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AMDM Focus Meeting

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AI/ML AND BEYOND - FDAS NEW PCCP AUTHORITY

Sheila D. Walcoff, J.D.

PCCPs - hottest new regulatory tool!

I. New FDA authority

II. AI/ML applications lead the way

III. No AI/ML component required

IV. Case Study – 23andMe's PGS test

V. Game changer for LDTs under pending LDT rule!

VI. FDA survival tips for LDTs

VII. A peek at the future from Los Gatos, CA

New FDA authority

Express authority for FDA granted in "FDORA" - *Food and Drug Omnibus Reform Act ("FDORA")**

- ✓ Expanded scope…but with some increased rigidity
- ✓ Goes beyond VALID Act "technical certification" provision
- ✓ Must be established through an FDA submission (e.g., De Novo, 510(k), PMA, PMA Supp.)
- ✓ Builds on earlier "PCCP" approaches more limited in scope:
  - ➢ Analytical changes in VDs/LDTs (e.g., MSK IMPACT DeNovo and NGS Guidance)
  - ➢ Machine learning algorithms

*See sec. 3308 of FDORA, Title III of Division FF of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022, which added section 515C to the FD&C Act.

AI/ML applications lead the way

FDA moved rapidly to implement its new PCCP authority…

- ✓ **April 2023** – FDA published draft guidance for AI/ML *Machine Learning-Enabled Device Software Functions ("ML-DSFs")*
- ✓ 3 major components of an "Authorized PCCP"
  1. Description of Modifications
  2. Modifications Protocols
  3. Impact Assessment

As with everything FDA – your focus should be on the details…

No AI/ML component required

What????...Didn't FDA limit the scope of PCCPs when it published the Draft Guidance for AI/ML PCCPs?... **Nope.**

- ✓ First PCCP draft guidance was focused on AI/ML applications, but the law is clear – PCCPs can be applied to all medical devices
- ✓ FDA reiterated this during its April 2023 Webinar on the Draft Guidance
  - ➢ *This provision applies to all devices—it is not specific to AI/ML-enabled devices or software devices. It applies to both premarket approval (PMA) applications and 510(k) applications.*
- ✓ **August 2023** – FDA clears first Authorized PCCP for IVD *without AI/ML*
- ✓ **October 2023** – FDA's FY 2024 Draft Guidance Agenda indicates plan for more PCCP guidance applicable to IVD/LDTs

Case Study – 23andMe's PGS Test

FDA authorized an expansive PCCP for continuous modification of 23andMe's PGS test report for BRCA1/BRCA2

- ✓ 510(k) submitted to add new variants & cancers to a previously authorized DTC hereditary cancer predisposition test
- ✓ 23andMe's PGS test includes software, but not AI/ML
- ✓ Company worked collaboratively with FDA to develop a PCCP template for authorized modifications to IVD that would otherwise be "substantial changes" requiring FDA review
  - ➢ Includes changes that require additional clinical, analytical, & software validation
  - ➢ Covers labeling modifications

Game changer for LDTs under FDA

PCCP is a regulatory tool *already in place* to support significant changes to LDTs *without additional FDA submissions*

- ✓ Uses a test-specific approach focused on processes, procedures & documentation
- ✓ Relies on FDA's early focus on LDT quality systems compliance to mitigate the risk of such ongoing modifications inherent to lab tests
- ✓ Opportunity for labs to manage anticipated increase in COGS due to submission costs & delays
  - ➢ Initial investment in quality systems and detailed PCCP can result in significant long-term savings!

FDA survival tips for LDTs

If finalized, FDA's Proposed Rule would end enforcement discretion for most LDTs

- ✓ **Mind the gap.** Understand what you have vs. what you will need
- ✓ **Act strategically.** Leverage what you have for basic lab QMS gapfill & build out SOPs needed to support product specific PCCPs
- ✓ **Skip the beauty pageant**. The best QMS design is the one that your team can and will follow operationally
- ✓ **Focus on SOP controls.** Documentation is the way to keep the FDA design/change control nightmares away

A peek at the future…

Game of Thrones for FDA Leadership…

- Dr. Robert Califf
- Dr. Jeff Shuren
- Dr. Tim Stenzel
- Dr. Courtney Lias

Groundhog Day for the clinical laboratory industry…