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

ASSOCIATION FOR MOLECULAR PATHOLOGY, et al., *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, et al., *Defendants*.	Case No. 4:24-cv-824-SDJ

BRIEF OF THE COLLEGE OF AMERICAN PATHOLOGISTS AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTERESTS OF *AMICUS CURIAE*

The College of American Pathologists (CAP) is the world's largest organization of Board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. Founded in 1946, the CAP represents licensed, Board-certified physicians, with over 18,000 members who specialize in diagnosing the causes and effects of disease through laboratory methods. They practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers, and federal and state health facilities. The CAP serves its members by fostering and advocating for excellence in this practice around the world. As medicine, technology, and pathology have evolved significantly since 1946, the CAP has consistently led the way in meeting new challenges to achieve better patient outcomes.

The CAP's members play a critical role in designing and using laboratory-developed tests (LDTs) to predict and diagnose disease, guide therapy selection, and assess patient responses to specific treatments. An LDT is typically developed because there is no FDA-authorized in vitro diagnostic (IVD) test kit that meets a specific clinical need. For this reason, clinical laboratories often design new LDTs for patients with rare diseases or other unmet needs. Most LDTs serve patients being cared for in a hospital or health care network where the laboratory is located. This allows pathologists overseeing LDTs to interact directly with other physicians caring for these patients. Although many LDTs employed by the CAP's pathologist members represent innovations in patient care, LDTs typically use well-established laboratory methods and have clinical validity that is well-documented in the medical literature. For the CAP's members, LDTs are an essential component of the high-quality clinical laboratory testing that they provide to patients.

The CAP's accreditation and proficiency testing programs also ensure that laboratories consistently maintain optimal levels of service when developing and using LDTs. Through the CAP accreditation program, the CAP accredits over 8,000 laboratories in the United States and

around the world. This program, which has been approved by the Centers for Medicare & Medicaid Services (CMS), assigns teams of practicing laboratory professionals, who serve as inspectors and assist laboratories in achieving the highest standards for accurate patient testing and compliance with local, state, and federal regulations. The CAP's program sets out prescriptive methods for establishing performance specifications for LDTs and provides specialty CAP checklists covering additional requirements for analytically validating tests within a specialty or subspecialty.

The CAP has an acute interest in this litigation. Plaintiffs in these consolidated cases challenge a Final Rule setting out the Food and Drug Administration's (FDA) plan to regulate LDTs as medical devices under the Federal Food, Drug and Cosmetic Act (FDCA). *See* 89 Fed. Reg. 37,286, 37,328 (May 6, 2024). The Final Rule imposes draconian new restrictions—and crushing compliance costs—on the development and use of LDTs. These new restrictions will substantially impair the ability of the CAP's pathologist members to provide high-quality diagnostic testing that is integral to their practice.

The CAP's involvement in LDT regulation is not new. The CAP has worked closely with FDA, Congress, and other stakeholders to develop the proper framework for LDT regulation. When FDA issued its proposed rule in October 2023, the CAP submitted comments setting out its "significant concerns that the rule as proposed would lead to a large reduction in the number of highly accurate LDTs available in hospital and health system laboratories, which would directly result in a dramatic decrease in the availability of safe, effective, and in many cases innovative

tests necessary for timely patient care."[1] The CAP then submitted a letter to the Office of Management and Budget outlining these "significant concerns with the proposed rule."[2] And the CAP's President testified before Congress to highlight the proposed rule's substantial defects.[3]

