UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No.: 4:24-cv-00479-SDJ
ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No.: 4:24-cv-00824-SDJ

PLAINTIFFS AMERICAN CLINICAL LABORATORY ASSOCIATION, HEALTHTRACKRX INDIANA, INC., AND HEALTHTRACKRX, INC.'s COMBINED REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The text, structure, and history of the FDCA and CLIA all lead to the same conclusion: A "device" within the meaning of the FDCA is a tangible, manufactured product, not a professional service. FDA's brief essentially throws in the towel on that point. Even though FDA argued in the final rule that a "device" can include "intangible thing[s]," *see* ACLA Br. 36, FDA does not attempt to defend the rule on that basis, expressly asserting that "the Final Rule is not based on" any purported authority to regulate services "that do not have a tangible form," FDA Br. 26.

FDA instead argues that it is not regulating the professional services provided by laboratories, but rather the collection of physical tools the laboratory uses to provide those services. This argument is also fatally flawed. When a clinical laboratory or other health care provider employs an assortment of tools to perform a test or other procedure, it is not "manufacturing" a "device" consisting of the sum of those tools. *See* ACLA Br. 37-38. FDA's contrary theory—that an assortment of physical objects used together to provide a professional service, but which are never packaged together or sold as a kit, constitute a manufactured device—is astonishingly broad and would mean that virtually every provider of a health care service is a device manufacturer. That cannot be right.

FDA tries to avoid the consequences of its overreaching theory by contending that the "device" regulated by the final rule is manufactured when a laboratory designs a testing protocol, rather than when the test is actually performed. But that assertion makes no sense and has no basis in the statute. When a surgeon writes down a series of steps for a new method of open-heart surgery—which calls for the use of tools such as scalpels, sutures, and needles—no ordinary speaker of English would say the surgeon is manufacturing a device. The same goes for a clinical laboratory that conceives a new method for diagnosing cancer using tools such as test tubes, chemical agents, and centrifuges. No one disputes that many individual tools are themselves devices that may be subject to FDA licensing and approval requirements. But the protocol developed by laboratory professionals for using

various devices to provide a professional testing service is not itself a new device. A laboratory developing a new test procedure is improving the delivery of a professional service, not fabricating a new line of physical products. And FDA does not even attempt to rebut ACLA Plaintiffs' argument that the FDCA's definition of "device" is limited to tangible products; indeed, for purposes of defending the final rule, FDA has expressly abandoned any theory that the "device" definition extends *beyond* tangible products.[1] The rule must therefore rise or fall solely on the basis of FDA's authority to regulate the manufacturing of physical products. And because developing a test protocol is not manufacturing a physical product, the rule must fall.

While the final rule can be held unlawful based solely on the statute's plain meaning, any ambiguity about whether developing a test protocol is manufacturing a physical product must be resolved in ACLA Plaintiffs' favor under the "major questions" doctrine and the rule of lenity. Contrary to FDA's suggestion that the final rule is merely a "garden-variety" regulation, FDA Br. 47, the rule is a sea change that upends a fundamental pillar of the U.S. health care system; sidelines Congress over the objection of leading representatives; classifies as criminal activity the widespread, longstanding practices of a vital profession; threatens lifesaving medical innovation; and imposes at least tens of billions of dollars in compliance costs (and hundreds of billions unless laboratories place their trust in FDA's non-binding "enforcement discretion" policies). The major-questions doctrine is a holistic inquiry, and the unusual combination of factors in play here surely triggers the doctrine's application. Moreover, FDA does not deny that the rule expands the reach of a statute that carries criminal penalties. The rule is therefore also subject to the time-honored rule of lenity.

Unable to defend the agency's untenable position, FDA's lawyers double down on a strategy of obfuscation and definitional sleight-of-hand. Again and again, they attempt to downplay the final

[1] "ACLA Plaintiffs" refers to Plaintiffs American Clinical Laboratory Association, HealthTrackRX Indiana, Inc., and HealthTrackRX, Inc.

rule by suggesting that it simply eliminates a discretionary "exception" for clinical laboratories that manufacture devices. FDA Br. 3, 18, 22–23. But that assumes that clinical laboratory testing services are equivalent to the "manufacturing" of "devices" in the first place. The relevant question is what constitutes the "manufacturing" of a "device," and as the rule's preamble makes clear, FDA has dramatically reinterpreted those words to encompass the development or performance of laboratory testing protocols—an intangible professional service. Meanwhile, FDA repeatedly uses the term "IVD test systems"—which does not appear anywhere in the FDCA's "device" definition—to conflate tangible products packaged for commercial distribution (*e.g.*, test kits) with laboratory testing protocols, which are performed in individual laboratories and are not tangible products. FDA uses similar wordplay to distort the regulatory history and portray the final rule as a continuation of a position FDA took in a rulemaking in 1973. In fact, as ACLA Plaintiffs have explained, FDA only began asserting this authority in 1992 (and then only tentatively, informally, and intermittently), 16 years after the Medical Device Amendments and more than 50 years after the enactment of the FDCA. And for decades after that, every time the clinical laboratory sector challenged FDA's sweeping claims of authority over laboratory testing services, FDA backed down—a history that undermines, rather than supports, FDA's current position.

Attacking straw men, FDA also misrepresents ACLA Plaintiffs' arguments. According to FDA, ACLA Plaintiffs have asserted categorically that "laboratory-made IVD test systems are not 'devices'" and ACLA Plaintiffs "also take[ ] the position that clinical laboratories can *never* be device 'manufacturers.'" FDA Br. 28 (emphasis added). That is wrong. ACLA Plaintiffs readily acknowledge that "a prepackaged testing kit (like a COVID-19 test kit) may qualify as a device," ACLA Br. 2, and ACLA Plaintiffs have never disputed that a clinical laboratory that manufactures such products may qualify as a device manufacturer. Once again, FDA is using semantics to duck the real dispute—whether the development or performance of testing protocols constitutes device manufacturing.

