Health Industry Manufacturers Association

Annual Report 1978

202 - 452 - 8240

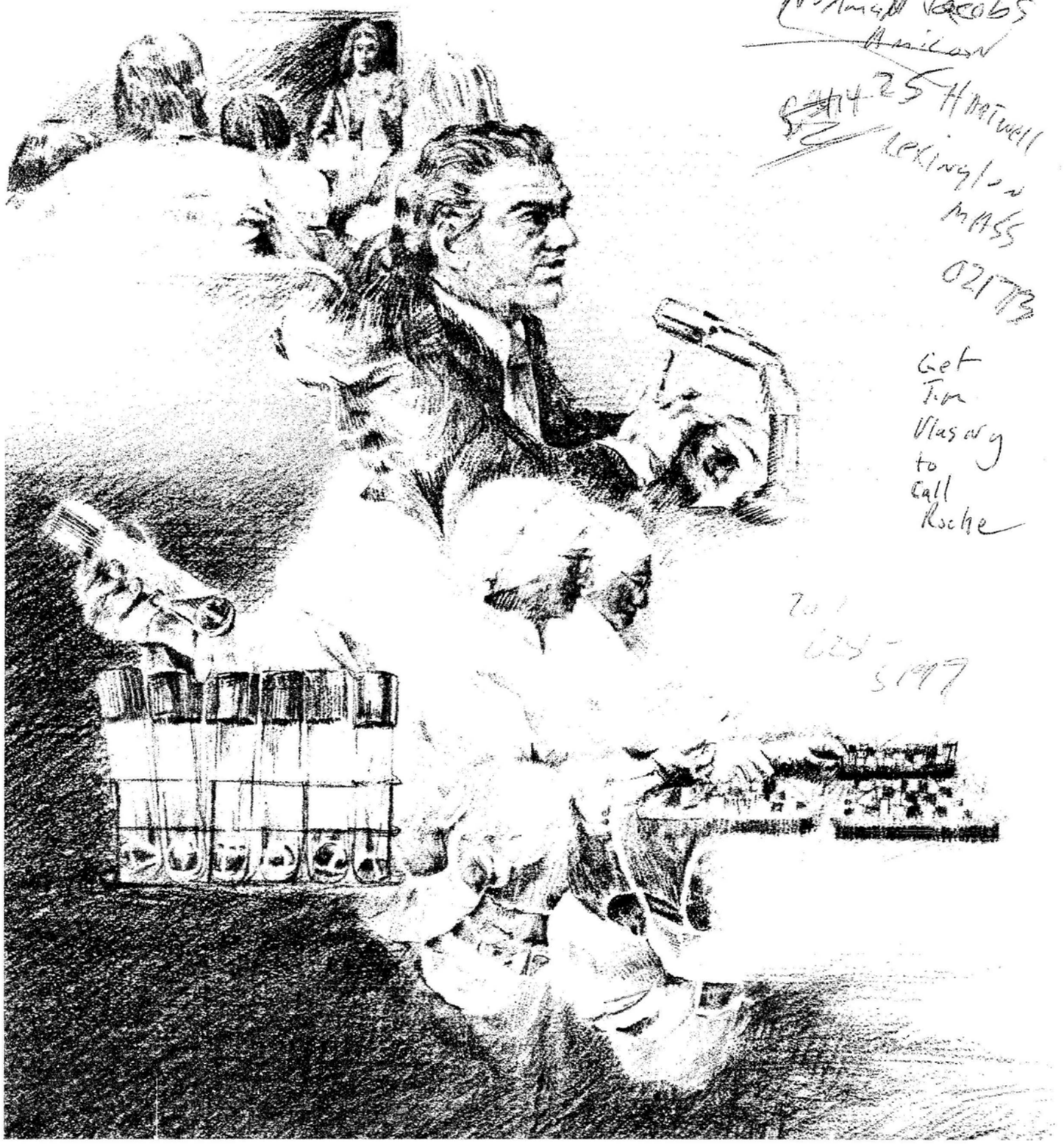
Tom Oberdorfer

Bill Roche

Norman Jacobs
American

~~814~~ 25 Hartwell
Lexington
Mass
02173

Get Tim Vlasary to call Roche



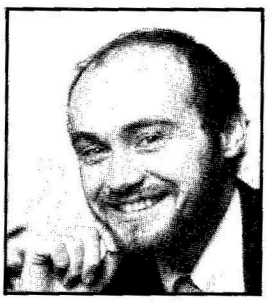




Debbie Proud, Manager, Credit and Marketing Activities, is responsible for managing HIMA's sales training activities, providing support to the Credit Committee, and to the Conventions and Exhibits Committee.



George Willingmyre, Director, Technical Services, is responsible for coordinating educational activities concerning Health Care Financing Administration reimbursement practices, Health Systems Agency planning personnel, technology assessment, cost containment, renal dialysis, and health planning.



Larry Worden, Director, Public Relations and Education, is responsible for directing the Public and Professional Relations Section, evaluating the editorial content of all communications, including the overall quality of regulatory comments, HIMA Reports, the *Reporter,* annual reports, and multi-member correspondence, arranging speaker programs, and planning general membership meetings.



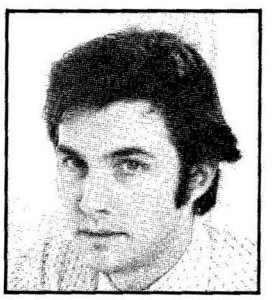
Cathy Americus, Manager, Communications, is responsible for editorial content of the *Reporter,* annual reports, meeting brochures, producing the Association's printed materials, establishing and maintaining press relations, providing support including the overall quality of regulatory comments, HIMA Reports, the *Reporter,* annual reports, and multi-member correspondence, arranging speaker programs, and planning general membership meetings.



Cathy Americus, Manager, Communications, is responsible for editorial content of the *Reporter,* annual reports, meeting brochures, producing the Association's printed materials, establishing and maintaining press relations, providing support to the Public and Professional Relations Section, producing and editing meeting publicity and HIMA Reports and proceedings



Mary Booher, Publications Assistant, is responsible for helping compose HIMA publications, and other documents prepared on the word processor.



David Ramroth, Manager, Scientific and Technical Education, is responsible for helping coordinate, schedule, produce, and edit publications, assisting in scientific and technical meeting planning, drafting and editing testimony and formal responses to proposed federal regulations, providing support to the Medical and Scientific Section, conducting scientific and technical research and technical editing of the *Reporter.*



Vita Iocco, Administrative Secretary, is responsible for administering activities of the Office of Scientific Affairs, providing administrative support to the Manufacturing, Engineering and Quality Assurance Section, the Environmental Issues Coordinating Committee, and planning scientific meetings.



Marilyn Whitney, Secretary, Word Processor, is responsible for providing administrative support to the Office for Scientific Affairs, and to the Public Relations and Education Office, and operating the word processor to assist in producing HIMA Reports and technical documents.



Betty Seward, Office Manager, is responsible for overall office management, financial affairs, purchasing, administrative staff, membership meetings, HIMA directories, Finance Committee sessions, and miscellaneous projects as assigned by the President.



Tess Bolger, Bookkeeper, is responsible for handling all bookkeeping details concerning the Association's financial affairs.



Art Butler, Clerical Assistant, is responsible for in-house printing production, including duplication, binding, and mailing of printed material distributed by HIMA.



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Jacquelyn Morris, Receptionist, is responsible for operating the office switchboard, greeting and assisting guests, and providing overall clerical support to the office.



Laura Washington, Secretary, is responsible for providing administrative support to the Office Manager, maintaining the HIMA library, and handling administrative aspects of membership recruitment and the Annual Report.



Jack White, Vice President, Technical Affairs, is responsible for directing the Standards Section, diagnostic company regulatory affairs, economic regulatory affairs, including technology assessment and health planning, maintaining professional relations with customer groups and standards organizations, membership recruitment, and product liability insurance.



Thi Dao, Ph.D., Director of Research and Economic Studies, is responsible for conducting economic studies on product liability, the cost of specific government regulations, and legislative proposals.



Connie Gore, Secretary, is responsible for efficient operation of the Technical Affairs Office, and providing administrative support to the General Counsel's Office.



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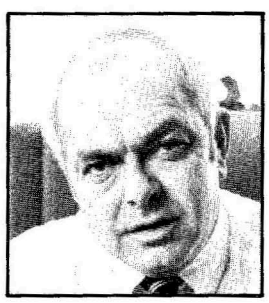
HIMA Staff 1978



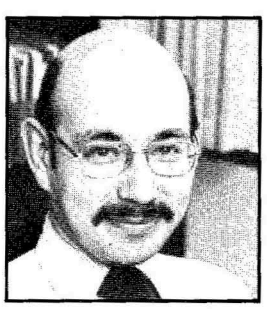
Hal Buzzell, President and Chief Administrative Officer, serves on the Board of Directors. In 1978 he represented the Association by serving on the National Steering Commitee for the Voluntary Effort to contain hospital costs.



Mary Lynch, Manager, Legislative Affairs, is responsible for monitoring health-related legislative and regulatory issues, including health planning, cost containment, technology assessment, Medicare/Medicaid reimbursement issues, providing direction to the Washington Representatives Committee, and developing materials for the Government Affairs Handbook.



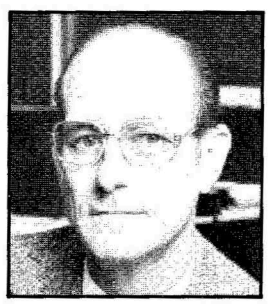
Bette Anne Starkey, Assistant to the President, is responsible for tasks associated with efficient operation of the President's Office.



Bill Roche, Staff Attorney, is responsible for monitoring legal aspects of health-related legislative and regulatory developments concerning health planning, technology assessment, Medicare/Medicaid reimbursement issues and federal procurement practices, supporting Legal and Regulatory Section activities and the Association's activities concerning renal dialysis.



Mike Cole, Vice President and General Counsel, is responsible for HIMA's legal, regulatory, and legislative product safety activities, and direction of the Legal and Regulatory Section, Board of Directors and Executive Committee sessions, and the Nominating Committee.

