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FDA's LDT Proposal, AI Oversight, Cybersecurity Top US Regulatory Interests In 2024

2024 Crystal-Gazing With Industry Leaders

by Medtech Insight Team

Views from industry experts and the US FDA on priorities and regulatory topics to watch in 2024.

Medtech Insight reached out to attorneys, consultants, the US FDA and other stakeholders about leading US regulatory issues and opportunities in the new year. Here's what they had to say...

FDA Spokesperson

Staying The Course

Heading into 2024, the FDA's Center for Devices and Radiological Health (CDRH) remains well-positioned to protect and promote the public health. Our plan is to stay the course and make good on the commitments we have already made, with a focus on continuing to advance medical device safety and innovation.

Health Equity

FDA's work touches on environmental, social, and governance issues, particularly when relevant to its work concerning public health. Various statutes, regulations, and policies govern the FDA's approach to these topics to ensure the safety and effectiveness of medical devices. This is evident as seen through the frame of HHS' and CDRH's stated priorities.

Strategic Goals

HHS' first strategic goal is to *Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare*, which dovetails with CDRH's strategic priority to *Advance Health Equity*. This strategic priority continues to drive several workstreams of the CDRH in 2024, including expanding participation by diverse populations in evidence generation and developing a framework for when a device should be evaluated in diverse populations.

Additionally, areas of CDRH's regulatory focus in 2024 are noted in the *A list and B list* of proposed guidance documents and inclusions on the *Unified Agenda of Regulatory Actions*.

> *Read about the FDA's updated guidance clarifying that health equity considerations may factor in Breakthrough Device designations.*

Jeff Shapiro
Partner
King & Spalding

I come at this question from the perspective of FDA regulatory counsel. I think most observers would agree that start-ups and small companies have led much of the innovation in medical device technology the past few decades, leading to tremendous improvements in patient care. These companies need predictable testing and data requirements to raise capital and manage spending. In this regard, there is significant uncertainty heading into 2024. For the 510(k)/de novo pathway, FDA has been good about hitting the MDUFA deadlines. But FDA has not done as well in providing timely interactive discussion of testing and data requirements. These informal discussions can drag on for months while the review clock is stopped. At the same time, FDA has been ratcheting up testing and data requirements in areas that were once straightforward such as biocompatibility or human factors. Many of these new requirements appear to arise more from bureaucratic mission creep rather than actual gaps in earlier requirements. Regardless, this up-regulation creates an even greater need for companies to interact informally with FDA to discuss how to satisfy the requirements.

In software, there also is regulatory uncertainty due to the new cybersecurity requirements adopted last year and continuing fundamental questions about how FDA will review artificial intelligence/machine learning (AI/ML) functionality. In short, the small company innovators in the medical device

industry head into 2024 with significant uncertainties in FDA's testing and data requirements.

Read more on the FDA's progress against MDUFA V goals.

Eric Henry
Senior Quality & Regulatory Compliance Advisor
FDA
&
Life Sciences Practice
King & Spalding

With regard to uncertainties, the ramp-up in post-COVID enforcement activity brings with it a degree of uncertainty regarding how that enforcement will manifest itself (eg, increased warning letters, a predicted ramp-up in consent decrees, withdrawn CE marks). The degree to which FDA will enforce recently finalized and soon-to-be finalized rules and guidance (eg, cybersecurity, software, pre-determined change control plans, laboratory-developed tests, quality management systems regulation) is very much up in the air as well.

Read stakeholder takes on the FDA's readiness to tackle lab-developed test oversight as proposed in October 2023.

Dennis Gucciardo
Partner
Morgan Lewis & Bockius

The biggest uncertainty in the device space? Well, I think there are two. One is obviously diagnostics. The FDA received 6,500 comments on the proposed LDT rule, a lot against [the proposal] as you can imagine, because this a big shakeup, but the FDA is full steam ahead.

Secondly, how is the FDA going to regulate AI? The FDA is touting predetermined change control plans and suggesting this is the mechanism that is at least available for regulating AI. I think predetermined change control plans work well with machine learning because you can easily define the four corners to which a machine can learn; but when it comes to more generative AI, that's not going to work as well because the algorithm may change, or the product itself may change. So I think the FDA will be looking to Congress in

order to deploy a regulatory structure that allows them to regulate AI.

Additionally, clinical trial diversity. The FDA has already spoken on what type of data it needs to be included in clinical trials because, to the extent that clinical trials aren't using diverse populations, you're going to have a limited understanding of what the clinical benefit of a particular product may be.

