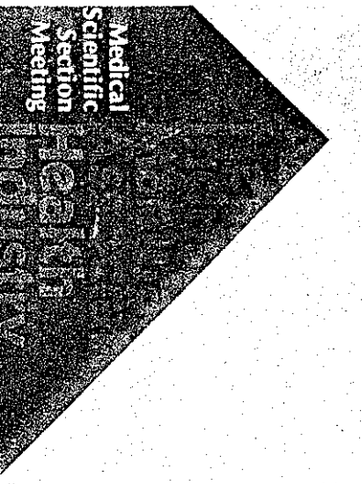


Registration Form

Make checks payable to HIMA
Registration Fee: $_____.

Mail with check to:
HIMA, Attn: Ms. Marilyn Whitney
1030 - 15th Street, N.W.
Washington, D.C. 20005

Name _____

Title _____

Name _____

Title _____

Name _____

Title _____

Check Preference
Diagnostics Sessions:
I ___
II ___
III ___

4 December, Monday

6:00-8:00 p.m.
Registration Desk Open

5 December, Tuesday

8:00 a.m.
Registration Desk Open

9:00 a.m.

GENERAL SESSION
Welcome and Opening Remarks

- Report from the Devices Division
- Report from the Diagnostics Division
- Risk-Benefit in the Regulatory Process

10 a.m.

DEVICES SESSIONS

I. Materials Testing

- Biocompatibility — FDA Proposed Protocols
- Testing of FDA Biocompatibility Protocols
- Questions & Answers

DIAGNOSTICS SESSIONS

I. Clinical Laboratories Improvement Act

- The Clinical Laboratories Improvement Act
- The State Laboratories Viewpoint
- Questions & Answers

Lunch

1:30 p.m.

II. Materials Testing

- Mutagenicity Testing — Relevance to Devices
- Interpretation Problems in Carcinogenicity Testing

III. Clinical Testing

- From Preclinical to Clinical
- Developing Good Clinical Protocols
- Investigational Strategies
- Questions & Answers

II. Working with the Regulators

- Regulatory Challenges.
- Good Laboratory Practices
- How to Prepare FDA Applications
- Successes in Reclassification
- Parametric Labeling — Status Update
- Questions & Answers

6:00 p.m. — Reception

6 December, Wednesday

8:30 a.m.

IV. FDA Interactions

- Avoiding the Pitfalls of Clinical Investigations
- Clinical Requirements for 510(k) Notices
- Presenting a Petition to a Classification Panel
- Practical Considerations for Investigational Devices
- Particulates in Commercial I.V. Administration Sets
- Questions & Answers

III. Standards & Testing

- Standards Development — Status Update
- Establishing a National Reference System for Clinical Chemistry
- Clinical Testing Guidelines
- Questions & Answers

Lunch

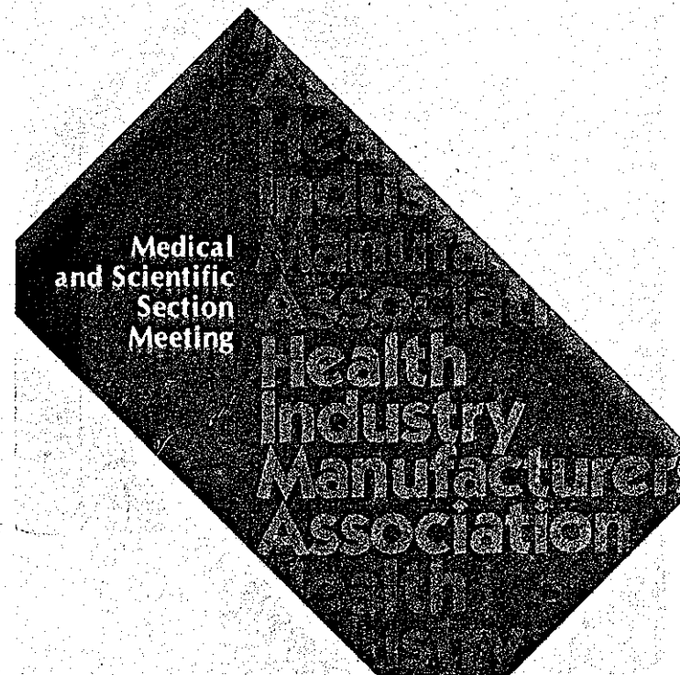
"Cost Containment — How Many Lives Can We Afford to Save?"
Speaker — Dwight E. Harken, M.D.

