Summary Testimony of Dara Aisner, Representative of the Academic Coalition for Effective Laboratory Developed Tests before the Health Subcommittee of the House Energy & Commerce Committee, United States House of Representatives, March 21, 2024

The Academic Coalition for Effective Laboratory Developed Tests (LDT) is concerned about the FDA's Proposed Rule, which would hinder academic and hospital-based labs' ability to provide timely and necessary care to patients across the country.

There is no substantive evidence of systematic or pervasive harm arising specifically from LDTs. While the FDA has maintained that the absence of its oversight over LDTs presents a safety and effectiveness risk to patients, no systematic study has demonstrated this. The FDA has also vastly underestimated the scope of which they are trying to regulate. By moving forward with its Proposed Rule, the FDA is not prepared to properly provide labs with the necessary oversight to properly bring life-saving and safe LDT to patients in a timely manner.

Specifically, the Proposal Rule would limit patients' ability to receive timely tests, increase the costs of conducting tests for academic and hospital labs, hinder the development and innovation needed to create timely LDTs, and impact the training of our next generation of pathologists. To make sure we are delivering top-level tests to patients across the country, adding a burdensome regulatory process that increases lab costs will only restrict access to care.

Instead of the regulatory framework, we believe there are numerous alternatives to the approach proposed by the FDA, including modernizing the Clinical Laboratory Improvement Amendments (CLIA) at the Centers for Medicare & Medicaid Services (CMS); establishing enhanced proficiency for LDTs, which would allow additional transparency while minimizing the burden to laboratories as well as the FDA; and increasing investment in reference materials and proficiency testing samples to facilitate validation and proficiency testing.

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Before the U.S. House Energy and Commerce Subcommittee on Health

Evaluating Approaches to Diagnostic Test Regulation
and the Impact of the FDA's Proposed Rule
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Chairman Guthrie, Vice Chairman Buschon, Ranking Member Eshoo, and Honorable Members of the Subcommittee on Health of the U.S. House Energy Commerce Committee, thank you for the opportunity to provide testimony to the House Energy and Commerce Committee regarding the proposed FDA rule for the regulation of Laboratory Developed Tests (LDTs). My name is Dr. Dara Aisner, and I am a scientist and pathologist with board certification in Anatomic Pathology, Molecular Genetic Pathology, and Clinical Informatics. I am a Professor of Pathology at the University of Colorado School of Medicine and the medical director of the Colorado Molecular Correlates Laboratory, where we perform personalized medicine testing for patients across various testing areas, including oncology, genetics, and infectious disease.

I am here today as a representative of the Academic Coalition for Effective Laboratory Developed Tests ('the Coalition'), and my testimony today does not reflect the views of my employer. The Coalition represents over 325 pathologists and professionals from 100 academic and hospital-based laboratories across 38 states and the District of Columbia. We are all committed to quality care in diagnostics, and while we are predominantly practitioners in molecular diagnostics, we acknowledge and believe it is important for the committee to recognize that LDTs have an impact far beyond this one area.

I am grateful for the opportunity to express my concerns and the concerns of the Coalition regarding the proposed FDA rule on LDTs. It bears mentioning that my stake in this is not purely professional. I am a cancer patient. As a physician with specific expertise and training in laboratory

testing, I trust my care to LDTs, even when FDA-approved choices are available for the same clinical questions.

There are a number of specific issues with the FDA proposed rule and legislative solutions that have been considered in the recent past. The Coalition opposes the FDA proposed rule and instead favors exploring all available alternatives to regulatory reform, including but not limited to modernizing the Clinical Laboratory Improvement Amendments (CLIA) at the Centers for Medicare & Medicaid Services (CMS).

