ASCLS/CLMA 2017
Legislative Symposium
Update

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ASCLS Legislative Symposium

- Annual event - an ASCLS tradition since 1989
  - Was held March 20-21, 2017 in Alexandria, VA
  - 130 attendees from 43 states

- Other organizations involved include:
  - CLMA
  - ASCP
  - AMT
  - AGT
The 2017 Arkansas Delegation
ASCLS Legislative Symposium

- Purpose is to make the concerns of our profession known to members of Congress
- Attendees:
  - Learn how to lobby.
  - Receive tips on how to communicate with their congressional representatives.
  - See our political system in action.
  - Discover they CAN make a difference!
2017 Legislative Symposium

Claude Rector, Audrey Skaggs, and Letycia Nunez take a break from learning about the issues they will be discussing the next day with Arkansas legislators.
2017 ASCLS Legislative Symposium

Topics:

- PAMA (Protecting Access to Medicare Act)
- Shortages of clinical lab personnel need to be addressed.
- Regulation of LDTs.
PAMA

- Extend the deadline for data collection and reporting periods for the clinical lab fee schedule (CLFS) under Medicare to March 31, 2018.
- Delay enforcement of the updated CLFS until January 1, 2019.
- Revise the definition of “applicable laboratory” to mean a facility identified by a CLIA number.
Clinical Lab Personnel Shortage

- Enhance recruitment and retention efforts within the Veterans Health Administration.
- Authorize and appropriate funding for a program within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratory workforce.
- Authorize the Government Accountability Organization (GAO) to study the shortage of clinical laboratory personnel and make recommendations to Congress.
Regulation of LDTs

- FDA released a discussion paper on LDTs rather than a final guidance on January 17, 2017.
  - Made distinction between clinical validity and clinical utility
  - 4-year phase-in process instead of 9 years
  - Grandfather in traditional LDTs
  - Risk-based approach to oversight
  - PMA/510k documentation of new LDTs
- Leave Behind was ASCLS’s response to the paper.
Links

- Legislative Symposium Leave Behinds
  - [http://www.ascls.org/advocacy-issues/legislative-symposium](http://www.ascls.org/advocacy-issues/legislative-symposium)

- FDA Discussion Paper on LDTs
  - [https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf](https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf)
Senator John Boozman
Rep. Rick Crawford
Meeting with Sen. Tom Cotton
Sen. Cotton Tweeted About Our Meeting!

Thanks to Annette Bednar, Assistant Professor of Clinical Laboratory Science at ASU in Jonesboro, for talking with me today.
Results of 2017 Lobbying Efforts

- Letter sent to Secretary Price asking for a delay in the implementation of PAMA on March 24, 2017.
  - Signed by a broad coalition of lab groups
- March 30, 2017 CMS announced a 60-day enforcement discretion until May 30, 2017 for the data reporting period for applicable laboratory information.
- Not really what we were asking for, but is a start.
Diagnostic Accuracy and Innovation Act

- New piece of legislation offered by Rep. Bushon and DeGette to address the issue of LDTs
  - 215 pages
  - “Modernizes” CLIA
  - Applies to any in vitro clinical test (IVCT)
    - finished products (test kits, platforms)
    - laboratory test protocols (LDTs)
  - Lab operations regulated exclusively by CMS and CLIA
How to Get Involved!!

- Make an appointment to see the legislators when they are back home in Arkansas.
- Set up a State Legislative Day.
- Use Facebook Town Hall for contacting representatives.
- e-Mails
Heading Home!
Questions?

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