GETTING NEW PRODUCTS TO THE MARKET — Medical and Scientific Section Meeting

December 5-6, 1978

Health Industry Manufacturers Association
Hyatt Regency O'Hare Hotel
Chicago, Illinois

Program Committee
Geoffrey H. Lord, D.V.M., Ph.D., Chairman
Francis J. Meyer, Ph.D.
Royce Haynes, Ph.D.
Ronald Abrahams, Ph.D.
L. Leslie Hamilton, Ph.D., P.E.



Background

In the two-and-a-half years since passage of the Medical Device Amendments, the thrust of regulatory requirements for medical devices and diagnostic products has increasingly impacted introduction of new products to the marketplace. In perspective, the viability of any, and especially this, industry depends upon a flow of new and modified products able to meet the demands of the world's most sophisticated and constantly improving health care system. While much of the Food and Drug Administration's energies were at first directed at classifying and establishing good manufacturing processes and other requirements for existing medical devices and diagnostic products, the FDA has already begun to shift its emphasis to regulation of new or improved products. This change is now being manifested in formalized investigational regulations, good laboratory practices, proposed pre-clinical and clinical guidelines, product development protocols, and finalized premarket notification and premarket approval procedures.

The regulatory tide for product introduction is gaining momentum, and as the onrushing rules gather speed, the need to study their impact — to stop and look ahead to possible problems and their solutions — becomes more and more crucial. The HIMA Medical and Scientific Section has since its inception directed its energies to studying this developing situation. The experience of the Section's membership as it begins its fourth active year will form the basis of this seminar — to explore details involved with new product introduction.

Objectives

Since the seminar is based on the assumption that today's regulatory climate compels new routes and methods of product introduction, it is critical that manufacturers be able to review and study the rules of today's game. Therefore, the seminar objective is twofold: it aims to inform attendees about current and proposed regulations regarding new product introduction; and to highlight potential problems which manufacturers may encounter, along with proposed solutions.

Further, the objective of this meeting is to acquaint attendees with Section activities and related medical and scientific developments. Expert physicians and scientists will present current and useful data and viewpoints on various aspects of investigations, both pre-clinical and clinical. The latest developments in standards and regulatory activities will be featured, as well as proposed and recently enacted legislation. Qualified speakers will cover risk/benefit considerations in the regulatory process and

Proceedings

Following the seminar each registrant will receive at no extra charge an edited and bound text of all seminar proceedings. Additional copies of the proceedings will be available for purchase following the seminar from the HIMA Publications Department.

Lodging

To assure availability of lodging, the Association has reserved rooms at the Hyatt Regency O'Hare Hotel, Chicago, Illinois. However, registrants are required to make their own reservations and are urged to do so promptly. Use the enclosed hotel reservation form. If you make your reservation by phone — (312) 696-1234 — please be sure to indicate that you are attending the HIMA/M&S Meeting, thereby ensuring that you receive the preferred rate.

The Hyatt Regency O'Hare Hotel is five minutes from Chicago's O'Hare Airport. Complimentary limousine service is provided to and from the airport.

Program Schedule

The meeting begins at 9:00 a.m., Tuesday, December 5 and concludes at 1:30 p.m., Wednesday, December 6. The registration desk opens Monday, December 4 at 8:00 a.m. Included in the program are:

Luncheon, December 5
Informal Reception (Cash Bar), December 5 from 6:00 to 7:00 p.m.
Luncheon, December 6, presentation by Dwight E. Harken, M.D., Professor of Surgery Emeritus, Harvard Medical School

Registration

The meeting is open to HIMA member company representatives. The $135 registration fee includes a copy of the proceedings, all instructional materials, coffee during session breaks, two luncheons, and the reception. Because of limited space, early registration is urged.