As ACLA Plaintiffs have observed, FDA's ad hoc, non-binding enforcement-discretion carveouts only underscore how far FDA has strayed from the statutory text and do not adequately address concerns about the final rule's massive disruption of reliance interests. FDA's response does not meaningfully engage with ACLA Plaintiffs' point that FDA's need to create these carveouts shows that its statutory interpretation took a wrong turn. And while disputing that it acted arbitrarily or capriciously in addressing reliance interests, FDA does not dispute that regulated parties cannot genuinely "rely" on the enforcement-discretion policies because, as FDA's brief reaffirms, those policies do not alter the legal effect of the rule and FDA "retains discretion" to bring an enforcement action "at any time." FDA Br. 16 (quotation marks omitted). In short, to save the agency from the disastrous consequences of its own legal interpretation, FDA wants thousands of clinical laboratories to engage in conduct that FDA contends is a federal crime, without any assurance that the government will not turn around and prosecute them for it. That is a shocking position for the United States government to take.

Finally, for preservation purposes, FDA argues that instead of vacating the final rule, this Court should limit any relief to ACLA Plaintiffs and their members. As FDA acknowledges, however, this argument is foreclosed by Fifth Circuit precedent, and the Fifth Circuit's "ordinary practice is to vacate unlawful agency action." *Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 859–60 (5th Cir. 2022) (quoting *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019)). There is no basis for departing from that well-established practice here.

ARGUMENT

I. The final rule exceeds FDA's statutory authority.

A. FDA has waived any argument for upholding the final rule on the theory that an intangible professional service may be a "device."

FDA's authority to regulate "devices" encompasses only manufactured goods that can be distributed in commerce. *See* ACLA Br. 24–34. Congress enacted the FDCA in 1938 to address

concerns about manufactured medical products shipped in interstate commerce. Consistent with that historical backdrop, the FDCA's "device" definition, including as revised by the Medical Device Amendments of 1976, has always made clear that a "device" is a material thing: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." 21 U.S.C. § 321(h)(1). None of those terms refers to laboratory services carried out by trained medical professionals. To address that very different medical sector, Congress established a separate regulatory regime in CLIA, which Congress enacted in 1967 and augmented in 1988.

Despite enacting CLIA shortly before the Medical Device Amendments and amending CLIA shortly thereafter, at no point did Congress indicate that CLIA and the FDCA were supposed to do double duty in regulating professional clinical laboratory testing services. *See* Charrow Memorandum, Compl. Ex. F at 3–4 (noting that laboratory testing services "were never mentioned in the [Medical Device Amendments], in the House Report accompanying it, or during the floor debates," and that CLIA "appeared to have occupied the field for regulating" laboratory services). Congress's bifurcated approach is hardly surprising given the long-standing difference between regulating the manufacture of articles for sale in interstate commerce, where safety is regulated primarily through manufacturing process controls, and regulating professional services performed in a laboratory setting, where the exercise of professional judgment is regulated through licensing and professional standards. *See* ACLA Br. 6, 28-30; *see also* Margaret P. Battin & Arthur G. Lipman, *Drugs, Addiction, Therapy, and Crime Symposium*, 2009 Utah L. Rev. 1, 2 (2009) (noting that FDA has authority to regulate manufacturing involving interstate commerce, but that the licensure of health professionals, which "falls into the constitutional category of police powers," has been largely left to the purview of state and local regulators).

In the final rule, FDA tried to dispute the common-sense understanding of "devices" as tangible things, explaining that "FDA does not read the definition of device to encompass only

physical objects." AR46. To advance this intangible-device theory, FDA relied on cherry-picked definitions of isolated terms such as "contrivance" and a flawed analogy to software. *See id.* As ACLA Plaintiffs explained, however, applying fundamental principles of statutory interpretation, the text, structure, and history of the FDCA and CLIA clearly foreclosed this attempt to stretch the bounds of the FDCA's "device" definition to encompass professional services. *See* ACLA Br. 21–38.

In response, FDA no longer argues that the final rule can be upheld on the basis that intangible professional services can be considered a "device." FDA Br. 26. Instead, FDA relies entirely on its position that by using a "collection of physical objects" to perform testing services, a laboratory professional is "manufacturing" a new "device." FDA Br. 27 n.12, 28. Accordingly, while asserting in conclusory fashion that "FDA disagrees" that the statutory definition of "device" is limited to tangible products, FDA says this Court "does not need to decide this issue because the Final Rule is not based on" the theory that intangible services can be devices. FDA Br. 26. This renunciation of the intangible-service theory means that FDA has waived any reliance on it as a legal basis for the final rule. *See Schofield v. Saul*, 950 F.3d 315, 322 (5th Cir. 2020) ("We typically hold parties—even administrative agencies—to their waivers."). If the final rule is to survive, it can do so only on the basis of the argument FDA relies on in its brief—that the performance or development of laboratory testing procedures that employ physical tools is somehow equivalent to the manufacturing of physical products.

B. The final rule cannot be upheld on the theory that the development or performance of professional testing procedures that involve the use of physical tools is the "manufacturing" of a "device."

Because the best reading of the FDCA's "device" definition is limited to tangible articles, FDA is left arguing that laboratory professionals are manufacturing "devices" whenever they use physical tools, or whenever they design protocols that call for the use of physical tools. This theory fares no better than FDA's now-abandoned attempt to classify the professionals' services themselves as

"devices." As ACLA Plaintiffs have explained, the fact that a laboratory professional may *use* devices while performing a test does not make the test *itself* a device. *See* ACLR Br. 37–38. Otherwise, virtually every medical service—from a doctor's physical examination to a surgical procedure—would constitute the manufacturing of a device. *Id.* Attempting to avoid that impossibly overbroad result, FDA shifts to arguing that the process of "designing" the testing protocol is the manufacturing of a device. *See* FDA Br. 28–29. But that argument merely rearranges the problem without solving it: A testing protocol is not itself a tangible article, even if some of the steps in the protocol call for the use of physical tools. Developing a new method of laboratory testing is no more a form of device manufacturing than developing a new method of surgery.

1. The final rule treats the development or performance of testing protocols by laboratory professionals as the "manufacturing" of a "device."

