ASCLS TODAY

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February

Roslyn McQueen
Region IV Director

As I write this article for the February ASCLS Today, snow is falling and the temperature is in single digits. Initially, I was planning to write an article on organizational commitment, reflecting on the importance of member's psychological attachment to the organization and discuss ways for members to become more committed to their organizations. Sounds boring, doesn't it? I pondered the scope and breadth of this topic, but was drawn to reflect on key aspects of the month in which this article will be printed.

This article will appear in February which is the shortest month of the year. Some interesting trivia about the month is that February starts on the same day of the week each year as both March and November, and the same day of the week as August in leap years. February ends on the same day of the week as October every year and on the same day of the week as January, except in leap years. This year there are four even weeks in February.

Unique to the month of February are special days such as: President's Day, in honor of the United States' great leaders, Valentine's Day, which celebrates the beauty of a loving relationship and the designation of February as Black History Month, to commemorate the achievements of African Americans. To me, these three events resonated as a month for "love, leadership and diversity." Ultimately, I was drawn to reflect on the achievements of African Americans in the area of science in commemoration of Black History month.

Since the achievements and contributions of *clinical laboratory scientists* are frequently overlooked and under reported, I felt a significant parallel between the two groups. The precursor to Black History Month was Black History Week, a transition that might serve as a good point of reference for laboratorians.

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Member Wins Free Annual Meeting Registration!

Dave Falleur, M.Ed., MT(ASCP)

Congratulations to Dyan Monte Verde from New York. She is the winner a free registration to the 2015 ASCLS Annual Meeting to be held July 28-August 1 in Atlanta, Georgia. How did she do it? She simply submitted a completed evaluation form at the 2014 ASCLS Annual Meeting in Chicago. Everyone who submitted an evaluation, either online or paper, was automatically entered into a random drawing. Dyan's evaluation was the lucky one selected as the winner.

We thank Dyan and all who submitted an evaluation form. The evaluation forms provide valuable information to the Annual Meeting Steering Committee each year and assist them when planning future meetings.

You can find information about, and register for, the 2015 Annual Meeting by visiting the ASCLS Annual Meeting website:

www.ascls.org/annualmeeting

Today's Agenda

President's Message

Susanne Norris Zanto, MPH, MLS(ASCP)CMSM
ASCLS President 2014-2015

Government and Legislative Advocacy

In my continuing efforts to clarify our ASCLS Strategy Canvas for 2014-15, this column will discuss our efforts to strengthen our government and legislative advocacy. ASCLS has been a leader in healthcare government affairs, particularly the laboratory community, but we can always strengthen our advocacy.

In preparing this message, I came across a Community Tool Box website produced as a service by Work Group for Community Health and Development at the University of Kansas. This resource mentions several ingredients that make for effective advocacy. These ingredients, with some ASCLS specifics added, include:

- The rightness of the cause
- Clinical laboratory scientists feel passionately about our profession, and ASCLS supports positions on laboratory issues that we feel are in the best interest of our members
- The power of the advocates (i.e., more of them is much better than less)
- There is definitely power in numbers, as we harness the power of ASCLS membership, and that of our partners
- The thoroughness with which the advocates researched the issues, the opposition, and the climate of opinion about the issue in the community
- Their skill in using the advocacy tools available (including the media)
- Above all, the selection of effective strategies and tactics

The ASCLS Government Affairs Committee (GAC) members including our Executive Vice President, Elissa Passiment, and our Government Affairs Consultant, Patrick Cooney, are extremely knowledgeable about legislative and government healthcare issues, and develop appropriate actions based on a thorough analysis of the issues.

Our ASCLS Legislative Symposium has been a tradition for over 25 years, and over the years we have been joined by other laboratory organizations (CLMA, ASCP, AGT and AMT) to provide our members with tools to lobby Congress on issues that impact the medical laboratory community. Those who have attended "Leg Day" and gone on "Hill Visits" feel the power of the legislative process in our nation's Capital; this symposium should be on everyone's professional bucket list.

But this once-a-year opportunity is not the only time government and legislative advocacy is exercised and not the only time advocacy is needed. The ASCLS Government Affairs Committee continually monitors proposed legislation and government regulations and the potential impact on our workplaces, our profession, and our jobs, and determines appropriate responses, which can include a call to action for all members.