1. LDTs are not devices.

Referring LDTs as medical devices obfuscates the reality that these are processes in which every step of the process is validated and overseen in a fastidious manner. There is a misconception that because there is a series of technical steps, this is a purely technical exercise and, therefore, is well suited to regulatory structures. However, the process of assembling the various technical steps, understanding how those technical steps interact with each other, and how the data from these steps are to be interpreted is in and of itself a professional service; it is the practice of laboratory medicine. They cannot be reduced to a single manufactured device, any more than a physical examination can be reduced to a stethoscope or a surgery can be reduced to a scalpel.

The inter-relatedness of these steps and the fact that the LDT neither exists nor functions without professionals trained in evaluating and interpreting the data is a crucial part of why this process amounts to medical practice. Learning to put a stethoscope in your ears isn't the same as understanding what you are listening for – that takes training and experience. Similarly, someone without training in laboratory medicine and assay validation can't just walk into a lab and develop an assay; that also takes training and experience.

The proposed FDA regulation is premised on the idea that In Vitro Diagnostics (IVDs) in a boxed-and-shipped kit should be regulated the same as an LDT. This does not account for the marked difference between these two testing modalities, as LDTs are overseen and monitored by professionals

trained to recognize even the smallest performance differences. Since the laboratorians that manage and maintain/quality control an LDT are part of the laboratory performing the assay, real-time feedback on assay performance is possible and, indeed, is routine, further underlining that an LDT is not a device.

An apt analogy here relates to food and meals. The FDA regulates food, but not meals, except for pre-packaged meals, the infamous 'TV dinner'. Much like the FDA regulation of food does not extend to regulating restaurants and the recipes they utilize, and any suggestion of such an application of regulation would be counterintuitive, the application of device frameworks to LDTs is counterintuitive. LDTs are not devices; they are not pacemakers or artificial knees. Utilizing a framework that treats them as such is unquestionably counterintuitive. The Coalition urges consideration of the distinction between tests and devices and the distinction between IVDs and LDTs in evaluating any proposed regulatory schema.

2. There is no substantive evidence of systematic or pervasive harm arising specifically from LDTs.

While the FDA has maintained that the absence of its oversight over LDTs presents a safety and effectiveness risk to patients, no systematic study has demonstrated this. In fact, the most comprehensive systematic studies are those evaluating proficiency testing results, which consistently demonstrate a high level of laboratory performance for clinically relevant analytes.[1] Proficiency testing (PT) involves testing unknown samples under routine conditions similarly to regularly tested specimens, followed by submitting results to the PT provider to analyze and grade the laboratory's test performance. One study specifically examined whether the regulatory status of the assay determined the outcomes and came to the clear conclusion that it was not, as the rate of acceptable results did not differ between FDA-approved/cleared assays and LDTs.[2]

In 2015, on the eve of an Energy and Commerce hearing on LDTs, the FDA published a list of 20 so-called 'problematic assays.' This list was highly dependent on anecdotes and did not endeavor to objectively understand the magnitude of the perceived problem by understanding the proportion of tests

[1] Merker et al, Arch Pathol Lab Med 2018; Surry et al, Arch Pathol Lab Med 2019; Tsuchiya et al, Arch Pathol Lab Med 2023, Moncur et al, Arch Pathol Lab Med 2019
[2] Kim et al, JAMA Oncology 2018

that were so-called problems. The production of this list fails even basic principles of fairness, let alone scientific analysis. By only evaluating LDTs, the question of whether FDA-approved tests outperform LDTs is left completely unanswered; moreover in failing to ascertain the denominator of the field (i.e., how many tests are 'problematic' out of how many tests are available), the FDA failed demonstrate a problem at a scope commensurate with the level of the proposed regulatory approach. More importantly, multiple subsequent analyses demonstrated that this list of 20 assays included those with fraudulent intent, those never utilized in direct patient care, and numerous examples in which the proposed regulatory schema from the FDA would not have prevented the stated errors, which were pre-analytic or post-analytic. The scientific conclusions of the limited number of other studies cited by the FDA have all been called into question, and clearly demonstrate 'cherry picking' rare studies to support a predetermined conclusion, rather than evaluating all available data. Strategically selecting flawed studies while simultaneously ignoring well-documented evidence of the safety and accuracy of LDTs demonstrates the extent to which the FDA has doggedly pursued this regulatory expansion despite the absence of clear and pervasive harms.