FDA tries to obscure the final rule's far-reaching effects with semantics, calling the final rule a regulation of "IVD test systems made by laboratories." FDA Br. 18. FDA then defines "IVD test system"—a term that does not appear in the statute—as "a set of physical components that function together to produce a test result." *Id.* at 18–19. By "a set of physical components" FDA means any "collection of physical objects … employ[ed] to produce a test result." *Id.* at 27 n.12. In other words, as construed by FDA, the term "IVD test system" encompasses two distinct things: (1) a discrete set of tangible articles packaged as a product for commercial distribution (*e.g.*, a COVID-19 test kit), and (2) an assortment of physical tools that laboratory professionals use in transient relationships to each other to deliver a service. *See* ACLA Br. 38. FDA's "IVD test system" terminology collapses that distinction. As ACLA Plaintiffs have acknowledged, if a laboratory makes a test kit for commercial distribution, it may well be manufacturing a device. *See id.* at 2, 11, 38. But when laboratory professionals use a series of tools to perform a test (or for that matter, when they develop new test protocols that call for the use of such tools), they are *not* manufacturing devices; they are carrying out

(or conceiving) professional services. FDA tries to create confusion by lumping together those two very different scenarios.

A similar sleight of hand is embedded in the final rule itself. The final rule amends 21 C.F.R. § 809.3(a), which defines "in vitro diagnostic products" as "those reagents, instruments, and *systems* intended for use in the diagnosis of disease or other conditions" and states that such "products are devices as defined in [the FDCA]." *Id.* (emphasis added). The final rule adds the phrase "including when the manufacturer of these products is a laboratory." AR1–2; *see* ACLA Br. 14. In isolation, and on its face, this language might be understood as referring exclusively to "systems" such as test kits, which may indeed be manufactured products. That would be consistent with how FDA used "systems" in its 1973 rulemaking, 38 Fed. Reg. 7096, 7098 (Mar. 15, 1973) (requiring information to be affixed to the "retail package" of the "article"). *See* ACLA Br. 32. Yet if the final rule merely regulated test kits, FDA would not have needed to promulgate the final rule in the first place. Nor, in that case, would fully enforcing the final rule (as the proposed rule had contemplated) impose costs that FDA itself estimated in the hundreds of billions of dollars. *See id.* at 15. Nor would the final rule affect about 80,000 existing tests, as well as more than 10,000 new tests offered every year, while more than doubling the annual number of premarket applications FDA needs to review. *See id.* at 18.

As the preamble to the final rule confirms, the final rule does much more than regulate test kits. The rule is so costly and so impactful precisely because FDA is *breaking with* its traditional understanding of the "manufacturing" of test "system" products and interpreting that language to encompass a whole new sphere of activity that had previously been regulated only under CLIA—*i.e.*, laboratory testing services. By way of illustration, consider FDA's response to a comment on the new rule. The commenter objected that laboratories primarily produce "standard operating procedure document[s]," which are not manufactured devices. AR59. FDA disagreed, arguing that laboratories manufacture devices when they "produce test systems" that are performed using physical tools. *Id.*

FDA explained: "[W]hen a laboratory develops a test for the measurement of hormone levels using mass spectrometry, [it] must *source or* manufacture calibrators and qualify a mass spectrometry instrument in order to perform that test," and "[t]hese calibrators and instrument, along with other components, comprise a test system." *Id.* (emphasis added). In other words, the final rule treats the development and/or performance of a testing protocol as device manufacturing, even when the laboratory merely "sources" (*i.e.*, obtains) the tools used in that test.

ACLA included a similar example of a laboratory-developed mass-spectrometry test in its comment on the proposed rule to illustrate that such tests "are professional services, not devices." FDA2177-6369 at 5–6 (ACLA Comment). Mass spectrometry is a chemical analysis technique that can assist in the diagnosis of hormonal disorders, cancer, Alzheimer's disease, and other conditions. Compl. ¶ 29. As ACLA explained, a typical mass-spectrometry test consists of a series of pre-analytical, analytical, and post-analytical steps carried out by laboratory professionals. FDA2177-6369 at 5–6. Pre-analytical steps may include receiving a blood sample, entering it into the laboratory's information system, and following standard operating procedures such as centrifuging the sample or diverting a portion of the sample into a separate tube for testing. *Id.* Analytical steps include pipetting the samples into other containers, extracting the analyte of interest using an automated liquid-handling instrument, entering relevant information into instrument software, and completing the test with other tools, including a high-resolution mass spectrometer (a machine used to detect the masses of certain molecules). *Id.* at 6. Post-analytical steps include a review of the results by a second laboratory scientist or lead scientist to confirm that they were interpreted accurately. *Id.* at 6. As this example shows, a typical laboratory-developed test is a series of tasks performed by skilled healthcare professionals. Some of those tasks may entail using various devices, but the test itself is not a manufactured device. In the final rule, however, FDA did not deny that such a test would qualify as a "device" under its new interpretation, and as discussed above, FDA's own example of what it considers "manufacturing"

a "device" confirms that such testing services fall squarely within the scope of FDA's new regulatory regime.

As ACLA noted in its comment, and as ACLA members observed in the declarations attached to ACLA Plaintiffs' complaint, a typical laboratory-developed testing procedure bears no resemblance to any ordinary understanding of a "manufactured" "device." *Id.* at 6; *see also, e.g.*, Compl. Ex. A ¶ 23 ("The molecular diagnostic services that HealthTrackRx's professionals perform … involve medical procedures, protocols, and processes that are used to analyze at the molecular level tissue, blood, and other patient specimens as part of the practice of laboratory medicine"); Compl. Ex. B ¶ 14 ("The professionals at Labcorp are expert technicians, M.D.s, and Ph.Ds; they are not manufacturers"); Compl. Ex. C ¶ 15 ("The professional diagnostic services that Quest provides are not physical objects or articles that qualify as medical devices"); Compl. Ex. D ¶ 45 ("Mass spectrometers and other manufactured equipment used by healthcare professionals are only tools used in performing a laboratory-developed test. … When laboratory clinicians develop the processes and procedures necessary to perform laboratory-developed testing services, they are no different than other health care professionals who develop protocols or methodologies for treating patients or diagnosing diseases"); Compl. Ex. E ¶¶ 50–52 (describing a typical "test in a CLIA-certified laboratory" and noting that the "interaction and collaboration between a clinical laboratory and the care team … is completely at odds with the idea of a laboratory as a device-manufacturer"). But make no mistake—these are the kinds of tests FDA has swept up in its new rule.