Although ASCLS, especially the GAC, continues to work to address issues affecting our profession, there is more that could be done. However, many of our fellow professionals in the laboratory community do not step up to help, and are willing to let others fight the good fight. This is not just a reflection of the laboratory community, but of our nation as a whole. According to the Washington Post, voter turnout for the 2014 November mid-term elections was the lowest in any election cycle since World War II (1942). While almost 73 percent of the population is registered to vote, less than 40 percent actually voted in the most recent General Election. Older citizens were more likely to vote, with a turnout of nearly 70 percent among voters over the age of 65. In contrast, less than 13 percent of citizens between the ages of 18 and 24 voted. Midterm voter participation has steadily declined since the 1964 election, when voter

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Medical Laboratory Science: The Faceless Profession

Cecile Sanders, M.Ed., MLS (ASCP)^{CM},
Adjunct MLT Professor, Austin Community College

In the October 2014 edition of *ASCLS Today*, Beth Warning provided a very thorough and thoughtful analysis of the discussion regarding 2012 NAACLS accreditation standards for phlebotomy instruction. She provides a convincing argument for continuing to include phlebotomy in both MLT and MLS educational curriculum. This article adds some additional thoughts about her conclusions.

Clinical laboratory professionals have continually lamented the lack of respect from the lay community and the fact the lay community does not have an understanding of the profession. This should come as no surprise, given that laboratory professionals are "faceless" to patients and healthcare colleagues. It appears all patients, nurses, doctors, etc., know about laboratory medicine is that blood is drawn, urine is collected, and other specimens are taken and sent to an unknown place for processing and analysis. Arguably, laboratory educators are reinforcing that lack of knowledge about the profession by not placing a strong emphasis on phlebotomy in the MLT/MLS curriculum. Drawing blood is the ONLY contact we have with patients; without that contact, we are further isolated. A lack of patient interaction reinforces a "faceless" image for the clinical laboratory profession. Patients become nothing more than bar-coded tubes of blood.

Additionally, for the majority of clinical laboratory employers, graduation from MLT/MLS programs implies at a minimum an entry level competency in phlebotomy and other pre-analytic factors. It is inconceivable to many hospitals and clinics, especially in small and rural communities, that an MLT/MLS would apply for employment with little or no firsthand knowledge and skills in phlebotomy. It has been offered that employers could provide phlebotomy training, if the job requires it. However, the healthcare community has long abandoned the idea of on-the-job training, especially in such a critically important area of patient care, where the quality of laboratory testing is only as good as the specimen on which it is performed.

Many states are now pursuing licensure for laboratory professionals. With the general lack of understanding about the analytical knowledge and skills needed to produce accurate and reliable laboratory results, there is little support from the public or legislators to recognize the clinical laboratory profession as unique and sufficiently critical to require licensure. There is little appreciation of the level of education and skill needed to perform the highly complex laboratory analyses that are essential to quality patient care. So we need to make sure that patients are confident that we can deliver skillful phlebotomy services, the one skill for which they do know us.

Moreover, laboratory professionals seem to be willing to give away critical elements of their scope of practice. Blood gas analysis has been shunted off to respiratory care practitioners. Point of care testing and phlebotomy are increasingly in the hands of the nurses and first responders. Even pharmacists are chipping away at clinical labs by offering blood glucose and protime/INR testing. While this trend may be unavoidable and beneficial in terms of convenience for the patient, this movement once again adds to the faceless aspect of *clinical laboratory science*. As a profession, we should be searching for more ways to interact directly with patients by providing testing and quality assurance at a level only attainable by certified laboratory professionals, starting with strong phlebotomy instruction.

"As a profession, we should be searching for more ways to interact directly with patients ..."

Curriculum Changes and the Effects on the Quality of Coagulation Education in a South Carolina MLT Program

Michelle Mantooth

In 2012, Trident Technical College evaluated its curriculum delivery for the purpose of improving student success. The curriculum delivery changes would include all programs - healthcare or otherwise. As a result, all faculty members were involved in evaluating the different programs of study, and determining how to best compress the traditional 14 week semester into a 7 week semester. There were exceptions to this based on clinical instructional time needs, but it was strongly encouraged for all programs to address the curriculum, and restructure into a 7 week format.

