UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION, ET AL. v. U.S. FOOD AND DRUG ADMINISTRATION, ET AL.	§ § § § § § § §	CIVIL NO. 4:24-CV-479-SDJ
ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL. v. U.S. FOOD AND DRUG ADMINISTRATION, ET AL.	§ § § § § § § §	CIVIL NO. 4:24-CV-824-SDJ

MEMORANDUM OPINION AND ORDER

Laboratory-developed test services are in-house diagnostic tests developed, validated, and performed by trained professionals within a single clinical laboratory. They are performed on blood, urine, tissue, or other types of specimens at the request of an individual physician, in the context of a specific doctor-patient relationship. Treating doctors rely on such laboratory-developed test services for patient diagnosis, care, and treatment, ranging from routine tests such as pap smears and gram stains, to sophisticated molecular and genetic sequencing tests for cancer, heart disease, and rare and infectious diseases.

For many years, laboratory-developed test services have been comprehensively regulated by both the States and by the Centers for Medicare and Medicaid Services

("CMS"). CMS administers the detailed requirements that Congress enacted in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") that were specifically tailored to and targeted at clinical laboratories and their tests. After decades of comprehensive CMS oversight, the Food and Drug Administration ("FDA") issued a final rule on May 6, 2024, announcing its intent to treat all laboratory-developed test services as medical devices and to regulate them under the Federal Food, Drug, and Cosmetic Act ("FDCA").

Before the Court are two consolidated cases challenging the validity of FDA's final rule.[1] Plaintiffs include the American Clinical Laboratory Association ("ACLA"), a national trade association that represents the clinical laboratory sector, the Association for Molecular Pathology ("AMP"), a professional society in the field of molecular pathology, infectious disease laboratories HealthTrackRX Indiana, Inc., and HealthTrackRX, Inc. (collectively, "HealthTrackRX"), and Michael Laposata, M.D., a medical doctor and clinical pathologist (collectively, the "Laboratory Plaintiffs"). The Laboratory Plaintiffs contend that FDA's final rule must be vacated under the Administrative Procedure Act ("APA") because it is "in excess of [FDA's] statutory jurisdiction, authority, or limitations" and is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C); *see also id.* § 706(2) (requiring courts to "hold unlawful and set aside" such agency actions). FDA maintains that the final rule is well within its authority under the

[1] Defendants include FDA; the U.S. Department of Health and Human Services ("HHS"); Robert F. Kennedy Jr., in his official capacity as Secretary of Health and Human Services; and Sara Brenner, M.D., in her official capacity as Acting Commissioner of Food and Drugs, FDA.

FDCA and does not otherwise violate the APA.

The parties have submitted cross-motions for summary judgment on the administrative record. Because the Court concludes that the final rule exceeds FDA's statutory authority, the Laboratory Plaintiffs' summary-judgment motions are granted and FDA's cross-motion is denied.

The Court's opinion proceeds in three stages. First, the Court examines the history of laboratory-developed test services, the regulation of such medical services over time, and FDA's historical regulation of medical devices. This review culminates in FDA's final rule. Second, after addressing the Laboratory Plaintiffs' standing, the Court explains why the text, structure, and history of the FDCA and CLIA make clear that FDA lacks the authority to regulate laboratory-developed test services. Third, having concluded that FDA's final rule exceeds its authority and is unlawful, the Court considers the appropriate remedy under the APA and controlling circuit precedent.

I.

A.

FDA's authority to regulate medical devices began with the enactment of the FDCA in 1938. *See* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(h), 52 Stat. 1040. At that time, FDA was authorized to regulate "foods," "drugs," "devices," and "cosmetics," all of which were physical products that were mass-manufactured and commercially distributed. *Id.* § 201(h), 52 Stat. at 1041 ("The term 'device' . . . means instruments, apparatus, 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 other animals; or (2) to affect the structure or any function of the body of man or other animals."); *see also id.* § 201(f), (g), (i), 52 Stat. at 1040–41 (defining "food," "drug," and "cosmetic," respectively).

In 1976, Congress expanded FDA's authority over medical devices in the Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, 90 Stat. 539. The MDA amended the FDCA to "impose[] a regime of detailed federal oversight" on medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). The post-MDA statute now provides that before any new medical device can be "introduced or delivered for introduction into interstate commerce for commercial distribution," FDA must grant one of three types of premarket authorization—(1) a substantial equivalence clearance (often called a "510(k) clearance"), (2) a de novo classification, or (3) a premarket approval—unless FDA by regulation has exempted that type of device from such review.[2] Once approved, a medical device remains subject to certain FDA-determined postmarket controls. *See, e.g.*, 21 U.S.C. § 360c(a)(1).

"[T]o provide a reasonable assurance of . . . safety and effectiveness," FDA uses a device's risk classification to decide on the type of premarket review and any required postmarket controls. *Id.* § 360c(a)(1)(A)(i). Class I devices are low risk and are thus subject to only the "general" controls that apply to all devices. *Id.*

[2] *See* 21 U.S.C. § 360(k); *id.* § 360c(c)(2)(C)(ii) (providing that classification status depends on whether a given device was "introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or is within a type of device which was so introduced or delivered before such date") (internal enumeration omitted); *id.* § 360c(f)(1) (virtually identical); *id.* § 360e(b)(1) (same).

§ 360c(a)(1)(A). Class II devices are moderate risk and can be subject to additional "special" controls. *Id.* § 360c(a)(1)(B). Devices that pose the highest risk are placed in class III and require premarket approval, which provides for the most stringent postmarket controls. *Id.* § 360c(a)(1)(C).

FDA regulations exempt most class I devices and a minority of class II devices from premarket review. *Id.* § 360(l)–(m). By contrast, most class II devices and a minority of class I devices require 510(k) clearance. *Id.* § 360c(2)(A). Novel devices are placed in class III by default but may be eligible to be placed in class I or class II via the de novo classification process if they can be shown to pose only low to moderate risk with the use of appropriate controls. *See id.*

Although the three device categories differ by level of risk, they each regulate only tangible, physical products: Class I devices include "elastic bandages and examination gloves," class II devices include "powered wheelchairs and surgical drapes," and class III devices include "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Riegel*, 552 U.S. at 316–17. The FDCA defines "device" as follows:

> The term "device" . . . means *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory*, which is—
>
> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and

> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h)(1) (emphasis added). All the terms used in the FDCA's definition of device—"instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent"—refer to tangible, physical objects. The statute also uses the term "article" as a catchall for all other "devices." The meaning of "article" does not include intangible services. *See infra* Part IV.B.1–2.

B.

Congress created a separate statutory and regulatory framework for laboratory test services, commonly known as "CLIA": the Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, § 5, 81 Stat. 533, 536, which was significantly expanded by the Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903, (codified as amended at 42 U.S.C. § 263a). A clinical laboratory is defined as "a facility for the . . . examination of materials derived from the human body for the purpose of providing information for the 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). The object of CLIA regulation is thus a facility performing health care services.

A "laboratory-developed test" is a methodology or process by which a laboratory generates biochemical, genetic, molecular, or other forms of clinical information about a patient specimen for use by the treating physician. Each laboratory uses its own unique knowledge of the protocols, performance characteristics, and means of

analysis to develop such methodologies and processes. Laboratory-developed tests are offered as *services*. Unlike a drug or device, which is a manufactured and packaged article of commerce with user instructions, a laboratory-developed test service is a proprietary methodology performed by only the developing laboratory. That service generates information from test results and transmits that information to the ordering physician. The testing service is not sold as a kit, and the protocol is not transferred in any manner to other laboratories, hospitals, or other facilities outside the developing laboratory entity. No physical product is sold, and no article of personal property is transferred such that title passes from one party to another.

CMS is primarily responsible for administering CLIA, and in that role it has issued extensive implementing regulations. *See* 42 C.F.R. Part 493. CLIA and its regulations reflect that performing and interpreting laboratory tests requires significant scientific and technical knowledge, training, experience, and judgment. In this regard, the laboratory testing process is different from manufacturing devices. Under CLIA, all laboratories that perform clinical tests on human specimens must be certified by CMS or accredited through certain CMS-approved accreditation organizations. 42 U.S.C. § 263a(b). Both CMS and the accreditation organizations issue standards to ensure that laboratories' performance is "consistent" and that their tests are "valid and reliable," including quality-control standards and standards for the qualifications of the personnel supervising and performing the tests. *Id.* § 263a(f)(1).

By law, laboratory testing services are provided by skilled, credentialed, and highly regulated professionals. Laboratories that develop and perform high-

complexity tests must be overseen by a laboratory director who must either be a licensed physician or hold a doctoral degree in a relevant science. 42 C.F.R. § 493.1443. The laboratory director must ensure that the laboratory's test methodologies are "capab[le] of providing the quality of results required for patient care," that "[l]aboratory personnel are performing the test methods as required for accurate and reliable results," and that "consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions." *Id.* § 493.1445(e)(3)(i), (e)(3)(iii), (e)(9).

The laboratory must also have a technical supervisor with appropriate training or experience for the types of tests performed by the laboratory, *id.* § 493.1449, and a clinical consultant qualified to "consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care," *id.* § 493.1455. The clinical consultant provides "consultation regarding the appropriateness of the testing ordered and interpretation of test results." *Id.* § 493.1457.

Under CLIA, laboratory test services are also subject to strict quality controls. A laboratory that introduces a newly developed diagnostic test and begins reporting patient results must generally establish "performance specifications" for accuracy, precision, analytical sensitivity, and other characteristics "required for test performance." *Id.* § 493.1253(b)(2). CLIA's quality-control system also requires, among other things, calibration and control procedures; maintenance and function

checks for instruments and equipment; and ongoing quality monitoring. *Id.* §§ 493.1200–1299.

