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' Combined Summary Judgment Reply

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INTRODUCTION

The Final Rule implements FDA's[1] unambiguous statutory authority to protect the public from unsafe or ineffective test systems. As the Federal Defendants have explained, such systems are diagnostic "apparatuses" or "contrivances" made up of physical components that work together to produce a test result. That makes them "devices" under Congress's definition of the term. The Final Rule simply 1) clarifies FDA's longstanding view of that statutory authority, and 2) states how the agency intends to enforce it going forward as to nearly all laboratory-made IVD test systems. The Federal Defendants are entitled to summary judgment because that action was not arbitrary, capricious, or contrary to law. Plaintiffs' arguments to the contrary cannot overcome either the plain meaning of the FDCA or the Final Rule's careful balancing of competing public health interests.

First, neither the major questions doctrine nor the rule of lenity entitles Plaintiffs to a thumb on the interpretive scale. The major questions doctrine does not apply because FDA did not make its own policy judgment that it *should* have jurisdiction over laboratory-made IVD tests. Rather, the agency simply implemented Congress's plain textual directive that it *does.* The purpose of major-questions review is to ensure that agencies making their own policy judgments do not exceed their statutory authority to do so. Applying it to a congressional policy judgment would flip the doctrine on its head by constraining rather than conserving Congress's ability to make major decisions for itself. Moreover, even if the major questions doctrine could theoretically control a case that does not involve a delegation of discretion to an agency, it still would not apply here. Whether a particular subclass of diagnostic tests should be regulated as medical devices is not the sort of "extraordinary" political or economic question that triggers the doctrine under Supreme Court and Fifth Circuit precedent. The rule of

[1] All acronyms and other terms have the same meaning as in the Federal Defendants' opening memorandum. *See* Dkt. #54 (Fed. Defs. Mem.).

lenity is similarly inapposite because this case does not present the sort of grievous statutory ambiguity that could justify its use.

Second, the Federal Defendants are entitled to summary judgment because laboratory-made IVD test systems fall within the literal meaning of the FDCA's device definition. *See United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (explaining that FDCA's coverage should be interpreted "as broad[ly] as its literal language"). A system of physical components used together to produce a test result is a diagnostic "apparatus" or "contrivance," *see* 21 U.S.C. § 321(h)(1), and developing the specifications of such a tangible system is part and parcel of manufacturing it. None of Plaintiffs' arguments—including their analogy to medical treatments like surgeries—can elide these basic facts. Just as a skilled doctor cannot perform a safe and effective procedure using a device with a seriously defective design, not even the most proficient laboratory can wring reliable diagnostic meaning from a test with a design that lacks clinical validity. Regulating whether the design of a device is safe and effective is distinct from regulating a laboratory's proficiency in using the device to provide a service.

For similar reasons, Plaintiffs are wrong that either CLIA or the Social Security Act have somehow displaced FDA's jurisdiction under the plain language of the FDCA. It is unremarkable for multiple statutes and regulatory schemes to bear on similar or overlapping topics, and Plaintiffs bear a heavy burden in identifying a conflict sufficient for one to displace the other. No such conflict exists here. Unlike CLIA (which focuses on laboratory proficiency and regulates test validity in only a narrow analytical sense) or the Social Security Act (which determines whether medical products are covered by a specific social insurance program for a specific subset of patients, not whether they may be sold in the first instance to the public at large), the FDCA empowers FDA to ensure that tests designed and offered by laboratories are capable of generating *clinically valid* results on which *all indicated patients* may safely and effectively rely.

Third, the Federal Defendants are also entitled to summary judgment on Plaintiffs' claims that the Final Rule is arbitrary and capricious. In developing its new enforcement discretion policies, FDA expressly considered laboratories' reliance interests. FDA also considered how protection of those interests may trade off with the potential for enforcement against problematic tests that fall within an enforcement discretion policy. In turn, FDA's conclusion that the benefits of the Final Rule will outweigh its costs is amply justified by a reasonable projection based on the evidence before the agency.

Finally, in the event the Court grants summary judgment for Plaintiffs in any respect, Fifth Circuit precedent gives this Court flexibility to fashion an appropriate remedy. Plaintiffs are wrong to suggest otherwise. However, an appropriate remedy cannot be identified until the content of the Court's decision is known. Because the parties cannot, at this stage, make informed arguments concerning an appropriate remedy, the Federal Defendants respectfully request the opportunity to brief the issue further if the Court grants any part of Plaintiffs' summary judgment motions.

ARGUMENT

I. The Final Rule Does Not Implicate Either the Major Questions Doctrine or the Rule of Lenity.

A. Whether the FDCA's Plain Language Applies to One Subset of the *In Vitro* Diagnostic Testing Market Is Not a Major Question.

This case presents an ordinary question about the textual reach of a federal statute. Congress has empowered FDA to protect the public from unsafe or ineffective diagnostic devices. The FDCA defines those devices broadly to include any "apparatus" or "contrivance" intended for diagnostic use. *See* 21 U.S.C. § 321(h)(1). As FDA has done for decades, the Final Rule reads the plain text of that provision to unambiguously include all IVD test systems.

Plaintiffs disagree. They argue that a test system—a set of physical components that function together to produce a test result—becomes a device under the FDCA only

when its components are brought together for physical sale to a third party. *See* Dkt. #66 (ACLA Opp.) at 1, 3, 7; Dkt. #67 (AMP Opp.) at 17, 20. Put in practical terms, Plaintiffs' theory is that IVD test systems are beyond FDA's authority so long as they are manufactured by a laboratory that opts to commercialize them on a fee-for-service basis rather than through physical sale to other users.

That challenge raises a straightforward and unremarkable question of statutory interpretation: Did Congress include this specific subcategory of tests in the FDCA's definition of "device," 21 U.S.C. § 321(h)(1)? For multiple reasons, this is not a question that triggers "extraordinary" scrutiny under the major questions doctrine. *See Mayfield v. U.S. Dep't of Labor*, 117 F.4th 611, 616 (5th Cir. 2024) (quoting *West Virginia v. EPA*, 597 U.S. 697, 723 (2022)).

To begin with, Plaintiffs have not shown that FDA's assertion of jurisdiction rests on a claim of delegated *policymaking* authority of the type that the major questions doctrine is meant to police. The Supreme Court has not applied the doctrine to every agency action that applies the terms of a broadly worded statute to a subject that has attracted some level of congressional attention or that has some degree of economic significance. *Massachusetts v. EPA*, 549 U.S. 497 (2007), is a case in point.

Massachusetts considered whether the Clean Air Act's "sweeping[ly]" broad definition of an "air pollutant" includes the greenhouse gases that are responsible for global climate change. *See id.* at 528-29. The Environmental Protection Agency concluded that because the issue was "so important," and because Congress had later declined to enact legislation specifically addressing such emissions, Congress "could not have meant the Agency to address" them unless it "spoke with exacting specificity." *See id.* at 511-13. The Supreme Court rejected that argument, holding that "[t]he statutory text foreclose[d] EPA's reading." *Id.* at 528. "On its face," the statute "unambiguous[ly]" provided that "air pollutant" includes "*any* physical [and] chemical . . . substance or matter which is emitted into or otherwise enters the ambient

air." *Id.* at 528-32 (last two alterations in original). That this "capacious" definition did not specifically mention greenhouse gases did not change the fact that they "fit well within [it]," *id.* at 532, and neither the importance of the issue nor the subsequent history of "congressional actions and deliberations" on the subject justified "read[ing] ambiguity into a clear statute" or required Congress to speak with "exacting specificity" to accomplish its purpose, *see id.* at 512, 529-32.

Massachusetts that shows Congress does not trigger the major questions doctrine by making its *own* important policy judgments. Instead, the Supreme Court has applied the doctrine in cases where, as a threshold matter, the challenged action was a "policy decision[]" made *by the agency* pursuant to some form of discretion *delegated* by Congress. *See West Virginia*, 597 U.S. at 723; *see also id.* at 729-30 (discussing doctrine in terms of likelihood that Congress would leave "certain policy judgments" to "agency discretion") (quotation omitted). As Justice Gorsuch has explained, the doctrine applies when an agency "seeks to resolve for itself the sort of question normally reserved" for the legislative branch. *Id.* at 746 (Gorsuch, J., concurring). Regardless of a policy judgment's political or economic significance, if it is made by Congress directly rather than an agency, major questions review simply does not apply.