Furthermore, there are numerous examples of FDA-approved assays issuing unreliable results, and there has been no systematic effort to quantify whether FDA-approved assays actually achieve superior performance when compared to LDTs. A 2018 study published in JAMA, looking at over 7000 test results, demonstrated that LDTs outperformed FDA-approved assays when examining mutations in three genes - *EGFR*, *KRAS,* and *BRAF*. These tests are used for the selection of therapy for lung cancer, colon cancer, and melanoma. In another example, an FDA-approved test for a virus, CMV, was identified to have a high level of false positive results, which was identified precisely because highly trained laboratorians who are used to validating and monitoring assay performance identified the issue as part of their practice of laboratory medicine.

Members of this Coalition are highly experienced laboratory professionals who intimately understand the assays developed and maintained in their practices. We urge the commission of a

comprehensive and thorough study to examine the impact of LDTs on medical care, as we believe the harms are overstated and benefits are understated.

3. The FDA has vastly underestimated the scope of what they are proposing to regulate.

As part of the proposed rule, the FDA estimates that approximately 80,000 LDTs would be impacted. This is a vast underestimate, as numerous external organizations have estimated 175,000 to be the lowest likely number of DNA-based LDTs alone. The FDA utilized imperfect logic to reach their estimate of ~80,000 LDTs and even admits the agency does 'not know the exact number of laboratories or IVDs offered as LDTs that would be affected by this proposed rule.' This expansive, paradigm-changing proposal has been issued without the barest understanding of the true scope of the proposal.

Any attempt to understand the proposed rule's impact is fundamentally premised on the number of LDTs in utilization and the number of laboratories that develop them. The Pew Charitable Trust estimates that of the 267,000 clinical laboratories in the United States, approximately 12,000 are likely to use LDTs[3]. Even if one were to stipulate that, on average, such a laboratory has 10 LDTs within its menu and would likely develop 1-2 per year, suggesting a starting number of at least 120,000 tests with 12,000-24,000 submitted yearly.

An analysis of the testing database approved in New York State via the Wadsworth Center demonstrated over 10,000 LDTs in just that state alone. It also found that submissions were dominated by laboratories located in New York State and national reference laboratories[4], indicating that this number likely represents a microcosm of what might be expected for any state with a substantial population base.

Ultimately, a regulatory shift as drastic as the one proposed deserves to be well-studied before rulemaking and implementation, and proposing sweeping changes without knowing how many tests would be impacted is reckless. A reasonable first step in this evaluation is a mechanism to gather data on the number of LDTs and the number and type of labs providing them.

[3]The role of lab-developed tests in the in vitro diagnostics market. The Pew Charitable Trusts. (2021, October 22). https://www.pewtrusts.org/en/research-and-analysis/reports/2021/10/the-role-of-lab-developed-tests-in-the-in-vitro-diagnostics-market

[4]Bonislawski, A. (2023, September 11). NY State Database offers glimpse into laboratory- ... 360 DX. https://www.360dx.com/clinical-lab-management/ny-state-database-offers-glimpse-laboratory-developed-testing-landscape

4. The process proposed by FDA will lead to marked delays in implementation of essential care

The FDA process for review can be slow and unpredictable and would likely lead to market delays for essential patient care. During the COVID-19 pandemic, the FDA received approximately 5000 emergency use authorization submissions; however, fewer than 500 were authorized. This was despite pausing the review of all non-COVID-19 submissions and redirecting substantial staff resources to this influx. If ~5000 submissions, all focused on one disease area overwhelmed the entire capacity of the FDA to review any other testing submissions, what is the expected outcome when at least 40,000 assays (by the FDA's own estimate, and likely a substantial underestimate) are submitted all at once?

