ASHI on the Hill

In the first quarter of 2022, ASHI has continued to closely monitor developments surrounding potential regulatory changes to laboratory developed tests (LDTs) used in support of transplantation. While much of the attention in this arena has been placed on competing legislative proposals concerning broader LDT regulatory jurisdiction, including the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021 and the Verified Innovative Testing in American Laboratories (VITAL) Act, ASHI is now working to combat a recent regulatory development specific to a narrow category of tests, including Human Leukocyte Antigen (HLA) tests.

Specifically, on January 21, 2022, the Food and Drug Administration (FDA) issued a Proposed Rule to classify HLA, Human Platelet Antigen (HPA), and Human Neutrophil Antigen (HNA) devices into class II. FDA classifies into class II devices those for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. FDA has indicated that it does not intend to exempt these device types from premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Efforts to classify these tests span multiple decades; however, most recently in 2017, FDA sought recommendations from the Blood Products Advisory Committee to discuss the classification of HLA, HPA, and HNA devices. Notably, in 2017, FDA clarified that the following devices are not included in the proposed classification:

- HLA, HPA, or HNA devices used as a companion diagnostic device, a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product.
- HLA, HPA, or HNA assays that are intended for clinical use and designed, manufactured, and used within a single laboratory (LDTs).

However, ASHI is concerned that the current proposed rule only provides the following exemption:

- "The following devices are not included in the proposed classification: HLA, HPA, or HNA devices used as a companion diagnostic device, a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product."

Given the omission of an exemption for LDTs in this proposed rule in tandem with FDA's intention to require premarket notification for these tests, this proposed rule is highly concerning to ASHI. Beyond the issue of LDTs, ASHI is also concerned about the impact this classification and accompanying special controls will have on test manufacturer incentives to continue innovating with respect to these tests. ASHI's National Clinical Affairs Committee (NCAC) is working to develop formal comments to submit in opposition to these changes outlined in the proposed rule. FDA is accepting comments on the proposed rule through April 21, 2022, and information regarding submission of comments may be found in the proposed rule (hyperlinked above) in the event ASHI members wish to comment as well. ASHI is committed to opposing misguided policies concerning regulation of tests used in support of transplantation and will continue its related advocacy work on both the legislative and regulatory fronts.