



RESULTS

American Clinical Laboratory Association

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RESULTS is a monthly report to ACLA members companies

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President's Message

Shortly after the election, I commented that the change in Congress would present challenges and opportunities on ACLA's priority issues. That is the case with the FDA and competitive bidding issues.

Both regulatory and legislative proposals with respect to FDA and laboratory developed tests (LDTs) are "challenges". I spoke at the FDA public meeting on the IVDMIA draft guidance in February and the statement was widely reported in the trade press. There was an encouraging consensus among many of the presenters that, while they shared the goal of the FDA, the draft guidance was flawed.

We are also concerned about legislation that Senator Kennedy has drafted on LDTs and the FDA, and are actively working to ensure any legislation in the realm does, indeed, protect public health while not impeding innovation that holds the promise of better health for everyone.

In the "opportunities" category, ACLA is in the midst of one of its most extensive advocacy campaigns. We are meeting with all of the key members of Congress and their staff in an attempt to have legislation introduced and passed that would repeal the Medicare Competitive Bidding Demonstration Project. We are encouraged by the response in Congress, but there is a very long way to go.

I want to bring special attention to two important events in April. All ACLA members and members of the laboratory community are encouraged to attend both the "roll out" of the ACLA value campaign, "Results for Life," on April 18 as well as the 2007 ACLA Annual Meeting on April 19-20. See the ACLA website for details.

Thanks to all of ACLA's members who have been helping on all of these topics – and more!

Finally, I'm pleased to welcome ACLA's newest member, Clariant, Inc., and its President, Ronald Andrews!

Alan Mertz



Save the Date!

April 18, 2007 - 3:00 p.m.

ACLA Value Campaign Roll-out Event
"Results for Life: Lab Testing. Better Health. Improved Outcomes"

Guest speaker: Kelly Ripken (Wife of legendary baseball great Cal Ripken Jr.)

– avid spokesperson for the value of lab testing for thyroid disorders

**Capitol Hill
Washington, DC**

SAVE THE DATE!

April 19-20, 2007

ACLA Annual Membership Meeting
**"The Laboratory Connection:
Patients, Providers, Policymakers"**

Keynote Speaker: Chris Matthews

**The Grand Hyatt Hotel
Washington, DC**

More information at www.clinical-labs.org

ACLA Voices Concern to FDA on IVDMIA Guidance

The Food and Drug Administration (FDA) held a meeting on February 8th to hear public comment on the draft In Vitro Diagnostic Multivariate Index Assays (IVDMIA) Guidance Document. FDA said it will require premarket review for certain laboratory developed tests that combine assays and algorithms to produce results tailored to a specific patient. FDA believes most of these tests will be categorized as medical devices subject to class II and III special controls. Over 300 representatives were present at the

public meeting and over thirty comments were received from clinical laboratories, manufacturers, government officials, academia and others. FDA has posted the presentations on their web site at <http://www.fda.gov/cdrh/oivd/meetings/020807agenda.html>. Some common themes emerged from the presentations – namely that all laboratory tests should be safe, clinically valid and effective. But also communicated to FDA was that the FDA guidance, as proposed, raised concerns and questions that need further clarification and stakeholder involvement.

ACLA's President Alan Mertz, in his presentation to FDA, indicated support for the goal of the draft guidance – namely, to dispel the existing confusion and lack of clarity regarding FDA's regulatory approach toward certain laboratory-developed tests. He further stated that the Guidance Document falls short of achieving the goal. ACLA offered FDA three recommendations to achieve the goals of the IVDMA Draft Guidance. ACLA advocated that FDA should:

- Issue a proposed rule through formal notice and comment rulemaking process rather than guidance.
- Consider proposals to narrow and clarify the definition of IVDMIAs.
- Work with CMS and through HHS to address its concerns through enhancement and better enforcement of the regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

ACLA further provided the following linked factors that FDA should consider in formulating a definition of IVDMIAs:

- Employs a new, single-source test system.
- Uses patient and/or clinical data derived from one or more in vitro diagnostic assays together with a proprietary, non-published algorithm.
- Generates a patient-specific, binary result that is intended definitively to diagnose a condition or to direct behavior for the cure, mitigation, treatment, or prevention of disease.
- Presents significant safety and effectiveness risks not present in test systems which have become part of the standard of care.

In ACLA's view, test systems should not be deemed IVDMIAs when they meet one or more of the following criteria: low-risk consequences of invalid or inaccurate test results, independent verification by one or more labs, support of clinical relevance in peer-reviewed literature, transparent algorithms, interpretation support for clinicians, support in clinical guidelines, established use, CPT code assignment, and payer recognition.