That limitation traces back to the doctrine's roots in the separation of powers. *See West Virginia*, 597 U.S. at 723; *id.* at 739-41 (Gorsuch, J., concurring) (explaining doctrine as a prophylactic against Congress "divest[ing] its legislative power to the Executive Branch"); *Biden v. Nebraska*, 143 S. Ct. 2355, 2380-81 (2023) (Barrett, J., concurring) (explaining doctrine as an interpretive expectation that "in a system of separated powers," Congress will "make the big-time policy calls itself"). It reflects the fact that separation-of-powers concerns that may arise when executive agencies make their own policy judgments are absent when agency action (however significant it might be in a practical sense) simply implements decisions that Congress itself has already made. Indeed, applying extraordinary scrutiny in the latter category of cases would pervert

the doctrine's basic rationale by constraining rather than conserving Congress's ability to make its *own* major policy decisions. "The question . . . is not whether something [can] be done; it is who has the authority to do it." *Nebraska*, 143 S. Ct. at 2372 (per curiam).

That is one reason (though not the only one, *see infra* at 19-21) why it matters that FDA's jurisdiction over laboratory-made IVD test systems is based *directly* on the FDCA's unambiguous language. *See* Fed. Defs. Mem. at 18-20; AR43. It is also a reason why it matters that FDA's literal interpretation of that language has been consistent for decades. *See* Fed. Defs. Mem. at 21-26, 43-44. And it is likewise a reason why it matters that Plaintiffs are wrong in arguing that the agency has somehow "reinterpreted those words to encompass" something more than they have always included on their face. *See* ACLA Opp. at 3, 17-19; *see also* AMP Opp. at 2-4 (arguing that the Final Rule will leave Plaintiffs subject to regulation under the FDCA "for the first time").

FDA has not resolved *for itself* the question of whether laboratory-made IVD test systems *should* be subject to device regulation. Rather, it has concluded that those systems *are* within its jurisdiction because they fall within the plain language of the device definition that *Congress* included in the FDCA. AR43-49. The language of that statute, together with the record in this case, shows that FDA is implementing Congress's policy judgment rather than making its own.

Start with the language of the device definition itself, which simply describes what Congress intended to regulate as a device,[2] without telling FDA to make discretionary judgments regarding which products should be included. *See* 21 U.S.C. § 321(h)(1). That distinguishes this case from others in which a statute's express terms contemplated the exercise of policymaking discretion by an agency. *See West Virginia*,

[2] Congress has been clear in delineating what is a device, *see, e.g.*, 21 U.S.C. §§ 321(h)(1), 360j(n), and what is not, *see, e.g.*, *id.* § 360j(o).

597 U.S. at 724-32 (major questions doctrine constrained agency's express discretion to decide which "adequately demonstrated" approach to reducing carbon dioxide emissions would be "best"); *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 760-61, 764 (2021) (per curiam) (same, for express discretion to make "judgment[s]" about which regulations are "necessary" to control the spread of disease); *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor*, 595 U.S. 109, 114, 117 (2022) (per curiam) (same, for express discretion to decide which workplace safety standards are "reasonably necessary or appropriate"); *Gonzales v. Oregon*, 546 U.S. 243, 250-51, 254, 267-68 (2006) (same, for express discretion to determine whether permitting a physician to prescribe controlled substances would be "inconsistent with the public interest"); *All. for Fair Bd. Recruitment v. SEC*, — F.4th —, 2024 WL 5078034, at *14-17 (5th Cir. Dec. 11, 2024) (en banc) (same, for express discretion to determine whether securities exchange rules are designed to "protect investors and the public interest").

This is also unlike major questions cases in which an agency has asserted comparable policymaking authority based on an implicit delegation. Even before *Loper Bright*, FDA expressly disclaimed any argument that the device definition itself contained such a delegation under *Chevron*. *See* AR45. That distinguishes *King v. Burwell*, 576 U.S. 473, 485-86 (2015) (major questions doctrine constrained agency's discretion under *Chevron*), *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 315, 321-24 (2014) (same), and *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132, 159-61 (2000) (same). Nor has FDA argued that any other statutory provision gives it discretion to modify the device definition that Congress wrote. That sets this case apart from *Biden v. Nebraska*, 143 S. Ct. at 2368-69, 2372-74 (major questions doctrine limited reach of agency's express authority to waive or modify statutory requirements as it "deem[ed] necessary"), and *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218, 224-25, 229-32 (1994) (same, for express authority to modify statutory requirements "in [the agency's] discretion and for good cause").

In sum, FDA's assertion of jurisdiction over laboratory-made IVD test systems is based on the unambiguous text of the device definition that Congress enacted. It is not based on any power—"newly uncover[ed]" or otherwise—for FDA to decide for itself whether or not a test system is a device. *See* Fed. Defs. Mem. at 43 (quotation omitted). That should be the end of the major questions inquiry.

Nevertheless, even if major questions review could *potentially* apply in this case as a threshold matter, the Final Rule still would not present a question of sufficiently "vast political or economic significance" to *actually* trigger the doctrine. *See Mayfield*, 117 F.4th at 616. The Federal Defendants have demonstrated as much. *See* Fed. Defs. Mem. at 21-26, 42-48. For the reasons explained below, neither ACLA nor AMP has shown otherwise.

Political Significance. The major questions doctrine applies in "extraordinary" cases where an agency makes a policy judgment of "vast" political significance, not in every case involving an issue that is in some sense "politically controversial." *See Mayfield*, 117 F.4th at 616-17. In policy terms, the question underlying this case is a narrow one: Should FDA's existing medical device authorities apply to one subclass of clinical diagnostic tests? Although the Court need not address the issue if it agrees that Plaintiffs' major questions arguments fail at the threshold for the reasons just discussed, this is "not in line with the types of [questions]" that the Supreme Court and Fifth Circuit have "considered politically contentious enough to trigger the doctrine." Fed. Defs. Mem. at 43 (quoting *Mayfield*, 117 F.4th at 617).

Plaintiffs do not argue otherwise, *cf.* ACLA Opp. at 18-22; AMP Opp. at 2-6, and their failure to engage with the actual questions that the Supreme Court has held to be major is telling. Compared to those past questions, *cf., e.g.*, *West Virginia*, 597 U.S. at 724, 729-31 (whether the federal government should "substantially restructure the American energy market" by "requir[ing] a large shift from coal to natural gas, wind, and solar"); *Brown & Williamson*, 529 U.S. at 132, 159-61 (whether tobacco products with a "unique

place in American history and society" should be outlawed as unsafe),[3] and given FDA's extremely broad jurisdiction to regulate medical products, *see MCI*, 512 U.S. at 229-30 ("[W]hether a change [to a body of law] is minor or major depends to some extent upon the importance of the item changed to the whole."), whether FDA should enforce regulatory requirements under its existing medical device authorities for one specific subset of tests is neither an extraordinary nor a vastly significant political question.[4] Plaintiffs' two arguments to the contrary are unpersuasive.

First, Plaintiffs dispute whether FDA "has previously claimed . . . authority" to regulate laboratory-made IVD test systems as devices. *See Mayfield*, 117 F.4th at 617; *see also* ACLA Opp. at 18-19; AMP Opp. at 2-4. As the Federal Defendants have explained, the record clearly shows that it has. *See* Fed. Defs. Mem. at 21-26. To briefly review: Congress has empowered FDA since 1938 to regulate *any* diagnostic "apparatus" or

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[3] *Cf. also Nebraska*, 143 S. Ct. at 2372-74 (whether to grant mass student loan forgiveness to mitigate the financial burden of a global pandemic); *Nat'l Fed'n of Indep. Bus.*, 595 U.S. at 117 (whether more than ¼ of all Americans should be required to "either obtain a COVID-19 vaccine or undergo weekly medical testing at their own expense"); *Ala. Ass'n of Realtors*, 594 U.S. at 764 (whether residential evictions should be forbidden across 80% of the United States); *King*, 576 U.S. at 485-86 (whether tax credits indispensable to the Affordable Care Act's health insurance reforms should be available in states without their own insurance exchange); *Utility Air*, 573 U.S. at 310-11 & n.2, 323-24 (whether global climate change should be addressed by adopting "de facto [nationwide] zoning" applicable to "virtually every sector of the economy"); *Gonzales*, 546 U.S. at 248-49, 267-68 (whether the prescription of controlled substances for use in physician-assisted suicide should be criminalized); *MCI*, 512 U.S. at 229-32 (whether to largely abolish rate regulation in market for long-distance telephone service).

[4] ACLA also briefly suggests that this Court should consider the existence of criminal liability for FDCA violations as an "amplif[ying]" factor in its major questions analysis. ACLA Opp. at 22 (quoting *Ala. Ass'n of Realtors*, 594 U.S. at 765). The Supreme Court, however, has never suggested that the major questions doctrine applies to every agency interpretation of a criminal statute, nor held that the possibility of criminal punishment tipped a question over the line separating major from not. In other words, it is at best unclear what lesser degree of weight this factor might hold. Because this is not a close case from a major-questions perspective, the Court need not resolve the question.

