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FDA Proposed Rule – Medical Devices and Laboratory Developed Tests

Fast Facts

- Published in the Federal Register on 10/3/2023: Docket No. FDA-2023-N-2177
- Comment period through 12/3/2023
- This rulemaking would amend the definition of "in vitro diagnostic products" in FDA regulations to state that IVDs are devices under the FD&C Act "**including when the manufacturer of these products is a laboratory**."
- FDA recognizes potential public safety concerns if not managed appropriately, so there will be a 4-year phaseout of their general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured in a lab would fall under the same enforcement as other IVDs.
- The proposed phaseout of FDA's general enforcement discretion approach is designed to redress the imbalance in oversight and protect the public health.
- There are noted exceptions to the phase out approach for IVDs offered as LDTs. This list has never fallen within the scope of the FDA general enforcement discretion approach (see below).
- **The FDA is seeking comments on other potential carve outs for Academic Medical Centers (AMC):** FDA has received feedback that IVD's created in AMC labs should be exempt from this updated definition. FDA is seeking comments to understand how AMC labs are unique/different and why that might mean the FDA applies the general enforcement discretion approach rather than apply the updated regulatory definition.
- FDA anticipates that the benefits of phasing out their general enforcement discretion approach for LDTs would include a reduction in healthcare costs associated with several things, including unsafe or ineffective tests, and from therapeutic decisions based on the results of those tests.

Background

- Since the Medical Device Amendments of 1976 (MDA), "the FDA has generally exercised enforcement discretion such that it generally has not enforced applicable requirements for most LDTs."
- The FDA recognizes that the LDT landscape has significantly evolved since 1976. "Today, many LDTs rely on high-tech or complex instrumentation and software to generate results and clinical interpretations. They are often used in laboratories outside of the patient's healthcare setting and are often manufactured in high volume for large and diverse populations."
- **FDA is concerned that firms are offering IVDs as "LDTs" when they aren't LDTs (because they're not designed, manufactured, and used within a single laboratory).**

Scope

- "While FDA's general enforcement discretion approach has been focused on LDTs, FDA is proposing a broader scope for the phaseout policy. Specifically, FDA is proposing to apply the

phaseout policy to IVDs that are manufactured and offered as LDTs by laboratories that are certified under CLIA and that meet the regulatory requirements under CLIA to perform high complexity testing, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory."

Exceptions

- The FDA recognizes that not all labs have understood the limited nature of FDA's general enforcement discretion approach and have been offering IVDs based on the approach even when they don't fit what the FDA would consider to be an LDT.
- The tests below are not part of the phaseout approach as they have never fallen under the FDA general enforcement discretion approach:
    1. "Tests that are intended as blood donor screening or human cells, tissues, and cellular and tissue-based products (HCT/Ps) donor screening tests required for infectious disease testing under 21 CFR 610.40 and 1271.80(c), respectively, or for determination of blood group and Rh factors required under 21 CFR 640.5."
    2. "Tests intended for emergencies, potential emergencies, or material threats declared under section 564 of the FD&C Act."
    3. "Direct-to-consumer tests. FDA's general enforcement discretion approach has not applied to tests intended for consumer use (without meaningful involvement by a licensed healthcare professional), given the greater risks to patients presented by these tests."

Continued General Enforcement Discretion Approach

- The following list are tests that the FDA does apply the general enforcement discretion approach:
    - "For certain categories of tests manufactured by laboratories, FDA is proposing to continue to apply the current general enforcement discretion approach going forward. One such category of tests is referred to in this preamble as "1976-Type LDTs.""
    - "FDA is also proposing to continue to apply the general enforcement discretion approach to Human Leukocyte Antigen (HLA) tests that are designed, manufactured, and used in a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and "virtual" HLA crossmatch tests."
    - "FDA also intends to maintain its longstanding enforcement discretion approach for tests intended solely for forensic (law enforcement) purposes."
    - "In addition, tests exclusively used for public health surveillance are distinct from other tests where: (1) they are intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control, and (2) test results are not reported to patients or their healthcare providers. These tests would not be affected by the phaseout policy."