For over a decade, the CAP has advocated for the adoption of a new statutory framework for LDT regulation that would enhance patient safety, maintain quality laboratory testing, and promote innovation without creating unnecessary regulatory burdens on pathologists, clinical laboratories, and other professionals involved in laboratory testing. Most recently, the CAP has supported proposed legislation, the Verifying Accurate Leading-edge IVCT Development Act of 2023, H.R. 2369 (the VALID Act), which would create a three-tiered risk-based system, expressly authorizing FDA to regulate high-risk LDTs, while leveraging existing structures to improve and promote patient safety. At the same time, the CAP has opposed proposals that would vest CMS with exclusive jurisdiction over LDTs. CMS currently oversees laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Rather than expanding CMS's oversight under CLIA, the CAP believes that a proper framework for LDT regulation in the future would involve both FDA and CMS. Under such a framework, Congress would allocate authority between the agencies, taking into account FDA's expertise in ensuring the effectiveness and safety of highly complex tests and CMS's expertise in overseeing general laboratory operations.

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[1] *See* Coll. of Am. Pathologists, Docket No. FDA-2023-N-2177, *Comment Letter Re: FDA Proposed Rule, "Medical Devices; Laboratory Developed Tests"* at 1–2 (Dec. 4, 2023), https://tinyurl.com/yp86v3sp (CAP Comment Letter).

[2] *See* Coll. of Am. Pathologists, Letter to OMB, HHS/FDA Final Rule, *Medical Devices; Laboratory Developed Tests* at 2 (Apr. 19, 2024), https://tinyurl.com/39r2praf.

[3] *See Summary of Testimony of Dr. Donald Karcher Before the H. Energy and Commerce Comm.'s Subcomm. on Health Hearing: Evaluating Approaches to Diagnostic Test Regulation and the Impact of FDA's Proposed Rule* (Mar. 21, 2024), https://tinyurl.com/2e53akub.

The CAP's keen interest and deep experience in the practical issues surrounding LDT regulation will benefit the Court's decisionmaking in this case. The CAP submits this brief for two reasons. First, the brief underscores why the Court should vacate the Final Rule as arbitrary and capricious, thereby allowing the Court to avoid deciding whether FDA has statutory authority to regulate LDTs at all.[4] Second, should the Court choose to decide the statutory question, this brief provides the Court with guidance on how to cabin its ruling to avoid unintended consequences for LDT regulation going forward.

INTRODUCTION

LDTs are critical to public health in the United States. Every day, in laboratories across the country, LDTs are used to diagnose rare genetic diseases, guide the selection of life-saving therapies, and assess a patient's response to cutting-edge drugs and treatments. But with a deceptively simple tweak to the Code of Federal Regulations, FDA's Final Rule has subjected *all* LDTs to the full panoply of medical-device requirements under the FDCA. *See* 89 Fed. Reg. at 37,286–87 (amending 21 C.F.R. § 809.3(a)). Notwithstanding FDA's attempt to downplay the Final Rule's impact through a dizzying labyrinth of exceptions currently set forth in the rule's preamble, the new requirements will impose billions of dollars in compliance costs on clinical laboratories' development and use of these essential tests. Those costs, in turn, will hinder LDT innovation, limit access to existing tests, and, ultimately, hurt patients.

In taking this drastic action, FDA failed to engage in the reasoned decisionmaking that the Administrative Procedure Act (APA) demands. Reasonable regulation requires that an agency

[4] The CAP takes no position regarding FDA's statutory authority to regulate LDTs, which is challenged in Count 1 of each of the plaintiffs' respective complaints. As explained above, the CAP believes that the optimal framework for LDT regulation would involve both FDA and CMS and has urged adoption of proposed legislation that would expressly authorize FDA to regulate certain LDTs.

grapple with the negative consequences of its chosen path. Here, FDA instead found a way to ignore those consequences by asserting that its novel, complex, and nonbinding scheme of "enforcement discretion policies" articulated in the Final Rule's preamble would prevent the catastrophic consequences that so many stakeholders have predicted. Yet the Final Rule never explains how the agency's slew of explicitly nonbinding policies will, in fact, safeguard LDT innovation and patient access, especially when the agency repeatedly asserts that it may change its nonenforcement policies and prosecute failures to comply with the FDCA at any time.