The original MLT Program structure included two 4 credit hour lecture/lab courses in hematology. The first hematology course was taught in the spring semester, and the second hematology course was taught in the fall semester. The original spring hematology course focused on automation, quality control, hematopoiesis, red blood cells, hemoglobin, and anemias. The original fall hematology course focused on coagulation, white blood cell disorders, leukemias, and body fluids. In the original 14 week semester, coagulation was allotted 3 weeks for lecture and 3 labs out of 14.

It was the opinion of the instructor that coagulation should be separated from the original hematology courses and have its own 2 semester credit hour lecture and lab course. So when the college began the process of changing its curriculum delivery, coagulation received its own stand-alone course by breaking the original 4 credit hour hematology lecture/lab courses into four 2 credit hour courses. The first course covers automation, quality control, and hematopoiesis; the second course covers red blood cells, hemoglobin, and anemias; the third course covers coagulation, and the fourth course covers white blood cell abnormalities.

In this new course layout, coagulation would now be taught in 7 weeks versus 3, and would also have 4 more laboratory sessions. Spreading the lecture material over 7 weeks was not the most challenging portion of the course changes. The additional laboratory sessions required was a bit more difficult based on the minimal equipment available for teaching coagulation in the laboratory. The labs had to be based on mechanical or tilt tube methods. The lab equipment available included 2 fibrometers and plenty of test tubes and nichrome loops. The labs finally selected for the course included the bleeding times and platelet counts; prothrombin time; activated partial thromboplastin time; mixing study using normal pooled plasma; lupus anticoagulant; and d-dimer & fibrin degradation products. Great efforts were made to coordinate the lecture topics with the testing being performed in the lab session for the week.

The MLT Program Director started giving the MLT students an exit survey concerning the entire program and how prepared the students felt heading into the clinical setting in 2013. Under the hematology question, approximately one third of the students stated they needed more time and hands on lab practice with coagulation. However, the students' ASCP Board of Certification Exam scores demonstrate the exact opposite of their perceived need. Based on the instructor's belief and the students' perceived need established by exit survey responses, it was decided to compare the original 3 week coagulation course to the new 7 week coagulation course. The statistical hypothesis for this comparison was that there would be a measurable difference demonstrated by an improvement in exam scores and student readiness perceptions with respect to coagulation.

To assess the curriculum changes, the first class of students taking the new 7 week coagulation course was given an open-ended question survey at the end of the course to help compare the perceptions of the two groups of students being used in this evaluation. The final exam for the 7 week course cohort and exam 2 for the 3 week course cohort were identical, and the case study set used for the 2 cohorts was also identical.

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Cirriculum *From Page 4*

The following chart includes the statistical analysis comparisons for the exams and case studies:

Statistical Parameter (Westgard.com QC Calculators used)	Fall 2013 Exam 2	Fall 2014 Final Exam	Fall 2013 Case Studies	Fall 2014 Case Studies
Mean	90.93	88.95	84.87	80.26
%CV	8.53	10.18	8.47	13.22

Because of the uneven cohort size, an unpaired t Test was used to determine if there was a difference between the two cohorts. Based on the lecture examinations, a two-tailed P value of 0.5200, with a confidence interval of 2.179, a t of 0.6529, a df of 24, and a standard error of difference of 3.337 was calculated using an on-line statistics calculator called QuickCalcs. These same calculations were performed on the case studies sets – a two-tailed P value of 0.1991, with a confidence interval of 4.603, a t of 1.3205, a df of 24, and a standard error of difference of 3.486 was determined.

Based on the statistical analysis of these numbers, it was determined no statistical difference between the 2 cohorts exists based on these 2 grading events.

Student perceptions haven't changed - approximately 40% still want more time working with the material. The 7 week cohort made recommendations for improving the course, too – change the order of the factors and coagulation cascade discussions, offer more quizzes/assignments, and increase the number of in-class practice sessions with case studies. The 7 week students unanimously agreed the additional labs and the charts used in both lecture and lab, and the order in which these were assigned/taught, helped immensely with their understanding of the material and ability to apply what they learned to the case studies. Their performance on the ASCP BOC coagulation questions will hopefully be as strong as the 3 week students or better.