As FDA works toward tighter controls, ACLA is meeting with Hill staff on two legislative initiatives targeted at laboratory developed tests. Senator Edward Kennedy (D-MA), chairman of the Senate HELP Committee, and Senator Barack Obama (D-IL) each are drafting legislative language.

ACLA's statement as well as comments to FDA on IVDMIAs and ASRs are available on the ACLA website, www.clinical-labs.org.

ACLA Continues Hill Meetings to Find Lawmakers to Sponsor Repeal Legislation

ACLA continues its efforts to identify Members of Congress who may introduce legislation to repeal the Medicare competitive bidding demonstration project for clinical laboratory services. In February, ACLA met with several House and Senate congressional offices. In concert with those meetings, ACLA member companies located throughout the country have called, faxed, and emailed congressional offices urging lawmakers to introduce this vital legislation. ACLA has met with the following lawmakers who, in addition to serving on either the House Energy & Commerce or Ways & Means committees, also represent a potential metropolitan statistical area (MSA) under the demonstration project: Representatives Bart Gordon (D-TN), Diana DeGette (D-CO), Anna Eshoo (D-CA), Lloyd Doggett (D-TX), and Jim Matheson (D-UT). ACLA was joined by Bio-Reference Laboratories' Marc Grodman, MD, and Rich Faherty, along with Kristen Cusick from Quest Diagnostics, Kay Cox with AmeriPath, and Pat Lanza of Sunrise Medical Laboratories on February 21 to urge New York Senator Chuck Schumer (D) to consider introducing legislation to repeal the demonstration project.

Permanent TC Grandfather Fix Introduced in Congress

Legislation providing for a permanent extension of the TC Grandfather provision has been introduced in both the Senate and

House. Senator Blanche Lincoln (D-AR) introduced S. 458, the "Physician Pathology Services Continuity Act" in the Senate and Representative John Tanner (D-TN) introduced the companion legislation H.R. 1105. ACLA is working with a coalition that includes the College of American Pathologists, the American Hospital Association and the Federation of American Hospitals as well as representatives of rural health organizations.

ACLA Holds LabLINE Audio Conference on MUEs

On February 22, ACLA hosted a LabLINE audio conference on Medically Unlikely Edits (MUEs). The program, "Medically Unlikely Edits: What's New? What Do They Mean For You?", was one of a continuing series of audio conferences designed to bring up-to-date information on topics of interest to the laboratory community and was approved by the American Academy of Professional Coders for continuing education credits.

Speakers were Ms. Lisa Zone, the Deputy Director of the CMS Program Integrity Group and Dr. Niles Rosen, the CMS contracted Medical Director of the MUE program and the National Correct Coding Initiative. Both speakers communicated considerable new and clarifying information. For example, the next phase of MUE edits – comprising about 40% of the total to be proposed – will be based on clinical judgment criteria. How those criteria will be developed, the review and appeal process, was discussed on the call.

ACLA's CPT Advisory Committee has commented on the first two Phases of the MUE roll-out and is now reviewing Phase III. ACLA appreciates that the proposed MUEs are made available directly for comment.

Look for information on the next ACLA LabLINE in the near future.

IQLM Closes Operations – CDC Plans Laboratory Institute

In early February, ACLA received notice that the Institute for Quality Laboratory Medicine (IQLM) was ceasing operations because funding was not sufficient to support the needs of the Institute. Subsequently, in an announcement at the February Clinical Laboratory Improvement Advisory

Committee (CLIAC) meeting, the Centers for Disease Prevention and Control announced two activities that were consistent with the goals of the IQLM.

CDC will sponsor an Institute on Critical Issues in Laboratory Practice in September 2007. The purpose of the Institute is to drive changes needed to better integrate laboratory services in improving health care. To inform the Institute, CDC has contracted a project to Define Best Practices in Laboratory Medicine.

The timeline has the project culminating in September 2007 to coincide with the Institute. More information on the project can be found at <http://www.phppo.cdc.gov/DLS/bestpractices/>

ACLA Presents to CLIAC on Need for a Genetic Testing Specialty in CLIA

The Clinical Laboratory Improvement Advisory Committee (CLIAC) met in Atlanta on February 14 and 15. As part of their agenda, CLIAC received a presentation update from the Centers for Medicare and Medicaid Services (CMS) on the Status of the Notice of Proposed Rulemaking (NPRM) for Genetic Testing. The reasons why CMS made the decision not to move forward on a NPRM that would establish a genetic testing specialty in CLIA were reiterated. Those reasons include: a strengthened quality assurance/quality control program is in place for all testing; the existing requirement for labs to check each test accuracy twice a year even if proficiency testing is not available; that all genetic testing is performed in high complexity labs with the most stringent CLIA require-

ments; that survey data does not indicate a problem with genetic testing and that it would be difficult to define a specialty for genetic testing and thus the impact would cut across nearly all existing specialties.

