UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 4:24-cv-479-SDJ JUDGE SEAN D. JORDAN (Administrative Procedure Act case)
ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 4:24-cv-824-SDJ JUDGE SEAN D. JORDAN (Administrative Procedure Act case)

Defendants' Cross-Motion for Summary Judgment, Opposition to Plaintiffs' Motions for Summary Judgment, and Combined Memorandum of Points and Authorities

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INTRODUCTION

There is nothing new about the U.S. Food and Drug Administration's (FDA) jurisdiction over *in vitro* diagnostic test systems ("IVD test systems"). FDA has had the power to regulate these systems since the Federal Food, Drug, and Cosmetic Act (FDCA) was first enacted in 1938, and has expressly asserted its authority to do so since 1973. And for over fifty years, FDA has enforced the FDCA—including requirements established by the Medical Device Amendments of 1976 (MDA)—as to IVD test systems designed and manufactured outside a clinical laboratory. None of this is in dispute.

Historically, however, FDA has generally exercised discretion not to enforce these requirements for most "laboratory developed tests" (LDTs). These are IVD test systems that (among other attributes discussed later) are designed, manufactured, and used within a single laboratory. FDA's general enforcement discretion approach was based on the LDTs of the 1970s—relatively simple tests created and used within a single institution directly involved in patient care. These systems were similar to common well-characterized tests and produced in small volumes to fit the needs of individual patients and local communities. For these reasons and others, FDA generally declined to enforce statutory and regulatory requirements for most LDTs.

But times have changed. LDTs are no longer simple, well-characterized tests made in small numbers for use in one institution based on the needs of a small number of patients. They are often highly complex systems. And many laboratory-made IVD test systems on the market today are not LDTs at all—they are not designed, manufactured, and used within a single laboratory. Rather, they are merely "offered as LDTs," and are in widespread use beyond the laboratory that designed them—just like the IVD test systems that non-laboratory manufacturers have produced for decades without falling within FDA's general enforcement discretion approach. These changes raise significant public health concerns, particularly given the numerous examples of

potentially inaccurate, unsafe, ineffective, or poor quality IVDs offered as LDTs that have or may have caused patient harm.

FDA has concluded that in light of these dramatic developments in the testing landscape, it no longer serves the public health to maintain different enforcement approaches for similar IVD test systems based solely on whether or not they are manufactured by a laboratory. Under the Final Rule challenged here, the agency is phasing out its general enforcement discretion approach for LDTs, and has adopted new targeted enforcement discretion policies applicable to specific categories of laboratory-made IVD test systems. When FDA's phaseout is complete, IVD test systems will generally fall under the same enforcement approach regardless of whether they are manufactured by a laboratory. The Final Rule is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations—including patient access and reliance.

Plaintiffs—the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP)[1]—challenge the Final Rule as exceeding FDA's statutory authority and as arbitrary and capricious in violation of the Administrative Procedure Act (APA). Neither challenge has merit, and Defendants are entitled to summary judgment for multiple reasons.

First, and foremost, Plaintiffs are incorrect when they argue that laboratory-made IVD test systems are intangible services, rather than physical systems, and thus are not subject to FDA's device authorities. The fact that an IVD test system is made by a laboratory, or the fact that a laboratory chooses to monetize the tests it develops on a

[1] Each organizational plaintiff is joined in this lawsuit by one or more of its members. No member plaintiff, however, raises arguments different from those made by the respective organization to which it belons. So for the sake of simplicity, this memorandum refers to ACLA and AMP only.

fee-for-service basis, does not change the fact that the test system itself—the actual object of regulation under the FDCA—is comprised of physical components that function together to produce a test result based on a physical specimen taken from the human body.

That physical system is not an intangible professional service. Rather, the system as a whole is an "instrument, apparatus, implement, machine, contrivance . . . , or other similar or related article" and therefore unambiguously a "device" as Congress has defined that term in the FDCA.[2] 21 U.S.C. § 321(h)(1). As the Supreme Court has explained, "Congress fully intended that the [FDCA]'s coverage be as broad as its literal language." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). That language unambiguously includes IVD test systems—with no exception for IVD test systems made by laboratories—and FDA has for decades consistently interpreted it as such. This Court need only apply that plain language here.

Second, Plaintiffs are incorrect when they argue that the Clinical Laboratory Improvement Amendments of 1988 (CLIA) has somehow displaced FDA's jurisdiction to regulate laboratory-made IVDs like any other device subject to the FDCA. The two statutes complement rather than conflict with each other. Unlike the FDCA, regulation under CLIA addresses the proficiency with which laboratories perform tests rather than design them. And unlike CLIA, regulation under the FDCA addresses the design of test systems to help ensure that their results are clinically valid and support safe and effective patient care. This Court can and should give effect to both statutes.

Third, this case is not subject to either the rule of lenity or the major questions doctrine. There is no statutory ambiguity for lenity to resolve, and this is an ordinary

[2] Unless otherwise specified, references to the FDCA are to the as-amended statute now codified in Chapter 21 of the U.S. Code.

case of federal regulation pursuant to unambiguous Congressional authorization, not an extraordinary one presenting major political, economic, or federalism questions.

Fourth, Plaintiffs cannot show that FDA's phaseout of the general enforcement discretion approach for LDTs, or its choice of targeted enforcement discretion policies, was arbitrary and capricious. The agency carefully weighed a substantial body of evidence, considered reliance interests and patient access, and reached a reasoned decision that more than satisfied the APA's highly deferential standard of review. Notwithstanding Plaintiffs' overheated accusations, the Final Rule is not a "power grab"—it is a prudent public health measure taken based on changed circumstances documented in a thorough rulemaking record.

Finally, even if Plaintiffs prevail on the merits, they are not entitled to universal vacatur of the Final Rule—a remedy of recent vintage that is not required by the text of the APA and is at odds with the longstanding equitable practice that the statute was meant to codify.

STATEMENT OF THE ISSUE

Whether FDA's adoption of the Final Rule was arbitrary, capricious, or beyond its statutory authority to regulate medical devices under the FDCA.

BACKGROUND & STATEMENT OF UNDISPUTED MATERIAL FACTS

A. IVD Test Systems and Laboratory Developed Tests.

This case is about FDA's approach to enforcing the FDCA and its implementing regulations for IVD test systems generally, and for LDTs in particular. A few terms used in this memorandum are important to understand from the outset:

An **IVD test system** is one type of *in vitro* diagnostic product. *See* 21 C.F.R. § 809.3(a). Specifically, an IVD test *system* is a "set of components—such as reagents,

instruments, and other articles," AR46,[3] that is "intended for use in the diagnosis of disease or other conditions" by "collection, preparation, and examination of specimens"—like blood or tissue—that are "taken from the human body," 21 C.F.R. § 809.3(a). The components of an IVD test system "function together to produce a test result," AR46, that is attributable to the system as a whole rather than to any single component, *see* AR47-48.

A subset of IVD test systems are intended for clinical use, and are manufactured by and performed within clinical laboratories that are certified under CLIA and that meet the regulatory requirements under CLIA to perform high complexity testing. *See* AR1 n.1. This memorandum refers to these tests[4] interchangeably as **"laboratory-made IVD test systems" or "IVD test systems made by laboratories."**

Moreover, laboratory-made IVD test systems fall into further subcategories relevant to this case. The first category consists of **LDTs.** FDA has generally considered an LDT to be an IVD test system "that is intended for clinical use and that is *designed, manufactured, and used within a single laboratory* that is certified under [CLIA] and meets the regulatory requirements under CLIA to perform high complexity testing." AR4. The second category consists of **"IVDs offered as LDTs."** AR1 n.1. These are IVD test systems "that are manufactured and offered as LDTs by laboratories that are certified under [CLIA] and that meet the regulatory requirements under CLIA to perform high

[3] To conserve agency resources, the parties agreed that Defendants would produce and Bates-stamp 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).

[4] Like the Final Rule, *see* AR3, this memorandum refers interchangeably to "tests" and "test systems."

complexity testing, and [that are] used within such laboratories," but may "not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory." *Id.* As used in this memorandum, the term "laboratory-made IVD test systems" includes both LDTs and IVDs offered as LDTs.

B. The Testing Landscape Has Changed Significantly Since the 1970s.

FDA's Prior General Enforcement Discretion Approach. When Congress enacted the 1976 MDA to create the comprehensive system of device regulation that is still in force today, IVD test systems made by laboratories were mostly true LDTs. They were limited in terms of market reach and technical complexity, and tended to be designed, manufactured, performed, and interpreted within a single healthcare institution directly involved in patient care. AR7126. These tests were "mostly manufactured in small volumes by laboratories that served their local communities," were either tailored to "the needs of a local patient population" or "generally similar to well-characterized, standard tests," did not use automation, and tended to be made "using components legally marketed for clinical use . . . [and] marketed in compliance with FDA regulatory requirements." *Id.*

"Due to these and other factors, FDA generally exercised enforcement discretion such that it generally has not enforced applicable requirements for most LDTs." *Id.*[5] In

[5] Importantly, some IVD test systems made by laboratories have never fallen within this general enforcement discretion approach. For example, as explained in more detail in the Final Rule, *see* AR11, FDA has not applied the general enforcement discretion approach to (1) certain blood typing tests, and certain tests intended to screen for infectious disease in donated blood, human cells, tissues, and cellular and tissue-based products; (2) tests intended for use in emergencies, potential emergencies, or material threats declared pursuant to 21 U.S.C. § 360bbb-3; and (3) direct-to-consumer tests intended for use without meaningful involvement by a licensed healthcare professional. Likewise, the phaseout policy adopted in the Final Rule, *see infra* at 14-16, does not apply to these categories of test systems.

doing so, the agency has explained that it was exercising enforcement discretion, and emphasized that it both retained the authority to regulate more actively and would do so if necessary to protect public health. *See, e.g.*, AR8020-21 (noting in 2006 the "scope of laboratory-developed tests over which FDA has generally exercised enforcement discretion"); 61 Fed. Reg. 10484, 10484 (Mar. 14, 1996) ("[I]n-house developed tests have not been actively regulated by the Agency . . . . However, at a future date, the agency may reevaluate whether additional controls . . . may be needed to provide an appropriate level of consumer protection."); 62 Fed. Reg. 62243, 62249 (Nov. 21, 1997) (emphasizing that decision to adopt a regulation focused narrowly on analyte specific reagents would "not preclude future regulatory activity by FDA . . . from developing mechanisms to improve the quality of . . . test production"); *accord id.* at 62252.

Concerning Developments Since the 1970s. The Final Rule phases out this general enforcement discretion approach because radically changed circumstances are putting patients at risk. Laboratory-made IVD test systems are no longer a small and technically straightforward segment of the testing market—they are "ubiquitous," are "used in some of the most complex areas of medicine," and themselves "rely on high-tech or complex instrumentation and software to generate results and clinical interpretations." AR7126-27; *see also* AR4 (noting cybersecurity risk as an area of growing concern). In other words, today's laboratory-made IVD testing systems lack the "characteristics and institutional safeguards that originally justified FDA's general enforcement discretion approach." AR7127. Moreover, many such tests are "launched as LDTs" despite not being designed, manufactured, and used within a single laboratory. AR10-11, AR7127; *see also* AR4.

Other developments also contribute to FDA's concern that the IVD test systems made by laboratories today are substantially riskier than their 1970's-era predecessors. They are used "outside of the patient's healthcare setting." AR4. They are run "in very large volumes" and "for large and diverse populations." *Id.* And they are "commonly

manufactured with instruments or other components not legally marketed for clinical use" (*e.g.*, that are labeled for research use only, *see* 21 C.F.R. § 809.10(c)). *See* AR4.

