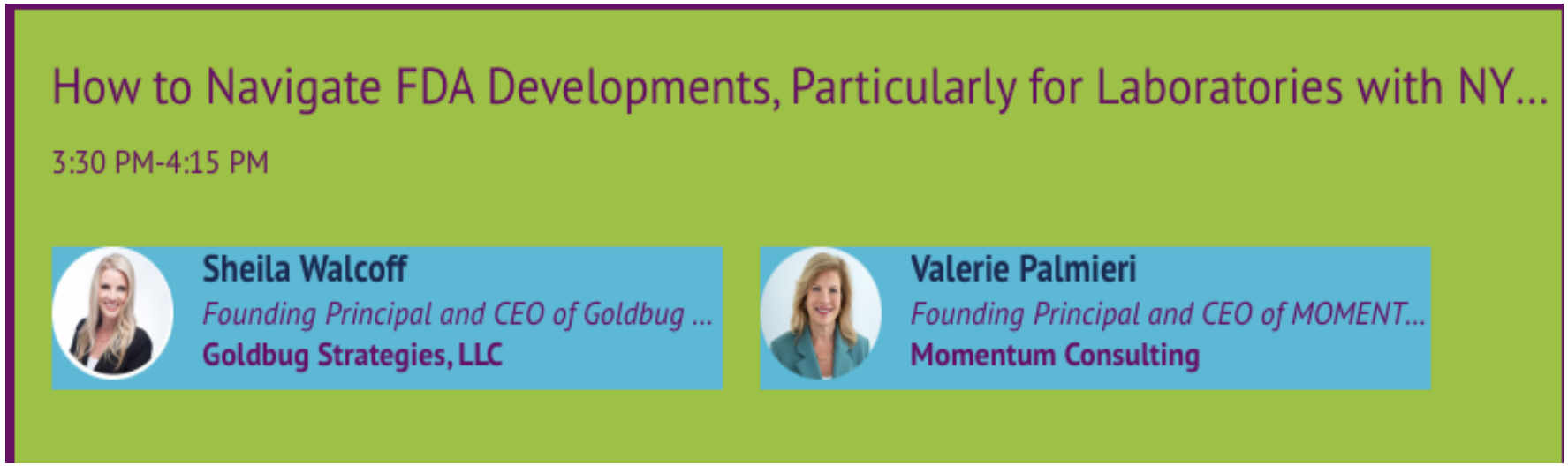
How to Navigate FDA Developments, Particularly for Laboratories with NYS CLEP



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☒ We have no financial conflicts of interest to disclose

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What's Next with FDA Oversight of LDTs?

Understanding the landscape post-District Court Decision and HHS/FDA rescission of the Final Rule:

- ✓ The next FDA enforcement paradigm
- ✓ Considerations for evaluating shifting financial and operational uncertainties

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NAVIGATING AN UNSTABLE FDA ENFORCEMENT PARADIGM

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- Former HHS senior official, FDA associate commissioner, and Congressional Committee counsel
- 20+ years advising disruptive biotech, LDTs/IVDs, and investors
- Emphasis on molecular AI/ML, digital pathology, LDTs/IVDs, cybersecurity, and CLIA/ISO/FDA/IVDR requirements

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Clinical lab tests: "LDT" or FDA medical device?

The Final FDA LDT Rule is history!

- HHS chose not to appeal the District Court Decision.
- FDA formal rescission of the Final LDT is in process at the WH; will be "official" when published in the Federal Register.

But…not all lab tests are "LDTs"

- District Court's definition of "LDT" is very narrow.
- There are an increasing number of FDA authorized LDTs (known as "single-site IVDs")
- FDA maintains authority over critical LDT components (e.g., reagents, instruments)

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NEW Definition of "LDT" is specific and narrow

The District Court defined a "laboratory-developed test" (LDT) as:

- ✓ **A methodology or process** by which a laboratory generates [...] forms of clinical information about a patient specimen **for use by the treating physician**.
- ✓ **Each laboratory** uses **its own unique knowledge** of the protocols, performance characteristics, and means of analysis **to develop** such methodologies and processes.
- ✓ A **proprietary methodology** performed **by only the developing laboratory**.

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NEW Definition of "LDT" is specific and narrow cont.

AND....

- ✓ Generates information from test results and transmits that information **to the ordering physician**
- ✓ Not sold as a kit, and **the protocol is not transferred in any manner** to other laboratories, hospitals, or other facilities outside the developing laboratory entity.
- ✓ No physical product is sold, **and no article of personal property is transferred such that title passes** from one party to another.

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Can FDA still require labs to comply with medical device regulations?

Yes. The District Court did **NOT** limit FDA's authority to regulate:

- Non-"LDT" clinical lab tests (i.e., outside Court's narrow definition)
- Reagents, instruments, software, databases, bioinformatics, protocols used by labs or in LDTs (e.g., labeled as "Research Use Only")
- Lab tests (e.g., protocols) developed by 3rd parties and sold or licensed to labs as LDTs (e.g., "RUO" with instructions for clinical use)
- Direct-to-consumer lab tests, often with self-collected specimens

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What does this mean for clinical labs?

