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Susan Van Meter on...
ACLA Files Federal Lawsuit Challenging FDA's LDT Rule

Filed May 29 in Texas Court

(See pages 6-8)

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

LDT Rule Is Now a Fact! What Will Be Consequences?

TODAY, THE NEW RULE FOR REGULATION OF LABORATORY DEVELOPED TESTS (LDTs) issued by the federal **Food and Drug Administration** (FDA) is an accomplished fact. In taking this action, the FDA has created a regulatory scheme that is widely viewed as disruptive and counter-productive by pathologists and clinical lab executives involved in performing LDTs in support of patient care.

In drawing this battle line, the FDA has forced the clinical laboratory profession to take the serious step of filing a lawsuit in a federal court in Texas to challenge the FDA's actions. This happened on May 29 and you will read our assessment of this case on pages 3-5.

The intelligence briefing that follows is an exclusive interview with Susan Van Meter, President of the **American Clinical Laboratory Association** (ACLA), the lead plaintiff in the lawsuit against the FDA and the federal **Department of Health and Human Services** (HHS). You will gain an inside perspective as to why ACLA believed it was necessary to take the serious step of suing one of its major federal regulators. *(See pages 6-8.)*

For further insights into the lab industry's valid criticisms of the FDA rule and the importance of the ACLA's lawsuit, we interviewed two experienced lab industry attorneys. Jane Pine Wood, JD, of **McDonald Hopkins** and Danielle Sloane, JD, of **Bass, Berry and Sims**. The requirements of the final LDT rule in how labs are to develop LDTs, apply for FDA review, and comply with ongoing quality reporting are widely understood to be prohibitively expensive and time-consuming. Wood and Sloane provide details and context for these issues. *(See pages 9-11.)*

Nowhere else but in THE DARK REPORT will you read the information presented in the intelligence briefing that follows the Wood and Sloane interview on pages 12-15. Our editorial team revisits three times in past decades that federal regulators pushed laws and regulations that triggered major disruptions in either lab operations or lab billing activities.

We close our coverage in this issue with Virchow's take on how the managed care companies will change how they handle LDT test claims once the requirements of the FDA's LDT rule go into effect. *(See pages 17-18.)*

Coming in the next issue of THE DARK REPORT will be an analysis of why the FDA's LDT rule has the potential to become the single biggest federal action that radically transforms the clinical laboratory market as we know it today. TDR

ACLA Files Court Challenge to FDA's Final LDT Rule

HHS and FDA named as defendants: ACLA and HealthTrackRx are plaintiffs; Case filed in Texas

CEO SUMMARY: Discussing the FDA's final LDT rule, one pathologist tracking this matter wrote, "In many ways, the FDA's plan [final LDT rule] is like the guy who gets three wishes from a genie, and he asks for unlimited wishes." ACLA and HealthTrackRx are challenging the FDA's "genie" in federal court, with the goal of obtaining an injunction to stop the FDA from implementing the rule and a court order vacating the LDT rule.

BATTLE LINES ARE NOW DRAWN ON WHAT IS PROBABLY THE BIGGEST CONFRONTATION between the clinical laboratory industry and federal regulators in the past 50 years.

On May 29, the **American Clinical Laboratory Association** (ACLA) with co-plaintiff **HealthTrackRx** filed a major lawsuit against the federal **Department of Health and Human Services** (HHS) and **Food and Drug Administration**.

The ACLA's lawsuit directly challenges the FDA's final rule giving it oversight over laboratory developed tests (LDTs). The final LDT rule was published in the *Federal Register* on May 6, 2024, and becomes effective on July 5, 2024.

With the goal of claiming oversight powers concerning LDTs, the FDA moved swiftly. It published the draft rule on Oct. 3, 2023, and public comment was closed on Dec. 4. 2023. *(See TDR, "FDA Issues Proposed Rule to Further Regulate LDTs," Oct. 2, 2023, and "Who's For and Against FDA Draft LDT Rule?" Feb. 5, 2024.)* Six months later, the FDA published its final LDT rule.

To launch its legal challenge to HHS and FDA, ACLA filed the case in the **United States District Court, Eastern District of Texas, Sherman Division**. Knowledgeable observers point out that this could help ACLA.

For example, on his blog (*www.discoveriesinhealthpolicy.com*), pathologist Bruce Quinn, MD, PhD, wrote, "As I predicted at several conferences, [ACLA] filed the case in Texas, where I think an initial ruling against the government is likely, which will start the ball rolling on various appeals and counter-attacks. The Texas filing, I think, raises the chance of an injunction while issues simmer. Grounds for this include the $101M in

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projected spending by labs to comply, just in the first months of the 5-year plan."

Plaintiffs are asking the court for three outcomes, quoted as follows from the court documents:

> *WHEREFORE, Plaintiffs request that the Court:*
>
> *A. Enter a declaratory judgment that FDA's final rule is contrary to law; in excess of statutory jurisdiction, authority, or limitations; and arbitrary or capricious, and that FDA is not authorized to regulate laboratory testing services as medical devices under the FDCA.*
>
> *B. Enter an order that vacates FDA's final rule and enjoins FDA from enforcing the final rule and regulating laboratory testing services as medical devices under the FDCA.*
>
> *C. Order such other and further relief as the Court deems just and proper.*

Three Primary Arguments

In their lawsuit, the plaintiffs assert three primary arguments in challenging the FDA's actions:

- **"Laboratory developed tests are services carried out by highly skilled and trained laboratory professionals."** Plaintiffs assert that "Laboratories that develop and perform these tests are providing professional healthcare services; they are not acting as device manufacturers."
- **"FDA's statutory authority to regulate medical devices does not extend to professional services."** Plaintiffs stated that "The FDCA was originally enacted by Congress in 1938. It authorized FDA to regulate 'foods,' 'drugs,' 'devices,' and 'cosmetics,' all of which were physical *products* that were mass-manufactured and commercially distributed." After describing how the FDCA described medical devices, plaintiffs concluded this argument, writing, "Viewed collectively, these provisions confirm what the statutory definition of 'device' makes clear: A 'device' under the FDCA is a physical product or manufactured good, not an intangible professional service."
- **"Congress created a separate and distinct framework for regulating laboratory testing services."** On this point, plaintiffs said, "Congress created a separate statutory and regulatory framework to regulate laboratory testing services: the Clinical Laboratory Improvement Act of 1967 ... which was significantly expanded by the Clinical Laboratory Improvement Amendments of 1988. This framework is commonly referred to as 'CLIA'." Plaintiffs further said, "Although CLIA was enacted nine years before the Medical Device Amendments and significantly expanded twelve years after those Amendments, neither CLIA nor its legislative history acknowledges any authority of FDA to regulate laboratory testing services as medical devices. In short, there is no indication that Congress, when it enacted CLIA, believed that clinical laboratories' provision of testing services was already subject to regulation under the FDCA."