Those concerns are not merely theoretical—they are borne out in the record supporting the Final Rule. Evidence from a wide variety of sources "points to fundamental uncertainty in the marketplace about whether IVDs offered as LDTs provide accurate and reliable results" on which patients and providers may safely rely. AR7127-29; *see also* AR36-37. Briefly, by way of example: case studies show instances in which laboratory-made IVD test systems not authorized by FDA have yielded many false positive test results (which may result in patient exposure to inappropriate and potentially dangerous treatments), many false negative test results (which may result in patients failing to receive needed care), or *both*. FDA2177-0054 at 8-18; *see also* AR7127. In other cases, FDA has identified IVD test systems made by laboratories that purport to aid in diagnosis by detecting a factor with "no clear relevance" to the disease in question, AR7308-13, or based on "disproven scientific concepts," AR7313-15. Multiple scientific publications have documented "high variability"—a tendency for the same test system run on the same sample to nevertheless produce different results—in tests for multiple conditions designed and offered as LDTs by multiple laboratories. AR7127-28 & Refs. 12-17. FDA itself has also identified "significant concerns" with laboratory-made IVD test systems in the course of reviewing submissions for premarket authorization, applications for approval of an investigational device exemption, or requests for emergency use authorization. AR7128; *see also* AR7522-29; AR7394-96.

To be sure, this "do[es] not mean that every laboratory is manufacturing bad tests or that no patient can rely on IVDs offered as LDTs." AR7128. Indeed, FDA recognizes that "maintain[ing] access to those beneficial [laboratory-made IVD test systems] on which patients currently rely" is one of the "key public health interests" balanced in the Final Rule. AR5-6. But the "overall picture presented by th[e] evidence" remains that "a change in oversight is needed to better assure the safety and

effectiveness of IVDs offered as LDTs." AR7129. At bottom, "there is no longer a sound basis to generally treat LDTs differently from other IVDs." AR36.

C. FDA Has Broad Authority to Regulate Medical Devices For the Protection of Public Health.

FDA has a considerable range of tools with which to address concerns regarding the safety and effectiveness of devices. Congress has charged the agency with administering "a regime of detailed federal oversight" over devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the system of device regulation established by passage of the MDA in 1976, FDA oversees in detail who makes devices, which devices may be marketed, and how those devices must be tested, made, labeled, and otherwise controlled to reasonably assure their safety and effectiveness. When FDA deems it necessary, the agency also has substantial power to act when an existing device threatens the public health. Because they are relevant to many of the issues raised in this litigation, these basic building blocks of device regulation under the FDCA are summarized below.[6]

Establishment Registration and Device Listing. Federal law generally requires "every person who owns or operates any establishment . . . engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices" to register itself and each of its establishments with FDA. 21 U.S.C. § 360(b)(2), (d); *see also* 21 C.F.R. § 807.20(a). Persons required to register must also submit to FDA a list of all devices that they are manufacturing, propagating, preparing, compounding, or processing for commercial distribution. 21 U.S.C. § 360(j)(1); *see also* 21 C.F.R.

[6] In addition to being devices regulated under the FDCA, certain IVDs may *also* be biological products subject to licensure under section 351 of the Public Health Service (PHS) Act, *see* 42 U.S.C. § 262; 21 C.F.R. § 809.3. Such IVDs must, in some cases, comply with additional or different requirements than one regulated under the FDCA alone. Those differences are beyond the scope of this memorandum because neither ACLA nor AMP raise any argument implicating the PHS Act.

§ 807.20(a). Among other things, these requirements facilitate inspections to ensure that devices are being manufactured in accordance with federal law—FDA cannot inspect what it does not know about. *See generally* 21 U.S.C. § 360(h).

Like FDA's other device authorities, the obligation to register and list is broadly drawn. Unless an exemption applies, *see* 21 U.S.C. §§ 360(g)(1)-(5); 21 C.F.R. § 807.65, registration and listing is required whenever an establishment is engaged in "the making by chemical, physical, biological, or other procedures," 21 C.F.R. § 807.3(d), of any device that is "in commercial distribution," *id.* § 807.20(a). Notably, this includes establishments that commercially distribute a device for which they "[i]nitiat[e] . . . specifications"—even if they do not perform any of the other steps involved in making it. *Id.* § 807.3(d)(3); *see also* 42 Fed. Reg. 42520, 42520 (Aug. 23, 1977) (explaining that a person "initiating specifications for a device" is "engaged both in the manufacture and in the propagation of a device and therefore should register with FDA").

Premarket Authorizations. Beyond requiring certain entities to register their establishments and list their devices, FDA also has broad authority to regulate the devices themselves. It does so in part by enforcing the FDCA provisions that require certain devices to receive FDA authorization before they may be legally marketed.

There are multiple pathways for premarket authorization. Whether premarket authorization is required for a given device, and which pathway applies, is based in part on the device's level of risk and degree of novelty.

"Class I" devices present the lowest risk, such that "general controls" are sufficient to provide reasonable assurance of their safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(A); *see also* 21 C.F.R. § 860.3 (defining "Class I"). Almost all devices in Class I may be marketed without premarket authorization. *See* 21 U.S.C. §§ 360(k)-(l).

"Class II" devices present greater risks. For these devices, general controls alone will not reasonably assure safety and effectiveness, but there is enough information to establish additional "special controls" that will. *See* 21 U.S.C. § 360c(a)(1)(B); *see also* 21

C.F.R. § 860.3 (defining "Class II"). Some Class II devices are also exempt from premarket authorization requirements. *See* 21 U.S.C. § 360(m).

"Class III" devices present the greatest risk, and placement in that class carries with it the most intensive regulation. *See* 21 U.S.C. § 360c(a)(1)(C); *see also* 21 C.F.R. § 860.3 (defining "Class III"). Class III devices are generally required to obtain approval of a premarket approval application (PMA) prior to marketing.

As is most relevant here, there are three pathways for a device to receive premarket authorization. First, for most Class II (and some Class I) devices, if the device is "substantially equivalent" to an existing legally marketed product as set forth in the statute ("predicate device" is the term of art), its manufacturer may submit a so-called "premarket notification" (often called a "510(k) notification"). *See* 21 U.S.C. §§ 360(k), 360c(f)(1), 360c(i); 21 C.F.R. §§ 807.81-.100. Authorization through the 510(k) pathway is sometimes referred to as "premarket clearance." Second, if there is no existing predicate device, the manufacturer may seek the device's classification into Class I or Class II and simultaneous premarket authorization via a "*de novo* classification request." *See* 21 U.S.C. § 360c(f)(2); 21 C.F.R. §§ 860.200-.260.

Third, if a device is in Class III, the manufacturer is generally required to obtain approval of a PMA. 21 U.S.C. § 360e(a); 21 C.F.R. § 814.1(c). PMA review is a "rigorous process" in which FDA carefully assesses whether there is a "reasonable assurance of the device's safety and effectiveness" for its intended use based on a "multivolume application" that includes, *inter alia*, reports of all studies and investigations, a statement of the device's components, and descriptions of the device's manufacture and processing. *Riegel*, 552 U.S. at 317-18 (quotations omitted); *see also* 21 U.S.C. § 360e(d)(2); 21 C.F.R. §§ 814.20, 814.44-.45.

Investigational Devices. The FDCA and its implementing regulations also have requirements governing the clinical investigation of devices. *See generally* 21 U.S.C. § 360j(g); 21 C.F.R. Parts 50, 56, and 812. Investigational devices are exempt from most

FDCA requirements, *see* 21 C.F.R. § 812.1(a); 21 U.S.C. § 360j(g)(2)(A), provided that they comply with requirements intended to ensure, among other things, that clinical studies in which they are used are conducted ethically and do not expose participants to unreasonable risks. *See generally* 21 C.F.R. Part 812.

Quality System Requirements. FDA also has broad authority to oversee design and production processes that "assure that [a] device will be safe and effective and otherwise in compliance with [the FDCA]." *See generally* 21 U.S.C. § 360j(f). These and other quality requirements are codified in FDA's Quality System Regulation (QSR), *see* 21 C.F.R. Part 820, and are among the "general controls" applicable to all devices absent an exemption, *see* 21 U.S.C. § 360c(h)(1). Design controls in particular are a "key area of focus" because "the intrinsic quality of devices, including their safety and effectiveness, is established during the design phase." AR7 (quotations omitted); *see also* 21 C.F.R. § 820.30. The QSR also requires manufacturers to keep records that enable both internal control and FDA oversight. *See* 21 C.F.R. §§ 820.180-.198. These include specifications for design, production, quality assurance, and maintenance; records for each batch, lot, or unit produced; and records that document, review, and evaluate product-related complaints. *See id.*

Other General and Special Controls. FDA also enforces other general controls (for all devices) and special controls (for Class II devices) as Congress and/or the agency have deemed necessary to provide a reasonable assurance of safety and effectiveness. *See generally* 21 U.S.C. §§ 360c(a), (h)(1). In addition to the quality system requirements just discussed, general controls include prohibitions regarding adulterated devices, *see generally* 21 U.S.C. § 351, and prohibitions regarding devices that are misbranded because (among other reasons) their labeling is false, misleading, or not adequate for safe and effective use, *see generally*, 21 U.S.C. §§ 352(a)(1), (f); 21 C.F.R. Part 801. Other general controls require reporting certain safety incidents directly

to FDA. *See, e.g.*, 21 U.S.C. §§ 360i(a), (c), (g); 21 C.F.R. Part 803 (deaths, serious injuries, and certain device malfunctions); *id.* Part 806 (device corrections and removals).

For Class II devices, FDA has broad and flexible authority to establish special controls, specific to a particular device type, that are deemed necessary to provide a reasonable assurance of safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(B). Such special controls may include, for example, performance standards, postmarket surveillance, and/or patient registries. *Id.*; *see generally* 21 C.F.R. Parts 862-892.

Other Postmarket Controls. Lastly, Congress has empowered FDA to take other actions when a marketed devices threatens public health.[7] FDA may compel "the persons . . . best suited under the circumstances involved" to notify patients, prescribers, and others about a device that presents an unreasonable risk of substantial harm, 21 U.S.C. § 360h(a), and under certain circumstances may also order that the device be replaced or repaired, or its purchase price refunded, *id.* § 360h(b). If there is a reasonable probability that the device will cause serious adverse health consequences or death, FDA also has authority to issue a mandatory recall order. *Id.* § 360h(e); *see also* 21 C.F.R. Part 810. The United States may also seek in federal district court an *in rem* seizure of adulterated and/or misbranded devices. 21 U.S.C. § 334(a)(2).

D. The Final Rule Phases Out FDA's Enforcement Discretion Approach For Laboratory Developed Tests.

The Final Rule—which FDA issued after notice and comment—makes clear that laboratory-made IVD test systems are subject to FDA's jurisdiction under the agency's comprehensive device authorities. To begin with, the Final Rule amends FDA's regulatory definition of *in vitro* diagnostic products to expressly state the agency's position that such systems "are devices as defined in [the FDCA] . . . *including when the*

[7] The authorities summarized in this paragraph are also subject to additional substantive and procedural requirements omitted as not directly relevant here.

manufacturer of these products is a laboratory." 21 C.F.R. § 809.3(a) (emphasis added to new language); *see also* AR160.

In addition to that clarifying regulatory amendment, the Final Rule also includes a policy that will, over four years, phase out FDA's general enforcement discretion approach for LDTs. As Defendants have explained, *see supra* at 6-7, FDA historically has not enforced requirements under the FDCA and FDA regulations for most LDTs. This included requirements "related to registration and listing, reporting adverse events to FDA, current good manufacturing practices . . . , or premarket review." *See* AR4. The phaseout policy included in the Final Rule has two primary components: a multi-stage phaseout process for this general enforcement discretion approach, and several "targeted enforcement discretion policies for specific categories of IVDs manufactured by a laboratory." AR11. This phaseout policy applies to nearly all laboratory-made IVD test systems—in other words, to both LDTs and IVDs offered as LDTs.

