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2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FDA's Proposal to Regulate Laboratory Developed Tests Vulnerable to a "Major Questions" Challenge

by Jeffrey N. Gibbs and Steven J. Gonzalez

Laboratory Developed Tests (LDTs), which are diagnostic tests developed, manufactured, and used within a single laboratory, play an essential role in health care in the United States. For example, LDTs are routinely used in genetic screening of couples considering having a child, prenatal testing of the fetus, newborn screening, testing for rare diseases and conditions, and pharmacogenomic testing to determine whether a particular drug is suitable for a patient.

The continued availability of these tests, though, is threatened by a proposed regulation issued by the Food and Drug Administration (FDA). On October 3, 2023, FDA proposed that LDTs be regulated in the same way as in vitro diagnostic (IVD) tests manufactured by companies and then shipped to customers (the "Proposed Rule"). Under FDA's proposal, laboratories with LDTs would need to comply with all device requirements, including complex and extensive manufacturing regulations (the Quality System Regulation, 21 C.F.R. Part 820), and most tests would need to undergo FDA premarket review. There would be no grandfathering; nearly a hundred thousand tests currently on the market would need to undergo the long, complicated, and costly FDA submission and review process.

The Proposed Rule marks a dramatic shift from FDA's longstanding policy of not regulating LDTs and would effect that transformation in just four years. The agency seeks to justify this upheaval on safety and policy grounds. As we—and others—explained in detailed comments, FDA's rationale does not stand up to close scrutiny. *See* Hyman, Phelps & McNamara, Comments to the Proposed Rule.

FDA acknowledges that its proposal rests on speculation and uncertainty. On more than a dozen occasions in its preliminary regulatory impact analysis (PRIA), FDA admits that it lacks sufficient information on key points, including such basic information as the precise number of laboratories or LDTs that would be affected by the Proposed Rule. *See* PRIA at 21. FDA seeks to justify its proposed rule based on health risks allegedly presented by LDTs, but FDA's assertions rest on shaky ground, and ignore all the benefits LDTs do provide.

Moreover, FDA recognizes that the regulation would force some laboratories out of business and mean the discontinuation of many tests. Yet the agency is blasé about this risk, hypothesizing that larger, better-funded laboratories would acquire some of these tests. Although the agency professes to be concerned by the "distortion" of a market where IVDs and LDTs are regulated differently, the agency is singularly unconcerned that its proposal will cause a different kind of distortion: significant market concentration.

FDA's proposal, if adopted, would dramatically increase FDA's workload. FDA projects it will receive up to 20 times more LDT submissions in a single year than it receives ***for all device***

Jeffrey N. Gibbs is a Director, and **Steven J. Gonzalez** is an Associate, with Hyman, Phelps & McNamara, P.C. in Washington, D.C.

types in a typical year. PRIA, Table 4 at 28. The increase in submissions during the COVID-19 pandemic caused gridlock at FDA. The proposed regulation contemplates a far larger number of submissions, without no realistic plan to cope with the surge of applications.

Even if the Proposed Rule were not seriously flawed, FDA lacks statutory authority to subject LDTs to the statutory requirements it seeks to apply.

When agencies invoke longstanding legislation to justify significant new regulatory requirements, "something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to 'clear congressional authorization' for the power it claims." *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014) (rejecting EPA's attempt to regulate greenhouse gas emissions from small sources despite its admitted textual plausibility)). That is so because "[e]xtraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle devices.'" *Id.* (quoting *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001)). At least three different categories of cases are subject to this "major questions doctrine":

- where Congress previously has considered but declined to expressly grant an agency the regulatory authority it claims;
- where upholding the agency's claimed authority would subject a significant number of parties to new regulatory requirements; and
- where compliance with the agency's new federal mandates would require "billions of dollars in spending each year," *King v. Burwell*, 576 U.S. 473, 485 (2015).

The Proposed Rule triggers all these criteria.