Factor of New Administration

In his blog notes about the case, Quinn described another factor that might help the plaintiffs as this court case moves forward. "Much may depend on the next administration: if it is a change of regime they might provide a lukewarm defense, or less, of the regulation. For example, some LGBT-related regulations have gone through three literal 180-degree flip-flops across the three Obama, Trump, and Biden administrations," Quinn noted.

The complaint filed by the ACLA and HealthTrackRx is 59 pages, supported by another 391 pages of exhibits. ACLA posted the lawsuit on its website. (*https://tinyurl.com/5yx26z3j.*)

With the filing of this lawsuit, ACLA assumes a leading role representing the

substantial number of clinical laboratories, anatomic pathology groups, and genetic testing labs that oppose the FDA's steps to regulate laboratory developed tests.

In deciding to file this federal lawsuit, ACLA had the support of the nation's largest clinical laboratory organizations. The lawsuit includes five exhibits. Each exhibit was prepared by one of the nation's largest laboratories and describes the negative consequences that the FDA's final LDT rule will have on patient care; why the rule will inhibit innovation on developing new tests; and why the LDT rule will raise the cost of developing a novel LDT and submitting it to the FDA for review to a prohibitive level.

Five Labs Submitted Exhibits

These exhibits were submitted by:

- **Exhibit A: HealthTrackRx**, signed by Jay Reddy, PhD, Senior Vice President of Laboratory and Clinical Strategy.
- **Exhibit B: Labcorp**, signed by Marcia Eisenberg, PhD, Senior Vice President and Enterprise Chief Scientific Officer.
- **Exhibit C**: **Quest Diagnostics**, signed by Yuri A. Fesko, MD, Chief Medical Officer.
- **Exhibit D**: **ARUP Laboratories**, signed by Jonathan Genzen, MD, PhD, Chief Medical Officer and Senior Director of Government Affairs.
- **Exhibit E: Mayo Clinic**, signed by William Morice II, MD, PhD, President of **Mayo Clinic Laboratories** and Chief Executive Officer and President of **Mayo Collaborative Services**, which includes Mayo Clinic Laboratories.

Three Elements to Consider

In the weeks and months to come, a federal judge will be considering three primary elements that have a role in this case. One is the history of how LDTs have (or have not) been regulated. The second involves the arguments by plaintiff labs that the FDA lacks statutory authority to use the LDT rule to redefine LDTs as a medical device under the Food, Drug, and Cosmetic Act (FDCA). The third is the disruption to ongoing innovation in laboratory medicine because of the imposition of burdensome device approval requirements on tests currently subject to a different regulatory regime. TDR

ARUP Labs Supports ACLA's Federal Lawsuit

OF THE FIVE CLINICAL LABORATORY ORGANIZATIONS THAT PROVIDED STATEMENTS to the federal court in support of the ACLA's lawsuit against the federal Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA), only ARUP Laboratories issued a press release about the federal lawsuit.

The press release presented the following quote: "I am deeply concerned about the FDA's final rule, the enormous costs it will impose on clinical laboratories, and the harm it will cause to patients across the nation," wrote Jonathan Genzen, MD, PhD, chief medical officer and senior director of governmental affairs, in ARUP's declaration. "The rule poses serious risks to patients by threatening to reduce access to safe testing services over time, which will disproportionately harm patients with rare diseases, underserved patient populations, patients with cancer, and children."

ARUP Labs' press release also noted one interesting aspect about the lawsuit, saying that "'ACLA's lawsuit does not ask for an emergency injunction,' said Ashley Parrish, JD, attorney for ACLA. 'We are not going to ask the court to make a quick decision or to immediately put a stop to the rule. We think this is an important case, and we want the court to have the time to consider the issues on a reasonable schedule,' Parrish said."

ACLA President Van Meter Discusses LDT Lawsuit

Did FDA exceed its statutory authority by issuing its LDT rule? A federal court will now hear this case

Susan Van Meter, ACLA

CEO SUMMARY: On July 5, the final laboratory developed test (LDT) rule issued by the federal Food and Drug Administration (FDA) takes effect. In response, the American Clinical Laboratory Association (ACLA) filed a lawsuit in federal court in Texas to challenge the FDA's actions. In this exclusive interview, ACLA President Susan Van Meter provides insight and context for ACLA's decision to file the lawsuit.

When the federal **U.S. Food and Drug Administration** (FDA) published its final rule on regulation of laboratory developed tests (LDTs), many legal observers expected that litigation would soon follow. Sure enough, on May 29, the **American Clinical Laboratory Association** (ACLA), along with co-plaintiff **HealthTrackRx**, filed a federal lawsuit seeking a court order to vacate the final rule and prevent the agency from regulating LDTs as medical devices.

Necessary Step

"We don't take any decision to file suit against the government lightly," said ACLA President Susan Van Meter in an exclusive interview with The Dark Report. "We were very deliberate about this. But it's clear that this step was necessary. We do not believe FDA has the authority under current law to regulate laboratory developed testing services as medical devices."

Given the negative impact on clinical labs, as well as patient access to testing services, "we had no choice but to move forward with the suit," stated Van Meter.