The Phaseout Process. The phaseout process will take place in five stages over four years. At the conclusion of that process, FDA will expect that all laboratory-made IVD test systems comply with all applicable FDCA and regulatory requirements unless they fall within a "targeted enforcement discretion polic[y]." *See* AR9. An important goal of the phaseout policy is that "IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs" AR4. The phaseout process is described in the Final Rule, *see* AR22-26, and summarized below:

Stage	Years from Publication of Final Rule	Requirements With Which FDA Will Generally Expect Compliance Where Applicable[8]
1	1 Year	Adverse event reporting, correction and removal reporting, and maintenance of complaint files

[8] The descriptions in this table and in the table, *infra*, regarding FDA's targeted enforcement discretion policies are intended to provide a summary overview for the

[footnote continues on following page]

Stage	Years from Publication of Final Rule	Requirements With Which FDA Will Generally Expect Compliance Where Applicable[8]
2	2 Years	Requirements not covered during other stages, including registration and listing, labeling, and investigational use
3	3 Years	Remainder of Quality System Regulation Requirements
4	3 ½ Years	Premarket review for "high risk" tests that may be classified into Class III or that are subject to licensure as a biological product
5[9]	4 Years	Premarket review for moderate-risk and low-risk tests

Targeted Enforcement Discretion Policies. In addition to the phaseout process itself, the phaseout policy also includes several new enforcement discretion policies. *See* AR11-22. As summarized below, FDA generally does not intend to enforce some or all applicable requirements for devices that fall within one of these policies:

Tests	Requirements
• "1976-Type LDTs"—IVDs that are performed by laboratory personnel with special expertise, using manual techniques and components legally marketed for clinical use, and that are designed, manufactured, and used within a single CLIA-certified laboratory that meets CLIA requirements for high complexity testing. AR12. • Tests manufactured, performed, and used for patients being tested and treated within the Department of Defense or Veterans Health Administration. AR13. • Certain human leukocyte antigen (HLA) tests designed, manufactured, and used within a single laboratory certified under CLIA to perform high complexity testing and used in connection with organ, tissue, and stem cell transplantation. AR12-13. • Tests intended solely for law enforcement use. AR13.	All Requirements

convenience of the Court. They are not intended to capture every detail of the phaseout policy included in the Final Rule. The table regarding targeted enforcement discretion policies, *infra*, summarizes most but not all enforcement discretion policies included in the Final Rule.

[9] In both Stage 4 and Stage 5, FDA also intends to exercise enforcement discretion while it is reviewing any premarket submission that the agency has received by the beginning of the relevant stage. AR9.

Tests	Requirements
• IVDs offered as LDTs that were first marketed prior to issuance of the Final Rule and have been modified either not at all or in certain limited ways. AR19-21. • LDTs 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. AR16-19. • Certain LDTs for rare red blood cell antigens when there is no alternative IVD available to meet the patient's need for a compatible blood transfusion. AR10.	Premarket Review & Most QSR Requirements
• Tests approved, conditionally approved, or within an approved exemption from full technical documentation under the N.Y. State Dept. of Health Clinical Laboratory Evaluation Program (NYS CLEP). AR14-16.	Premarket Review Requirements

Importantly, FDA has emphasized that the phaseout policy does not "alter the fact that it is illegal" to offer IVD test systems without complying with applicable requirements. *See, e.g.*, AR10. "FDA retains discretion to pursue enforcement action for violations of the [FDCA] at any time, and intends to do so when appropriate." *Id.*

E. Procedural History.

This litigation consolidates two cases under Federal Rule of Civil Procedure 42. *See* Dkt. #24.[10] The consolidated cases are Cause No. 4:24-CV-479 ("*ACLA*") and Cause No. 4:24-CV-824 ("*AMP*"). The *ACLA* Plaintiffs filed suit in this Court on May 29, 2024. *See* Dkt. #1. The *AMP* Plaintiffs filed their complaint in the Southern District of Texas on August 19, 2024. *See AMP* Dkt. #1. *AMP* was subsequently transferred to this Court on September 10, 2024. *See AMP* Dkt. #24, #25.

ACLA moved for summary judgment on September 3, 2024. *See* Dkt. #20 ("ACLA Mem."). AMP moved for summary judgment on September 27, 2024. *See* Dkt.

[10] Unless otherwise specified, all cites to "Dkt. #__" are to the docket in *ACLA*, Cause No. 4:24-CV-479, which the Court has designated the Lead Case. *See* Minute Order (Sept. 20, 2024).

#27 ("AMP Mem."). The Court has entered a consolidated schedule for summary judgment briefing. *See* Dkt. #25.

LEGAL STANDARD

The agency in an APA case is entitled to summary judgment when its actions were consistent with the APA's standard of review. The question is whether the challenged action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In applying this highly deferential standard, the reviewing court may not "substitute its judgment for that of the agency," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but must instead uphold the agency's action if it is "rational, based upon consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute," *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). That determination is based on the Court's review of the administrative record, rather than its own factfinding. *See, e.g.*, *Camp. v. Pitts*, 411 U.S. 138, 142 (1973). The meaning of a statute, however, is for courts to decide, and they "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). In construing the language of a statute, a court must determine its "single, best meaning." *Id*. at 2266. "Careful attention to the judgment of the Executive Branch may help inform th[at] inquiry." *Id.* at 2273.

ARGUMENT

I. The Text of the FDCA, as Consistently Interpreted by FDA For Decades, Empowers the Agency to Regulate IVD Test Systems Made by Laboratories.

A. An IVD Test System—a Set of Physical Components That Function Together to Produce a Test Result—is a Device Under the Plain Language of the FDCA.

The statutory basis for the Final Rule is straightforward: IVD test systems are "devices" within the ordinary meaning of the FDCA whether they are made by a laboratory or not. *See generally, e.g., Barr v. Sec. and Exch. Comm'n*, 114 F.4th 441, 448-49 (5th Cir. 2024) ("When interpreting acts of Congress, courts seek the ordinary meaning of the enacted language."). The statute defines a "device" in broad terms. As relevant here, a "device" is any:

> *instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article*, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions . . . and which does not achieve its primary intended purposes through chemical action within or on the body . . . and which is not dependent upon being metabolized . . . .

21 U.S.C. § 321(h)(1)(B) (emphasis added). This statutory definition contains no exception for products made by clinical laboratories. *See id.* Moreover, FDA regulations have explained since 1973 that the statutory definition encompasses IVD test *systems*. *See* 21 C.F.R. § 809.3(a) (emphasis added) (defining "*In vitro* diagnostic products"); *see also infra* at 21-26 (reviewing regulatory history). That longstanding regulatory definition likewise contains no exception for IVD test systems made by clinical laboratories.

Since the laboratory-made IVD test systems addressed in the Final Rule are clearly intended for diagnostic use, and the FDCA's definition of a "device" contains no exception for test systems made by laboratories, the only question for the Court to decide is whether such a system is an "instrument, apparatus, implement, machine,

contrivance . . . , or other similar or related article." *See* 21 U.S.C. § 321(h)(1). The answer is unequivocally and unambiguously "yes."

No matter who makes it, an IVD test system fits easily within that statutory language. An IVD test system is a set of components—such as reagents, instruments, and other articles—that function together to produce a test result. *See* AR46; *see also* AR7134 (same); 21 C.F.R. § 809.3(a); Merriam-Webster, *System* (last visited Oct. 22, 2024) ("a regularly interacting or interdependent group of items forming a unified whole," such as "a group of devices or artificial objects . . . forming a network especially for . . . serving a common purpose," *e.g.*, "a heating *system*"), https://perma.cc/9JLB-WH4A.

The broad statutory definition of a "device" clearly encompasses IVD test systems because it includes, among other things, the terms "apparatus" and "contrivance." *See* 21 U.S.C. § 321(h)(1). An IVD test system is "a set of equipment [or] tools . . . that is used for a particular purpose," *see* Cambridge Dictionary, *Apparatus* (last visited Oct. 22, 2024), https://perma.cc/2BU5-QR8K; *accord* Merriam-Webster, *Apparatus* (last visited Oct. 22, 2024) ("a set of materials or equipment designed for a particular use"), https://perma.cc/D5N7-UR5Q; Oxford English Dictionary, *Apparatus* (last visited Oct. 22, 2024) ("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."), https://perma.cc/3VYW-LXC8. It is also an "artificial arrangement" and "a thing contrived." *See* Meriam-Webster, *Contrivance* (last visited Oct. 22, 2024), https://perma.cc/B4E6-BRSA.

The ordinary meaning of these terms is dispositive. An IVD test system is a diagnostic "apparatus" or "contrivance," and a diagnostic "apparatus" or "contrivance" is a "device." 21 U.S.C. § 321(h)(1). There is no need to go further, because "[i]f a statute's text is clear and unambiguous, the interpretive inquiry ends." *Barr*, 114 F.4th at 448-49. "Congress fully intended that the [FDCA's] coverage be as broad as its literal

language indicates," *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and simply applying that language here is enough to reject Plaintiffs' claim that the Final Rule is contrary to law.

Even so, going further would only buttress FDA's position. The MDA's legislative history makes clear that Congress "carefully defined 'device' so as to specifically include . . . *in-vitro* diagnostic products," S. Rep. No. 94-33 at 17 (1975), a term that FDA had already defined in 1973 to include test *systems*, *see* 38 Fed. Reg. 7096, 7098 § 167.1(a) (Mar. 15, 1973) ("1973 IVD Rule") (now codified as amended at 21 C.F.R. § 809.3(a)). *Amicus* Competitive Enterprise Institute (CEI) criticizes FDA's reference to this committee report as an attempt to "override [the] statute's clear and unambiguous language." Dkt. #44 at 9 ("CEI Amicus Mem."). In fact the reverse is true. The report further demonstrates that when Congress wrote the definition of "device"—the text of which unambiguously encompasses the IVD test systems at issue here—it had precisely those products in mind.

The agency's plain-meaning interpretation of the FDCA also finds additional support in at least two other federal laws that expressly contemplate that tests made by laboratories are subject to FDA regulation. Congress has provided that certain requirements under CLIA may be waived for clinical laboratories that perform only "laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use." *See* 42 U.S.C. § 263a(d)(3). It has also enacted special Medicare payment provisions applicable to "clinical diagnostic laboratory test[s]" that are "offered and furnished only by a single laboratory" that is "the original developing laboratory," on the condition that "[t]he test is cleared or approved by the Food and Drug Administration." *See id.* § 1395m-1(d)(5)(B). Neither of these provisions would make sense if IVD test systems made by laboratories were categorically beyond FDA regulation, or if they were otherwise not subject to FDA's premarket clearance or approval requirements.

B. The Final Rule is Consistent With FDA's Longstanding Interpretation of Its Own Device Authorities.

Plaintiffs' proposal to exclude laboratory-made IVD test systems from the FDCA entirely is not only wrong on the plain text of the statute. It is also inconsistent with decades of FDA practice and would lead to nonsensical results. Although agencies no longer receive conclusive *Chevron* deference, the Supreme Court has emphasized that their interpretations continue to "constitute a body of experience and informed judgment to which courts . . . may properly resort for guidance." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262 (2024) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

FDA's interpretation of "device" arose close to "contemporaneously" with Congress's passage of the MDA in 1976 (which created FDA's modern device authorities), and has since "remained consistent over time." *Id.* That means it is "especially useful in determining the [FDCA's] meaning" here. *Id.* Notwithstanding Plaintiffs' cursory accusations, *see* ACLA Mem. at 31-32; AMP Mem. at 15-16, FDA's jurisdiction over IVD test systems—including those manufactured by clinical laboratories—is far from a new development.

