Alternative Proposals for Lab Test Regulation

Are There Opportunities for Consensus?

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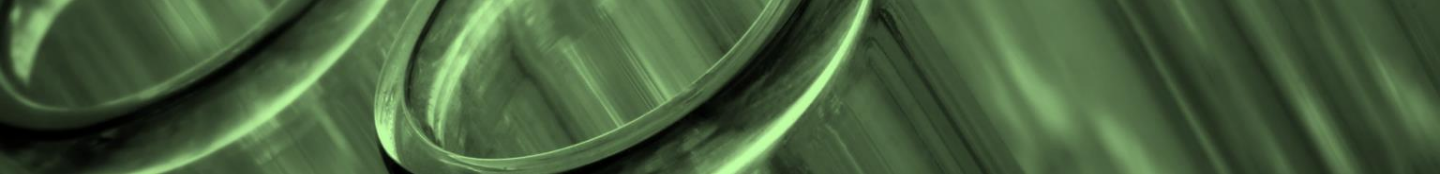


Amid Multiple Proposals on LDT Regulation, Are There Opportunities for Consensus?

By Turna Ray

The lab industry entered 2016 in a staring contest with the US Food and Drug Administration that began two years ago when the agency released its draft guidance on regulating laboratory-developed tests (LDTs).

During the course of 2015, pathologists and lab industry players fought the agency's bid to regulate LDTs on several fronts. The American Clinical Laboratory Association (ACLA) hired lawyers to build a legal argument against FDA's authority to regulate the tests and there was a congressional hearing in November to discuss the matter.

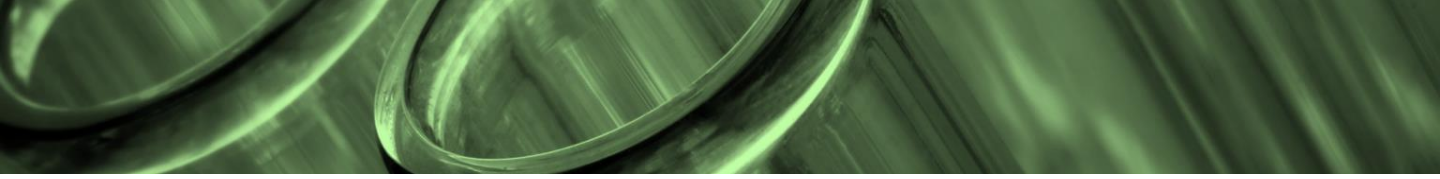
Underscoring the discord in the lab community on this topic is the fact that several groups issued alternative regulatory proposals during 2015. Three influential organizations — the Diagnostic Test Working Group, the Association for Molecular Pathology, and the College of American Pathologists — have taken regulatory proposals to Congress, while other stakeholders are working with the FDA and legislators on finding a solution to the LDT oversight issue.

CAP, which issued a regulatory plan in October, wants to improve regulation for the majority of LDTs through the Clinical Laboratory Improvement Amendments, the framework administered by the Centers for Medicare & Medicaid Services under which LDTs have been regulated since 1992. However, the organization wants FDA oversight for high-risk tests, including tests that "produce a result that is not independently verifiable."

Under AMP's approach, released in August, all lab-developed testing procedures (LDPs) — a term the group maintains more accurately describes the role of labs than LDTs — would be overseen under CLIA. However, AMP proposes that if a laboratory offering so-called multi-analyte algorithm-based assays (MAAAs), which are tests using proprietary algorithms, does not want to reveal those procedures to third-party reviewers, then it can submit the LDP for review by the FDA.

The DTWG's plan, meanwhile, would create a whole new category of tests, dubbed *in vitro* clinical tests (IVCTs) — a term comprising LDTs and kits. Under this plan, FDA would have authority over test development and validation, CMS would remain in charge of traditional lab activities necessary to perform tests, and states would oversee accuracy of test interpretation. DTWG involves Becton Dickinson, Roche, Mayo Clinic, LabCorp, Abbott, and ARUP Labs.

Meanwhile, the diagnostics manufacturers' group AdvaMedDx is standing behind an FDA-led risk-based framework for regulating all LDTs. The group hasn't taken a formal position on



these alternative proposals, but representatives from AdvaMedDx have indicated to GenomeWeb that regulatory plans that would subject only a subset of LDTs to FDA regulation are inconsistent with its policy stance.

