January 5, 2015

Chairman Fred Upton
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

DELIVERED ELECTRONICALLY

RE: Response to December 9th, 2014 White Paper, "21st Century Cures – Request for Feedback: A Modernized Framework for Innovative Diagnostic Tests"

Dear Chairman Upton:

This letter is submitted on behalf of the American Clinical Laboratory Association (ACLA) in response to the Energy & Commerce (E&C) Committee's December 9th, 2014 White Paper entitled, "21st Century Cures – Request for Feedback: A Modernized Framework for Innovative Diagnostic Tests" (hereinafter "White Paper").

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories. Our diverse membership represents a broad array of clinical laboratories, including national independent labs, reference labs, esoteric labs, hospital labs, and nursing home laboratories. ACLA members are actively engaged in the creation and performance of innovative and much-needed Laboratory-Developed Testing services (LDTs) that have helped transform the standard of clinical care in the country and provide great hope for further improvements.

ACLA applauds the 21st Century Cures Initiative launched in partnership with Rep. Diana DeGette and your continued recognition of the value of diagnostics and the need for robust innovation in, and patient access to, clinical laboratory services. As ACLA testified before the E&C Health Subcommittee on September 9th, 2014, these services are integral and longstanding components of the practice of medicine. They also enable and guide diagnostic and treatment decisions by physicians and patients. [1] First and foremost, ACLA strongly advocates policies that will ensure robust and undisrupted patient access to innovative, accurate, reliable, and meaningful clinical laboratory diagnostic services.

[1] Mertz, Alan, "Statement of Alan Mertz, President, the American Clinical Laboratory Association for U.S. House of Representatives, Energy and Commerce Committee, Subcommittee for Health, Hearing on '21st Century Cures: Examining the Regulation of Laboratory Developed Tests'", September 9, 2014, available at: http://www.acla.com/acla-written-statement-for-21st-century-cures-hearing-on-ldt-regulation/.

The Food and Drug Administration's (FDA) October 3rd, 2014 draft guidance proposals to regulate these laboratory testing services as devices (hereinafter, "draft proposals"), however, represent direct threats to clinical laboratory innovation and to patient access to such medical services. Rather than improve the public health (as the FDA contends), the draft proposals: 1) are unauthorized by the relevant statutes; 2) represent improper agency encroachment on the practice of medicine; and 3) will harm patient access to vital and innovative clinical laboratory services without offering any clear offsetting benefit. In short, these proposals are starkly contrary to the spirit of the 21st Century Cures Initiative, which seeks to "accelerate the pace of cures and medical breakthroughs in the United States"[2], not to increase and duplicate costs and regulatory burdens that would pose significant new barriers to medical innovation and to prompt patient access to the benefits of that innovation.

Given this harmful overreach, ACLA calls on the FDA to rescind its draft proposals to regulate LDTs as though they were "medical devices," and ACLA further urges the Committee and Congress to continue the statutory precedent of treating laboratory testing services and medical device manufacturers as the separate and distinct entities that they in fact are within the health care system.

1) Regulating LDTs as medical devices is contrary to statute.

Question 2 of the E&C Committee's White Paper appropriately points out the difficulty of identifying the "device" subject to regulation in the context of a laboratory-developed testing service. This difficulty is inherent in the FDA's pending proposals and highlights the fatal flaw in those proposals: it is that laboratories are *not* medical device manufacturers at all, and that laboratory-developed testing services simply are not medical devices as the relevant legal provisions, or ordinary speakers, use that term.

For decades, Congress and the Administration have recognized that testing laboratories and manufacturers are separate and distinct entities within the health care system. Since 1967, these laboratories have been governed by the Clinical Laboratory Improvement Act, renamed the Clinical Laboratory Improvement Amendments (CLIA) with the last major overhaul in 1988, administered through the Centers for Medicare and Medicaid Services (CMS), an entity within the U.S. Department of Health and Human Services. Since 1976, medical device manufacturers, in contrast, have been regulated under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (FFDCA), administered through the FDA.

[2] Upton, Fred & DeGette, Diana, "A Path to 21st Century Cures", Energy & Commerce Committee, April 30, 2014, http://energycommerce.house.gov/press-release/path-21st-century-cures.