From a statutory perspective, the present definition of "device" is the same in most relevant respects as what Congress enacted in the original 1938 FDCA. There too, Congress empowered FDA to regulate as a device any diagnostic "instrument[]," "apparatus," or "contrivance[]," together with their "components, parts, and accessories." FDCA, Pub. L. No. 75-717, 52 Stat. 1040 § 201(h)(1) (1938). The same statute also authorized the agency to regulate as a "drug" any "article[]"intended for use in diagnosing disease (but excluding devices or components, parts, or accessories thereof). *Id.* § 201(g)(2).[11] The ordinary meaning of these broad definitions covered IVD test

[11] While Congress amended them in other respects not relevant to this litigation, the statutory drug and device definitions retained this basic structure from 1938 until passage of the MDA in 1976. *See* 21 U.S.C. §§ 321(g)(1)(B), (h)(1) (1970).

systems—with no exception for products made by a laboratory—even before passage of the MDA in 1976.

Acting under those longstanding definitions, FDA explained in 1972 that because *in vitro* diagnostic products "are used for the diagnosis of disease . . . , they clearly fall under [FDA's] jurisdiction." 37 Fed. Reg. 819, 819 (Jan. 19, 1972). It further emphasized that "rapid growth in [the] development" and increasing "reliance on the results" of these products called for "closer scrutiny because of the possibility that inaccurate and unreliable results may be obtained." *Id.* FDA therefore announced its intention to "propose regulations governing *in vitro* diagnostic products." *Id.* The agency issued its *in vitro* diagnostic product regulations just over a year later. *See generally* 38 Fed. Reg. at 7096 (codified as amended in 21 C.F.R. Part 809); *see also* 37 Fed. Reg. 16613 (Aug. 17, 1972) (notice of proposed rulemaking).

Crucially, the 1973 IVD Rule defined the "*in vitro* diagnostic products" subject to regulation to include IVD test "*systems* intended for use in the diagnosis of disease." 38 Fed. Reg. at 7098 § 167.1(a) (emphasis added). That definition is still in force today as amended, and has remained substantively unchanged for half a century. *Compare id.*, *with* 21 C.F.R. § 809.3(a). Since 1973, in other words, FDA's regulations have expressly asserted the agency's jurisdiction over IVD test systems. This definition does not contain, and has never contained, any exception for IVD test systems made by a laboratory. *See* 21 C.F.R. § 809.3(a).

The MDA was enacted only three years later. *See* Pub. L. No. 94-295, 90 Stat. 539 (1976). Among other changes, that statute expanded and clarified the statutory definition of "device," and imposed the system of risk-based classification, premarket authorization, and postmarket controls discussed above. *See generally supra* at 9-13. Relevant here, it also clarified that *in vitro* diagnostic products are devices rather than drugs (a point of some confusion before 1976), and made clear that the former category includes "*in vitro* reagent[s]" as well as "other similar or related articles." 21 U.S.C.

§ 321(h)(1); *see also* S. Rep. 94-33 at 17 (noting that the MDA's device definition "specifically include[s] . . . *in-vitro* diagnostic products").

The MDA did not, however, call into question FDA's view—a view that the agency had re-emphasized over the years immediately preceding the MDA's enactment—that IVD test systems are among the diagnostic products that Congress meant for it to regulate. By its plain text, pre-1976 law gave FDA jurisdiction (whether as a drug or as a device) over any diagnostic "instrument," "apparatus," "contrivance," or "article." *See* 21 U.S.C. §§ 321(g)(1)(B), (h)(1) (1970). FDA repeatedly explained in the years leading up to the MDA that it interpreted that language literally, *see* 37 Fed. Reg. at 819; 37 Fed. Reg. at 16613; 38 Fed. Reg. at 7096, and the Supreme Court upheld that interpretive approach as consistent with Congress's intent, *see Bacto-Unidisk*, 394 U.S. at 798.

Congress withdrew none of that authority when it enacted the MDA. Instead, it incorporated each of the terms that had defined FDA's pre-1976 jurisdiction into an expanded definition of "device"—one that *also* added an express reference to *in vitro* reagents—and used that sweeping definition to set the scope of a new regulatory regime that contained no exception for devices made by a clinical laboratory. *See* 21 U.S.C. § 321(h)(1) (defining devices to include any diagnostic "*instrument*, *apparatus*, implement, machine, *contrivance*, implant, in vitro reagent, or other similar or related *article*, including any component, part, or accessory") (added emphasis indicates words carried over from pre-1976 law). Passage of the MDA, in other words, only reinforced FDA's jurisdiction to regulate IVD test systems.

FDA continued to assert that authority as it implemented the MDA. The agency updated its regulations to make clear that all *in vitro* diagnostic products—by definition including IVD test systems—were subject to its new device authorities. *See* 43 Fed. Reg. 31508, 31513 (July 21, 1978) (agreeing that device manufacturing practices regulation "applies to all devices, including IVD products"); 45 Fed. Reg. 7474, 7484 (Feb. 1, 1980)

(updating definition of "*in vitro* diagnostic products" to specify that they are devices under post-1976 law).

Importantly, these updates did not introduce any general exemption from the definition for test systems made by a laboratory. *See id*. The opposite is true. In its very first rulemaking implementing the MDA in 1977, FDA recognized that laboratories may be device manufacturers subject to regulation, and provided only a limited exemption from registration and listing for those "clinical laborator[ies]" that primarily "provide a service through the use of a previously manufactured device." 42 Fed. Reg. 42520, 42528 (Aug. 23, 1977) (codified at 21 C.F.R. § 807.65(i)). No such exemption would have been necessary if clinical laboratories could not be device manufacturers, or if laboratory-made IVD test systems could not be devices.

Over the following decades, FDA has consistently and publicly maintained that laboratory-made IVD test systems are devices under its jurisdiction. In both the Final Rule and Notice of Proposed Rulemaking, the agency identified numerous statements it has made regarding that authority and actions it has taken based upon the same. *See generally* AR7132-33; *see also generally* AR43, AR67.

In 1992, for example, the agency noted in a draft compliance policy that some laboratories were making "home brew" tests, "either from products already on the market, or from components," and emphasized that "[t]hese products are subject to the same regulatory requirements as any unapproved medical device." AR2764. The agency reiterated that view in 1996, 61 Fed. Reg. 10484, 10484 (Mar. 14, 1996), and in 1997, 62 Fed. Reg. 62243, 62249 (Nov. 21, 1997), during a rulemaking regarding "analyte-specific reagents"—chemicals that may be used as part of an IVD test system to identify or quantify the presence of a specific substance, *see* 21 C.F.R. § 864.4020(a) (defining "Analyte specific reagents"); *id.* § 864.4010(a) (defining "general purpose reagent"). The preamble to the resulting final rule stated in no uncertain terms that "clinical

laboratories that develop [in-house] tests are acting as manufacturers of medical devices and are subject to FDA jurisdiction." 62 Fed. Reg. at 62249.

FDA repeated its position the following year in denying a citizen petition that argued that "an in-house assay system or method is not a device," AR2819-20, three years after that in the preamble to a final rule regarding over-the-counter sample collection systems used in testing for drugs of abuse, 65 Fed. Reg. 18230, 18231 (Apr. 7, 2000), and several years after that in draft guidance regarding the regulatory status of certain IVD test systems, AR8020. And while there is no need to belabor the point, the agency has continued to do so since, *see* AR7132-33 (summarizing more recent history), while also reviewing and approving numerous requests—under authorities that apply only to FDA-regulated products—to market IVD test systems made by laboratories, *see* AR7133, AR67 & Refs. 144-55; FDA2177-0076 at 7-14.

In short, there is nothing novel in the notion that IVD test systems made by laboratories are devices subject to FDA's jurisdiction. FDA announced its intent to actively regulate IVD test systems shortly before passage of the MDA. *See* 38 Fed. Reg. at 7098. It announced soon after the MDA's 1976 enactment that such systems fell within the agency's new device authorities. *See* 43 Fed. Reg. at 31513; 45 Fed. Reg. at 7484. And in its very first post-MDA rulemaking in 1977, it clearly stated that "clinical laborator[ies]" that manufacture a device are subject to those authorities as well. *See* 42 Fed. Reg. at 42528.

Because FDA's interpretation arose "contemporaneously with the statute at issue" and has "remained consistent over time," the Court may properly look to it "for guidance . . . in determining the statute's meaning." *See Loper Bright*, 144 S. Ct. at 2262 (quotations omitted). Plaintiffs' interpretation would not only be inconsistent with decades of regulatory practice, but would also leave FDA in a bizarre position—able to "oversee the safety and effectiveness of . . . individual test components," but not the "test system as a whole." AR46. Put another way, Plaintiffs' bottom-line argument is

that FDA's jurisdiction to protect the public health extends to test *parts* and *components*, but suddenly vanishes when those same articles are used together as part of a single test *system*—even though that system is used for diagnosis and it is the system as a whole, rather than any individual component, which produces the test result upon which patients and providers rely. As FDA has recognized for decades, *see* 21 C.F.R. § 809.3(a), Congress did not intend that absurd result, *see* 21 U.S.C. § 321(h)(1).

II. Plaintiffs Identify No Textual or Other Reason to Bar FDA From Regulating IVD Test Systems Made by Laboratories.

A. Plaintiffs' Textual Arguments Cannot Overcome the FDCA's Plain Language.

1. Plaintiffs Read Limits into the Definition of "Device" That Appear Nowhere in the Statute Itself.

Both ACLA and AMP devote much effort to arguing that IVD test systems are not "devices" as the FDCA defines that term. Some of these arguments rely on the language of the device definition itself. Others point to purported inconsistencies between FDA's plain-meaning interpretation of that definition and other provisions of the FDCA. And still others gesture broadly at what Plaintiffs believe were Congress's true intentions in 1976. All, however, are meritless.

First, Plaintiffs argue that the statutory definition of "device" includes only "tangible, physical products." *See* ACLA Mem. at 24-27, 35-37; AMP Mem. at 28-29 (arguing that the "device" definition "refer[s] to material goods"). FDA disagrees. *See* AR45-46. The Court, however, does not need to decide this issue because the Final Rule is not based on FDA's authority to regulate devices that do not have a tangible form (such as software). Regardless of how far that authority extends, FDA would still have authority to regulate IVD test systems under Plaintiffs' position because "a test system manufactured by a laboratory is a physical product and a material thing." AR46. Specifically, it is a "set of components—such as reagents, instruments, and other articles—that function together to produce a test result." *Id.* "[T]hese individual

components are physical or tangible, and there is no reason to think that uniting [them] in a system takes away from their physical or material nature." *Id.* As explained above, *see supra* at 18-20, and in the Final Rule, *see* AR46, such a multi-component system clearly fits within the language of the statutory device definition.[12] The Final Rule addresses that physical device—not an intangible service.

Second, Plaintiffs and one *amicus* argue that the statutory definition of "device" cannot include intangible "professional services" (ACLA) or "laboratory procedures" (AMP), because *other* provisions of the FDCA impose requirements—relating to device attributes or actions taken with respect to a device—that Plaintiffs do not believe could apply to an "intangible" service or procedure. *See* ACLA Mem. at 28-29; AMP Mem. at 29-30; CEI Mem. at 6-7. That argument is beside the point because IVD test systems are physical products made from physical items. There is no question that these systems have components, ingredients, and properties, and that they can be manufactured, processed, packaged, labeled, stored, installed, replaced, repaired, or recalled. *Cf.* ACLA Mem. at 28-29; AMP Mem. at 29-30; CEI Mem. at 6-7. Even on its own terms, however, Plaintiffs' argument does not show that laboratory-made IVD test systems are not devices. As FDA has explained, not every statutory requirement will apply to every device. To the extent some requirements are truly inapplicable to a given product, that

[12] This also disposes of *amicus* CEI's argument that the inclusion of the word "system" in FDA's definition of *in vitro* diagnostic products somehow conflicts with the statutory definition of a "device." *See* CEI Mem. at 3-6. CEI argues that IVD test systems are not "reagents" or "instruments," but ignores FDA's actual position—that such a system falls within the language of the device definition, which includes any "apparatus," "contrivance," or "other similar or related article[s]." *Id.* CEI's fallback position is that a "system of *reagents, instruments, specimen collection devices*, software, and testing protocols" that "function[] together within a laboratory" is somehow "an intangible concept." *Id.* at 6 (emphasis added). Not so. A collection of physical objects intended for use in diagnosing disease or other conditions by examining a physical specimen taken from the body is not any less physical simply because employing it to produce a test result may involve using software and will require following directions.

means the product is not subject to those requirements in particular—not that the product is entirely beyond FDA's jurisdiction because it is not a device at all. AR48-49.