FDA has contended that the rule is necessary due to the way that LDTs have evolved since 1976, when Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). The tests, the agency said, are more complex, used more widely, often performed at high volumes, and sometimes marketed nationwide.

In its final rule, the FDA wrote, "In this regard, most LDTs today are similar to other IVDs [*in vitro* diagnostics] that have not been under FDA's general enforcement discretion approach."

The plaintiffs' response: "The statutory definition of 'device' makes clear that FDA's regulatory jurisdiction under the FDCA is limited to physical products and does not encompass professional services," including laboratory developed testing.

This is true "regardless of how the field has changed over time," Van Meter told The Dark Report. The plaintiffs also take issue with the FDA's notion of "enforcement discretion," the idea that the agency has long been empowered to regulate LDTs and has simply chosen not to exercise that authority.

Should Congress Reintroduce the VALID Act? ACLA Describes Elements Missing from Current Bill

IN ITS PRESS RELEASE ANNOUNCING THE LAWSUIT, the ACLA stated that "legislation is the right—and only—approach for FDA to regulate professional testing services offered by laboratories."

But what would that legislation look like? In three consecutive sessions, Congress considered the VALID Act, which would establish a new regulatory framework for all IVDs, including LDTs. However, lawmakers failed to pass the bill each time.

"At the end of 2022, we were working to secure improvements to the VALID Act up until the last minute," said ACLA President Susan Van Meter in an interview with THE DARK REPORT. At the time, the group did not formally endorse the bill. "We were never in a position to support it, because we continued to seek changes," she said. In March, speaking before the **U.S. House Energy and Commerce Subcommittee on Health**, she described it as "the right approach moving forward."

At the time, the subcommittee was hearing testimony about the FDA rule, and one member, Rep. Anna Eshoo (D-California), suggested that the FDA issued the rule only after Congress failed to vote on the VALID Act.

"We don't see VALID as the only potential legislation," Van Meter told THE DARK REPORT. But if that's the vehicle, she pointed to at least one change she'd like to see, involving the bill's provision for technology certification.

This would allow test developers, including laboratories, to submit a representative assay to the FDA. Then, they could secure approval for other assays based on the same technology, based on a review of that representative assay.

Keeping Pace with Science

"In this way, post-market, the laboratory could make iterations on those assays without having to come back into the agency," explained Van Meter. "We would finally have a regulatory mechanism that keeps pace with the science. We thought that had great promise." The problem?

"The VALID Act, as written, wouldn't allow high-risk tests to go through that pathway," she said. "We think that was a mistake. There's a tremendous amount of innovation in high-risk laboratory tests. So, we need a regulatory apparatus that can reflect that science while allowing useful tests to reach patients who need them."

"FDA's rule would mean that the entire clinical laboratory sector—which is a significant part of the U.S. healthcare system—has been breaking the law for nearly 50 years, and possibly much longer," the complaint states. "And it would mean that going forward, the entire profession is operating unlawfully and can be subject to civil and criminal penalties at any time, with its only protection coming from a policy of enforcement discretion that FDA insists it is free to revoke at any time."

Under the rule, FDA said it will phase out its enforcement discretion in five stages over four years, beginning May 6, 2025. But even a year from now, the rule imposes "some rather substantial requirements," Van Meter said.

"These requirements are things like compliance with complaint handling and medical device reporting (MDR)," she added, "as well as medical device correction and removal reporting requirements clinical laboratories are required to do, in what feels like a short timeline, to provide information to the FDA. The bigger the test menu a laboratory has, the more significant the lift, in terms of hiring regulatory experts and generating the data necessary to submit this information to the FDA."

She also pointed to "gray areas where we need significant guidance from the

agency in order to attempt to comply." For example, she said, laboratories will be required to report adverse events involving LDTs to the agency. "With a traditional medical device or a kitted test, it's clear enough how to think about adverse event reporting," she said. "But when it's a laboratory developed test—a professional service—we need clarification of what constitutes a malfunction."

The rule provides carveouts for certain categories of LDTs, such as those first marketed prior to May 6, 2024. These tests won't have to undergo premarket review, but will be subject to other requirements, including adverse event reporting. The carveouts, the plaintiffs contend, are additional examples of enforcement discretion that the FDA can revoke.

As one justification for the rule, the FDA alleged numerous problems with LDTs, citing accounts "in the scientific literature, news articles, and anecdotal reports submitted to the Agency, among other sources."

But the lawsuit contends the FDA used "cherry-picked, anecdotal, and unverified 'evidence'" to support its position.

"We've been disappointed that the federal agency painted the clinical laboratory industry with such a negative and broad brush, using highly prejudicial language," Van Meter said. "They have had a dearth of scientifically grounded examples of faulty lab tests. They've relied on media reports and other non-scientific bases for suggesting that there are widespread problems. We simply do not see that."

Lawsuit Co-Plaintiffs

The complaint includes supportive declarations from representatives of five clinical laboratories: HealthTrackRx, the co-plaintiff, along with **Labcorp**, **Quest Diagnostics**, **ARUP Laboratories**, and **Mayo Clinic**.

"These are compelling personal narratives that describe the challenges that will result from the application of the ill-suited medical device authorities to laboratory developed testing services," she said.

HealthTrackRx, based in Denton, Texas, specializes in PCR testing to detect infectious diseases, wrote senior VP of laboratory and clinical strategy Jay Reddy, PhD, in his declaration.

Regulatory Uncertainties

"Although FDA has announced carveouts that are supposed to reduce the consequences of FDA's decision to regulate laboratory developed tests as medical devices, the carveouts create intolerable regulatory uncertainty, as FDA's rule states that the agency could change its mind at any time," he noted.

Reddy also cited the costs of obtaining FDA approvals or clearances, and questions about whether FDA has the resources to handle a high volume of submissions. "I am therefore concerned that when HealthTrackRx submits a test for FDA approval and clearance, the company will be forced to wait many months (if not longer) for approval or clearance."

The lawsuit was filed in the U.S. District Court in the Eastern District of Texas, where HealthTrackRx is located.