Contrary to FDA's suggestion, ACLA Plaintiffs' challenge to the final rule does not seek an "exception" from the FDCA's requirements for clinical laboratories that do in fact manufacture devices. *See* FDA Br. 3, 18, 22–23. Nor do ACLA Plaintiffs "take[ ] the position that clinical laboratories can never be device 'manufacturers.'" *Id.* at 28; *compare, e.g.*, ACLA Br. 2 (acknowledging that "a prepackaged testing kit … may qualify as a device"); *id.* at 11 (similar); *id.* at 38 ("[P]erforming

a professional service like a clinical laboratory test or a surgical procedure, while it may employ some of the same items found in a kit, is not the same as manufacturing the kit itself"); Compl. ¶ 9 (distinguishing test kits from laboratory-developed tests). The real question, of course, is what constitutes the "manufacturing" of a "device" in the first place. That FDA needs to distort ACLA Plaintiffs' position so badly only underscores how little confidence FDA has in its own position on that key question.

2. Neither the performance nor the development of laboratory testing protocols is the "manufacturing" of a "device."

FDA cannot prevail because its position flies in the face of the statute. The statutory term "device" refers to a tangible, manufactured product. The ordinary meaning of "manufacture" is "[t]o make or process (a raw material) into a finished product, especially by means of a large-scale industrial operation." The American Heritage Dictionary of the English Language 796 (1969); *see also, e.g.*, Oxford English Dictionary (2024), https://www.oed.com/search/dictionary/?scope=Entries&q=manufacture ("To make (a product, goods, etc.) *from, of,* or *out of* raw material; to produce (goods) by physical labour, machinery, etc., now esp. on a large scale"); Merriam-Webster Dictionary (2024), https://www.merriam-webster.com/dictionary/manufacture#dictionary-entry-2 ("make into a product suitable for use" or "make from raw materials by hand or by machinery"); Webster's New International Dictionary of the English Language 1499 (2d. ed. 1935) ("To work, as raw or partly wrought materials, into suitable forms for use; as, to *manufacture* wool, iron, etc."). Because FDA no longer claims that intangible professional services can be devices, FDA must show that either the performance or development of laboratory testing procedures is the manufacturing of a tangible finished product. FDA cannot make that showing—let alone with the clarity required by the major questions doctrine and the rule of lenity. *See* ACLA Br. 21–24, 31–34.

1. The performance of a laboratory testing service is not the manufacturing of a device. According to FDA, the "device" regulated by the final rule is the collection of various physical tools,

"such as reagents, instruments, and other articles," that laboratory professionals use "to produce a test result." FDA Br. 19; *see id.* at 26, 27 n.12. As ACLA Plaintiffs have explained, however, such tools are *used* (not *made*) by laboratory professionals when they perform tests. *See* ACLA Br. 2, 37–38. And while they are used together to perform a service, they are not assembled into a new physical product (like a test kit). As FDA implicitly acknowledges, the output of a testing service is not a new device but a piece of information—a "test result." FDA Br. 19.

FDA nonetheless insists that a "device" is "manufactured" every time various "articles are used together" to perform a test. *Id.* at 26; *see also* AR46 (suggesting that laboratory professionals "unit[e] those physical objects in a system"). The implications of that theory are staggeringly broad. If using an assortment of physical tools according to an established procedure or protocol to perform a healthcare service were equivalent to manufacturing a device, then virtually every service provided by a health care professional would qualify as device manufacturing. A nurse who conducts a physical examination using a stethoscope and blood-pressure cuff; a surgeon who uses a scalpel, sutures, and needles to perform a surgery; and a pathologist who analyzes cells from a fluid specimen using a syringe, test tubes, a centrifuge, and a microscope would all be device manufacturers. *See* ACLA Br. 37–38. As FDA is ultimately forced to concede, that theory cannot be right. *See* FDA Br. 28–29 (purporting to disclaim the theory that "IVD test systems" are manufactured "every time they are performed"). Using a collection of tools to perform a professional service is not the same as manufacturing a new tool.

2. FDA tries to avoid the extreme consequences of its theory by arguing that the "manufacturing" of a "device" is "the process of *designing and developing* a test system intended for a particular use." FDA Br. 29 (emphasis altered); *see also id.* ("[IVD test systems] are manufactured by the laboratories that establish and review their design specifications and step-by-step instructions for use" (cleaned up) (citation omitted)). But that theory makes no sense and lacks any basis in the ordinary

meaning of the statute. When a laboratory develops a test that calls for the use of a test tube, a reagent, and a centrifuge, the laboratory is establishing an intangible protocol or procedure to guide the analytical process; it is not manufacturing a tangible product. Yet FDA has conceded that the "device" subject to the final rule must be a tangible product. *See* FDA Br. 26 (abandoning the contention that the rule can be upheld on the basis that intangible services are devices); *id.* at 18 (defining "IVD test system" as a "[s]et of [p]hysical [c]omponents"). By FDA's own logic, then, designing a test protocol cannot be the "manufacturing" of a "device."

Nor is it possible to square FDA's position with any ordinary understanding of what it means to "manufacture" a "device." "Manufacturing" generally refers to the fabrication of finished products from raw materials, and a "device" is a tangible instrument. Like developing a new procedure for open-heart surgery or a new technique for physically examining a patient, designing a new testing protocol is not fabricating a tangible product; it is developing a new method of providing a healthcare service. Although such procedures and protocols may include "step-by-step instructions for use" of physical tools, FDA Br. 29, and although FDA may well have authority to regulate the individual physical tools as medical devices, the procedures and protocols are not themselves manufactured products. Once again, FDA's position defies common sense.