Third, Plaintiffs suggest that the "historical context" of the FDCA and MDA shows that those statutes have "nothing to do with clinical laboratory testing services" and only reach devices that are "mass-manufactured" (ACLA) or "mass-produced" (AMP). ACLA Mem. at 6, 29; AMP Mem. at 6, 34. That claim fails because it has no basis in the statutory text, which has always defined "device" to include *any* apparatus or contrivance intended for diagnostic use, *see supra* at 18-20, and does not condition FDA's authority on production of a minimum number of devices, *see* 21 U.S.C. § 360j(b) (specifically addressing "custom devices" that by definition are not mass-produced). Whether and to what extent IVD test systems developed in-house by laboratories were at the forefront of Congress's thinking makes no difference to the fact that such systems are within the plain meaning of the text it enacted. *See Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1737 (2020) ("[T]he limits of the drafters' imagination supply no reason to ignore the law's demands.").

2. Laboratories That Develop IVD Test Systems Are Device Manufacturers That Are Subject to Applicable FDCA Requirements.

In addition to asserting that laboratory-made IVD test systems are not "devices," ACLA also takes the position that clinical laboratories can never be device "manufacturers." *See* ACLA Mem. at 14, 37-38. It argues that using multiple physical items—like reagents, instruments, and other articles—as parts of an IVD test system is like using "a scalpel, needle, and sutures to perform a surgery." *Id.* at 37. If the latter does not constitute manufacturing a device, ACLA argues, neither does the former. *Id.*

That argument misses the mark. At the outset, it ignores FDA's explicit statement that an IVD test system (a device) is distinct from "the use of the device[]—*i.e.*, the performance of a test—in accordance with [the] manufacturer's instructions for use." *See* AR58. By definition, the *performance* of an IVD test according to its manufacturer's

instructions takes place subsequent to the process of designing and developing a *test system* intended for a particular use. So by the time a test is performed, there is no question that the underlying test system—the device subject to FDA regulation—has already been "manufactured" by the laboratory or other entity that developed it.

This accords with FDA's decades-old view that a person who markets a device will be considered its manufacturer if they were responsible for "initiation of [its] specifications"—even if another party is responsible for its physical assembly according to those specifications. *See* 21 C.F.R. § 807.3(d)(3); *see also* 42 Fed. Reg. at 4250. It is also consistent with FDA's position—unchanged since 1973—that a test may be regulated as a single device manufactured by its developer even if the user must independently obtain or provide some of the components necessary to perform it. *See* 21 C.F.R. §§ 809.10(b)(8)(i)-(ii) (recognizing that an IVD test system may include materials such as "reagents, instruments and equipment" that are "required but not provided"), 809.10(b) (recognizing that use of an IVD test "system[]" may involve use of a "multiple-purpose instrument" that is "not committed to [that] specific . . . system[]" alone); *see also* 38 Fed. Reg. at 7099.

Laboratory-made IVD test systems, in other words, are not manufactured anew by laboratory personnel every time they are performed. They are manufactured by the laboratories that "establish[] and review[]," *see* ACLA Mem. at 37-38, their design specifications and step-by-step instructions for use (among other things). Those detailed specifications, instructions for use, and intention to produce a single test result attributable to the system as a whole rather than any individual components, are what distinguishes such a test system—subject in its own right to FDA's jurisdiction—from a mere collection of separate objects "in transient relationships to each other." *See* 21 U.S.C. § 321(h)(1) (defining "device" based upon intended use); *cf.* ACLA Mem. at 38. Oversight under the FDCA is crucial to ensuring that such systems are appropriately

safe and effective when used according to their specifications, and the statutory text makes clear that FDA is empowered to regulate the laboratories that manufacture them.

3. Devices Otherwise Subject to the FDCA Are Not Exempt From FDA's Jurisdiction Because They Are Marketed on a Fee-For-Service Basis.

Plaintiffs' next set of arguments offer variations on another claim: that clinical laboratories' choice of business model—selling test results for a fee rather than packaging and selling the test system itself—immunizes them from FDA oversight. That is incorrect. How an IVD test system is monetized by its manufacturer makes no difference to whether that product is a device under the FDCA. Congress made this clear when it decided in 1976 to regulate IVD test systems that are offered as "diagnostic service[s]," *see* S. Rep. 94-33 at 4-5, and defined a "device" without regard to its manufacturer's choice of business model, *see* 21 U.S.C. § 321(h)(1). Plaintiffs and *amicus* CEI offer three unavailing arguments in support of their position.

First, Plaintiffs and CEI focus on the fact that laboratories do not generally package their IVD test systems in a "container" to which a "label" can be applied. *See* ACLA Mem. at 28-29; AMP Mem. at 29-30; CEI Mem. at 6-7. That is true but irrelevant. It is a function of a laboratory's chosen business model rather than any attribute of laboratory-made IVD test systems themselves, which consist of physical components that could be packaged if desired. And even if packaging such systems were genuinely impossible, that would not somehow mean that they are not devices or otherwise entirely beyond FDA's reach. It would only mean that the FDCA's requirements specifically related to packaging are inapplicable, including the requirement that devices have a label on their "immediate container," *see* 21 U.S.C. § 321(k), "*if* [it is] in package form," *id.* § 352(b) (emphasis added); *see also* AR48-49.[13]

[13] A device's "label" should not be confused with its "labeling." A "label" is "written, printed, or graphic matter *upon the immediate container* of any article." 21 U.S.C. § 321(k) (emphasis added). "Labeling" is significantly broader. It includes "all labels" [footnote continues on following page]

Second, CEI argues that the FDCA's refund remedy would be inapplicable to IVD test systems made by laboratories. CEI Mem. at 6. Under certain circumstances, FDA may issue an order under that provision "[t]o refund the purchase price of [a] device" (discounted if it has been "in the possession of the device user" for a year or more). 21 U.S.C. § 360h(b)(2). CEI argues that this provision cannot apply to an IVD test system marketed on a fee-for-service basis, because the device "does not have a purchase price" and "is not in the possession of the device user." CEI Mem. at 6. FDA disagrees. *See* AR48 ("[T]he purchase price of the system could be refunded to the same extent and in the same manner as for most other devices that are used in medical practice."). But even if CEI were right on this narrow point, it still would not prove its broader one. A device that fits the statutory definition does not duck the FDCA completely because one separate remedial subsection of the statute might not apply. *See* AR48-49.

Third, AMP and CEI argue, *see* AMP Mem. at 32-35; CEI Mem. at 7, that laboratories' choice of business model exempts them from FDA regulation because certain specific FDCA requirements apply only if a device is or will be in "commercial distribution," *see, e.g.*, 21 U.S.C. § 360(j) (listing requirement applies to devices "manufactured, prepared, propagated, compounded, or processed . . . for commercial distribution"); *id.* § 360(k) (requiring premarket notification in advance of "introduction or delivery for introduction into interstate commerce for commercial distribution"). Once again, this argument's major premise is false—regulation under the FDCA is not an all-or-nothing proposition, and a device may fall outside the scope of certain provisions without divesting FDA of jurisdiction altogether. *See* AR53-54, AR7137; *see also supra* at 28.

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plus all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying* such article." *Id.* § 321(m) (emphasis added). Detailed directions for use, as well as warnings, are typically required to appear in a device's labeling rather than on its label. *Compare id.* § 352(b) (label), *with* § 352(f) (labeling); *compare* 21 C.F.R. § 809.10(a) (label), *with* 21 C.F.R. § 809.10(b) (labeling).

AMP and CEI's minor premise is wrong too—a laboratory that sells the use of an IVD test system to the public in exchange for money has introduced that test for commercial distribution. The ordinary meaning of "commercial" is straightforward—"[o]f, relating to, or involving the selling of goods or services for profit; mercantile <commercial advertising>." *Commercial*, Black's Law Dictionary (12th ed. 2024).

AMP insists that the term can only refer to an exchange involving the physical transportation and transfer of commodity goods. AMP Mem. at 33-34. But the ordinary meaning of "commercial" is not so cramped. There are such things as "commercial services," *see* Meriam-Webster, *Commercial* (last visited Oct. 22, 2024), https://perma.cc/B6RA-6Q6P, and "commercial property" is not any less so because it is "used for . . . providing services for money" rather than for shipping goods, or because the property itself is not transported from one place to another, *see* Cambridge Dictionary, *Commercial* (last visited Oct. 22, 2024), https://perma.cc/XH6M-Q72J. In the ordinary sense of the word, something is "commercial" if it involves or relates to selling goods *or* services. "Distribution," in turn, is "supply[ing] something" for sale. *See* Cambridge Dictionary, *Distribute* (last visited Oct. 22, 2024), https://perma.cc/3H75-25B6.

"Commercial distribution" of an IVD test system, in other words, does not need to involve physical transportation or a change of title to the physical system itself. *Cf.* AMP Mem. at 33-34. It is enough that laboratories supply the public with use of the system, for money. *See* AR53-54. That ordinary-meaning interpretation is consistent with Congress and FDA's contemporaneous understanding of "commercial distribution" as equivalent to the phrase "on the market" used in its "popular" sense. AR53 (quoting H.R. Rep. No. 94-853 at 36 (Feb. 29, 1976), and 41 Fed. Reg. 37458, 37459 (Sept. 3, 1976)); *cf.* AMP Mem. at 35 (interpreting colloquial phrase using narrow, technical dictionary definition). It is consistent with legislative history showing that Congress specifically intended to regulate devices commercially distributed on a fee-

for-service basis. *See* S. Rep. 94-33 at 4-5. And it prevents manufacturers of potentially dangerous devices from avoiding important FDA oversight through business decisions that are irrelevant to their products' safety or effectiveness. This Court should reject AMP and CEI's narrow reading of the statute in favor of the one that "its literal language" unambiguously includes. *See Bacto-Unidisk*, 394 U.S. at 798.

4. Regulation of Laboratory-Made Tests Is Fully Consistent With the FDCA's Narrow Exception for Licensed Practitioners Who Personally Make Devices Solely for Use in Their Own Practice.

AMP offers Plaintiffs' last argument that is purportedly based on the text of the FDCA itself. It argues that 21 U.S.C. § 360(g)(2)—which exempts certain licensed practitioners from the FDCA's registration, listing, and 510(k) notification requirements—and 21 U.S.C. § 360i(c)(1)—which, as relevant here, exempts the same practitioners from the FDCA's adverse-event reporting requirements—should be read to bar enforcement of almost all FDCA requirements against essentially any laboratory that is somehow affiliated with a licensed practitioner.[14] AMP is wrong on two points—about which persons are exempted, and about the statutory requirements from which they are exempt.

First, AMP asks the Court to extend these exemptions to manufacturers that lie far outside the statutory text. As relevant here, both § 360(g)(2) and § 360i(c)(1) state that they exempt a "practitioner . . . licensed by law to prescribe or administer devices . . . who manufactures . . . devices solely for use in the course of his professional practice" 21 U.S.C. § 360i(c)(1); *see also id.* § 360(g)(2) (referring to "their" rather than "his" practice). By their plain text, these exemptions apply only to individual licensed practitioners—not to other persons (like corporations, partnerships, or other entities, *see*

[14] AMP also cites, but does not rely upon, a separate provision that addresses healthcare practitioners who *prescribe or administer* a legally marketed device to a patient under certain circumstances. *See* AMP Mem. at 9 (citing 21 U.S.C. § 396). That provision is irrelevant here because the Final Rule addresses laboratories that manufacture devices, rather than healthcare practitioners who prescribe or administer them.

id. § 360(a)(2)) that are required to register and list to the extent that they own or operate a device establishment, *see id.* §§ 360(b)-(c). The text also specifies that the exemptions cover only a practitioner "who" manufactures a device, and then only for devices used solely in the course of "his" or "their" professional practice. *See id.* §§ 360i(c)(1), 360(g)(2).