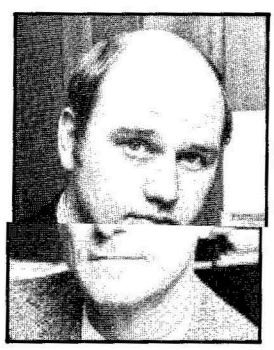


Briggs Phillips, Ph.D., Vice President, Scientific Affairs, is responsible for all HIMA scientific programs, providing overall staff support to the Manufacturing, Engineering and Quality Assurance Section, and Medical and Scientific Section, directing activities of the Environmental Issues Coordinating Committee, dealing with environmental, medical and occupational regulatory issues, and maintaining relations with scientific and professional groups.



Cass Foley, Executive Secretary, is responsible for efficient operation of the General Counsel's Office, and providing administrative support to the Legal and Regulatory Section.

Directors and Executive Committee sessions, and the Nominating Committee.



Tom Geddes, Technical Assistant, is responsible for managing activities of the Manufacturing Engineering and Quality Assurance Section, conducting scientific literature searches, planning and conducting scientific and technical symposia, helping to

Scientific Section, directing activities of the Environmental Issues Coordinating Committee, dealing with environmental, medical and occupational regulatory issues, and maintaining relations with scientific and professional groups.



Cass Foley, Executive Secretary, is responsible for efficient operation of the General Counsel's Office, and providing administrative support to the Legal and Regulatory Section.



Tom Geddes, Technical Assistant, is responsible for managing activities of the Manufacturing Engineering and Quality Assurance Section, conducting scientific literature searches, planning and conducting scientific and technical symposia, helping to produce scientific documents, and answering specific requests for information about the medical device and diagnostic industry.

Precision Dynamics Corporation
Burbank, California
Daylin, Inc.
Los Angeles, California

J. A. Preston Corporation
New York, New York

The Procter & Gamble Company
Cincinnati, Ohio
The Buckeye Cellulose Corp.
Memphis, Tennessee
Paper Products Division
Cincinnati, Ohio

Propper Mfg. Company, Inc.
Long Island City, New York

Puritan-Bennett Corporation
Kansas City, Missouri
Bennett Respiration Products
Los Angeles, California

PyMaH Corporation
Somerville, New Jersey

Quinton Instrument Company
Seattle, Washington

Radiation Dynamics, Inc.
Melville, New York

Richard-Allan Medical Industries
Richland, Michigan

Robertshaw Controls Company
Industrial Instrumentation Div.
Anaheim, California

Roche Medical Electronics Inc.
Cranbury, New Jersey

Sage Products, Inc.
Elk Grove, Illinois

Sarns Inc.
Ann Arbor, Michigan

R. P. Scherer Corp.
Troy, Michigan
Storz Instrument Company
St. Louis, Missouri
Surgical Mechanical Research
Newport Beach, California

Scientific Mfg. Industries
Berkeley, California

G. D. Searle & Company
Skokie, Illinois
G. D. Searle & Company
Des Plaines, Illinois
Will Ross Health Group
Milwaukee, Wisconsin

Sears, Roebuck and Co.
New York, New York

Senco Products, Inc.
Cincinnati, Ohio

Sherwood Medical
St. Louis, Missouri

Shiley Incorporated
Irvine, California

Simmons Company
Atlanta, Georgia
Hausted
Medina, Ohio
Thonet Industries Inc.
York, Pennsylvania

S. J. Medical Inc.
St. Paul, Minnesota

J. Sklar Mfg. Co. Inc.
Long Island City, New York

Smalley & Bates, Inc.
Nutley, New Jersey

Sparta Instrument Corporation
Fairfield, New Jersey

Spartan Healthcare Products
Spartanburg, South Carolina

Spenco Medical Corporation
Waco, Texas

E. R. Squibb & Sons, Inc.
Princeton, New Jersey
Edward Weck & Company, Inc.
Research Triangle Park,
North Carolina

Stan Pak, Inc.
Clifton, New Jersey

Steelcraft, Inc.
Millbury, Massachusetts

Stryker Corporation
Kalamazoo, Michigan

Sunlite Plastics, Inc.
Milwaukee, Wisconsin

Surgical Appliance Industries
Cincinnati, Ohio

Surgicot, Inc. Medical Products Division
Hauppauge, New York

Surgidev Corporation
Santa Barbara, California

Survival Technology, Inc.
Bethesda, Maryland

Sybron Corporation
Rochester, New York
Medical Products Division
Rochester, New York
Castle Operation
Rochester, New York
Liebel-Flarsheim Operation
Cincinnati, Ohio
Taylor-Arden Operation
Arden, North Carolina

Syva Company
Palo Alto, California

Technicare Corporation
Solon, Ohio
Invacare Corporation
Elyria, Ohio
Ohio-Nuclear, inc.
Solon, Ohio

Telectronics, Ltd.
Suffield, Connecticut
Telectronics, Ltd.
Milwaukee, Wisconsin
Telectronics Proprietary Ltd.
Englewood, Colorado

Telemed Corporation
Hoffman Estates, Illinois

Thermo Electron Corporation
Waltham, Massachusetts

The Torrent Corporation
Lake Geneva, Wisconsin

Tower Products, Inc.
Mundelein, Illinois

Union Carbide Corporation
Medical Products Division
New York, New York
Medical Products Division
Rye, New York
Clinical Diagnostics Business
Rye, New York
Union Carbide Imaging Systems
Norwood, Massachusetts
Union Carbide Nuclear Products
Tuxedo, New York
Linde Division
Linde Home Care Medical
Systems, Inc.
New York, New York
Linde Div.-Specialty Gases
South Plainfield, New Jersey
Linde Div.-Speedway Factory
Indianapolis, Indiana
Tarrytown Technical Center
Tarrytown, New York

United States Surgical Corp.
Stamford, Connecticut

U.S.I. Film Products
Tyler, Texas

Vacudyne Altair
Chicago Heights, Illinois

Valleylab, Inc.
Boulder, Colorado

Vernitron Corporation
Great Neck, New York
American Medical Instrument
Flushing, New York
LIFEMED Division
Compton, California
Vernitron Medical Products
Carlstadt, New Jersey

Viscot Industries, Inc.
East Hanover, New Jersey

Vitek, Inc.
Houston, Texas

The Vollrath Company
Sheboygan, Wisconsin
Medical Division
Schiller Park, Illinois

Warner-Lambert Company
Morris Plains, New Jersey
American Optical Corporation
Southbridge, Massachusetts
General Diagnostics Division
Morris Plains, New Jersey
Nuclear-Medical Laboratories
Dallas, Texas
Hospital Products Division
Morris Plains, New Jersey
Parke, Davis & Company
Greenwood, South Carolina
The Deseret Company
Sandy, Utah
Orthopedics Division
Greenwood, South Carolina

Waters Associates, Inc.
Milford, Massachusetts

Welch Allyn, Inc.
Skaneateles Falls, New York

The West Company
Phoenixville, Pennsylvania

WR Medical Electronics Co.
St. Paul, Minnesota

Xomed Inc.
Jacksonville, Florida

Zimmer • USA, Inc.
Warsaw, Indiana
The Pelton and Crane Company
Charlotte, North Carolina

Associate Member

American Hospital Association
Chicago, Illinois

Sherwood Medical
St. Louis, Missouri

Shiley Incorporated
Irvine, California

Simmons Company
Atlanta, Georgia
Hausted
Medina, Ohio
Thonet Industries Inc.
York, Pennsylvania

S. J. Medical Inc.
St. Paul, Minnesota

Telectronics, Ltd.
Milwaukee, Wisconsin
Telectronics Proprietary Ltd.
Englewood, Colorado

Telemed Corporation
Hoffman Estates, Illinois

Thermo Electron Corporation
Waltham, Massachusetts

The Torrent Corporation
Lake Geneva, Wisconsin

Tower Products, Inc.
Mundelein, Illinois

Parke, Davis & Company
Greenwood, South Carolina
The Deseret Company
Sandy, Utah
Orthopedics Division
Greenwood, South Carolina

Waters Associates, Inc.
Milford, Massachusetts

Welch Allyn, Inc.
Skaneateles Falls, New York

The West Company
Phoenixville, Pennsylvania

Hollister Incorporated
Chicago, Illinois

Hospal Medical Corporation
Littleton, Colorado

Hudson Oxygen Therapy Sales
Temecula, California

Humboldt Products Corporation
Columbus, Mississippi

Hycel, Incorporated
Houston, Texas

IBM Corporation
Information Records Division
Mt. Kisco, New York

ICL Scientific
Fountain Valley, California

IMED Corporation
San Diego, California

Intermedics, Inc.
Freeport, Texas

Ipco Hospital Supply Corp.
White Plains, New York
- Whitestone Products Division
  Piscataway, New Jersey

IPM, Inc.
Ann Arbor, Michigan

Irex Corporation
Medical Systems Division
Upper Saddle River, New Jersey

IVAC Corporation Sub. of Eli Lilly & Company
San Diego, California

Jewett Refrigerator Company
Buffalo, New York

Johnson & Johnson
New Brunswick, New Jersey
- Arbrook, Inc.
  Arlington, Texas
- Codman & Shurtleff, Inc.
  Randolph, Massachusetts
- Ethicon, Inc.
  Somerville, New Jersey
- Extracorporeal Medical Specialties
  King of Prussia, Pennsylvania
- JELCO Laboratories
  Raritan, New Jersey
- Johnson & Johnson
  Dental Products Company
  East Windsor, New Jersey
- Johnson & Johnson
  Products, Inc.
  Buffalo, New York

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  Raritan, New Jersey
- Johnson & Johnson
  Dental Products Company
  East Windsor, New Jersey
- Johnson & Johnson
  Products, Inc.
  New Brunswick, New Jersey
- Critikon Division,
  McNeil Laboratories, Inc.
  Irvine, California

- Rampon Products, Inc.
  Asheboro, North Carolina
- Theradyne Corporation
  Lakeville, Minnesota

Kallestad Laboratories, Inc.
Chaska, Minnesota

The Kendall Company
Boston, Massachusetts
- MedaSonics, Inc.
  Mountain View, California
- Plastronics, Inc.
  Milwaukee, Wisconsin
- Respiratory Care Inc.
  Arlington Heights, Illinois

James R. Kendrick Co., Inc.
Philadelphia, Pennsylvania

Kimberly-Clark Corporation
Neenah, Wisconsin
- Washington Office
  Washington, D.C.