In its analysis, the FDA presented numbers which indicate a >800% increase in 510(k) premarket notifications and a >6000% increase in de novo classification requests, with an estimated increase across all premarket authorization related submissions of >5000%.[5]

5. Unpredictable and/or high costs will shutter labs and lead to a contraction of laboratories

The FDA proposal does not provide any specific details as to what costs laboratories can expect for submission of assays and whether a user-fee model will be applied. This introduces unpredictability, which is detrimental to the laboratory industry and will lead to a contraction in investment in diagnostic laboratory innovation.

If a user-fee model is applied, it is unclear whether those laboratories that likely have the highest proportion of LDTs - hospital-based and academic laboratories- will have any expectation of reduced fees. Even with any reductions, the combined user fees may ultimately be more than the annual budget for a laboratory. Separately from user fees, laboratories will be obligated to hire additional personnel to specifically focus on the FDA submission process. Invitae, in their written response to the proposed FDA rule, elaborated that their experience with the time required to perform tasks was dramatically higher than the FDA estimates, in some cases over 1000-fold higher.

[5] Office of Economics and Analysis, Laboratory Developed Tests Proposed Rule: Preliminary Regulatory Impact Analysis (2023). Retrieved from https://www.fda.gov/media/172557/download?attachment.

Laboratories that likely have the highest proportion of LDTs, hospital-based and academic laboratories, are the least positioned to weather additional budgetary burdens for laboratory operations. In contrast to commercial laboratories and startup ventures which focus specifically on testing, a clinical laboratory in a hospital or academic medical center is just one operational unit of a much larger institution, and a need to substantially increase the budget of such a unit is likely to be met with a decision to outsource rather than increase the investment. This will erode the benefits that hospital-based and academic medical center laboratories offer - care that is tailored to the local population, informed by direct access to the patient's medical record, and can be resulted rapidly. Hospital-based and academic medical centers tend to have extensive lists of LDTs, as the patient care needs specific to their population require the development of testing for novel specimen types and areas of local expertise, as well as the ability to rapidly perform testing for acutely ill patients across a wide spectrum of medical specialties.

Unlike commercial reference laboratories and startup ventures, which use proportionally fewer LDTs, tend to focus on a small number of tests, hospital-based and academic medical center laboratories will likely bear the greatest fiscal brunt of the proposed FDA rule even the highest-resourced academic centers have indicated the inability to meet the anticipated costs. For instance, Dr. David Klimstra, former Chair of Pathology at Memorial Sloan Kettering Cancer Center, stated at a Senate Health, Education, Labor, and Pensions Committee hearing in 2016 that if the institution were required to submit their 350 LDTs for FDA approval, there would be no way the institution could afford the cost associated with formal FDA review.[6]

The FDA review process itself is a source of considerable uncertainty. A predictable approach to testing timelines is essential for patient care and business planning for any laboratory (whether hospital-based, academic or commercial). The FDA has not provided clear guidance with benchmarks that would clarify for laboratories what level of testing evidence will be required for any individual submission. As evidenced by interactions during the COVID-19 pandemic, the response any individual laboratory will get

[6] Senate., Laboratory testing in the era of precision medicine: Hearing of the Committee on Health, Education, Labor, and pensions, United States Senate, One Hundred Fourteenth congress, Second Session, on examining laboratory testing in the era of precision medicine, September 20, 2016.

will depend entirely on the assigned FDA reviewer. In the absence of clearly defined criteria and benchmarks, laboratories are likely to face protracted and unpredictable back-and-forth discussions, further contributing to cost and timeline inconsistency and discouraging submission altogether.