"contrivance." *See* 21 U.S.C. § 321(h)(1); *see also* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(h)(1), 52 Stat. 1040, 1041 (1938). In 1972 and 1973, FDA responded to "rapid growth in [the] development" of IVD tests, as well as increasing "reliance on [their] results," by affirming that such tests "clearly fall under [the agency's] jurisdiction" to regulate diagnostic products, 37 Fed. Reg. 819, 819 (Jan. 19, 1972), and by promulgating under that authority rules applicable to *all* IVD test "systems," 38 Fed. Reg. 7096, 7098 § 167.1(a) (Mar. 15, 1973) (now codified as amended at 21 C.F.R. § 809.3(a)). Congress subsequently expanded FDA's authority over devices and their manufacturers in the Medical Device Amendments of 1976, which imposed the system of establishment registration, premarket authorization, and postmarket controls that is still in force today. *See* Pub. L. No. 94-295, 90 Stat. 539 (1976). And in FDA's very first rulemaking to implement those new requirements, the agency recognized its authority to enforce them against clinical laboratories that manufacture their own devices and subsequently "provide a service through the[ir] use." *See* 42 Fed. Reg. 42520, 42521, 42528 (Aug. 23, 1977) (codified at 21 C.F.R. § 807.65(i)). Plaintiffs' responses cannot muddy this clear history.

To begin with, both ACLA and AMP misunderstand the relevance of FDA's 1977 rulemaking, which exempted a subset of clinical laboratories from registration and listing under the FDCA. *See id.* at 42528; Fed. Defs. Mem. at 24. Plaintiffs suggest that FDA thereby "clarified" (AMP) or "emphasized" (ACLA) that laboratories offering testing services are categorically beyond regulation as device manufacturers. *See* AMP Opp. at 2; ACLA Opp. at 18. AMP argues in addition that FDA "recognized" as much by moving the exemption for clinical laboratories from a subsection that expressly uses the word "manufacturer" to one that does not. ACLA Opp. at 2-3.

In fact the opposite is true. In the 1977 rulemaking, FDA exercised its authority to exempt by rule certain establishments from requirements *that would otherwise apply to them based on the statute alone*. *See* 42 Fed. Reg. at 42528 (invoking 21 U.S.C. § 360(g)). As

the agency has explained, that exemption "is premised on the position that laboratories are device manufacturers. If they were not device manufacturers, there would have been no need to exempt them . . . ." AR60. In other words, in extending a limited exemption to laboratories that primarily "provide a service through the use of a previously manufactured device," 42 Fed. Reg. at 42528, FDA necessarily concluded both 1) that a laboratory may be a manufacturer subject to registration and listing even if it offers devices as a service rather than for physical sale, and 2) that a laboratory is *not* exempt from those requirements if it offers a device of its own design (*i.e.*, one that is not a "previously manufactured device").

ACLA also incorrectly accuses FDA of "distort[ing]" the meaning of the agency's 1973 rulemaking for IVD test "systems." *See* ACLA Opp. at 18. At bottom, ACLA argues that because one section of that rule requires an IVD system's label to appear on the outside of its "retail package," the rule as a whole must refer exclusively to products akin to packaged test kits rather than to laboratory-made tests. *Id.* (quoting 38 Fed. Reg. at 7098 § 167.2(a)). The Federal Defendants have explained why that does not follow: The FDCA itself expressly contemplates the existence of devices that do not exist "in package form," and makes clear that such devices are simply not subject to the statute's requirements regarding a physical label. Fed. Defs. Mem. at 30 & n.13 (quoting 21 U.S.C. §§ 321(k), 352(b)). Likewise, the fact that FDA included in the 1973 IVD Rule certain requirements applicable only to packaged IVDs does not suggest that those are the only IVDs subject to the rule.

Next, Plaintiffs argue that even if FDA did assert jurisdiction over laboratory-made IVD test systems in 1973 and 1977, the agency still triggered the major questions doctrine by doing so too long after the relevant portions of the device definition were

enacted in 1938. *See* AMP Opp. at 3; ACLA Opp. at 19.[5] That is not the case. FDA adopted the 1973 IVD Rule scarcely a year after it noted new concerns regarding the increased prominence and complexity of *in vitro* test systems. *See* 37 Fed. Reg. at 819. An administrative action does not present a major question simply because the agency used an old statute to address a new problem. *See Massachusetts*, 549 U.S. at 506-07, 510-13, 532 (holding that major questions doctrine did not bar initial regulation of greenhouse gases as "air pollutants" 33 years after Congress defined that term in the Clean Air Act). Nor did FDA answer a major question in 1977 when it determined that clinical laboratories may be subject to registration and listing requirements that did not exist prior to passage of the MDA only one year earlier. *See generally* Fed. Defs. Mem. at 9-10 (summarizing requirements).

ACLA raises one last challenge to the Federal Defendants' demonstration that FDA's position on these issues has remained the same for decades.[6] Pointing to the so-called Charrow memorandum, ACLA insists that the Court can and should consider it as evidence of inconsistency in FDA's position. *See* ACLA Opp. at 18-19 & n.2. That argument fails in part because the Charrow memorandum is not part of the certified administrative record produced by FDA in this case, *see* Dkt. #17, which is presumed to be complete and properly designated "absent clear evidence to the contrary."[7]. *Knight*,

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[5] AMP also asserts that the long tenure of FDA's position does not "immunize it from challenge." *See* AMP Opp. at 3-4. That is neither here nor there. FDA's argument is that the stability of the agency's position over time weighs against Plaintiffs' claim that it presents a major question—not that it is immune from judicial review.

[6] ACLA makes a passing accusation that FDA has expressed this position only "sporadically and hesitantly," ACLA Opp. at 19, but the Federal Defendants have explained that this claim is belied by the record, *see generally* Fed. Defs. Mem. at 24-25; AR43, AR67, AR7132-33.

[7] The bare fact that FDA acknowledged the Charrow memorandum's existence in the Notice of Proposed Rulemaking, *see* AR7133, and acknowledged its citation by commenters in the Final Rule, *see, e.g.*, AR79-80, is not clear evidence that the agency

[footnote continues on following page]

2019 WL 3413423, at *1. If ACLA believes the Charrow memorandum should have been included, the proper vehicle for saying so would have been a timely motion to complete or supplement the record. Moreover, even if the Charrow memorandum were part of the record, the fact of statements made by a *single non-FDA official* in the course of *internal deliberations*[8] would not undermine the consistency of the *agency*'s *public position*.

Second, Plaintiffs argue that this case presents a major political question because Congress has considered but not enacted legislation that would have changed how laboratory-made IVD tests are regulated.[9] The Federal Defendants have explained in detail that *none* of these proposals support Plaintiffs' invocation of the major questions doctrine because *none* would have enacted the "program"—regulation of such tests by FDA under its existing medical device authorities—embodied by the Final Rule. *See West Virginia*, 597 U.S. at 731-32; *see also* Fed Defs. Mem. at 45-46. Plaintiffs' argument fails because they cannot show that Congress has "considered and rejected" that approach *even once*—let alone "consistently" or "multiple times." *See West Virginia*, 597 U.S. at 731-32.

Plaintiffs' sole response is to accuse the Federal Defendants of "hairsplitting" and argue that it is enough for Congress to have considered proposals "similar" to what FDA has done. ACLA Opp. at 19-20; *see also* AMP Opp. at 6. But the Supreme Court has been clear that what matters is whether Congress has "*consistently* rejected" on "*multiple*" occasions the "*same basic scheme*" as the agency has adopted. *West Virginia* 597

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actually considered it in its decisionmaking, *see Knight v. U.S. Army Corps of Eng'rs*, 2019 WL 3413423, at *2 (E.D. Tex. July 29, 2019).

[8] The Federal Defendants emphasize again that the Charrow memorandum has never been authorized for public release and is available to Plaintiffs only because it was leaked to the press. *See* AR7133 & Refs. 61-64.

[9] ACLA continues to suggest that the Court should also consider *post hoc* non-legislative statements by individual members of Congress or congressional committees. *See* ACLA Opp. at 20. That suggestion is still wrong for the same reasons the Federal Defendants have previously explained. *See* Fed. Defs. Mem. at 44-45.

