June 16, 2022

VALID Act Advances Towards Full Senate Vote

On June 14th, the Senate HELP Committee voted to advance the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022, a complex bill that would treat board-certified laboratory professionals like manufacturers and require all laboratory-developed tests (LDTs) to be regulated by the Food and Drug Administration (FDA) in addition to the Clinical Laboratory Improvement Amendments (CLIA). The VALID Act was passed as part of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022. The FDASLA includes the new user fee agreements for medical devices, drugs, generic drugs, and biosimilars, which must be passed by Sept. 30th, 2022 to avoid disruption of FDA's review activities. The FDASLA also includes many other provisions on topics unrelated to FDA user fees, such as regulation of cosmetics, supplements, and infant formula.

ACMG, together with other associations, clinical laboratories, and many individual ACMG members, has been advocating for removal of the VALID Act from the fast-moving user fee package so that additional stakeholder concerns can be properly addressed (see joint letter here). As an alternative, we also advocated for an amendment to be added that exempts the majority of clinical testing laboratories from the VALID Act while leaving in place reforms to the regulatory pathway for manufactured test kits.

Senator Tuberville (R-AL) introduced an amendment that would have at least exempted academic medical centers from all provisions of the VALID Act. Unfortunately, that amendment did not move forward and instead was tabled by a 12-10 vote.

The FDASLA Act, including the VALID Act, now goes to the full Senate for a vote. The version passed by the full Senate will most likely be different than the version previously passed by the House which does not include the VALID Act or many of the other provisions included in the current Senate bill. Following passage by the Senate, the bill will go through a negotiation process to reconcile differences between the House and Senate versions.

As the bill continues to move, ACMG will continue to advocate for removal of the VALID Act or for an exemption for certain clinical testing laboratories. Our advocacy thus far has captured the support from many members of Congress, some of which was the result of ACMG members meeting with and emailing their Senators' office. However, there is still a lot more work to be done, and ACMG's members will continue play an important role in this effort as we expand our focus to more members of Congress. Please keep an eye out for future alerts with opportunities for ACMG members to get involved.

Additional information about LDTs and the VALID Act is available here.

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Taking Action and Advocating for Medical Genetics