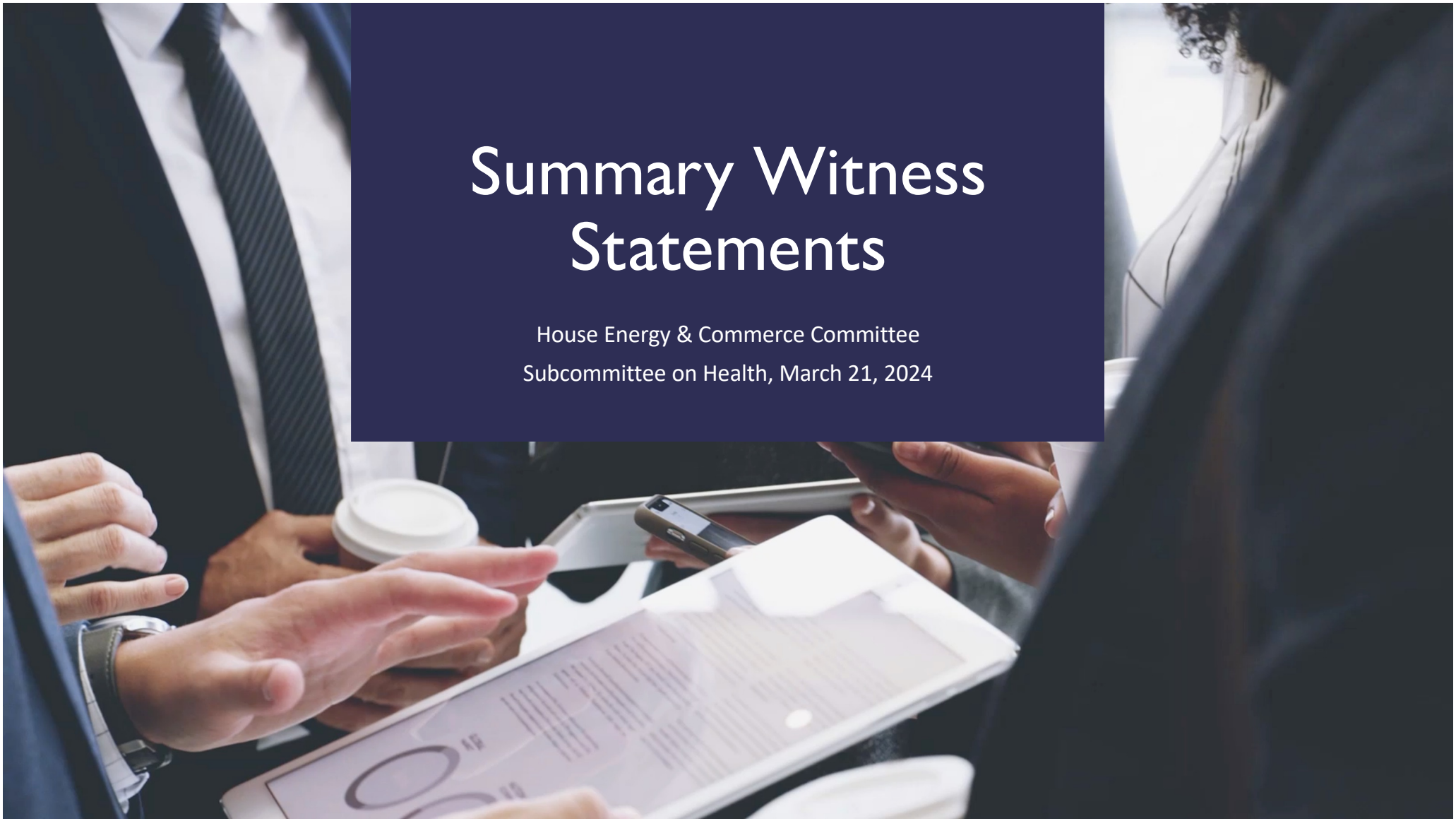
Summary Witness Statements

House Energy & Commerce Committee

Subcommittee on Health, March 21, 2024



Susan Van Meter 

- The witness, Susan Van Meter, is **against FDA oversight** of Laboratory Developed Testing services (LDTs).
- She argues that subjecting LDTs to medical device regulation, as proposed by the FDA's Proposed Rule, would have significant adverse consequences.
- Van Meter contends that FDA oversight would impede innovation, limit access to tests, increase healthcare costs, and exceed the FDA's statutory authority.
- She advocates for legislation as the appropriate approach to regulating laboratory diagnostics, rather than FDA oversight.