CMS proposed using existing CLIA regulations to enhance outcomes. This could translate to more specific guidance to State Surveyors, having genetic testing experts conduct training, explore survey alternatives with oversight agencies, design alternative PT/QC mechanisms. CLIAC discussed the issues following the presentation and will form a workgroup to study the issue.

ACLA made public comment at the meeting that articulated the specific CLIA requirements that provide for clinical relevance and effective patient care. Comments are available on the ACLA website, www.clinical-labs.org.

ACLA Asks OIG for Fraud Alert on PODs

In response to the Office of Inspector General's solicitation of new safe harbors and Special Fraud Alerts, ACLA requested the issuance of a Special Fraud Alert related to "POD" or "condo" labs. ACLA pointed

out that these labs, a type of laboratory joint venture arrangement, implicate the anti-kickback statute, affect the way anatomic pathology services are being billed to Medicare, provide incentives for referring physicians to overutilize services, and highlight other potential program vulnerabilities. The comments are available on the ACLA website, www.clinical-labs.org.

Lab Groups Blast FDA's IVDMA Strategy

Excerpts from March 2007 G-2 Compliance Report

"... Alan Mertz, president of the American Clinical Laboratory Association (ACLA), concurred, saying the FDA should issue a proposed rule to address the matter.

"The procedural recommendation in favor of notice and comment rule making is important for several reasons," he testified. "Since the draft guidance announces that laboratory-developed tests deemed IVDMIAs are Class II or Class III devices requiring FDA premarket clearance or approval, it represents a significant change from the agency's historical practice regarding laboratory-developed tests and has a present, binding effect.

"Rather than merely stating the agency's current thinking on the topics without creating or conferring any rights or binding FDA or the public, the draft guidance operates as a substantive rule; as such, its subject matter should be vetted through the formal, on-the-record, notice and comment rule-making procedures of the Administrative Procedure Act," he says.

Excerpts reprinted under agreement with Washington G-2 Reports

ACLA Welcomes New Member Clairient, Inc.

Ronald Andrews is President and CEO of ACLA's newest member, Clairient Inc. which is based in Aliso Viejo, California. Clairient provides technologies, services and expert support for the characterization, assessment and treatment of cancer.

More information is available at <http://www.clairientinc.com>.
Welcome Ronald Andrews and Clairient.

Calendar of Events

March 1	Ways & Means Health Subcommittee Hearing on MedPac	Washington, DC
March 2	ACLA Member Weekly Call	Conference Call
March 7	ACLA Science Committee Meeting	Conference Call
March 8	ACLA Billing Committee Meeting	Conference Call
March 8	ACLA FDA Committee Meeting	Conference Call
March 8	Clinical Laboratory Coalition Meeting	Conference Call
March 9	ACLA Member Weekly Call	Conference Call
March 12	AHIC Personalized Workgroup Meeting	Washington, DC
March 13	ACLA PODs Workgroup Meeting	Conference Call
March 14	ELINCS Steering Committee Meeting	Conference Call
March 16	ACLA Member Weekly Call	Conference Call
March 20	AHIC EHR Workgroup Meeting	Washington, DC
March 21	Fundraiser for Rep. Frank Pallone (D-6th/NJ)	Washington, DC
March 23	ACLA Member Weekly Call	Conference Call
March 27	ACLA PODs Workgroup Meeting	Conference Call
March 30	ACLA Member Weekly Call	Conference Call
March 30	ACLA PR Committee call (Value Campaign)	Conference Call

ACLA in the News

National Intelligence Report - February 26, 2007

FDA Restraint Urged in Regulating Lab 'Home Brew' Tests

"Clinical laboratory and pathology groups are calling on the Food & Drug Administration to clarify and limit its draft guidance that would expand agency oversight of lab-developed tests. In comments to a recent FDA public forum on the guidance, the **American Clinical Laboratory Association** and the College of American Pathologists said current lab testing requirements under CLIA (the Clinical Laboratory Improvement Amendments) already provide sufficient safeguards for home brew use without impeding genetic testing advances. **ACLA specifically noted** that enforcement of the CLIA rules is "consistent with the FDA's emphasis on 'smart regulation' and following the 'least burdensome' approach to tackle the issues raised in the guidance."

