

• **Message from Dr. Sundwall:** ACLA will review and revise our legislative and regulatory goals at our Annual Membership Meeting on January 15.

• **Growing Response to Bioterrorism:** The past month has been characterized by multiple efforts to address current and future challenges posed by bioterrorism.

• **ABN Update:** The website was amended to include an additional Q&A state that the best practice in this situation is for the patient to receive any necessary ABN at the physician's office."

• **Billing and Reimbursement:** ACLA wrote to CMS in response to a request that we identify our top laboratory claims processing issues.

For more information regarding ACLA, please call 202-637-9466, or visit our website - [www.clinical-labs.org](http://www.clinical-labs.org)

2001 will be remembered forever as the year America was attacked by terrorists from foreign lands and suffered unprecedented casualties among our civilian population. But it will *not* be remembered for constructive attention to health care issues by our national government. We have all heard how much the world has changed since 9/11, and no where is this more apparent than here in Washington where attention has been focused almost entirely on our war on terrorism - at home and abroad. And in my opinion, this is how it should be.

A lead editorial in the Washington Post recently bemoaned what it called "The Health Care Fade", criticizing Congress for promising, and then forgetting, to add a prescription drug benefit to the Medicare program and expand health insurance coverage for the seventh of our population who has none. While these remain important and worthy objectives, our national priorities have shifted. Whether or not Congress returns to seriously consider domestic issues in the coming year will depend a lot on the success of our campaign against terrorism and the state of the country's economy.

ACLA has a lot of left over business from last year, and we will review and revise our legislative and regulatory goals at our Annual Membership Meeting on January 15. But we have achieved some significant objectives to improve the regulatory climate for the clinical lab industry (see reports below). We face 2002 with a much more sober view of the world and understand that we will need to vigorously represent our members interests during this time of intense competition for government's attention and support.

*David N. Sundwall*

## Growing Response to Bioterrorism

The past month has been characterized by multiple efforts to address current and future challenges posed by bioterrorism. While this is not a comprehensive list of what's happening, the following illustrates efforts by public and private sectors:

1. As Congress wrapped up its business for the year, the Senate passed a \$3.2 billion bioterrorism package that boosts vaccine stockpiles and sends millions to local hospitals and clinics - but final passage won't occur until next year. The House had passed its bill - a \$2.9 billion package earlier, and the differences will be reconciled in conference.
2. The RAND Corporation Science and Technology Policy Institute hosted two summits [11/14/01 and 12/20/01] on the Information Technology Infrastructure for Bioterrorism exploring what is needed for rapid detection, containment, response and recovery. Clearly, clinical labs are key to these efforts, and must address issues related to uniform reporting requirements and standardized electronic language.
3. At the request of DHHS Secretary Tommy G. Thompson, Booz-Allen-Hamilton and The Council for Excellence in Government co-sponsored a two day conference [12/17-18] to link government and the private sector to address potential threats from bioterrorism. Participants included a broad spectrum of senior representatives from the health care industry, as well as government officials from DHHS, NIH, FDA, and CDC. ACLA participated in this conference and expects to be invited

to be part of a permanent entity linking public/private sectors.

4. ACLA co-sponsored an AACC teleconference on bioterrorism on December 5th. This brought together government officials and academics who provided for laboratory personnel current information on "best practices" standards for detection and reporting of potential infectious and chemical agents which might be used in bioterrorism.

At the ACLA Annual Membership Meeting (January 15), we will hear from Dr. D.A. Henderson, Director of DHHS Office of Emergency Preparedness. We can expect to be challenged to work closely with the government to improve our capacity to deal with these issues.

## ABN Update

In the December issue of Results we reported that at least one carrier was briefing providers on the new ABN form in advance of the program instructions being issued, advising them that getting the ABN for lab services is solely the laboratory's responsibility. We contacted CMS representatives who in turn contacted the carrier in question to advise providers that the program instructions were not finalized. We also expressed our concerns that the "Frequently Asked Questions on ABNs" on the Medicare Learning Network website stated that it was the responsibility of the lab to obtain the ABN, without encouraging the treating physicians to assist the laboratories. In response to our query, the website was amended to include an additional Q&A stating that while the physician is not required by law to execute an ABN for a lab test, "a physician endeavoring to provide the best

care to patients may wish to deliver an ABN.... The best practice in this situation is for the patient to receive any necessary ABN at the physician's office."

## Billing and Reimbursement

On December 7, 2001, ACLA wrote to Glenn Kendall at CMS in response to his request that we identify our top laboratory claims processing issues. We responded with the following issues: the chronic difficulties that laboratories face when submitting a claim that includes a "lab-to-lab referral," that is, the laboratory performs some tests in one location and then sends the specimen on to another location for other testing; and the inappropriate application of Purchased Diagnostic Testing requirements to claims for services paid on the Clinical Laboratory Fee Schedule.

In our letter we reiterated our strong support for the regional carrier mandate of the Balanced Budget Act of 1997 but offered to work with CMS on other alternatives to resolve the lab-to-lab referral problem. We proposed that each laboratory company that furnishes services in multiple states have the option of choosing (or being assigned to) a carrier that would be responsible for processing all of its laboratory claims. Further, we urged the establishment of a single carrier to have jurisdiction over all laboratories that furnish services to ESRD patients.

With respect to the inappropriate application of Purchased Diagnostic Testing requirements, we recommended that a program memorandum be issued to Part B carriers to clarify that claims for services on the clinical laboratory fee schedule are not subject to purchased diagnostic service requirements.

## ACLA's Annual Meeting

Our Annual ACLA Membership Meeting will be here in Washington earlier than has been our custom, only 2 weeks from now! We will have a one day program including speakers representing Congress, CMS, the newly established Office of Emergency Preparedness, and the FDA. We will also elect officers for the coming year, and hold concurrent advisory committee and Board meetings. Please mark your calendars now and plan to attend.

**Tuesday - January 15, 2002**  
**9:00 a.m. - 4:00 p.m.**

Marriott at Metro Center  
775 12th Street, NW  
Washington, DC 20005  
202-737-2200

### New Members!

ACLA is pleased to announce the addition of two new members -

**Satellite Laboratory Services**  
**Redwood City, CA**  
**and**  
**ViroLogic, Inc.**  
**South San Francisco, CA**

Representatives of these companies will attend ACLA's Annual Membership Meeting where we can officially welcome them to our association.

## Calendar of Events — January 2002

<b>January 7</b>	Lab Budget Coalition Meeting	<i>Washington, DC</i>
<b>January 8</b>	ACLA Legal Committee Meeting	<i>Conference Call</i>
<b>January 10</b>	ACLA Billing and Reimbursement/ESRD Committee Meeting	<i>Conference Call</i>
<b>January 10</b>	ACLA CPT Committee Meeting	<i>Conference Call</i>
<b>January 14</b>	ACLA ESRD Committee Meeting	<i>Washington, DC</i>
<b>January 15</b>	ACLA Annual Membership Meeting	<i>Washington, DC</i>