As ACLA proceeds with the litigation, the group is having discussions with other laboratory organizations, including professional societies, about supporting the lawsuit, Van Meter said.

"Laboratory professionals recognize the challenges that exist with this rule, even in areas of so-called partial enforcement discretion," she said.

"There are still significant requirements, incongruent with laboratory developed testing services, that need to be met over the course of a relatively short timeframe," Van Meter added.

A larger point, she said, "is how inappropriate the medical device authorities are for diagnostics in general. They're ill-suited for what we think of as IVDs, including manufactured and kitted tests. It's a framework that's unable to keep pace with science." TDR

Contact the ACLA at press@acla.com.

Attorneys Assess Impact of FDA's Final LDT Rule

Some lab clients already signaling concerns that compliance costs will end their LDT offerings

Jane Pine Wood, JD

CEO SUMMARY: Publication of the Food and Drug Administration's final rule on laboratory developed tests (LDTs) is already causing some labs to consider withdrawing their existing LDTs because of compliance costs. Two experienced lab industry attorneys discuss aspects of the LDT rule and what they hear from their clinical laboratory clients.

Danielle Sloane, JD

THROUGHOUT THE CLINICAL LABORATORY INDUSTRY, lab executives and their attorneys are dissecting the final rule on laboratory developed tests (LDTs) recently issued by the federal **Food and Drug Administration** (FDA). *(See pages 3-8.)*

THE DARK REPORT caught up with two attorneys who have studied the 475 pages of the FDA's final LDT rule. They have also begin to look through the 450 pages of the lawsuit filed on May 29 by the **American Clinical Laboratory Association** (ACLA) that challenges the FDA's actions in issuing the LDT rule.

Consequences of LDT Rule

Each attorney has useful insights about the consequences of the FDA's LDT rule for labs performing LDTs. Both also urge labs to educate lawmakers about the serious repercussions expected as labs struggle to comply with the final LDT rule.

The main contention of the highly anticipated May 6, 2024, final rule involves the fact that the FDA now considers LDTs to be medical devices and LDTs will be held to a very rigid regulatory framework.

"Existing FDA regulations are designed for devices, physical things. They don't fit well with laboratory tests," said Jane Pine Wood, JD, an attorney with **McDonald Hopkins**, in an interview with THE DARK REPORT.

"Many questions have been raised on how the FDA can make a laboratory test fit the entire regulatory framework of the federal Food, Drug, and Cosmetic Act (FDCA) that was written for primarily implantable devices or medicines one might take," Wood commented. "A clinical laboratory test is not a medical device. It is not something implanted in a patient or ingested by a patient, like a prescription drug."

Congress has never stated that a laboratory test is a device. It wasn't until the 1990s—approximately 20 years after Congress enacted the medical device amendments to the FD&C Act—that the FDA started expressing concerns about LDTs being devices. Nearly 30 more years passed before the federal agency enacted its final, controversial LDT rule stating that it had the authority to regulate laboratory developed tests as medical devices.

"Stepping back from the LDT rule itself, I think the overarching problem is that complying with both CLIA [Clinical Laboratory Improvement Amendments] and the FDA's rules is simply not feasible and does not make sense," stated Danielle Sloane, JD, **Bass, Berry and Sims PLC**, in an interview with THE DARK REPORT. "The FDA and CMS seem to agree that greater regulation at the individual test level is necessary.

Treatment Decisions

"In the final LDT rule, the FDA makes a compelling case that clinical laboratory testing has become increasingly important to treatment decisions and patients make important decisions based on test results," she continued. "However, laboratories already operate on relatively thin financial margins."

Wood concurs and pointed out how the FDA estimates that compliance with the new LDT rule will cost labs more than a billion dollars per year over the next two decades. An impact analysis statement released by the FDA in May states, "the annualized costs range from $566 million to $3.56 billion at a 7% discount rate with a primary estimate of $1.29 billion, and from $603 million to $3.79 billion at a 3% discount rate with a primary estimate of $1.37 billion."

Labs Under Financial Stress

"It is common knowledge that laboratories run on a shoestring budget and their profit margins are incredibly low," said Wood. "For every new LDT developed today, the estimates are between $500,000 and $2 million to get the test through the premarket review process.

"When labs are barely making it because of all the price cuts they've faced, the cost to comply with the LDT rule requirements will stifle innovation," she continued. "What lab will spend money developing new tests or making substantial improvements to existing LDTs if it must spend all these extra dollars on FDA compliance—additional compliance layered on top of existing federal and state laboratory regulations?"

Lab managers know that labs are already highly regulated. Labs are required to comply with CLIA and maintain accreditation, along with state laboratory regulations. In addition to costs, this new layer of LDT regulations could be prohibitive to many labs that wish to develop new diagnostic tests.

Both attorneys noted that the FDA's final timeline for regulatory compliance for LDT's includes five phases that will occur over a period of four years. The first stage, which includes medical device reporting and quality system requirements, will begin on May 6, 2025.

Stopping R&D Efforts

"I have clients who are already discussing putting on hold their R&D efforts or any improvements they might make to their LDT tests out of concern that it's going to kick them into a premarket review process. And that's not good for patients," Wood asserted.

"On this point, even the FDA mentioned in the final rule that it expects there will be laboratories that will not be able to afford compliance," she added. "But FDA officials seem hopeful that enough labs will still provide LDTs that this will not negatively impact patient care."

The final rule includes numerous pages regarding how the FDA will enforce the regulations and its exercise of enforcement discretion. It repeatedly states the agency can alter the rules (and its enforcement discretion) at any time.

Wood explained that under this FDA rule's guidance, labs with: a) currently marketed LDTs (marketed prior to May 6, 2024); b) LDTs with NYS CLEP (New York State Clinical Laboratory Evaluation Program) approval; and, c) limited categories of LDTs offered by integrated health systems are only

required to comply with the FDA's medical device reporting, the labeling and registration requirements, and some of the medical record keeping.