Kimble Division
Owens-Illinois, Inc.
Toledo, Ohio

Kleen Test Products, Inc.
Milwaukee, Wisconsin

The Larkotex Company
Texarkana, Texas

Linmedco, Inc.
Roselle, New Jersey

L & M Instruments, Inc.
Sunnyvale, California

Lumex Inc.
Bay Shore, New York

Mallinckrodt, Inc.
St. Louis, Missouri
- National Catheter Corporation
  Argyle, New York

Marion Health & Safety, Inc.
Rockford, Illinois

Mark One Hospital Products
Philadelphia, Pennsylvania

Market Forge Division of Beatrice Foods Company
Everett, Massachusetts
- Ille Division/Market Forge
  Williamsport, Pennsylvania

Mars Manufacturing Company
Division of Workwear Corporation
Asheville, North Carolina

Marshall Electronics, Inc.
Skokie, Illinois

Meadox Medicals Inc.
Oakland, New Jersey

Med General, Inc.

Mallinckrodt, Inc.
St. Louis, Missouri
- National Catheter Corporation
  Argyle, New York

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Oakland, New Jersey

Med General, Inc.

Medical Incorporated
Inver Grove Heights, Minnesota

Medical Engineering Corp.
Racine, Wisconsin

Medical Specialties, Inc.
Charlotte, North Carolina

Medishield Inc.
Lancaster, New York
- Fraser Sweatman, Inc.
  Lancaster, New York
- Harlake Cyprane Inc.
  Lancaster, New York
- Medishield Surgical
  Fairfield, New Jersey
- Pioneer Viggo, Inc.
  Beaverton, Oregon

Medline Industries, Inc.
Northbrook, Illinois

Medrad, Inc.
Pittsburgh, Pennsylvania

Medtronic, Inc.
Minneapolis, Minnesota

Mennen Greatbatch Inc.
Clarence, New York

Metal Bellows Corp.
Sharon, Massachusetts

Metropolitan Wire Corporation
Wilkes Barre, Pennsylvania

Mettler Electronics Corp.
Anaheim, California

Midmark Medical
Minster, Ohio

Miles Laboratories, Inc.
Elkhart, Indiana
- Professional Products Group Staff
  Elkhart, Indiana
- Ames Company Division
  Elkhart, Indiana
- Dome Division
  West Haven, Connecticut
- Lab-Tek Products Division
  Naperville, Illinois

Millipore Corporation
Bedford, Massachusetts
- Worthington Biochemical Div.
  Freehold, New Jersey

Minnesota Mining & Mfg. Co.
St. Paul, Minnesota
- Bird Corporation
  Palm Springs, California

Elkhart, Industrial Corporation

- Professional Products Group Staff
  Elkhart, Indiana
- Ames Company Division
  Elkhart, Indiana
- Dome Division
  West Haven, Connecticut
- Lab-Tek Products Division
  Naperville, Illinois

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- Worthington Biochemical Div.
  Freehold, New Jersey

Minnesota Mining & Mfg. Co.
St. Paul, Minnesota
- Bird Corporation
  Palm Springs, California
- McGhan Medical Corporation
  Santa Barbara, California

Mistogen Equipment Company
Oakland, California

Natvar Corporation
Div. of Electronized Chemicals Corp.
Clayton, North Carolina
- Natvar Corporation
  Burlington, Massachusetts

NDM Corporation
Dayton, Ohio

New England Nuclear Corp.
Medical Diagnostics Division
North Billerica, Massachusetts

Nice-Pak Products, Inc.
Mount Vernon, New York

North American Science Associates, Inc.
Northwood, Ohio
- North American Science Associates
  of California, Inc.
  Irvine, California

Norton Company Plastics & Synthetics Division
Akron, Ohio

Ohio Medical Products
Madison, Wisconsin

Olympic Medical Corporation
Seattle, Washington

Oximetrix, Inc.
Mountain View, California

Pacesetter Systems, Inc.
Sylmar, California

Pall Biomedical Products Corp.
Glen Cove, New York

Paper Manufacturers Company
Southampton, Pennsylvania

Parker Laboratories, Inc.
Orange, New Jersey

Pedicraft, Inc.
Jacksonville, Florida

Pennsylvania Engineering Co.
Philadelphia, Pennsylvania

Pfizer, Inc.
New York, New York
- Howmedica, Inc.
  New York, New York
  - Deknatel, Inc.
    Floral Park, New York
  - Holgrath
    Cheshire, Connecticut
  - Orthopaedics Division
    Rutherford, New Jersey
  - United
    Largo, Florida
- Diagnostics Products Group
  New York, New York

Orange, New Jersey

Pedicraft, Inc.
Jacksonville, Florida

Pennsylvania Engineering Co.
Philadelphia, Pennsylvania

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  New York, New York
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    Floral Park, New York
  - Holgrath
    Cheshire, Connecticut
  - Orthopaedics Division
    Rutherford, New Jersey
  - United
    Largo, Florida
- Diagnostics Products Group
  New York, New York

Pharmaceutical Innovations Inc.
Newark, New Jersey

California Intraocular Lens Corp.
Huntington, West Virginia

Cardiac Pacemakers, Inc.
St. Paul, Minnesota
- Derata Corporation
St. Paul, Minnesota

Cavitron Corporation
New York, New York
- Cardio Pulmonary/KDC Divisons
Anaheim, California
- Syntel, Inc.
Irvine, California

Central States Diversified, Inc.
St. Louis, Missouri

Century Mfg. Company
Aurora, Nebraska

Chase Instruments Corporation
Poultney, Vermont

Chattanooga Pharmacal Co.
Chattanooga, Tennessee

Chemetron Corporation
Medical Products Division
St. Louis, Missouri

Chesebrough-Pond's Inc.
Hospital Products Division
Greenwich, Connecticut

Cincinnati Sub-Zero Products, Inc.
Cincinnati, Ohio

Clinitemp, Inc.
Indianapolis, Indiana

Cobe Laboratories, Inc.
Lakewood, Colorado

Conco Medical Company
Bridgeport, Connecticut

Concord Laboratories, Inc.
Keene, New Hampshire

Continental Group, Inc.
Flexible Packaging Division
Greenwich, Connecticut

Cordis Corporation
Miami, Florida
- Cordis Laboratories, Inc.
Miami, Florida
- Hyperion, Inc.
Perrine, Florida
- Norland Instruments
Fort Atkinson, Wisconsin
- Washington Office
Washington, D.C.

Cordis Dow Corp.
Miami, Florida

CPM Inc.
Claremont, New Hampshire

Cutter Laboratories, Inc.
Berkeley, California

Damon Diagnostics
Division of Damon Corp.
Needham Heights, Massachusetts

Dart Industries
Health Care Sector
Wallingford, Connecticut
- Seamless Hospital Products Co.
Wallingford, Connecticut
- Absorbent Cotton Company
Valley Park, Missouri
- Lawton Instruments
Wallingford, Connecticut
- Seamless Latex Products
Fayette, Alabama
- Seamless Plastics Products
Fayette, Alabama

Datascope Corporation
Paramus, New Jersey

Davis & Geck
Pearl River, New York

Davol Incorporated
Cranston, Rhode Island

Delka Corporation
Newton, Massachusetts

The DeVilbiss Company
Health Care Division
Toledo, Ohio

Devon Industries, Inc.
Northridge, California

The Dexter Corporation
- C. H. Dexter Division
Windsor Locks, Connecticut
- GIBCO/INVENEX
Grand Island, New York

DHD Medical Products, Div. of Diemolding Corporation
Canastota, New York

Diack Incorporated
Beulah, Michigan

Diagnostic Products Corp.
Los Angeles, California

Diamed Div. of Illinois Tool Works
Elk Grove, Illinois

Diamond Shamrock Corporation
Cleveland, Ohio
- Diamond Shamrock
Medical Products, Inc.
Wausau, Wisconsin

Diatek, Inc.
San Diego, California

Dittmar and Penn Corp.
Philadelphia, Pennsylvania

DKS A Div. of David Kopf Instruments
Tujunga, California

Dow Diagnostics
Indianapolis, Indiana

Dravon Medical, Inc.
Clackamas, Oregon

Dynamed Corporation
Elmsford, New York

Edco Inc.-Pasco Inc.
Division of Temco Products Inc.
Passaic, New Jersey

Electro-Biology, Inc.
West Caldwell, New Jersey

Electro-Med Health Industries
Miami, Florida

Electro-Nucleonics, Inc.
Fairfield, New Jersey
- Electro-Nucleonics, Inc.
Bethesda, Maryland

EMI Medical Inc.
Northbrook, Illinois

Ethox Corp.
Buffalo, New York

Faser Industries/ Beacon Converters Inc.
Saddle Brook, New Jersey

Ferno-Washington, Inc.
Wilmington, Ohio

Frohock-Stewart, Inc.
Northboro, Massachusetts

Gambro, Inc.
Barrington, Illinois
- Gambro, Inc.
Newport News, Virginia

Gaymar Industries, Inc.
Orchard Park, New York

Gelman Instrument Co.
Ann Arbor, Michigan

General Atomic Company
Medical Products Division
San Diego, California

General Electric Company
Medical Systems Division
Milwaukee, Wisconsin
- Medical Systems Division
Washington, D.C.