House Bill Calls for Permanent TC 'Grandfather' Protection

"The push to get Congress to make permanent the current "grandfather" protection for certain pathology technical component (TC) billings by independent labs got another boost under a bipartisan bill recently introduced in the House. The legislation—H.R. 1105, sponsored by Reps. John Tanner (D-TN) and Kenny Hulshof (R-MO)—would permanently allow certain independent clinical laboratories to bill Medicare directly for the TC of pathology services to hospital inpatients and outpatients. A companion measure was introduced in the Senate January 31. Key backers of the legislation—entitled the Physician Pathology Services Continuity Act of 2007 in both Houses—include the College of American Pathologists, the American Society for Clinical Pathology, and the **American Clinical Laboratory Association.**"

'Pod' Lab Arrangements Draw Renewed Fire

"The controversy over "pod" or "condo" lab arrangements has reignited in the wake of calls from pathology and laboratory organizations for government agencies to crack down on these ventures. The Centers for Medicare & Medicaid Services, citing the potential for service overutilization, proposed new pod lab curbs last year, but yanked them from the final 2007 physician fee schedule rule. The **American Clinical Laboratory Association** has asked the HHS Office of Inspector General to issue a Special Fraud Alert on pod lab arrangements, warning of potential violations of the federal anti-kickback statute. The OIG began scrutinizing pod labs in 2004."

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National Intelligence Report - February 12, 2007

FOCUS ON: The FY 2008 Medicare Budget: Bush's Proposals on Collision Course With Democratic Health Leaders

"Lab Competitive Bidding: The American Clinical Laboratory Association has registered its opposition to the nationwide bidding plan, saying that the whole notion of competitive bidding is unworkable in the lab arena since it treats testing as a commodity, rather than as a complex medical service. **ACLA** is also lobbying key congressional health committees to get the demo project repealed..."

"Threat to Lab Fees: If the democrats are willing to cut Medicare spending, what would that mean to providers, including clinical labs? Would lab services be put back on the table? Lab groups need to be vigilant, Mertz said, to oppose competitive bidding, any extension of the fee update freeze, and any restoration of a 20% co-pay."

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Diagnostic Testing & Technology Report - March 2007

Industry Players Seek Clarification, Offer Criticism on IVD/MIA Guidance

"Over 350 biotechnology and laboratory industry players, including lobbyists and government officials, assembled in Gaithersburg, Maryland, on February 8 for the FDA's day-long public meeting on its recently issued draft guidance for in vitro diagnostic multivariate index assays (IVDMIA's).

"**American Clinical Laboratory Association (ACLA) President Alan Mertz** offered the FDA three recommendations to achieve the IVD/MIA draft guidance's goal. First, Mertz advocated that the FDA issue a proposed rule to address the issue through the formal notice and comment rule-making process rather than through sub-regulatory guidance. He also urged the FDA to consider proposals to narrow and clarify its definition of IVD/MIA's. Finally, he recommended that the FDA work with the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) to address its concerns through enhancement and better enforcement of CLIA regulations.

"As written, the draft guidance could be interpreted to apply to many well-established tests that are part of the standard of care," said **Mertz**. "Upon citing examples of such tests to the FDA, ACLA was informed by FDA officials that it was not their intent to include such well-established tests within the scope of the draft guidance, and FDA requested our assistance in clarifying and narrowing the definition of IVD/MIA's to conform to its intended application."

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The Dark Report – February 9, 2007

FDA Gets an Earful During Public Meeting on Guidance Document for IVD-MIAs

"Yesterday's public forum conducted by the Food and Drug Administration (FDA) on proposed guidance to regulate a certain category of molecular diagnostic assays drew a surprisingly large and diverse number of presentations and comments from the laboratory, biotech, and healthcare industries.

"Dark Daily received the presentation materials from Alan Mertz, President of the American Clinical Laboratory Association, who made the following statement: "We appreciate that the FDA arranged the meeting," said Mertz. "It was clear by the number of presenters how important this issue is to all sectors of healthcare, not just labs. I was struck by the number of concerns expressed about the current draft guidance by such a diverse group of stakeholders. We hope that FDA will take these concerns into full consideration if they choose to move forward."

NOTE the entire article is posted on the ACLA website, www.clinical-labs.org

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