First, since 2006, Congress has considered, but not passed, nearly a dozen different pieces of legislation that would have authorized FDA to regulate LDTs. Each of those bills had one common feature: none presumed that the 1976 Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") vested FDA with authority to regulate LDTs as medical devices. Yet the Proposed Rule claims that FDA has had such authority ever since the MDA's passage and simply chose to "not enforce applicable requirements" for medical devices. 88 Fed. Reg. 68,006, 68008. Indeed, the Proposed Rule acknowledges that FDA had not publicly announced that it could regulate LDTs until a 1997 rulemaking and, even then, FDA did not espouse the same rationale as it does now. *See Id.* at 68,015.

The Agency's attempt to ground its regulatory authority in a 50-year-old statute that FDA admits it did not apply for decades makes this case comparable to many others in which federal agencies—including FDA itself—have sought to overcome Congress's refusal to authorize their actions by claiming that ancient legislation conferred such authority. *See, e.g.*, *West Virginia*, 142 S. Ct. at 2610 ("[W]e cannot ignore that the regulatory writ EPA newly uncovered conveniently enabled it to enact a program that, long after the dangers posed by greenhouse gas emissions 'had become well known, Congress considered and rejected' multiple times.") (quoting *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 144 (2000) (rejecting FDA's attempt to regulate the safety of tobacco products)).

Second, FDA's PRIA for the Proposed Rule estimates that thousands of laboratories, including as many as 160,800 existing LDTs and up to 15,552 new LDTs per year, will now be subject to complex, burdensome, and costly federal regulations. PRIA at 25, 75-76, 85. That makes this case akin to *Utility Air*, where the Supreme Court rejected EPA's attempt to subject small sources to EPA's Prevention of Significant Deterioration permitting regulations because doing so would cause "annual permit applications [to] jump from about 800 to nearly 82,000; annual administrative

costs [to] swell from $12 million to over $1.5 billion; and decade-long delays in issuing permits [to] become common, causing construction projects to grind to a halt nationwide." 573 U.S. at 322 (citing 75 Fed. Reg. 31,514, 31,557 (2010)).

Third, the Proposed Rule will impose billions of dollars in compliance costs on laboratories. *See, e.g.*, *West Virginia*, 142 S. Ct. at 2621 ("[A]n agency must point to clear congressional authorization when it seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities.") (internal citations and quotations omitted). The PRIA projects that FDA's new regulatory mandates will impose up to $355.73 billion in regulatory compliance costs during its first 20 years, along with up to $3.0 billion in upfront user fee costs. *See* PRIA at 87, 93. If anything, FDA's estimates substantially understate the actual costs.

Thus, the Proposed Rule raises a major question for which FDA "must point to 'clear congressional authorization' for the power it claims." *West Virginia*, 124 S. Ct. at 2609 (quoting *Utility Air*, 573 U.S. at 324). But the MDA supplies no such clear statement. Instead, its text and structure affirmatively undermine the Proposed Rule's core claims.

FDA's central contention is that its authority to regulate LDTs as medical devices stems from the MDA's definition of "device" in 21 U.S.C. § 321(h)(1), which FDA says "encompasses test systems regardless of where or by whom they are manufactured. In particular, the definition contains no exception or limitation for devices manufactured by laboratories." 88 Fed. Reg. at 68,018.

FDA cannot claim far-reaching regulatory authority based solely on a definition; the Supreme Court repeatedly has rejected such an approach. *See, e.g.*, *Utility Air*, 573 U.S. at 315-16, 319-21 (rejecting claims that Congress clearly authorized EPA to regulate greenhouse gases simply because they fell within a literal interpretation of statutory definition of "air pollutant"); *Solid Waste Agency v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172-73 (2001) (rejecting claims that Congress granted the Army Corps of Engineers regulatory authority over isolated wetlands simply because they fall within the literal definition of "waters of the United States"); *Brown & Williamson*, 529 U.S. 120 (rejecting claims that Congress empowered FDA to regulate tobacco products even though those products fell within the FDCA's broad definitions of "drug," "device," and/or "combination product").

