

RESULTS

American Clinical Laboratory Association

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RESULTS is a monthly report to ACLA member companies

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President's Message

While next month is known for "March Madness," the real action will be right here in Washington, DC April 17-18 for the 13th ACLA Annual Meeting. The team of confirmed speakers includes some of the best players in government, media, and the lab world. They include political commentator and Hardball host Chris Matthews, Senate Finance Committee member Senator Pat Roberts (R-KS), Senator Barack Obama's (D-IL) health counsel Dora Hughes, CMS Deputy Administrator Herb Kuhn, and many others. If you have not already registered, don't wait for the clock to run out. See www.clinical-labs.org for registration information.

ACLA's membership continues to grow in size and laboratory diversity with the addition of two outstanding members this month, Aculabs, Inc and Machaon Diagnostics. Aculabs, Inc. is a full service laboratory serving Medicare and Medicaid beneficiaries in New Jersey, Pennsylvania, Delaware and Maryland. Machaon Diagnostics is a clinical reference laboratory based in Oakland, California specializing in the diagnosis, treatment and monitoring of hemostatic and thrombotic conditions. We welcome Pete Gudaitis and his team at Aculabs, Inc and Mike Ero and his team at Machaon Diagnostics to the ACLA family.

I was proud to participate in the Results for Life campaign's first "media tour" last month in Salt Lake City, Utah. ACLA's Chairman of the Board and ARUP Laboratories' President Dr. Ron Weiss joined me for a whirlwind tour of key newspapers and electronic media in the SLC area. Ron and I had a very good response from editorial board members and reporters as we delivered the "value of laboratory services" message. Both SLC newspapers printed a terrific "op ed" piece by Dr. Weiss shortly after our tour!

In spite of my message above about all of the action in April with our Annual Meeting, there will be a fair amount of "March Madness" here at ACLA as we continue our push on Capitol Hill to repeal the competitive bidding demonstration. We will also hold an important "LABLine" on

March 18 entitled "CLIA Steps Up Enforcement: What Does It Mean for You?" Sign up today on the ACLA website, www.clinical-labs.org.

There are many other issues for ACLA this month which are discussed the more detail in this [Results](#).

I look forward to seeing all of you April 17-18 for our Annual Meeting!

Court Denies TRO for San Diego Demo/ ACLA Asks Leavitt to Suspend Demo

On February 14, in response to the lawsuit filed by San Diego-based laboratories seeking to halt the submission of bids for the Medicare clinical lab competitive bidding demo, the US District Court of Southern California denied the temporary restraining order (TRO) and ordered the plaintiffs to show why the case should not be dismissed altogether. Consequently, the February 15 bid submission deadline remained in effect, and the parties to the suit prepared to respond to the court by the February 29 deadline. The government will then have until March 14 to respond.

The court denied the TRO on the grounds that there had not been a showing of irreparable injury that would occur prior to the submission of bids and that any potential harm would come only after the winners are announced on April 11. The court also appeared to agree with the government's contention that, under Medicare, plaintiffs are required to exhaust their administrative remedies prior to judicial review.

The plaintiffs filed their response on February 29 arguing that the government misrepresented and overstated the applicability of the principles of jurisdiction, reviewability, ripeness and standing and that the plaintiffs should not have to wait "for the axe to fall" on April 11 before obtaining preliminary injunctive relief. The plaintiffs will file a separate motion seeking preliminary injunctive relief prior to April 11.

In a February 13 letter to HHS Secretary Michael Leavitt, ACLA asked HHS to suspend

immediately for a period of at least 180 days any action to implement the competitive bidding demo project, stating that there continue to be serious flaws and uncertainties that remain uncorrected. We wrote that until the existing design of the project is altered to address the flaws and uncertainties, Medicare beneficiaries living in the demo area will almost certainly be denied access to laboratory testing services, especially innovative new tests that save lives and dollars. We argued that esoteric labs that bill only a few tests could be required bidders under the demo and would be very unlikely to be winning bidders.

CMS responded to our letter with its standard arguments in support of the design of the demonstration and claimed to have identified only “a few laboratories that bill only a few codes” and found almost no niche labs that bill only a few codes and are required bidders. CMS went on to state that if these labs were non-winning labs, they would continue to be able to provide and bill for services to beneficiaries in Medicare Advantage plans and to beneficiaries residing outside the demonstration area. CMS did not address how the fee for service beneficiaries covered by the demo would be able to receive services from these laboratories.

Repeal Effort Continues; Grassroots a Key Role in Bolstering Support

Despite the latest setback in the legal challenge to the competitive bidding demonstration project, efforts continue on Capitol Hill to enlist more support in the House and Senate to repeal the project. Just this month the House repeal bill, HR 3453, enjoyed the addition of three new co-sponsors: Susan Davis (D-CA); Barney Frank (D-MA); and Timothy Walz (D-MN). The addition of Congresswoman Davis is particularly important as she represents the City of San Diego. With these latest additions the bill has a total of 34 co-sponsors.