The tables that follow this article outline the similarities and differences between these stakeholder positions. There are fundamental disagreements about whether FDA has the statutory authority to regulate LDTs at all, there are gradations of support for FDA playing a limited role, and there are finer sticking points that have long divided the lab and diagnostics industry, such as the oversight of proprietary, brand name assays versus non-proprietary "generic" tests.

All the plans have their own way of classifying tests into risk categories. Implementation times for these proposals vary from two years to nearly a decade. Some groups want to fund their proposed changes by completely relying on user fees under CLIA, other plans will require congressional appropriations and user fees to FDA.

The various groups have taken their position statements and alternative proposals to Congress, but as of this report, it's unclear where legislators stand. The House Energy & Commerce Committee has incorporated the DTWG's ideas into draft legislation, which was slated for discussion at a November hearing.

However, legislators spent the session grilling FDA and CMS officials about whether regulation of LDTs should be shared between the two agencies, whether one agency should take the brunt of the responsibility, or if the government should just stay out of it. Representatives from FDA and CMS both presented a unified front that FDA should oversee LDTs and that CMS lacked the resources to take up the task.

Meanwhile, the Senate has also expressed interest in addressing diagnostics regulation as it works on its version of the 21st Century Cures legislation, and according to experts following the process, may be amenable to an approach involving both CMS and FDA. The FDA is certainly aware of the alternative ideas stakeholders have put forth in response to its draft guidance, but the agency seems decidedly focused on finalizing guidelines this year.

If that happens, there's a risk that some in the lab industry will sue the agency. Absent a legislative solution, another, more optimistic possibility is that these different stakeholders with disparate interests — pathologists, labs, platform manufacturers, and diagnostics firms — will focus on areas of agreement and work with the FDA to advance a solution. Some stakeholders and labs are attempting just that, and have joined a coalition organized by the American Medical Association and facilitated by the Personalized Medicine Coalition to find common threads among the different proposals.

	What is being regulated?	Which agency is in charge?
FDA[1]	**Lab-developed tests (LDTs):** *in vitro* diagnostic tests that are designed, manufactured, and used within a single lab.	FDA extends its oversight for all LDTs in a three-tier risk-based framework. However, the agency wants to work with third party-reviewers, and sees a role for them in reviewing 510(k)s for lower risk LDTs. FDA and CMS have also formed a task force to ensure labs won't have duplicative requirements and to identify areas of commonality between FDA's quality systems regulations and CLIA requirements.
DTWG[2]	**In vitro clinical tests (IVCTs):** diagnostic test kits (referred to as "finished products") and lab test protocols intended by the developer for use in the collection, preparation, analysis, or in vitro clinical examination of specimens from the human body in the context of a disease or condition.	• FDA regulates IVCT design, development, validation, platform manufacturing, and preparation of reagents for use in more than one CLIA lab or third party; • CMS keeps jurisdiction over typical lab activities, such as preparing reagents used at a single lab, developing lab operating procedures, pre-analytical processes, performing an IVCT, and reporting the IVCT output; • The states continue to look after interpretation of test results.
AMP[3]	**Lab-developed testing procedures (LDPs):** testing procedure or service performed in a single CLIA-certified lab, where the development, validation, monitoring, quality assurance, continuous improvement, performance, and interpretation of the results of that procedure/service are conducted.	• CMS regulates LDPs under CLIA considered low, moderate, and high risk. • CMS develops minimum standards, utilizing advisory board of subject matter experts, and establishes a mechanism for laboratories to appeal classification of individual tests. • CMS or designated third parties review proprietary LDP data, but labs can choose not to disclose proprietary data and instead submit their tests to FDA. • CMS develops continuously updated, searchable database with information on all high- and moderate-risk LDPs. • CMS will establish a process for approving third-party reviewers.
CAP[4]	**LDTs:** lab procedure that is intended to be designed, manufactured, and performed in a single, CLIA-certified lab.	• Provides statutory authority to FDA to regulate high-risk LDTs but not moderate- or low-risk LDTs. Would require amending Federal Food, Drug, & Cosmetic Act. • CMS under CLIA regulates moderate- and low-risk LDTs, but not high-risk LDTs. Would require amending CLIA provisions of the Public Health Service Act.
AdvaMed[5]	***In Vitro* Diagnostic Products (or IVDs):** reagents, instruments, and systems intended for use in diagnosis of diseases or other conditions in order to cure, mitigate, treat, or prevent disease or its sequela.	The group hasn't issued an alternative regulatory proposal, but has long supported a risk-based approach to regulation of all diagnostics, which calls for improving the current oversight framework for diagnostics, including companion diagnostics, with FDA at the helm. AdvaMed has submitted comments in response to FDA's draft guidance for regulating LDTs, and believes that the definition of a medical device in the Federal Food, Drug, and Cosmetic Act comprises LDTs.
ACLA[6]	The group has not issued an alternative regulatory proposal. ACLA maintains that the FDA does not have the statutory authority to regulate lab-developed tests, which the lab group defines as lab procedures and not medical devices in interstate commerce.	Refer to statement in column 1.