2015 ASCLS Awards Nominations Season Fast Approaching

Marcella Yee
ASCLS Awards Chair

Now is the time to identify the outstanding ASCLS members around you, and to nominate them for an award. Society categories cover a broad range of ASCLS activities - from outstanding publications or newsletters, websites, to activities that give ASCLS a "Face" in the community (promoting the profession). For individual awards, consider who you can nominate for the New Professional, Student Forum Leadership, or the Lifetime Achievement Award. You can also submit the name of the Member of the Year from your Constituent Society, and he or she will be recognized on stage at the Annual Meeting in July.

The Awards section on the ASCLS webpage has moved, to http://www.ascls.org/about-us/scholarships-and-awards-celebrate. There are links on the right side of the page to each of the individual awards, as well as overall guidelines. The Awards Committee at ascls@awards.org is available to help with any questions.

Many of the awards, but not all of them, have a **February 15th deadline**. Nominations **must** be submitted by the deadline to be considered. Winners will be recognized at the 2015 ASCLS Annual Meeting Awards Ceremony. The Awards Committee challenges each constituent society to nominate a worthy member for each award. Don't miss this opportunity to recognize the achievements of your fellow ASCLS members!

Transitioning the Region VIII IMSS

Joni Gilstrap, Region VIII Director

In 1962 Utah Society for Medical Technology had the idea of starting an Intermountain State Seminar. Idaho joined in and the proposed site was Jackson Hole, Wyoming if Wyoming would join forces. Not only did Wyoming agree but Montana also wanted to participate. All four states realized a combined seminar would provide noted speakers, quality workshops and active participation. Colorado joined as the fifth state in 1970. The first seminar (Inter Mountain States Seminar - IMSS) was held in May of 1964. Subsequent meetings have been held in September. The five states developed a rotation for hosting the annual convention as follows: Idaho, Utah, Colorado, Wyoming and Montana. In 1967, a Coordinating Committee was established to assist in planning and to provide continuity to the Seminar. The Coordinating Committee has been comprised of two members from each of the five states serving terms of five years. An exhibitor liaison was also a member of this committee. All of these members were volunteers. Profits from the seminar were split 7 ways (each state, IMSS Planning Committee, and Region VIII).

For 50 years IMSS has been planned by the Coordinating Committee. Coordinating Committee members made huge time commitments to be on this Committee. The state hosting the meeting would recruit a Planning Committee that would meet in Jackson Hole along with the Coordinating Committee to discuss the meeting and how things were progressing every June. The past several years this meeting with the Coordinating Committee has changed to a conference call to help contain costs. There would also be conference calls in October and February to discuss the seminar and other things relating to IMSS. One Coordinating Committee member of the state planning the meeting was the General Chair for the meeting.

Many things have led to the transition from a Coordinating Committee to the Region VIII Council. Much discussion and many options were considered. Over the 50 years of IMSS, Jackson Hole has become a famous tourist retreat. The beautiful scenery, great skiing, hiking, wonderful shopping and restaurants has drawn people from all over the world. Yet only one hotel has enough rooms needed to accommodate the 100+ attendees. Because of the increasing costs the meeting has moved to an "off season month," October. Currently we are in the process of utilizing a pavilion that is located close to the convention center for exhibitors and educational meeting rooms. Because on-line continuing education hours are easily accessible and employers do not support participants as they have in the past, there has been a steady decrease in attendance. Engaging volunteers to help with the planning of the meeting has also been a struggle.

This year the Coordinating Committee and the ASCLS Region VIII Council worked together on the 51st Annual Meeting held in Jackson Hole, Wyoming. Each position essential to coordinate the meeting (General Chair; Program; Social; Exhibits; Registration; Publicity; Awards; PACE and Finance) had a co-chair to learn and share information on the position this year. The plan is to continue this model for future IMSS meetings.

So we celebrated fall and Oktoberfest (Harvest the Knowledge!) with brats, beer, pretzels and Friday night karaoke at the Banquet held at the Snow King Pavilion. The Pavilion was also the site of our exhibits this year. Twenty-five (25) exhibitors with new instrumentation and information from their companies helped support this meeting as they have for the last 51 years. Fourteen (14) P.A.C.E.® credits were possible in the 3 day event and topics included all disciplines of the clinical laboratory. A Scientific Assembly breakfast or lunch is held every year. The 2014 IMSS meeting included Keynote Dr. Bill Sukov of the Mayo Clinic presenting a molecular topic entitled "HER2 FISH". Our ASCLS President, Susie Zanto, spoke on "ASCLS: One Vision, One Voice" sharing her Blue Ocean message for the future.