Summary of Susan Van Meter's Testimony:

1. **Indispensable Role of Laboratory Developed Testing Services**: Susan Van Meter emphasizes the crucial role that laboratory developed testing services (LDTs) play in the healthcare system, providing diagnostic information vital for clinical care, precision medicine, therapeutic development, and combating emerging pathogens. She argues against the FDA's Proposed Rule, which would subject LDTs to medical device regulation, stating that it would impede innovation, limit access to tests, and exceed the FDA's statutory authority.
2. **Consequences of FDA's Proposed Rule**: Van Meter outlines the adverse effects of the Proposed Rule, including increased healthcare costs, diminished innovation in diagnostics, and a bottleneck in access to tests due to FDA review. She highlights concerns about the financial burden on laboratories, potential withdrawal of tests from the market, and the impact on underserved populations. Additionally, she argues against granting exemptions for academic medical centers, stating that it would exacerbate health disparities.
3. **Legal and Regulatory Concerns**: Van Meter contends that regulating LDTs as medical devices exceeds the FDA's jurisdiction and conflicts with existing statutory frameworks such as the Clinical Laboratory Improvement Amendments of 1988 (CLIA). She argues that LDTs are professional services, not physical products, and therefore fall outside the FDA's regulatory authority. She calls for legislative action as the appropriate approach to regulating laboratory diagnostics, advocating for collaboration between stakeholders to establish a regulatory system that balances innovation and access to tests.

Zach Rothstein

- The witness, Zach Rothstein, is in favor of FDA oversight of Laboratory Developed Tests (LDTs). He advocates for comprehensive legislative reform to modernize the regulatory framework for diagnostics, which includes bringing LDTs under FDA oversight.
- Rothstein argues for a unified oversight program overseen by the FDA, tailored review standards for diagnostics, transparency, and a risk-based approach.
- He emphasizes the importance of regulatory certainty and a clear landscape for fostering innovation in diagnostic tests. Therefore, the witness supports FDA oversight of LDTs as part of broader regulatory reform efforts.

Summary of Zach Rothstein's Testimony

1. Fragmented Regulatory Landscape: Diagnostic tests play a crucial role in patient care, but the regulatory oversight is fragmented. While CLIA focuses on overall laboratory operations, it lacks oversight on the clinical validity of tests. FDA's review of in vitro diagnostic (IVD) devices covers both safety and effectiveness, ensuring a reasonable assurance for patients. Currently, FDA exercises enforcement discretion over Laboratory Developed Tests (LDTs), but many have received FDA clearance or approval.
2. Advocacy for Legislative Reform: AdvaMedDx advocates for comprehensive legislative reform to modernize the regulatory framework for diagnostics. They support a unified oversight program overseen by FDA, tailored review standards for diagnostics, transparency for patients and providers, a risk-based and flexible approach, and pathways for innovation while ensuring access to testing for unmet needs.
3. FDA's Proposed Rule and Need for Reform: FDA's proposed rule clarifies that IVDs are devices, including those manufactured by laboratories. AdvaMedDx recognizes the need for regulatory reform to close gaps in oversight and increase confidence in diagnostics. They argue that a unified oversight mechanism would increase investment in and deployment of IVDs, fostering innovation and benefiting public health.

Donald Karcher

- The witness believes this proposed rule to end enforcement discretion for all LDTs and use the existing FDA framework for the regulation of LDTs, as written, will severely stifle medical innovation, increase regulatory burden on clinical laboratories, introduce unsustainable costs as part of the development of LDTs by clinical laboratories, and in the end hinder the delivery of potentially life-saving testing to patients.
- For these reasons, the witness, representing CAP does not support the proposed rule in its current form.