CLIA also requires laboratories to demonstrate proficiency in their tests multiple times a year. 42 U.S.C. § 263a(f)(3); *see also* 42 C.F.R. § 493.801. A laboratory that fails to achieve satisfactory proficiency scores may face sanctions, including suspension, limitation, or revocation of its CLIA certificate. 42 C.F.R. §§ 493.803(b), 493.1806. As an additional safeguard, CLIA-certified laboratories are subject to inspections by HHS, state agencies, and authorized accrediting bodies. *See, e.g.*, 42 U.S.C. § 263a(g); 42 C.F.R. 493(Q).

* * * *

The sequence of legislative enactments underpinning FDCA and CLIA reflects that Congress viewed (1) ensuring medical-device safety and effectiveness, and (2) ensuring laboratory-testing accuracy, as distinct problems requiring different regulatory solutions. Congress passed the FDCA in 1938, the Clinical Laboratories Improvement Act in 1967, the Medical Device Amendments in 1976, and the Clinical Laboratory Improvement Amendments in 1988. Despite this alternating sequence, Congress never indicated that there was any overlap between these regulatory schemes. On the contrary, the Senate Report on the 1967 CLIA bill addressed concerns about possible overlap between regulation of clinical laboratories under CLIA and under the Medicare statute, but it did not mention any role for the FDCA in regulating clinical laboratories. *See* S. Rep. No. 90-724 (1967), *as reprinted in* 1967 U.S.C.C.A.N. 2076, 2084. Likewise, the House Report on the 1988 CLIA bill described "[t]he Current Regulatory System" as involving federal regulation of laboratories

"under two programs"—the Clinical Laboratories Improvement Act of 1967 and the Medicare statute—and did not mention regulation under the FDCA. H.R. Rep. No. 100-899, at 11 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3828, 3831. The Report also stated that CLIA's purpose was to ensure that laboratory test services are governed by a single "unified regulatory mechanism." *Id*. at 12.

C.

1.

The legislative history of the FDCA and CLIA, demonstrating that Congress understood medical-device safety and the accuracy of laboratory-developed test services as distinct areas for regulatory oversight, was largely mirrored in the approach taken by FDA and CMS as the respective agencies charged with oversight of medical devices and laboratory-developed test services. In the approximately thirty-five years since the 1988 CLIA amendments, FDA has occasionally claimed authority to regulate laboratory-developed test services as "devices" under the FDCA, but failed to act on such claims until the issuance of the final rule in 2024.

For well over a decade following Congress's enactment of the Medical Device Amendments to the FDCA, from 1976 through 1992, FDA did not claim any authority to regulate laboratory test services as "devices." Nor had FDA ever claimed such authority under the FDCA as enacted in 1938, even though that statute included a similar definition of "device." Congress acted on the same understanding when it enacted CLIA to create a single, unified, comprehensive system for the federal regulation of laboratory test services.

FDA first suggested that it might possess authority to regulate laboratory-developed test services as devices in 1992—sixteen years after Congress enacted the Medical Device Amendments and fifty-four years after it first enacted the FDCA.[3] At that time, FDA issued a draft Compliance Policy Guide, in which FDA claimed that it could regulate laboratory-developed tests as medical devices. The claim was made in passing in a document that generally addressed the marketing and distribution of in vitro diagnostic ("IVD") test kits. In a brief aside, FDA stated that "laboratories have been manufacturing 'home brew' products, either from products already on the market, or from components, and utilizing these unapproved products for diagnostic purposes," and added that "[t]hese products are subject to the same regulatory requirements as any unapproved medical device." AR2764.[4] The laboratory profession immediately objected, including on the ground that FDA's authority does not extend

[3] In its final rule, FDA cites a 1973 rulemaking as evidence that it treated tests as devices before Congress enacted the MDA. 89 Fed. Reg. 37,286, 37,328 (May 6, 2024) (citing 38 Fed. Reg. 7096 (Mar. 15, 1973)). But that rulemaking defined "[i]n vitro diagnostic *products*"—not services—as diagnostic "reagents, instruments and systems." 38 Fed. Reg. at 7098 (emphasis added). Although FDA now suggests that the term "systems" was intended to include testing services, the context makes clear that the only "systems" subject to the rule were finished products, not laboratory tests. For example, the 1973 rule included labeling provisions requiring that certain information be affixed to the "retail package" of the "article." *Id*. The 1973 rule thus confirms that FDA originally sought to regulate only physical products, not professional laboratory procedures or techniques. Moreover, when Congress amended the definition of "device" in 1976, it did not include the term "system" or even the term "in vitro product," but only the narrower term "in vitro reagent."

[4] On agreement among the parties, FDA has produced and Bates-stamped only a portion of the administrative record in this case. Stamped portions of the record are cited by their Bates page number preceded by the prefix "AR" (e.g., AR8582). The remaining portions of the record are publicly available under four dockets posted on Regulations.gov: FDA-2023-N-2177, FDA-2011-D-0357, FDA-2011-D-0360, and FDA-2010-N-0274. Comments and other materials posted to these dockets are cited by the last four digits of the docket number, followed by the number of the cited document (e.g., Comment of Alzheimer's Ass'n, FDA2177-6445).

to "services" such as testing procedures developed by clinical laboratories for in-house use. *See* AR2813–15, AR2819. Thereafter, FDA declined to finalize the guidance and assured laboratories that it did "not intend to routinely exercise its authority over home-brew tests." *IVD Policy Will Not Include Exemptions for "Standard-of-Care" Tests*, THE GRAY SHEET (Oct. 11, 1993).[5]

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[5] In its briefing before this Court, FDA has also referenced its 1977 rulemaking following enactment of the MDA. According to FDA, this rulemaking on "Establishment Registration for Manufacturers of Devices," demonstrates that FDA immediately "recognized its authority to enforce its system of establishment registration, premarket authorization, and postmarket controls" on clinical laboratories "that manufacture their own devices and subsequently 'provide a service through the[ir] use.'" *See* (Dkt. #68 at 10–11) (quoting 42 Fed. Reg. 42,520, 42,521, 42,528 (Aug. 23, 1977) (codified at 21 C.F.R. Part 807)). The notion that the post-MDA 1977 rulemaking shows FDA claimed authority to regulate laboratory-developed tests is far-fetched, at best.

Relevant here, the rulemaking requires any "owner or operator" of a non-exempt "establishment" who is "engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use" to register with FDA. 42 Fed. Reg. at 42,527. The rulemaking defines the term "establishment" as "a place of business . . . at which a device is manufactured, assembled, or otherwise processed." *Id.* at 42,526. It also defines "manufacture, preparation, propagation, compounding, assembly, or processing" of a "device" as "the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in [the FDCA]." *Id.* The rulemaking further defines this group of terms, i.e., "manufacturing," etc., to include "[r]epackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of distribution of the device . . . [i]nitial distribution of imported devices, or [] initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating the specification." *Id.*

Of course, none of this has anything to do with test services performed by clinical laboratories. Nonetheless, FDA points to language in the rulemaking stating that certain "classes of persons" are exempt from FDA registration requirements, including "[p]ersons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device." *Id.* at 42,528. This part of the rulemaking provides examples of the "classes of persons" exempted: "for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic X-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device." *Id.* It appears FDA reads this provision to indicate that, in its first rulemaking, it had zeroed in on its authority under the FDCA to regulate clinical laboratories' test services as "manufactured" "devices," but was exempting them by regulation. This proves too much. If this paragraph of the 1977 rulemaking is read

FDA next asserted that it had jurisdiction over laboratory test services in the non-binding preamble to a 1996 proposed rule regarding device classification levels for certain "active ingredients used in preparing in-house developed [laboratory] tests." 61 Fed. Reg. 10,484, 10,485 (Mar. 14, 1996). In the preamble, FDA noted that it had previously regulated as devices only (i) "diagnostic tests that are traditionally manufactured and commercially marketed as finished products" (i.e., test kits), and (ii) tangible articles used as test "ingredients," such as "laboratory apparatus" and "chemicals or antibodies," that laboratories "purchase from biological or chemical suppliers." *Id*. at 10,484.

In the preamble to the 1996 final rule, FDA stated that it "believes that clinical laboratories that develop such [in-house] tests are acting as manufacturers of medical devices." 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997). FDA recognized, however, that "the use of in-house developed tests 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*. FDA therefore stated that it would continue to focus on regulating "ingredients . . . that move in commerce" and other

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to announce that FDA possessed such authority to regulate clinical laboratories' test services as "manufactured" "devices," then the rulemaking also, necessarily, made the very same announcement as to any "persons . . . whose major responsibility is to render a service necessary to provide [a] consumer with . . . the benefits to be derived from the use of a device," including "personnel from a hospital, clinic, [etc.]" *Id*. Indeed, read as broadly as FDA now suggests, the 1977 rulemaking asserted FDA's authority to regulate essentially *any medical examination or procedure* that involves the use of medical equipment: for example, stethoscopes, thermometers, scalpels, sponges, monitors, etc. The list goes on and on. But FDA has never claimed that this single paragraph in the 1977 rulemaking asserts such sweeping authority over virtually all medical procedures, and for the same reasons it makes little sense to read the paragraph to claim such authority over clinical laboratory test services, which manifestly do not "manufacture" any "device." *See infra* Part IV.

tangible articles, not laboratory test services. *Id.*; *see also id.* at 62,250 (concluding that "regulation of all in-house developed tests" was not "appropriate at this time").

Over the next twelve years, FDA occasionally suggested—in draft non-binding guidance—that it could regulate professional laboratory test services as manufactured devices but was merely choosing not to. But FDA never took any final regulatory action to back up these sporadic, non-binding statements.