In the Senate, our focus has turned to a handful of Senators who, we’re told by Senate staff, would be the most likely to support our efforts to repeal the demo project: Senators Jon Kyl (R-AZ); Kent Conrad (D-ND); Debbie Stabenow (D-MI); Jon Ensign (R-NV); and Blanche Lincoln (D-AR). In addition, we are also targeting Senator Mitch McConnell (R-KY) as he is the Minority Leader in the Senate and served as the lead negotiator on a final Medicare bill last December. ACLA and the Clinical Laboratory Co-

alition are asking companies/members in these states to call, email or fax these Senators and urge them to co-sponsor S. 2099, the Preserving Access to Laboratory Services Act of 2007, and support efforts to repeal the competitive bidding demonstration project. ACLA and the CLC plan to follow up these communications with meetings in the Senator’s offices to help drive home the point and communicate the sense of urgency.

The timeline for consideration of a Medicare bill by the Senate remains the same. The earliest the Senate Finance Committee will begin work on a bill is mid-April. Until then, ACLA and the entire lab industry’s efforts will be focused on increasing bipartisan support for the repeal as the start of the demonstration project on July 1st inches closer.

President’s 2009 Budget Request

For the second year, President Bush has proposed to take competitive bidding for laboratory services furnished to Medicare beneficiaries nationwide as a permanent change to the program at a savings of more than \$2 billion over five years. The FY 2009 Medicare budget proposal, which would reduce outlays by more than \$178 billion over the next five years, has been labeled “dead on arrival” by Congressional leaders. The budget also announced that CMS plans to have its systems ICD-10 compliant by October 2011 and is in the process of preparing a proposed rule to implement ICD-10 by that date. ACLA continues to participate in a broad-based coalition led by Blue Cross Blue Shield Association to ensure that providers and CMS have enough lead time to transition successfully to ICD-10. Past experiences with compliance and transition issues associated with the 4010 claims forms and the NPI point to the necessity of proceeding cautiously and deliberately.

SACGHS Finalizes Genetic Test Oversight Recommendations

At a February 12-13 meeting of the HHS Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) in Washington, D.C., the committee finalized a broad range of recommendations, which it plans to send to HHS Secretary Michael Leavitt by February 29. Last March, SACGHS was commissioned by HHS to draft a plan to address observed gaps in genetic test oversight. A draft of the report and its accompanying recommendations was released for public comment November 5th. ACLA provided extensive written comments to SACGHS and public comment at the meeting

– both are posted on the ACLA web site.

ACLA’s commended SACGHS in recognizing the need for a flexible risk-based approach to genetic test oversight and the important role laboratory developed tests (LDTs) play to keep pace with the rapid developments in this area. However, ACLA cautioned that if the FDA’s Food Drug and Cosmetic Act requirements are applied to genetic test oversight without interagency coordination, needless redundancies and duplications will result. ACLA recognizes an important role for FDA – but it would be premature for SACGHS to definitively support FDA regulation of LDTs without recognizing the important first step of interagency coordination and requirement harmonization.

ACLA submitted a regulatory model to SACGHS, FDA and CMS that builds on interagency coordination, is consistent with principles of least burdensome regulation, fills all the regulatory “gaps,” avoids overlapping and potentially conflicting regulatory oversight and allows for a participatory approach that draws on the expertise of industry stakeholders, CMS, and FDA. By invoking public-private partnerships, these models avoid significant new costs for the agencies. ACLA strongly encouraged SACGHS to adopt recommendations consistent with these principles.

The discussion at the SACGHS meeting, on the recommendation for regulatory oversight, recognized a concern in oversight related to clinical validity. The committee discussed ways to approach those concerns including having all laboratory tests addressed by FDA in a manner that takes advantage of its current experience in evaluating laboratory tests. There was recognition that this is a resource intensive process which will require commitment of additional resources. Recommendations in this area included that HHS convene a multi-stakeholder public and private sector group to determine the criteria for risk stratification and a process for systematically applying these criteria. This group should consider new and existing regulatory models and data sources and address and eliminate duplicative oversight procedures. The Committee further discussed the need for establishment of a mandatory test registry of laboratory developed tests. SACGHS called for a stakeholders meeting later this year to inform the lead HHS agency in determining the data elements associated with analytic validity, clinical validity, clinical utility, and accessibility that could be included in the test registry.

After submitting its specific recommendations to Secretary Leavitt this month, SACGHS plans to finalize a more detailed report on genetic test oversight by April 30.

