



Advancing
Clinical Laboratory
Science Worldwide

May 2006

To: Companies Marketing IVD Products in the US

Subject: Special Educational Program
U.S. Regulation & Reimbursement of *In Vitro* Diagnostic Products

Location: 2006 AACC Meeting & Clinical Lab Expo

Date/Time: Sunday, July 23, 2006 – 1:00 PM to 5:00 PM

This workshop is specifically directed to the needs of individuals with product development or product marketing responsibilities for the U.S. market. It is organized by the AACC and the Clinical Lab Expo, with the support of the DxMA – Diagnostics Marketing Association, to help industry executives to better understand the U.S. regulatory and reimbursement environment. The AACC welcomes the Diagnostics Marketing Association in the presentation of this program.

The following should attend this workshop:

- Chief executives of new IVD companies
- Export executives
- Regulatory specialists
- Marketing staff
- Product development personnel
- Product managers
- Anyone new to the IVD industry

The presenters of these sessions are recognized experts in regulatory, reimbursement, and marketing aspects of the process of bringing IVD products to the US market

The workshop begins with Approvals to Market, followed by a session on Coverage, Reimbursement and Coding. The final session will provide an overview, IVD Marketing: Regulatory Limitations and Restrictions.

The following pages are:

- The program
- Learning objectives for each session
- The registration form.

Program and Registration form >>

Program

AACC Annual Meeting - Special Session
July 23, 2006

U.S. REGULATION AND REIMBURSEMENT OF *IN VITRO* DIAGNOSTIC PRODUCTS

1:00 - 1:05 Welcome
Jerry Goldsmith, VP Marketing Programs, AACC
Richard Eberly, Meridian Biosciences, President, Diagnostics Marketing Association
Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

1:05 – 2:30 **APPROVALS TO MARKET**

IVD Regulation by the FDA in the United States
Alberto Gutierrez, MD
Division Director, Chemistry & Toxicology
Food and Drug Administration

Questions and Answers

Learning objectives for this session include:

- The manner in which the U.S. FDA. regulates IVDs
- The different classifications of IVD products and the requirements for each.
- How to decide which classification is appropriate for new products
- Sources of additional information

2:30 - 3:00 **COFFEE BREAK**

3:00 - 4:30 **COVERAGE, REIMBURSEMENT AND CODING**

Decision-making in the U.S
Joan Logue, Health Systems Concepts

Questions and Answers

Learning objectives for this session include:

- The factors affecting government and private payor coverage decisions;
- The government's Medicare fee schedules and their influence on private payment amounts;
- The limitations of the current coding system, criteria for new test codes and the ability to influence payment through coding;

4:20 - 4:45 **IVD MARKETING: REGULATORY LIMITATIONS AND RESTRICTIONS**

Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

Learning objectives for this session include

- The manner in which the U.S. regulates the marketing of IVDs
- A brief examination of the marketing practices that have attracted government scrutiny;
- Sources of additional information.

4:50 - 5:00 **QUESTIONS, ANSWERS AND WRAP UP**

Jerry Goldsmith, VP, Marketing Programs, AACC
Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

Registration form >>>

Presented in cooperation with the
DxMA - The Diagnostics Marketing Association



Registration Form

U.S. REGULATION AND REIMBURSEMENT OF *IN VITRO* DIAGNOSTIC PRODUCTS

July 23, 2006 – 1:00 PM to 5:00PM

Registrants will be advised of the location by May 1, 2006

Please complete one form for each registrant:

Workshop Fee

2006 Annual Meeting Exhibitor \$225 Non-exhibitor \$300

Visa MasterCard American Express

Credit card number _____

Expiration date (mm/yy) _____

Exact spelling of name on credit card _____

Company/Organization _____

Name of registrant (if different from name on credit card) _____

Title _____

Phone (Include Country Code) _____

Fax (Include Country Code) _____

Email _____

Country: _____

Registration confirmation will be sent to you by fax and email.

Please fax to Herb Burklund at +1 212 643 1758

Email inquiries: herbb@scherago.com

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DxMA - The Diagnostics Marketing Association