

MICHIGAN SECTION AACC NEWSLETTER

WINTER, 2014

Raymond Karcher, Editor

Message from the Chair

Kenneth Simkowski

Unfortunately, Winter is upon us and as we struggle with the cold and snow, I would like to recap what has been occurring with the Michigan AACC during 2014. It has been a busy but rewarding year for the Michigan Section AACC. We bade farewell to Veronica Luzzi, Chair for 2014 and wished her well in her move to the Pacific Northwest in July. There was an exciting AACC National Meeting in Chicago in July as well, where there was excellent science and a chance to meet old friends and make new acquaintances as well as an excellent opportunity to network with colleagues.

The Michigan section had three excellent scientific meetings during 2014. On March 6, 2014, Dr. James Nichols from Vanderbilt University School of Medicine presented "*Managing Quality in a POCT Program*" as well as "*Quality Control based on Risk Management: CLSI EP23 and CMS IQCP CLIA Interpretive Guidelines*" at the VisTaTech Center at Schoolcraft College in Livonia, MI. Always a great venue for our dinner meetings put on by the culinary students at the college. On September 25, 2014, the attendees got to hear point and counter-point on the new AHA/ACC Guidelines for evaluating cardiovascular disease risk from Dr. Rodney Hayward and Dr. Robert Brook, both from the University of Michigan at Weber's Inn in Ann Arbor, MI. Finally, as has been our tradition, the current President of the AACC, Dr. Steven Wong presented "*Pharmacogenomics and Pharmacometabolomics for Personalized Medicine*", again at the VisTaTech Center at Schoolcraft College. Dr. Wong also gave our members an update as to the activities of the National AACC during 2014 and a look ahead.

The Michigan Section members have elected a new Executive Board for 2015 (*please see Steven Truscott's report in this Newsletter for the names of the elected Executive Board*). I look forward to working with them and setting the goals for the MI Section for 2015. Early in 2015, the Executive Board will be meeting to schedule next years' meetings and scientific presentations. We will again have meetings in March, September and November. On March 18, 2015, Dr. David Keren and a speaker from The Binding Site will give presentations on the HevyLite® Assay from the Binding Site. If you have any ideas/recommendations or suggestions for topics and speakers for our meetings, please forward these to myself or any member of the Executive Committee.

I would like to extend to everyone a Happy Holidays. Keep warm and I hope to see all of you at the March 18, 2015 meeting.

Ken

Legislative Liaison Report

Raymond Karcher

The following are excerpts from Government Affairs Updates by Vince Stein at the National Office and reflect his expectations based on results of the national mid-term election.

Revisions to health care reform will clearly be a high priority for the Republicans. Issues such as re-establishing 40 hours as the definition of full time employment, repealing the medical device tax and eliminating the Independent Payment Advisory Board have a greater likelihood of getting enacted as part of a package of health care reforms if the White House and Congress decide to work together and make 'improvements' to the Affordable Care Act. Although there will be some discussion of repealing the measure, the chances of that occurring are unlikely given that the Republicans don't have the 60 votes to end a filibuster nor the two-thirds majority needed to override a presidential veto.

One of the incumbents who lost was Senator Kay Hagan (D-NC), who was the lead sponsor of the newborn screening legislation in the Senate. She will remain in office until Jan. 1 and AACC will work with her in an effort to get the final version of the newborn screening measure through the Senate and to the President. If the bill is not voted upon in the next few weeks, Congress will need to revisit the issue next year.

Over at Senate Finance, the new Chair will be Senator Orrin Hatch (R-UT), a strong supporter of the medical device industry and a leading sponsor of legislation to repeal the Medical Device Excise Tax. With the Republican takeover, and Senator Hatch serving as Chair, the possibility that the device tax may be eventually repealed increased significantly. AACC supports the repeal of the device tax. Senator Hatch is also one of the sponsors of the Newborn Screening Saves Lives Reauthorization Act, supported by AACC. If the bill does not gain final passage before the end of this session, the Association will working closely with him next year to enact the measure.

The main health committee in the Senate is the Health, Education, Labor and Pensions (HELP) panel. Senator Lamar Alexander will be the new Chair and is viewed as a moderate to conservative Republican with a keen interest in health and education issues. He is likely to hold hearings on the Affordable Care Act and identify elements of the law that can be refined or repealed. Look for Senator Alexander to work with Senator Hatch in crafting legislation that modifies areas of ACA where there may be bipartisan interest. Senator Alexander also has a strong interest in pediatrics,

sponsoring legislation that was signed into law that strengthened ongoing efforts to track, prevent, and treat premature births.

The House and Senate may also attempt to fix problems associated with the physician sustainable growth rate (SGR) calculation. Each year this formula, designed to restrain physician Medicare payments, proposes deep cuts in payments to clinicians-often in the 20 percent range. To avoid these cuts, Congress regularly cuts reimbursement to other providers, including clinical laboratories. If Congress pursues a 'permanent' fix, laboratory payments could once more be on the table. Congress has until March 2015 to determine how to move forward with this issue when the current 'temporary' fix expires.

The Centers for Medicare and Medicaid Services (CMS) sent a document to its State Surveyors '<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-11.pdf>' addressing the application of the CLIA'88 regulation to blood glucose monitoring systems (BGMS). The memo restates that blood glucose monitors that are used in situations or with populations not specified in the manufacturer's instructions are being used off-label and subject to the CLIA high complexity standards. Also, included in the document are two Q&A sections - one drafted by CMS and the other by FDA - addressing some of the many commonly asked questions.

Ray

Election Results

Steven Truscott

Dear Members,

Thank you for voting in the 2015 Local Section Election. Below are the election results:

- Chair-Elect: Yvonne Posey, MD
- Secretary: Steven Truscott, PhD
- Treasurer: Donald Giacherio, PhD
- Delegate: Seetharam Chittiprol, PhD
- Membership Chair: Lee Schroeder, MD, PhD
- Legislative Liaison: Raymond Karcher, PhD
- Nominating Committee Chair: Elizabeth Sykes, MD

Congratulations to the winners!

Steve

Local Interest

During 2014, the Michigan Section added 25 new members in the Full, Affiliate and Student categories. Welcome to all these members. We hope you will find attendance at section meetings helpful to your professional activities and look forward to meeting you.

To submit content for the newsletter, please send to raykarcher@sbcglobal.net.