FDA has explained that this plain language does not exempt clinical laboratories from any requirement based merely on their affiliation with or employment of a licensed practitioner—it exempts only individual practitioners who meet each textual condition. AR62-63. AMP calls that interpretation "preposterous" and "absurdist," and claims that FDA has made it "impossible to practice medicine in America." AMP Mem. at 36-37. Not so. *See Amicus* Memorandum of College of American Pathologists, Dkt. #37 at 12-14 (explaining that developing and using IVD test systems is not itself the practice of medicine). And tellingly, AMP proposes no different way for the Court to read the sharply limited language that Congress actually passed. *See id.*[15]

Second, AMP is also wrong about the statutory requirements from which licensed practitioners may be exempted. Section 360(g)(2) expressly exempts practitioners who meet the statutory criteria from the FDCA's registration requirements. *See* 21 U.S.C. § 360(g)(2) (providing exemption from §§ 360(b)-(f)). By operation of law, that exemption also extends to the statute's listing requirements, *see id.* § 360(j) (applying only to persons who register), and its premarket notification requirements, *see id.* § 360(k) (applying only to persons required to register). Section 360i(c)(1), for its part,

[15] AMP is also wrong in claiming that FDA interprets these exemptions as inapplicable whenever a professional "seeks payment." *See* AMP Mem. at 37. The Final Rule merely noted that the narrow statutory language reflects Congress's intent to continue regulating activities that "extend[] beyond ordinary professional practice into commercial activity." *See* AR60-61 (quoting H.R. Rpt. 94-853 at 24 (Feb. 29, 1976)). That intent is vindicated fully by enforcing the statute as written—there is no reason to separately parse the boundary between the "ordinary" and the "commercial."

expressly exempts practitioners who meet the statutory criteria from adverse event reporting requirements under Section 360i(a). *See id.* § 360i(c)(1). These exemptions extend no further than expressly stated in their text.

AMP argues briefly that practitioners covered by these exemptions are also exempt from the statute's "*de novo* classification and PMA requirements" as well. AMP Mem. at 35-36. Its only support for that claim is a string of five citations to statutory provisions that say no such thing.

First is a description of how FDA will determine the intended use of a device for purposes of a substantial equivalence determination (which is not a determination made during review of a *de novo* request or a PMA). *See* 21 U.S.C. §§ 360(i)(E)(i)-(iii). A second provides that manufacturers *may* submit a *de novo* request either after or in lieu of a 510(k) notification (but neither imposes any requirement to do so, nor bars *de novo* filings from persons not subject to Section 510(k)). *See id.* §§ 360c(f)(2)(A)(i)-(ii). A third requires a particular certification be included in certain 510(k) notifications (and says nothing at all about any other pathway for premarket authorization). *See id.* § 360c(f)(4). A fourth *allows* a manufacturer who is submitting a 510(k) notification or PMA for one device to simultaneously ask that FDA classify an accessory to that device via the *de novo* pathway (it does not require anyone to do anything). *See id.* § 360c(f)(6)(C). And a fifth requires FDA to withdraw an approved PMA if it finds, among other things, that the applicant failed to report adverse events as required under Section 360i(a), or failed to comply with registration, listing, or 510(k) requirements under Section 360 (a person cannot fail to comply with requirements from which they are exempt). *See id.* § 360e(e)(1)(D).

In short, AMP relies on statutory provisions that relieve (1) individual licensed professionals who meet certain specific criteria from (2) their personal duty to follow a particular set of FDCA requirements. Those exemptions are fixed in plain statutory text, and this Court should reject AMP's invitation to dramatically expand them.

B. Plaintiffs' Non-Textual Attacks Likewise Fail to Undermine the Final Rule.

1. CLIA Does Not Displace FDA's Authority to Regulate Medical Devices Made by Laboratories.

There is no basis to conclude that CLIA limits FDA's authority to regulate laboratories that manufacture IVD test systems. None of Plaintiffs' arguments to the contrary come close to meeting their "heavy burden" to show that CLIA somehow "displace[d]" the FDCA's plain language. *See Dept. of Agric. v. Kirtz*, 601 U.S. 42, 63-64 (2024).

The Final Rule explains that CLIA has not displaced the FDCA because on their face, the two statutes regulate different things. *See generally* AR63-67. In general, Centers for Medicare and Medicaid Services (CMS) determines whether a laboratory and its personnel meet CLIA requirements, whereas FDA's statutory mandate is to review and evaluate the tests themselves to ensure that they have appropriate assurance of safety and effectiveness for their intended use. AR66. To the extent CLIA provides oversight of a test system's validity, it is focused on *analytical validity*—the accuracy and reliability with which the test system detects or measures the analyte that it is supposed to detect or measure—and requires the establishment of performance specifications only in the absence of FDA clearance or approval. 42 C.F.R. § 493.1253(b)(2); *accord* CMS, *LDT and CLIA FAQs* at 2 (Oct. 22, 2013), https://perma.cc/X3DE-G5H9.

The FDCA goes several steps further. For one thing, FDA's review of analytical validity is significantly different than CMS's. FDA review takes place before a test is offered to patients and healthcare providers, is focused on the test system's safety and effectiveness, and is more in-depth and more comprehensive than review of analytical validity under CLIA (considering, among other things, whether a test system is analytically valid outside the confines of a specific laboratory). *See* CMS, *LDT and CLIA FAQs*, *supra*, at 2. Also unlike CLIA, the FDCA provides human subject protections for individuals who participate in clinical research trials, and requires adverse event reporting. *See* AR28.

FDA also goes beyond analytical validity to consider a test system's *clinical validity*—the accuracy and reliability with which it identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient. *See* AR31. CMS's CLIA program does not address the clinical validity of any test. *See* CMS, *LDT and CLIA FAQs*, *supra*, at 2.

Laboratory-specific analytical validity does not guarantee clinical validity, nor vice versa. For example, a test system that accurately and reliably identifies the presence or absence of a protein biomarker in blood samples when performed in a given laboratory is *analytically valid* for detection of that protein by that laboratory. However, if the test system is intended to be used to diagnose Alzheimer's disease, it would not be clinically valid if, for example, the presence of the protein were not meaningfully related to the diagnosis of Alzheimer's disease or if the clinical cutoff used by the test were not able to accurately and reliably distinguish patients with Alzheimer's disease from those without. In such cases, the test system would be *clinically meaningless*. Use of a test that incorrectly diagnoses Alzheimer's disease would have potentially serious consequences for any patient treated, or not appropriately treated, based on its results. The FDCA's requirement to demonstrate a reasonable assurance of safety and effectiveness for a specific intended use, *see* AR21—not CMS's rules for showing analytical validity under CLIA—is what protects the public from that type of risk.

CLIA, in other words, is a narrow statute that complements rather than conflicts with the FDCA. Standing alone, it would leave crucial areas of safety and efficacy with no federal oversight. CLIA itself, along with CMS's regulations, show as much.

CLIA bars a clinical laboratory from "solicit[ing] or accept[ing]" for testing any "materials derived from the human body" unless it has a certificate issued by CMS. 42 U.S.C. § 263a(b). As relevant here, obtaining a CLIA certificate requires showing that the laboratory "will be operated in accordance with standards issued by [CMS]." *Id.* §§ 263a(c)(1), (d)(1)(B). The statute is clear about the purpose of those standards—"to

assure consistent performance . . . of *valid* and reliable laboratory examinations and other procedures." *Id.* § 263a(f)(1) (emphasis added); *see also id.* § 263a(f)(1)(E) (referring to "*accurate* and reliable" examinations and procedures) (emphasis added). As CMS has explained, "valid" as used in CLIA refers to analytical validity. CMS, *LDT and CLIA FAQs*, *supra*, at 2.

CMS, in turn, has issued performance standards that specify what is needed to show that a "test system . . . not subject to FDA clearance or approval" is valid under CLIA. *See* 42 C.F.R. §§ 493.1253(a)-(b). Such a test system will meet CMS's performance standard if (as relevant here) the laboratory adequately demonstrates its "[a]ccuracy," "[p]recision," "[a]nalytical sensitivity," and "[a]nalytical specificity." *Id.* § 493.1253(b). CMS has explained that these are "performance characteristics relating to analytical validity"—not clinical validity. CMS, *LDT and CLIA FAQs*, *supra*, at 2. A test is *accurate* for CLIA purposes if it produces correct results regarding the presence, absence, or measurement of the analyte of interest, *precise* if repeated testing of the same sample reproduces the same result regarding the analyte, *sensitive* to the extent it avoids false negative results regarding the analyte, and *specific* to the extent it avoids false positive results regarding the analyte. *See* CMS, *State Operations Manual Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* at 179-83 (Rev. 166 Feb. 3, 2017), https://perma.cc/GN2T-R9GW. These are important characteristics for a test system to demonstrate, to be sure. But they do not answer the central question under the FDCA—is there a reasonable assurance that the test system will be safe and effective for patients?

Under the FDCA, FDA provides critical oversight of laboratory-made IVDs that is outside of CMS's purview under CLIA. That is important because "if a laboratory test system lacks clinical validity . . . [it] will not provide meaningful diagnostic information no matter how great the expertise or experience of the professionals performing [it]." AR57; *see also* AR28-29 (reviewing years of CMS statements regarding distinction

between its role and FDA's); 55 Fed. Reg. 20896, 20901 (May 21, 1990) ("FDA['s] mandate and regulatory effort have a different and narrower focus than does [CLIA]."). Plaintiffs' responses do not show otherwise.

First, Plaintiffs fault Congress for not saying expressly that CLIA was intended to complement the FDCA rather than displace it. *See* ACLA Mem. at 29-30 ("If Congress had intended CLIA and the FDCA to be overlapping . . . one would expect that approach to be reflected in the statutes and their legislative histories."); AMP Mem. at 30-31 (criticizing Congress's "fail[ure] even to suggest that FDA might have a role to play in regulating laboratory procedures"). But that argument gets it exactly backwards. When it enacts a "statute[] touching on the same topic" as one already on the books, Congress does not need to name-check its earlier work in order to avoid repealing it by implication. *Kirtz*, 601 U.S. at 63-64. AMP is wrong to argue that implied repeal is "the usual rule" under these circumstances "even absent a conflict." AMP Mem. at 31-32.[16]

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[16] AMP's claim that an implied repeal is presumed anytime two statutes even "conceivably could apply to a single object," *see* AMP Mem. at 31-32, fails not only because a unanimous Supreme Court said exactly the opposite only eight months ago, *see Kirtz*, 601 U.S. at 63-64, but also because AMP's chosen authorities say no such thing. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), involved an actual conflict between two statutes. The Court in that case explained that Congress's decision to enact a separate statute "explicitly prohibit[ing] any federal agency from imposing any health-related labeling requirements on cigarettes" was "incompatible" with an "integral aspect of the FDCA"—FDA's mandate to regulate the safety and effectiveness of drug and device labeling. *See Brown & Williamson*, 529 U.S. at 148-49, 155-56. *Train v. Colorado Public Interest Research Group, Inc.*, 426 U.S. 1 (1976), also presented an actual conflict—between the Clean Water Act's specific requirement that the Environmental Protection Agency must make rules to subject discharges of radioactive material to the "best practicable control technology" by a certain date, and the Atomic Energy Act's open-ended delegation to the Atomic Energy Commission of power to adopt, for certain types of radioactive materials, whatever standards it "deem[s] necessary or desirable . . . to protect health." *See Train*, 426 U.S. at 5-9. Lastly, *D. Ginsberg & Sons v. Popkin*, 285 U.S. 204 (1932), simply did not consider whether one statute displaced another, because the issue in that case was the relationship between two subsections of the same statute (Sections 2(15) and 9(b) of the Bankruptcy Act of 1898). *See Ginsberg*, 285 U.S. at 206-08.