This distinction carries through to reimbursement, whereby laboratories receive direct reimbursement as health care providers through federal health programs such as Medicare. Manufacturers receive no such direct reimbursement. The Affordable Care Act (ACA) in 2010 recognized this difference through its use of distinct budgetary offsets from both industries: a medical device tax for manufacturers, and a Medicare reimbursement cut for laboratories.

A simple tour of either type of facility bears out the differences. A medical device manufacturing facility revolves around the production of a physical product that is shipped and sold around the country to laboratories, physician offices, and hospitals. On the other hand, a laboratory that provides testing services revolves around the appropriate handling and processing of patient specimens, the application of the laboratory's own protocols, and the provision of clinical testing as ordered by health care providers. While a device is a finished, packaged, off-the-shelf article of commerce accompanied by instructions for use by others, a testing service is a proprietary methodology that only the developing laboratory can execute and that does not move in interstate commerce.

Laboratory-developed tests cannot be deemed "medical devices" solely for the convenience of an agency seeking new regulatory power. Calling a service, "a device", cannot make it one. As explained in ACLA's September 9th testimony, "[LDTs] are know-how, not physical articles."[3] LDTs are not "articles" or "commodities" as contemplated by well-settled medical device law; rather, LDTs are services provided by highly trained and certified laboratory personnel, such as pathologists, microbiologists, and other laboratorians. Nor can LDTs be captured by the FDA merely because they may share some of the same purposes and functions with *in vitro* diagnostic (IVD) test kits. If that functional overlap could suffice, the interpretive services of a radiologist could be deemed "medical devices" merely because they are based on images produced by devices such as x-ray or CAT-scanning machines.

If the Committee chooses to legislate in the area of diagnostics, ACLA strongly urges the Committee to continue the practice of regulating laboratories and manufacturers as separate and distinct entities and again clarifying that, as current law establishes, laboratory-developed testing services are not medical devices. Thus, the Committee's focus should be on the legitimate question whether CLIA could be revised to enhance the legal authority and funding authorization for CMS. Unfortunately, the FDA has chosen to bypass the Committee and Congress altogether by seeking, illogically and unlawfully, to treat laboratory services under the FFDCA.

[3] Mertz, p. 7-8.

2) The FDA is encroaching on the practice of medicine.

Since its creation, the FDA has been charged with ensuring that medical products made available to physicians and patients are safe, effective, and free from adulteration, misbranding, or putrification. Similarly, since its creation, the FDA has *not* been granted the mandate to govern how health care providers (in particular, physicians) utilize their education, training, and know-how to diagnose and treat individual patients, also known as the practice of medicine.

Trained and certified pathologists, microbiologists, geneticists, and other laboratorians perform diagnostic test services in response to orders from physicians treating particular patients. These trained and certified laboratory personnel utilize their education, training, and knowledge to test patient specimens to provide vital clinical information to help the treating physician arrive at a diagnosis and to recommend a course of treatment. These laboratory-developed testing services are part and parcel of the practice of medicine. To regulate the generation of information that a physician asks a consultant or a consulting laboratory to provide – by performing tests on specimens provided by the physician in order to assist that physician in diagnosing the patient's illness or in prescribing a course of treatment – interferes with that physician's decisions of what to prescribe or administer to his or her patient.

Question 1 of the E&C Committee's White Paper asks how clear and logical lines can be drawn separating the practice of laboratory medicine from manufacturing. The answer already exists through the CLIA designation of a high complexity laboratory. This is the only category of laboratory allowed by law to create LDTs, because this kind of lab is required to have highly-trained and certified laboratory personnel possessing the appropriate education, training, and know-how.[4] A high complexity laboratory is engaged in the practice of medicine through the performance of LDT services, not in anything that could be called manufacturing.

[4] The FDA has put forward other actions to potentially impinge on the practice of laboratory medicine, such as limitations on communications between manufacturers of Research Use Only (RUO) and Investigational Use Only (IUO) products and the laboratories that utilize these products. The agency's 2011 Draft Guidance for RUO/IUO products would have restricted even the marketing of RUO/IUO products. The 2013 RUO/IUO Final Guidance still creates ambiguity as to what communication between an RUO/IUO manufacturer and client laboratory may be deemed "inappropriate" by the FDA. These actions can choke off areas of access and innovation by chilling the collaborative relationship between laboratory professionals and the manufacturers of laboratory products. In the end, the patient suffers through less availability of innovative and higher quality diagnostics. H.R. 3005, *the Medical Testing Availability Act of 2013*, as introduced by Rep. Michael Burgess, is an example of a solution to the FDA's actions particular to RUO/IUO.