This pressure and likely reduction in hospital-based and academic medical center laboratory services will lead to marked contraction of the number of available laboratories, likely leading to an oligopoly instead of a competitive marketplace. Numerous analysts evaluating the investment potential in the laboratory industry have commented that the FDA rule or similar regulations would lead to a contraction in the market, with a disproportionate benefit derived from large commercial laboratories. Laboratories that have the resources to pursue FDA approval are likely to prioritize those for which there is a substantial marketplace or where reimbursement is significant, as there will be less incentive to invest in lower volume or less profitable tests.

6. Inequity in medical care will be magnified

Academic medical centers assume a disproportionate burden of care for medically indigent, underserved, and marginalized populations. With a marked reduction in laboratory services at these facilities and the inevitable emergence of an oligopoly for laboratory testing, the dominant feature defining access to specialty testing is the ability to pay for such services. For example, prior to the unanimous 2013 *Association for Molecular Pathology v. Myriad Genetics Inc.* Supreme Court decision, a single company-controlled testing for the *BRCA1* and *BRCA2* genes had profound implications for patient access. At that time, some States' Medicaid programs did not contract with the company for testing, which meant these patients were unable to receive a highly impactful set of medical information based on their socioeconomic status. Since the decision, access to *BCRA1* and *BRCA2* gene testing has shifted, the cost per test has plummeted, and patients can expect a result in one to two weeks instead of months beforehand.[7] Additionally, academic medical centers, public hospitals and hospital-based laboratories can more easily absorb the cost of uninsured/underinsured patients for testing they are already offering, as

[7] Modell et al, Cancer genetic testing in marginalized groups during an era of evolving healthcare reform; J Cancer Policy 2021

the incremental cost for one patient is markedly less than covering a reference laboratory test at the list price.

The FDA has also acknowledged in its impact analysis that laboratories in rural areas are likely to be disproportionately impacted, another example of magnification of inequity in care.

Pediatric populations and populations with rare diseases will also be disproportionately impacted, as the clinical market for testing for these areas is small. There is a marked dearth of FDA-approved assays in existence today. Laboratories that currently run testing for these patient populations (primarily pediatric hospitals and academic medical centers) will be unable to support the outlay for the FDA approval process; laboratories that can afford the FDA approval process will not be incentivized to establish these assays, and no vendor will be incentivized to produce a boxed-and-shipped kit.

7. Adoption of new technology into laboratory medicine will stagnate

Innovation and adoption of practice are a cornerstone of the clinical laboratory landscape. For example, the mortality for lung cancer has been steadily declining, and this has been attributed to personalized medicine. In 2010, we used polymerase chain reaction (PCR) tests to examine one gene to effectuate personalized medicine in lung cancer. Today, we use Next Generation Sequencing and can evaluate dozens or hundreds of genes at a time. This has been a clinical reality for approximately 10-15 years, and this field has flourished because laboratories can utilize this new and transformative technology to bring benefit to their patients.

The ability to bring innovate enables progress in laboratory medicine. A regulatory schema that requires pre-authorization will disincentivize investment in the applied science required to translate promising technologies into clinical reality. Next-generation sequencing (NGS) testing serves as an excellent example. For example, in September 2023, the FDA authorized the Invitae Common Hereditary Cancers test. Prior to this authorization, the test had been offered for many years and was widely utilized to evaluate hereditary cancer risk. Experts in the field held the testing in high regard, and the company regularly contributed to national databases to aid in interpreting genetic results. In their docket comments

regarding the proposed FDA rule, Invitae noted that "We do not believe the FDA authorization provides any new or additional benefit or improved quality of services for patients; rather the multi-year endeavor confirmed what we already knew - in meeting standards governed by CLIA and CAP as well as our internal standard, Invitae has achieved high-quality testing for our patients." The process for this highly regarded company was a 'multi-year endeavor' despite the fact that NGS was a commonly utilized laboratory technique when they submitted their assay for consideration.