CLIA Celebrates Twenty Years of CLIA

The February 20 and 21st meeting of the Clinical Laboratory Improvement Advisory Committee (CLIA) recognized and celebrated the twentieth anniversary of the CLIA regulations. The three agencies involved with CLIA – CMS, FDA and CDC – provided presentations to CLIA about their roles over the past 20 years and how laboratory testing has benefited. Objective evidence was provided in the form of decreased inspection deficiencies over time and increased performance on external quality assurance among other findings. Presentations from Accrediting Organizations and CLIA exempt states echoed the agencies message.

On the second day, FDA's Dr. Steve Gutman provided an agency update. Of note, Dr. Gutman referenced FDA's receipt of three alternative regulatory proposals for IVDMA's. The proposals are from the 21st Century Medicine Coalition, AdvaMed and ACLA. The proposals are under review by FDA as are the recommendations from SACGHS on the subject – see related story in this RESULTS. SACGHS was also updated by CDC that a MMWR topic "Good Laboratory Practice for Ensuring the Quality of Genetic Testing" is underway. A draft will be available for stakeholder review (including ACLA) in July and presented to the full CLIA at their September meeting. The MMWR is scheduled for November.

The CMS update from Judy Yost, Director, Division of Laboratory Services, indicated although no new policy changes there is stepped up CLIA enforcement. She said that based in part on recommendations

from the June 2006, U.S. Government Accountability Office (GAO) report on clinical lab quality and on the new quality control requirements for non-waived testing issued in 2003 (most of which are no longer educational, but now required), CMS and its partners have heightened interest in laboratory quality oversight. ACLA will hold an audio conference LABLine on the topic March 18th at 2 PM eastern time. More information about the LABLine is available on the ACLA website and in this [Results](#).

Results for Life Update

Be on the look out for print articles in your local newspapers communicating the *Results for Life* message -- laboratory services save lives and save dollars. The *Results for Life* campaign is working with the North American Precis Syndicate in placing both print articles and 60 second radio spots nationwide. In a related effort, Representative Diana DeGette (D-CO), co-chairwoman of the Congressional Diabetes Coalition, authored an excellent article in "The Hill" newspaper publication widely read by Capitol Hill members and staff. The title of the article is "Best Defense Against Diseases: Early Detection and Treatment" which speaks to the rising cost of chronic disease and the value of laboratory tests in early detection and cost savings.

Results for Life will be prominently represented at three meetings in March - the AdvaMed Annual Meeting, the Carolinas Clinical Connection and CLMA's ThinkLab. These are opportunities to bring visibility to the campaign and to recruit Ambassadors to be local advocates of the program. Our next Ambassador training program is March 4th.

On January 23rd, *Results for Life* hosted a luncheon in Washington for employer and payer groups. The event com-

municated the role of laboratory services in an effective, cost-effective health care system and discussed ways to work together in advocating forward-thinking steps to improve health care delivery. Representatives from over 20 groups attended and the feed back was very positive.

State Issue Update

ACLA has been successful in obtaining a meeting the third week in March with officials of the Florida Medicaid agency to discuss reductions in payment for certain CPT codes as well as developing an ongoing more formal relationship with the agency on laboratory policy issues.

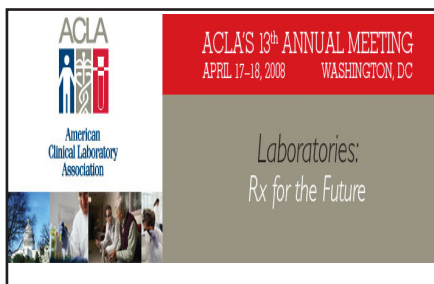
ACLA contacted the members of the Minnesota House and Senate health committees opposing legislation to establish state laboratory personnel licensure requirements. We also wrote to the members of the Michigan House health policy committee opposing personnel licensure requirements.

ACLA wrote to the chairman of the California Assembly Budget Committee opposing the proposed 10% cut in Medi-Cal payments for clinical laboratory services.

ACLA Welcomes Two New Member Companies!

AcuLabs Inc., a full service laboratory that has provided superior quality laboratory testing for over 35 years and is fully accredited, is based in East Brunswick, New Jersey.

Machaon Diagnostics Inc., a clinical reference laboratory specializing in the diagnosis of hemostatic and thrombotic conditions, is based in Oakland, California.



Please visit ACLA's website, www.clinical-labs.org, for more information.