U.S. at 731-32 (emphasis added). *West Virginia*'s isolated reference to considering congressional rejection of "similar measures" only proves the point. *See id.* Although *West Virginia* itself involved a cap-and-trade system of carbon pricing, the Supreme Court noted that *in addition* to rejecting actual cap-and-trade proposals, Congress had declined to pass the "similar measure" of a carbon tax. *See id.* Cap-and-trade and carbon taxes are both mechanisms for putting a price on carbon emissions—two "paths . . . leading to the same result." World Bank Group, *What is Carbon Pricing?* (last visited Dec. 23, 2024), https://perma.cc/UMU6-G3CG. In other words, they were so similar as to amount to the "same basic scheme" for purposes of the major questions doctrine. *West Virginia*, 597 U.S. at 731-32.

The same cannot be said of Plaintiffs' examples. Congress has rejected multiple proposals to *strip* FDA of jurisdiction over LDTs in favor of CMS,[10] a proposal to create for genetic tests a special review pathway administered by both agencies,[11] a proposal to create a new FDCA regulatory category and framework for "in vitro clinical tests,"[12] and a proposal for FDA to regulate LDTs as a subcategory of devices subject to special new requirements.[13] It is impossible to conclude from this chaotic and contradictory array of failed proposals that Congress has said *anything* "consistently" about the merits of *any* "basic scheme," let alone the "same" one—regulation of laboratory-made diagnostic tests under FDA's existing device authorities—embodied in the Final Rule. *See West Virginia*, 597 U.S. at 731-32. At most, Congress's sporadic engagement with the subject suggests that clinical test regulation is in some sense "a politically controversial

[10] *See* Modernizing Laboratory Test Standards for Patients Act of 2011, H.R. 3207 §§ 2-3, 112th Cong. (2011); VITAL Act of 2020, S.3512 § 2, 116th Cong. (2020).

[11] *See* Genomics and Personalized Medicine Act of 2006, S.3822 §§ 7(b)-(d), 109th Cong. (2006).

[12] *See* VALID Act of 2020, H.R. 6102 § 3, 116th Cong. (2020).

[13] *See* Laboratory Test Improvement Act of 2007, S.736 §§ 2(a), 4(d), 5(a), 5(b)-(c), 110th Cong. (2007).

topic." *See Mayfield*, 117 F.4th at 617. That does not a major question make. *See id.*

Economic Significance. The major questions doctrine may also apply in cases where an agency decides "to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities." *Mayfield*, 117 F.4th at 616; *see also Nebraska*, 143 S. Ct. at 2373 (applying doctrine where agency decided to forgive billions of dollars in loans owed to the government). If the Court reaches the issue of economic significance (which it need not do if it agrees that Plaintiffs' arguments fail at the threshold for the reasons discussed *supra* at 3-8), it should hold that neither criterion is satisfied in this case.

First, the performance of laboratory-made IVD test systems is not a "significant [enough] portion of the American economy" to present a major question. *See Mayfield*, 117 F.4th at 616. Even according to ACLA's own rosy numbers (which appear to include laboratories that do not make tests offered as LDTs), the testing industry claims credit for only about 0.47% of the national economy. *See* John Dunham & Assocs., *2022 Economic Impact Study of Independent Clinical Laboratories* at 2 (Oct. 2022), https://perma.cc/8YV7-B9ZC; *see also* ACLA Opp. at 20. *But see* AR427 (estimating that only 10% of high-complexity laboratories actually manufacture tests offered as LDTs).

That is a much narrower impact than those regulations that have been deemed to raise major economic questions. It is roughly 1/4 the size of the rental housing market at issue in *Alabama Association of Realtors*.[14] It is roughly 1/200 the size of the would-be object of regulation (virtually the entire economy) in *Utility Air*. *See Utility Air*, 573 U.S. at 310-11 & n.2. And while the comparison is not apples-to-apples, the coal-fired power plants targeted for regulation in *West Virginia* were responsible for producing 38% of

[14] *See Ala. Ass'n of Realtors*, 594 U.S. at 764 (explaining that eviction moratorium covered 80% of the country); *see also* Fed. Res. Bank of St. Louis, *Rental of Tenant-Occupied Nonfarm Housing* (last updated Sept. 26, 2024), https://perma.cc/3LSP-Q2Y5 (showing $569 billion in nationwide expenditure on residential rents in 2021, 80% of which amounted to slightly less than 2% of GDP).

the nation's electricity. *See West Virginia*, 597 U.S. at 720. Indeed, 0.47% is a *smaller* share of the national economy than the 1.2 million workers at issue in *Mayfield* were of the national labor force (0.71%). *See Mayfield*, 117 F.4th at 617; Bureau of Labor Statistics, *Employment Status of the Civilian Population by Sex and Age* (last modified Nov. 1, 2024), https://perma.cc/M6K3-EFRS (reporting labor force of about 168 million people).

Plaintiffs respond that the testing industry is "significant" for reasons other than its economic scale—many people entrust their health in part to clinical test results. *See* ACLA Opp. at 20; AMP Opp. at 4. FDA agrees that safe and effective tests are important to protect public health; but from a major-questions perspective Plaintiffs' argument proves far too much. The doctrine is not supposed to apply in ordinary cases, and there is nothing extraordinary about a federal agency acting to regulate an industry on which depends the physical safety of millions of Americans. In more concrete terms—federally-regulated airlines carry more than 800 million passengers per year, *see* Bureau of Transportation Statistics, *TranStats* (last visited Dec. 23, 2024), https://perma.cc/5TJ2-52GT, and federally-regulated motor vehicles travel more than three trillion miles, *see* Alternative Fuels Data Center, Department of Energy, *Annual Vehicle Miles Traveled in the United States* (last updated Oct. 2024), https://perma.cc/7PM9-SKYC, but not every regulatory burden on the aerospace or automotive sectors will raise a major question. The same is true for the narrow subset of medical products at issue in this case.

Second, Plaintiffs also argue that the major questions doctrine applies because clinical laboratories will need to spend significant amounts of money to comply with FDCA requirements. As the Federal Defendants have explained, the Final Rule is projected to cost private parties an average of $1.17 billion per year over 20 years. *See* Fed. Defs. Mem. at 47 (citing AR440). That is far less than the $430 billion in student loans proposed to be forgiven immediately in *Nebraska*, 143 S. Ct. at 2372-73, the $40 billion per year in lost economic production projected in *West Virginia*, 597 U.S. at 715,

or the $50 billion per year in rent payments potentially lost in *Alabama Association of Realtors*, 594 U.S. at 764. It is far closer to the $472 million per year that the Fifth Circuit held non-significant in *Mayfield*. *See* 117 F.4th at 616.[15] Plaintiffs' primary response is to argue that for various reasons the Court should reject FDA's cost projections as unreliable.

AMP begins by arguing that those projections have been inconsistent, and it faults the agency for choosing "the lowest possible number." *See* AMP Opp. at 5 n.4. Neither accusation has any basis in the record. AMP's claim that FDA has offered inconsistent estimates conflates one estimate that includes costs to industry only, *see* AR440, with another one (higher, naturally) that also includes costs to FDA, *see* AR386-87.[16] And its claim that FDA has presented the lowest estimate possible is simply wrong. $1.17 billion is FDA's *primary* estimate of the Final Rule's yearly cost to industry. The agency's *low* estimate is that the cost per year will be $510 *million*. *See* AR440.

Both Plaintiffs also argue that this Court should simply ignore the reductions in cost to industry that will flow from FDA's enforcement discretion policies for certain categories of tests. They speculate as a factual matter that laboratories might "fully comply[]"with those requirements anyway, *see* ACLA Opp. at 21, in AMP's case based on extra-record declarations that say no such thing, *see* AMP Opp. at 5-6 (citing physician statements that do not discuss spending money to comply with requirements

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[15] ACLA argues that *Alabama Association of Realtors* shows that "*tens* of billions of dollars in costs are sufficient" to trigger major-questions review. ACLA Opp. at 21. But that elides the fact that the Supreme Court in that case estimated the "economic impact" of a COVID-era eviction moratorium by reference to the nearly $50 billion in emergency rental assistance that Congress had appropriated (and the executive had largely spent) in the eight months between December 2020 and August 2021. *See Ala. Ass'n of Realtors*, 594 U.S. at 770 (Breyer, J., dissenting) (noting appropriations statutes). Compared on the same annualized basis, that is more than 50 times the projected impact of the Final Rule.

[16] ACLA made the same mistake in its opening memorandum. *See* ACLA Mem. at 18 (citing AR388).

for which FDA had generally exercised enforcement discretion). FDA's expert judgment in that regard, however, is entitled to deference so long as it is "within a zone of reasonableness." *See FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Plaintiffs have identified no basis in the record for this Court to disregard FDA's conclusion that laboratories likely will not spend money to comply with requirements (*e.g.*, premarket review) that fall within an enforcement discretion policy. The same laboratories have already relied on FDA's general enforcement discretion approach for many years,[17] and there is no reason in practice to think they will take FDA's more targeted enforcement discretion policies any less seriously.