General Medical Corporation
Richmond, Virginia
- Dillon Manufacturing Company
Atlanta, Georgia

Glasrock Plastics Group
Fairburn, Georgia

W. L. Gore & Associates, Inc.
Newark, Delaware

Gould Inc.
Rolling Meadows, Illinois
- Instruments Division
Cleveland, Ohio
- Medical Products Division
Oxnard, California

Grant Airmass Corporation
Stamford, Connecticut

Graphic Controls Corporation
Buffalo, New York

Grasyn Industries, Inc.
Affiliate of Tolas Corp.
Newtown, Pennsylvania

Green Bay Papers
Baycare Disposables Division
Green Bay, Wisconsin

GST Laboratories Incorporated
Chicago, Illinois

Guardian Products Co., Inc.
North Hollywood, California

Gudebrod, Inc.
Philadelphia, Pennsylvania

Haemonetics Corporation
Braintree, Massachusetts

Hausmann Industries, Inc.
Northvale, New Jersey

Heelbo, Inc.
Niles, Illinois

Helena Laboratories
Beaumont, Texas

Hermitage Hospital Products
Niantic, Connecticut

Hill-Rom Company, Inc.
Batesville, Indiana

Cutter Laboratories, Inc.
Berkeley, California

Damon Diagnostics
Division of Damon Corp.
Needham Heights, Massachusetts

Dart Industries
Health Care Sector
Wallingford, Connecticut
- Seamless Hospital Products Co.
Wallingford, Connecticut
- Absorbent Cotton Company
Valley Park, Missouri
- Lawton Instruments
Wallingford, Connecticut

Electro-Biology, Inc.
West Caldwell, New Jersey

Electro-Med Health Industries
Miami, Florida

Electro-Nucleonics, Inc.
Fairfield, New Jersey
- Electro-Nucleonics, Inc.
Bethesda, Maryland

EMI Medical Inc.
Northbrook, Illinois

Ethox Corp.
Buffalo, New York

Haemonetics Corporation
Braintree, Massachusetts

Hausmann Industries, Inc.
Northvale, New Jersey

Heelbo, Inc.
Niles, Illinois

Helena Laboratories
Beaumont, Texas

Hermitage Hospital Products
Niantic, Connecticut

Hill-Rom Company, Inc.
Batesville, Indiana

Membership 1978

Members

Abbott Laboratories
North Chicago, Illinois
- Buffalo Plant
  Buffalo, New York

Acme Scale Company
San Leandro, California

Acme United Corporation
Bridgeport, Connecticut
- Fremont, N.C. Plant
  Fremont, North Carolina

ADAC Laboratories
Sunnyvale, California

Adjustable Fixture Co.
Milwaukee, Wisconsin

Affiliated Hospital Products
New York, New York
- MPL, Inc.
  Chicago, Illinois
- MPL Solopak Division
  Franklin Park, Illinois

Air Products and Chemicals
Allentown, Pennsylvania

Akron Catheter, Inc.
Akron, Ohio

Alberox Corporation
New Bedford, Massachusetts

Alza Corporation
Palo Alto, California

American Can Company
Greenwich, Connecticut

American Cystoscope Makers
Stamford, Connecticut
- American Latex Corporation
  Sullivan, Indiana

American Home Products Company
- Corometrics Medical Systems
  Wallingford, Connecticut
- Analytab Products
  Plainview, New York

American Hospital Supply Corp.
Evanston, Illinois
- Arnar-Stone Laboratories
  McGaw Park, Illinois
- Convertors Division
  Evanston, Illinois
- Dade Division
  Miami, Florida
- Midwest American Dental Division
  Des Plaines, Illinois
- V. Mueller Division
  Niles, Illinois
- Pharmaseal Division
  Glendale, California

American Medical Products Corp.
Freehold, New Jersey

American Medical Systems, Inc.
Minneapolis, Minnesota

American Monitor Corporation
Indianapolis, Indiana

American Pacemaker Corporation
Woburn, Massachusetts

American Safety Equipment Corp.
Encino, California
- Health Care Division
  San Fernando, California

American Sterilizer Company
Erie, Pennsylvania
- AMSCO/Hall Surgical
  Santa Barbara, California

Amersham Corporation
Arlington Heights, Illinois

Amicon Corporation
Lexington, Massachusetts

Amko Manufacturing Company
Mount Ephraim, New Jersey

H. W. Andersen Products Inc.
Oyster Bay, New York

The Applied Radiant Energy Corp.
Lynchburg, Virginia

Arbeka Webbing Co.
Pawtucket, Rhode Island

Argon Medical Corp.
Garland, Texas

Arrow International, Inc.
Reading, Pennsylvania

Arvey Corporation
Chicago, Illinois
- Lamcote Division
  Chicago, Illinois
- Lamcote Division
  Jersey City, New Jersey

Avco Medical Products
Everett, Massachusetts

Baka Manufacturing Company
Plainville, Massachusetts

L. T. Baker Chemical Company
- Hyland Labs-Therapeutics Division
  Costa Mesa, California

Beckman Instruments, Inc.
Fullerton, California

Becton Dickinson and Company
Paramus, New Jersey
- Bard-Parker Division
  Lincoln Park, New Jersey
- BBL
  Cockeysville, Maryland
- B-D Immunodiagnostics
  Orangeburg, New York
- Becton-Dickinson Division
  Rutherford, New Jersey
- Becton Dickinson Medical Systems
  Sharon, Massachusetts
- Clay Adams
  Parsippany, New Jersey

Bemis Health Care, Inc.
Sheboygan Falls, Wisconsin

Bentley Laboratories, Inc.
Irvine, California

Ben Venue Laboratories, Inc.
Bedford, Ohio

Bergen Brunswig Corporation
Los Angeles, California
- Plasta-Medic
  Carson, California

Bio-Dynamics, Inc.
Indianapolis, Indiana
- Bio-Dynamics/bmc
  Indianapolis, Indiana
- Boehringer Mannheim Biochemical
  Indianapolis, Indiana
- DePuy
  Warsaw, Indiana
- Envirco
  Albuquerque, New Mexico

The Birtcher Corporation
El Monte, California

Blickman Health Industries
Fair Lawn, New Jersey

Bourns, Inc.
- Life Systems Division
  Riverside, California

E. F. Brewer Company
Menomonee Falls, Wisconsin

Alza Corporation
Palo Alto, California

American Can Company
Greenwich, Connecticut

American Cystoscope Makers
Stamford, Connecticut
- American Latex Corporation
  Sullivan, Indiana

American Home Products Company
- Corometrics Medical Systems
  Wallingford, Connecticut
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Bourns, Inc.
- Life Systems Division
  Riverside, California

E. F. Brewer Company
Menomonee Falls, Wisconsin

Brimms Inc.
Tonawanda, New York

Briox Technologies, Inc.

Publication Services

Publications

Coinciding with the growing number and quality of HIMA educational seminars, the Association's publications program experienced a landmark year in 1978. Over 15 new publications were sent to press. They covered such topics as Medicare/Medicaid regulations, ethylene oxide, pyrogen testing, medical device sterilization, metric conversion, microbiological containment, product liability insurance, and others. More than 2,500 of these reports were distributed to members.

In a significant break with past practice, nearly all of the publications were produced independent from educational meetings. Instead of relying on seminar proceedings for publication content, HIMA committees, task forces, and staff wrote and compiled instructional material for the reports.

Another 15 documents are projected for publication in 1979. They will cover design of medical device manufacturing facilities, regulatory compliance for inspections and recalls, meeting proceedings, and five additional titles in the medical device sterilization monograph series.

1978 publications included the following:

"The Feasibility of Establishing a Captive Insurance Company for HIMA Members"

"Ethylene Oxide Technical Report: 1978 Submission to the Environmental Protection Agency"

"HIMA Medical Device Sterilization Monographs" (five separate titles)

"American National Metric Council Medical Device Proposed Conversion Plan"

"Microbiological Containment Bibliography"

"Guideline for Evaluating the Safety of Materials Used in Medical Devices"

"Guideline for the Use of Limulus Lysate Test (LAL) for Pyrogen Testing of Medical Devices"

"Safety Procedures for Biohazards Control"

"The Industry and Government: Regulation of the Health Care Marketplace"

"General Design Criteria for Medical Device and Diagnostic Product Manufacturing Facilities"

"Getting New Products to the Market"

"Medical Devices and Government Regulations Medicare/Medicaid Programs"

The Association also continued to make available to member companies a wide range of documents—from Federal reports and regulations to minutes from HIMA meetings. These materials included:

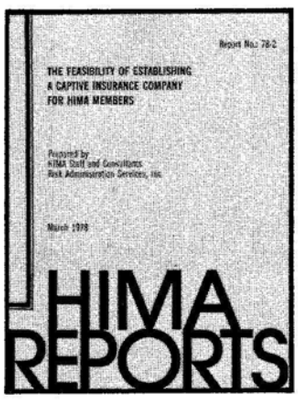
The *HIMA Reporter*, the Association's monthly newsletter

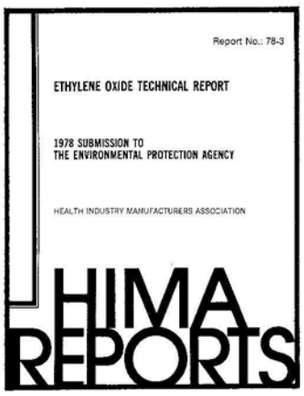
Minutes of HIMA Section and Committee Meetings

Minutes of FDA Classification Panel Meetings

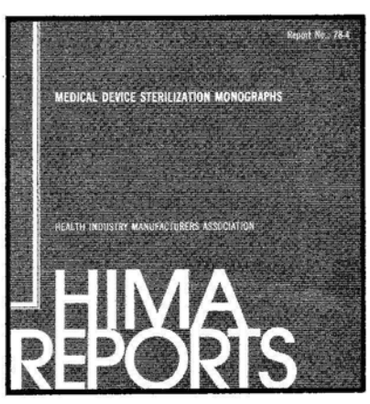
Position papers and reports developed by HIMA Sections and Committees

Selected Federal reports and guidelines.









Minutes of FDA Classification Panel Meetings

Position papers and reports developed by HIMA Sections and Committees

Selected Federal reports and guidelines.

20



A. White House aide Dr. Gilbert Omenn (Office of Science & Technology) shares his views with HEW's Seymour Perry, interim Director of the Office of Health Technology, during a Fall Meeting panel presentation.

B. Dwight Harkin, M.D., Harvard University, was the keynote speaker at the Medical & Scientific Section's seminar on product development and FDA compliance.

C. National economist Arnold Weber, Ph.D., former Secretary of Labor, addresses the audience at the Fall Meeting in Washington, D.C.

D. Walter Hennig (U.S. Surgical Corporation) addressing the closing session of the Technical Symposium, sponsored by the Manufacturing, Engineering & Quality Assurance Section.

E. Appearing at the Medical & Scientific Section's seminar, December 5-6 in Chicago, was Robert Kennedy, Classification Coordinator at the Bureau of Medical Devices.

F. Arthur H. Murphey (Hausted) poses a question to a HIMA Briefing panel during the Fall Meeting.

G. Senator Richard Schweiker (R-PA), minority leader of the Health Subcommittee, joins in conversation with HIMA Board Member Robert Beechner (Dart Industries) prior to his evening address to the Fall Meeting.

H. Donald Healton, Executive Director of Regional Operations, presented FDA's positions on plant inspections at the Octobert Legal & Regulatory Briefing.