FDA tries to salvage its argument by relying on one of its regulations, 21 C.F.R. § 807.3(d)(3), which FDA cites for the proposition that "manufacturing" a device can mean developing the "specifications" for that device. FDA Br. 10, 29. But even assuming FDA's own regulation could override the statute (it cannot), that is not what the regulation says. Section 807.3(d) provides:

> Manufacture … of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities: … (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

This regulation does not state that anyone who develops "specifications" for a "device" is a manufacturer. Instead, the regulation addresses a narrow situation where the person who develops the specifications contracts out the physical manufacturing of the device to an agent and then distributes the device itself. FDA has explained that this regulation applies "only if the person initiating specifications has the device manufactured for him for commercial distribution and the device is marketed under the name of the person initiating the specifications." 42 Fed. Reg. 42,520, 42,521 (Aug. 23, 1977). FDA does not suggest (and could not plausibly maintain) that the final rule here is limited to laboratories that develop "specifications" for a test system and contract out the manufacturing of that system to a second party.

Moreover, even if the regulation could be read to make the development of "specifications" for a laboratory testing procedure the "manufacturing" of a "device," that would mean that every performance of the procedure—when the "physical components" that FDA claims constitute the device, FDA Br. 3, are actually brought together and used to perform a test—would *also* be an act of device manufacturing. The regulation does not *limit* "manufacturing" to the initiation of specifications; it says only that in some circumstances, manufacturing may *include* the initiation of specifications *in addition to* the actual "making" of the physical product. In taking the position that developing specifications is the initial step of "manufacturing" a collection of physical tools, FDA is necessarily implying that the manufacturing is completed when those tools are actually collected—contrary to FDA's conclusory assertion that "IVD test systems … are not manufactured anew by laboratory personnel every time they are performed." FDA Br. 29. While FDA is desperate to avoid that untenable conclusion, it follows ineluctably from FDA's position that the "device" regulated by the final rule is the "collection of physical objects … employ[ed] to produce a test result." *Id.* at 27 n.12.

In any event, FDA's reliance on § 807.3(d)(3) faces the same problem as its broader argument: In developing laboratory testing procedures, laboratory professionals are not designing a physical

article, but rather conceiving of a professional service that may involve the use of such articles by a skilled healthcare professional. Accepting FDA's position would erase the distinction between developing *methods* and manufacturing *products*.

3. CLIA, not the FDCA, regulates the development and performance of laboratory testing protocols.

That laboratory testing protocols are not "devices" does not mean that they are unregulated. Laboratory testing services have long been regulated by state law and, since 1967, by the "unified regulatory mechanism" that Congress established in CLIA. ACLA Br. 7–10. CLIA appropriately treats clinical laboratory testing as a professional healthcare service, not a form of manufacturing, and is tailored to work in tandem with state and local requirements governing the work of healthcare professionals. CLIA's extensive implementing regulations include rigorous accreditation, licensing, and quality-control requirements to ensure that test results are "valid and reliable," that laboratories' performance is "consistent," and that laboratory personnel are highly qualified. *Id.* As ACLA Plaintiffs noted, CLIA's quality controls include requirements that apply specifically to newly developed tests: Laboratories that introduce such tests must generally establish "performance specifications" for accuracy, precision, analytical sensitivity, and other characteristics "required for test performance." ACLA Br. 9 (quoting 42 C.F.R. § 493.1253(b)(2)). At no point does CLIA (or for that matter, the FDCA) indicate that these requirements overlap with the FDCA's "device" authorities.

Attacking another straw-man version of ACLA Plaintiffs' arguments, FDA insists that CLIA is irrelevant because it did not effect an "implied repeal" of the FDCA. FDA Br. 36–39. But ACLA Plaintiffs are not arguing that CLIA repealed the FDCA. ACLA Plaintiffs' point about CLIA is not that it abrogated the FDCA, but that the plain meaning of the FDCA—that it does not authorize FDA to regulate laboratory testing services as if they were manufactured devices—is reinforced by the existence of a separate, comprehensive regulatory regime that addresses the very testing services targeted by the final rule. *See United States v. Carrion-Caliz*, 944 F.2d 220, 224 (5th Cir. 1991) ("[I]t would

not be reasonable to expect the Congress to adopt redundant statutes"); ACLA Br. 29–30. If FDA were correct that laboratory testing is governed by both the FDCA and CLIA, it would create a strange world in which clinical laboratory tests are uniquely subject to overlapping and burdensome requirements despite the involvement of laboratory professionals; device manufacturers in general would only have to comply with the FDCA, while laboratory tests would be subject to both regulatory regimes.

FDA contends that treating laboratory testing services as devices is nevertheless essential—despite FDA's nearly 90 years of inaction after the enactment of the FDCA and nearly 50 years of inaction after the Medical Device Amendments—because, FDA says, CLIA is focused on the tests' "analytical validity" (*e.g.*, how reliably and accurately a test can detect a particular protein) rather than their "clinical validity" (*i.e.*, the implications of the test result for the patient's diagnosis). FDA Br. 36–37. FDA says this makes CLIA "a narrow statute" that leaves "major gaps in federal oversight." *Id.* at 37–38. On the contrary, CLIA is widely recognized as "a *comprehensive* regulatory system" for clinical laboratory testing. *Consumer Fed'n of Am. v. HHS*, 906 F. Supp. 657, 659 (D.D.C. 1995) (emphasis added), *rev'd on other grounds*, 83 F.3d 1497 (D.C. Cir. 1996). What FDA's argument misses is that clinical laboratory testing is a service carried out by trained, highly skilled healthcare professionals working in consultation with the patient's doctor or other healthcare provider. *See* ACLA Br. 8, 28–29. The law has long distinguished between the judgment of licensed professionals and the manufacturing of products for sale in interstate commerce. *See* ACLA Br. 6, 28. As CLIA contemplates, the professional judgment of qualified laboratory professionals helps to ensure *both* "the quality of the test results reported" (what FDA calls "analytical validity") *and* "their interpretation concerning specific patient conditions" (what FDA calls "clinical validity"). *Id.* at 8 (quoting 42 C.F.R. § 493.1445(e)(9)).