Who Should Attend

Program attendance is limited to and designed for HIMA member company representatives with responsibilities for medical, scientific, research, and technical activities. The

Program Highlights

So that all attendees may receive optimum benefit from the seminar there will be concurrent breakout sessions for devices and diagnostics manufacturers. **Please note on the attached registration form if you prefer to attend the devices or diagnostics portion of the meeting.**

Seminar Faculty

The program faculty is comprised of experts from industry, academia, and government. They are:

Ronald Abrahams, Ph.D.
Director, Drug and Device Compliance
American Hospital Supply Corporation

Thomas H. Adams, Ph.D.
Director of Biochemistry Research
Hyland Laboratories

David Bayse, Ph.D.
Director, Clinical Chemistry Division
Bureau of Laboratories
Center for Disease Control

Jesus M. Botero, M.D.
Vice President, Medical Affairs
Ames Company Division/Miles Laboratories

K. Gerhard Brand, M.D.
Professor of Microbiology
University of Minnesota Medical School

John E. Campion, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
Medical Specialties Group/AHSC

Theodore R. Carski, M.D.
Corporate Medical Director
Becton, Dickinson and Company

Edward R. Duffie, Jr., M.D.
Corporate Medical Director
Becton, Dickinson and Company

Russell J. Eilers, M.D.
Medical Director
Bio-Science Enterprises

Richard A. Flink, Esq.
Vice President and General Counsel
C.R. Bard, Inc.

Jerry Gallwas
Program Manager, Clinical Instruments Division
Beckman Instruments, Inc.

Dwight E. Harken, M.D.
Clinical Professor of Surgery

John Paul Jones, Jr., M.D.
Director, Biological Research
Ethicon, Inc./J&J

Robert S. Kennedy, Ph.D.
Classification Coordinator
Bureau of Medical Devices
Food & Drug Administration

John Kuchta
Vice President and Counsel
Zimmer • USA, Inc.

Joan Kurjian
Director, Regulatory Affairs
Ethicon, Inc./J&J

Ronald Laessig, Ph.D.
Assistant Director
Wisconsin State Laboratory of Hygiene

Geoffrey H. Lord, D.V.M., Ph.D.
Director, Research Foundation
Johnson & Johnson

Theodore J. Medrek, M.D.
Corporate Medical Director
Becton, Dickinson and Company

Francis J. Meyer, Ph.D.
Vice President — Biomedical and Quality Activities
Extracorporeal Medical Specialties/J&J

Kenneth R. Michael, R.Ph.
Vice President & Director, R.A.&Q.A.
IMED Corporation

Ben Morgan
Manager of Physical Technology
Abbott Laboratories

Vernon A. Ray, Ph.D.
Assistant Director, Safety Evaluation Department
Pfizer Inc.

Sandra J. Ronspies
Administrator, Regulatory Affairs
Diagnostic Division
Abbott Laboratories

Arthur L. Rosenthal, Ph.D.
Manager, Clinical Research
Medical Products Laboratory
3M Company

L. Wade Self, M.D., Ph.D.
Director, Medical Affairs
Searle Diagnostics/G.D. Searle & Company

W. Arthur Staub, M.D.
Vice President, Medical Affairs
C.R. Bard, Inc.

S.K. Vadlamudi, D.V.M., Ph.D.
Executive Secretary, Clinical Toxicology and Immunology Panels
Bureau of Medical Devices
Food & Drug Administration

B.L. Valentine, Ph.D.
Corporate Director, Product Integrity
Sherwood Medical

John L. Watters, M.D.
Corporate Medical Director
Becton, Dickinson Research Center

Jaxon A. White, Esq.
Assistant General Counsel
Health Industry Manufacturers Association

Robert D. Wurzel
Vice President, Regulatory Affairs and Professional Services
Nuclear-Medical Laboratories

Medical & Scientific/Section

Officers

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Chairman
Becton, Dickinson and Company

Francis J. Meyer, Ph.D.
Vice Chairman — Devices Division
Extracorporeal Medical Specialties

Joan Kurjian
Vice Chairman — Diagnostics Division
Ethicon, Inc.

Robert M. Collins
Board Liaison
Cobe Laboratories, Inc.

Steering Committee

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Ames Company

Robert M. Collins
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Joan Kurjian
Ethicon, Inc.

Geoffrey H. Lord, D.V.M., Ph.D.
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