CHAMBER HILL

INSIGHTS

House Energy and Commerce Discusses Concerns Over FDA's Regulation of Laboratory Developed Tests (LDTs)

House Energy and Commerce Discusses Concerns Over FDA's Regulation of Laboratory Developed Tests (LDTs)

On March 21, 2024, the House Energy and Commerce Health Subcommittee held a hearing on Food and Drug Administration (FDA) regulation of laboratory developed tests (LDTs) and the impact of FDA's proposed rule on patient access. Although some Democratic members expressed concerns about the potential harm of faulty tests, this hearing featured bipartisan concerns about the proposed rule's impact and the need for legislation.

WITNESSES

- Susan Van Meter, President, American Clinical Laboratory Association
- Zach Rothstein, Executive Director, AdvaMedDx
- Dr. Donald Karcher, MD, FCAP, College of the College on American Pathologists (CAP)
- Dr. Jeff Allen, PhD, President and CEO, Friends of Cancer Research
- Dr. Dara Aisner, MD, PhD, Medical Director, Colorado Molecular Correlates Laboratory, Professor of Pathology, University of Colorado, Representative, Academic Coalition for Effective Laboratory Developed Tests

MEMBER DISCUSSION

The hearing began with an opening statement by Subcommittee Chair Brett Guthrie (R-KY), where he discussed the importance of LDTs to help inform 70% of medical decision-making on everything from cancer to public health purposes like assisting local law enforcement in determining which illicit drugs are being sold in their communities. He also pointed out that LDTs undergo certification under the Clinical Laboratory Improvement Amendments (CLIA), state regulators, and independent accrediting agencies like CAP. He went on to highlight that, despite known benefits of LDTs, FDA has tried for nearly two decades to increase their regulation of diagnostics and now they have proposed to subject LDTs to medical device regulation, including pre-market review, an inflexible model that does not allow for test modifications or grandfathering. He took issue with FDA's citation of underperforming LDTs as justification for the rule and warned that medical device review disincentivizes diagnostic innovation. He ended by saying he opposes the rule and urged Congress to work with the FDA, the lab community, and patient and provider groups

on a legislative alternative to FDA's proposed rule.

Subcommittee Ranking Member Anna Eshoo (D-CA) echoed the importance of LDTs in medical decision making re-stating that they play a role in 70% of provider treatment decisions. She expressed the patient need for "certainty" in testing and a better approach than the status quo to validate tests. She cited FDA's assertion that the Center for Devices and Radiological Health (CDRH) reviewed 125 COVID test requests for Emergency Use Authorization (EUA) and they determined 2/3 of them had "major issues" such as inadequate or missing data. She expressed support for FDA's goal but said the proposed rule is not the only way to do it. She also expressed concerns with medical device review of diagnostics and cited the need for Congress to act on legislation based off VALID. She also asked witnesses whether they support VALID legislation.

Republican members of the Subcommittee were all unified in their opposition to the proposed rule, the value proposition of LDTs, and their concerns that medical device regulation will reduce access to testing for pediatric patients and patients with rare diseases. Reps. Bilirakis (R-FL), Latta (R-OH) and Joyce (R-PA) all asked witnesses about the rule's effect on these patients. Others, including Committee Chair Rodgers (R-WA) and Rep. Joyce (R-PA), asked about the use of LDTs to detect the presence of xylazine, citing reports the animal tranquilizer is being combined with fentanyl and its lack of response to overdose medication.

Other major themes raised by Republican members in the hearing included workforce challenges, duplicative regulation with CLIA, the prohibitive costs of compliance, and likely downstream effect of market consolidation. Reps. Harshberger (R-TN) Dunn (R-FL) and Burgess (R-TX) all highlighted these themes. Most notably, Chair Rodgers (R-WA) utilized Mayo's estimate that the rule would require them to submit approximately 1000 LDTs through pre-market review, which equates to a minimum of one submission a day, every day over the four year implementation timeline in her opening statement.

VALID sponsors Reps. Bucshon (R-IN) and DeGette (D-CO) used the hearing to emphasize the need for their legislation, calling on Congress to act in the wake of the FDA proposed rule. Both highlighted beneficial provisions of their bill, including grandfathering, risk classification and the technology certification process, a center of excellence model that allows test developers to forego pre-market review for tests that use the same methodology, once an exemplar test and specific validation protocols have been approved by the FDA. Several other members of the committee, and all the witnesses, echoed this sentiment and AdvaMedDx, Friends of Cancer Research, and CAP all endorsed VALID during the hearing.

Subcommittee Democrats, led by Committee Ranking Member Frank Pallone (D-NJ), used their time to highlight the patient risk inherent in unproven tests. Rep. Pallone (D-NJ) was the only member of the committee who fully endorsed the FDA rule. Other Democrats, including Reps. Dingell (D-MI) Ruiz (D-CA) and Schrier (D-WA) all asked questions related to the potential harm from tests that return inaccurate results, including false positives. Even so, several Democrats highlighted the importance of promoting

innovation and the need for legislation. Subcommittee Ranking Member Eshoo (D-CA) and Reps. DeGette (D-CO) Schrier (D-WA) and Ruiz (D-CA) included these themes in their approach to witnesses.

Notwithstanding the Democratic focus on the potential harm of faulty tests, the hearing was very beneficial. Both GOP and Democratic committee members highlighted the value of LDTs, opposition to the rule, and the need for a legislative alternative based off the progress of VALID.

We trust you found this summary useful. Please reach out to us with any questions.