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J. Dr. Sri Vadlamudi, Bureau of

Educational Services

Through steady expansion of HIMA's educational seminar program and publication effort, the Association continued as a major educational force in the medical device and diagnostic product industry during 1978.

Annual Meeting
Over 600 senior executives and spouses attended this major membership meeting held February 12-15 in Puerto Rico. The meeting's theme was "Future Trends in the Health Care Industry" and featured nationally-known individuals who spoke on a variety of related topics. The program committee was chaired by David Cutter (Cutter Laboratories, Inc.) and included Stuart Edgerly (Cordis Dow Corp.), Jack Low (3M Company), Walter Mosher (Precision Dynamics Corporation), and Arthur Murphey (Hausted/ Simmons Company).

West Coast Meeting
Attended by over 40 representatives on April 25, this program updated members on a variety of HIMA interests and projects. The session featured reports from several HIMA staff members, HIMA Chairman-Elect Kenneth Marshall (Sherwood Medical), and an address by Paul Ward, President of the California Hospital Association.

Medical Device Lawyers Workshops
Under the direction of Gary Lyons (3M Company), these two programs brought together 18 faculty members with collective experience in virtually every aspect of food and drug law. The programs held in Los Angeles on April 26-27 and in Boston on May 3-4, were attended by 120 member representatives. Topics included the lawyer's role in managing and planning for business and legal effects of FDA-rulemaking, submissions, negotiations, and remedial action.

Radiation Sterilization Update
A capacity audience of 175 representatives from HIMA member companies attended this two-day seminar that highlighted the many subject areas to be investigated before adopting radiation sterilization methods. The seminar provided a forum for discussion and explanation of specific management and technical information needed to evaluate feasibility and use of radiation to sterilize medical devices and diagnostic products. Member company representatives on the program committee included Kennard K. Morganstern, Ph.D. (Radiation Dynamics, Inc.), and Eugene R. L. Gaughran, Ph.D. (Johnson & Johnson).

GMP Workshop Series
On April 18, HIMA initiated the first of a series of GMP (good manufacturing practice) workshops. Under the direction of Les Hamilton, HIMA's Director of Medical Engineering and Electronics, the informal sessions were successfully repeated 12 times in eight cities across the country. A total of 400 representatives from member companies attended the workshops designed to provide a small group setting to discuss and learn about GMP philosophy, problems, and concerns. Regional Program Chairmen were: Floyd Benjamin (McGaw, American Hospital Supply Corporation); Arthur Murphey (Hausted, Simmons Company); J. Lee Clark (Plastronics, Inc., The Kendall Company); Kenneth Marshall (Sherwood Medical); Matthew Perry (American Hospital Supply Corporation); George Heinze (Johnson & Johnson); and George Bartlett (Gaymar Industries, Inc.)

Sales Training for the Operating Room
Joining with the Association of Operating Room Nurses (AORN), HIMA sponsored a one-day educational program on September 15 to orient sales representatives to operating room procedures and policies that may effect successful interaction with operating room decision-makers. Nearly 60 sales representatives attended the Boston meeting designed primarily for manufacturers' sales personnel with limited experience in selling operating room medical products. Program faculty included members of the AORN Collaboration with Industry Committee, supplemented by speakers from AORN's membership and HIMA.

Credit Manager's Workshop
Fifty-five credit managers, treasurers and comptrollers from HIMA member companies participated in the Fourth Annual Credit Managers Workshop, September 7 in New York City. The program, which covered topics ranging from financial trends in the medical supply dealer community to creditors rights, bankruptcy, foreign credit, and account information, was planned by the members of the Credit Committee's Workshop Subcommittee: Marcella Hanafin (PyMaH Corporation), Michael Hastings (C. R. Bard, Inc.), Ronald Klos (Ethox Corp.), Mayer Rashbaum (Affiliated Hospital Products), John Sklar (J. Sklar Mfg. Company Inc.), and Douglas Bergen (Becton Dickinson and Company).

Manufacturing, Engineering and Quality Assurance Technical Symposium and Section Meeting
The first comprehensive section meeting ever sponsored by HIMA, this three-day Manufacturing, Engineering and Quality Assurance Section program provided a forum for exchange of technical information including: product packaging and labeling; engineering; sterilization; metrication; quality assurance; and good manufacturing practices. The September 10-13 meeting included two full days of separate committee and task force sessions that reviewed the accomplishments of each committee, explored and discussed those accomplishments, planned future activities, and solicited increased participation from members. Special features of the Chicago meeting were facility tours of two HIMA member companies located in the area, and a comprehensive binder of meeting materials including nine *HIMA Reports* published expressly for the session. Program Chairman was Albert Jarvis (Cordis Dow Corp).

Legal and Regulatory Briefings
Held twice during the year, these meetings were attended by nearly 200 member company representatives. One informal session held at HIMA headquarters on May 24 featured Kenneth Baumgartner, FDA's Associate Chief Counsel for Medical Devices and Diagnostic Products. The second, larger briefing, on October 3, concentrated on investigational device and GMP compliance issues and featured presentations by two panels of FDA officials. The program, chaired by Michael Cole (Johnson & Johnson), and moderated by Cole and James Hulse (Becton Dickinson and Company), provided participants with an opportunity to meet and interact with prominent FDA officials.

Third Fall Meeting—The Industry and Government: Regulation of the Health Care Marketplace
Recognizing that government influence over the medical device and diagnostic product industry is no longer limited to direct product regulation, but now extends to indirect economic or marketplace regulation, HIMA sponsored a conference October 12-13 in Washington, D.C. Over 200 HIMA member company executives attended the meeting, as well as representatives from government agencies, Congress, professional and trade associations, the investment community, and the press. The Program Committee, chaired by Albert Baldock (J. T. Baker Chemical Company), structured the meeting to include panel presentations on health care technology assessment and health planning, as well as addresses by Representative Tim Lee Carter, Senator Richard Schweiker, columnist Joseph Kraft, and economists Walter Heller and Arnold Weber. An additional feature of the meeting was an issues briefing for HIMA members, presented by the Association's staff.

Medical and Scientific Section Meeting—Getting New Products to the Market
Information on how to cope with new and proposed product development and marketing regulations was the theme of this December 5-6 seminar held in Chicago. One-hundred-fifty member company representatives participated in two concurrent sessions dealing with devices and diagnostic products. The meeting's secondary objective was to acquaint attendees with Medical and Scientific Section activities and related medical and scientific developments. Program Chairman was Geoffrey H. Lord, D.V.M., Ph.D., (Johnson & Johnson).

Sales Training Program
The HIMA Sales & Educational Training Committee, chaired by John Hughes (The Kendall Company) sponsored seven sales training seminars attended by over 400 dealer representatives and sales personnel. These programs were structured to facilitate more informed sales presentations for purchasers of medical products. The Program Chairmen and the cities for which they organized seminars were: Don Kitzmiller (Midmark Corporation), Los Angeles; Ken Beane (The Medical Products Division, Sybron Operation), Atlanta; Russ Pennavaria (Puritan-Bennett Corporation), St. Louis; Lew Bennett (Dillon Manufacturing Co., General Medical Corporation), Tahoe City; Allen Pearson (Vernitron Corporation), Blue Mt. Lake.

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Several other workplace environmental issues have been addressed by the Association. In response to OSHA's proposal to restrict worker exposure to cotton dust, HIMA pointed out that only raw cotton caused the observed adverse effects and requested that medical grade cotton be exempted—OSHA, in 1978, agreed.

In testimony before EPA on the uses of Chloroflurocarbons (CFC's), HIMA Vice President for Scientific Affairs,



Dr. Briggs Phillips, recommended that health care uses of CFC's be exempted from any restrictions placed on non-propellant uses of these substances. Further action by EPA on this subject is still pending.

EPA, OSHA, and FDA are all currently considering regulations on which the Association has commented and are writing new proposals, which are yet to be published. It has been, and will continue to be the Association's position that sound scientific and technical studies are the most valid means of arriving at constructive workplace environment regulations. It is clear that protecting the worker and non-manufacturing environment from potentially toxic materials requires constant surveillance and increasingly sophisticated monitoring systems. The potential harm must be weighed against the established benefits derived by the use of certain substances.

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Product Liability Insurance

With the support of 80 member companies, the formation of a captive product liability insurance company became a major pursuit of HIMA in 1978. Beginning with an Association-sponsored conference on product liability insurance problems in April, 1976, HIMA recognized members' concern with this important subject and took deliberate action to provide assistance.

The first action assumed the form of several membership surveys conducted in 1977 that culminated in publication of a product liability profile (HIMA Report No.: 77-2) for the HIMA membership. The study concluded that product liability insurance not only was costing companies upwards of one percent of sales, but also had become increasingly difficult to obtain at any reasonable terms. Smaller companies, in particular, were hard-hit. Despite the fact that in general, their loss experience was favorable, several were required to pay premiums in excess of five percent of sales. It was clear from the study results that premium increases bore little or no relationship to loss experience.

A second report, a comprehensive study entitled, "The Feasibility of Establishing a Captive Insurance Company for HIMA Members" (HIMA Report No.: 78-2) was released in early March, 1978. The report, supported by 130 members, proposed that HIMA form a captive insurance company to alleviate the pressure of skyrocketing rates and problems of insurance availability. Outlined as potential benefits for captive insurance participants were:

- ownership by participants of any accumulated surplus;
- stable rates and terms of coverage;
- rates and policy terms dependent not on trends affecting the insurance industry as a whole, but on the actual loss experience of the insured;
- more premium dollar available for losses because of minimal normal insurance overhead; and
- insured pay only for those administrative, claims control and loss prevention services that relate to their particular need.

After a select committee of member company representatives reviewed the highly-favorable membership response to the feasibility study, they authorized the Association to begin the process of forming an insurance company. In early May, after contacting 110 member companies who had shown continued interest in the captive, 80 agreed to provide funding, consider premium quotations, and supply detailed information on their businesses.

By September of this year, HIMA elected a board of directors (designate) for the proposed captive and secured a representative number of nonbinding commitments from members to accept their quoted insurance premium and to found the company. Further commitments from a total of 39 companies were received in mid-October. This expression of interest was sufficient to use as a basis to secure fronting company and reinsurance proposals.