In reality, many clinical laboratories will be unable to rely on FDA's nonenforcement policies because the policies (i) explicitly permit continued enforcement at FDA's discretion and (ii) are so confusing and underinclusive that they make the risk of missteps (and prosecution) unacceptably high. Laboratories will thus be forced to comply with the FDCA's requirements and incur the attendant costs. Those costs will block the development of new LDTs and impair access to existing tests, especially for those in underserved patient populations. The agency's failure to come to grips with these obvious consequences of its Final Rule renders the action arbitrary and capricious, and the Court should vacate the rule on that basis.

Because the Final Rule should be set aside as arbitrary and capricious, there is no need for the Court to decide broader questions regarding FDA's statutory authority. That said, if the Court addresses the statutory question, the Court should avoid ruling in a way that could have unintended consequences for LDT regulation going forward. First, the Court should avoid implying that LDTs constitute "the practice of medicine," as some have argued. Not everyone who oversees or performs LDTs is a physician—*e.g.*, many are scientists with PhDs. And suggesting that laboratory testing involves the practice of medicine would raise difficult questions regarding the necessary scope of practice under state law and reimbursement under the Medicare and Medicaid programs.

Second, the Court should avoid implying that CLIA's existing regulatory framework renders additional FDA involvement in this area unnecessary or inappropriate. As noted already, the CAP believes that the optimal framework for LDT regulation would involve both FDA (with its expertise authorizing highly complex tests) and CMS (with its expertise overseeing laboratory operations more generally). The CAP has opposed plans to address existing concerns surrounding LDT regulation simply by expanding or amending CLIA. The CAP has instead supported the VALID Act, which would give FDA an important role in LDT regulation. The CAP therefore urges the Court not to cast doubt on such legislative proposals by suggesting that they are unnecessary (in light of CLIA) or otherwise inappropriate.

ARGUMENT

I. The Final Rule is arbitrary and capricious because FDA failed to adequately justify the rule's unsustainable costs, which will hinder innovation and harm patients.

"The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The Final Rule is neither. The Final Rule imposes unsustainable compliance costs on clinical laboratories. Those costs will impair LDT development and testing access, especially for vulnerable patients. Nor does FDA grapple with these "disadvantages," as reasoned decisionmaking requires. *See Michigan v. EPA*, 576 U.S. 743, 753 (2015). Instead, FDA simply asserts (without a reasoned explanation) that its scheme of nonbinding "enforcement discretion policies" will forestall those disadvantages. But especially given the Final Rule's sweeping impact on laboratory testing and public health, FDA's ipse dixits are a far cry from the reasoned decisionmaking the APA requires. The Court should vacate the Final Rule accordingly.

To begin, the consequences of subjecting LDTs to the full array of FDCA medical-device requirements would be catastrophic. The CAP explained as much in commenting on the proposed

rule, when it warned FDA that "us[ing] the existing FDA framework for the regulation of LDTs . . . will severely stifle medical innovation, increase regulatory burden on clinical laboratories, introduce unsustainable costs as part of the development of LDTs by clinical laboratories, and in the end hinder the delivery of potentially life-saving testing to patients." CAP Comment Letter at 10. FDA itself has conceded that the proposed rule would have cost clinical laboratories tens of billions of dollars to bring existing LDTs into compliance, along with billions more in compliance costs relating to new-test development. *See* FDA, Docket No. FDA-2023-N-2177, *Laboratory Developed Tests Proposed Rule: Preliminary Regulatory Impact Analysis* at 85 tbl. 3 (Oct. 3, 2023), https://tinyurl.com/ysm7vhs3. And in the Final Rule, FDA acknowledges that imposing its existing regulatory framework without exception would ultimately impair "patient access to clinical tests" and cause "the loss of access to safe and effective" LDTs "on which patients currently rely." 89 Fed. Reg. at 37,400, 37,293.[5]

