Advocating for Laboratory Developed Testing Procedures

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AMP Association for Molecular Pathology

Association of Pathology Chairs APC Established 1967

VALID Act – Current Status
(as of 9/16/2021)

- Introduced in House and Senate (6/24/2021)
- Assigned to House Energy & Commerce and Senate HELP Committees
- No committee hearing or other actions to date
- Bipartisan support but few cosponsors
- Supported by FDA, manufacturers, some large laboratories, and some patient groups
- Manufacturers interested in adding to MDUFA V legislation

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MDUFA:

Medical Device User Fee Agreements

- User fees support FDA pre- & post-market activities
- User fee agreements establish:
  - Fees required for different types of product applications (standard and small business)
  - FDA review timelines & performance goals
- Negotiations between FDA & affected stakeholders
- Closed-door discussions, some public meetings
- Reauthorized by Congress every 5 years
  - MDUFA V – FY 2023 – FY 2027
  - “Must pass” legislation (by Sept. 30, 2022)
  - Legislative vehicle for related FDA regulatory concerns (e.g., VALID?)

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VITAL Act – Current Status
(as of 9/16/2021)

- Introduced in Senate (5/18/2021)
- Assigned to Senate HELP Committee
- Need House companion bill
- Supported by laboratory associations (e.g., AACC, ACMG, AMP, APC), academic labs/institutions, certain reference labs
  - Letter of support from 30 organizations and academic departments sent to Congress on 9/8/2021
- No committee hearing or other actions to date

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Organization-Level Advocacy –
AACC, ACMG, AMP, APC

Shared positions:

- Regulatory reform needs to focus on modernization of CLIA
- Support the VITAL Act
- Laboratory developed testing procedures should not be treated like medical devices
- Not necessarily opposed to reform of regulatory pathways for manufactured tests and other medical devices

Goals:

- Increase support for CLIA modernization and the VITAL Act
- Raise awareness of potential harms of current VALID Act
- Engage CLIAC for support of CLIA modernization

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Current Legislative Priorities

Identify additional democrat and republican co-sponsors for VITAL Act in the Senate

Bipartisan introduction of VITAL Act in the House

Outreach to key legislators and congressional staff

Awareness among membership, institutions, medical associations, patient advocacy organizations

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How can members help?

Contact your institution's government affairs team

- Explain the issue and significance to laboratories and patient care
- Ask them to support VITAL Act
- Put them in contact with your association's policy team
- Share letter of support signed by other institutions

Educate and advocate within your institution and among colleagues in other specialties

- Emails
- Social media
- Round table discussions

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Reach out to your elected officials

- Email, Twitter, phone call, or request a meeting
- Invite them for a tour (virtual/in-person) of the lab to explain the process and CLIA regulations
- Inform them about how often you rely on laboratory developed testing procedures (LDTs/LDPs) to diagnose and treat your patients
- Contact your association if you have question or need help with outreach

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Be on the lookout for notifications from your association(s) about ways to get involved and additional resources!

Grassroots campaigns

- Often administered through online systems that makes it easy for members to notify their elected officials about a specific topic
  - Usually letters but can include phone and social media
- Amplifies the voice of our organizations

Virtual Hill Days

- Some of our associations occasionally host virtual Hill Days

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Contact your association if you have question or need help with outreach

AACC – vstine@aacc.org

ACMG – advocacy@acmg.net

AMP – policy@amp.org

APC – pmarkwood@apcprods.org