3) FDA regulation would entail an unnecessary and inefficient increase in costs and burdens.

a) Regulatory Uncertainty and Duplication

As previously discussed, laboratories are currently regulated by CMS under authority expressly granted by CLIA. Distilled to its most basic framework, CLIA establishes quality standards, inspections, user-fees, and penalties for non-compliance. In addition, all such laboratories are subject to inspection and licensure by state health authorities. For example, New York State requires separate test-specific pre-market approvals and inspections by its own authorities if a lab seeks to analyze specimens from patients in New York, regardless of whether the lab is physically located in the State of New York.

The laboratory marketplace has taken this oversight regime even further. A majority of moderate and high complexity laboratories often seek additional accreditation from "deemed authorities", such as the College of American Pathologists (CAP)[5], and, in some cases, are even subject to vendor qualification audits by clients. Under this regime, in any given year, a laboratory could find itself inspected by CMS, CAP, New York State, the state of the lab's location, its clients, and potentially others such as the American Society for Histocompatibility and Immunogentics, if the lab handles samples related to organ donation.

Through this range of authorities and reviews, a laboratory is subject not only to government compliance inspections, but also to multiple reviews by private entities such as CAP. This has created a rigorous regulatory environment in which a lab is part of a collaborative medical community seeking to improve patient care through the exchange of information between laboratory professionals. This combination of compliance and collaboration leads to better quality for patients.

In contrast, the draft proposals from the FDA offer little clear benefit, but *do* offer clear and significant increases in costs and burdens. Distilled to its most basic elements, the FDA's proposals would impose an overlaying set of quality standards, inspections, penalties, and, inevitably, user-fees, even though the agency has said it would initially seek to waive user-fees for labs.[6] These would be imposed on top of the quality standards, inspections, user-fees, and penalties already imposed under CLIA.

[5] A lab may opt into CAP accreditation under CLIA, as CAP is a CLIA "deemed authority"; however, even if a lab is CAP accredited, CMS still periodically sends its own inspection teams to the given lab.

[6] While the FDA has said in public comments that it intended to waive user fees initially for laboratories submitting LDT applications, the Food Drug Administration Safety and Innovation Act of 2012 (FDASIA) explicitly limits the FDA's waiver authority to no greater than 2 percent of user-fee revenues for a given year. (21 USC 379j(f)(2)). This limitation foreseeably would constrain FDA's ability to keep its promise to waive user-fees for *all* LDT applications unless FDA revises its draft proposals to limit the number of required applications.

The FDA's proposed overlay clearly threatens to impose unnecessary duplication on laboratories. Specifically in terms of quality standards, there is a tremendous overlap between (i) the regulatory requirements under the FDA medical device framework under 21 CFR §820 and (ii) the existing regulatory requirements under CLIA in 42 CFR §493 as they pertain to quality systems requirements, design controls, document controls, production and process controls, acceptance activities, nonconforming products, corrective and preventative actions, and records.

There is no reason to imagine that any of FDA's requirements is tailored to meet some demonstrable gap in the CLIA framework established by Congress – and, if there were any such gap, it would obviously be the role of Congress, not the FDA, to address it, just as Congress addressed gaps in the 1967 CLIA regime by enacting the 1988 amendments to CLIA. Bypassing Congress to impose potentially crippling redundant federal regulatory oversight at the FDA's unilateral initiative would imperil the rapidly advancing field of diagnostics at a time when, as Congress well understands, innovation and advancement are more urgently needed than ever.

On various occasions, FDA representatives have asserted in public comments that the agency is working with the Clinical Laboratory Standards Institute (CLSI) – a private laboratory standards setting organization made up of representatives of various laboratory stakeholders – to develop "education modules" that would purportedly aid a laboratory to both meet the FDA's new quality standards and guide the laboratory through potential duplication with CLIA. The nature and authority of these "modules" create questions and sources of uncertainty. At some times, the FDA has implied the CLSI is preparing the modules under contract; at others, the FDA has implied that the agency is merely "fact checking" the CLSI product. ACLA strongly objects to the FDA's action utilizing a private organization to provide guidance in an area that is beyond FDA's authority in the first place.

