FDA draft guidance document may limit patient access to tests

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The Association for Molecular Pathology (AMP) submitted comments to the US Food and Drug Administration on the draft guidance document titled, "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." AMP is very concerned that this guidance could compromise the quality of patient care by severely reducing the availability of certain reagents and laboratory developed testing services that have become the standard of care for many diseases or conditions. Specifically, if enforced in its broadest sense without sufficient accommodations for low test volume or sufficient time for manufacturers to achieve submission compliance, the draft guidance document could result in reduced availability of testing services would limit a healthcare provider's ability to manage patient care, and ultimately limit patient access to new or improved molecular tests.

"Some products used for laboratory tests are available only as research or investigational use only products," explained AMP Professional Relations Chair Dr. Elaine Lyon. "If this guidance were to be finalized, we're concerned that patients won't be able to access tests such as those for Hepatitis C genotyping, newborn screening and HLA testing," added Dr. Lyon.

AMP supports FDA clearance and approval of research use only (RUO) and investigational use only (IUO) products, especially test kits and test systems. However, to prevent disruption of patient care, accommodations should be made to ensure continued patient access to critical tests as manufacturers come into compliance and/or instances where low test volume would deter a manufacturer from submitting an application to the FDA for that product.

"While AMP appreciates the FDA concern over the use of RUO and IUO products in laboratory developed tests, the Association questions the underlying assumption that the guidance will encourage most manufacturers to seek clearance and approval for their RUO and IUO products," said Dr. Lyon. AMP members fear that instead of seeking FDA review, some manufacturers will choose to withdraw RUOs from the clinical market. This has already occurred for many analytes, from blood-borne pathogens to sexually transmitted diseases. This would then create a shortage of supplies to develop laboratory tests, resulting in a scarcity of tests, and ultimately, barriers for patients' access to medically necessary tests.

Dr. Lyon added, "Today we are asking the FDA to consider the downstream implications of the guidance on the supplies and materials for laboratory testing, and allow for circumstances where clinical laboratories can develop tests using RUO and IUO products when no other products are available."

AMP's recommendations include:

1. To avoid the disruption of patient care, carefully consider enforcement discretion or alternative regulatory pathways to address circumstances where no FDA cleared/approved products are available, particularly for those products with limited sales volume.

2. Direct enforcement requirements for 510(k) or PMA submissions toward test kits and test systems.

3. Create a consistent and clear pathway to encourage and facilitate ASR, 510(k) or PMA applications for RUO and IUO products, with a reasonable compliance timeline. The pathway must include flexibility to be responsive to rapidly evolving areas.

4. Accommodations should be made to enable certain reagents such as primer or probe mixes to be sold as ASRs. Alternatively, another regulatory

pathway could be designed for products that are too complex to qualify as ASRs but are not full test kits or test systems.

5. Clearly state the scope of the guidance. Clarify which products currently labeled as RUOs and IUOs the guidance covers, e.g., test kits, instruments, software, and reagents.

Provided by Association for Molecular Pathology