FDA changed course in June 2010, suggesting that it was "reconsider[ing] its policy of enforcement discretion" for laboratory-developed test services and that it intended to regulate all testing laboratories as device manufacturers. AR11252–53. FDA stated that it would "develop a draft oversight framework for public comment" that would "phase in . . . over time." AR11253. The laboratory industry objected again. Plaintiff ACLA, for example, submitted comments that emphasized how "laboratories are providers of testing services; they are not medical device manufacturers." FDA0274-0108 at 4. ACLA explained that, while it might be appropriate for FDA to regulate "the products used by clinical laboratories to perform tests," including "commercially distributed in vitro diagnostic test kits," FDA could not regulate the provision of "laboratory services" as devices. *Id.* at 4, 6.

Three years later, with FDA still not having published any proposed oversight framework, ACLA submitted a citizen petition asking FDA to acknowledge that laboratory test services are not devices. *See* FDA Docket No. FDA-2013-P-0667, Doc. ID 0001 at 7–9 (June 4, 2013). FDA denied the petition about a year later, asserting that laboratory-developed tests "are 'devices' as defined in the FDCA." AR2826.

In October 2014, FDA submitted to Congress and publicly released the draft guidance documents it had promised in 2010, proposing to phase in the regulation of laboratory-developed tests as devices over nine years. *See* AR10559–62, AR10564–67. The guidance documents were not well received by Congress. In 2016, the House Appropriations Committee criticized FDA for seeking to bring about "a significant shift in the way" laboratory-developed tests "are regulated"—one that would "change . . . expectations for patients, doctors, and laboratories for the first time since [CLIA] was passed in 1988." H.R. Rep. No. 114-531, at 72 (2016). It "direct[ed] [] FDA to suspend further efforts to finalize" its guidance and to "continue working with Congress to pass legislation that addresses a new pathway for regulation of [laboratory-developed tests] in a transparent manner." *Id*. at 72–73. In response, FDA retreated, announcing that it would not finalize the 2014 draft guidance documents "to allow for further public discussion on an appropriate oversight approach, and to give our congressional authorizing committees the opportunity to develop a legislative solution." AR1916.

2.

Although FDA's view of its authority to regulate laboratory-developed test services as devices has been a moving target for decades, the relevant statutory framework has not changed since 1988. In the last approximately twenty years, Congress has considered but declined to enact several pieces of legislation concerning the regulation of laboratory-developed test services. For example, legislation was introduced in 2007 that would have effectively centralized all regulatory authority over laboratory-developed test services in FDA. *See* Laboratory Test Improvement

Act of 2007, S. 736, 110th Cong. (2007). The bill would have amended the FDCA to expressly provide that "[a]ny laboratory-developed test shall be deemed to be a device under [21 U.S.C. § 321(h)]." *Id.* § 3. Under this regime, laboratory-developed test services would have been subject to all FDCA requirements, including premarket review and the exclusion of non-compliant laboratory-developed test services from the market. *Id.* §§ 5–7.[6] This legislation did not pass.

In 2011, Congress considered another regulatory approach.[7] The proposed bill would have required CMS—not FDA—to administer premarket review of most laboratory-developed test services by specifically excluding these products from the FDCA's device definition. *Id.* §§ 2–3. This bill also did not pass. Instead, Congress passed the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"). *See* Pub. L. No. 112-144, 126 Stat. 993. FDASIA effectively barred FDA from taking any action towards laboratory-developed test services without prior Congressional oversight: FDA was now precluded from issuing even a non-binding draft guidance document purporting to regulate such services "without, at least 60 days prior to such issuance—(1) notifying the [House and Senate] of the Administration's intent to take such action; and (2) including in such notification the anticipated details of such action." *Id.* § 1143 (codified at 21 U.S.C. § 371 (2012)).

[6] One notable exception is that laboratories would not have needed to comply with FDA's goods-manufacturing practice requirements, which could be satisfied by complying with CMS's CLIA regulations. *Id.* §§ 5–7.

[7] Modernizing Laboratory Test Standards for Patients Act of 2011, H.R. 3207, 112th Cong. (2011).

Thereafter, two alternative pieces of legislation were introduced—the VALID Act of 2020 and the Verified Innovative Testing in American Laboratories ("VITAL") Act of 2020.[8] These bills proposed different approaches to regulating laboratory-developed test services. The VALID Act would have created a new regulatory pathway, separate from both drugs and devices, for FDA premarket review and the regulation of laboratory-developed test services. VITAL, by contrast, expressly deemed laboratory services to be "professional health care activity" that would be regulated under CLIA. VITAL expressly excluded laboratory-developed test services from the FDCA. Neither the VALID Act nor VITAL were passed. And new versions of both bills have been introduced in subsequent Congresses without success.[9]

In sum, Congress has considered but declined to enact several bills over the past two decades that would have reshaped the regulatory framework over laboratory-developed test services. Under the circumstances, agencies cannot circumvent, and courts must enforce, the statutory framework Congress enacted as it exists under the FDCA and CLIA.

D.

In October 2023, FDA announced its intent to move forward with regulating virtually all laboratory-developed test services as medical devices. *See* 88 Fed. Reg.

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[8] *Compare* VALID Act of 2020, H.R. 6102, 116th Cong. (2020) *with* VITAL Act of 2020, S. 3512, 116th Cong. (2020).

[9] *See* Verifying Accurate Leading-Edge IVCT Development Act of 2021, H.R. 4128, 117th Cong. (2021); Verified Innovative Testing in American Laboratories Act of 2021, S. 1666, 117th Cong. (2021); Food and Drug Administration Safety and Landmark Advancements Act of 2022, S. 4348, 117th Cong. (2022); Verifying Accurate Leading-Edge IVCT Development Act of 2023, H.R. 2369, 118th Cong. (2023).

68,006 (Oct. 3, 2023); AR7123. In the proposed rule, FDA stated that it would amend the regulatory definition of "in vitro diagnostic products" to add the italicized language:

> [In vitro diagnostic products] are defined as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." . . . These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, *including when the manufacturer of these products is a laboratory*.

AR7134, 7148 (emphasis added) (proposed amendment to 21 C.F.R. § 809.3(a)). In the preamble, FDA made clear that it intended this amendment to clarify that all laboratory test services are "devices" and that whenever a laboratory scientist or technician performs a clinical laboratory test, he or she is engaged in "manufacturing" a "device." AR7124–26, 7134–36.

FDA acknowledged that the costs of the proposed rule would be significant. Specifically, it estimated that the cost of preparing and submitting premarket-approval applications, premarket notifications, and de novo classification requests for existing laboratory-developed tests would exceed $35 billion and could reach $113 billion. AR5279. It also projected that, going forward, annual compliance costs for affected laboratories would range from $4 billion to $14 billion. *Id.* FDA acknowledged that these costs would cause some existing tests to "come off the market" because laboratories would not be able to justify the high costs of obtaining the necessary approval or clearance for those tests. AR7131.

FDA received thousands of comments on the proposed rule, including from significant stakeholders in the field of medicine. For example, the American Medical Association expressed concern that FDA's proposed rule would force "a wholesale shift from how the industry has operated for decades," which would be "massively disruptive" and have a "significant and detrimental impact on patient care," as well as "a chilling effect on innovation in the diagnostic space, with resource strapped laboratories either unable or unwilling to engage in innovative test development." FDA2177-6342 at 1–3; *see also, e.g.*, Comment of Am. Hosp. Ass'n, FDA2177-5954 at 6–7 ("The unfortunate outcome [of the rule] likely would be the decline in the rate of clinical innovation, which would negatively impact the U.S.' ability to keep our health care system at the forefront of discovery, provide quality care to patients, and respond quickly to emerging public health risks."); Comment of Am. Acad. of Allergy, Asthma & Immunology, FDA2177-6071 at 2 ("The proposed rule will lead to clinical immunology laboratories abandoning the development of new [laboratory-developed tests], quelling innovation and diagnostic progress.").

FDA published the final rule on May 6, 2024. As contemplated in the proposed rule, FDA amended the regulatory definition of "in vitro diagnostic products" in 21 C.F.R. § 809.3(a) to add the language, "including when the manufacturer of these products is a laboratory." AR1–2 (quotation marks omitted). And, as in the proposed rule, FDA made clear that it considers the provision of laboratory-based test services a form of device "manufacturing." *See* AR1–2, 4, 8, 43–47, 59.

Departing from the proposed rule, however, the final rule's preamble states that, for now, FDA intends to exercise "enforcement discretion" for some or all

requirements over broad categories of laboratory-developed tests, including most existing tests. AR9–10. These non-binding "enforcement discretion policies" include the following:

- FDA generally will not enforce premarket review and Quality System ("QS") requirements (except certain recordkeeping requirements) for existing tests that are not modified or that are "modified in certain limited ways."
- FDA generally will not enforce premarket review requirements for tests approved by the New York State Department of Health's Clinical Laboratory Evaluation Program.
- FDA generally will not enforce premarket review and QS requirements (except certain recordkeeping requirements) for tests "manufactured and performed" by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.
- FDA generally will not enforce premarket review and QS requirements (except certain recordkeeping requirements) for non-molecular antisera tests for rare red blood cell antigens where such tests are "manufactured and performed" in blood establishments, including transfusion services and immunohematology laboratories, and where there is no alternative available to meet the patient's need for a compatible blood transfusion.
- FDA generally will not enforce any requirements for "1976-Type LDTs" (tests with certain characteristics that FDA says were common among laboratory-developed tests offered in 1976).
- FDA generally will not enforce any requirements for tests intended solely for forensic (law enforcement) purposes.
- FDA generally will not enforce any requirements for tests "manufactured and performed" within the Department of Defense or the Veterans Health Administration.

