ASHI on the Hill

Regulation of Histocompatibility Testing

Agency Efforts

In the last edition of ASHI on the Hill, we reported that ASHI became aware of an effort by the Food and Drug Administration (FDA) to classify HLA, Human Platelet Antigen (HPA), and Human Neutrophil Antigen (HNA) devices into class II, which would subject them to premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Notably, the Proposed Rule announcing this proposal omitted exemption for laboratory developed tests LDTs. In response to this misguided and problematic effort, ASHI developed and submitted comments opposing finalization of this proposal. Additionally, ASHI organized a comment campaign that resulted in the overwhelming majority of comments on the proposal opposing its finalization. The FDA has not announced any final action as of this writing, but ASHI will keep you apprised of further developments as they transpire.

Congressional Efforts

In the second quarter of 2022, ASHI has continued its multi-year advocacy campaign to prevent regulation of LDTs used in support of transplantation shifting from CMS to the FDA as is proposed by the Verifying Accurate Leading-edge IVCT Development (VALID) Act. The goal of the VALID Act's sponsors continues to be seeing its inclusion in the must pass FDA user fee reauthorization legislation that Congress is developing. The Congressional committees with jurisdiction over the FDA user fee reauthorization legislation and the VALID Act are the Senate Committee on Health, Education, Labor and Pensions (HELP) and the House Committee on Energy and Commerce. We will discuss the status of this effort in each committee of jurisdiction in turn.

The Senate HELP Committee is led by Chairwoman Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC), who is the lead Senate Republican sponsor of the VALID Act. On May 17th, Chairwoman Murray and Ranking Member Burr released a discussion draft of its FDA user fee reauthorization bill – the *FDA Safety and Landmark Advancements (FDASLA) Act*. Unfortunately, this discussion draft included the latest iteration of the VALID Act – the *Verifying Accurate Leading-edge IVCT Development Act of 2022*. This iteration of the VALID Act would subject Histocompatibility testing to *the most onerous and burdensome new in vitro test regulations under FDA*, including premarket approval requirements. ASHI developed comments on the discussion draft urging the Committee to refrain from including the VALID Act of 2022 in this legislation, explaining in detail the significant consequences this legislation would have for our field. ASHI also signed onto a letter with over 70 organizations and has met with key members of Congress in coalition efforts making a similar request of the Committee. Subsequently, on May 27, Chairwoman Murray and Ranking Member Burr formally introduced the FDASLA Act with the VALID Act included, and the Committee plans to consider the bill on June 8th. ASHI continues to monitor developments closely and advocate against advancement of the legislation in its current form.

On May 18th, the House Energy & Commerce Committee considered and approved its version of the FDA user fee reauthorization bill – the *Food and Drug Amendments of 2022* (H.R. 7667). Notably, this legislation advanced out of Committee *without* inclusion of the VALID Act; however, the lead House sponsors of the legislation voiced that they would push to include the measure before the full House of Representatives votes on the bill.

ASHI continues to vigorously advocate that any final FDA user fee reauthorization legislation not include the VALID Act in its current form considering the significant unintended consequences it would have on HLA labs and patient access to transplant. We will continue to provide updates on this effort and encourage those of you willing to reach out to your members of Congress on this issue to connect with ASHI for assistance doing so.

Virtual Crossmatch Update to CLIA Histocompatibility Regulations

ASHI is keenly aware of the need for updates to the Clinical Laboratory Improvement Act of 1988 (CLIA) Histocompatibility regulations and has continued advocating for revisions. CMS issued an RFI in 2018 requesting feedback on updating certain aspects of CLIA, which has not undergone a significant update of its Histocompatibility regulations since 1992. As you are aware, CLIA currently requires a pre-transplant physical crossmatch, and ASHI has advocated that the regulations be updated to allow virtual crossmatching as opposed to only physical. In the 2018 RFI, CMS solicited feedback on updating CLIA to allow virtual crossmatching, and ASHI commented that this revision should be made; however, CMS has not taken any action since issuing this RFI. As a result of this inaction, ASHI and numerous other transplant stakeholders sent a letter to CMS requesting this long overdue update be made. ASHI is also taking concerns over this inaction to the Hill to educate Congress on the need for the update and gain allies in this endeavor. ASHI will continue to provide updates on this effort as we continue working to see this important revision made by CMS.