None of these proposed FDA interventions into the CLIA regulatory framework carefully designed by Congress is warranted either by law or by common sense. As of now, stakeholders have no clarity as to what force of law any FDA-developed CLSI "education module" might carry and whether such modules will first be issued in draft form for stakeholder comment. Even if comments were allowed, education modules would not alter the fact that laboratories would suddenly be subject to oversight by two distinct federal agencies and two separate and potentially conflicting federal regulatory structures, rather than by one, as Congress clearly contemplated. FDA has yet to offer any coherent means by which laboratories could discern how to comply with CLIA while at the same time meeting FDA's new proposed requirements.

A partial answer to the Committee's White Paper Question 8 would therefore be that (i) FDA's congressionally unauthorized proposals invariably would create duplication and inefficiency, and (ii) FDA's unsupported notion that CLSI somehow will resolve conflicts between CLIA and the FDA lacks grounding in reality and would create nothing but confusion. The legal and regulatory uncertainty occasioned by the FDA's ill-advised proposals would only hinder the Committee's regulatory objectives.

b) Patients left waiting

The costs and burdens threatened by FDA's proposals will not come in the form of dollars alone. The FDA is proposing to subject LDTs and laboratories that offer them to an excruciating and costly process that is already overburdened and not working effectively for in vitro diagnostic devices.

A recent analysis by the *FDA Law Blog* of medical device 510(k) application review times at FDA found that not only have the review times of medical device 510(k) applications increased, but that *in vitro* diagnostic device 510(k)s already take "significantly longer to review than 510(k)s for other types of devices."[7][8] This review of 510(k) application times does not even include *de novo* or premarket approval (PMA) applications. Looking at PMAs, the FDA only approved 21 premarket applications in 2013. The FDA has said publicly that it is anticipating at least 100 LDTs to qualify as high risk and require a PMA in the first round of the proposed framework. Assuming that the number of other device PMAs remains constant, LDTs would create a five-fold increase in PMA workload.

In short, attempting to include LDTs will affect not only LDTs, but traditional IVD manufacturer applications as well; overall, patients will have to wait longer to access increasingly accurate, precise and higher quality laboratory diagnostic services.

The very real risk of "FDA overload" will color any answers to Committee Questions 3 through 6. Any complete evaluation of benefits and costs of regulation must assess the various theoretical approaches in light of the practical effects of such regulation. Here, the FDA's overreach will have potentially harsh impacts on public health. Indeed, the FDA proposals themselves will create danger, and threaten the overall efficacy of laboratory medicine as a key component of the health care system.

c) New barriers to innovation and access

In partial answer to Committee Question 11, the FDA's proposals would create *disincentives* to the development of new, more accurate and more efficient laboratory tests. In particular, the draft proposals would create barriers to in the areas of LDTs for unmet needs, as well as hospital-based LDTs.

[7] Gibbs, Jeffrey & Mullen, Allyson, "New Article Shows Surprising Trends in 510(k) Review Times", *FDA Law Blog*, December 14, 2014, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/12/new-article-shows-surprising-trends-in-510k-review-times.html.

[8] *See also* Gibbs & Mullen, "Contrary to expectations, there is no review-time advantage to submitting and Abbreviated 510(k) to a Traditional 510(k). " The Abbreviated pathway having had been sold as a faster path to FDA approval.

In the case of unmet diagnostic needs the FDA proposes to continue what it calls "enforcement discretion" by not exercising the regulatory jurisdiction it claims to possess over laboratory-developed tests if laboratories should choose to develop tests for those particular unmet needs, subject to various restrictions. However, the enforcement discretion would cease once a single comparable laboratory diagnostic device was approved or cleared by the FDA.[9] This proposal creates three dilemmas that will dangerously discourage innovation.

First, while labeled an accommodation for unmet needs, the proposal actually drastically increases the hazard for a lab choosing to develop an LDT. The lab would have to be willing to accept the risk that it would later have to obtain FDA review, once a competitor received FDA approval or clearance for a device claimed to serve comparable purposes. Especially given the amorphous and inevitably contested character of such a claim, no laboratory would have any objective way to assess the magnitude of that risk *ex ante* and thus would need to be highly risk-prone in order to invest significant resources in pursuing the development path.

