STATEMENT

of the

American Medical Association

for the Record

U.S. Food and Drug Administration

Public Workshop - Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)

January 8, 2015

Panel: Categories for Continued Enforcement Discretion

I am Katherine Johansen Taber, Director of Personalized Medicine within the American Medical Association's Division of Science and Biotechnology. The AMA appreciates the Food and Drug Administration (FDA) convening this workshop and providing stakeholders with the opportunity to comment on aspects of the Agency's draft guidance for regulation of laboratory-developed testing services.

Laboratory Developed Testing Services Constitute the Practice of Medicine

As a foundational matter, laboratory developed testing services constitute the practice of medicine, therefore it is not appropriate to apply commercial diagnostic kit regulations to them. Laboratory testing services are the technical expertise and clinical judgment of a physician who develops and validates the test and performs it under conditions that are already subject to oversight under the Clinical Laboratory Improvement Amendments (CLIA), and in many instances state regulators and third party accreditors. The physician makes a clinical determination as to what products to utilize, what patient sample preparation is needed, and what machines are used in order to perform the testing services. These are within the scope of a physician's practice and physicians have a legal responsibility for them. The physician's services cannot be packaged and shipped to multiple laboratories like a kit can be.

Scope and Nature of Needed Reforms

However, the AMA does support legislation that would modernize CLIA to enhance the oversight of laboratories where physician services are offered. And, for the purposes of today's meeting, the AMA is particularly concerned about tests that use complex, non-transparent, or proprietary algorithms to determine a result. These tests do not lend themselves to evaluation by physicians, and the AMA therefore believes that FDA oversight of this type of test may be appropriate.

Revise Proposed Carve-Outs

Without waiving our general legal objections and concerns about regulatory overreach, on the issue of continued enforcement discretion, we believe the proposed application of the regulatory framework to testing services for rare diseases, unmet needs, or emergency use is unworkable, dangerous to individual patients, and undermines public health.

Rare Diseases. Laboratory developed testing services are often the only option for those with suspected rare diseases since the commercial market for such tests is nearly non-existent. As currently written, the FDA's proposed exemption for rare diseases is inadequate in ensuring the continued availability of these services; its definition pertains to rarely-performed tests, not rare diseases. Because these tests often constitute a small volume of testing for most laboratories, subjecting them to FDA oversight requirements would result in many laboratories dropping the tests completely, leaving patients and physicians without an option for screening and diagnosis.

Unmet Needs. Similar to the lack of commercial availability for tests for rare diseases, many thousands of laboratory developed testing services exist because commercially-developed kits do not exist, that is, they fulfill "unmet needs." These services are for a broad range of conditions, and constitute the standard of care. For example, clinical guidelines recommend testing all newly-diagnosed colon cancers for Lynch syndrome. This type of testing has been available as a laboratory developed testing service for more than 10 years and has been continually improved-upon as new research data emerges. There are no FDA-approved tests for Lynch syndrome. This is true for thousands of laboratory-developed testing services. Yet, the FDA's proposed exemption for this "unmet needs" category ends as soon as a commercially-developed kit becomes available. When this happens, every laboratory that has previously developed a testing service would need to submit it to the FDA, likely as a pre-market approval application. The expense and burden required for such an activity would not be feasible for many laboratories, which would then decide not to continue offering testing. This would drive up costs, freeze further innovation and improvements, and leave patients without access to cutting-edge care.

Conclusion

In conclusion, we strongly urge the Agency to clearly define the scope of what it sees as the problem with laboratory developed testing services. To date, FDA has cited only a few anecdotal instances of problems with these services, some of which will not be solved by the proposed framework. We believe that a formal landscape analysis that clearly identifies the number, type, and scope of issues must be developed before such sweeping regulatory change is implemented.