ASHI Secures Meaningful Policy Victories; Significant Work Remains

Despite it being a presidential election year, numerous significant policy developments have taken place, and ASHI has worked tirelessly to ensure our members have a seat at the table when critical decisions are made.

ASHI has continued its fierce, multi-year efforts to ensure that Histocompatibility testing does not become subject to regulation by the U.S. Food and Drug Administration (FDA). On April 29, 2024, the FDA issued a Final Rule affirming its authority to regulate Laboratory Developed Tests (LDTs) as medical devices under the Federal Food, Drug, and Cosmetic Act. ASHI has advocated against FDA regulation of Histocompatibility LDTs for many years, including successfully thwarting Congressional efforts to establish FDA regulation via the VALID Act. After advocating against classification of Histocompatibility LDTs as medical devices through FDA's rulemaking, ASHI was pleased that the FDA opted to continue exercising enforcement discretion with respect to HLA tests for transplantation, meaning these tests will not be subjected to FDA oversight. While this was a significant victory, ASHI was disappointed that the FDA elected to regulate HLA tests for blood transfusion. This issue has garnered significant interest from Congress, and stakeholders have filed a lawsuit against the FDA challenging this Final Rule in Federal Court. ASHI continues monitoring developments out of Congress, the agency, and the courts as we work to ensure that the regulatory regime covering Histocompatibility remains optimal, sensible, and workable so that our members can continue providing lifesaving testing.

Once again, ASHI members face reimbursement uncertainty this year, as Congress' fourth and most recent temporary delay of Protecting Access to Medicare Act (PAMA)-related reimbursement cuts is currently slated to expire at the end of 2024. ASHI and the broader laboratory stakeholder community is continuing its advocacy for a permanent solution to the misguided and harmful laboratory reimbursement cuts resulting from PAMA. Specifically, we are advocating in support of the Saving Access to Laboratory Services Act (SALSA; H.R. 2377 / S. 1000), which would prevent reimbursement cuts from taking effect in January of 2025 and overhaul Medicare laboratory reimbursement in a sustainable manner going forward. ASHI is thrilled by the strong Congressional support for SALSA, as evidenced by the bill's 61 bipartisan co-sponsors in the House and four in the Senate. While ASHI and its coalition partners will continue our steadfast advocacy for a permanent solution via SALSA, it is imperative that Congress act to ensure that the reimbursement cuts slated to take effect in 2025 are once again thwarted. To that end, the House Ways & Means Committee recently advanced Legislation that would delay these harmful cuts by one additional year.

ASHI is constantly tackling new and evolving issues as we work to continue building ASHI's profile on Capitol Hill and expand our advocacy footprint. Our work and your advocacy are vital to informing key lawmakers about the impacts of policy changes on our labs. We anticipate a busy remainder of 2024, an especially busy 2025, and look forward to furthering ASHI's advocacy goals.