In attempting to distinguish the final rule from CLIA, FDA only succeeds in undermining its central argument. FDA insists that its rule is consistent with the statute because the "device" regulated

by the rule is the "collection of physical objects … employ[ed]" by a laboratory "to produce a test result." FDA Br. 27 n.12. Whether those physical objects can function properly to produce a test result (*e.g.*, whether they can "accurately and reliably identif[y] the presence or absence of a protein biomarker"), however, is a matter of "analytical validity," which FDA concedes is already addressed by CLIA. FDA Br. 37. As for how the test result should be interpreted and used to inform a patient's diagnosis and treatment, that question concerns not the suitability of the physical objects used to perform the test, but the skill and judgment of the healthcare professionals who interpret and apply the test result. FDA's argument thus lays bare that what FDA is really seeking to regulate is not the use of physical objects to produce a test result, but the intangible professional services rendered by those who care for patients by interpreting and applying the test result.

C. FDA's sweeping new assertion of authority is especially dubious in light of the major questions doctrine and the rule of lenity.

The plain meaning of the FDCA is reinforced by the major questions doctrine and, to the extent the statute leaves any ambiguity, the rule of lenity.

1. Under the major questions doctrine, courts must be wary of agency assertions that a "long-extant statute" grants the agency "transformative" new powers. ACLA Br. 22 (quoting *West Virginia v. EPA*, 597 U.S. 697, 724 (2022)). Congress must "speak clearly if it wishes to assign to an agency" such consequential authority. *Id.* (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)); *see also Mayfield v. U.S. Dep't of Lab.,* 117 F.4th 611, 616 (5th Cir. 2024) (requiring more than just a "plausible textual basis" for such delegations). As ACLA Plaintiffs have explained, the major questions doctrine is tailor-made for the striking regulatory overreach reflected in the final rule, which dramatically reinterprets a "long-extant statute" to transform a vast swath of the healthcare sector, *West Virginia*, 597 U.S. at 724; bypasses a skeptical Congress; imposes tens or hundreds of billions of dollars in compliance costs; supersizes the role of the FDA; and classifies as criminal the widespread, longstanding practices of a respected medical profession. *See* ACLA Br. 22–24, 32–33.

FDA tries to evade the major questions doctrine by downplaying the novelty, impact, and controversial nature of the agency's assertion of authority over laboratory testing services. According to FDA, the final rule is nothing new because it "has claimed this authority continuously since 1977." FDA Br. 43. FDA does not identify how or where it supposedly made this claim of authority in 1977. Elsewhere in its brief, however, FDA cites a 1977 rulemaking in which FDA emphasized that clinical laboratories are *not* subject to FDA registration and listing requirements when they "provide a service through the use of a previously manufactured device." FDA Br. 24 (quoting 42 Fed. Reg. at 42,528). To the extent FDA is relying on the 1977 rule, then, it only underscores that FDA's new regulatory approach is a stark departure from past practice.

FDA also says that the final rule is "partly" a continuation of authority that it asserted "pre-1976"—again without specifying how and where it purportedly claimed that authority. FDA Br. 23, 44. Elsewhere in its brief, FDA says it "had th[is] power … since the [FDCA] was first enacted in 1938, and has expressly asserted its authority … since 1973." FDA Br. 1. This appears to be a reference to FDA's 1973 rule defining "in vitro diagnostic products" to include certain IVD test "systems." *Id.* at 18. As ACLA Plaintiffs have already explained, however, the only "systems" subject to the 1973 rule were finished products (e.g., test kits shipped in a "retail package"), not laboratory testing procedures. *See* ACLA Br. 31–32. FDA's vague allusion to "pre-1976" authority is thus another distortion of the regulatory history.

In reality, the regulatory history makes clear that FDA's assertion of authority in the final rule is a late-breaking attempt to reinvent a long-extant statute. *See* ACLA Br. 10–13. As the general counsel of HHS confirmed in the Charrow Memorandum, FDA did not even hint that it sought to claim such authority until 1992, more than half a century after the FDCA and 16 years after the Medical Device

Amendments. *Id.* at 12–13.[2] Even after 1992, FDA asserted such authority only sporadically and hesitantly in guidance documents and other non-binding statements. *Id.* at 10–12. Moreover, even assuming that FDA's distorted account of the regulatory history were correct, and that FDA embraced the theory underlying the final rule in 1973 or 1977, that would still be at least *35 years* after the enactment of the FDCA in 1938, when FDA says it first "had the power" it now claims. FDA Br. 1. By any measure, FDA's assertion of massive new authority came suspiciously late.

Worse yet, FDA's new "regulatory program" is one Congress has "conspicuously and repeatedly declined to enact itself." ACLA Br. 33 (quoting *West Virginia*, 597 U.S. at 724); *see id.* at 13. FDA quibbles that the proposed legislation would not have enacted the exact same program in exactly the same way. FDA Br. 45–46. For example, FDA says, the VALID Act—which Congress in recent years has repeatedly declined to pass—"would have created a new regulatory category entirely separate from 'drugs' and 'devices'" for the tests FDA seeks to regulate as "devices" in the final rule. FDA Br. 46. This hairsplitting misses the point, which is that Congress has clearly and conspicuously declined to grant FDA authority to regulate laboratory testing services. In *West Virginia*, the Court found it relevant that Congress had declined to enact measures, such as cap-and-trade proposals and a carbon tax, that were "similar" to the challenged EPA rule; it did not demand that the proposals Congress rejected must have been identical to the rule in every respect. If anything, that Congress considered creating an entirely new regulatory category for laboratory testing services—and did not

[2] With considerable chutzpah, FDA asserts that the Charrow memorandum—which is discussed in both the proposed rule and the final rule, *see* AR79–80, AR7133—"is not part of the administrative record in this case." FDA Br. 43 n.19. The "administrative record," however, includes *all* the "materials that [FDA] considered in making [its] decision." *Dep't of Com. v. New York*, 588 U.S. 752, 764 (2019); *see Thompson v. U.S. Dep't of Lab.*, 885 F.2d 551, 555-56 (9th Cir. 1989) (the administrative record in an APA case is not limited to "those documents that the *agency* has compiled and submitted as 'the' administrative record," but "consists of all documents and materials directly or *indirectly* considered by agency decision-makers and includes evidence contrary to the agency's position" (quotation marks omitted)). Because FDA expressly considered the Charrow memorandum in its rulemaking, *see* AR79–80, AR7133, the memorandum is unquestionably part of the administrative record in this case.

try to shoehorn them into the existing "device" category—casts further doubt on FDA's claim that Congress had already given FDA authority over these testing services as "devices."