Summary of Don Karcher's Testimony

1. **Definition and Importance of LDTs:** Laboratory-developed tests (LDTs) are vital for meeting specific clinical needs, particularly for patients with rare diseases or specific clinical requirements not addressed by FDA-approved tests. These tests are developed within individual clinical laboratories to serve their patient populations.
2. **Concerns about Ending Enforcement Discretion:** Ending enforcement discretion for all LDTs and adopting the existing FDA framework for their regulation is viewed as detrimental. It is argued that this move would stifle medical innovation, increase regulatory burdens on clinical laboratories, and introduce unsustainable costs in LDT development, hindering patient access to potentially life-saving testing.
3. **Advocacy for a Balanced Regulatory Framework:** The College of American Pathologists (CAP) advocates for a reasonable and balanced regulatory framework for LDTs. They support the three-tiered risk-based system proposed by VALID (Verifying Accurate Leading-edge IVCT Development), which focuses FDA resources on high-risk tests while minimizing regulatory burdens on laboratories and promoting patient safety. The CAP emphasizes the importance of maintaining innovation in laboratory testing while ensuring quality and patient care.

Jeff Allen

- The witness is in favor of FDA oversight of Laboratory Developed Tests (LDTs).
- They advocate for a modernized regulatory framework, such as the VALID Act, to establish consistent oversight across all diagnostic testing technologies, including LDTs.
- Friend of Cancer Research emphasize the importance of ensuring the quality, accuracy, and reliability of diagnostic tests to prevent potential patient harm, suggesting that FDA regulation would help address these concerns.

Summary of Jeff Allen

1. **Evolution of Oncology Diagnostics:** The testimony outlines the historical progression of cancer diagnostics from rudimentary methods to precision oncology driven by molecular understanding. It highlights significant advancements such as targeted therapies and immunotherapies, emphasizing the importance of diagnostic tests in identifying molecular alterations for effective treatment.
2. **Challenges in Regulatory Framework:** It discusses the complexities of the current regulatory paradigm for diagnostic tests, particularly the differentiation between FDA-regulated diagnostic kits and Laboratory Developed Tests (LDTs) regulated under CLIA. The testimony points out the growing disparity in oversight, highlighting concerns about inconsistent performance and accuracy of tests, leading to potential patient harm.
3. **Need for Modernized Regulation:** The testimony underscores the necessity for a modern regulatory framework to ensure the quality and reliability of diagnostic tests. It presents the VALID Act as a proposed solution, aiming to establish a flexible yet comprehensive framework to regulate diagnostic testing technologies, create consistency across all tests, and mitigate risks associated with inaccuracies or inconsistencies.

Dara Aisner

- The witness is against FDA oversight of Laboratory Developed Tests (LDTs). They express concern about the FDA's Proposed Rule and advocate for alternatives to the FDA's approach, suggesting that the current regulatory framework could hinder academic and hospital-based labs' ability to provide timely and necessary care to patients.

Dara Aisner

1. **Concerns about FDA's Proposed Rule**: The Academic Coalition for Effective Laboratory Developed Tests (ACELDT) is apprehensive about the FDA's Proposed Rule, which they believe could impede academic and hospital-based labs from delivering timely and necessary care to patients nationwide.
2. **Alternatives to FDA's Approach**: Rather than endorsing the FDA's regulatory framework, ACELDT proposes alternatives such as modernizing the Clinical Laboratory Improvement Amendments (CLIA) at the Centers for Medicare & Medicaid Services (CMS), implementing enhanced proficiency testing for LDTs to improve transparency without overburdening labs or the FDA, and investing in reference materials and proficiency testing samples to streamline validation and proficiency testing processes.
3. **Impact on Access and Affordability**: The proposed FDA rule could disproportionately affect hospital-based and academic medical center laboratories, potentially limiting access to essential tests and increasing costs for patients. This contrasts with the positive outcomes observed in the past when regulatory changes facilitated improved access, reduced costs, and quicker turnaround times for tests like BRCA1 and BRCA2 gene testing.