In the Final Rule, FDA never tries to justify these costs or the impact they will have on public health. Nor could the agency reasonably justify them. The safety concerns about "certain IVDs offered as LDTs" that FDA highlights, *see id.* at 37,320–22, are few and far between when considered in relation to the tens of thousands of LDTs currently in use. And the benefits of imposing the FDCA's regime wholesale are speculative at best. So instead of grappling with and justifying these costs, the Final Rule purports to adopt a complex and non-binding scheme of enforcement-discretion and phaseout policies to "reduce the overall impact" of the agency's sweeping regulation. *See id.* at 37,400–01. In other words, FDA asks the regulated industry simply to

[5] FDA has long recognized that significantly changing LDT regulation "could have negative effects on the public health." *See* 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997) (emphasizing that "significant regulatory changes" to LDT regulation "could have negative effects on the public health").

trust in the agency's nonbinding (and admittedly temporary) intention not to enforce the FDCA's requirements against certain LDTs. *Id.* at 37,294–95. And FDA asserts that the existence of its nonenforcement and phaseout policies will prevent the loss of innovation and testing access resulting from regulation. The "agency's ipse dixit" that these nonbinding policies avoid such ramifications "cannot substitute for reasoned decisionmaking." *Music Choice v. Copyright Royalty Bd.*, 970 F.3d 418, 429 (D.C. Cir. 2020). Indeed, these "enforcement discretion policies" cannot prevent the severe consequences for LDT development that stakeholders have predicted.

First, and most importantly, the nonbinding nature of the agency's nonenforcement policies will create an unacceptable risk of prosecution that will compel compliance and chill LDT development. FDA made clear that "regardless of the policy for currently marketed IVDs offered as LDTs or any other enforcement discretion policy, included in the phaseout policy, FDA retains the authority to enforce any applicable requirements and pursue enforcement action *at any time*." 89 Fed. Reg. at 37,372 (emphasis added). Clinical laboratories cannot simply forego compliance with the FDCA for *any* LDT, blindly trusting nonenforcement policies that explicitly permit the agency to enforce the FDCA "at any time." *Id.* Indeed, FDA repeatedly warns against overreliance on its policies. *See id*. at 37,390 (emphasizing that the nonenforcement policy is "subject to change as circumstances warrant"); *see also id.* at 37,301 (threatening that the agency may "pursue enforcement action at any time"). As one CAP member has explained, "clinical laboratories that want to protect themselves . . . will need to seek FDA clearance or approval for the tens of thousands of tests that are already on the market and for every new testing protocol they might develop in the future." *See* Compl. Ex. E, Morice Decl. ¶ 60 (ECF No. 1-5).

Even if FDA's nonenforcement policies *were* binding, that would not eliminate the Final Rule's harmful effects. For example, FDA asserts that it will not prosecute FDCA noncompliance

for certain existing tests but *will* do so once those tests are modified. The problem with penalizing modification, however, is that "modifying a test" is frequently "necessary to adapt to specific needs or to adapt to urgent reagent shortages." *See, e.g.*, Compl. Ex. D, Genzen Decl. ¶ 27 (ECF No. 1-4). This creates a powerful incentive *not* to make an important modification to a test, due simply to the fact that the resulting costs of compliance are prohibitive. The outcome—as CAP member and CMO of ARUP Laboratories recently explained—will be to "undermine the provision of health care and stifle innovation in a critical sector of our health care ecosystem." *Id.* ¶ 47.