Not surprisingly, FDA's unilateral action in the final rule has provoked a strong reaction on Capitol Hill. As ACLA noted, for example, the House Appropriations Committee has "direct[ed] the FDA to suspend its efforts" to "greatly alter" the nation's laboratory testing infrastructure, and the incoming chair of the Senate Committee on Health, Education, Labor, and Pensions has publicly rebuked FDA for its "egregious overstep." ACLA Br. 2, 33 (quoting H.R. Rep. No. 118-583, at 88 (2024) & Letter from Sen. Bill Cassidy to Dr. Robert Califf, Comm'r of Food and Drugs ("Cassidy Letter"), at 3 (June 30, 2024), *available at* https://www.help.senate.gov/imo/media/doc/loper_bright_letter_fdapdf.pdf). Those sharp objections from sitting members are still more evidence that FDA's assertion of authority is both novel and "politically contentious." FDA Br. 43 (quoting *Mayfield*, 117 F.4th at 617).

FDA next questions whether the final rule regulates a "significant portion of the American economy" or "require[s] billions of dollars in spending by private persons or entities." FDA Br. 43 (quoting *Mayfield*, 117 F.4th at 616). In fact, the final rule does both. Clinical laboratory testing is a $118 billion sector employing more than 650,000 Americans, *see* ACLA, *Economic Impact of Clinical Labs* (Mar. 2023), https://www.acla.com/economic-impact-of-clinical-labs, and it is vitally important because of its implications for lifesaving medical innovation and public health, including the nation's ability to respond quickly to major public health emergencies, *see* Amicus Br. of Ass'n for Academic Pathology at 1–11; Amicus Br. of Am. Ass'n of Bioanalysts at 6–19; *Ala. Ass'n of Realtors v. HHS,* 594 U.S. 758, 764 (2021) (per curiam) ("[T]he stake[s] are not merely financial"). And according to FDA's own (lowball) estimate, the rule will impose well over $1 billion every year in compliance costs, with costs reaching as high as about $80 billion over the next two decades. ACLA Br. 18.

Citing *Mayfield*, FDA suggests that economic impact matters only if it is in the *hundreds* of billions of dollars. FDA Br. 47. But neither the Supreme Court nor the Fifth Circuit has ever imposed such an arbitrary cutoff. Although the Fifth Circuit observed that some recent Supreme Court cases applying the major questions doctrine involved regulations with costs in the hundreds of billions of dollars, it noted that "no case has set the threshold for 'economic significance.'" *Mayfield*, 117 F.4th at 616. And in fact, the Supreme Court has indicated that *tens* of billions of dollars in costs are sufficient. *See Ala. Ass'n*, 594 U.S. at 764–65 (approximate economic impact of "nearly $50 billion"); *Biden v. Nebraska,* 600 U.S. 477, 502–03 (2023) (describing a rule with costs in the hundreds of billions of dollars as having "ten times the 'economic impact' that we found significant in [*Ala. Ass'n*]").

Moreover, FDA's cost estimates for the final rule are based on the doubtful assumption that laboratories will forgo incurring additional compliance costs in reliance on FDA's non-binding enforcement discretion policies, even though FDA has repeatedly emphasized that parties who rely on those policies are violating federal law and can be subject to an enforcement action at any time. If laboratories instead reasonably seek to protect themselves by fully complying with what FDA says the final rule requires, then by FDA's own estimates, the compliance costs for existing tests alone would range from $35 billion to $113 billion, and going forward, annual costs would range from $4 billion to $14 billion every year. That means ten-year costs could far exceed $200 billion.[3]

[3] FDA contends that the relevant cost of the rule for major-questions purposes is not the cost that would result from fully enforcing the rule, but the cost that would result if FDA adheres to its initial, non-binding "enforcement discretion" policies. But that cannot be right. Whether a statutory-interpretation question is "major" cannot turn on an agency's day-to-day or year-to-year enforcement-discretion choices. That approach would enable agencies to evade major-questions scrutiny by promulgating a massive new rule, larding it up with temporary "enforcement discretion" policies, and then changing those policies down the road. Nor did *Mayfield* sanction such a loophole. Although *Mayfield* cautioned against looking to "the broadest possible rule that is consistent with [the agency's] asserted authority," FDA Br. 47 n.20 (quoting 117 F.4th at 616 n.3), in this case ACLA Plaintiffs do not need to hypothesize a broader rule; the final rule itself imposes legal requirements that, if fully enforced, would impose costs quickly reaching into the hundreds of billions of dollars.

FDA also gives short shrift to other non-economic factors that may play a role in the major-questions inquiry. For instance, as the Supreme Court has indicated, the threat of "criminal penalties" can "amplif[y]" the stakes of a regulatory question. ACLA Br. 33 (quoting *Ala. Ass'n*, 594 U.S. at 765). In assessing whether FDA's final rule triggers the major questions doctrine, it is surely relevant that the FDCA imposes criminal penalties and that FDA's position would mean that tens of thousands of laboratory professionals are engaged in an ongoing criminal enterprise (and, in FDA's view, have been for decades). *See Cleveland v. United States*, 531 U.S. 12, 24–25 (2000) ("We resist the Government's reading … because it invites us to approve a sweeping expansion of federal criminal jurisdiction in the absence of a clear statement by Congress").