[1]Above information from FDA draft guidance and publicly available reports.
[2]The Diagnostic Test Working Group involves BD, Roche, Mayo Clinic, LabCorp, ARUP Labs, and Abbott. Above information from DTWG proposal.
[3]The Association for Molecular Pathology includes as members pathologist and doctoral scientist lab directors, as well as individuals from academic and community medical centers, government, and industry. Above information from AMP proposal.
[4]The College of American Pathologists represents board-certified pathologists and inspects and accredits labs under deemed CMS authority. Above information from CAP proposal.
[5]AdvaMed is a medical device trade association. Above information from AdvaMed's public comments to FDA draft LDT guidance.
[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

	High risk: Definition	High risk: Requirements
FDA[1]	Class III: high-risk tests regulated under general controls and usually requiring premarket approval. [*The FDA has said it will issue additional guidance on risk classifications and form advisory panels — Ed.*]	Registration, listing, and medical device reporting; premarket review and quality systems requirements enforced in a risk-based, phased-in manner. [*FDA will announce a priority list within 24 months of guidance finalization — Ed.*]
DTWG[2]	An IVCT for a serious or life-threatening disease or disorder that is the sole determinant for directing or changing treatment, where the wrong result has a high risk of serious health injury, and the test is not well characterized.	Submit to FDA prior to commercialization: reports that provide "reasonable assurance" of safety and efficacy of the IVCT's intended use from published or known sources; summary description of the IVCT's components and characteristics; a declaration of conformity to quality requirements. Inspection is not a condition of approval. FDA must make a decision within 90 calendar days.
AMP[3]	An LDP for diagnosis, predicting risk, or estimating prognosis of a disease that is associated with significant morbidity or mortality; and which includes methodologies such as proprietary algorithms, for which test results cannot be directly tied to analytical data or subjected to inter-laboratory comparisons. Multi-analyte algorithm based assays (MAAAs) are an example of a type of test that may be high risk. Third-party reviewers can choose to review only moderate-risk tests, and won't be required to review high-risk LDTs as a condition of approval as a reviewer.	• Submit evidence of analytical and clinical validity. • Subject to standard publication requirements. • CMS and third-party reviewers will evaluate pre-introduction submissions in 90 days. If that timeline isn't met, the LDP is presumptively approved. • Labs must disclose proprietary information only to reviewers.
CAP[4]	An LDT that produces a result that is not independently verifiable and the consequences of an incorrect result or interpretation include a high risk of serious morbidity/mortality. (Examples: Tests to gauge risk of disease progression or patient eligibility for therapy; or tests that use proprietary algorithms and cannot be subject to inter-laboratory comparisons.)	Subject to FDA premarket and postmarket requirements; CMS and third-party accrediting bodies assess compliance.
AdvaMed[5]	In statements, AdvaMed has supported use of a risk-based, phased approach by FDA to regulate LDTs. The group maintains that tests present the same risk to a patient, regardless of where they are made. In AdvaMed's view, the degree of regulation of a diagnostic test should be determined by the risk the use of the test result presents to patients. Regulators should also consider novelty of the analyte and technology, and other mitigating factors.	Most tests would be low- or moderate-risk devices and would not require PMA, but would be subject to premarket notification or 510(k). AdvaMed has asked FDA to focus its resources on tests that pose higher risks to patients while considering additional exemptions from premarket review for low risk, well-established tests. Among recommendations: • Agrees with FDA that if a test maker represents the test as being used in the context of a disease, condition, or treatment, the test's analytical and clinical validity must be established; • Supports better use of available scientific data, including published literature, to establish clinical validity of diagnostics; • Suggests that the FDA, in cases where it exercises enforcement discretion over certain LDTs, require labs to inform doctors that the test has not been cleared or approved by FDA; • Labs should follow quality systems regulations in developing LDTs but AdvaMed would like FDA to clarify aspects of this issue through additional guidance.
ACLA[6]	Refer to statement on page 4.	Refer to statement on page 4.

