

## ASHI on the Hill

### ASHI Continues Fighting Misguided Changes to Regulation of Histocompatibility Testing

ASHI has continued its fierce advocacy to prevent regulation of LDTs used in support of transplantation shifting from CMS to the FDA as proposed by the Verifying Accurate Leading-edge IVCT Development (VALID) Act. You will recall that the proponents of the VALID Act are attempting to include this bill into the broader FDA user fee reauthorization legislation, which Congress must pass by September 30, 2022. As overviewed in the last edition of ASHI on the Hill, 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.

ASHI is pleased that the House of Representatives voted in favor of the FDA user fee legislation advanced out of the House Energy & Commerce Committee by a vote of 392-28 on June 8. This legislation – the Food and Drug Amendments of 2022 (H.R. 7667) **does not** include the VALID Act.

Despite the success on the House side, the VALID Act was included in the Senate HELP Committee's FDA user fee reauthorization bill – *the FDA Safety and Landmark Advancements (FDASLA) Act*; however, the committee was divided in its support of the bill during the June 14<sup>th</sup> markup. Indeed, the legislation was approved by the committee by a vote of 13-9, with Committee Ranking Member Richard Burr (R-NC), who is the lead sponsor of the VALID Act, voting against the bill. In addition to concerns over partisan amendments added to the bill during the markup, Ranking Member Burr expressed frustration over the FDA's handling of the infant formula crisis and openly questioned the wisdom of giving the FDA additional authorities over diagnostic tests and other areas. Subsequently, Ranking Member Burr introduced *the Food and Drug Administration Simple Reauthorization Act*, which would reauthorize the FDA user fees as already negotiated and **does not include** the VALID Act.

No FDA user fee bill has received a vote in the full Senate and talks are ongoing to attempt to reach a compromise on legislation that can pass in both the Senate and House. With the Senate returning from its summer recess on September 6<sup>th</sup> and the House on September 13<sup>th</sup>, Congress has limited time to reach agreement on a final FDA user fee package. Though the situation remains fluid, ASHI continues to vigorously advocate that any final FDA user fee reauthorization legislation not include the VALID Act in its current form. If you have not reached out to your members of Congress to request that the VALID Act be excluded from any final FDA user fee legislation, please contact ASHI for assistance in doing so.

### CMS Proposes Long-Awaited Updates to CLIA Histocompatibility Regulations

After years of advocating that the Centers for Medicare and Medicaid Services (CMS) move forward with updates to the Clinical Laboratory Improvement Act of 1988 (CLIA) Histocompatibility regulations, ASHI was thrilled that CMS issued a [Proposed Rule](#) to this effect in late July. Some of the most significant proposals concerning HLA labs include allowing virtual crossmatching as opposed to only physical, as well as changes to personnel requirements associated with performance of high complexity testing. The ASHI National Clinical Affairs Committee quickly pulled together a team to develop ASHI's comments on these proposals. The comment period closed on August 25, 2022, and we now await CMS' determination on finalization of these proposals considering stakeholder feedback, which includes over 15,000 comment submissions. Should these changes be finalized by CMS, they would represent the first significant update of the CLIA Histocompatibility regulations since 1992.

## **Key Congressional Committee Continues Organ Transplant Oversight Focus**

On August 3, 2022, the Senate Finance Committee held a hearing titled, “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network.” The purpose of this hearing was to provide an update on the committee’s multi-year investigation into the United Network for Organ Sharing (UNOS) and the country’s organ procurement and transplant system.

As a result of its investigation, the Committee has concluded that:

- The Organ Procurement Transplantation Network (OPTN) is failing to provide adequate oversight of the nation’s 57 OPOs resulting in fewer organs available for transplant.
- The lack of oversight of Organ Procurement Organizations (OPOs) by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety. These failures include testing procedure errors, transportation issues resulting in life saving organs being lost or destroyed in transit, and process and procedure failures.
- UNOS lacks technical expertise to modernize the OPTN IT system resulting in the risk of system interruption or technical failure with the potential to harm patients across the country.

Finance Committee staff made several recommendations to improve the OPTN based on the investigation’s findings, including:

- Remove barriers to competition by removing the specific requirement for HHS to contract only with a “non-profit entity that has an expertise in organ procurement and transplantation;”
- Increase the pool of potential bidders;
- Promote innovation in all OPTN functions (e.g., policy development, compliance and patient safety mentoring, IT infrastructure, coordinating transport of organs, etc.) as the best qualified entities with distinct skill sets could compete for contracts for these functions;
- Remove a major barrier for entry for bidders by providing authority for HHS to procure a government owned, contractor operated modern IT system to facilitate the OPTN functions;
- Increase security and innovation in the OPTN system by ensuring the new IT system is based on current technologies and operated and maintained by a contractor with adequate IT knowledge and experience;
- Ensure the continued viability of the OPTN by authorizing HHS to collect fees from transplant hospitals when adding a patient to the national organ transplant waitlist;
- Increase transparency and accountability for chain of custody and transportation of organs procured for transplant by providing for public reporting, as appropriate, on the status of organs in transport; and
- Increase accountability for organs lost, damaged, or delayed in transport by requiring oversight and corrective action for such incidents.

Finance Committee Chairman Ron Wyden (R-OR) indicated that the committee’s investigation will continue and ASHI is continuing to monitor developments closely.