Rather, courts review such statutes "with a strong presumption [that] they can coexist harmoniously," and impose a "heavy burden" on any party arguing that one statute displaces another. *Kirtz*, 601 U.S. at 63-64 (quotation omitted).

Plaintiffs cannot meet that heavy burden merely by pointing out the fact that Congress did not explicitly describe the relationship it intended between CLIA and the FDCA, *see* ACLA Mem. at 29-30; AMP Mem. at 30-31, or by citing to a committee report's isolated reference to CLIA as a "unified regulatory mechanism." *See* ACLA Mem. at 10, 30 (quoting H.R. Rep. 100-899 at 12 (1988)). Because CLIA's actual text (and CMS's implementing regulations) make clear that the "two laws are merely complementary," this Court's role "lies not in preferring one over another but in giving effect to both." *See Kirtz*, 601 U.S. at 63-64.

Second, Plaintiffs do not show a conflict between CLIA and the FDCA by offhanded citation to CMS's CLIA regulations rather than the statute itself. *See* AMP Mem. at 12, 13, 30-31. As a threshold matter, CMS's regulations cannot narrow the scope of the FDCA as Congress enacted it. Regardless, however, FDA has explained in detail why its approach is consistent with and complementary to CMS's, *see* AR28-33, AR63-67, and CMS has consistently agreed, *see* AR28-29; 55 Fed. Reg. at 20901.

Plaintiffs' arguments that the two statutory schemes are in conflict are unavailing. While AMP argues that CMS's reference to in-house tests "not subject to FDA clearance or approval," *see* 42 C.F.R. § 493.1253(b)(2), is inconsistent with FDA jurisdiction over laboratory-made IVD test systems, the Final Rule makes clear that the FDCA contemplates the existence of devices that do not require premarket authorization based on classification or an exemption from 510(k) requirements. *Compare* AMP Mem. at 13, 31, *with* AR65. AMP also highlights the CMS requirement that a laboratory's quality system "ensure[] continuous improvement of the laboratory's performance and services through ongoing monitoring," *see* 42 C.F.R. § 493.1200(b), but that is fully consistent with the FDCA, which likewise subjects test manufacturers to "a

variety of ongoing requirements" related to "product performance." *Compare* AMP Mem. at 12, *with* AR30. Lastly, AMP's emphasis that "proficiency testing is the method Congress chose for [oversight of] LDTs" under CLIA also fails to show any inconsistency with the FDCA, which regulates whether a test system is safe and effective—not whether a laboratory is proficient in using it. This shows once again that the two statutes are complementary. *Compare* AMP Mem. at 31, *with* AR58. Plaintiffs' failure to identify "any actual inconsistency" between CLIA and the FDCA means they cannot show that passage of the former displaced the latter. *See Kirtz*, 601 U.S. at 64 (quotation omitted).

Third, ACLA is incorrect that FDA's position before 1992 was that "it lacks jurisdiction under the FDCA to regulate" laboratory-made IVD test systems, and that Congress's passage of CLIA in 1988 "effectively ratified" that position under *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). As discussed in detail above, ACLA is wrong on the facts. Far from *disclaiming* jurisdiction over the test systems at issue here, FDA has *asserted* it repeatedly. *See supra* at 21-26. Indeed, even if FDA had merely been silent on the issue, that still would not trigger *Brown & Williamson*'s ratification canon, which the Supreme Court has specifically limited to cases where Congress's purported ratification occurred against a "'backdrop' of disclaimers of regulatory authority." *See Massachusetts v. EPA*, 549 U.S. 497, 531 (2007) (quoting *Brown & Williamson*, 529 U.S. at 144). Because no such backdrop existed at the time of CLIA's enactment in 1988, *Brown & Williamson* is inapposite.

2. The Rule of Lenity and Major Questions Doctrine Do Not Apply to FDA's Longstanding Assertion of Authority Under an Unambiguous Statute.

For all the reasons discussed above, the Final Rule is amply supported by the ordinary meaning of the FDCA. That should be the end of any claim that FDA exceeds its statutory authority by regulating laboratory-made IVDs. Plaintiffs, however, urge this Court to move the interpretive goalposts. Rather than giving the statute its *ordinary*

meaning, they urge that the Court should read the statute "strictly" under the rule of lenity, *see* ACLA Mem. at 22, 33-34, or require that Congress provide a "clear statement" under the major questions doctrine, *see id.* at 22, 32-34; AMP Mem. at 25-28, 32-33. Neither doctrine helps Plaintiffs here, and the Court should reject these attempts to avoid Congress's unambiguous intent.

Rule of Lenity. ACLA argues that because FDCA violations may carry criminal penalties, *see* 21 U.S.C. § 333(a), the rule of lenity requires that the statute be "construed strictly," ACLA Mem. at 33-34. Lenity, however, is not a free-floating instruction to read criminal statutes narrowly against the government.[17] Rather, it is a tool for "resolv[ing] [an] *ambiguity* in a defendant's favor." *See United States v. Northington*, 77 F.4th 331, 334 (5th Cir. 2023) (emphasis added). Judges have disagreed over the "standard[] for whether a statute is *sufficiently* ambiguous to trigger the rule of lenity," *Cargill v. Garland*, 57 F.4th 447, 469 (5th Cir. 2023) (en banc) (emphasis added) (discussing issue and declining to settle it), but the law is clear that it is inapplicable where there is no ambiguity at all. Because no party—not ACLA, not AMP, and not Defendants—argues that there is any ambiguity to resolve in this case, lenity simply does not apply.

Major Questions Doctrine. In "certain extraordinary cases" in which an agency takes on a "major question[]," courts have required more than a "plausible textual basis" to conclude that Congress meant to empower the agency to answer it. *Mayfield v. U.S. Dep't of Labor*, — F.4th —, 2024 WL 4142760, at *2 (5th Cir. Sept. 11, 2024) (quoting *West Virginia v. EPA*, 597 U.S. 697, 723 (2022)).[18] If the major questions doctrine applies,

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[17] Indeed, even if that approach to lenity were generally the law, applying it to the FDCA in particular would contradict the Supreme Court's instruction in *Bacto-Unidisk* that the statute should be read "as broad[ly] as its literal language indicates." *Bacto-Unidisk*, 394 U.S. at 798.

[18] Neither Plaintiff's summary judgment memoranda addresses *Mayfield*, which the Fifth Circuit decided sixteen days before AMP's memorandum was submitted on

[footnote continues on following page]

"[t]he agency instead must point to clear congressional authorization for the power it claims." *Id.*

The Fifth Circuit recently held that "[t]here are three indicators that each independently trigger the doctrine: (1) when the agency claims the power to resolve a matter of great political significance; (2) when the agency seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities; and (3) when an agency seeks to intrude into an area that is the particular domain of state law." *Id.* (quotations omitted). This case presents none of the three.

First, the Final Rule does not implicate a "matter of great political significance." *See id.* At the threshold, whether a particular subclass of medical products should be subject to regulation under FDA's existing device authorities "is not in line with the types of issues that have been considered politically contentious enough to trigger the doctrine." *Id.* at *3 (citing as examples major questions of "how much coal-based energy generation the country should engage in," or "how to store nuclear waste").

This is also not "a case in which the agency newly uncovers power that conveniently enables it to enact a program that Congress considered and rejected multiple times." *Id.* (quotations and modifications omitted). As discussed in detail *supra*, at 21-26, FDA has not "newly uncover[ed]" jurisdiction over laboratory-made IVD test systems. The agency has claimed this authority continuously since 1977, partly as a continuation of pre-1976 authority that had been upheld by the Supreme Court's decision in *Bacto-Unidisk* several years before the MDA's passage.[19] So even if the

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September 27, 2024 (and eight days after ACLA's memorandum was submitted on September 3, 2024).

[19] The so-called Charrow memorandum—which expressed the views of only a single official, was never authorized for public release, and is not part of the administrative record in this case—does not change the fact that FDA's position has

[footnote continues on following page]

phaseout policy's move to more active enforcement against laboratory-made IVD test systems and the laboratories that manufacture them "is novel, the assertion of authority . . . is not." *See Mayfield*, — F.4th —, 2024 WL 4142760, at *4.

Nor has Congress "considered and rejected multiple times" proposals to do what the Final Rule has done—clarify that all IVD test systems, including those made by laboratories, are subject to oversight as devices under the FDCA's existing regulatory scheme. *See id.* at *3 (quotations omitted). Plaintiffs point to a scattering of purported examples, *see* AMP Mem. at 17, 27-28 (cross-referencing AMP Compl., *AMP* Dkt. #1 ¶¶ 78-89), ACLA Mem. at 13, 33. None hold up to scrutiny.

To begin with, Plaintiffs rely on a handful of instances in which various actors—individual members of Congress, congressional committees, or Congress itself—did something other than consider and reject legislation. These examples do nothing to advance Plaintiffs' argument. The fact that the Final Rule has been criticized *post hoc* by a single Senator, *see* ACLA Mem. at 33 (citing 2024 letter by Senator Cassidy), or congressional committee, *see id.* (citing H.R. Rep. No. 118-583 at 88 (2024)); *see also* AMP Mem. at 28 (citing same), says nothing at all about what Congress had *previously* considered and rejected. Neither does the fact that two Representatives once circulated a "discussion draft," apparently without actually introducing it for the House to consider at all. *See* AMP Compl., *AMP* Dkt. #1 ¶ 86. Nor did the House Appropriations Committee either consider or reject whether to enact something like the Final Rule when it criticized FDA draft guidance on process grounds (*e.g.*, lack of public input) without questioning the agency's underlying authority to regulate. *See* AMP Mem. at 27-28 (citing H.R. Rep. No. 114-531 (2016)). And finally, the fact that Congress once

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been consistent for decades. *Cf.* ACLA Mem. at 12-13, 29, 31; AMP Mem. at 17-18, 31. Notably, the Charrow memorandum informed an HHS policy that has since been withdrawn by the Secretary of Health and Human Services. Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory-Developed Tests (Nov. 15, 2021), https://perma.cc/3EWN-HNPE.

instructed FDA to notify it before issuing "any draft or final guidance on the regulation of laboratory-developed tests under the [FDCA]" suggests—if anything—a belief that the agency already had authority to regulate such tests. *See* AMP Mem. at 27 (citing Pub. L. No. 112-144, 126 Stat. 1130 § 1143 (July 9, 2012) (codified at 21 U.S.C. § 371 (note)).

Plaintiffs fare no better in pointing to legislation that Congress considered but failed to pass. To be sure, passage of their cited examples would have changed the *status quo*. But in none of these cases did Congress consider and reject the same "program" as the Final Rule—clarifying that FDA's existing device authorities apply to laboratory-made IVD test systems on the same terms as IVD test systems made by non-laboratory manufacturers. *See Mayfield*, — F.4th —, 2024 WL 4142760, at *3 (quotations omitted). The Genomics and Personalized Medicine Act of 2006 would have created a special review pathway for genetic tests only, which would have been regulated by both FDA and CMS. *See* S. 3822 §§ 7(b)-(d), 109th Cong. (2006) (cited by AMP Compl., *AMP* Dkt. #1 ¶ 81). The Laboratory Test Improvement Act of 2007 would have created a new regulatory classification of "laboratory-developed tests" regulated by FDA as devices but subject (among other differences) to different classification rules, premarket authorization requirements, quality system requirements, and enforcement procedures as compared to other IVD test systems. *See* S. 736 §§ 2(a), 4(d), 5(a), 5(b)-(c), 110th Cong. (2007) (cited by AMP Mem. at 17; AMP Compl., *AMP* Dkt. #1 ¶ 82). The Modernizing Laboratory Test Standards for Patients Act of 2011 would have prohibited any regulation of LDTs under the FDCA, including by expressly excluding such tests from the statutory device definition, and would have created a new pathway for premarket authorization to be administered by CMS. *See* H.R. 3207 §§ 2-3, 112th Cong. (2011) (cited by AMP Compl., *AMP* Dkt. #1 ¶ 83). The VITAL Act of 2020 would have classified LDTs as professional services regulated by CMS and expressly excluded them from FDA's jurisdiction. *See* S. 3512 § 2, 116th Cong. (2020) (cited by AMP Mem. at 17; AMP

Compl., *AMP* Dkt. #1 ¶ 88). And the VALID Act of 2020 would have created a new regulatory category entirely separate from "drugs" and "devices," with "in vitro clinical tests" subject to regulation under an entirely new subchapter of the FDCA. *See* H.R. 6102 § 3, 116th Cong. (2020) (cited by ACLA Mem. at 13; AMP Mem. at 17; *AMP* Dkt. #1 ¶ 88).