In November, the captive was given the name Medical Device Mutual Assurance and Reinsurance Company, Limited (MEDMARC). Concurrent with other November activities, special counsel submitted an enabling act to the Bermuda Parliament to form a mutual insurance company and filed a no-action letter with the Securities and Exchange Commission.

In the closing weeks of December, representatives of prospective members of MEDMARC and the HIMA staff appeared before government officials in Bermuda to finalize the organization of the company. Also completed during this period was the terms of an insurance treaty arrangement with a large, national underwriter to provide insurance policies which are, in turn, backed by MEDMARC. During the final days of December, the company came into legal existence with the subscriptions of 29 member firms contributing an annualized primary insurance premium of $1.7 million for coverage limits of $500,000 per occurrence and in aggregate. Also made

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method used by HEW to limit expenditures and also has the potential to expand to other product areas.

New Methods Of Purchasing For The Medicaid System

In 1978 HEW began to consider using new purchasing methods as a way of reducing Medicaid expenditures for eyeglasses and hearing aids. While the proposal was limited to only two items, it also points the way to more extensive volume-purchasing arrangements, or to maximum amounts that government would pay for products.

HIMA staff, in addition to preparing for increased legislative activity on Capital Hill, is also paying more attention to policies and developments at HEW that are likely to affect the market. As witnessed in 1978, this added attention is necessary because of increasing government initiatives in this area. HIMA member companies should begin considering the steps they could take—both in terms of internal company planning and liaison with HIMA—to deal with these issues. For better or worse, government has its eye on health care costs. And this increasing government involvement in the marketplace demands serious attention for all those who participate in it.

The Workplace Environment

Maintaining a safe workplace environment has always been an important consideration for manufacturers. With increased government attention to workplace issues, primarily generated by the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA), 1978 was a particularly significant year. Both EPA and the Food and Drug Administration proposed regulations to restrict and control the use of ethylene oxide (EtO). A gaseous substance widely used in the medical device and diagnostic product industry, EtO has unique properties that make it a highly desirable and efficacious sterilant applicable to many materials (especially those sensitive to heat) that cannot be sterilized by other means. The use and availability of this gas has been an important factor in development of low cost, single-use, sterile, medical items now in widespread use throughout the health care system.

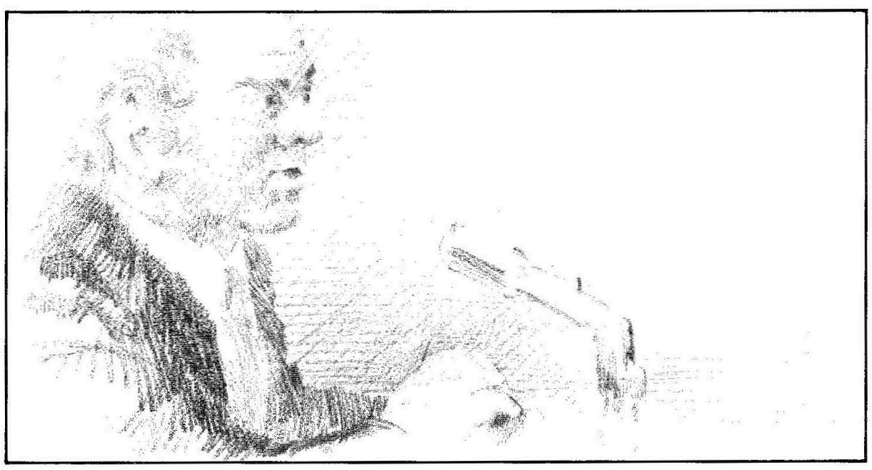
Understandably, HIMA has been concerned about and involved with potential regulation of EtO since EPA first announced in 1976 its intention to ban or restrict its use. EPA based its intended regulation on reports that EtO is a mutagen and possibly a carcinogen. Since then, FDA and the National Institute for Occupational Safety and Health (NIOSH) have joined EPA and begun their own studies of possible long-term toxic effects from workplace or treatment-related exposure to EtO. In response to the evolving EtO situation and other potential environmental concerns, HIMA's Executive Committee established, in 1976, an Environmental Task Force to work with EPA, FDA, and NIOSH to prepare for the pending regulatory process.

Throughout 1977 HIMA monitored regulatory developments related to EtO. In addition to preparing to respond to government actions, the Association undertook the task of educating its membership on regulatory developments concerning EtO. Through articles printed in the *HIMA Reporter*, a 1977 seminar called "EtO Update," and, in 1978, publication of HIMA's responses to proposed regulations, the Association's work in both areas—representation and education—continued to be a high priority.

EPA's January 27, 1978 publication of a rebuttable presumption against registration of EtO began a year of HIMA responses to proposed EtO regulations. The Environmental Task Force was upgraded to the Environmental Issues Coordinating Committee to better utilize various member resources. The comprehensive 400-page technical document, that constituted HIMA's response to EPA, was submitted on May 15. EPA has not yet taken further action, but has recently released a "benefits" study that confirms HIMA's position that EtO is essential to the U.S. health care system.

In June, FDA published proposed maximum limits for residual EtO and its major breakdown products, ethylene chlorohydrin and ethylene glycol, on treated products. The proposal was confusing, unworkable, and distressing in its insufficiency. HIMA submitted, on October 13 an 80-page analysis of FDA's proposal and suggested that it be considered an advanced notice of a proposed rule. In effect, HIMA asked FDA to reject the proposal and start again. The Association is awaiting FDA's next action.

Less directly related to the medical device and diagnostic product industry and so somewhat less publicized by HIMA, was OSHA's proposed generic approach to classifying potential carcinogens. The 1978 proposal may, in fact, be the most long-reaching of current proposed workplace or environmental regulations. This regulation proposes to establish classes of chemicals and regulate them by class rather than by consideration of individual substances. It is very possible that if OSHA accepts this approach, EPA and FDA will follow. Because of its potential for wide-ranging effects over many industries, the American Industrial Health Counsel (AIHC) was formed to challenge OSHA's generic carcinogen proposal. HIMA joined AIHC and presented testimony in July 1978 supporting an alternative plan before OSHA's committee. OSHA has not yet taken further action.



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16

proposal would limit hospital costs by placing a ceiling on revenue increases, as well as establishing a maximum figure for capital expenditures. Although the proposal would most directly affect hospitals, its passage would also have major consequences for the medical device and supplies market.

No hospital cost containment legislation has been enacted by Congress, in large part because of the successful "Voluntary Effort" to reduce cost increases sponsored by the American Hospital Association, the American Medical Association, the Federation of American Hospitals, HIMA, Blue Cross/Blue Shield, and others. HIMA supported these efforts, with President Hal Buzzell serving on the National Steering Committee. Despite the program's success, however, hospital cost containment is a high priority on the Administration's legislative agenda for 1979, and is an issue that is likely to reappear in the next Congress.

Assessment Of Medical Technology

One of government's successful cost control initiatives this year was establishing a National Center for Health Care Technology and an advisory body called the National Council on Health Care Technology. Increased interest in technology assessment demonstrates that government has expanded its sights beyond present concerns with safety and efficacy of medical devices, and is beginning to ask whether benefits resulting from use of particular technologies are worth the cost.

The National Center has a broad charter to assess health care technology. Evaluation activities will include a look at the technical and cost effectiveness, social, ethical, and economic affects of particular medical technologies. The center is also authorized to recommend to HEW policies for Medicare reimbursement. The National Council on Health Care Technology is authorized to develop "standards, norms and criteria" concerning use of health care technologies.

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Planning;" second, the Department attempted to amend the Federal health planning law.

The guidelines, issued in March 1978, recommend policies for developing Health System Plans. For instance, they recommend usage standards for hospital bed supply, obstetrical services, neonatal special care units, and radiation therapy, all with emphasis on cost containment.

Amendments to the Federal health planning law concerned State health planning approval for purchase of major medical equipment (costing over $150,000) that is to be located outside of hospitals. The issue remains unresolved and is likely to be addressed in 1979 by Congress.

End Stage Renal Disease Program Amendments

Motivated by a desire to keep program expenses from expanding, Congress in 1978 amended the end stage renal disease program to promote increased use of self-dialysis and kidney transplantation. The amendments also introduced incentive reimbursement methods to encourage economy in delivery of services. Although it will be some time before any actual savings are known, these amendments, with their emphasis on cost containment, again demonstrate government's concern with health care costs.

National Health Insurance

While there was no substantive legislative action on national health insurance during the past year, there have been two significant developments.

First, President Carter issued a set of principles for comprehensive health care coverage and a plan which would include aggressive cost containment measures. HEW was given responsibility by the President to develop a "tentative plan" on national health insurance, which will

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HEW Regulations And Policies

HEW assumed an active role in 1978 in the cost containment arena through changes in the Medicare-Medicaid reimbursement system. This trend is likely to intensify in the future, as health care cost containment moves more and more into the public spotlight. The several HEW regulations and policies which are presented below, have importance to the device industry beyond their immediate impact. They represent possible cost control mechanisms which could expand into a national health insurance program.

The Lowest Charge Level Regulation For Durable Medical Equipment And Certain Laboratory Tests

HEW published in July 1978, a regulation setting a reimbursement formula for home-use hospital beds, wheelchairs, and outpatient diagnostic lab tests based on the "lowest charge level" at which equipment and supplies are available in a locality. The regulation's net effect is that if prices vary a great deal for a given item or service, those with higher price tags will not be reimbursed fully and the Medicare patient will have to make up the difference. The purchaser, over the long run, may attempt to buy equipment at low prices without paying proper attention to the quality of the item. This regulation may expand to cover additional lab tests and durable medical equipment.

Dollar Amount Reimbursement Limits Set For CT Scans

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In 1978, HEW also made a policy decision to recommend a maximum dollar amount which Medicare claims processors should

Issues Report: 1978

Of the many issues the Association dealt with in 1978, four were particularly significant, each for a different reason. Implementation of the Medical Device Amendments continued to be a major concern; the threat of more government control of the health care marketplace increased in scope and activity; government attention to workplace safety indicated possible restrictions on many substances used in manufacturing processes; after two years of intense activity, the Association's efforts to alleviate the product liability insurance dilemma culminated in formation of a captive insurance company. The next four pages provide a more detailed look at these topics.

The Amendments

Continuing implementation of the 1976 Medical Device Amendments, FDA proposed five new regulations and finalized six others. In the two years since the Amendments were enacted, FDA has proposed a total of 20 regulations directly affecting devices, 8 of which are now in final form.