Id. These extensive carveouts are necessary, the final rule explains, because "expecting compliance with full [quality system] and premarket review requirements for all currently marketed" laboratory-developed tests "could lead to the loss of access to safe and effective" tests "on which patients currently rely." AR8. FDA also "recognize[d] that healthcare professionals may have made significant financial

investments in reliance on access to certain tests" and that "laboratories may have made financial investments and other decisions based on" FDA's longstanding approach. AR20; *see also* Comment of ACLA, FDA2177-6369 at 71 (noting that "countless business decisions affecting the landscape of the U.S. health care system" have been made in reliance on the prior regulatory regime).

In the final rule, FDA states that the FDCA has always classified laboratory test services as medical devices and that for the entire history of the medical-device requirements, FDA has declined to apply them to laboratory-developed tests simply as a matter of "enforcement discretion." AR2. The final rule also states that FDA will phase out this purported "general enforcement discretion approach" over four years. AR9. As a result, excepting the "enforcement discretion policies" discussed above, FDA will begin enforcing medical-device requirements for laboratory-developed test services in several stages measured from the date of publication of the final rule. Reporting, registration, and labeling mandates, among other requirements, will be enforced starting in years one and two, while enforcement of premarket review requirements will begin in years three and four. *Id*.

At the same time, the final rule emphasizes that the phased-in approach and the enforcement carveouts are merely matters of prosecutorial discretion and that laboratories are legally required to comply immediately with all medical-device regulations. AR10. Indeed, FDA repeatedly warns that, "regardless of this or any other enforcement discretion policy," FDA may pursue an enforcement action for violations of the FDCA "at any time." AR10, AR16, AR19, AR22. As to existing tests, the final rule also cautions, vaguely, that FDA will expect compliance with premarket

review and quality-system requirements whenever the test is "changed in certain, more significant ways that could affect its basic safety and effectiveness profile." AR20.

FDA recognizes that the final rule will impose major burdens on laboratories. In fact, the new requirements will initially affect about 79,114 existing tests offered by 1,181 existing laboratories. AR318. Going forward, it will continue to affect about 10,013 new tests every year. *Id.* The final rule also substantially increases FDA's workload. Even assuming that FDA will adhere to its non-binding enforcement discretion policies, *see* AR300–01, FDA estimates that it will need to review an additional 103 premarket applications, 1,090 premarket notifications, and 267 de novo classification requests each year—an across-the-board increase that includes more than doubling the number of premarket applications subject to review. *See* AR320. FDA estimates that the compliance costs for laboratories will total well over $1 billion per year. AR265, AR398, AR441. Over the next two decades, FDA projects that total costs associated with the rule will range from $12.57 billion to $78.99 billion. AR388. According to FDA, this huge "increased cost to laboratories" may cause price increases and "reduce the amount of revenue a laboratory can invest in creating and/or modifying" tests. AR390.

II.

The Laboratory Plaintiffs contend that FDA's final rule must be vacated under the APA because it exceeds FDA's statutory jurisdiction, authority, or limitations.[10]

[10] The Laboratory Plaintiffs further contend that the final rule implicates the major questions doctrine. The major questions doctrine counsels that "decision[s] of such magnitude

The Court agrees, and therefore need not address the Laboratory Plaintiffs' additional claim that the final rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

Although FDA does not challenge the Laboratory Plaintiffs' standing to sue, the Court is obligated to independently consider this Article III requirement. *Bertulli v. Indep. Ass'n of Cont'l Pilots*, 242 F.3d 290, 294 (5th Cir. 2001) (Standing "goes to the constitutional power of a federal court to entertain an action, and th[e] court has the duty to determine whether standing exists even if not raised by the parties."). Article III standing requires a plaintiff to prove "(i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380, 144 S.Ct. 1540, 219 L.Ed. 2d 121 (2024). As the Supreme Court has explained, causation and redressability are often "flip sides of the same coin." *Id.* (quotation omitted). Thus, "[i]f a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury." *Id.* at 381.

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and consequence on a matter of earnest and profound debate across the country must rest with Congress itself, or an agency acting pursuant to a clear delegation from that representative body." *Biden v. Nebraska*, 600 U.S. 477, 504,143 S.Ct. 2355, 216 L.Ed.2d 1063 (2024) (cleaned up). When the doctrine applies, it "requires agencies to point to 'clear congressional authorization' for actions of major 'economic and political significance.'" *Rest. L. Ctr. v. DOL*, 120 F.4th 163, 174 n.9 (5th Cir. 2024) (quoting *West Virginia v. EPA*, 597 U.S. 697, 721, 724, 142 S.Ct. 2587, 213 L.Ed.2d 896 (2022) (citations and internal quotation marks omitted). The Court need not consider whether this doctrine applies because the final rule exceeds FDA's authority under the FDCA's plain text.

The Laboratory Plaintiffs assert that they are injured by the final rule's "massive compliance costs." (Dkt. #20 at 27). Plaintiff ACLA's members include well-established laboratory services providers such as HealthTrackRX, Quest Diagnostics, Labcorp, Mayo Clinic Laboratories, and ARUP Laboratories. These organizations provide thousands of existing laboratory-developed tests that would be treated as unapproved devices under the final rule, making them direct "object[s] of the [r]egulation" challenged. *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264–65 (5th Cir. 2015). Plaintiff AMP's roughly 3,000 members include medical doctors and doctoral-scientist laboratory directors, basic and translational scientists, and technologists who work in academic and community medical centers, government, and industry in every State.

The Laboratory Plaintiffs and their members engage in research-and-development efforts to bring to market new and modified tests that would likewise be treated as unapproved devices under the final rule. *See, e.g.*, Cause No. 4:24-CV-479 (Dkt. #1-1, 1-2, 1-3, 1-4, 1-5). Laboratory-developed tests are often updated and customized (under the supervision of a CLIA-qualified laboratory director) to account for the latest scientific developments and the needs of particular patients and clinicians. *See, e.g.*, Cause No. 4:24-CV-479 (Dkt. #1-1,1-4). The final rule will upend these practices—overturning decades of settled expectations, imposing large compliance costs, creating regulatory uncertainty, and hindering the development of novel testing protocols. *See, e.g.*, Cause No. 4:24-CV-479 (Dkt. #1-1, 1-2, 1-3, 1-4, 1-5). In this regard, once the final rule takes effect, laboratories across the country will confront heavy costs, often amounting to hundreds of thousands or millions of dollars

per test, in order to ensure compliance with federal law. *See* AR379, AR385; *see also, e.g.*, Cause No. 4:24-CV-479 (Dkt. #1-1, 1-3, 1-4).

When, as here, "a plaintiff is an object of a regulation," there is "'ordinarily little question'" that the plaintiff has standing. *Contender Farms*, 779 F.3d at 264 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). The "economic harm" caused by the final rule is "a quintessential Article III injury." *Book People, Inc. v. Wong*, 91 F.4th 318, 331 (5th Cir. 2024) (cleaned up). Plaintiffs ACLA and AMP also have associational standing because (1) at least one of their members has standing, (2) this case is germane to ACLA's and AMP's organizational missions, and (3) ACLA and AMP seek only "prospective or injunctive relief," which does not require individualized proof. *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.,* 517 U.S. 544, 546, 116 S.Ct. 1529, 134 L.Ed.2d 58 (1996).

HealthTrackRX and other members of ACLA and AMP will begin incurring compliance costs immediately. Even assuming FDA adheres to its non-binding enforcement discretion policies, the agency admits that compliance costs will exceed $100 million dollars in year one and will rapidly accelerate. *See* AR388 (estimating compliance costs will rise to $113 million in year two, $386 million in year three, and more than $1.6 billion every following year). Laboratories will similarly incur costs immediately in response to the premarket review requirements. The Laboratory Plaintiffs therefore have standing to bring these consolidated actions.[11]

[11] Under the APA, plaintiffs must also satisfy an additional test for standing: "The interest [t]he[y] assert[] must be 'arguably within the zone of interests to be protected or regulated by the statute' that [t]he[y] say[] was violated." *Match-E-Be-Nash-She-Wish Band*

III.

A.

"Summary judgment is appropriate only when 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Shepherd ex rel. Shepherd v. City of Shreveport*, 920 F.3d 278, 282–83 (5th Cir. 2019) (quoting FED. R. CIV. P. 56(a)). When the only issues before the Court are "pure questions of law"—as is the case here—summary judgment is an appropriate mechanism to resolve the dispute. *See Maxim Crane Works, L.P. v. Zurich Am. Ins.*, 11 F.4th 345, 350 (5th Cir. 2021) (quotations omitted); *see also Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 214 (5th Cir. 1996) (per curiam) ("We have consistently upheld, without comment, the use of summary judgment as a mechanism for review of agency decisions."). "When there are cross-motions for summary judgment, [courts] review each party's motion independently, viewing the evidence and inferences in the light most favorable to the nonmoving party." *Texas v.*

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of Pottawatomi Indians v. Patchak, 567 U.S. 209, 224, 132 S.Ct. 2199, 183 L.Ed.2d 211 (2012) (quoting *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153, 90 S.Ct. 827, 25 L.Ed.2d 184 (1970)). The zone-of-interests test "is not meant to be especially demanding." *Id.* at 225 (quotation omitted). The test "forecloses suit only when a plaintiff's 'interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that' 'Congress authorized that plaintiff to sue.'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130, 134 S.Ct. 1377, 1389, 188 L.Ed. 2d 392 (2014) (quotation omitted).