Second, whereas today, laboratories can improve an LDT to enhance accuracy or broaden the test's applicable patient population, the added risk of FDA oversight and uncertainty of FDA approval would chill this kind of incremental innovation, because each new iteration would require FDA premarket approval. Labs routinely modify existing laboratory developed tests in order to improve performance, respond to the latest scientific advancements, and advance the diagnostic capabilities of tests. Requiring full premarket approval for any modification to an existing test, no matter how insignificant, as the FDA proposes, would result in a stagnation of the science and sharply curtail innovation.

Third, the proposal creates a new form of market exclusivity within laboratory medicine whereby any organization (laboratory or IVD test kit manufacturer) could "clear the field" of competing products for a given unmet need by simply filing with the FDA and receiving approval. Such approval would not guarantee that the "first filer" offered the highest quality or most accurate test, merely that the filer was the first to volunteer for duplicative and burdensome FDA regulation. While the burden will fall on all laboratories in the diagnostic space, this approach creates an even greater barrier for smaller, innovative labs.

Fourth, FDA is proposing to exercise enforcement discretion where the particular LDT is developed and performed in a hospital laboratory for a patient being treated at that same facility.[10] This arbitrary restriction would threaten patient access to LDTs developed and performed in non-hospital independent laboratories, unnecessarily leaving unmet the needs of the countless patients for whom no hospital-based LDT is developed and no approved test kit exists – a common gap often filled by independent laboratories today.

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[9] FDA, "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) Draft Guidance, October 3, 2014, at p. 22, available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf.

[10] *Id. at 21-22.*

Whereas an academic medical center laboratory could tailor an LDT for a patient within its walls, the same LDT would be considered high-risk and subject to burdensome FDA review if, instead, it were offered by the same academic medical center lab to patients of a rural hospital or Veterans Affairs Hospital – even if the hospital were across the street. Instead of the smaller hospital simply being able to send out a patient sample, the FDA would require the transfer of the patient. This extreme result would cost time and money, in addition to creating delay and medical risk for a patient already receiving appropriate diagnosis and treatment.

d) Costs beyond FDA

The FDA's draft proposals not only risk levying needless costs on laboratories directly through the FDA, but could also trigger obligations beyond the FDA. As previously mentioned, the ACA levied a fee specific to laboratories in the form of a 5-year cut to the Medicare Clinical Laboratory Fee Schedule. Separately, the ACA also levied a tax on the medical device industry. As implemented by the Internal Revenue Service (IRS), that tax is paid by medical device manufacturers, and not by clinical laboratories. However, under the FDA's draft proposals, laboratories would be required to list LDTs with the FDA as medical devices once their test service received either clearance under 510(k) or approval under a PMA.[11] For medical device manufacturers, this listing is the regulatory trigger under the IRS for the medical device tax. Laboratories already pay the tax indirectly as purchasers of medical devices, but now actions by the FDA could also force laboratories to pay the tax directly on LDTs cleared or approved by the FDA. Thus far, the IRS has not needed to distinguish between manufacturers and laboratories, inasmuch as the ACA clearly targeted the tax on medical device manufacturers. The FDA proposals now, however, risk subjecting an industry to a tax for which the tax was not intended.

In addition to medical device tax liability, FDA regulation of LDTs as medical devices could subject laboratories to the compliance costs of federal and state "physician payment sunshine" laws applicable to medical device manufacturers. It could also trigger the more onerous strict liability standards of civil liability under state product liability laws, in addition to the negligence standard of civil liability to which laboratories are currently subject.

All of these problems not only point to the folly of the FDA's proposals but confirm that laboratory-developed testing services simply are not medical "devices." The FDA's proposals are an attempt to fit a square peg in a round hole.