Many of FDA's nonenforcement policies are also confusing and underinclusive. One policy purports to cover tests "manufactured and performed by a laboratory integrated within a healthcare system to meet an *unmet need* of patients receiving care within the same healthcare system." 89 Fed. Reg. at 37,294–95 (emphasis added). However, this provision is narrowly defined and confusing, which will have unintended consequences for patients and clinical laboratories. Similarly, the no-modification policy contains a carveout allowing tests to be "modified in certain limited ways." *Id.* at 37,295. While the Final Rule's preamble offers a handful of details to explain these exceptions-within-exceptions, they still leave the regulated community largely in the dark about their scope and impose a "heavy burden" of parsing these myriad new policies.[6] These ill-defined "enforcement discretion" policies will inevitably "invite arbitrary enforcement" and give FDA "unguided discretion to determine when" to prosecute. *See Butcher v. Knudsen*, 38 F.4th 1163, 1175 (9th Cir. 2022). Those prosecution risks will further chill LDT development and force many clinical laboratories to cease offering tests as the only sure way to avoid prosecution.

[6] *See, e.g.*, CAP Today, *Labs Juggle String of LDT Unknowns* (July 2024), https://tinyurl.com/4kvcus5e.

One thing is certain: the Final Rule's costs will be immense. FDA's impact analysis for the Final Rule projects compliance costs of over a billion dollars per year by the fourth year of the phaseout policy—and those projections assume the "enforcement discretion policies" will operate as the agency hopes. *See, e.g.*, FDA, Docket No. FDA-2023-N-2177, *Laboratory Developed Tests Final Rule: Final Regulatory Impact Analysis* at 123–24 tbl. 36 (May 6, 2024), https://ti-nyurl.com/47jv85na. Even assuming that most LDTs generated sufficient revenue to justify the costs of obtaining authorization under FDA's existing regime, those costs—which exist on top of the costs for all preexisting regulatory compliance burdens—will directly reduce the funds that clinical laboratories could otherwise devote to research and development into new and more effective LDTs. As a result, innovation will suffer. And innovation is crucial in the LDT context, where new clinical tests are constantly being developed to target specific patient needs. Of course, many—perhaps most—tests do not come close to generating the sort of revenue that could justify the cost of obtaining FDA authorization. *See, e.g.*, Morice Decl. ¶ 60 (explaining that "[m]any [LDTs] are low-volume tests that are used infrequently" and "do not generate sufficient revenue to justify going through the very expensive FDA clearance and approval process"). And that is especially true for LDTs that serve rare-disease patients, patients in rural or underserved areas, and patients receiving new treatments/drugs or for new prognostic markers of disease. The upshot of imposing FDA's scheme is fewer tests for the people who need them most.

The consequences of these costs are not hypothetical. The CAP is already fielding concerns from its pathologist members that these new restrictions will limit test access and harm patient care. Recently, the CAP heard from pathologists in Oregon operating a robust multidisciplinary lung cancer program that the Final Rule will force them to abandon (i) in-house blood tests used to determine whether patients with non-small cell lung cancer could benefit from targeted therapies

and (ii) immunohistochemistry tests that assist in cancer-type identification. The CAP's members explained that these restrictions would extensively delay diagnoses and treatment of cancers while samples are sent out to large laboratories capable of absorbing the Final Rule's immense compliance costs. Similarly, CAP members in Puerto Rico have noted that the Final Rule will require them to send samples to the mainland, delaying treatment and resulting in massive bills for patients. Those delays and increased healthcare costs will impair laboratory function and may cost some patients their lives.

Throughout the Final Rule, FDA repeatedly avoids grappling with these consequences. For example, FDA acknowledges stakeholders' concerns that the Final Rule could "exacerbate health inequities for underrepresented patient populations" but then simply asserts that increased oversight will improve performance for those patient populations and thus "help *advance* health equity." 89 Fed. Reg. at 37,404 (emphasis added). But that is a non sequitur. The point is that vulnerable populations are better off with tests than without them. Improved tests cannot benefit patients when they do not exist. Yet time and again FDA waives away these concerns by pointing to its nonbinding "enforcement discretion policies" as a cure-all for the rule's disadvantages. *Id.* at 37,405

In sum, the Final Rule will harm LDT development and hinder testing access. As a result of increased costs and delays in diagnosis, many patients will not receive the treatment and care that they need. The agency's failure to "come to grips with the[se] obvious ramifications of its approach" renders the Final Rule arbitrary and capricious. *NRDC, Inc. v. EPA*, 859 F.2d 156, 209–10 (D.C. Cir. 1988) (per curiam). Nor can the agency's litany of ineffective and vague "enforcement discretion" policies obviate the Final Rule's harms or satisfy the APA's requirements for "reasoned decisionmaking." *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020).