[1]Above information from FDA draft guidance and publicly available reports.
[2]The Diagnostic Test Working Group involves BD, Roche, Mayo Clinic, LabCorp, ARUP Labs, and Abbott. Above information from DTWG proposal.
[3]The Association for Molecular Pathology includes as members pathologist and doctoral scientist lab directors, as well as individuals from academic and community medical centers, government, and industry. Above information from AMP proposal.
[4]The College of American Pathologists represents board-certified pathologists and inspects and accredits labs under deemed CMS authority. Above information from CAP proposal.
[5]AdvaMed is a medical device trade association. Above information from AdvaMed's public comments to FDA draft LDT guidance.
[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

	Moderate risk: Definition	Moderate risk: Requirements
FDA[1]	Class II: moderate- to high-risk tests regulated under general and special controls and usually requiring 510(k).	Registration, listing, and medical device reporting; premarket review and quality systems requirements enforced in a risk-based manner, phased in after Class III products. [*FDA will announce a priority list four years after guidance finalization — Ed.*]
DTWG[2]	An IVCT that would be high risk, but it is well characterized and is unlikely to have a serious health impact due to a wrong result; or IVCTs that are not well characterized, not the sole determinant for directing or changing treatment; and where wrong results may cause a serious health injury.	Submit to FDA prior to commercialization: data that establishes analytical validity and "reasonable belief" in clinical validity. If FDA doesn't respond in 60 calendar days the IVCT is considered approved. Improved third-party review process will be developed for moderate-risk submissions.
AMP[3]	An LDP for diagnosis, predicting risk, estimating prognosis of, or predicting therapeutic response for a disease that is associated with significant morbidity or mortality and for which the test methodology lends itself to interlaboratory comparisons or proficiency testing.	• Submit evidence of analytical and clinical validity. • Subject to standard publication requirements. • CMS and third-party reviewers will evaluate pre-introduction submissions in 30 days. If that timeline isn't met, the LDP is presumptively approved. • LDPs introduced prior to enactment are exempt from pre-introduction review. • LDPs introduced before April 24, 2003, are exempt from review and publication requirements.
CAP[4]	An LDT producing an independently verifiable result and the risk of serious injury, morbidity, or mortality due to an incorrect result or interpretation is moderate or high. (Example: Tests for gauging disease prognosis or determining treatment eligibility where the lab makes clinical accuracy claims.)	• HHS Secretary or accrediting body informs lab that an LDT is “moderate risk” • Lab must submit information on analytical and clinical validation to accreditors for review. • Upon approval from accreditors that test meets analytical and clinical validity criteria, and lab meets standards, the test can be offered commercially.
AdvaMed[5]	Refer to definition on page 5.	Refer to requirements on page 5.
ACLA[6]	Refer to statement on page 4.	Refer to statement on page 4.

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[2]The Diagnostic Test Working Group involves BD, Roche, Mayo Clinic, LabCorp, ARUP Labs, and Abbott. Above information from DTWG proposal.
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[4]The College of American Pathologists represents board-certified pathologists and inspects and accredits labs under deemed CMS authority. Above information from CAP proposal.
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[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

	Low Risk: Definition	Low Risk: Requirements
FDA[1]	Class I: low- to moderate-risk tests regulated under general controls, and usually exempt from premarket 510(k) notification	Registration, listing, and medical device reporting
DTWG[2]	An IVCT that carries a risk of serious injury due to a wrong result but is not the sole determinant for directing or changing treatment and is well characterized; or an IVCT where a wrong result doesn't have a serious or life-threatening impact.	Notify FDA within 10 days of commercialization, including IVCT name, intended use, and a summary explanation.
AMP[3]	• An LDP that isn't appropriately used as the sole determinant of diagnosis, prognosis, or therapy selection; or for which an incorrect LDP result is unlikely to result in morbidity or mortality. • LDPs for rare diseases, public health emergencies, infectious agents that are not serious public health threats are also in this category.	• Exempt from pre-introduction review. • Labs validate the LDP and put it into service.
CAP[4]	An LDT producing an independently verifiable result and the risk of serious morbidity or mortality due to an incorrect result or interpretation is low. (Example: Tests are used alongside other information to establish or confirm diagnosis, and the lab doesn't make claims that the test is the sole determinant of prognosis or treatment strategy).	• Labs internally establish analytical validation and determine "adequacy" of clinical validation prior to market introduction. • Accreditors would verify validation studies during normally scheduled inspections.
AdvaMed[5]	Refer to definition on page 5.	Refer to requirements on page 5.
ACLA[6]	Refer to statement on page 4.	Refer to statement on page 4.