Read about the FDA's draft guidance aimed at bringing underrepresented racial and ethnic groups into more medical device clinical trials.

Jeffrey N. Gibbs
Director
Hyman, Phelps & McNamara

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Gail H. Javitt
Director
Hyman, Phelps & McNamara

On October 3, 2023, FDA published a proposed rule that would result in regulating laboratory developed tests (LDTs) in the same manner as in vitro diagnostic (IVD) medical devices. If adopted as written, this rule would mean that thousands of laboratories would be regulated by FDA for the first time in history and would either need to comply with FDA requirements or discontinue their tests within four years of the effective date of the rule.

Tens of thousands of tests relied on my physicians and patients stand to be affected. This rule would profoundly shake up the laboratory industry and, because of the huge increase in workload for FDA, could significantly hinder FDA's ability to effectively regulate other types of diagnostic devices. Thousands of stakeholders submitted comments to FDA in response to the proposed regulation, some of which strongly objected. A final rule is expected by mid-2024, perhaps with some minor modifications. If that happens, FDA will likely be sued.

In the meantime, the pendency of the proposal may lead Congress to revisit legislative proposals for LDT oversight. In sum, FDA's proposed rule has led to significant uncertainty as to the fate of diagnostic regulation in the US.

Read about the legal battle expected over the FDA's proposed regulation of

LDTs.

Susan Van Meter
President
American Clinical Laboratory Association

Getting Congress to act: In 2024, ACLA will be focused on seeking enactment of the bipartisan Saving Access to Laboratory Services Act (SALSA). Without congressional action, year-over-year cuts to Medicare payment for clinical laboratory services will resume on January 1, 2025, reducing patient access to care, discouraging investment in diagnostic innovation, and undermining the nation's critical laboratory infrastructure.

Congress has acted four times to delay these cuts, but it is time we secure a long-term and sustainable solution to this problem. In 2024, dozens of cosponsors joined the bipartisan and bicameral champions of SALSA to support the legislation, endorsed by 70 patient and provider organizations, laying strong groundwork for passage of SALSA next year.

Concerns over LDT rule: Another top priority for ACLA is urging the FDA to withdraw its proposed rule that would unilaterally impose the ill-suited medical device authorities on laboratory developed tests (LDTs). ACLA has grave concerns the FDA's proposed rule would result in a loss of patient access to critically needed LDTs, including those for which there is no FDA cleared/approved test, and dampen innovation in testing including for cancer and infectious disease.

ACLA believes the proposed rule exceeds FDA's authority and any expanded FDA oversight would require congressional action. ACLA is committed to continuing work with FDA, Congress, and key stakeholders on legislation that would establish an appropriate regulatory framework for all diagnostics, complementary to the already robust oversight of LDTs. ACLA believes FDA should withdraw the rule and work to seek legislation that reflects the unique characteristics of LDTs.

Read about the Verifying Accurate, Leading-edge IVCT Development (VALID) Act reintroduced in the US House in March 2023.

Neil O'Flaherty
Partner
Amin Talati Wasserman

Evan Phelps
Partner
Amin Talati Wasserman

One key uncertainty facing the medical device industry is how the US Food and Drug Administration's proposed rule to actively regulate laboratory-developed tests will play out. The proposed rule would amend FDA regulations to make explicit that in vitro diagnostic products meet the definition of a 'device' under the Federal Food, Drug, and Cosmetic Act, including when the IVD manufacturer is a clinical laboratory. Driving the proposed rule (and FDA's prior attempts to actively regulate LDTs) is its concern that results from faulty LDTs could cause unnecessary treatments or delay in or lack of proper treatment. This Agency concern is heightened by the fact that LDTs have become increasingly sophisticated and more efficient to run in larger capacities. These circumstances did not exist when FDA originally decided not to actively regulate LDTs as medical devices. The proposed rule is already being criticized by many clinical laboratory stakeholders, similar to preceding attempts by FDA to actively regulate LDTs. Actively regulating LDTs as medical devices may well trigger notable challenges. Many clinical laboratories would be drawn into the world of FDA-regulated manufacturers for the first time, facing new compliance costs and the significant effort needed to achieve and maintain FDA medical device compliance.

Which clinical laboratories would be able comply? Moreover, bringing LDTs into the actively regulated medical device fold will test an already busy FDA staff at the Center for Devices and Radiological Health and its limited resources. Will CDRH be able to effectively oversee LDTs and get the additional support it needs to do so?