Each state nominated one person for Region VIII 2014 CLS/MLS of the Year. This award has been given since 1966 and has been sponsored by Baxter Scientific Products in the past and currently by Bio-Rad Inc. The 2014 award went to Stephanie Mihane from Colorado.

If you haven't attended IMSS in the past, please consider adding this meeting to your calendar for 2015. The camaraderie, networking, education and beautiful scenery make IMSS a great seminar.

Keys to the Future

Marcella Yee
LDC Committee, Region X

The Keys to the Future are the new "sprouts" that are the future of ASCLS. This award serves to recognize and encourage members who have demonstrated their leadership potential.

Now is the time to recognize the new talent around you! Each Constituent Society can submit the names of up to 3 members who have become recently active. They may be new members, or members of long standing who have also recently become active. Recipients are awarded a unique Key to the Future pin at the annual ASCLS meeting. In addition, each nominee should be recognized by his or her Constituent Society for his/her contributions.

So put your thinking caps on—is there a new professional who has stood out this year? A new member who has made an impact? A "seasoned" member who is just now becoming active in your society? Someone who quietly mentors or provides support to other members?

The **deadline is April 30**, and it is the hope that every Constituent Society submits the maximum 3 nominees for this award. See http://www.ascls.org/keys-to-the-future for complete instructions and qualifications. Questions? Please contact Leadership Development Chair Tim Randolph at randoltr@slu.edu; nominees should also be submitted to Tim.

Double-Win Effect

Kimaria Baker, MS, MLS(ASCP)^{CM}
Student Forum Secretary

Each healthcare profession has individualized roles, skills, and responsibility that contribute to the enhanced efficacy of patient care. However, the knowledge and understanding of each other's responsibilities in patient care is absent. This lack of understanding has led to a widening gap between efficient treatment of the patient and the members of the healthcare team providing that care. As medical laboratory scientists, our roles in patient care are without question, extremely vital to patient diagnosis/prognosis. We have a full understanding of who we are and our contributions to patient outcomes, but other healthcare professions do not share that same knowledge. For this reason, it is very important to have interprofessional activities among healthcare professionals so that we each learn what the other contributes to patient care.

Interprofessional education for healthcare professionals has become the golden goose to improving patient care. Interprofessional education involves two or more healthcare professions teaming up to make a collaborative effort to improve patient care. A few healthcare education programs have begun to introduce and implement this concept in a student setting. Collaboration of health professions is needed for effective patient treatment, because it can be so different with each case. As students to gain knowledge of each other's professional roles, communication and collaboration between health professionals will significantly improve as will patient outcomes. Interprofessional education in the student setting increases the confidence of everyone on the patient care team. Although I only took a couple of interprofessional sessions during school, they helped me to understand other health professionals' skills and responsibilities immensely. It made me feel more comfortable speaking up and sharing my knowledge. I learned the importance of being flexible without overstepping professional boundaries. It also created a nurturing and stable environment for me to practice expressing my professional opinions.

Some patients have complex health needs which typically require more than one discipline to address matters concerning their health status. That is why it's imperative to conduct interprofessional activities among healthcare professionals. As with all new concepts and ideas, there are positives and negatives; however, the positives are far greater than what we may consider negative. If interprofessional education exposure were increased in student and professional settings, the double-win effect would be achieved. What would be the double-win effect in this case? A win for the patient AND a win for healthcare!

As the FDA Plans to Regulate Laboratory Developed Tests (LDTs): Here is What ASCLS Said on Your Behalf

ASCLS wrote comments in response to the FDA's request for input and comment concerning oversight of Laboratory Developed Tests (LDTs) ASCLS commended the FDA for its attempt to frame the issues surrounding LDTs which include the need to carefully define what will be considered a LDT; the enforcement discretion that FDA should use; how the risk will be categorized; how to document clinical validity and how the information collection process will work.