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[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

	Exclusions & Unique Aspects	What happens if an already regulated lab test or procedure is changed?
FDA[1]	• LDTs used in forensics and those for transplantation performed in high-complexity, CLIA-certified labs are exempt; • Traditional, rare disease, and unmet needs LDTs have to meet registration, listing, and reporting requirements; • LDTs with the same intended use as cleared/approved companion diagnostics, approved Class III devices, and certain tests to gauge safety/efficacy of blood products have to list, register, and meet premarket requirements within a year of guidance finalization for currently marketed LDTs or after finalization for new LDTs. Quality system requirements are enforced once a PMA is submitted or FDA issues a clearance order.	A lab that modifies an FDA-cleared/approved device in a manner impacting its performance or intended use, such as altering the type of sample gauged, the kind of analysis performed, the test's purpose, or its target population, is subject to premarket submission requirements.
DTWG[2]	• IVCTs are a standalone regulatory category; • Investigational-use IVCTs are outside FDA oversight unless they pose significant risk; research-use IVCTs are beyond FDA and CMS oversight and not subject to regulatory requirements; rare disease and emergency-use IVCTs are subject to special premarket requirements that enable rapid commercialization; unmet need IVCTs are regulated as moderate-risk IVCTs. • Labs with IVCTs commercialized before legislative enactment or before new regulations become effective have flexibility in the way they inform FDA of analytical and clinical validity data. • Harmonize terms across agencies.	Modification of high- and moderate-risk tests triggers submission to FDA if the change has a meaningful clinical impact, such as a different patient diagnosis, or alters the IVCT intended use. For low-risk IVCTs, no FDA submission is necessary unless the change alters the risk classification to a higher category. Examples of modifications that wouldn't be subject to review include altering the specimen type and changing from a manual to an automated process.
AMP[3]	• Exemptions: LDPs for public health surveillance, compassionate use, and LDPs with approval from CLIA-exempt states that evaluate analytical and clinical validity before tests are placed into use; • Labs that have successfully launched approved LDPs in the same or higher risk classification will gain conditional approval to begin testing with LDPs using similar technologies until a review is conducted; • Expand the proficiency testing requirements for LDPs and regularly update the list of analytes for which proficiency testing is mandated.	If the contact, certification, or licensure information for a laboratory changes, the lab submits an update form and LDPs are not subject to additional review. If LDP performance characteristics change "significantly" or if changes result in reclassification of an LDP into a higher risk category, a new review is required. For non-material changes to LDP characteristics, the lab can submit an update form without review.
CAP[4]	• Tests for public health emergencies are exempt from premarket requirements and LDTs that hold exempt status under CLIA won't be subject to duplicative requirements; • Tests marketed before April 23, 2003, are exempt from requirements; • LDTs for rare diseases, unmet needs, traditional and low-volume LDTs, and public health lab tests don't require premarket review, but must submit premarket notification. However, the HHS Secretary may deem premarket review necessary for certain tests in the category; • Establishes a process where validation summaries of moderate-risk tests are publicly available.	Labs will have to report to accreditors any change to a moderate- or low-risk LDT that imparts a "meaningful clinical impact," defined as an alteration that results in a change to patient diagnosis or therapeutic strategy. The accreditor determines if the change requires premarket review for moderate-risk tests.
AdvaMed[5]	The group supports regulatory flexibility for diagnostics, including LDTs, for certain unmet needs and calls for expanding the limit for humanitarian use devices beyond diseases impacting 4,000 individuals in the US.	Changes to LDTs that could significantly affect safety or effectiveness warrant a new submission. "We think it will be helpful to emphasize to laboratories that not all changes trigger submissions to FDA," AdvaMed states in comments to the FDA draft LDT guidance.
ACLA[6]	Refer to statement on page 4.	Refer to statement on page 4.