What might the process look like for a truly novel technology? Will innovators be willing to withstand such a timeline and uncertainty? How many patients benefitted from this test and others like it because it was available under CLIA and not subject to the FDA timeline. Numerous technologies are on the cusp of clinical reality, and American patients deserve the opportunity to take advantage of the most cutting-edge options.

Had a requirement for FDA-preauthorization been in effect at the inception of this and other NGS testing, it's probable that this technology, which today we regard as a standard of care, would still not be in clinical production at this or any other company or institution.

If the FDA rules proceed, other implications for innovation in laboratory medicine relate to including the most up-to-date information in clinical testing. As the science evolves, it is common for laboratorians to update a test. This can mean validating a new specimen type, adding a gene with new clinical evidence of utility to an existing panel, expanding the detection of specific variants (mutations) that are regarded as disease-causing, among many other changes. The FDA proposal would disincentivize such updating, stagnate testing at the state of scientific knowledge at the time of approval. The ability to remain nimble and respond to scientific advancement keeps U.S. medical care at the forefront of precision medicine.

8. The milieu of testing is relevant

The FDA's proposal for regulating LDTs does not account for the distinction between commercial entities that market testing services and healthcare organization-based laboratories that maintain vast

menus of testing services to assure rapid and effective care for their patients. In this context, health care organizations do not maintain their laboratories to generate revenue; rather, they recognize the critical role these professional services play in the care of patients and maintain the laboratories despite the fact that in many instances, they are not profitable.

Academic and hospital-based laboratories serve a unique role in the healthcare system. They must be prepared to offer testing for a large volume of 'routine' testing while also offering specialty testing to support their role in escalated care for complex medical situations and rare diseases. They are often secondary, tertiary, or even quaternary care centers for entire geographical regions. For example, the University of Colorado Health system serves as a referral center for not only Colorado, but also Wyoming, Nebraska, Kansas, South Dakota, and New Mexico. From emergency rooms and intensive care units to outpatient and preventative care visits, laboratory services comprise upward of 70% of the medical record for each patient, and the ability of an individual healthcare system to prioritize testing approaches specific to their population, clinical needs, geographic distribution, and other factors is paramount for effective care. In order to offer these services, academic medical center labs must maintain vast menus of laboratory testing, many of which are LDTs.

Within this type of environment, the role of LDTs in the care of patients is critical. Still, they have inherent checks and balances regarding the accuracy of results and reporting of adverse events. The ability to cross-reference the results against the patient's medical record, concurrent and prior testing, and have one-on-one provider-to-provider discussions serves as a significant mitigator of risk for the individual patient and the testing modality.

Grouping all laboratories that utilize LDTs – including academic/hospital based and commercial labs - into the exact regulatory oversight mechanism will be disproportionately burdensome for academic and hospital based labs. The Coalition recommends that the risk mitigation engendered by the site of practice be factored into the burden imposed in any approach to modernizing laboratory testing oversight.

9. Impact on the training of the next generation of pathologists and Laboratory professional

Given the user fees and the need for additional staff to submit new or modified tests to the FDA, many academic medical center labs will dramatically cut back their pathology departments and outsource their testing to large commercial labs. This will directly impact the training of the next generation of pathologists and laboratory professionals, which necessarily occurs at academic medical centers. With fewer tests in any individual lab to serve as the basis for education and without the element of ongoing assay validation, the opportunities to present meaningful experiential education will be reduced. The training of laboratory technologists will also suffer, as only routine boxed-and-shipped test kits will have widespread implementation.

Furthermore, innovation in Pathology and Laboratory Medicine will be dampened by the proposed rule (as elaborated above), thereby dissuading the best and brightest from pursuing a career in this dynamic field because of the inability to bring novel ideas and technology to bear. There is a known shortage of pathologists and laboratory staff, which is expected to become more pronounced. The FDA's proposed rule will exacerbate this shortage. The Coalition urges evaluation of the proposed rule on the state of medical education.