Plaintiffs are also wrong as a legal matter in arguing that this Court should assess the cost of the broadest phaseout policy that FDA *could* have adopted (*i.e.*, one that includes no enforcement discretion policies at all), rather than the one it *actually did*. The Fifth Circuit's binding decision in *Mayfield* says the opposite. *Mayfield*, 117 F.4th at 616 n.3; *cf.* AMP Opp. at 5 (arguing that *Mayfield* is "at odds with the major questions doctrine's rationale"). It makes no difference, moreover, that FDA chose to account for reliance interests by including enforcement discretion policies in the Final Rule rather than by other means. When an agency has authority to make a decision, it *always* retains discretion to "change [that decision] down the road." *Cf.* ACLA Opp. at 21 n.3. That is a feature of agency decisionmaking generally, not the exercise of enforcement discretion in particular. *See Am. Petrol. Inst. v. EPA*, 906 F.2d 729, 739 (D.C. Cir. 1990). This Court should consider the cost to industry of the action FDA actually took, and hold that it is not enough to trigger major-questions review.

[17] Even if the Court credits Plaintiffs' (incorrect) view of when FDA first asserted its jurisdiction over laboratory-made IVD test systems, laboratories have been relying on the agency's exercise of enforcement discretion since at least 1997. *See* AMP Opp. at 3; *see also* ACLA Opp. at 18-19 (arguing that agency first "sought to claim such authority" in 1992).

B. The Rule of Lenity Does Not Apply.

The Federal Defendants have explained that because lenity is a tool for dealing with statutory ambiguity, it does not apply where (as here) there is no ambiguity to resolve. Fed. Defs. Mem. at 42 (citing *United States v. Northington*, 77 F.4th 331, 334 (5th Cir. 2023)). In response, ACLA has abandoned its original position that lenity requires always reading criminal statutes narrowly. *Cf.* ACLA Mem. at 22. Rightly so. *See Maracich v. Spears*, 570 U.S. 48, 76 (2013) (explaining that lenity applies "at the end of the process" of interpretation to resolve ambiguities, "not at the beginning as an overriding consideration of being lenient to wrongdoers"); *Cargill v. Garland*, 57 F.4th 447, 470 (5th Cir. 2023) (en banc) (cautioning against "apply[ing] lenity in an unprincipled manner to statutes that are not really ambiguous").

Instead, ACLA now argues that lenity may apply "to the extent" that a criminal statute is ambiguous. *See* ACLA Opp. at 22-23. At bottom, that amounts to a theoretical observation that lenity exists—it is not an argument for how or why to apply it in this case. The fact remains that in dozens of pages of briefing on the meaning of the relevant FDCA provisions, no party has so much as suggested that they cannot be fully understood using the "traditional tools of statutory construction." *See Cargill*, 57 F.4th at 469; *see also Maracich*, 570 U.S. at 76 (explaining that lenity applies only where there is such "grievous ambiguity" that a court can only "guess" at Congress's intent even "after considering text, structure, history, and purpose"). Because those traditional tools are enough to resolve this case, there is no occasion to apply the rule of lenity.

II. FDA Has Unambiguous Statutory Authority Over Laboratory-Made IVD Test Systems.

A. IVD Test Systems Are Devices Within the Plain Meaning of the FDCA.

Plaintiffs resist the commonsense reality that diagnostic test systems comprised of physical components are "apparatuses" or "contrivances" and therefore "devices" under the FDCA. *See* Fed. Defs. Mem. at 19-20. They insist that laboratory-made IVD test systems are not physical products, only intangible services beyond FDA's power to

regulate. FDA's interpretation, Plaintiffs say, would sweep so widely as to encompass services like surgeries. Plaintiffs' statutory interpretation is artificially narrow, their conception of IVD test systems is cramped, and their analogy to medical services is flawed.

The Supreme Court has emphasized that the FDCA's device definition should be interpreted "as broad[ly] as its literal language." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).[18] Plaintiffs struggle mightily to exclude laboratory-made IVD test systems from the FDCA's definition of "device," which includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." 21 U.S.C. § 321(h)(1). None of their arguments survive scrutiny.

Test Systems. Both Plaintiffs focus to no avail on FDA's longstanding position that the statutory device definition includes IVD test "systems." *See* 21 C.F.R. § 809.3(a). AMP argues that a "device" cannot be made up of "one or more previously manufactured devices." AMP Opp. at 7-8. That definition, however, expressly states that devices may be made up of "components[s]" that are also devices in their own right. 21 U.S.C. § 321(h)(1) (providing that "any component" of a device is itself a device). Indeed, the statute has said as much since it was first enacted. *See* FDCA, Pub. L. No. 75-717, § 201(h)(1), 52 Stat. 1040, 1041 (1938) (same). The device definition has always clearly included a test system that is comprised of multiple devices working together as "components" of a larger "apparatus." Congress did not have to expressly

[18] *Brown & Williamson*'s holding that FDA lacked jurisdiction to regulate tobacco products is not to the contrary. The Supreme Court in that case assumed for purposes of argument that tobacco products *do* fall within the device definition, but held that FDA nevertheless lacked jurisdiction for other reasons. *See Brown & Williamson*, 529 U.S. at 131-32. The Federal Defendants have explained that those other reasons have no purchase here. Fed. Defs. Mem. at 42-48 (explaining that this case does not present a major question); *supra* at 3-18 (same); Fed. Defs. Mem. at 41 (explaining that this case does not implicate *Brown & Williamson*'s ratification canon).

use the word "system" to accomplish that result in 1938, and the fact that FDA later did so in an implementing regulation did not change the plain meaning of the relevant statutory terms—"apparatus," "contrivance," and "component"—particularly where Congress re-enacted them without change as part of the 1976 MDA. *Cf.* AMP Opp. at 7-8. If Congress had meant the MDA to *narrow* FDA's authority over test systems, it would have altered the language that it used to grant the agency that authority in the first place. AR45.

ACLA also faults FDA for supposedly "breaking with" past practice in the Final Rule by treating systems other than packaged "test kits" as regulated devices. *See* ACLA Opp. at 8. The Federal Defendants have already explained that this assertion misreads the regulatory history. *See supra* at 11. ACLA is likewise wrong to insist that the components of laboratory-made test systems are only in "transient relationships to each other" because they are not packaged as kits. *See* ACLA Opp. at 7-8. The FDCA does not require that all the "component[s]" of a test system be packaged together before FDA may regulate the system as a whole. *See* 21 U.S.C. § 321(h)(1). Rather, the question is whether those components are "intended for use" as a single diagnostic "apparatus" or "contrivance." *Id.* § 321(h)(1)(B); *see also* Fed. Defs. Mem. at 29-30. Nothing in those terms requires physical unity among a device's components. *See* Fed. Defs. Mem. at 19 (explaining that an IVD test system is both "a set of equipment [or] tools" and an "artificial arrangement"). Indeed, in most cases, even a packaged test kit does not contain all relevant components of a test system, so ACLA's proposed reading of the FDCA would prevent FDA regulation of *most* test systems (the devices that actually produce a diagnostic test result affecting patients). This Court should reject ACLA's invitation to rewrite the FDCA by defining devices in terms of their physical configuration rather than their intended use.

Test Manufacture. Plaintiffs also take an artificially narrow view of what constitutes device "manufacture." *See* ACLA Opp. at 10. As FDA previously explained,

that term (which is itself shorthand for a broad range of activities which trigger certain FDCA requirements[19]) has consistently embraced a test designer's initiation of specifications, including specifications that require the end user to independently obtain some or all of a test's physical components. Fed. Defs. Mem. 29-30 (citing 21 C.F.R. §§ 807.3(d)(3)), 809.10(b)(8)(i)-(ii)). Indeed, Congress has specifically authorized FDA to regulate "pre-production design validation." 21 U.S.C. § 360j(f)(1)(A); *see also* AR7. While ACLA criticizes the Federal Defendants' invocation of 21 C.F.R. § 807.3(d)(3) because that subsection describes "[i]nitiation of specifications" for devices in a "narrow situation," ACLA Opp. at 14, a single illustrative example in a regulation does not constrain the statute's broad meaning. The point is that physical assembly is not the *sine qua non* of acting as a manufacturer, because other steps also "occur[] within the manufacturing establishment as part of the manufacturing process," and may cause a device to be unsafe or ineffective even if it is physically assembled according to specifications. *See* 42 Fed. Reg. at 42520-21.

Plaintiffs' next logical misstep is to insist that designing a test system cannot be "manufacturing" because the design specifications are not a "physical" or "tangible" item. ACLA Opp. at 4-6, 11-13. That argument ignores that the test system being designed is comprised of physical components. *See* Fed. Defs. Mem. 3. In other words, designing a test system is a necessary step in a broader process of physical manufacture.