None of these proposals show that Congress considered and rejected the policies issued or interpretations reiterated in the Final Rule. And even if they did, FDA adopted the Final Rule based on authority under the FDCA that it has asserted consistently for decades. That matters because this is not a case "in line with the types of issues" that have presented questions that are facially major. *See Mayfield*, — F.4th —, 2024 WL 4142760 at *3. Triggering the major questions doctrine here based on political significance therefore requires showing both that FDA has "enact[ed] a program that Congress considered and rejected multiple times," *and* that it has used "newly uncover[ed]" power to do so. *Id.* (quotations and modifications omitted). Because Plaintiffs have made neither showing, they have not shown that this case presents a politically major question.

Second, Plaintiffs have also failed to show that this case presents a major economic question. The Final Rule does not seek to "regulate a significant portion of the American economy." *Id.* Rather, it relates to one subset (laboratory-made IVDs) of one subset (*in vitro* diagnostic products) of one subset (devices) of the medical products over which FDA has jurisdiction. This is not akin to cases like *Utility Air Regulatory Group v. EPA*, 573 U.S. 302 (2014), in which the Environmental Protection Agency claimed the power to make regulations that would "have a profound effect on virtually every sector of the economy" and "every household in the land," *Utility Air*, 573 U.S. at 310-11, or *Alabama Association of Realtors v. Department of Health and Human Services*, 594 U.S. 758 (2021), in which the Centers for Disease Control and Prevention claimed the power to

halt all residential evictions across 80% of the United States, *see Ala. Ass'n of Realtors*, 594 U.S. at 764.

Nor will the Final Rule lead to "spending by private persons or entities" on the scale that courts have held presents a major question. *See Mayfield*, — F.4th —, 2024 WL 4142760, at *3. "[R]ecent cases applying the doctrine based on economic significance have involved hundreds of billions of dollars of impact"—on the order of $430 billion in loans forgiven immediately, or $1 trillion in lost economic production over 25 years ($40 billion per year). *Id.* The Final Rule, by contrast, is projected to cost private parties an average of $1.17 billion per year (annualized over 20 years). AR177.[20] This is a different order of magnitude than the cases highlighted in *Mayfield* as presenting major economic questions.

Finally, FDA has not "intrude[d] into an area that is the particular domain of state law." *Mayfield*, — F. 4th —, 2024 WL 4142760, at *3. Safety regulation of medical products in general has been substantially federalized since 1938, and device regulation in particular is even more firmly committed to FDA's control. *See* 21 U.S.C. § 360k (tightly restricting, including by express preemption, states' power to make laws regarding device safety and effectiveness). Neither ACLA nor AMP argues otherwise.

To sum up, Plaintiffs' attempt to saddle FDA with a "heavy [interpretive] burden" is unavailing because this is neither a lenity case nor a major-questions one. *See* ACLA Mem. at 21-23. Rather—to borrow ACLA's words—this is "a garden-variety case

[20] AMP argues that the relevant cost for major questions purposes is the cost if FDA were to enforce all FDCA requirements against all laboratory-made IVD test systems, rather than accounting for the enforcement discretion policies actually contained in the Final Rule—most significantly for purposes of cost to industry, the policy covering premarket authorization for IVDs offered as LDTs that are already on the market. AMP Mem. at 27 n.4. The Fifth Circuit, however, says the opposite. *Mayfield*, — F.4th —, 2024 WL 4142760, at *3 n.3 (holding that courts should look to costs of "the promulgated rule" rather than "the economic impact that could result from the broadest possible rule that is consistent with [the agency's] asserted authority").

of statutory interpretation." *Cf.* ACLA Mem. at 24. The question is whether FDA's actions are consistent with the statute's ordinary meaning. Because the answer to that question is "yes," Defendants are entitled to summary judgment regarding FDA's legal authority.

III. FDA's Decision to Phase Out the General Enforcement Discretion Approach for LDTs and Adopt Targeted Enforcement Discretion Policies is Not Arbitrary or Capricious.

Plaintiffs also argue in summary fashion that FDA's adoption of the Final Rule's enforcement discretion policies was arbitrary and capricious. ACLA argues in two paragraphs that the agency failed to consider laboratories' reliance interests on the general enforcement discretion approach for LDTs. *See* ACLA Mem. at 39-40. AMP argues that the Final Rule is based on low-quality evidence of the potential risk that laboratory-made IVD test systems pose to public health, *see* AMP Mem. at 38-39, and that FDA's decision to retain significant areas of enforcement discretion even as it phases out the general enforcement discretion approach should have caused the agency to reconsider its interpretation of the FDCA, *id.* at 40. These arguments are unavailing.

First, ACLA is wrong in asserting that FDA did not adequately consider the reliance interests that may be affected by the Final Rule. The agency carefully considered such interests. Indeed, FDA modified the Final Rule after commenters raised concerns that the proposed rule, if promulgated without change, would disrupt laboratory and patient expectations regarding the availability of certain tests. In response to those comments, FDA determined that it would generally decline to enforce premarket review and most quality system requirements with respect to laboratory-made IVD test systems already on the market. *See generally* AR16-21, AR82-88. ACLA faults the agency for relying on enforcement discretion "rather than establishing actual safe harbors," but identifies no provision of the FDCA that the agency could have invoked to do so. *See* ACLA Mem. at 40. Moreover, FDA explained that although it was including targeted enforcement discretion policies to account for patient access and

reliance (among other public health interests), those policies would not prevent the agency from taking enforcement action "on a case-by-case basis" as needed to address "any public health concerns" that come to light via "FDA surveillance for potentially poor performing LDTs." AR18-19. In other words, the agency will continue balancing reliance and patient access interests with others over time.

Second, AMP's attack on the evidence supporting the Final Rule's phaseout of the general enforcement discretion approach is based on a limited view of the record. It claims that FDA has identified only "52 total concerns with LDTs." AMP Mem. at 38 (citing AR37 n.52). The cited footnote to the Final Rule, however, is only discussing case studies identified in a single agency memorandum. *See* AR37 n.52 (citing AR535-48). As discussed *supra*, at 7-9, the total body of evidence supporting the Final Rule is significantly broader and deeper than a single collection of case studies. *See, e.g.*, AR36 ("[M]ore precise numbers would not affect the fundamental public health concerns that have motivated this rulemaking . . . FDA already possesses enough information to conclude that there is no longer a sound basis to generally treat LDTs differently from other IVDs"); AR7127-28 (describing multiple studies "document[ing] high variability in performance among" IVDs offered as LDTs); AR7330-40 (reporting on a study showing that only 7 of 19 laboratories correctly reported all results on a given sample); AR7341-7351 (finding "substantial discordance between the final output of two different gene panels analyzed by CLIA-certified laboratories").

Finally, AMP argues that FDA should have reconsidered whether the statute "could or should" be interpreted in such a way that the public might be harmed by enforcing it immediately, without enforcement discretion policies covering (for example) existing tests. *See* AMP Mem. at 40. ACLA makes a similar argument, based on the Supreme Court's decision in *Utility Air Regulatory Group v. EPA*, 573 U.S. 302 (2014), in support of its final claim that FDA's interpretation was contrary to law. *See* ACLA Mem. at 38-39.

Utility Air, however, is wholly inapposite because it involved an agency that adopted a narrowed construction of a statute rather than exercising discretion in enforcing it. *Utility Air*, 573 U.S. at 325-26. Moreover, FDA's decision to exercise enforcement discretion is not based on a permanent, fundamental mismatch between the statutory text and the agency's regulatory goals as in *Utility Air*. *See id.* at 321-22. The enforcement discretion policy for "currently marketed" laboratory-made IVDs, for example, is based in part on inherently time-limited reliance interests that emerged under FDA's prior enforcement approach. As that approach recedes further into the past, new laboratory-made IVDs enter the market, and old ones are retired, "compliance with premarket review and QS requirements will be phased in according to the natural lifecycle of test development and use." AR19. Similarly, the enforcement discretion policy for LDTs that serve an unmet need will no longer apply to the extent that FDA authorizes new tests in the future that meet the needs in question. *See* AR18. The agency's decision to rely on those market and technological forces to over time more closely align its enforcement approach with its statutory authority was not arbitrary and capricious.

IV. Plaintiffs Are Not In Any Event Entitled to Universal Vacatur of the Final Rule.

Even if they are correct on the merits, which they are not, Plaintiffs ask for more relief than this Court should grant. Both ACLA and AMP request that this Court vacate the Final Rule outright. *See* ACLA Compl., Prayer for Relief ¶ A; AMP Compl., Prayer for Relief ¶ A. While Fifth Circuit precedents do hold that so-called "universal vacatur" is an available remedy under the APA, *see, e.g.*, *Tex. Med. Ass'n v. U.S. Dept. of Health and Hum. Servs.*, 110 F.4th 762, 779-80 (5th Cir. 2024), the APA itself does not reference vacatur at all, instead authorizing plaintiffs to seek traditional equitable remedies like injunctions. *See* 5 U.S.C. § 703. Nor is there good reason to believe that Congress intended the APA to *sub silentio* create a new and radically different remedy of

universal vacatur. *See United States v. Texas*, 599 U.S. 670, 693-702 (2023) (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (detailing "serious" arguments that "warrant careful consideration" as to whether the APA "empowers courts to vacate agency action"). Defendants respectfully preserve for further review their argument that universal vacatur is not available under the APA.

But even assuming *arguendo* that universal vacatur were theoretically available, it still would not be needed to grant full relief to Plaintiffs here. Rather, any relief should be limited to Plaintiffs and their members. Ordinary principles of Article III standing and equity generally require that a court tailor remedies to address the plaintiffs' injury. *See, e.g.*, *Gill v. Whitford*, 585 U.S. 48, 70-72 (2018); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Courts should thus "ask[] whether party-specific relief can adequately protect the plaintiffs' interests" before choosing a remedy with a broader sweep. *Texas*, 599 U.S. at 702-03 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment). Equitable relief entered only with respect to the plaintiffs to this suit (and their members) would remedy the injuries they claim.

Lastly, a final note on Plaintiffs' potential remedies. Defendants have repeatedly noted that several of Plaintiffs' arguments would—if accepted by this Court—result in specific FDCA requirements being unenforceable as to laboratory-made IVD test systems, rather than such systems being outside FDA's jurisdiction altogether. The precise grounds for this Court's ruling may therefore affect the scope of any relief to which Plaintiffs would be entitled. In light of that fact, Defendants respectfully request that if the Court grants any part of Plaintiffs' summary judgment motions, it also provide an opportunity for the parties to submit further briefing on an appropriate remedy.

CONCLUSION

For these reasons, the Court should grant the Federal Defendants' motion for summary judgment, and deny Plaintiffs' cross-motions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2024, a true and correct copy of this document was served electronically by the Court's CM/ECF system on all counsel of record.

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