However, unlike constitutional standing, a zone-of-interest challenge to standing can be waived. *See, e.g.*, *Laub v. U.S. Dep't of Interior*, 342 F.3d 1080, 1087 n.6 (9th Cir. 2003) ("[B]ecause the zone of interests test is merely prudential rather than constitutional it is waivable."). FDA has not raised any zone-of-interest challenge to the Laboratory Plaintiffs' standing, so it is waived. In any event, the test is met. The Laboratory Plaintiffs' interests fall squarely within the "zone of interests" regulated under the final rule, particularly the contemplated changes in the regulatory oversight of laboratory-developed test services.

United States, 50 F.4th 498, 522 (5th Cir. 2022).

B.

In *Loper Bright Enters. v. Raimondo*, the Supreme Court made clear that "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority. . . ." 603 U.S. 369, 412, 144 S.Ct. 2244, 219 L.Ed.2d 832 (2024). The exercise of such independent judgment, the Court explained, is rooted in the "solemn duty" imposed on courts under the Constitution to "say what the law is." *Id*. at 385 (citing *United States v. Dickson*, 40 U.S. (15 Pet.) 141, 10 L.Ed. 689 (1841) (Story, J.); *Marbury v. Madison*, 5. U.S. (1 Cranch) 137, 177, 2 L.Ed. 60 (1803)).

The Court also observed that the exercise of independent judicial judgment to decide legal questions is embodied in the APA, which "directs that '[t]o the extent necessary to decision and when presented, [a] reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action.'" *Loper Bright*, 603 U.S. at 391 (quoting 5 U.S.C. § 706). Likewise, under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law." *Id*. (quoting § 706(2)(A)). "The APA thus codifies for agency cases the unremarkable, yet elemental proposition reflected by judicial practice dating back to *Marbury*: that courts decide legal questions by applying their own judgment." *Id*.

And "[w]here . . . Congress has clearly delegated discretionary authority to an agency," courts discharge their duty by "'independently interpret[ing] the statute and

effectuat[ing] the will of Congress subject to constitutional limits.'" *Mayfield v. DOL*, 117 F.4th 611, 617 (5th Cir. 2024) (quoting *Loper Bright*, 603 U.S. at 395). Thus, courts must "independently identify and respect [constitutional] delegations of authority, police the outer statutory boundaries of those delegations, and ensure that agencies exercise their discretion consistent with the APA." *Id.* (quoting *Loper Bright*, 603 U.S. at 374). "Doing so requires using 'all relevant interpretive tools' to determine the 'best' reading of a statute; a merely 'permissible' reading is not enough." *Id.* (quoting *Loper Bright*, 603 U.S. at 400).

IV.

The final rule contemplates expanding FDA's jurisdiction to cover laboratory-developed test services as medical "devices" under the FDCA. That expansion is foreclosed by the text, structure, and history of the FDCA and CLIA. Congress considered the unique regulatory issues raised by clinical laboratories and the tests they develop and perform. It addressed those issues through the comprehensive but distinct statutory regime of CLIA, not through the FDCA. And Congress vested authority over those regulations in CMS, not in FDA.

The FDCA's text reflects this division of labor by granting FDA authority over "devices," defined in terms that make clear that devices are articles of commerce, not the kinds of services performed by doctors and laboratories. Furthermore, several canons of construction underscore that Congress has not *sub silentio* granted FDA the regulatory power that it seeks to exercise through the final rule. This conclusion is also buttressed by the structure of the FDCA, the broader statutory framework that includes CLIA, and the history of these laws.

A.

"Administrative agencies are creatures of statute." *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 117, 142 S.Ct. 661, 211 L.Ed.2d 448 (2022). Accordingly, they "must point to explicit Congressional authority justifying their decisions." *Inhance Techs., L.L.C. v. EPA*, 96 F.4th 888, 893 (5th Cir. 2024); *see also VanDerStok v. Garland*, 86 F.4th 179, 187 (5th Cir. 2023) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.") (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988)).

To determine whether a statute grants an agency the authority it claims, the Court looks to the statute's text. *VanDerStok*, 86 F.4th at 188; *see also BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183, 124 S.Ct. 1587, 158 L.Ed.2d 338 (2004) (explaining that statutory interpretation "begins with the statutory text, and ends there as well if the text is unambiguous"). And when there is an ambiguity "about the scope of an agency's own power . . . abdication in favor of the agency is *least* appropriate." *Loper Bright*, 603 U.S. at 401 (emphasis in original).

B.

1.

The FDCA's text makes clear that the "devices" within its purview do not include professional medical services. Under the FDCA, Congress authorized FDA to protect public health by regulating the safety and effectiveness of "any food, drug, device, tobacco product, or cosmetic" that is "introduc[ed] into interstate commerce." 21 U.S.C. § 331(a). Thus, the agency may regulate manufacturers of only

commercially distributed medical "devices," including devices used to perform standardized clinical tests (known as "test kits"). But laboratory-developed test services are professional medical services that are qualitatively and categorically different from the tangible goods that FDA may regulate as "devices." Statutory text and basic principles of interpretation confirm that laboratory-developed test services are not medical "devices" under the FDCA.

The FDCA defines the term "device," in relevant part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory. . . ." 21 U.S.C. § 321(h)(1). Because the statute does not define those terms further, they must be given their "ordinary, contemporary, common meaning." *Rest. L. Ctr. v. DOL*, 120 F.4th 163, 171 (5th Cir. 2024) (internal quotation marks and citations omitted); *see also* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 69–77 (2012) ("The ordinary-meaning rule is the most fundamental semantic rule of interpretation."). Dictionary definitions may serve to inform a term's ordinary meaning. *United States v. Radley*, 632 F.3d 177, 182–83 (5th Cir. 2011). The "ordinary" meaning of a word is not "the broadest possible meaning that the definition of the word can bear"; it is how the word is "normally" and most "natural[ly]" understood. *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 569, 132 S.Ct. 1997, 182 L.Ed.2d 903 (2012).

All the operative terms listed in the FDCA's "device" definition—"instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent"—ordinarily refer to tangible, physical products. FDA does not contend

otherwise for most of these terms, focusing only on the words "apparatus" and "contrivance" as conceivably including intangible processes. In FDA's view, the "broad statutory definition of 'device' clearly encompasses" laboratory-developed test services because the definition of device includes the terms "apparatus" and "contrivance." (Dkt. #54 at 19). To support this assertion, FDA identifies three definitions of "apparatus":

- "[A] set of equipment [or] tools . . . used for a particular purpose."[12]
- "[A] set of materials or equipment designed for a particular use."[13]
- "The things collectively in which [a] preparation consists, and by which its processes are maintained; equipments . . . ; material appendages or arrangements[,]" especially "[t]he mechanical requisites employed in scientific experiments or investigations."[14]

FDA also points to a definition of "contrivance" as an "artificial arrangement" and "a thing contrived."[15]

The dictionary definitions identified by FDA are generally consistent with definitions of "apparatus" and "contrivance" that the Court has reviewed.[16] These

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[12] (Dkt. #54 at 19) (quoting CAMBRIDGE DICTIONARY, *Apparatus*, https://perma.cc/2BU5-QR8K). Notably, this definition references a synonym to "apparatus" as "equipment," and uses the following example sentence: "The divers checked their breathing apparatus." *Id.*

[13] (Dkt. #54 at 19) (quoting MERRIAM-WEBSTER, *Apparatus*, https://perma.cc/D5N7-UR5Q).

[14] (Dkt. #54 at 19) (quoting OXFORD ENGLISH DICTIONARY, *Apparatus*, https://perma.cc/3VYW-LXC8).

[15] (Dkt. #54 at 19) (quoting MERRIAM-WEBSTER, *Contrivance*, https://perma.cc/B4E6-BRSA).

[16] *See* WEBSTER'S SECOND NEW INTERNATIONAL DICTIONARY (1934) (defining "apparatus" as "[a] collection or set of materials, implements, or utensils for a given work, experimental or operative," and as "[a]ny complex instrument or appliance, mechanical or chemical, for a specific action or operation; machinery; mechanism"); OXFORD ENGLISH

definitions are unhelpful to FDA. Virtually every definition of "apparatus" and "contrivance"—even those relied on by FDA—describes these terms as encompassing a physical product or a group of physical products, including "instruments," "materials," "equipment," "implements," "utensils," and "tools" that will be used for a particular "purpose" or "use," including for "scientific experiments or investigations."[17] But neither side disputes that tangible equipment, instruments, materials, tools, and related products used in laboratory-developed tests, such as microscopes, centrifuges, and mass spectrometers, are subject to FDA regulation under the FDCA, and have been for decades. A laboratory-test process and methodology, however, is far afield from such tangible products, equipment, "apparatuses" or "contrivances."

And just as the use of mechanical tools, instruments, and equipment for a scientific "experiment" or "investigation" does not render the experiment or investigation *itself* an "apparatus" or "contrivance," the use of such products as part of a laboratory-developed test service does not transform this medical *service* into an apparatus or contrivance under the FDCA. Laboratories across the country use equipment of many kinds to perform clinical testing services, but that does not render

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DICTIONARY (1933) (defining "contrivance" as "a mechanical device or arrangement"); WEBSTER'S SECOND NEW INTERNATIONAL DICTIONARY (1934) (defining "contrivance" as "[a] mechanical device; an appliance").