Plaintiffs also argue that laboratory-made IVD test systems cannot be devices because some medical services also involve a professional's use of tools according to a procedure. *See* ACLA Opp. at 11-12; AMP Opp. at 8-9. But the Final Rule does not address "physical examination[s]," "surger[ies]," or other medical services performed

[19] *See* AR1 (explaining that FDA uses "'manufacture' . . . as a shorthand for the various activities that constitute manufacturing as described in FDA regulations (*e.g.*, design, preparation, propagation, assembly, and processing); *see also* 21 C.F.R. § 807.30(a); 21 U.S.C. § 360(a)(1).

using previously manufactured devices. *Cf.* ACLA Opp. at 11-12; AMP Opp. at 8-9. It addresses diagnostic tests—physical systems designed by the laboratories that manufacture them to function together as a single apparatus in order to produce a single test result. *See* AR46-47; 21 U.S.C. § 321(h)(1) (defining "device" based upon intended use). Such systems clearly fall within the plain meaning of the FDCA's device definition, and the Court should disregard Plaintiffs' continued efforts to redirect its attention to medical procedures well beyond the scope of the Final Rule.

ACLA is also wrong to suggest that professional involvement in the performance of a test somehow transforms a physical test system into an intangible service. *See* ACLA Opp. at 9-11. An example in the Final Rule illustrates the distinction between a practitioner or a laboratory's provision of services using one or more devices, and the manufacture of a device itself. Imagine a cardiologist is placing a stent in a patient but discovers that the device has a defect that makes the procedure impossible. AR57. The cardiologist is undoubtedly performing services when performing the procedure. But whether the cardiologist performs that procedure in a safe and effective manner is a different question than whether the stent itself has a safe and effective design. *Id.* Similarly, if a test lacks clinical validity as designed, no amount of laboratory expertise in performing it according to its designed specifications could resolve that defect and produce a clinically valid result. *Id.* Thus, while the performance of many tests requires human involvement, *see* ACLA Opp. at 9-10 (providing an example), that does not transform the test itself into a service. As FDA observed in the Final Rule, following ACLA's argument to its logical conclusion would mean that "few or no test systems" would be devices, which would "run counter to 50 years of established IVD regulation and enforcement." AR57. Contrary to ACLA's suggestion, its argument seeks an exception from that long history of regulation and enforcement. ACLA Opp. at 10-11.

Licensed Practitioner Exceptions. AMP argues that the Final Rule conflicts with the FDCA's exemption of certain licensed practitioners from statutory registration,

listing, and adverse-event reporting requirements. *See* 21 U.S.C. §§ 360(g)(2), 360i(c)(1). It says that these exceptions would be "self-defeating" unless they include "institutions and entities" that are "affiliated" with health care practitioners. AMP Opp. at 13-15. But an exception is not self-defeating merely because it is narrow. The language Congress chose—which refers to "practitioner[s]" manufacturing devices "solely for use in the course of [their] professional practice," *see* 21 U.S.C. §§ 360(g)(2); 360i(c)(1)—is plainly narrow, as it does not include "institutions and entities" that are "affiliated" with health care practitioners, *cf.* AMP Opp. at 13-15. Indeed, when Congress wants to exempt institutions and entities from FDCA requirements, it knows how to do so. *See, e.g.*, 21 U.S.C. § 360(g)(1) (referring to "pharmacies" rather than pharmacists); *id.* § 360(g)(3) (referring to "persons"); *id.* § 321(e) (defining "person" to include an "individual, partnership, corporation, and association").

AMP fares no better in maintaining that these exceptions—which by their terms only exempt covered practitioners from the FDCA's registration, listing, and adverse-event reporting requirements—extend to other statutory requirements as well. *See* Fed. Defs. Mem. at 34-35. It asserts broadly that the statute's *de novo* classification and PMA provisions are "inextricably tied to" or "interdependent with" requirements from which licensed practitioners are exempt, AMP Opp. at 14, but largely ignores the Federal Defendants' point-by-point showing that the statutory text says no such thing, *see* Fed. Defs. Mem. at 35.

As to only one of those points, AMP insists that Class III devices made by licensed practitioners must be entirely exempt from PMA requirements because 21 U.S.C. § 360e(e)(1)(D) requires FDA to withdraw an approved PMA if it finds deliberate non-compliance with "applicable regulation[s]" for adverse-event reporting, or non-compliance with "the requirements of [21 U.S.C. §] 360"—requirements and regulations from which licensed practitioners are exempt. AMP Opp. at 14-15. AMP's argument appears to be that because licensed practitioners are exempt from certain separate

requirements that Congress incorporated by reference into only one of the FDCA's seven grounds for PMA withdrawal, *see* 21 U.S.C. §§ 360e(e)(1)(A)-(G), then the devices they manufacture must be exempt from PMA requirements altogether. That does not follow, and it was hardly "nonsensical," *see* AMP Opp. at 15, for Congress to relax practitioners' registration, listing, and reporting obligations, but continue to require that any Class III devices they manufacture have reasonable assurances of safety and effectiveness, be made according to federal manufacturing standards, and have labeling that is not false or misleading. *See* 21 U.S.C. § 360e(a) (generally requiring that Class III devices have PMA); *id.* § 360e(d)(2) (PMA approval criteria); *id.* §§ 360e(e)(1)(A)-(B), (E)-(F) (requiring withdrawal of a PMA based on certain adverse findings relating to a device's safety, effectiveness, manufacturing, or labeling).

AMP also complains that reading the FDCA's licensed practitioner exceptions to protect practitioners themselves rather than "affiliated" entities would "interfere with the authority of a health care practitioner" to prescribe or administer devices. AMP Opp at 13-15 (quoting 21 U.S.C. § 396). But the text of 21 U.S.C. § 396 is likewise limited to the authority "*of a health care practitioner*," not any entity "affiliated" with one. AMP's maximalist view of § 396 would risk swallowing device regulation altogether if the potential for an indirect effect on healthcare practitioners barred FDA from acting as to other regulated entities within its jurisdiction. Further, that provision only addresses the prescribing or administering of a "legally marketed" device. 21 U.S.C. § 396. It does not address the question at issue here: the circumstances under which a device may be legally marketed in the first place.

Commercial Distribution. Finally, AMP says that even if laboratory-made IVD test systems are devices, laboratories' choice to market them on a fee-for-service basis deprives FDA of jurisdiction to regulate those systems by keeping them out of "commercial distribution." *See* AMP Opp. at 9-12. That is wrong as a threshold matter because not all FDCA provisions incorporate a "commercial distribution" requirement.

See Fed. Defs. Mem. at 31. AMP is simply incorrect when it asserts that FDA has "identifie[d] no material requirement[]" of the statute that is "not derivative" of a provision which requires commercial distribution. *See* AMP Opp. at 9-10. The agency did exactly that in the Final Rule. *See* AR53 (explaining that, for example, commercial distribution is not needed to trigger or enforce the PMA requirements, 21 U.S.C. § 360(k), and is not a prerequisite to FDA's authority to seize adulterated devices, 21 U.S.C. § 334(a)(2)(D)). And the Federal Defendants did so again in their opening memorandum, *see* Fed. Defs. Mem. at 32 (citing AR53-54, AR7137).

But even assuming incorrectly that "commercial distribution" is a prerequisite to applying *any* portion of the FDCA, AMP's cramped interpretation of that phrase still runs afoul of the Supreme Court's instruction to read the statute "as broad[ly] as its literal language." *Bacto-Unidisk*, 394 U.S. at 798. The Federal Defendants have explained that the literal meaning of "commercial distribution" easily encompasses a business model in which a laboratory supplies the public with the use of a test system in exchange for money. *See* Fed. Defs. Mem. at 32 (discussing dictionary definitions). They have also shown that this interpretation is supported by Congress and FDA's contemporaneous understanding that the term simply tracks the "popular" phrase "on the market," *id.* (citing AR53),[20] as well as legislative history showing that Congress specifically intended to regulate devices offered to the public as "diagnostic service[s],"

[20] AMP protests ignorance of whether this common usage was known in the 1970s, *see* AMP Opp. at 11-12, but describing services as being offered "on the market" is hardly a new phenomenon. *See, e.g.*, Milton Friedman, *Inflation and Unemployment* at 281 (Dec. 13, 1976), https://perma.cc/JSP4-KDGZ ("In the modern world, governments are themselves producers of services sold on the market . . . ."); Joseph P. Biniek, Congressional Research Service, *Pollution Taxers, Effluent Charges, and Other Alternatives for Pollution Control* at 257 (May 1, 1977) ("In the absence of any official intervention, research and development would be . . . a service offered on the market[.]"); *Muller v. Nelson, Sherrod & Carter*, 563 S.W.2d 697, 701 (Tex. Civ. App. 1978) (discussing an attorney's "[professional] services and their value on the market").

id. at 32-33 (citing S. Rep. 94-33 at 4-5 (1975)).