Good Manufacturing Practice (GMP) regulations for medical devices and diagnostic products stood out as the most significant regulation implemented by FDA in 1978. The short-term effects of this regulation are potentially great; future effects may change the shape of the industry. The regulations, consisting of manufacturer requirements and guidelines for design, implementation, and monitoring of comprehensive quality assurance programs are tailored to specific manufacturing needs for each device. They became effective on December 18, 1978, following more than three years of development. During those three years, HIMA continuously monitored FDA's progress and provided substantial input at key points in the regulations' development. As a result, the final regulation was a considerable improvement over previous drafts and, in fact, contained many of HIMA's proposed changes.

With completion of this pivitol rule, regulatory concerns now shift for the first time from theoretical concepts to coping with actual problems of enforcement and compliance. Many questions still remain regarding specific GMP compliance issues. And these questions may not be answered until FDA begins enforcing the regulation in 1979. The status of many products which may be considered as "critical" devices, and therefore subject to more stringent regulation, is still uncertain. Conversely, the list of general products that may be exempted from GMP requirements is neither final nor all inclusive.

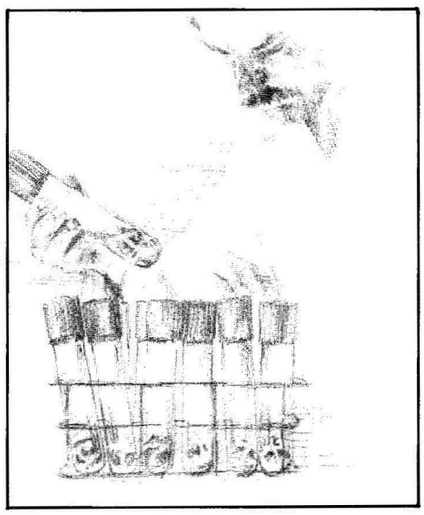
Unresolved questions concerning specifics of compliance with GMP regulations and other proposals that become final will characterize 1979 as a year of transition. This will occur as FDA's enforcement arm and manufacturers learn to deal with demanding new requirements and assure adequate and reasonable compliance.

The most significant regulations currently in proposed form, that will probably be finalized during 1979, deal with FDA supervision of product development. Under authority of a series of proposed bioresearch regulations, (*i.e.*, Investigational Device Exemptions, Clinical Investigations—Obligations of Sponsors and Monitors, Standards for Institutional Review Boards for Clinical Investigations, and Obligations of Clinical Investigators of Regulated Articles). FDA would augment its Bioresearch Monitoring Program by reviewing and certifying preclinical and clinical research data. FDA's primary interest in regulating product research investigations is to assure validity and reliability of data that it receives from manufacturers. Data compiled for submission to FDA in support of research or marketing permits will have to be obtained according to requirements of the proposed regulations. Failure to do so could result in disqualification of the study or the entire application.

So far, FDA's bioresearch proposals cover well over 100 pages of *Federal Register* material. HIMA spent a considerable amount of time analyzing these proposals in 1978. The Association has already submitted more than 60 pages of comments to FDA and has testified at two public hearings. The thrust of this commentary has been to seek clarification and better explanation of the rulemaking language and to urge FDA to regulate through less restrictive, nonmandatory guidelines.

The potential significance of these proposals cannot be overemphasized since, as currently written, they govern virtually any study conducted on a medical device prior to its being approved for the use under study. When combined with the post-marketing authority of the GMP's, FDA will be able to exercise stringent regulatory control over a product—from inception through its useful life.

The past four years of comment and work with FDA has been undertaken with that control in mind. For it is only through open, clear lines of communication and understanding that fair and effective regulations have been and will be developed.



The Market Place

One of the most notable regulatory trends of 1978 was government's increased attention to health care costs and, in particular, possible methods to reduce the rate at which costs are increasing. Some proposals, such as the Administration's hospital cost containment proposal, were broadbased. Others, such as the Medicare-Medicaid "lowest charge level regulation for medical equipment, supplies, and services" were directed at specific medical technology and products. In 1979, and beyond, we will continue to see government initiatives affect the market for medical devices and diagnostic products. The following is a review of the various 1978 government initiatives, some enacted and others proposed, which in some manner affect or will affect the marketplace.

Hospital Cost Containment

When President Carter took office two-years-ago, he pledged to devise a means for hospital cost control. The resulting

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Sections

Standards

Functioning primarily as a coordinating body in 1978, HIMA's Standards Section, chaired by John Gallagher (Physico-Control Corporation), represented HIMA among a number of private and Federal organizations and standards efforts.

Throughout the year, Section members monitored regulatory classification of medical devices and *in vitro* diagnostic products by expert FDA panels. They were also active in nominating new industry representatives to serve on a number of these panels and monitoring FDA reorganization of classification panels to assure continuity of industry representation. In addition, section members organized presentations before several panels to rebut proposals that would have moved cardiac defibrillators and hemodialysis equipment from performance standards to premarket approval.

In mid 1978, FDA proposed regulations for procedures required to identify and develop mandatory performance standards. The Standards Steering Committee actively participated in the review and comment process on this proposal.

Steering Committee member Robert Flink (Medtronic, Inc.) provided the Section with frequent reports on activities of Working Group 62D of the International Electrotechnical Commission (IEC). Preparations were begun by the Section in 1978 to assist in organizing a 1979 international meeting of the IEC medical device interests to be held in Washington, D.C. As in past years, HIMA maintained its role as international secretariat for IEC 62D.

Following a well-established precedent, Section members participated in voluntary standards organizations activities concerned with medical devices and diagnostic products. Frank Samuel (former HIMA Vice President and General Counsel) served through September as the HIMA representative on the Executive Committee of the Medical Device Standards Management Board of the American National Standards Institute. This link with ANSI provided an advocate to oppose proposed government requirements that would have reduced effectiveness of voluntary standards organizations.

The Section continued its representation on the American Society for Testing and Materials F.4 Committee on medical instruments and significantly expanded its involvement with the National Committee for Clinical Laboratory Standards (NCCLS). Representation as administrative secretariat was also maintained for the ANSI luer taper standard 270.1 and the MD 105 Committee.

As the Section prepares for 1979, it hopes to strengthen ties with voluntary standards organizations by first surveying the existing level of industry involvement in such groups and then designing more formal liaison arrangements with the most significant organizations.

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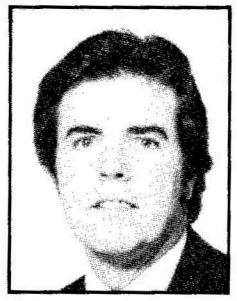
Robert C. Flink
Medtronic, Inc.

Thomas Nickel
Baxter Travenol Laboratories, Inc.

Gerald E. Gallwas
Beckman Instruments, Inc.



John T. Gallagher,
Chairman
Physio-Control Corporation

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Committee on International Standards
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Committee on Professional and Voluntary Standards
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Committee on Regulatory Standards
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Baxter Travenol Laboratories, Inc.

Representative to the Medical Device Standards Management Board of American National Standards Institute
Jaxon A. White
HIMA

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HIMA

Public and Professional Relations

The Public and Professional Relations Section Steering Committee, chaired by John Morran (Akron Catheter, Inc.), met throughout 1978 to help the Association and its members effectively deal with emerging issues. A major accomplishment this year was the more precise delineation of the Section's purpose within the Association and creation of an organizational structure to reflect this. Recognizing that, unlike the other functional units of HIMA, the Public and Professional Relations Section mostly provides Association support services, the Steering Committee divided its activities into three areas of responsiblity—Communications Support, Meeting Support, and Section and Task Force Support.

Communications Support is concerned with HIMA's member communications activities and provides input to the *HIMA Reporter, Annual Report,* and *HIMA Report Series.* Section members worked closely with HIMA staff in planning and accomplishing the initial design and layout for this *Annual Report.* In 1979, the Communications Support Group will concentrate on revising and expanding the *HIMA Public Relations Guidebook* (HIMA Report No. 77-8).

Meeting Support activities are concerned with planning and arrangements for HIMA's Fall Meeting. Section members served on the 1978 Fall Meeting Planning Committee, and contributed to the promotion and press relations aspects of the meeting. As a result, the meeting received wider and more comprehensive press coverage than any other HIMA Fall Meeting to date. In 1979, this group will also assist HIMA staff and members to plan and promote other meetings and educational seminars.

Section and Task Force Support activities have the broadest mandate. Through this group, the Section monitored activities of other HIMA Sections and committees to assure proper utilization of public and professional relations opportunities.

The general 1979 focus of the Section will be to build on this new organization and recruit new members to become actively involved in expanding Section activities.



In promoting good public relations, the Public & Professional Relations Section was involved with the planning aspects of the 1978 Fall Meeting. This yearly, top management meeting focuses on the latest national developments applicable to U.S. industry and specifically, HIMA members. Above, HIMA Chairman John Baum stresses a point with National columnist Joseph Kraft, shortly following his remarks opening 1978's meeting.



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12

Steering Committee

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Robert Biel
Cordis Dow Corp.

Allen Fisch
American Sterilizer Company

Lothar Gumberich
Metropolitan Wire Corporation



John Morran, Chairman
Akron Catheter, Inc.

Sections

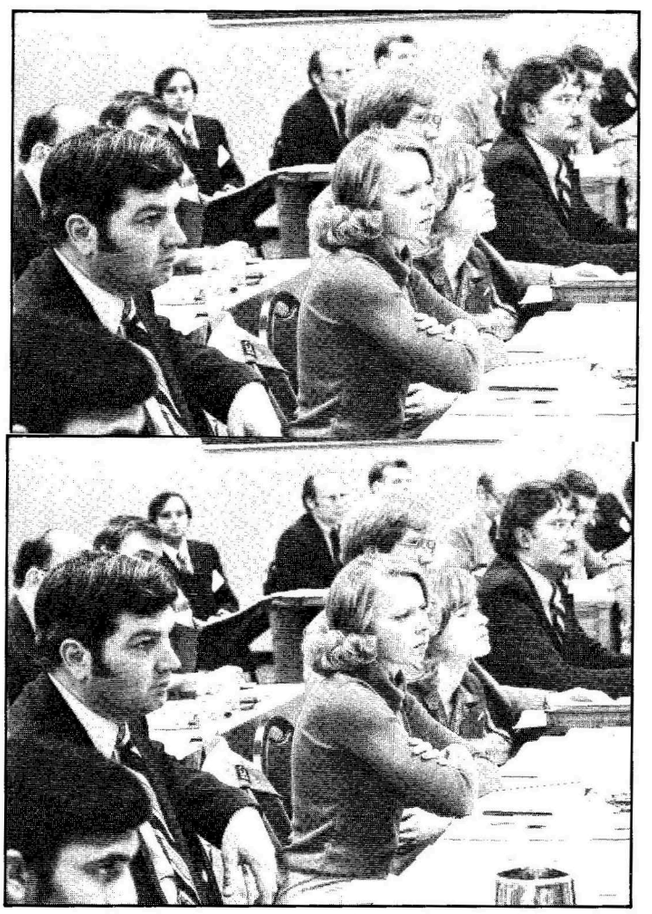
Medical and Scientific

The Medical and Scientific Section, chaired by John L. Watters, M.D. (Becton Dickinson and Company), continued to aid HIMA members in 1978 with projects in the areas of education, product safety, and comments on proposed regulations.