One concern voiced by labs is what happens in the future if the FDA changes its mind and forces the above-referenced categories of labs to adhere to a premarket review process for these LDTs that the FDA has designated for its enforcement discretion.

Tests No Longer Offered

"Were this to occur, some laboratories may stop offering certain tests and may not put the same amount of resources into test development given the additional burden of obtaining FDA approval," Sloane said. "On the flip side, obtaining FDA approval for an LDT and its 'intended use' is likely to make it easier for that lab to receive reimbursement from payers and the Medicare MolDx program.

"One reason I enjoy working with clinical laboratory clients is because I see the potential that innovative testing has to help pinpoint the cause of a patient's problem and, as a result, quickly set them on the path to recovery," she continued. "Laboratory developed tests can contribute to improved patient care and that is an important benefit to LDTs.

Obtaining Test Coverage

"However, I have also seen small innovative laboratories struggle to obtain coverage from payers, including MolDx," she added. I think FDA approval, even as an IDE [Investigational Device Exemption], could help small innovative laboratories obtain payer coverage for their testing."

FDA regulation does not guarantee perfection or absolutely safeguard patient health. Several drugs and medical devices have been removed from the market after initially being approved by the FDA.

"FDA regulation is important, but in laboratory testing, we already have a very well-developed regulatory framework with CLIA," Wood stated. "The laboratory industry has operated for a really long time without a lot of issues. I don't think patients realize it yet, but if the ACLA litigation is unsuccessful, patients will have reduced access to care.

"If nothing else, having litigation filed also puts additional pressure upon the FDA to engage in conversations with stakeholders regarding concerns about the final LDT rule," she observed. "It also can put pressure on members of Congress regarding what may or may not be some legislative solutions to the issue.

"So, the fact that litigation is filed doesn't necessarily mean that someday everyone ends up in court," Wood concluded. "But it is one of the tools in the toolbox to address a rulemaking outcome that raises significant patient jeopardy concerns." TDR

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Steps Labs Can Take to Assist ACLA Lawsuit

CLINICAL LABORATORIES CAN HELP THE ACLA SUCCEED in its lawsuit. Attorneys Jane Pine Wood and Danielle Sloane both suggest labs contact the FDA and elected officials in their areas.

Both attorneys encourage labs to also contact their congressional representatives to explain exactly what the lab does and how the new FDA LDT rule could negatively affect the lab industry and patient care, emphasizing the patient jeopardy issues.

Labs should also contact patient constituency groups that represent patients with certain diseases and speak to them about the potential ramifications of the new FDA rule. This action is particularly important for more specialized labs and patients with rare diseases.

Several Times, Feds Tried to 'Redirect' Lab Activities

During the past five decades, federal regulators attempted several times to recast how labs operated

CEO SUMMARY: Regulation of laboratory developed tests (LDTs) by the Food and Drug Administration (FDA) may turn out to be one of the most impactful federal laws or regulations ever promulgated, so far as it pertains to clinical laboratories. THE DARK REPORT provides this historical look back at other important federal laws and regulations that triggered major changes in the operation and finances of clinical laboratories. These include CLIA, competitive bidding, and PAMA price surveys.

MULTIPLE TIMES IN THE PAST FIVE DECADES officials in different federal departments asked **Congress** to pass legislation intended to give regulators more authority over how clinical laboratories operated and billed government health plans for laboratory testing services.

Each time one of these initiatives was written into law and passed by Congress, the consequence was to require all labs to make substantial changes in how they performed testing and how they submitted laboratory test claims to government health programs.

Cost of Compliance

In some cases, these new laws—and the regulations cooked up by regulators to administer the intent of the law—raised the cost of compliance for clinical laboratories and anatomic pathology groups. In other cases, **Medicare** officials persuaded Congress to pass laws that gave them powers to address the cost of clinical lab testing to the Medicare and **Medicaid** programs. Whatever government regulations and actions followed, neither Medicare officials nor clinical lab operators were happy with the outcomes.

Seen in this context, the new final LDT rule published by the federal **Food and Drug Administration** (FDA) last month is the latest example of federal officials moving forward with a regulatory initiative that will have serious and unknown consequences in how the nation's clinical laboratories develop and introduce new diagnostic assays in support of patient care.

Throughout the clinical laboratory profession, it is widely understood that the FDA's final LDT rule will require additional costs and major compliance changes by a large number of clinical laboratories. At the same time, the popular view is that this rule—if implemented as written—will retard the development of clinically useful new LDTs, if not totally discourage labs from investing time and money to create innovative new tests that improve patient care.

This intelligence briefing is a retrospective on three past examples of government regulators prevailing upon Congress

to pass a law intended to cause a major change in the ways labs operated and submitted lab test claims to government health programs. Our narrative starts five decades ago, with an important law passed by Congress in 1988 that continues to govern the daily operations of all licensed laboratories in the United States.

1988: Federal Law on Lab Quality

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

The original Clinical Laboratory Improvement Act of 1967 (CLIA '67) established certain quality standards for clinical laboratories. Few notable modifications were made to this statute until 1988. That's when a Pulitzer-Prize winning reporter published an exposé of shabby and fraudulent practices at certain labs that put patients at risk.

During 1987, reporter Walt Bogdanich of *The Wall Street Journal* wrote three front-page stories about ongoing problems and lab errors that were injuring patients. His stories triggered additional news coverage and Congress recognized the need to respond with a law to address the problem.

In one story, titled, "Lax Laboratories: The Pap Test Misses Cervical Cancer through Labs' Errors—Cut-Rate 'Pap Mills' Process Slides Using Screeners to Rush," Bogdanich described how certain Pap testing laboratories had bonus arrangements that encouraged lab techs to read up to 200 Pap cases per day. Bogdanich also reported situations where, each day, a cytotech did a full shift at one lab, then did a full second shift at another lab, reading hundreds of Pap smears and being paid a per-case fee by both labs.

Congress Acted Swiftly!

