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Tips For Responding to FDA's Proposed Rule on Laboratory Developed Tests (LDTs)

Who should comment on the FDA proposed rule?

- All interested stakeholders should consider submitting their own comments in response to the FDA proposed rule on regulating LDTs. This includes entities such as academic medical centers, clinical testing laboratories, public health laboratories, testing companies, hospitals/clinics, professional organizations, patient organizations, etc. We also encourage individuals to submit their own comments, including healthcare professionals that order clinical testing, laboratory professionals, patients, healthcare advocates, etc.
- When possible, we encourage submission of separate comments rather than stakeholder sign-on letters.

How do I submit comments on the proposed rule?

- Comments should be submitted electronically to the Federal Register, Docket number FDA-2023-N-2177 here. Comments must be submitted by 5:00pm ET on December 4, 2023. Despite requests from a variety of stakeholders, the FDA has announced that they will not extend this deadline.
- Comments submitted to the Docket are public. DO NOT include confidential information if submitting a comment to the Docket. You can view the comments submitted to date here.
- Alternatively, comments may be submitted by traditional mail. Use this option if you intend to include confidential information. Instructions for submitting written/paper comments can be found here, under the section labeled "Addresses".

How should my response be formatted?

- Comments can be submitted directly into the online Federal Docket form using plain text or as an attachment (e.g., PDF). Some commenters choose to submit comments in the form of a letter that is attached to the online form. If using a letter format, the letter can be addressed to:

  Robert M. Califf, M.D.
  Commissioner, U.S. Food and Drug Administration
  10903 New Hampshire Avenue
  Silver Spring, MD 20993

What changes are included in the proposed rule?

- The proposed rule would modify the regulatory definition for in vitro diagnostic products (IVDs) to say that IVDs are considered devices under the FD&C Act "*including when the manufacturer of these products is a laboratory*".
- All LDTs would be viewed as the same as manufactured and distributed test kits and regulated as medical devices.
- The proposed rule also lays out the FDA's plan to roll out enforcement of medical device regulations on LDTs over a four-year period.
- The FDA estimates that approx. 50% of LDTs would require some form of premarket review.
- Clinical testing laboratories would be required to pay user fees for each test requiring premarket review and establishment registration fees. Many labs will also need to hire dedicated regulatory staff to manage the development and submission of lengthy application requirements to FDA.
- Additional details of the proposed rule can be found here.

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What to include in a letter?

- Clinical testing laboratories/laboratory professionals
    - How would the proposed rule impact your test offerings? E.g., your ability to continue in-house testing vs. outsourcing
    - How would this impact the sustainability of your lab in general?
    - Include information about personnel requirements and the role of board-certified laboratory professionals in developing LDTs. Consider how this differs from personnel working for test kit manufacturers.
    - What factors influence your lab's decision to develop an LDT instead of using an FDA-approved IVD?
    - How would the FDA review process impact your lab's ability to accommodate specialized testing requests from ordering healthcare professionals?
    - How would the FDA review process impact innovation in clinical testing?
    - Include information explaining the difference between an IVD (i.e., manufactured test kit distributed and sold throughout the US) and LDT (i.e., procedure) performed in your laboratory.
    - Include information about the regulations that your lab already has to comply with (e.g., CLIA, NYS, CAP, etc.) and where FDA requirements would be duplicative and unnecessarily burdensome.
    - Include information about how your lab ensures quality and accuracy of clinical tests.
- Public health/newborn screening laboratories
    - How would the proposed rule impact follow-up diagnostic testing for babies with positive newborn screening results?
    - How would outsourcing f/u diagnostic testing impact turnaround times for diagnosing and treating affected babies, such as those with metabolic disease?
    - What is the volume of test ordering for f/u diagnostic tests? Even large testing facilities will likely have to consider the cost of taking a rare disease test through FDA in comparison to the volume of tests that would likely be ordered. How would this impact newborn screening programs?
- Healthcare clinics/hospitals/healthcare professionals ordering tests
    - How will reduction in test offerings affect patient care?
    - If you rely on in-house testing, how will this impact patients (e.g., test turnaround times) if more tests have to be outsourced?
    - If applicable, include information about how you work with clinical testing laboratories on specialized testing requests, such as alternative specimen types.
    - Include information about how you use results from LDTs to guide diagnosis and patient care decisions.
    - For those treating pediatric patients, keep in mind that many FDA-approved IVDs are approved for adults only. This means laboratories have to modify the test for use in pediatrics, thus turning it into an LDT.