2. Because of the FDCA's criminal penalties, the final rule also implicates the rule of lenity. FDA does not dispute that the FDCA imposes criminal penalties and that it may therefore be subject to the rule of lenity. FDA argues that ACLA Plaintiffs cannot invoke the rule of lenity in this case, however, because ACLA Plaintiffs do not take the position that the FDCA is ambiguous. FDA Br. 42. As FDA surely knows, that is not how the rule of lenity works. ACLA Plaintiffs do not need to concede that the statute is ambiguous; instead, the rule of lenity can be invoked "[*t*]*o the extent*" that the statute is determined to be ambiguous. ACLA Br. 24 (emphasis added); *see, e.g.*, *United States v. Hoang*, 636 F.3d 677, 681–82 (5th Cir. 2011) (holding that "the meaning of [the statute] is plain" but adding "[i]n the alternative" that "to whatever extent SORNA may be characterized as ambiguous, the rule of lenity requires that we interpret the statute in Hoang's favor"); *United States v. Kimbrough*, 69 F.3d 723, 730 (5th Cir. 1995) ("Furthermore, to the extent that the statute can be considered ambiguous, the rule of lenity requires us to resolve that ambiguity in favor of Kimbrough"). Nor has the Fifth Circuit applied the rule of lenity like a featherweight that can tip the scales only in the rarest of cases. On the contrary, the Fifth Circuit has extolled the rule of lenity as "'time-honored interpretive guideline'" and has "applied it many times to construe ambiguous statutes" that impose criminal

penalties. *Cargill v. Garland*, 57 F.4th 447, 471 (5th Cir. 2023) (quoting *Liparota v. United States*, 471 U.S. 419, 427 (1985)), *aff'd sub nom. Garland v. Cargill*, 602 U.S. 406 (2024).

II. FDA's ad hoc enforcement-discretion carveouts confirm that the final rule is contrary to law and arbitrary and capricious.

That the consequences of FDA's proposed rule would have been so devastating should have been a strong signal to the agency that it had wandered far off the lawful track. Instead of heeding the warning signs, however, FDA pressed ahead with its enormously disruptive regulatory campaign. In a ham-fisted attempt to soften the blow, FDA loaded the final rule with non-binding "enforcement discretion" policies that, as FDA acknowledges, do not track any "provision of the FDCA." FDA Br. 48. As ACLA has explained, this "need to rewrite" the statute "should have alerted [FDA] that it had taken a wrong interpretive turn." ACLA Br. 39 (quoting *Util. Air* , 573 U.S. at 328).

FDA contends that "*Utility Air* … is wholly inapposite because it involved an agency that adopted a narrowed construction of a statute rather than exercising discretion in enforcing it." FDA Br. 48. But that is a non-sequitur. Like the EPA in *Utility Air*, FDA is seeking to mitigate the devastating consequences of its unreasonable legal position. *See Util. Air*, 573 U.S. at 324–25. Whether an agency attempts to rewrite a statute through what it presents as a "narrowed construction" (as in *Utility Air*) or whether the agency seeks to do so through what it calls "enforcement discretion" (as here), the basic dynamic is the same. In both scenarios, instead of taking the dire consequences of a statutory interpretation as a sign that the interpretation is wrong, the agency tries to do damage control with atextual gerrymandering. The question is not, as FDA suggests, whether FDA has the power to promulgate "enforcement discretion" policies, *see* FDA Br. 48; the question is why such sweeping exercises of discretion are necessary in the first place. And the answer, as in *Utility Air*, is that the agency has strayed well beyond the limits Congress set in the statute.

Furthermore, because FDA has repeatedly emphasized that the "enforcement discretion" policies are non-binding and that FDA may change its mind at any time and decide to bring an enforcement action, it is arbitrary and capricious for FDA to present those policies as a solution to the problem of longstanding

reliance interests. FDA says it did not act arbitrarily or capriciously because it "considered" such interests. FDA Br. 48. But as the Supreme Court recently reaffirmed, agencies must offer a satisfactory explanation for their actions and cannot "ignore an important aspect of the problem." *Ohio v. EPA*, 603 U.S. 279, 292–93 (2024). FDA has failed that test because it did not consider how the non-binding nature of its "enforcement discretion" policies undermines their value as a protection for reliance interests. As a result, FDA is speaking out of both sides of its mouth. In one breath, FDA warns laboratory professionals *not* to rely on those policies (because FDA can come after them at any time). In the next breath, FDA claims credit for solving the reliance problem with those very same policies. FDA has never offered an explanation, let alone a satisfactory explanation, for that contradiction.

III. The appropriate remedy is vacatur of the final rule.

FDA concludes with a cursory argument that if the Court holds the final rule unlawful, it should not vacate the rule outright, but should instead grant relief from the rule only to ACLA Plaintiffs and their members. As an initial matter, as FDA acknowledges, its argument that vacatur is not even available is squarely foreclosed by binding Fifth Circuit precedent, which clearly holds that vacatur "is an available remedy under the APA." FDA Br. 50 (citing *Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 779–80 (5th Cir. 2024)). FDA also argues briefly that even if "universal vacatur were theoretically available," relief should still be limited to ACLA Plaintiffs and their members based on general principles of "equity." FDA Br. 51. But FDA does not cite any examples of courts taking that approach in APA cases, and the Fifth Circuit has held that "[v]acatur is the *only* statutorily prescribed remedy for a successful APA challenge to a regulation." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374–75 (5th Cir. 2022) (emphasis added); *see also Tex. Med. Ass'n*, 110 F.4th at 779–80 ("[T]he APA empowers *and commands* courts to 'set aside' unlawful agency actions" (emphasis added) (quotation marks omitted)).

In a "final note," FDA requests "further briefing on an appropriate remedy" if the Court rules for ACLA Plaintiffs. FDA Br. 51. ACLA Plaintiffs disagree that further briefing is necessary. As binding Fifth Circuit precedent holds, the appropriate remedy is vacatur. The only reason FDA offers for supplemental briefing is that some provisions of the FDCA do not make sense as applied to laboratory testing services. *See id.* Whenever FDA comes across a provision of the FDCA that does not work for laboratory testing services—such as the requirement that devices have a label on their "'immediate container'"—FDA waves a magic wand and deems it "inapplicable." FDA Br. 27, 30–31 (quoting 21 U.S.C. § 321(k)). The fact that so many provisions of the FDCA do not "fit" laboratory testing services, however, is a reason to hold the final rule unlawful and vacate it in its entirety, not a reason to gerrymander a remedy that leaves the core of the rule intact. FDA's peculiar remedial "note" is yet another chapter in its persistent effort to rewrite the FDCA on the fly, and another sign that the agency has acted contrary to law.

CONCLUSION

This Court should enter summary judgment for ACLA Plaintiffs, vacate FDA's final rule, and grant ACLA Plaintiffs' requested declaratory and injunctive relief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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