Some lab/LDTs….**including those with NYS-CLEP**…are still at risk for FDA enforcement

✓ **YES** NYS labs offering non-"LDTs"/single-site IVDs

❓ **MAYBE** NYS labs furnishing unmodified IVD test kits can be FDA medical device "user facilities"

- E.g., limited FDA requirements ("register" & "listing" with FDA; adverse event reporting)

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Which labs/LDTs need to remain "FDA vigilant"?

Factors suggesting a NYS- CLEP test may **not** be an "LDT":

- In-licensing intellectual property used in a lab test (i.e., not lab's "unique knowledge)
- Out-licensing/asset sale of LDT test protocols to another lab
- Part of workflow is outsourcing to a reference lab
    - e.g., NGS sequencing, significant dry-lab component/cloud-based bioinformatics driving clinical results
- Protocols developed by a 3rd party lab services entity

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How can labs mitigate FDA enforcement risk?

- ✓ Establish robust quality systems: e.g., **ISO 13485 …in addition to NYS-CLEP**
- ✓ 'Voluntarily' seek FDA authorization (e.g., CDx)
- ✓ VERY careful attention to/review of advertising and promotion materials and activities (incl. website)
- ✓ Don't assume FDA can not enforce based on type of lab facility (E.g., NYS, anatomical pathology) or location (e.g., NYS)
  - FDA risk generally driven by "risk (type of test / claims about results)

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What's next? "Back to the future…."

Will Congress act to limit FDA oversight of LDTs?

- Maybe…but less likely near term given lack of LDT political momentum, other priorities, and lack of stakeholder incentives and consensus
    - Perception that problem has been "resolved" by District Court Decision and FDA rescinding LDT Rule

Will FDA revisit the LDT Guidance or other broad enforcement paradigms?

- Unlikely, given HHS/FDA action to rescind the LDT Rule and not appeal District Court Decision
- Near term FDA enforcement activities involving clinical labs/tests likely to be targeted to "higher risk" indications and other IVD products that are squarely within FDA's medical device authorities
    - CDx for treatment selection, RUO labeled, 3rd party lab test developers, LDTs with complaints in FDA MAUDE system
    - Agenda Biosciences 2024 Warning Letter for RUO labeled test intended for clinical use

What FDA seek to initiate greater oversight of LDTs after Trump 2.0?

- Under new POTUS/Administration, FDA could move further into the lab (e.g., Obama and Biden-era regulatory approaches)

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Playbook – Balancing Financial and Operational Needs in Times of Uncertainty

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- Executive leader of high growth disruptive Public and Private Biotech companies for over 35 years
- Served as Public Company Chairwoman, Board Member, CEO/President, and Founder
- Emphasis on esoteric testing, LDTs/IVDs with AI/ML, anatomic and digital pathology, operations and large scale P&L management

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3 months post formal ruling being vacated...

Seeing Four Operational Perspectives for CLEP labs...

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#1 Embrace QMS as a Strategy

Stage 1 Ruling Impact

- Large hospital systems w/major consolidation and disparate systems
  - 10yrs – 8000→6000 hosp (-25%)
- Centralization of customer complaints, CAPA and process improvements.
- ***Seizing the moment for change!***

Joseph M Juran Describes Big Q vs. Little q

Big "Q" – Management	Little "q" – Control
• Proactive and Process Focused • Organizational-wide • Prevention Oriented • Development through Sustainment • ISO 9001/AS9100	• Product Focused • Production Focused • Reactive • Appraisal Oriented • Inspection System

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#2 ID Exceptions → De-Risk Plan*

Today:

- Revenue Contribution
- Margin Contribution

Tomorrow:

- Investment $
- Insource/Outsource evaluation

*** Majority of labs**

- **RUO reagents**
- **Algorithms which may be reviewed as software as a medical device.**
- **Direct to consumer testing**
- **Tests that are "commercialized"/ sold as kits**
- **LDTs performed outside of the "validation laboratory"**

*With the above and your LDT's, audit your marketing tools, literature with **a fine tooth comb!***

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#3 and 4 All or Nothing...

1) Full QMS Strategy + Exceptions
2) Do Nothing

Since the rule has been vacated….

- Large hospital systems are embracing full QMS centralization and integration
  - Quality cost reduction. Moving from Reactive to Proactive….
- Most labs have completed Stage 1 and are creating an exception plan- RUO, DTC, etc.
- Very few are doing nothing!

Considerations on How to Operationalize and Review Financial Impact

SUMMARY

- Higher Quality = $$$$ 
- Understand potential LDT exceptions
- Understand budget implications
- Have a plan to mitigate FDA enforcement risk

QUESTIONS?