Furthermore, the MDA's definitions cannot be read in isolation from the FDC Act's substantive provisions. For example, the statute plainly states healthcare providers, which includes laboratorians, are exempt from the MDA's basic registration, recordkeeping, reporting, inspection, and listing requirements for the devices they make and use while treating patients. *See* 21 U.S.C. § 360(g)(1)-(5); *id.* § 360i(c)(1). It is illogical to believe Congress exempted laboratories from these provisions but authorized FDA to apply the statute's far more burdensome and complex provisions to those same entities. *See, e.g.*, *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd.*, 484 U.S. 365, 371 (1988) ("A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme … because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.").

The Proposed Rule also directly conflicts with the statute's interstate "commercial distribution" requirements. Far from requiring that all medical devices obtain prior FDA review before use, the statute instead limits those requirements to devices that are or will be "***introduc[ed]*** or deliver[ed] into interstate commerce ***for commercial distribution***." *See* 21 U.S.C. § 360(k) (emphasis added); *see also id.* § 360c(c)(2)(C)(ii); *id.* § 360c(f)(1); *id.* § 360e(b)(1); *id.* § 360e(i)(1).

The statute does not define "commercial distribution," so courts must "look to the [phrase's] ordinary definition." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 284 (2011). "Commerce" refers to "the exchange or buying and selling of commodities especially on a large scale

and involving transportation from place to place." Webster's Third New Int'l Dictionary Unabridged. And in its most common and contextually appropriate sense, "distribution" refers to the "delivery" or "conveyance" of a good "from a main source" to another. *Id.* These definitions make clear that the statute's premarket submission requirements apply only where a device is moved from one place to another and from one entity to another.

That understanding perfectly fits typical medical device transactions. For example, after a device manufacturer produces a cardiac product, the good will be transferred from the manufacturer to a hospital. LDTs, by contrast, are not made commercially available to other entities. FDA itself has made this very distinction in prior rulemaking. 62 Fed. Reg. 62,243, 62,249 (expressly distinguishing analyte specific reagents "that move in commerce" from "tests developed in-house by clinical laboratories or ASR's created in-house and used exclusively by that laboratory for testing services").

FDA's own regulation similarly requires "distribution" of the product, not merely that it exist. *See* 21 C.F.R. § 807.3(b) ("Commercial distribution means any ***distribution of a device*** intended for human use which is held or offered for sale.") (emphasis added).

To support its position, FDA places great weight on a single district court decision. *See* 88 Fed. Reg. at 68,021 (invoking *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F. Supp. 990, 994–95 (W.D. Mich. 1985)). In the forty years since it was decided, the case has been cited just three times and never in support of the proposition for which FDA now says it stands. In that case the government itself "argue[d] that the FDA's definition of 'commercial distribution' has only minor relevance to this action … since the device in question did not exist prior to enactment of the [MDA]." This precedent does not justify FDA's view that no transfer, movement, transportation, or exchange of product is required for commercial distribution.

FDA's proposed regulation will have profound consequences for the laboratory industry, the availability of LDTs, and access to diagnostic testing by clinicians and patients. Nevertheless, the conventional wisdom is that due to the election calendar, FDA will finalize the rule in the first half of the year largely as it was written. Given the thousands of comments that FDA received, including some that are rather extensive, it will be challenging for FDA to stick to that timeline and comply with its Administrative Procedure Act (APA) obligations to fully respond to significant comments. *See e.g.*, *Chamber of Commerce of the U.S. vs. SEC*, 85 F.4th 760, 774 (5th Cir. 2023) (finding SEC's rulemaking was arbitrary and capricious, because the agency failed to "consider all relevant factors raised by the public comments and provide a response to significant points within.").

If FDA does issue a final rule, litigation is virtually inevitable. And the plaintiffs who bring that litigation will be well-armed with arguments, including the APA and the Major Questions Doctrine.

Possibly, FDA's threat to regulate laboratories in the same manner as device companies will lead Congress to pass legislation that expressly addresses how LDTs should be regulated. Congress has considered that issue before, and FDA's proposed regulation may spur Congress to act. Certainly, if the courts find FDA lacks sufficient statutory authority to issue a rule on such a major question, which they should, then the ball will be squarely in Congress's hands.