The national uproar from the *WSJ's* coverage of problems and abuses within the clinical lab industry caused Congress to swiftly propose and pass the Clinical Laboratory Improvement Amendments of 1988 (CLIA). By 1992, the federal **Health Care Financing Administration** (HCFA—now the **Centers for Medicare and Medicaid Services**) published the final CLIA regulations.

All clinical laboratories in the United States were required to comply with the new CLIA regulations by 1994. Subsequently, the CLIA rules were amended in 1993, 1995, and 2003.

2008: Federal Law on Medicare Test Prices

Competitive Bidding for Medicare Part B Clinical Lab Testing Services

Competitive bidding for Medicare Part B clinical lab testing was an idea that surfaced within the federal Health Care Financing Administration (HCFA–now the Centers for Medicare and Medicaid Services [CMS]) in the early 1980s.

It was not until 2003 that CMS officials finally persuaded Congress to pass a law mandating a competitive bidding demonstration project for clinical laboratory tests. Medicare officials hoped that competitive bidding for Part B clinical laboratory services would significantly reduce what Medicare was paid for these tests. *(See TDR, "Medicare Demo Bidders' Meeting Reveals Many Problems Ahead," December 10, 2007.)*

Bidding Project Announced

Following passage of the 2003 law, CMS worked on its plan to implement competitive bidding. On Oct. 16, 2007, CMS announced it would conduct a demonstration project for competitive bidding involving Medicare Part B clinical laboratory testing services. CMS chose the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) as the first clinical laboratory competitive bidding demonstration project.

Competitive bidding was unpopular with the clinical laboratory industry. The design of the bidding process was complex

and subjective. Labs were to submit their price bids for 303 test codes that CMS said represented 99% of Part B test claims. There would be winning labs selected. Other labs would be allowed to provide tests to Medicare beneficiaries during the demonstration project's two-year term, but they would only be paid at the low prices determined by CMS from the winning bids.

Doctors, Patients Objected

One significant development was how this competitive bidding project triggered objections from doctors in the San Diego region. They recognized that they might no longer be able to use their lab of choice. Similarly, patient advocacy groups quickly understood that there would be local labs that could not afford to provide testing at the final prices in the demonstration project. Thus, many Medicare patients would lose access to the phlebotomists at these smaller labs who had collected specimens from these patients for years.

Resistance to this project by the lab profession was immediate and substantial. In February 2008, CMS collected bids from a handful of labs that submitted bids. But a lawsuit by a group of clinical lab organizations filed in federal court in San Diego resulted in an injunction that prevented CMS from proceeding. CMS never again pursued competitive bidding for Part B clinical laboratory testing services. *(See TDR, "Three San Diego Labs Stop Competitive Bid Demo," Apr. 14, 2008.)*

2014: Federal Law on Medicare Test Prices

Private Payer Lab Test Price Survey Mandated by Protecting Access to Medicare Act of 2014 (PAMA)

Another federal law that proved disruptive to clinical laboratories was the Protecting Access to Medicare Act of 2014 (PAMA). There were six sections of this law that pertained to lab testing activities.

One section of this law required CMS to conduct a survey of the prices that private health insurers paid for clinical laboratory tests. The law directed CMS to use the price data it collected to adjust the Part B Clinical Laboratory Fee Schedule (CLFS). CMS was to repeat this market price survey every two years and use that data to update the CLFS.

There were two reasons for this section of PAMA. First, CMS had been using a lab test fee schedule originally created in 1984. Over the years, Congress had made alterations in ways that adjusted that original fee schedule to account for inflation and new diagnostic tests.

However, CMS recognized how—30 years later—lab automation and the latest generation of analyzers had reduced the cost of producing many common lab tests. Thus, CMS officials were itching to redo the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) and push down the prices on the CLFS.

THE DARK REPORT is among a number of lab observers who believe that another motivating factor was that CMS officials had seen the low-ball test price bids submitted to it in 2008 during the aborted CLFS demonstration project described earlier. They were ready to do a radical makeover of the CLFS to reap big savings for the Medicare program.

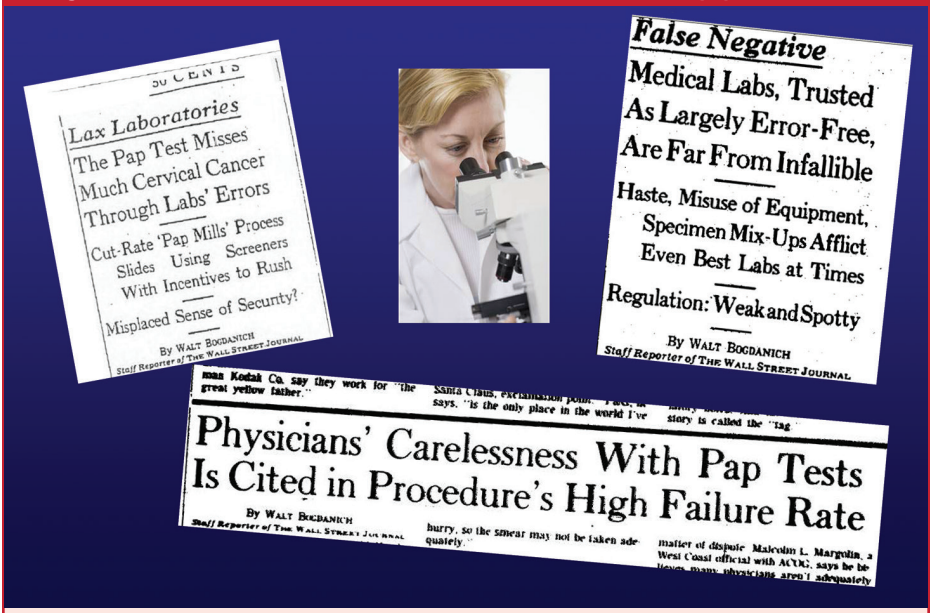
Biased Price Survey

It can be argued that subsequent events support this assumption. CMS created a process for collecting private payer clinical laboratory test pricing data that had substantial biases. Despite industry objections, in 2017 CMS proceeded with the first price survey and used that private payer price data to set CLFS prices for 2018 and 2019.