[17] Although FDA references a broad definition of contrivance, its source goes on to identify the most common meaning of "contrivance" is "a thing contrived, *especially*: a mechanical device." MERRIAM-WEBSTER, *Contrivance*, https://perma.cc/B4E6-BRSA. Again, the most common meaning of this term points to a tangible product, not an intangible methodology or process.

the services these laboratories perform *themselves* "medical devices." In this regard, FDA's belief that laboratory-developed test services involve the "manufacturing" of a "device," also misunderstands the meaning of the word "manufacture." In common parlance, manufacturing refers to "something made from raw materials by hand or by machinery," or "the process or operation of making wares or other material products by hand or by machinery." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1378 (1976), *Manufacture*.[18] Of course, laboratory-developed test services do not "make" any physical products, they generate information, based on test results, that is provided by the laboratory to a patient's treating physician.[19]

Resisting this common-sense understanding of laboratory-developed test services, FDA styles the final rule as a regulation of "IVD test systems made by laboratories." (Dkt. #54 at 18). FDA then defines "IVD test system"—a term that does not appear in the statute—as "a set of physical components that function together to produce a test result." (Dkt. #54 at 18–19). By "a set of physical components" FDA means any "collection of physical objects . . . employ[ed] to produce a test result."

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[18] *See also* MERRIAM WEBSTER DICTIONARY (2024), https://perma.cc/H99W-8Q95 (same).

[19] The FDCA does not define "manufacture," so the word should be given its ordinary meaning. *Rest. L. Ctr.*, 120 F.4th at 171. FDA resists this result, arguing that the common meaning of "manufacture," relied upon by the Laboratory Plaintiffs, is "artificially narrow." (Dkt. #68 at 21–22). Instead, FDA suggests that the Court should apply the agency's self-created, more expansive definition of "manufacture" that embraces "a test designer's initiation of specifications, including specifications that require the end user to independently obtain some or all of a test's physical components." *Id.* (citing 21 C.F.R. §§ 807.3(d)(3), 809.10(b)(8)(i)–(ii)). It's difficult to fathom how a test designer's "initiation of specifications" somehow transforms a laboratory-developed test service into the "manufacture" of a "device." Regardless, agencies can't evade established rules of statutory construction by fabricating their own definitions of commonly used terms, untethered to their ordinary meaning, as FDA has done here.

(Dkt. #54 at 27 n.12); *see also* (Dkt. #54 at 19) (describing the "device" regulated by the final rule as the collection of various physical tools, "such as reagents, instruments, and other articles," that laboratory professionals use "to produce a test result").

FDA's creative attempt to expand its jurisdiction under the FDCA fails for two reasons. First, FDA has no authority to alter or expand the FDCA's definition of "device" in § 321(h), including through a rulemaking inventing new "definitions" untethered to the statute. *See Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014) ("We reaffirm the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."). Only Congress can change the text of § 321(h). Second, FDA's self-created term "IVD test system" and related "definitions" affirmatively work against the FDCA's limits on FDA's jurisdiction. FDA conflates two distinct things: (1) a discrete set of tangible articles packaged as a product for commercial distribution (e.g., a COVID-19 test kit), and (2) an assortment of physical tools that laboratory professionals use in transient relationships to each other to deliver a service. FDA employs the "IVD test system" terminology to improperly collapse that distinction. Neither side disputes that, if a laboratory makes a test kit for commercial distribution, it is manufacturing a device. But when laboratory professionals use a series of tools to perform a test, or when they develop new test

protocols that call for the use of such tools, they are not manufacturing devices, they are conceiving and carrying out professional services.[20]

Taken to its logical conclusion, FDA's contrary view implicates limitless FDA oversight of all surgical procedures and physical examinations that use "devices." A few examples illustrate the point. When a radiologist reads an x-ray, he or she is providing a service that depends on a medical device—the x-ray machine. But the radiologist is rendering a service and is not subject to regulation under the FDCA. Similarly, when a heart surgeon conducts an operation to repair a valve or insert a pacemaker, the surgical procedure does not become a "device" merely because it involves the use of surgical instruments, sutures, and other medical equipment. Under FDA's overly broad reading of the term "device," however, the radiologist's x-ray analysis, the heart surgeon's valve-repair or pacemaker-insertion operation, and nearly every other medical procedure or examination would constitute "manufacturing" a medical "device," thereby implicating FDA oversight. Doing so would give the term "device" an extraordinary, expansive meaning with far-reaching consequences, rather than the ordinary and normal meaning required by Supreme

[20] The final rule includes similar semantics that appear designed to evade FDA's jurisdictional limitations under the FDCA. Specifically, the final rule amends 21 C.F.R. § 809.3(a), which defines "in vitro diagnostic products" as "those reagents, instruments, and *systems* intended for use in the diagnosis of disease or other conditions" and states that such "products are devices as defined in [the FDCA]." *Id.* (emphasis added). The final rule also adds the phrase "including when the manufacturer of these products is a laboratory." AR1–2. Again, FDA has no authority to invent its own add-ons to the FDCA's definition of "device" in § 321(h), for example by effectively pasting in the word "systems," not included by Congress, or "collection of physical objects . . . employ[ed] to produce a test result," another phrase unconnected to the legislative definition of "device" and plainly designed to broaden FDA's authority.

Court precedent. The Court will not go down that road. The plain text of 21 U.S.C. § 321(h) does not support FDA's assertion that laboratory-developed test services are "devices" subject to the FDCA.

2.

The conclusion that laboratory-developed test services are not "devices" under § 321(h) is confirmed by the application of two familiar canons of construction: *ejusdem generis* and *noscitur a sociis*. Beginning with *ejusdem generis*, this interpretive canon has "deep roots in our legal tradition." *United States v. Koutsostamatis*, 956 F.3d 301, 306–07 (5th Cir. 2020) (citing *Archbishop of Canterbury's Case*, (1596) 76 Eng. Rep. 519, 520–21 (KB) (using *ejusdem generis*)). Because courts have used canons such as *ejusdem generis* to interpret texts for centuries, courts may "presume that 'Congress legislates with knowledge of [these] basic rules of statutory construction.'" *Id.* at 307 (alteration in original) (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496, 111 S.Ct. 888, 112 L.Ed.2d 1005 (1991)). "The *ejusdem generis* canon applies when a drafter has tacked on a catchall phrase at the end of an enumeration of specifics . . . ." SCALIA & GARNER at 199. As the Fifth Circuit has confirmed, "[w]here it applies, *ejusdem generis* limits general terms which follow specific ones to matters similar to those specified." *Koutsostamatis*, 956 F.3d at 308 (quotation omitted). Thus, "when a list of specific X's is followed by the catchall phrase 'other X's,' *ejusdem generis* 'implies the addition of similar after the word other.'" *Id.* (quoting SCALIA & GARNER, supra, at 199).

Recall that, in defining the term "device," § 321(h) lists six examples (instrument, apparatus, implement, machine, contrivance, implant, and in vitro

reagent), followed by the catchall phrase "or other similar or related article." 21 U.S.C. § 321(h)(1). The statute then goes on to add to the list by also including in the definition "any component, part, or accessory [of the listed items and catchall]." 21 U.S.C. § 321(h)(1). Applying the *ejusdem generis* canon, the Court understands the residual phrase in § 321(h), "or other similar or related article," to encompass only materials similar to the preceding list of specific items. As explained herein, the six examples (instrument, apparatus, implement, machine, contrivance, implant, and in vitro reagent), ordinarily refer to tangible, physical products. Accordingly, the "other similar or related article" language in § 321(h) is best understood to also reference tangible, physical products. This reading is strengthened by Congress's express language limiting the catchall to "similar or related" items. *Id.*

Beyond the application of the *ejusdem generis* canon, dictionary definitions also confirm that "article" refers to tangible items.[21] Likewise, courts have consistently found that the term "article" references material things in various statutory contexts. *See, e.g.*, *ClearCorrect Operating, LLC v. ITC*, 810 F.3d 1283, 1290–94 (Fed. Cir. 2015) (finding it "clear that 'articles' means 'material things,' whether when looking to the literal text or when read in context"); *Kaiser Aluminum & Chem. Corp. v. U.S. Consumer Prod. Safety Comm'n*, 574 F.2d 178, 180 (3d Cir. 1978) (holding that the term "article" in the Consumer Product Safety Act "denote[s] 'any material thing'");

[21] *See, e.g.*, WEBSTER'S SECOND NEW INTERNATIONAL DICTIONARY (1934) (defining "Article" as "a thing of a particular class or kind . . . a commodity," as in "an article of merchandise"); WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 123 (1976) (defining "Article" as a "material thing" or "a thing of a particular class or kind as distinct from a thing of another class or kind").

AMP Inc. v. Gardner, 389 F.2d 825, 826–27 & n.4 (2d Cir. 1968) (noting that in the FDCA the term article refers to a "class of material things").[22] In sum, the best reading of "other similar or related article" in § 321(h) is that it references tangible items or products, like the list of terms preceding it.

Application of the *noscitur a sociis* canon also confirms this understanding. The canon provides that "a word is given more precise content by the neighboring words with which it is associated." *Fischer v. United States*, 603 U.S. 480, 487, 144 S.Ct. 2176, 219 L.Ed. 2d 911 (2024) (quotation omitted). Application of the *noscitur a sociis* canon "avoid[s] ascribing to one word a meaning so broad that it is inconsistent with the company it keeps." *Id.* It applies "when a string of statutory terms raises the implication that the words grouped in a list should be given related meaning." *United States v. Buluc*, 930 F.3d 383, 390 (5th Cir. 2019); *see also* SCALIA & GARNER at 195 (quoting *Third Nat'l Bank in Nashville v. Impac Ltd.*, 432 U.S. 312, 322, 97 S.Ct. 2307, 53 L.Ed.2d 368 (1977)) (explaining that the canon "especially holds that 'words grouped in a list should be given related meaning[s]'").