This year may well tell us if FDA is able to keep pace with the rapidly developing artificial intelligence and machine learning technologies. These technologies, when integrated into medical devices, can make digital health more accessible and easier for patients while potentially further reducing the need for patients to directly interact with caregivers. One of the advantages of AI and ML-based device software functions is that they can improve and change their performance through iterative modifications as they gain experience. However, FDA's traditional framework for the review of medical device changes requires the assessment of the change prior to its implementation which would tend to limit this advantage, possibly to the detriment of patients. In apparent recognition of this issue, FDA has introduced the concept of predetermined change control plans that would enable FDA to authorize anticipated AI/ML-based device modifications to device software products during the device's original premarket review process. While this is a step in the right direction, FDA has not always earned high marks for regulatory flexibility, and it is uncertain if this measure will be adequate to keep the agency's regulatory controls in pace with the advantages promised by AI and ML.

Read how the FDA is driving development of international standards for predetermined change control plans as a means of regulating machine learning-enabled devices.

Steve Silverman
President
The Silverman Group

Everybody's #1 prediction is that FDA's regulation of in vitro diagnostics is going nowhere next year. Opponents are already planning lawsuits to block FDA. These lawsuits are certain, so I'm not sure that I get credit for 'predicting' them. To be safe, I'll add two predictions. First, FDA will expand its digital device oversight, adapting current regulations to new technologies. And real world evidence will grow as a supplement to (not a replacement for) traditional clinical data. In both cases, FDA will leverage its regular authority; this means no congressional initiatives to get new powers.

Read about the FDA's December 2023 draft guidance on "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices."

Philip Desjardins
Partner
Arnold & Porter

As we approach 2024, the medical device industry grapples with considerable uncertainties, notably in the realm of digital health where the FDA is poised to intensify enforcement activities. Over the past five years, the FDA has consistently communicated its authority and expectations in the digital health domain, and 2023 witnessed a uptick in enforcement actions against companies deviating from existing guidance and regulations. Anticipating a more pronounced regulatory stance in the upcoming year, both in terms of volume and severity, it becomes evident that the FDA's focus on the digital health landscape is set to expand. Particularly noteworthy is the FDA's planned 2024 updates to guidance in the artificial intelligence/machine learning sector, a domain ripe for enforcement given its rapid evolution. Industry stakeholders should prepare for heightened scrutiny and ensure alignment with evolving regulatory frameworks in the dynamic landscape of digital health and AI/ML applications in medical devices.

Read about the FDA's formation of a Digital Health Advisory Committee in 2023.

Scott Trevino
Senior Vice President, Cybersecurity
TRIMEDX

One of the most pressing uncertainties, with the biggest impact, is simply the number of cyberattacks we'll see throughout 2024. Over the past several years, the number of cyberattacks on healthcare organizations has increased significantly. Healthcare organizations saw an 86% spike in cyberattacks in 2022 from the year prior. At TRIMEDX, we will be watching to see if that trend continues, and we are prepared if it does so.

Additionally, we'll be watching for any development or enforcement of meaningful measures to improve cybersecurity through regulation, legislation, and collaboration. Recently, the SEC charged SolarWinds and its chief information security officer with fraud for misleading investors about the company's cybersecurity practices and failing to disclose known risks during the time it was the target of a massive cyberattack. This could set a new precedent for the accountability expected and consequences for security professionals. Leaders must ensure rigorous cybersecurity practices are in place and followed with evidence.

The industry is closely monitoring how the FDA will enforce its new cyber mandates for medical devices and if Congress will advance additional cybersecurity legislation. As the FDA has indicated to Congress, cybersecurity collaboration between groups that service medical equipment, original

equipment manufacturers (OEMs), independent service organizations (ISO) and others that own and service equipment is highly encouraged in order to achieve the shared goal of improved patient care and patient safety. That could mean additional patches, more hardened medical devices, and more comprehensive medical device cybersecurity programs within health systems.

Listen to Trevino discuss the FDA's new cybersecurity oversight authorities.

Daniel Vukelich
President
Medical Device Reprocessors

The unpredictable political and environmental climates, both figuratively and literally, could create instabilities to the device supply chain, as we saw with COVID-19. Even the threat of instability to the supply chain is a reminder that circular strategies focused on reuse, or in our case, commercially reprocessed single-use medical devices, keep more products domestic and available longer. The Joint Commission should take steps now to assure a more stable supply chain by driving circular economies and requiring FDA-regulated solutions like

commercial reprocessing.

Read about the EU's Implementing Regulation on Common Specifications for the reprocessing of single-use devices.