ASCLS agreed with the definition as proposed but told FDA it should be sufficient that a network of laboratories in a system or in the public health system be able to submit a single notification from the network or the originating laboratory. As health care entities combine, standardization of patient care across all sites in the system occurs and clinical laboratories revise their testing systems so that patient test results will be equally interpretable regardless of where in the system that patient sample is tested. That means that the instrumentation and methodology needs to standardized and that would include the sharing of any in-lab developed tests.

To be practical, the FDA needs to narrow its definition of LDTs that require clearance to those methods that are novel and have never been reviewed by the agency and pose high risk because of highly complex/proprietary methods or claims that the test can diagnose, either specifically or by differentiation, or provide results that purport to determine/direct therapy.

ASCLS agreed that the attributes identified in the guidance are the correct criteria to use to decide the risk posed by an LDT:

- Manufactured with components that are not legally marketed for clinical use
- Offered beyond local populations and manufactured at high volume
- Used widely to screen for common diseases rather than rare diseases
- Highly complex (e.g. automated interpretation, multi-signal devices, use of non-transparent algorithms and/or complex software to generate device results)

We agree that FDA should continue to exercise enforcement discretion for traditional LTDs. We believe that it is part of scope of practice of laboratory scientists and pathologists to modify existing methods to improve performance, respond to the needs of patients, or expand the types of specimens tested. Laboratory tests always evolve as laboratorians modify tests, adjusting pH, reagent concentration, etc. or validate different specimen sources on an existing method. None of these changes affect the clinical validity or intended use of the test results. These modifications usually stay within that laboratory for its use on its own patients. We do not believe that these modifications should be considered laboratory developed tests. We believe that existing CLIA oversight of performance validation is sufficient for these modified tests.

Clinical Validity

ASCLS defines clinical validity as how well the test determines the presence, absence or potential risk of disease. We believe that clinical validity is the most important concern when formulating guidance for highly complex/high risk LDTs. To determine what processes are needed to establish clinical validity, ASCLS recommends that the FDA refer to the Center for Medical Technology Policy's document entitled "Evaluation of Clinical Validity and Clinical Utility of Actionable Molecular Diagnostic Tests in Adult Oncology at http://www.cmtpnet.org/docs/resources/MDX_EGD.pdf. We completely agree with the FDA's statements about the gaps between CLIA and FDA oversight. Current CLIA regulations for laboratories in the United States do not mandate the processes needed to prove clinical validity nor do they "include a review of the clinical validation of a LDT – that is, the accuracy with which the test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient." CMS CLIA has made this very clear. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf

The Collection Process

Clinical laboratories are going to struggle with FDA's terminology, approval processes and turn around time because most have never even heard of FDA's regulations much less submitted anything for FDA approval. Clinical laboratories will need help understanding what the FDA wants to see in the way of data,

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February From Page 1

Black History Week transitions to Black History Month

- In 1926, historian Carter G. Woodson and the Association for the Study of Negro Life and History announced the second week of February to be "Negro History Week."
- This week was chosen because it coincided with the birthday of Abraham Lincoln on February 12 and of Frederick Douglass on February 14, dates which Black communities had celebrated together since the late 19th century.
- In February 1970, the first celebration of the Black History Month took place at Kent State as proposed by the leaders of the Black United Students at Kent State University in February 1969.
- In 1976 as part of the United States Bicentennial, Black History Month was officially recognized under the administration of President Gerald Ford to "seize the opportunity to honor the too-often neglected accomplishments of black Americans in every area of endeavor throughout our history."

African-American chemists have made important contributions in physical, organic, nuclear, and analytical chemistry. Current data indicates African-Americans comprise nearly 4 percent of Ph.D. students in chemistry. I have chosen to highlight the achievements of a few African American scientists, although my research detected a much larger list.

George Washington Carver
emerged as a pioneer in agricultural research in the late 19th century. He found dozens of uses for chemicals he extracted from peanuts and potatoes. His research led to the development of hundreds of products, including ink, shampoo, and peanut butter. He later became a vocal supporter of growing peanuts as a source of protein.[2, 3,4,15]

Charles Drew
developed improved techniques for blood storage. Drew researched the use of blood plasma rather than whole blood transfusions while at Presbyterian Hospital in New York, NY. Later, he organized a blood bank in London during World War II.[5,6,7,8,15]

Lloyd A. Hall
president of the Griffith Chemical Company, discovered important food preservatives.[9,15]

