FDA and CMS Joint Statement regarding LDT Oversight

See: *FDA and CMS: Americans Deserve Accurate and Reliable Diagnostic Tests, Wherever They Are Made | FDA*

> https://urldefense.com/v3/__https:/www.fda.gov/medical-devices/medical-devices-news-and-events/fda-and-cms-americans-deserve-accurate-and-reliable-diagnostic-tests-wherever-they-are-made__;!!NHLzug!LFmclY4fAM7ewQT5gXUPqYE67PHWYYqSxiQMzrz1RFg-vYkJ07uypAFYbZ_LDz3krk1d5q5ZoyZqcjCZDyBk8uk9GGCzbQ$

Of particular importance is the joint statement from CMS and FDA that CLIA should not have oversight of test development. Specifically, this part of the statement reads:

> "Some have suggested that concerns with LDTs should be addressed through expansion of CLIA. This is not the answer. As was stated in our 2015 testimony, CMS does not have the expertise to assure that tests work; the FDA does. Moreover, establishing a duplicative system for the oversight of tests by expanding CLIA would create more government bureaucracy and inconsistencies. That makes no sense."
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> Testimony link: https://urldefense.com/v3/__https:/democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-examining-the-regulation-of-diagnostic-tests-and-laboratory__;!!NHLzug!LFmclY4fAM7ewQT5gXUPqYE67PHWYYqSxiQMzrz1RFg-vYkJ07uypAFYbZ_LDz3krk1d5q5ZoyZqcjCZDyBk8umKMixQjQ$