

ACLA's  
*20<sup>th</sup>*  
ANNUAL  
MEETING

FOCUS ON  
REIMBURSEMENT,  
REGULATION  
AND INNOVATION



American  
Clinical Laboratory  
Association



MAY 4-5, 2015 • GRAND HYATT HOTEL



# Welcome to the 20th ACLA Annual Meeting!

What a year it has been for clinical laboratories with respect to reimbursement and regulation. At the time of last year's meeting, Congress was finalizing the reform of the Clinical Laboratory Fee Schedule through "PAMA." A few months later, FDA issued draft Guidance on Laboratory Developed Tests. In addition to these two major policy changes, ACLA has been busy working on several other critical issues. Accordingly, this year's Annual Meeting will focus on key reimbursement and regulatory challenges for our industry, and we have perhaps the best line up of speakers in our 20 year meeting history to discuss these issues.



The ACLA Annual Meeting also provides a great opportunity for our members and others in the health community to get to know each other better, and we have built in time for this as well.

Again, welcome to the 20th ACLA Annual Meeting and we're happy to have you here!

A handwritten signature in dark ink that reads "Alan Mertz". The signature is fluid and cursive, with the first name "Alan" and last name "Mertz" clearly distinguishable.

Alan Mertz  
President, ACLA

MONDAY, MAY 4, 2015

8:30 – 11:30 am	ACLA Board of Directors Meeting	Alston and Bird LLP
9:00 am	Registration Open	Independence Ballroom B, C, D, E - Level 5B
11:45 – 12:45 pm	Lunch – All Registrants	Farragut/Lafayette Rm Level 5B
1:00 – 1:30pm	General Session President's Welcome Alan Mertz, President, ACLA Election of ACLA Board of Directors ACLA Chairman's Welcome Stephen H. Rusckowski, President and CEO, Quest Diagnostics	Independence Ballroom B, C, D, E - Level 5B
1:30 – 2:15 pm	FDA Proposed Guidance: A Legal Perspective Laurence Tribe, Carl M. Loeb University Professor and Professor of Constitutional Law at Harvard University Paul Clement, Partner, Bancroft PLLC Viet Dinh, Partner, Bancroft PLLC and Professor of Law at Georgetown University Law Center	Independence Ballroom B, C, D, E - Level 5B
2:15 – 3:15 pm	Congressional Staff Panel Moderated by Stephen Northrup, Partner, RampyNorthrup Grace Stuntz, FDA Policy Advisor, Senate Health, Education, Labor and Pensions Committee, Republican Staff Wade Ackerman, Senior FDA Counsel, Senate Health, Education, Labor and Pensions Committee, Democratic Staff John Stone, Counsel, House Energy & Commerce Committee, Republican Staff	Independence Ballroom B, C, D, E - Level 5B

3:15 – 3:30 pm	<b>Networking Break</b>	Independence Ballroom B, C, D, E - Level 5B
3:30 - 4:00 pm	<b>2015 Health Care Priorities for Congress and the Administration</b> Chris Dawe, Managing Director, Evolent Health	Independence Ballroom B, C, D, E - Level 5B
4:00 – 5:00 pm	<b>Keynote</b> Candy Crowley, former Chief Political Correspondent for CNN	Independence Ballroom B, C, D, E - Level 5B
5:00 – 7:00 pm	<b>Chairman's Reception</b>	Penn Quarter Room Level 1B
<b>TUESDAY, MAY 5, 2015</b>		
7:30 – 8:30 am	<b>Buffet Breakfast</b>	Independence Ballroom B, C, D, E - Level 5B
8:30 – 9:00 am	<b>View from Congress</b> Senator Richard Burr (R-NC)	Independence Ballroom B, C, D, E - Level 5B
9:00 – 9:45 am	<b>FDA Update</b> Elizabeth Mansfield, Director of Personalized Medicine, Food and Drug Administration	Independence Ballroom B, C, D, E - Level 5B
9:45 – 10:30 am	<b>Legal, Regulatory and Compliance Issues for Labs</b> Colin Zick, Partner, Co-Chair of Healthcare Practice Group, Foley Hoag LLP	Independence Ballroom B, C, D, E - Level 5B
10:30 – 11:30 am	<b>CMS Update</b> Marc Hartstein, Director, Hospital and Ambulatory Policy Group, Centers for Medicare and Medicaid Services	Independence Ballroom B, C, D, E - Level 5B
11:30 – 11:45 am	<b>Closing Remarks and Meeting Adjourns</b>	Independence Ballroom B, C, D, E - Level 5B