Percy Lavon Julian
was a research chemist and a pioneer in the chemical synthesis of medicinal drugs from plants. He was the first to synthesize the natural product physostigmine, and a pioneer in the industrial large-scale chemical synthesis of the human hormones progesterone and testosterone, from plant sterols such as stigmasterol and sitosterol. His work would lay the foundation for the steroid drug industry's production of cortisone, other corticosteroids, and birth control pills. Julian registered more than 130 chemical patents during the course of his career[10,11,12,15]

William A. Lester Jr.
theoretical chemist did research on the troubles of high-velocity molecular collisions and was chosen to manage the National Resource for Computation in Chemistry.[15]

James A. Harris
co-discovered Rutherfordium (atomic number 104) and Hafnium (atomic number 105) at Lawrence Livermore Laboratory.[12,13,15]

Jane Wright
former director of the Cancer Research Foundation, was noted for her contributions to chemotherapy and for pioneering the use of the drug methotrexate to treat breast cancer and skin cancer.[15]

In conclusion, as the snow continues to fall and the forecast is for freezing rain, I reflect again on the fact that many groups and organizations in the scientific arena have been underestimated or overlooked. Maybe in the near future, instead of national laboratory appreciation week, we may have a "National Laboratory Science Month" dedicated to the achievements and contributions of *clinical laboratory scientists*. Maybe in the not too distant future, when someone mentions the name "*medical laboratory scientists*" everyone will know what we do, and actively seek to become a part of the profession. Freezing raining changing to six inches of snow—don't you just love winter in Michigan?

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Advocacy *From Page 2*

turnout was at nearly 49 percent. The Sunnyside, WA *Daily Sun* News had a great infographic that demonstrates voter apathy, and I think this is not just a reflection of voter apathy, but also the current trend in joining professional societies and becoming involved.

So, joining ASCLS and becoming involved is one way to become an advocate. Another way is to contribute to the ASCLS Political Action Committee (PAC). By providing financial and educational support to the election campaigns of responsible candidates for Congress, the ASCLS PAC offers members a simple, convenient way to influence the elections process and actively participate in legislative decision-making. It is easy to contribute – just visit the ASCLS website at www.ascls.org, and click on the **yellow** *Donate* button, located toward the bottom of the main webpage. PAC fundraising also occurs during the Legislative Symposium, at the Annual Meeting, and solicitations are encouraged at each state and regional continuing education meeting.

Although strengthening our legislative and government advocacy is one key element of our ASCLS Strategic Canvas, two other key elements also contribute to the success of advocacy – maintaining our collaborative efforts with other healthcare related organizations, and creating a strong social media presence. When we lobby Congress, or take positions on laboratory issues, we often partner with other organizations, or join with the Clinical Laboratory Coalition, to speak with one powerful voice. In addition, research has started to address how advocacy groups are using social media to facilitate civic engagement and collective action.

There are many opportunities in ASCLS for a member to be a legislative or government advocate. It doesn't have to involve confrontation or conflict, and as I mentioned in my message last month, the start of my involvement with ASCLS included advocating and lobbying at the state level for personnel licensure. Maybe your first step is to donate to the ASCLS PAC, or maybe you decide to attend the ASCLS Legislative Symposium. This successful educational event will be held March 16-17, 2015, in Alexandria VA, and I would love to see you there!

Tests *From Page 8*

design of clinical and performance studies, etc. and the FDA's Quality System Regulation and FDA must provide that education.
ASCLS emphasized that:

- Modifying existing FDA approved assays with different specimen sources or similar changes that do not change the clinical validity is within the scope of practice of laboratorians and the agency should not require the assay to be submitted for FDA approval.
- A LDT developed within a system should be sharable without every site submitting separate applications for FDA clearance
- Education of FDA terminology and clarification of agency intent should be vital components of the implementation and registration process to ensure success.

ASCLS TODAY

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1861 International Dr., Ste. 200
McLean, VA 22102
Phone: 571-748-3770
Fax: 571-354-7570
Email: ascls@ascls.org
website: www.ascls.org

Elissa Passiment
Executive Vice President
elissap@ascls.org

Karrie Hovis
Education Office
karrieh@ascls.org

Patrick Cooney
Legislative Affairs

Andrea Hickey
P.A.C.E.® Membership Services Coordinator
andreah@ascls.org

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