AMP disagrees, arguing that the "contextually appropriate meaning" of the term refers only to physical distribution at scale. AMP Opp. at 10 (citing definitions of "commerce" and "commercial"). AMP says that this narrow meaning should prevail in part because FDA guidance has stated since 1978 that commercial distribution "generally" requires "delivery to occur immediately or at a promised future date," which AMP says reflects the agency's "contemporaneous understanding" of the term. AMP Opp. at 12 (quoting FDA, *Compliance Policy Guide* § 300.600 (reissued Sept. 24, 1987), https://perma.cc/J53M-3Q64)). To begin, an FDA statement that delivery "generally" occurs as part of commercial distribution is a far cry from a statement that delivery of a good is *required*. And in any event, AMP undermines its own argument in the very same paragraph, criticizing the Federal Defendants for referring to a 1976 committee report explaining that "commercial distribution" only requires that a device be "on the market." AMP Opp. at 11-12. To borrow AMP's words, *neither* source can "override the plain meaning of the statute's words." *Id.* at 11.

The difference is that the Final Rule reads the FDCA as the Supreme Court says to read it—"as broad[ly] as its literal language indicates." *Bacto-Unidisk*, 394 U.S. at 798. At bottom, AMP's argument is that because the words "commercial distribution" *can* be used narrowly to mean the physical sale of goods, that is what Congress *must* have meant. *Bacto-Unidisk*, however, dictates the opposite approach. *See also* AR53 (collecting other cases). FDA's reading is both clearly supported by the unambiguous literal meaning of the FDCA and consistent with other contemporaneous indicia of the commercial activity that Congress meant the statute to reach. That is more than enough to reject AMP's cramped interpretation and grant summary judgment for the Federal

Defendants.[21]

B. FDA Oversight of IVD Test Systems Made by Laboratories is Fully Consistent with CLIA.

Plaintiffs next claim that laboratory-made IVD test systems are not "devices" under the FDCA because they are also regulated by another statute. FDA's position, they say, makes CLIA "redundant." AMP Opp. at 18; ACLA Opp. at 16. AMP argues that since CLIA is the later-enacted and more specific statute, it negates any part of the FDCA that touches on the same products. AMP Opp. at 20-21. ACLA maintains that CLIA's enactment confirms that the FDCA never included laboratory-made IVD test systems, and that FDA's position would "create a strange world" where such tests are "uniquely subject to overlapping" regulations. ACLA Opp. at 15-16.

As an initial matter, the premise of Plaintiffs' argument—that it would be somehow unusual or suspect for two agencies to regulate the same industry—is incorrect. Rather, it is commonplace and unsurprising that a product might be affected by multiple agencies and regulatory schemes. As the Supreme Court has explained, two agencies can have "wholly independent" obligations that "may overlap, but there is no reason to think the two agencies cannot both administer their obligations and yet avoid inconsistency." *Massachusetts*, 549 U.S. at 532 (rejecting argument that EPA may not regulate tailpipe emissions of greenhouse gases by "tighten[ing] mileage standards" because Congress has assigned responsibility for such standards to the Department of Transportation under a separate statute); *see also Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1219 (9th Cir. 2008) (observing that two regulatory schemes "are not

[21] In a last attempt to cabin the meaning of "commercial distribution," AMP claims in an aside that the Federal Defendants' interpretation would render a reference to "interstate commerce" in 21 U.S.C. § 360(k) a "nullity." AMP Opp. at 12. But "commercial distribution" and "interstate commerce" are not coextensive terms, and it is unremarkable that Congress would intentionally use one term at times and the other term at others.

coextensive, but they often overlap").

Plaintiffs' flawed premise aside, they are also wrong that regulation of their products under the FDCA will be duplicative of regulation under CLIA. Their position apparently stems from confusion between clinical validity—a test's ability to help identify, measure, or predict the presence or absence of a *clinical condition*, which CMS does not regulate under CLIA—and analytical validity—a test's ability to detect what it is supposed to according to its established specifications.

AMP, for example, argues that CLIA must regulate clinical validity because it uses the terms "validity," "reliability," and "accuracy." AMP Opp. at 16-19. But CLIA uses these terms to require analytical validity. *See* Fed. Defs. Mem. at 37-39. AMP cites CLIA's reference to "valid and reliable laboratory" procedures, AMP Opp. at 19 (quoting 42 U.S.C. § 263a(f)(1)), but that subsection ultimately requires laboratories to "*assure consistent performance*" of "valid and reliable" procedures, 42 U.S.C. § 263a(f)(1) (emphasis added), a paradigmatic analytical validity concern. Unsurprising, CLIA's implementing regulations include "accuracy" in their definition of a"[p]erformance characteristic," which also lists other analytical validity concerns such as "precision," "analytical sensitivity," and "analytical specificity." 42 C.F.R. § 493.2. AMP also refers to portions of CLIA's implementing regulations, which set out requirements for tests developed in-house that are "not subject to FDA clearance or approval," alleging that they cannot be reconciled with the Final Rule. AMP Opp. at 22-23 (citing 42 C.F.R. § 493.1253(b)(2)). But setting aside the fact that regulations issued by CMS cannot conceivably narrow the scope of the FDCA, the cited provision merely allows for the possibility that laboratories may at times use devices not subject to premarket authorization (or authorized devices modified in a way that does not require further authorization). *See* AR65. In those cases, CLIA's regulations require the laboratory to establish the unauthorized device's "[a]ccuracy," "[p]recision," "[a]nalytical sensitivity," and other performance specifications for analytical validity. 42 C.F.R.

§ 493.1253(b)(2).

For its part, ACLA maintains that CLIA and the FDCA overlap because CLIA touches on professionals' "interpretation concerning specific patient conditions," which ACLA equates with the "clinical validity" of a test. ACLA Opp. at 16 (quoting 42 C.F.R. § 493.1445(e)(9)). But that provision of CLIA's implementing regulations only requires laboratory directors to ensure that "consultation is available" to discuss interpretation of test results. 42 C.F.R. § 493.1445(e)(9). As FDA explained in the Final Rule's preamble, the Final Rule helps to ensure that clinical tests offered by laboratories themselves "generate accurate and reliable test results," AR65, a topic wholly separate from the personnel and procedure requirement in CLIA's implementing regulations. Put simply: If a test is not clinically valid as designed, professional consultation regarding its results will not ensure that it is safe and effective. CLIA and the FDCA complement rather than conflict with one another.

For the same reason, it makes no real difference whether Plaintiffs' invocation of CLIA is described in terms of an implied repeal, *see* Fed. Defs. Mem. at 39-41, or some other (nominally distinct) theory under which one statute may partially "negate" or otherwise "change the meaning" of another one without saying so expressly, *see* AMP Mem. at 20-21. As the Federal Defendants have explained, *see* Fed. Defs. Mem. at 39-40 & n.16, these doctrines of implied displacement have one fundamental thing in common—they come into play only when needed to harmonize two statutes that would otherwise be in actual conflict. *See, e.g.*, *Brown & Williamson*, 529 U.S. at 148-49, 155-56 (actual conflict between FDCA labeling requirement and tobacco-specific labeling prohibition); *Train v. Colo. Pub. Int. Rsch. Grp., Inc.*, 426 U.S. 1, 5-9 (1976) (actual conflict between broad discretion to regulate radioactive material under one statute and mandate to make specific rules regarding such material under another); *D. Ginsberg & Sons v. Popkin*, 285 U.S. 204, 206-08 (1932) (actual conflict between one statutory provision generally authorizing issuance of orders necessary to enforce the Bankruptcy

Act, and another imposing specific limitations on orders to arrest a bankrupt debtor). However Plaintiffs choose to label their argument, they have not met their "heavy burden" to show that CLIA "displaces" any part—let alone the entirety—of the FDCA. *See Dept. of Agric. Rural Dev. Rural Hous. Serv. v. Kirtz*, 601 U.S. 42, 63-64 (2024).[22]

