Update from Region X Director and Legislative Symposium
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Region X Director (2017-2020)

The Legislative Symposium is an important and educational conference hosted by ASCLS in partnership with other laboratory organizations to provide an opportunity to speak to our national congressional delegation. Two Hawaii representatives went to DC for this conference. There are typically 2-3 critical issues to discuss with the congress people. I will discuss Laboratory Developed Tests and our national board meeting and planning day that takes place prior to the symposium. This provides the board an opportunity to have a face to face meeting and plan for the future of ASCLS.

The purpose of the planning day is to discuss where ASCLS is heading in the next 5+ years. We started this day by looking at what we have accomplished in the last few years, so we know how to move forward. Our last three years has seen a lot of change starting with our new Executive Vice President, Jim Flanigan. Under his leadership and guidance, the board has approved multiple projects to improve communication with members, upgrade our system for the Clinical Laboratory Science Journal, and create a new annual meeting that is more flexible and meets the needs of our membership. Communication was improved by an upgraded website management system, creating a marketing director position and national committee, and better national ASCLS communication with its membership through social media, ASLCS Today, and the website. The board and ASCLS staff understand that these changes have not been easy to execute or particularly popular. We appreciate the support and are excited for what the future of our organization and our profession holds. The remaining of the planning day was spent developing our "Why." This "Why" will dictate path on future projects and direction of ASCLS. We did not come to a final statement, and this information will be shared with the members once a final decision has been made.

The national board meeting was held the next day. For those of you that have never attended a board meeting, this is a meeting based on parliamentary procedure and provides an update from all ten regions and national committees. The major issues discussed are summarized below:

- Some of the concerns brought up by the regions were declining membership and recycled leadership at the state levels. We have the same concerns in region X. The national board has created a task force to help assess the health of each local/state chapter and will be able to respond appropriately with resources and assistance to support the chapter. Your association leadership will receive a survey soon. This survey will provide additional information to the board on what resources is needed by the chapter to address these concerns.
- There were also concerns regarding the changes in the national meeting. The national board recognizes that this a huge change; we are asking for everyone to try the new meeting and see what we have to offer. Although the cost of the meeting has not decreased this year; we are expecting lower costs for airfare, hotel and food while at the conference.
- Region III brought up a concern from Tennessee. The concern was that the state legislature was looking at a bill to remove licensure requirements for Medical Laboratory Personnel employed by private laboratories. ASCLS was notified of this issue and quickly mobilized the Tennessee members to speak to their congressional leaders and clarified the issues and concerns. The leaders agreed and no longer support the bill, which means it will not move forward. This is great news for the laboratory professionals of Tennessee because it protects their jobs and

ensures that all laboratories recognize the hard work and dedication these professionals have for their jobs. ASCLS is a great resource for helping address these issues.

- The membership committee presented a multi-year professional membership trial. This will allow professional members to renew their memberships for three years at one time. Some members have asked for automatic renewal of professional membership. Unfortunately, there are security concerns with storing financial information over the long term. The board agreed to a trial and we will determine how well it will be received. Information will be provided when this is available.
- The Coordinating Council for the Clinical Laboratory Workforce (CCCLW) has been working with ASCLS to create and maintain a Laboratory Science Careers website (http://www.laboratorysciencecareers.com/). This website was created to be a reference for recruiting future laboratory professional in the field. Please look at the website and send to those individuals who would benefit.

The board meeting provides an opportunity for an update across all of ASCLS. If you have any questions or concerns regarding any ASCLS business please contact Kristen Croom at kcroom80@gmail.com or call/text her at (808) 489-3893.

One issue that was discussed at Legislative Symposium was regulation of Laboratory Developed Tests (LDTs). An LDT is defined by the FDA as in vitro diagnostic tests that are designed, manufactured and used within a single laboratory. The explosion of genetic testing increased the awareness of LDT in the laboratory and medical community. Our patients and clients need to ensure the safety of our patients by providing accurate, safe and consistent results. The current process for LDT oversight does not provide a transparent process for ensuring that all laboratories are appropriately validating LDT adequately to protect our patients.

Historically, the FDA has declined to oversee LDTs and left oversight to CLIA. In 2014 due to the expansion of genetic testing LDT and the risk to our patients, the FDA release draft guidance stating they always had oversight and were going to exercise that discretion by releasing draft guidance. The draft guidance proposed a three-tier risk-based framework for this oversight. This draft was never finalized due to the need for additional discussion with stakeholders and ask congress for the opportunity to develop a legislative solution.

ASCLS supports the need for appropriate oversight of LDTs. ASCLS also want to ensure that those low-risk LDTs currently run in the lab (for example: chemistry tests validated on body fluids not included in the FDA approval) should be appropriately stratified to allow continued validation and use within the clinical laboratory. ASCLS's primary concern is the safety of our patients and to ensure that the healthcare team trusts the results provided by the laboratory.

I hope this article provided you the opportunity to see what has been going on at the ASCLS national level. For more information please visit www.ascls.org.