II. The Court should limit its ruling to avoid unintended negative consequences on the regulation of LDTs.

Given the Final Rule's procedural infirmity, the Court can vacate FDA's action without deciding broader questions regarding the agency's substantive authority to regulate LDTs. *See Flight Training Int'l, Inc. v. FAA*, 58 F.4th 234, 246 (5th Cir. 2023) (declining to address alternative ground for vacatur). Principles of "judicial restraint—if it is not necessary to decide more, it is necessary not to decide more—counse[l]" against a broader-than-necessary ruling. *PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (Roberts, J., concurring in part and concurring in the judgment).

That said, should the Court address plaintiffs' challenge to FDA's statutory authority, the CAP urges the Court to cabin its decision to avoid unintended consequences for LDT regulation going forward. Specifically, the Court should avoid suggesting either (A) that LDTs constitute "the practice of medicine" or (B) that CLIA's existing regulatory framework renders future FDA involvement in this area unnecessary or inappropriate.

A. The Court should not imply that LDTs are "the practice of medicine."

Plaintiffs in these consolidated cases contend that LDTs are not medical *devices* under the FDCA but are instead *services* or *procedures* performed by skilled laboratory professionals. ACLA MSJ at 24–30 (ECF No. 25); AMP MSJ at 28–32 (ECF No. 27). Assuming the Court agrees with plaintiffs on this score, the Court should nonetheless avoid going further and suggesting that LDTs constitute "the practice of medicine."

Many stakeholders commenting on FDA's proposed rule challenged FDA's statutory authority to regulate LDTs on the ground that Congress generally denied the agency authority to regulate the practice of medicine. *See* 89 Fed. Reg. at 37,347–48 (responding to comments on this issue). These stakeholders argued that FDA's regulation of LDTs was improper on the ground that

it violated the principle that the "practice of medicine" is outside FDA's jurisdiction under the FDCA. *See, e.g.*, *Chaney v. Heckler*, 718 F.2d 1174, 1179 (D.C. Cir. 1983) (noting that the "FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine"), *rev'd*, 470 U.S. 821 (1985); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (highlighting FDA's "mission to regulate … without directly interfering with the practice of medicine"); *see also* 21 U.S.C. § 360(g)(2) (exempting licensed practitioners from FDCA requirements when using the devices "in the course of their professional practice").

The problem with this argument is that defining LDTs as "the practice of medicine"—while it might undermine FDA's authority to regulate in this area—could have serious adverse consequences for the overall regulation of laboratory testing. LDTs are provided in connection with the practice of medicine, but that does not mean that the tests themselves represent the practice of medicine. Many physicians are involved in developing and using LDTs. But LDTs also involve a host of other highly skilled professionals including biologists, microbiologists, chemists, geneticists, medical technologists, medical technicians, phlebotomists, and lab assistants. *See, e.g.*, Morice Decl. ¶ 19.

If laboratory testing constitutes the "practice of medicine," questions regarding "scope of practice" for laboratory professionals and how that should be expanded or circumscribed at the state level (where the practice of medicine is regulated) could arise. It might also compromise the ability of non-physicians—*i.e.*, those who are not licensed to practice medicine—to oversee such lab testing at all. Finally, deeming LDTs to constitute the "practice of medicine" would also raise a host of coverage and reimbursement issues under the Medicare and Medicaid statutes.