Plaintiffs' remaining arguments are equally meritless. AMP contends that, under the Social Security Act, CMS must refuse Medicare payments for treatment that is "not reasonable and necessary," which AMP says is "in part" enforced by contractors who evaluate whether the treatment is "[s]afe and effective." AMP Opp. at 19-20 (quoting 42 U.S.C. § 1395y(a)(1)(A) and CMS, *Medicare Program Integrity Manual* § 13.5.4 (issued Feb. 12, 2019)). It asserts that CMS does in fact evaluate the clinical validity of laboratory-made IVD test systems, and that there is no daylight between CMS's authority with respect to those devices and FDA's. AMP Opp. at 20. That is wrong. First, the cited CMS authority is not specific to IVD test systems made by laboratories, and CMS's implementation of the reasonable and necessary standard applies to all FDA-regulated products under CMS's purview. AMP's argument, taken to its natural conclusion, would have CMS displace regulation for all such products, not just laboratory-made IVD test systems. Second, the question of whether a product is covered by a public insurance program under the reasonable and necessary standard is a separate issue entirely from the question of whether there are sufficient assurances of safety and effectiveness for it to be legally sold at all. *Compare* 42 U.S.C. § 1395y(a)(1)(A) (excluding payment for items and services "not reasonable and necessary") *with* CMS, *Medicare*

[22] AMP cannot distinguish *Kirtz* on the basis that the "heavy burden" in that case applied to an argument that an earlier-enacted general statute should control over a later-enacted specific one. *See* AMP Mem. at 21-22. The burden attaches to implied-displacement arguments in general, regardless of the particular configuration of the statutes involved in terms of timing and specificity. *See, e.g.*, *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 510-11, 523-24 (2018) (applying same heavy burden to reject argument that a later-enacted specific statute should control over an earlier-enacted general one).

Program Integrity Manual § 13.5.4 (listing "safe and effective" as one of several factors considered in determining whether an item or service is reasonable and necessary). And third, Medicare regulations only address whether CMS may pay for treatment rendered to the "intended Medicare population" (*i.e.*, the elderly). *See* 89 Fed. Reg. 65724, 6538 (Aug. 12, 2024). They do not address treatment paid by any other source or treatment offered to working-age Americans.

Finally, ACLA reprises its argument that clinical interpretation of tests is a service and is therefore only regulated by CLIA. ACLA Opp. at 16-17. But along the lines explained *supra* at 23, Plaintiffs elide the distinction between a professional's skill in interpreting test results and the capacity of that test's design to generate clinically valid results in the first place. CLIA regulates only the former, and only the FDCA regulates the latter. The Court should give full effect "to all of Congress's work, not just the parts [Plaintiffs] might prefer." *See Epic Sys.*, 584 U.S. at 524.

III. The Final Rule is Not Arbitrary or Capricious.

Contrary to Plaintiffs' arguments, the Final Rule appropriately accounted for reliance interests by fashioning thoughtful and reasonable enforcement discretion policies. The Final Rule "recognize[d] that patients, the healthcare community, and the laboratory industry have likely made decisions in reliance on access to, or the continued manufacturing of, many currently marketed IVDs offered as LDTs." AR19.

FDA responded to comments concerning reliance interests, including laboratory reliance interests, AR83, by explaining that its enforcement discretion policies will "appropriately balance[] the various competing interests at issue to best serve public health," because they would help to preserve the availability of beneficial tests "while incorporating targeted use of available tools to identify and act against . . . problematic" ones, AR19. S*ee also* AR81 (the phaseout policy was "crafted" to better protect the public health by helping to assure the safety and effectiveness of tests "while also accounting for other important public health considerations such as patient access and reliance").

ACLA complains that FDA failed to "consider how the non-binding nature" of the policies "undermines their value as a protection for reliance interests." ACLA Opp. at 23-24. But FDA expressly explained that its continuing discretion to take enforcement action "against currently marketed IVDs offered as LDTs that are problematic," and to otherwise act to protect public health "on a case-by-case basis" are key tools for "appropriately balanc[ing] . . . various competing interests," including patient access, laboratory reliance, and the uncertain safety and effectiveness of many laboratory-made IVD test systems on the market today. *See* AR18-19. In other words, FDA did exactly what ACLA says it did not. It understood that the possibility of continuing enforcement even as to tests within an enforcement discretion policy would necessarily trade off against the reliance interests that those policies are intended to protect, and it "balance[d]" those "competing interests" in the Final Rule. *See id.*

ACLA further maintains that the enforcement discretion policies in the Final Rule make it analogous to *Utility Air Regulatory Group v. EPA*, 573 U.S. 302 (2014), and that the policies therefore render the Final Rule arbitrary and capricious. ACLA Opp. at 23-24. To the contrary, *Utility Air* supports FDA's approach. In that case, the Court held that the EPA's statutory interpretation would have "calamitous consequences," which EPA sought to ameliorate by "rewriting" applicable "statutory thresholds." *Utility Air*, 573 U.S. at 325. The Court deemed this improper, holding that agencies cannot "'tailor' legislation . . . by rewriting unambiguous statutory terms." *Id.* The Court contrasted EPA's effort with the "unremarkable proposition that an agency may adopt policies to prioritize its expenditures within the bounds established by Congress." *Id.* at 327. FDA's enforcement policies here are exactly the sort of "unremarkable" agency action the Court endorsed in *Utility Air*: FDA has the statutory authority to regulate laboratory-made IVD test systems and, *within those bounds*, has elected to "adopt policies to prioritize its expenditures." *Id.*

AMP separately argues that the rule is arbitrary and capricious because the

expected benefits of the Final Rule do not justify its costs. AMP Opp. at 23-25. AMP apparently faults FDA for not justifying its conclusion via "empirical or statistical studies," something that "[t]he APA imposes no general obligation on agencies" to do. *Prometheus Radio Project*, 592 U.S. at 427. That is "especially" true when the agency "relies on unquantifiable benefits." *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 455 (5th Cir. 2021). The Final Rule is expected to reap those kinds of benefits, such as the benefit of more consistently reliable tests, which are not readily susceptible to quantification, *see* AR36-37, or the intangible fairness benefit of regulating similar products in the same way, *see* AR36. AMP's argument imposes an evidentiary burden that does not exist, and the Final Rule is amply justified by FDA's "reasonable predictive judgment based on the evidence it had." *Huawei*, 2 F.4th at 455 (quoting *Prometheus Radio Project*, 592 U.S. at 427).

IV. The Court Should Not Order Universal Vacatur and Should Permit Additional Briefing on Remedies if Appropriate.

The Federal Defendants maintain that universal vacatur is not an available remedy under the APA while acknowledging that Fifth Circuit precedent has held that it is. Fed. Defs. Mem. 50-51. Plaintiffs incorrectly reply that universal vacatur is the "require[d]" remedy, AMP Opp. at 23, or "the appropriate remedy," ACLA Opp. at 25. But Fifth Circuit precedent does not *require* universal vacatur. Instead, it embraces a more flexible approach that permits the Court to tailor an appropriate remedy consistent with its equitable powers. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) ("The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances"); *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) (statutory remedies should be construed against the backdrop of the "traditions of equity practice"). For example, remand without vacatur is appropriate where there is a "serious possibility that the agency will be able to correct the rules defects on remand" and vacatur "would produce disruptive consequences." *Chamber of*

Com. of United States v. SEC, 88 F.4th 1115, 1118 (5th Cir. 2023); *see also Cent. and S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding final rule without vacatur to allow agency the opportunity to provide a reasoned statement for why it declined to adopt a proposal in a comment to a proposed rule). Moreover, "party-specific vacatur is definitely appropriate" in some situations. *Tex. Med. Ass'n v. HHS*, 120 F.4th 494, 510 (5th Cir. 2024). Contrary to Plaintiffs' suggestions, this Court retains considerable discretion when fashioning a remedy in this case.

ACLA nevertheless objects to the Federal Defendants' request for further briefing on the topic of remedy, arguing that the rule should be vacated "in its entirety," citing the government's observation that not all provisions of the FDCA apply to all products and asking the Court to refuse to fashion a "gerrymander[ed]" remedy. ACLA Opp. at 25. But the Court should not so blithely dispense with "several hundred years of history" of equitable practice. *Hecht*, 321 U.S. at 329. Consistent with those centuries of practice, the parties cannot make arguments concerning the appropriate remedy until the Court resolves the parties' arguments on the merits. If the Court were to agree with Plaintiffs on a ground narrowly applicable to specific devices or laboratory business models, a correspondingly narrow remedy may be appropriate. Or, if the Court were to find that the Rule cannot lawfully be applied to a defined group of individuals, the Court could fashion injunctive relief that would apply to those parties without disturbing the aspects of the rule that are otherwise lawful.

Because the parties cannot, at this stage, make informed arguments about what the appropriate remedy in this case would be (if any), the Federal Defendants respectfully request the opportunity to submit further briefing on that topic in the event that the Court grants summary judgment for the Plaintiffs in any respect.

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 December 23, 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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