[11] The FDA draft proposals would permit "notification" in lieu of registration and listing for LDTs during an applicable enforcement discretion period, but this alternative would only temporarily delay application of the medical device tax, since registration and listing would be required once enforcement discretion ends as specified under the draft proposals.

e) The FDA is no panacea

Throughout its history, the FDA has played a vital role in our healthcare system to ensure patient access to safe and effective medical products. The agency, however, also bears significant limitations. First, the FDA is not the source of medical innovation in the United States. The sources of innovation in the United States are medical researchers and health care providers working collaboratively to share knowledge and give birth to new discoveries to improve the quality of care available to patients. The federal agencies primarily tasked with discovery and innovation are the National Institutes for Health and the Centers for Disease Control and Prevention. The intervention of the FDA cannot settle a debate in medical science, nor can it discover the next cure.

Suggestions that, despite these limitations, the FDA's intervention with respect to laboratories is needed because there may have been instances in which CLIA regulation by CMS has proven to be imperfect make no sense. Without ruling out the possibility that Congress might make useful improvements in the CLIA regime, the Committee should resist proceeding on the misleading premise that absolute perfection is attainable in any regulatory regime. If that is not obvious on the face of it, it has been demonstrated anew with respect to FDA as recently as 2014. The FDA's experience last year reaffirmed that not even that agency can offer a guarantee that a device or product cleared or approved under its jurisdiction is totally safe or effective. Just in the past twelve months, the FDA placed the strongest form of warning on a surgical device for hysterectomies. Various versions of the device have been used by surgeons *for decades*, yet only recently has the FDA determined that the device's use can actually *worsen* a patient's cancer.[12] Similar recalls have occurred with hip replacements[13] and anti-inflammatories[14]; and we have seen post-approval discovery of life-threatening side effects that have sharply curtailed use of other products such as antibiotics.[15]

None of this is to deny that the FDA does, of course, play a vital role in reviewing medical products for safety and effectiveness. However, when the agency's inherent limitations are combined with the significant burdens and costs the agency is set to impose upon laboratories and patients, there is substantial doubt whether the agency could genuinely improve rather than endanger the public health by duplicating regulation on an already heavily regulated industry, intruding into the practice of medicine, and interfering with patient access to testing services that have proven essential to the successful diagnosis and effective treatment of disease.

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[12] Kamp, Jon & Levitz, Jennifer, "Surgical Tool Gets Strongest Warning", *The Wall Street Journal*, November 24, 2014, *available at* http://www.wsj.com/articles/fda-adds-new-warning-to-labels-for-laparoscopic-power-morcellator-1416842439.

[13] Meier, Barry, "With Warning, a Hip Device is Withdrawn", *The New York Times*, March 9, 2010, *available at* http://www.nytimes.com/2010/03/10/business/10device.html.

[14] Neilan, Terence, "Merck Pulls Vioxx Painkiller From Market, and Stock Plunges", *The New York Times*, September 30, 2004, *available at* http://www.nytimes.com/2004/09/30/business/30CND-MERCK.html.

[15] Harris, Gardiner, "FDA Warns of Liver Failure After Antibiotic", *The New York Times*, June 30, 2006, *available at* http://query.nytimes.com/gst/fullpage.html?res=9407E5D81430F933A05755C0A9609C8B63.

Conclusion

Laboratory developed testing services have been an American success story in medical innovation and patient care. Under the CLIA framework, laboratories competitively and nimbly put into practice advances in medical science and knowledge that ultimately lead to improved patient access to higher quality diagnostic services. These improved services allow for more accurately diagnosed disease, and better selection of appropriate treatments that lower the cost of patient care and increase its quality.

The FDA is proposing to increase costs, duplicate regulatory burdens, discourage collaboration among laboratory practitioners and between health care providers, choke off paths to innovation, and slow, even harm, patient access to increasingly accurate, precise, and meaningful laboratory diagnostics.

For these reasons, ACLA calls on the FDA to rescind its draft proposals to regulate LDTs as medical devices, and ACLA further urges the Committee and Congress to continue the legislative precedent of treating laboratories and medical device manufacturers as separate and distinct parts of the health care system.

ACLA welcomes the opportunity to work with the Committee on these and other questions raised by the Committee related to the oversight of diagnostics. Above all, consistent with the Hippocratic Oath by which medicine is wisely bound, we ask that no harm be done through duplicative and unnecessary federal regulation on the path to the new cures we all seek, particularly through the ill-advised framework currently proposed by the FDA. Working together, we can foster robust and undisrupted patient access to innovative, accurate, reliable, and meaningful laboratory-developed testing services.

Sincerely,

Alan Mertz
President