ALAN MERTZ  
PRESIDENT, ACLA



*President's Welcome*

STEPHEN H. RUSCKOWSKI  
PRESIDENT & CEO, QUEST DIAGNOSTICS  
ACLA CHAIRMAN, BOARD OF DIRECTORS



*Chairman's Welcome*

LAURENCE TRIBE

CARL M. LOEB UNIVERSITY PROFESSOR  
AND PROFESSOR OF CONSTITUTIONAL LAW AT HARVARD UNIVERSITY

*FDA Proposed Guidance:  
A Legal Perspective*



PAUL CLEMENT

PARTNER, BANCROFT PLLC

*FDA Proposed Guidance:  
A Legal Perspective*



VIET DINH

PARTNER, BANCROFT PLLC AND PROFESSOR OF LAW AT GEORGETOWN UNIVERSITY LAW CENTER



*FDA Proposed Guidance:  
A Legal Perspective*

CHRIS DAWE

MANAGING DIRECTOR, EVOLENT HEALTH



*2015 Health Care Priorities  
for Congress and the  
Administration*



**CANDY CROWLEY**

FORMER CHIEF POLITICAL CORRESPONDENT FOR CNN

*Keynote***SENATOR RICHARD BURR (R-NC)***View from Congress*

ELIZABETH MANSFIELD

DIRECTOR OF PERSONALIZED MEDICINE  
FOOD AND DRUG ADMINISTRATION



*FDA Update*

COLIN ZICK

PARTNER, CO-CHAIR OF HEALTHCARE PRACTICE GROUP  
FOLEY HOAG LLP



*Legal, Regulatory and  
Compliance Issues for Labs*

MARC HARTSTEIN

DIRECTOR, HOSPITAL AND AMBULATORY POLICY GROUP  
CENTERS FOR MEDICARE AND MEDICAID SERVICES



## CONGRESSIONAL STAFF PANEL

GRACE STUNTZ

FDA POLICY ADVISOR, SENATE HEALTH, EDUCATION, LABOR AND  
PENSIONS COMMITTEE, REPUBLICAN STAFF

WADE ACKERMAN

SENIOR FDA COUNSEL, SENATE HEALTH, EDUCATION, LABOR AND  
PENSIONS COMMITTEE, DEMOCRATIC STAFF

JOHN STONE

COUNSEL, HOUSE ENERGY & COMMERCE COMMITTEE, REPUBLICAN STAFF

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Spectra Renal Management

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Laboratory Billing Solutions

McKesson

Medivo

Mintz Levin

Premier Source

Quadax, Inc.

Roche

Siemens

Vermillion

Xifin

**Edward Ashwood, MD**

(ACLA Vice Chair)  
President and CEO  
ARUP Laboratories

**Peter G. Gudaitis**

President  
Aculabs, Inc.

**Dr. Frank Basile**

President and Chief Executive Officer  
Miraca Life Sciences

**David P. King**

Chairman and Chief Executive Officer  
Laboratory Corporation of America

**Nicholas R. Brownlee, Ph.D.**

President  
Spectra Renal Management,  
Fresenius Medical Care

**Dr. Tom Lohmann**

Chief Executive Officer  
Sonic Healthcare USA

**Mark C. Capone**

President  
Myriad Genetics, Inc.

**Alan Mertz**

President  
American Clinical Laboratory  
Association

**Curtis A. Hanson, MD**

Chair, Laboratory Medicine and  
Pathology  
Mayo Medical Laboratories

**Kimberly J. Popovits**

President and CEO  
Genomic Health, Inc.

**Cynthia Collins**

(ACLA Treasurer)  
CEO  
Clariant/GE

**Stephen H. Rusckowski**

(ACLA Chair)  
President and CEO  
Quest Diagnostics

**Marc Grodman, MD**

President, CEO, Chairman of the Board  
BioReference Laboratories, Inc.

## STAFF

**Alan Mertz**  
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Senior Vice President

**JoAnne Glisson**  
Senior Vice President

**Francesca Fierro O'Reilly**  
Vice President  
Government Relations

**Thomas Sparkman**  
Vice President  
Government Relations

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Executive Administrator

**Brooke Parker**  
Coordinator

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**Ellen Flannery**  
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## Laurence Tribe

Carl M. Loeb University Professor and  
Professor of Constitutional Law at  
Harvard University

**Paul Clement**  
Partner  
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**To access Wifi, log in under  
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ACLA2015**

## NOTES

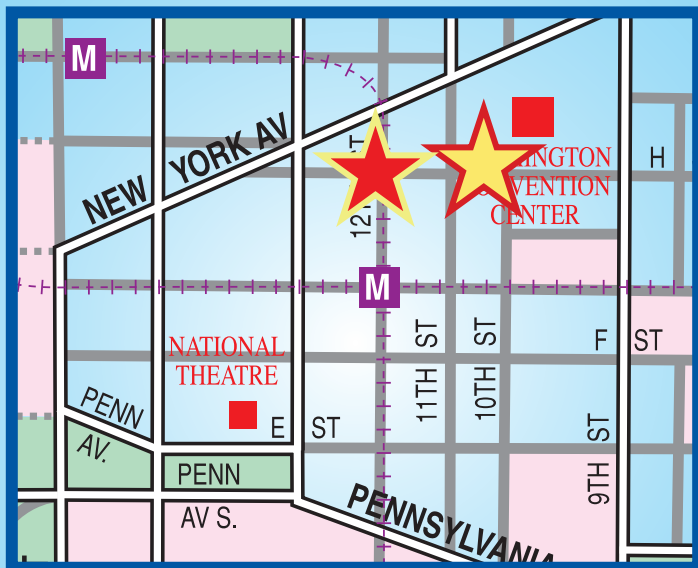
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## NOTES

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# ACLA

1100 New York Avenue, NW  
Suite 725 West  
Washington, DC 20005



★ Grand Hyatt Hotel  
1000 H Street, NW

★ Metro Center Marriott  
775 12th Street, NW

*ACLA will be sharing annual meeting photos and updates on social media using #ACLA15. We encourage you to like, share and post your own photos and updates using #ACLA15*