[22] In the final rule's preamble, FDA asserts that the term "article" cannot be limited to tangible goods because, in FDA's view, computer software can qualify as a medical device despite being "an intangible thing." 89 Fed. Reg. at 37,331–32. Even assuming FDA is correct that software may sometimes qualify as a device, that does not support FDA's assertion that the "device" definition can be stretched to cover the intangible professional services provided by laboratory medical professionals, which are different from manufactured medical devices. As the Supreme Court has explained, while it is possible to conceive of "software in the abstract: the instructions themselves detached from any medium," "[w]hat retailers sell, and consumers buy," are "tangible," "physical cop[ies] of the software" that, whether "delivered by CD-ROM" or "downloaded from the Internet," are ultimately "contained in and continuously performed by" a piece of physical hardware such as a computer. *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 446–48, 449–51, 127 S.Ct. 1746, 167 L.Ed.2d 737 (2007).

Relevant here, the two terms highlighted by FDA to support its claim that laboratory-developed test services are "devices" under the FDCA are "apparatus" and "contrivance." The Court has explained why each of these terms, on its face, is best read to reference material things or products, not medical methodologies, processes, or services. *See supra* Part IV.B.1. This understanding is confirmed by the *noscitur a sociis* canon because "apparatus" and "contrivance" do not appear in isolation. Rather, they are included in a series of words in § 321(h) that refer to tangible, physical products: "instrument," "implement," "machine," "implant," "in vitro reagent," and the catchall phrase's key word—"article." 21 U.S.C. § 321(h)(1). The *noscitur a sociis* canon therefore affirms that the words "apparatus" and "contrivance" in this context should not be construed expansively, but consistent with the neighboring words in the statute. Because all these words describe tangible products, neither "apparatus" nor "contrivance" covers methodologies, processes, or professional services.

C.

Besides being contrary to the ordinary meaning of § 321(h)'s definition of "device," FDA's "interpretation [also] sits uncomfortably with" several other FDCA provisions. *Rest. L. Ctr.*, 120 F.4th. at 173; *see also K Mart Corp. v. Cartier*, *Inc.*, 486 U.S. 281, 291, 108 S.Ct. 1811, 100 L.Ed.2d 313 (1988) (explaining that, "[i]n ascertaining the plain meaning of [a] statute," courts must look to both the particular statutory language at issue, "as well as the language and design of the statute as a whole"). For example, the statute repeatedly and consistently refers to the making of

devices as "manufacturing."[23] As explained herein, the ordinary meaning of "manufacture" is to "make into a product suitable for use" or "make from raw materials by hand or by machinery." *See supra* Part IV.B.1. Unlike physical products, professional services are not "manufactured."

Moreover, several FDCA provisions are triggered only when a device is shipped or received in interstate commerce, commercially distributed, or held for sale—actions that, in ordinary parlance, can be performed on a manufactured product but not on a professional service. For example, an application for premarket approval for a device must include, among other things, (i) a description of "the components, ingredients, and properties" of the device; (ii) a description of the methods, facilities, and controls used in "the manufacture, processing, and when relevant, packing and installation" of the device; and (iii) "such samples of such device and of components thereof as the Secretary may reasonably require" (or "information concerning the location of one or more such devices readily available for examination and testing"). 21 U.S.C. § 360e(c)(1)(B), (C), (E). Professional services do not have ingredients, properties, or components. Nor are they manufactured, processed, packed, or installed. And samples of a service cannot be submitted to FDA or made readily available for inspection. The statute also allows for FDA to order certain

[23] *See, e.g.*, 21 U.S.C. § 331(g) (prohibiting "[t]he manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded"); *id.* § 321(h)(2) (defining "counterfeit device," in relevant part, as one that "is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device"); *id.* § 351(h) (defining a device as "adulterated" if, inter alia, "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements").

manufacturers, importers, or distributors to "repair the device" or "replace the device with a like or equivalent device." 21 U.S.C. § 360h(b). Unlike manufactured products, professional services cannot be repaired or replaced.

Several of FDA's device regulations can similarly be understood to apply only to manufactured products. For instance, an FDA regulation requires the "label of every medical device" and "[e]very device package" to bear a unique device identifier. 21 C.F.R. § 801.20(a). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article," and "device package" is defined as "a package that contains a fixed quantity of a particular version or model of a device." 21 U.S.C. § 321(k); 21 C.F.R. § 801.3. These requirements make sense for manufactured devices: the primary and expected means of communication between the manufacturer and purchaser is through the standardized label. They make no sense for clinical laboratory services, which entail direct communication between professional laboratory clinicians and healthcare providers. Taken together, the FDCA's statutory scheme further confirms that a "device" is a manufactured product, not a professional service.

D.

The "broader context of the [statutory scheme] as a whole," *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341, 117 S.Ct. 843, 136 L.Ed.2d 808 (1997), and the history of the FDCA and CLIA, lends further credence to the Court's conclusion. The FDCA and the MDA were not enacted to regulate clinical laboratory test services. Instead, they addressed concerns with faulty manufactured products such as "quack machines," defective "surgical instruments," "contraceptive[s]," "kidney dialysis units," and

"pacemakers." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–76, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (quotation marks omitted). The MDA came after the Dalkon Shield intrauterine device, introduced in 1970, "was linked to serious infections and several deaths." *Riegel*, 522 U.S. at 315. With the passage of the MDA, Congress established a detailed federal regime for the regulation of medical devices. Recall that the post-MDA statute now provides that, generally, before any new medical device can be introduced or delivered for introduction into interstate commerce for commercial distribution, FDA must grant premarket authorization through a substantial equivalence clearance, a de novo classification, or a premarket approval. *See supra* Part I.A. The FDCA's post-1976 device requirements are strict, inflexible, and designed to regulate mass-manufactured commodities that are distributed by the thousands or millions.[24]

Meanwhile, nothing in the legislative history suggests that the FDCA was intended to reach professional services. Indeed, when Congress enacted the FDCA, it was well-established that "direct control of medical practice . . . [was] beyond the

[24] Take FDA's rigorous premarket approval process. It reviews each application and determines whether there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d); *Riegel*, 552 U.S. at 317. Certain devices are designated as "class III," including devices such as replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. 21 U.S.C. § 360c(a)(1)(C). For these devices, the applicant must submit, among other things, full reports of all information known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for the manufacturing and installing the device. *See* 21 U.S.C. § 360e(c)(1) (describing the components of a premarket-approval application). Once a device has received premarket approval, the manufacturer cannot change the design, manufacturing process, labeling, or any other characteristic if that change would affect the device's "effectiveness or safety" without first applying for, and receiving, supplemental premarket approval. 21 U.S.C. § 360e(d)(6)(A)(I). Certain devices are also subject to ongoing reporting requirements even after receiving approval. 21 U.S.C. § 360i.

power of the federal government." *Linder v. United States*, 268 U.S. 5, 18, 45 S.Ct. 446, 69 L.Ed. 819 (1925). Against this historical backdrop, "[i]t would be peculiar to conclude that" the FDCA as amended "reaches far beyond the . . . scenarios that prompted the legislation in the first place." *Fischer*, 603 U.S. at 492.

It would be even more peculiar to conclude that the FDCA reaches into a professional field—clinical laboratory-developed test services—for which Congress has established a separate, comprehensive, specialized regulatory framework. In this regard, clinical laboratories have been regulated by the federal government in various ways, going back to at least 1967. But at no time did Congress suggest that FDA could regulate such laboratories. For example, laboratories engaged in interstate commerce were initially regulated under CLIA. Concurrently, laboratories participating in Medicare also had to meet separate regulatory requirements established in Medicare's Conditions of Participation or Conditions of Coverage. *See* Medicare, Medicaid, and CLIA Programs; Revision of the Laboratory Regulations for the Medicare, Medicaid, and Clinical Laboratories Improvement Act of 1967 Programs, 55 Fed. Reg. 9538–39. Nothing in those regulations suggests that FDA, rather than CMS (referenced as CMS's predecessor, HCFA, the Health Care Financing Administration) had authority over laboratory-developed testing. In fact, when HCFA revised the Medicare and CLIA regulations in 1990, it noted that FDA had authority over blood-bank programs but made no mention of authority over laboratory-developed test services. *Id*.

In CLIA's 1988 amendments—passed twelve years after the MDA—Congress created a more detailed statutory framework to govern clinical laboratories and their

tests. Congress centralized oversight under HHS, and in turn, CMS, not FDA. CLIA requires the certification of clinical laboratories, defined as any facility for "examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings." 42 U.S.C. § 263a(b). CLIA further provides that CMS "shall issue standards" to ensure quality control, including standards "adequate and appropriate for the validity and reliability of the laboratory examinations" and standards for the personnel "qualifications . . . for the direction, supervision, and performance of examinations and procedures within the laboratory." *Id.* § 263a(f)(1)(A)(C). CLIA also requires laboratories to participate in regular "proficiency testing." *Id.* § 263a(f)(1)(D).

If, as FDA asserts, Congress intended the MDA to subject laboratory-developed test services to the FDCA's regime of device regulations, the enactment of the CLIA Amendments in 1988 makes little sense. The reason is straightforward: Under FDA's theory, by the time Congress amended CLIA in 1988, FDA already had authority to regulate those same tests—authority that it was simply declining in its discretion to exercise. That theory cannot be sustained without rendering CLIA largely, if not entirely, pointless.

FDA's theory becomes even more tenuous considering that neither CLIA's statutory text nor its legislative history make any reference to FDA's allegedly preexisting authority to regulate laboratory-developed test services as "devices." This legislative silence is telling, especially when Congress's avowed objective in amending CLIA was to replace the "patchwork of inconsistent and overlapping standards"

regulating clinical laboratories at that time with a "unified regulatory mechanism." S. Rep. No. 100-561, at 3 (1988); H.R. Rep. No. 100-899, at 12 (1988). That legislative history is also replete with references to the overlapping standards of CLIA, the Medicare statute, and of state regulations. For example, the House Report states that clinical laboratories had, to date, been "governed by two separate and distinct statutes, Medicare and CLIA," and included a section entitled "Current Regulatory System." H.R. Rep. No. 100-899, at 11–12 (1988). Conspicuously absent from that section is any reference to FDA. So although Congress made changes to streamline and strengthen federal regulations over clinical laboratory testing, there is no indication that those changes contemplated a role for FDA.