By declining to suggest that LDTs constitute the "practice of medicine," the Court can avoid these thorny issues. Nor is there any need for the Court to address them. Characterizing LDTs as professional services or procedures (as plaintiffs ask the Court to do) does not require the Court to go further and define *any*—let alone *all*—aspects of the use and development of LDTs as the "practice of medicine."[7]

B. The Court should not imply that CLIA renders future FDA involvement in LDT regulation unnecessary or inappropriate.

To support their position that FDA lacks statutory authority to regulate LDTs under the FDCA, plaintiffs emphasize that CLIA already provides "a separate, comprehensive, specialized regulatory framework" for overseeing "clinical laboratory-developed testing services." ACLA MSJ at 29; *see also* AMP MSJ at 30 ("Since 1967, Congress has maintained CLIA for the specific purpose of regulating laboratory procedures[.]"). According to plaintiffs, CLIA's existing regulatory framework "confirms" that laboratory services are not devices subject to regulation under the FDCA. ACLA MSJ at 30. However, that CLIA provides an existing framework for federal regulation of LDTs does not mean—and the Court should not imply—that it would be unnecessary or inappropriate for Congress to give FDA a new role in LDT regulation going forward.

CLIA currently provides a framework largely focused on CMS oversight of the laboratories that perform patient testing. LDTs have changed dramatically since CLIA was enacted in 1967

[7] Plaintiffs in Case No. 24-cv-479 do not suggest that LDTs constitute the practice of medicine. Plaintiffs in Case No. 24-cv-824, however, make a form of this practice-of-medicine argument when they contend that the Final Rule "conflicts with the statute's practice-of-medicine exemption" applicable to licensed healthcare providers. *See* AMP MSJ at 35–37 (discussing application of 21 U.S.C. § 360(g)(2)). But even if some healthcare providers use LDTs in connection with their medical practice, as these plaintiffs argue, that does not mean that LDTs themselves constitute "the practice of medicine." Nor, in any event, does the Court need to opine on this question to delineate the bounds of FDA's statutory authority.

and then expanded in 1988. CLIA was not designed to give FDA a role in evaluating the effectiveness of many of the highly complex tests offered today. But when it comes to ensuring that these complex, potentially high-risk tests are safe and effective, the CAP believes that FDA should have such a role, given the agency's expertise in ensuring the effectiveness and safety of highly complex tests. For this reason, the CAP has supported the VALID Act, *see* Verifying Accurate Leading-edge IVCT Development Act of 2020, H.R. 6102, 116th Cong. (2020) (companion bill S.3404), which would expressly authorize FDA to regulate certain LDTs, focusing the agency's resources on high-risk tests.

Under the VALID Act, CLIA would still have a role, but it would not provide the exclusive regulatory framework for LDT regulation. In fact the CAP has opposed legislative proposals that would simply modernize or extend CLIA to address the regulation of high-risk, highly complex tests. Again, for such tests, FDA's wealth of experience in reviewing and authorizing highly complex diagnostic tests for patients makes it—and not solely CMS—an appropriate regulator.

This ongoing legislative debate makes it vital that the Court not cast doubt on the propriety of proposed legislation—like the VALID Act—that would give FDA an important new role in LDT regulation. Nor should the Court suggest that CLIA's existing framework already addresses all aspects of possible oversight of high-risk LDTs. Indeed, a key defect in FDA's sweeping rule-making is that, at a time when Congress has been considering a new regulatory framework, the Final Rule has "circumvent[ed] the political process." Morice Decl. ¶ 67. To avoid undermining that process, the Court should not say more than is necessary when addressing the role of CLIA and the propriety of additional FDA regulation in this area.

CONCLUSION

For these reasons, the Court should vacate the Final Rule as arbitrary and capricious.

Dated: October 7, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served on all counsel of record in accordance with the Federal Rules of Civil Procedure and this Court's CM/ECF filing system on October 7, 2024.

/s/ *Eric D. McArthur*