The PAMA law specified that CMS could not cut the prices of individual tests by more than 10% in 2018 and 10% in 2019. CMS proceeded to do that each year.

At the end of 2017, THE DARK REPORT wrote, "CMS officials say these fee cuts

Exposé on Bad Clinical Lab Business Practices by Wall Street Journal in 1988 Triggers CLIA



SHOWN ABOVE ARE THE HEADLINES OF THE THREE STORIES PUBLISHED IN 1987 by *The Wall Street Journal* that described bad quality, lax management of testing, and examples of outright fraud in how some clinical laboratories performed testing. The stories reported the findings of the investigation conducted by reporter Walt Bogdanich.

In one of the three stories, Bogdanich described how many physicians—when collecting a Pap smear—did not perform the collection correctly nor fix the slide properly before sending it to the lab. He noted that there was no quality control on how physicians collected Pap smear specimens. In a second story about Pap testing, he described "Pap mills"—labs that bid low prices, then pushed cytotechnologists to read large numbers of Pap smears daily, rewarding them on a piecework basis (a reimbursement arrangement that encouraged them to speed through cases).

As the *WSJ* published each story in this series, other news outlets picked up the topic. Public reaction was so great that within 12 months Congress was forced to respond. It passed the Clinical Laboratory Improvement Amendments Act of 1988 (CLIA). By 1992, Medicare officials published the final CLIA rule that required all clinical laboratories to comply with a comprehensive quality and compliance program.

The *WSJ* published Bogdanich's stories on Feb. 2, 1987; Nov. 2, 1987; and Dec. 29, 1987. For this investigative reporting, Walt Bogdanich was recognized with a Pulitzer Prize in 1988.

will produce savings of $670 million in 2018 and will be followed by additional fee cuts in the following years 2019 through 2022." *(See TDRs, Oct. 9, Oct. 30, and Nov. 20, 2017.)*

The first years of CMS' price cuts were so draconian many labs filed bankruptcy or got sold. Congress responded by passing laws each year since 2020 that pushed back scheduled PAMA CLFS price cuts. **TDR**

Lab Regulatory Update

What if Congress Chooses to Pass an LDT-Specific Law?

Despite the FDA's decision to issue its LDT rule, possibility remains of Congress tackling this subject

Congress has yet to speak specifically on the issue of regulating laboratory developed tests (LDTs). Influential advocates on both sides of this issue have lobbied lawmakers on this issue for a decade.

Given the stakes involved in the specifics of how laboratory developed tests are regulated, it is reasonable to assume that representatives and senators will continue to be pressed to enact legislation that would be the "last word" on regulation of LDTs.

VALID ACT Proposed in 2018

Attention can be focused on one proposed bill, the Verifying Accurate Leading-edge IVCT Development (VALID) Act. The first proposed draft legislation of the VALID Act was introduced in the House of Representatives in 2018. It was described as a bi-partisan bill, put forth by Representatives Larry Bucshon, MD, (Republican-Indiana) and Diana DeGette, (Democrat-Colorado).

Some version of the VALID Act has been introduced in each successive Congress. This is evidence that there is enough lobbying clout by proponents to keep this bill in the docket. Despite a description as "bi-partisan," opponents of the VALID Act as written have managed to keep this bill from advancing to a vote by both houses of Congress.

Advocates of the VALID Act are primarily non-lab groups and associations. For example, in an advocacy update in 2021, the **College of American Pathologists** wrote, "Signatories on the letter to support the advancing of the VALID Act as part of the pending FDA User Fee legislation included the **American Society of Clinical Oncology** (ASCO), **American Cancer Society Cancer Action Network**, **BD (Beckton, Dickson and Co.)**, **Bio-Rad Laboratories**, **Center for Science in the Public Interest**, **Cepheid**, **Friends of Cancer Research**, **Hologic**, **Muscular Dystrophy Association**, **Ovarian Cancer Research Alliance**, **Pew Charitable Trusts**, and **Roche Diagnostics**."

In the same update in 2021, CAP listed supporters of the VALID Act, writing, "Laboratory organizations such as the **Association for Molecular Pathology**, the **American Association for Clinical Chemistry**, and **Association of Pathology Chairs** have expressed opposition to the VALID Act. In general, the groups have opposed FDA regulatory oversight of LDTs and cite other reasons for opposing the bill."

Congress Might Still Speak

It should be understood that groups for and against the proposed VALID Act continue lobbying in attempts to get the language they favor included in whatever version of the bill that finally comes to a vote by both houses. It is important that clinical lab executives and pathologists recognize any pending version of the VALID Act could be revised in ways that nullify the FDA's final LDT rule—a version which Congress could then vote into law. TDR

Virchow

Medicine Money Managed Care

This column is named after the famous German pathologist Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

How Private Health Insurers May Respond to FDA LDT Regulation

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

HOW MIGHT PRIVATE HEALTH INSURERS REACT TO THE **U.S. Food and Drug Administration's** (FDA) final rule on regulation of laboratory developed tests (LDTs)? The answer to this question can have significant financial consequences for the nation's clinical labs.

Each time a lab submits a claim for a test, in a perfect world, the health plan wants to know:

- Is this test appropriate for the patient's diagnosis, as documented by the ordering physician?
- Does the test meet the health plan's coverage guidelines?

Most clinical laboratories have long been opposed to FDA regulation of LDTs, but commercial payers welcomed the prospect, at least in principle. Here's why.

When a lab submits a claim for a test, the insurer wants to know what it is paying for. This is true for any kind of test, but many LDTs are complex genetic tests where it can be especially difficult to determine clinical utility or validity.

If the test has been cleared or approved by the FDA, the payer might not have all the information it needs to make a coverage decision, but at least it knows the test has undergone independent scrutiny to determine safety and effectiveness.

Suppose a lab tweaks an existing test and gives it a different name. The lab tells the payer, "This isn't Test A any longer. It's Test B. It's a better test, and now we want $300 more for it."