Although the FDCA's text alone is enough to conclude that FDA lacks authority to regulate laboratory-developed test services as medical "devices," *see supra* Part IV.B, the broader statutory framework of the FDCA and CLIA, and the historical underpinnings of these laws, reinforces the conclusion that the final rule attempts to assert authority over professional medical services that FDA lacks.

E.

FDA's interpretation of the FDCA is troublesome for another reason—it turns on the assumption that a breathtaking amount of criminal activity has been occurring in the clinical laboratory field for many years. No one disputes that the FDCA has not only civil but criminal applications, including offenses that carry penalties of years of imprisonment. *See, e.g.*, 21 U.S.C. § 333(a). FDA's final rule takes the interpretive position that, in 1976, when Congress expanded FDA's authority to regulate medical devices in the MDA, it also quietly intended to outlaw—and subject

to substantial civil and criminal monetary penalties—any professional laboratory-developed test services that were not first approved or cleared by FDA.

The logic of FDA's position is that tens of thousands of professionals across the country performing millions of diagnostic testing services every year, working with thousands of doctors and patients, have done so for decades in open and direct violation of the law. According to FDA, the only reason laboratories have not been civilly and criminally punished is because FDA has chosen to exercise unreviewable "enforcement discretion." Put more bluntly, accepting FDA's interpretation of the FDCA, as articulated in the final rule, would mean that the entire clinical laboratory sector, a significant part of the healthcare system, has been breaking the law for nearly fifty years, and possibly much longer. And it would mean that, going forward, the entire profession is operating unlawfully and can be subject to civil and criminal penalties at any time, with its only protection coming from a policy of enforcement discretion that FDA maintains it is free to revoke at any time.

Given the threat of criminal penalties for violations of the FDCA under FDA's novel interpretation, the Laboratory Plaintiffs maintain that the rule of lenity should be applied in construing the statute. The Court disagrees. The rule of lenity applies "only if 'after seizing everything from which aid can be derived,' there remains 'grievous ambiguity'" in a statute's language. *Pugin v. Garland*, 599 U.S. 600, 610, 143 S.Ct. 1833, 1843, 216 L.Ed. 2d 572 (2023) (quoting *Ocasio v. United States*, 578 U.S. 282, 295 n. 8, 136 S.Ct. 1423, 194 L.Ed.2d 520 (2016)); *see also Cargill v. Garland*, 57 F.4th 447, 469 (5th Cir.), *cert. granted*, 144 S.Ct. 374, 217 L.Ed. 2d 202 (2023), *and aff'd*, 602 U.S. 406, 144 S.Ct. 1613, 219 L.Ed.2d 151 (2024) ("the rule of

lenity applies if the statute is ambiguous"). That is not the case here. On the contrary, the FDCA's relevant text is unambiguous and cannot support FDA's interpretation. *See supra* Part IV.B. The larger context of the FDCA itself, CLIA, and the history of these statutes further confirm that FDA lacks authority to regulate laboratory-developed test services as medical "devices." *See supra* Part IV.C–D.

That said, "the fallout" from FDA's interpretation of the FDCA "underscores [its] implausibility. . . ." *Van Buren v. United States*, 593 U.S. 374, 394, 141 S.Ct. 1648, 210 L.Ed.2d 26 (2021). "It is 'extra icing on a cake already frosted.'" *Id.* (quoting *Yates v. United States*, 574 U.S. 528, 557, 135 S.Ct. 1074, 191 L.Ed.2d 64 (2015) (Kagan, J., dissenting)). In other words, FDA's untenable interpretation of the FDCA is underscored by the pragmatic consequences of accepting that interpretation. Beyond the necessary implication that the laboratory industry has operated for decades as a professional class of unwitting, unprosecuted violators of federal criminal laws, FDA's theory renders inexplicable its decades-long exercise of "enforcement discretion" as FDA has never before sought to enforce the FDCA against clinical laboratories. It also means that FDA itself will need years to bring the laboratory industry into compliance with laws that carry significant criminal penalties, and the agency will have to adapt to the enormous administrative burdens that its asserted jurisdiction would entail. Those implausible implications affirm that FDA's strained reading of the FDCA flouts, rather than effectuates, Congress's intent.

* * * *

FDA's asserted jurisdiction over laboratory-developed test services as "devices" under the FDCA defies bedrock principles of statutory interpretation, common sense, and longstanding industry practice. The FDCA—a statute targeted at mass-produced, mass-marketed, and mass-distributed drugs and devices moving in interstate commerce—is a poor fit for the distinct regulatory issues raised by laboratories that provide vital diagnostic tools for doctors. Blinking this reality, FDA's final rule creates a "square peg into round hole" problem that is not just about a tortured reading of an unambiguous statute, or about FDA attempting to fill a regulatory gap or administer a statute in the face of congressional silence. The more fundamental problem is that Congress has already considered the distinct issues raised by laboratory-developed test services in CLIA, and chose to address those issues by vesting regulatory authority in CMS, not in FDA. Through the final rule, it appears that FDA is attempting to circumvent that legislative decision. It has no authority to do so.

V.

Having concluded that the final rule exceeds FDA's authority and is unlawful, the Court must consider the appropriate remedy. Under the APA, the Court "shall . . . hold unlawful and set aside agency action" that violates the law. 5 U.S.C. § 706(2). In the Fifth Circuit, "vacatur under § 706 is . . . the 'default' remedy for unlawful agency action." *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 952 (5th Cir. 2024); *see also Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 110 F.4th 762, 789 (5th Cir. 2024) (explaining that "[b]inding Fifth Circuit precedent recognizes" that

"the APA empowers and commands courts to 'set aside' unlawful agency actions, allowing a district court's vacatur to render a challenged agency action void" (cleaned up)).

The Fifth Circuit has also clarified the scope of the vacatur remedy, explaining that "setting aside agency action under § 706 has nationwide effect, is not party-restricted, and affects persons in all judicial districts equally." *Braidwood*, 104 F.4th at 951 (internal quotation marks and citations omitted); *see also Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (explaining that "[n]othing in the text of . . . Section 706[ ] suggests that . . . ultimate relief under the APA needs to be limited to [the party] or its members"); *accord Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S.799, 830–31, 144 S. Ct. 2440, 219 L.Ed.2d 1139 (2024) (Kavanaugh, J., concurring) (observing that the Supreme Court has affirmed "countless decisions that vacated agency action, including agency rules," and noting that "[t]hose decisions vacated challenged agency rules rather than merely providing injunctive relief that enjoined enforcement of the rules against the specific plaintiffs").

When an agency rule is set aside under § 706(2), the Court may fashion the remedy in one of two ways: remand the rule with vacatur or remand the rule without vacatur. *See Texas v. United States*, 50 F.4th 498, 529–30 (5th Cir. 2022). The ordinary practice is to vacate and remand the rule. *See Data Mktg. P'ship v. DOL*, 45 F.4th 846, 859 (5th Cir. 2022); *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019). As the Fifth Circuit has noted, "remand without vacatur" is appropriate only in "rare cases." *Rest. L. Ctr.*, 120 F.4th. at 177 (internal quotation

marks and citations omitted) (emphasis in original). Evaluating whether a "rare case" is presented "turns on two factors: (1) the seriousness of the deficiencies of the action, that is, how likely it is the agency will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." *United Steel*, 925 F.3d at 1287.

Here, FDA has not argued that either factor favors a remand without vacatur, and the Court finds that this exceptional remedy is not warranted. There is no likelihood that FDA can justify its decision on remand, given that the final rule exceeds its authority under the FDCA. *See supra* Part IV. And FDA has not pointed to any "disruptive consequences" that would call for remand without vacatur. The final rule is not scheduled to go into effect until May 2025. And in any event, any threat of disruptive consequences "cannot save a rule when its fundamental flaws 'foreclose [the agency] from promulgating the same standards on remand.'" *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008) (quoting *Nat. Res. Def. Council v. EPA*, 489 F.3d 1250, 1261–62 (D.C. Cir. 2007)).

In sum, the Fifth Circuit has made clear that district courts should generally "nullify and revoke" illegal agency action, *Braidwood*, 104 F.4th at 951. The Court finds that such relief is appropriate here. The final rule will initially impact nearly 80,000 existing tests offered by almost 1,200 laboratories, and it will also affect about 10,013 new tests offered every year going forward. The estimated compliance costs for laboratories across the country will total well over $1 billion per year, and over the next two decades, FDA projects that total costs associated with the rule will range from $12.57 billion to $78.99 billion. FDA acknowledges that the enormous increased costs to laboratories may cause price increases and reduce the amount of revenue a

laboratory can invest in creating and modifying tests. Under the circumstances, considering the volume and variety of the trade organizations' members who are entitled to relief, it would be impractical, if not impossible, to fashion party-tailored relief here. Therefore, consistent with controlling circuit precedent, the proper remedy is vacatur of the final rule and remand to FDA for "further consideration in light of this opinion." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019).

VI.

For these reasons, it is **ORDERED** that the Laboratory Plaintiffs' Motions for Summary Judgment, (Dkt. #20, #27), are **GRANTED**. The final rule is hereby **SET ASIDE** and **VACATED**.

It is further **ORDERED** that Defendants' Cross-Motion for Summary Judgment, (Dkt. #54), is **DENIED**.

A final judgment will follow.

So ORDERED and SIGNED this 31st day of March, 2025.

SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE