to delays in diagnosis and treatment that jeopardize patient care for hundreds of millions of Americans. AMP Br. at 39.

Those costs perhaps could be justified if the Agency had identified a credible evidentiary basis for them—one that did not "run[] counter to the evidence before the agency" or reflect "a clear error of judgment," and which otherwise was based on "examin[ing] the relevant data." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Final Rule tried to do so, breathlessly asserting "that the evidence of problematic IVDs offered as LDTs has been growing, a trend that increases FDA's concerns." AR36-37. As our brief explained, however, the study on which FDA based that claim provides no support: Collecting data from 2008 to 2024, it identified only 52 total "concerns" among the up to 160,800 LDTs the Final Rule estimates are in use, or less than 0.02% when calculated on an annual basis. AMP Br. at 38 (citing AR37 n.52). That is hardly a basis for imposing billions of dollars in new regulatory mandates (let alone hundreds of billions of dollars), and FDA's brief does not even try to argue otherwise: It makes no effort to defend the Final Rule's reliance on that study, but instead dismisses its significance as "only discussing case studies identified in a single agency memorandum," FDA Br. at 49—as though that excuses the Agency's invocation of such paltry data to claim there is "a trend that increases FDA's concerns" and justifies the Final Rule. AR36-37.

Instead, FDA now says that its decision was based on "a total body of evidence [that] was significantly broader and deeper than a single collection of case studies." FDA Br. at 49. But our brief acknowledged that evidence as well, noting that it was comprised of admittedly anecdotal reports that FDA concededly "'ha[d] not confirmed,'" AMP Br. at 19 (quoting AR7127-28 & n.10); a few small-scale studies (including one with such severely flawed methods and data-

misrepresentation issues that several of its co-authors took the extraordinary step of withdrawing), *id*. (citing AR7127-28 & Comment of AMP, FDA2177-6150 at 12-14 (discussing *inter alia* AR7330-40, referenced at FDA Br. at 49)); and an undisclosed number and unrepresentative collection of allegedly poor-quality applications that FDA had received, *id*. (citing AR7127-28).

FDA's brief, however, fails to acknowledge—and so has waived its right to address—any of those challenges to the evidentiary showing it made in support of the Final Rule. Nor does it seriously grapple with the harms that would be caused by the loss of safe and effective LDTs. This is not reasoned agency decision-making—let alone reasoning sufficient to justify the extraordinary compliance costs and public health risks the Final Rule will unleash. 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 and capricious 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 November 25, 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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