How is the payer supposed to evaluate that? Why is this test better than the one it replaced? How is it going to change the outcome for the patient? How does it justify the cost? The payer really doesn't know.

Enter the FDA

Now, the FDA has stepped in with its new LDT rule. Are payers jumping with joy? Not necessarily. From what I hear, they're taking a wait-and-see approach. They're still reviewing the rule to see what it means. But even at first glance, it's clear that this is not a magic bullet that will suddenly give payers more clarity when making coverage decisions about LDTs.

For one thing, the FDA now faces litigation over the rule. That could take years to resolve. In the meantime, litigants seeking to block the rule will try to get an injunction to keep it from taking effect.

The new policy also contains major exceptions. For example, LDTs currently

on the market will be exempted from premarket review and most quality system requirements, though they will be subject to other requirements, including medical device reporting.

LDTs at Healthcare Systems

The same will also be true of LDTs "manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system when an FDA-authorized test is not available," an FDA press release noted.

These exceptions were not in the original draft of the rule that the agency proposed in October. The FDA adopted the changes after receiving comments from organizations representing laboratories. One of those groups, the **College of American Pathologists** (CAP), said it welcomed the exceptions. Nonetheless, CAP said that the new rules impose a "great cost and regulatory burden" on labs that offer the tests. It is no surprise that the issue is now in a federal court.

How Payers Evaluate LDTs

Meanwhile, payers are left scratching their heads. "It would be great if this were simple," they're saying. "The lab changed an LDT. They want more money for it and now we want to understand why."

That's not what the new LDT rule is giving them, even if it does survive the legal challenges. So, payers will likely continue to rely on their current policies to determine coverage. They could follow guidelines from the **Centers for Medicare and Medicaid Services** (CMS) or Medicare Administrative Contractors (MACs) that process claims in different regions. In the past, some LDTs have been MAC-specific, and often times state-specific.

But even if CMS covers an LDT in a certain region, payers might choose not to do so "until there's more evidence in the literature," which is one of their favorite phrases. They might wait to see if there's a large clinical trial. In many cases, they'll demand prior authorization, with onerous criteria for approval.

As payers await more certainty regarding LDT regulation, some have turned to **Palmetto GBA's** Z-Codes and the accompanying DEX Diagnostics Exchange to facilitate claim submissions. DEX is a registry of molecular diagnostic tests, mostly LDTs, each of which is identified by a unique Z-Code.

Labs submit information about their tests, which Palmetto GBA uses to perform a risk-based technical assessment. That's a lot easier than going to the FDA, even if it doesn't carry the weight of an FDA clearance or approval.

Palmetto GBA, a regional Medicare contractor, originally used the system for Medicare claim submissions. But it also licenses the system to commercial payers.

In 2021, **UnitedHealthcare** (UHC) became the first of several insurers to require inclusion of Z-Codes in claim submissions to Medicare Advantage plans. Beginning in June, UHC now requires Z-Codes in its commercial plans as well.

Other commercial plans are likely to follow suit. They like the system because it offers clarity about genetic tests.

Revisiting the VALID Act

FDA officials made it clear that they proposed the new LDT rule only after **Congress** failed to bring to a vote the Verifying Accurate, Leading-edge IVCT Development (VALID) Act, which would establish a new regulatory framework for all IVDs, including laboratory developed tests.

Some labs, particularly those associated with academic medical centers, are opposed to the FDA rule and VALID. But even if the rule is tied up in the courts, Congress could always revisit the VALID Act. I believe payers would welcome that, because they would have both the Z-Codes and FDA approvals or clearances to guide their coverage decisions. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Once a high-flier lab test manufacturer with a market valuation of $2 billion, **Cue Health** of San Diego filed for Chapter 7 bankruptcy on May 28. Analysts now say the company is valued at about $15 million. Founded in 2010, Cue Health was developing a test system that consumers could use at home. Its components included a collection swab, a sample-specific cartridge, and a reader that accepts the cartridge, performs the assay, and uses Bluetooth to transmit results to the Cue app.

MORE ON: *Cue Health*

Cue Health's moment to shine came during the SARS-CoV-2 pandemic. In 2021, it was awarded $481 million by the federal government to ramp up the manufacture of its COVID-19 test kits. Leveraging that news, Cue Health launched an initial public offering (IPO) in the fall of 2021 that raised $200 million. In the years since, the company was unable to follow up the COVID-19 test success with other types of test kits. In fact, early in May, Cue Health received a warning letter from the federal **Food and Drug Administration** (FDA). *Fierce Biotech* reported that the federal agency stated concerns that the company "made undisclosed changes to the reagents and design of its reader that could affect the accuracy of its over-the-counter COVID test." In the weeks following receipt of the letter, Cue Health announced that it was laying off all of its employees and that it would use a bankruptcy filing to liquidate the company.

ROCHE, LUMIRADX DEAL TO BE SCRUTINIZED IN UK

MarketWatch reports that the U.K.'s **Competition and Markets Authority** is considering whether the acquisition of **LumiraDx's** point-of-care technology business by **Roche Holding** could be anti-competitive in that country. The $295 million deal was announced last December.

TRANSITIONS

- Modena Henderson announced the start-up of **Beyond Results, LLC**, a consulting business "serving healthcare, laboratory, diagnostics, and pathology." Previously, she held executive positions at **Allina Health**, **Atrium Health**, **Solstas Lab Partners**, and **Carilion Labs**.

- Beverly Monahan opened a consulting practice in genomics and precision medicine in Chicago this month. Monahan previously held positions at **NeoGenomics**, **Biocartis**, **PierianDx**, **Labcorp**, **N-of-One**, **PathGroup**, **Poplar Healthcare**, **simplifyMD**, **CBLPath**, and **Caris Diagnostics**.

- John Erickson announced that he is President & Founder of **First Light Medical & Consulting LLC**, a company that provides "contracted full-service enterprise sales executives and sales leaders." Erickson's prior positions were with **FrontrunnerHC**, **ARUP Laboratories**, and **Ventana Medical Systems**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 1, 2024.

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