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[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

	Adverse events or lab errors in reporting results	How will it be funded?	Years to implement
FDA[1]	Medical device reporting regulations apply. Medical device manufacturers must report to FDA information "reasonably suggesting" a marketed device has caused or contributed to a death or serious injury, and report test malfunctions that could cause such events.	User fees; congressional appropriations.	9
DTWG[2]	Report to FDA any IVCT error "reasonably believed" to have caused serious injury or death, or could lead to such if the error happened again. [*An IVCT error is when the test fails to perform as intended, not including errors in lab operations or errors due to human factors — Ed.]*	User fees will contribute around 25 percent of needed funds. User fee amounts should track with risk of IVCT for high-/moderate-risk tests. Small businesses will see reduced fees. Corporations, but not individual facilities, will be subject to registration fees. CLIA fees will be credited against FDA fees. FDA will have to agree to performance goals.	3 to 4
AMP[3]	• Labs must report result errors to person ordering test; record the errors; document complaints and problems reported to the lab; conduct investigations; issue a corrected report (currently required under CLIA); • Third-party reviewers must notify CMS within 10 days when lab deficiency may present serious risks to patients or the public health; • Labs must establish a mechanism to enable ordering doctors to report possible lab errors. When investigations reveal potential hazards to patients, labs must report that to CMS. CMS will communicate this information to the public through the database it creates.	User fees under CLIA commensurate with the number and aggregate volumes of LDPs performed by labs, with fees limited to cost recovery. Public health labs will be exempt from paying fees beyond those for standard accreditation inspections.	4
CAP[4]	The proposal requires the HHS Secretary to develop a public mechanism for reporting. Adverse events will be reported to the HHS Secretary or accrediting bodies. Labs that believe a moderate- or low-risk test may have caused death or serious injury must investigate the event. If the lab determines that test may have caused such an event, it must be reported to the Secretary within 10 days. Labs must maintain reports of all investigations and reports.	User fees under CLIA	2
AdvaMed[5]	• Test makers should be required to report adverse events; • AdvaMed recommends FDA create a new section in the LDT guidance or the Notification/Medical Device Reporting guidances to clarify aspects of adverse event reporting; • Supports implementation of adverse event reporting system.	AdvaMed supports FDA's enforcement of its regulatory oversight for LDTs using a combination of user fees and congressional appropriations as it does for review of all medical devices. The association notes that by employing a risk-based approach for oversight of all diagnostics, FDA will be able to focus its resources on higher-risk diagnostic tests and make more efficient use of its existing infrastructure and substantial expertise.	No comment
ACLA[6]	Refer to statement on page 4.	Refer to statement on page 4.	Refer to statement on page 4.

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[6]The American Clinical Laboratory Association is the advocacy group for the clinical lab industry. Above information from ACLA white paper.

Resources

Alternative Regulatory Framework Proposals

US Food and Drug Administration, October 2014: Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)

Diagnostic Test Working Group, March 2015: A Proposed Regulatory Framework for In Vitro Clinical Tests

Association for Molecular Pathology, August 2015: Proposal for Modernization of CLIA Regulations for Laboratory Developed Testing Procedures (LDPs)

College of American Pathologists, October 2015: Legislative Proposal for the Regulatory Framework of Laboratory-Developed Tests (LDTs)

AdvaMedDx, January 2015: Public Comments to FDA Draft LDT Guidance

American Clinical Laboratory Association, January 2015: Laboratory Testing Services, as the Practice of Medicine, Cannot Be Regulated as Medical Devices

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Recent GenomeWeb Reports on LDT Regulation

January 13, 2016: Q&A: FDA's Gutierrez, Mansfield Discuss Regulatory Efforts in 2015; Set 2016 Expectations

December 31, 2015: In 2015, Precision Medicine Options Grew; FDA, Labs Still at Odds; Payment Remained Mostly Elusive

December 16, 2015: Pathologists' Group Accuses FDA of Making 'Dubious Claims' in LDT Harms Report

November 17, 2015: House E&C Committee Questions FDA, CMS About Scope of LDT Regulatory Problem

August 7, 2015: Pathologists Take Alternative Lab Test Regulation Proposal to Senate

July 31, 2015: At AACC, Clinical Labs Air Concerns Regarding FDA's Draft LDT Guidance

June 17, 2015: Seeking Broader Support, House Committee Moves Dx Regulatory Proposal into Draft Legislation