ACLA'S LABLINE KEEPING YOU CURRENT

**CLIA STEPS UP ENFORCEMENT:
WHAT DOES IT MEAN FOR YOU?**

Tuesday, March 18, 2008 • 2:00 - 3:30 pm (Eastern)

**Judy Yost, M.A., M.T.
Centers for Medicare and Medicaid Services**

**Dr. Bruce Williams
College of American Pathologists**

Sign up at www.clinical-labs.org

National Intelligence Report – February 25, 2008
ACLA to SACGHS: Clarify CMS, FDA Roles in Genetic Test Oversight

Contrary to the squabbling in the presidential primaries, words have meaning—and they have the power to steer both thought and action, as George Orwell drove home forcefully in 1984. And that’s the point of recent comments made by the American Clinical Laboratory Association to the HHS Secretary’s Advisory Committee on Genetics, Health & Society (SACGHS). The top federal advisory panel met February 12-13 to finalize its draft report and recommendations to Secretary Michael Leavitt on filling gaps in governmental and private oversight of genetic testing, including lab-developed tests or LDTs. The final version is slated to go to Leavitt at the end of April and could be a springboard for further action by HHS and Congress. ACLA urged SACGHS to amend “one particularly important recommendation that, if not carefully communicated to the Secretary, could have unintended consequences.” In the recommendation, SACGHS affirms its support for the Food & Drug Administration’s regulation of LDTs and the flexible risk-based approach the agency is taking to prioritize review of these tests. Concerned that this could be interpreted to mean that FDA requirements should be applied to LDTs without interagency coordination, ACLA noted: “Though there are many similarities between FDA’s and CLIA’s quality validation, there are clear redundancies and duplications that, if not coordinated, harmonized, and streamlined will stifle innovations in this area. These include separate requirements for inspection, quality systems, reporting and labeling, and other rules for design control, corrective action, and prevention.” ACLA asked SACGHS to make clear that interagency coordination is the goal for LDT regulation. This is in line, ACLA said, with the “overarching” guidance in the SACGHS draft report to “enhance interagency coordination” and “promote public-private partnerships” to tackle knowledge gaps concerning clinical validity and utility. ACLA suggested the following revised wording: “SACGHS supports an interagency role for FDA in CMS’s regulation of LDTs (italics added) and the flexible risk-based approach the agency is taking to prioritize LDTs, an approach that should be robust enough to accommodate new genetic testing technologies and methodologies.” The draft SACGHS report advised the FDA to take a “go slow,” broader consultative approach to LDT oversight. ACLA and the College of American Pathologists contend that CMS’ CLIA program should be the lead federal agency to oversee genetic testing services, while the FDA’s role should be consultative.

San Diego Union Tribune – February 16, 2008
Local Labs Seek Halt to Federal Program

SAN DIEGO -- Opponents of an experimental federal program aimed at cutting medical laboratory costs in San Diego County have drawn support from a congressional leader and a national group that represents the medical lab industry in Washington. Laboratories that aren't chosen by CMS could lose more than half of their overall business, said Alan Mertz, president of the American Clinical Laboratory Association. “This is basically the government putting a gun to the head of the labs and saying you either guess at a really low bid no matter how below cost it is for doing business or we're going to pull the trigger and take away the business,” Mertz said.

North County Times - December 12, 2007
Cost-cutting experiment could save money, but quality of care questioned

SAN DIEGO -- Large blood testing labs will bid against each other for Medicare business in an experimental program to take place in San Diego County. They will learn more about the process in a Wednesday meeting in downtown San Diego. Alan Mertz, president of the American Clinical Laboratory Association, said those concerns are shared across his organization, a trade group for clinical laboratories. The association has asked Congress to repeal the project, which it mandated in 2003. “We’re worried about the impact it could ultimately have on reducing access that senior citizens have to lab services and potentially the quality of services that they get under Medicare,” Mertz said. If labs don't bid low enough, they will be “arbitrarily cut out of business with Medicare” for the next three years, Mertz said. Some of those labs may provide services that qualifying labs don't provide, or their locations may be inconvenient to patients. This would be especially difficult for seniors with impaired mobility.

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Calendar of Events/Meetings

March 4	<i>Results for Life</i> Ambassador Training Session	Conference Call
March 7	ACLA Weekly Call	Conference Call
March 11-14	Alan Mertz attends AdvaMed Annual Meeting	La Quinta, CA
March 11	Chairman Frank Pallone (D-NJ) Fundraiser	Washington, DC
March 13	Senator Pat Roberts (R-KS) Fundraiser	Washington, DC
March 13	ACLA FDA Committee Meeting	Conference Call
March 14	ACLA Weekly Call	Conference Call
March 18	ACLA Audioconference - CLIA Steps Up Enforcement	Conference Call
March 19	ACLA CPT Committee Meeting	Washington, DC
March 20	ACLA Billing Committee Meeting	Conference Call
March 27	<i>Results for Life</i> Presentation to Carolina's Clinical Connection (CCC)	Wilmington, NC
March 28	ACLA Weekly Call	Conference Call
March 28	<i>Results for Life/PR</i> Committee Meeting	Conference Call
April 17-18	ACLA’s 13th Annual Meeting - Laboratories: Rx for the Future	Washington, DC