Recommendations and alternatives to the FDA's approach:

As elaborated above, the FDA has not demonstrated a problem with LDTs that require such a significant change in how medicine is practiced in the U.S. The Coalition does believe there is room for regulatory advancement in line with advances in laboratory science. There are numerous alternatives to the approach proposed by the FDA, yet they remain under-evaluated. The proposed rule is, frankly, an extreme and inflexible one, bringing laboratory testing for anything other than the most routine tests to a grinding halt. Alternative approaches should be thoroughly examined to determine feasibility before selecting the most extreme 'solution.' Some examples of alternate approaches include:

A. CLIA modernization, an example of which has been proposed by the Association for Molecular Pathology and is endorsed by multiple professional societies.
B. A model focused on proficiency testing.

C. Increased investment in reference materials and proficiency testing samples.

CLIA modernization remains an attractive alternative, as the initial 1967 CLIA infrastructure, updated in 1988, establishes clear authority of laboratory operations and stipulates clinical and analytical validity requirements. Modernizing this framework would maximally leverage expertise and infrastructure already in place. The Association for Molecular Pathology has drafted a CLIA modernization legislative proposal, and the premise of CLIA modernization as a path forward has been endorsed by over 50 organizations.[8]

An alternate approach in which proficiency testing is a crucial component to determine regulatory status would allow additional transparency while minimizing the burden to laboratories as well as the FDA. For any test in which the analyte is well-defined and for which external proficiency testing available, pre-release and ongoing proficiency testing performance documentation submitted to a regulatory body should be adequate to ensure ongoing quality. Indeed, many laboratory professionals would agree that a premarket authorization approach to review laboratory testing misses the mark, and the best approach to ensure assay performance is regularly monitor assay performance. Testing for which proficiency testing does not yet exist would be held to a higher regulatory standard than simply proficiency testing. Notably, an approach like this one focuses on an outcomes which directly impact patients. A regulatory system should hold everyone to the same safety standard, but that means ensuring that outcomes are similarly safe, not that regulations are similarly burdensome.

The development and/or acquisition of suitable material for proficiency testing is a recurrent challenge in laboratory medicine. Either separately or in concert with an expansion of proficiency testing, resources could be directed toward improving the pipeline for and access to such materials. This would not be without costs, but it is reasonable to assume that such costs would be a small fraction of Analogous to this approach, one in which the enormous proposed investment precipitated by the FDA rule. These

[8]Stakeholder sign on letter CLIA modernization legislation . (2023, November 1). Association for Molecular Pathology. https://amp.org/AMP/assets/File/advocacy/Stakeholder%20sign%20on%20letter%20CLIA%20modernization%20legislation%20November%201%202023.pdf?pass=1.

resources would also have the benefit of being directly associated with ensuring safe outcomes, rather than adding administrative regulatory burden.

The above comprise a few possible approaches that can and should be considered. We do not know the full scope of the relative costs and benefits of each approach because they have not been evaluated. As specified by the Unfunded Mandates Reform Act, FDA is required to identify and consider a reasonable number of regulatory alternatives and, from those alternatives, select the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule.

Conclusion

The current proposed FDA rule regarding LDTs and multiple proposed legislative solutions that preceded it does not appropriately account for the scale, complexity, or nuances of the laboratory testing enterprise. The Coalition is opposed to the proposed FDA rule and urges the FDA to reconsider it, as it will hinder access to care, exacerbate existing inequities in care, diminish investment in innovative diagnostic technologies, and lead to a consolidation of the laboratory industry, further exacerbating these very concerns. The Coalition further supports a comprehensive and well-reasoned evaluation of all alternatives to the proposal and urges a re-evaluation of the proposed rule's impact, which, as presented, is based on incomplete data.

Thank you again for the opportunity to testify today. We look forward to working collaboratively with the members of the Subcommittee as you continue to explore the impact of the proposed rule and consider potential legislation that impacts LDTs.