The Section sponsored a national meeting on "Getting New Products to the Market" to assist members with the transitional period, as product development and innovation gradually come under FDA regulations. In addition to the proceedings from this meeting, the Section published *Guideline for Evaluating the Safety of Materials Used in Medical Devices* (HIMA Report No. 78-7).

The Devices Division, directed by Francis J. Meyer, Ph.D. (Extracorporeal Medical Specialties, Inc.), made significant contributions to HIMA's comments on proposed ethylene oxide regulation. The Section also submitted comments to FDA on regulatory proposals relating to device clinical studies and investigational device exemptions. In other areas, the division made progress in the third phase of particulate matter studies and the Postmarket Surveillance Committee drafted additional quidelines for product safety and handling.

The Section's Diagnostic Division, directed by Royce Haynes, Ph.D. (Harleco Division, American Hospital Supply Corporation), and later by Joan Kurjian (Ethicon, Inc., Johnson & Johnson), continued its ongoing projects including interpreting regulatory requirements, conducting product stability studies, and gathering and distributing product development information.



An attentive audience hears a presentation in a device workshop during the Medical & Scientific Section's seminar on getting new products to

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Francis J. Meyer, Ph.D., Chairman
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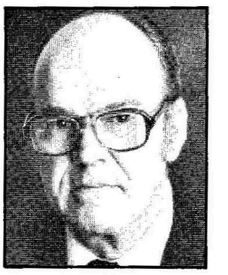

John L. Watters, M.D.,
Chairman
Becton Dickinson and Company

Manufacturing Engineering and Quality Assurance

The Manufacturing, Engineering and Quality Assurance (ME&QA) Section, chaired by Dr. Gordon Edwards (Dade Division, American Hospital Supply Corporation), observed another year of continued growth and accomplishment. The Section produced numerous technical reports, sponsored several educational seminars for HIMA members, and presented a successful first annual Section meeting. Building on work from previous years, the Section's nine committees and thirteen task forces successfully met the challenges and needs posed by current or anticipated FDA regulations. Over 190 technical personnel from more than 90 HIMA member companies contributed to the areas of good manufacturing practice regulations, proposed regulations for restricting use of ethylene oxide, future requirements for sterile products, pyrogen testing of medical products, metrication, and facility design for manufacturing.

Through HIMA's role as secretariat to the American National Metric Council, the Metrication Committee provided leadership in writing and publishing a metric conversion plan for the medical device industry.

Of major importance was publication of five sterilization monographs under the auspices of the Biological Division. These monographs covered specific methodologies and systematized technical sterilization information. Additional publications included a guideline for pyrogen testing, a microbiological containment bibliography, and two facilities design books. The Quality Assurance Committee concentrated its efforts on FDA's now final Good Manufacturing Practice Regulation and was successful in influencing decisions to have a flexible "what" rather than "how" regulation, and favorably changing more than 50 percent of the language in the final order. As part of HIMA's overall response to GMP's during 1978, 12 GMP workshops covering critical and non-critical devices were held in eight different cities in the U.S. These workshops, attended by almost 400 persons from 169 HIMA member companies, provided line personnel with opportunities to learn about compliance with GMP requirements. The Education Committee initiated meetings with FDA to provide technical education to FDA investigators on medical device manufacturing processes.

Key economic issues dealt with by the Section in 1978 were proposed EtO regulations and pyrogen testing. The Section responded to two major proposed regulations for EtO: the Environmental Protection Agency's proposal to ban or restrict use of the sterilizing gas, and FDA's proposal to impose maximum residue limits for medical devices. Pyrogen testing efforts were directed at simplifying and clarifying means of using the limulus ambeocyte lysate (LAL) test in place of the more expensive rabbit test. During 1978, the ME&QA Section sponsored three educational seminars—two on product sterilization (EtO and Radiation), and a detailed workshop covering all aspects of the Section's programs. The attendance at these meetings was well over 800 industry engineers, quality assurance personnel, top management officials, architects, attorneys, and other representatives from member companies.

Much of the Section's future activity will continue to revolve around GMP development, especially for sterile devices. However, efforts will also be directed at EtO residual measurement, packaging, labeling, distribution, plant environment, facility design, metrication, and plant safety. 1979 plans include liaison with United States Pharmacopeia for a proposal to develop, review, and recommend possible methods of validating microbiological test methods. Finalization and publication of additional technical reports will be an ongoing Section activity.

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10



Gordon C. Edwards, Ph.D.
Chairman
Dade Division
American Hospital Supply Corporation

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Air Products and Chemicals

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Sections

Legal and Regulatory

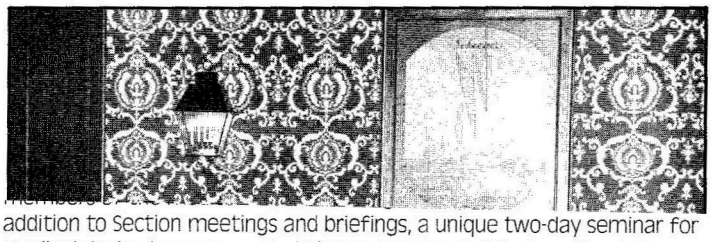
The Legal and Regulatory Section, chaired by Donald R. Stone (Medtronic, Inc.), continued its involvement with FDA's implementation of the Medical Device Amendments during 1978. The Section also vigorously pursued expansion into related and new areas of importance to HIMA members.

Representatives of the Legal and Regulatory Section participated in preparing and submitting comments to FDA on all regulations proposed during 1978 that affect the medical device and diagnostic product industry. Among the significant comments developed were those concerning investigational device exemptions, exemption and variance petitions from good manufacturing practice regulations, the final GMP's themselves, Freedom of Information regulations, bioresearch monitoring regulations, and proposed maximum residual limits for ethylene oxide. The Section also worked on comments submitted to other Federal agencies. Most significant of these was an extensive rebuttal of the Environmental Protection Agency's presumption against registration of ethylene oxide. Comments were also submitted to HEW on important Medicare/Medicaid proposals.

The Section continued to involve itself significantly in non-FDA Federal activities. This involvement was even more extensive than in 1977, and included Section participation in matters concerning hospital cost containment, health planning amendments, technology assessment, Clinical Laboratories Improvement Act, national health insurance, and end stage renal disease program reform.

The Section also continued its outstanding educational programs for members of the medical device and diagnostic product community. In addition to Section meetings and briefings, a unique two-day seminar for medical device lawyers was held in Los Angeles and Boston. Also, two one-day briefing sessions were held in Washington, providing attendees with an opportunity to question key FDA and industry personnel concerning GMP implementation and compliance and device research regulations.

1979 promises to be even more active than 1978 for Legal and Regulatory Section programs. Activities will emphasize new regulatory proposals, FDA compliance, Agency and Congressional testimony, economic and environmental concerns, and new educational programs.



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3M Company

Richard D. Manthei
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General Electric Company

Warren Whyte
Abbott Laboratories

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Education Committee
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3M Company

Legislation Committee
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American Hospital Supply Corporation

Product Regulation Division

Michael F. Cole, Chairman
Johnson & Johnson

Barbara Black, Vice Chairman
Syva Company

Task Force Chairmen:

Restricted Device:
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Baxter Travenol Laboratories, Inc.

GMP:
Jeffrey L. Dow
Roche Medical Electronics, Inc.

Premarket Approval:
Warren Whyte
Abbott Laboratories

Compliance:
Stanley N. Garber
Sherwood Medical

510 (k):
Richard A. Flink
C. R. Bard, Inc.

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Stanley N. Garber
Sherwood Medical

510 (k):
Richard A. Flink
C. R. Bard, Inc.

Ethylene Oxide/RPAR:
Michael F. Cole
Johnson & Johnson

Investigational Device

Special Committees

Cost Containment

Under the direction of this committee, chaired by Frank Ehmann (American Hospital Supply Corporation), the Association was successful in its program to avoid mandatory controls to contain hospital costs.

In anticipation of possible mandated hospital cost containment, the Association became an active participant in the Voluntary Effort. HIMA's President, Hal Buzzell, was selected as industry representative on the National Steering Committee (the Voluntary Effort's directive body).

This program, as it enters its second year, is successfully meeting the challenge with 1978's increase in hospital expenditures having dropped by over three percentage points.

During 1979, the Association will continue to participate in a voluntary program, in order to once again discourage mandatory legislation—expected once again to be a legislative priority of the Administration.

William F. Ballhaus
Beckman Instruments, Inc.

Robert L. Beechner
Dart Industries
Health Care Sector

Harold O. Buzzell
HIMA

Paul Creager
Warner-Lambert Company
Hospital Products Division



Frank A. Ehmann, Chairman
American Hospital Supply Corporation

Dimitri V. d'Arbeloff
Millipore Corporation

Henry E. Fish
American Sterilizer Company

Richard S. Grimm
Technicare Corporation

Robert A. Hagglund
EMI Medical Inc.

W. August Hillenbrand
Hill-Rom Company, Inc.

Vernon R. Loucks, Jr.
Baxter Travenol Laboratories, Inc.

Robert H. McCaffrey
C. R. Bard, Inc.

Walter L. Robb
General Electric Company

John E. Robson
G. D. Searle & Company

Environmental Issues

Chaired by Dr. Briggs Phillips (HIMA), the Environmental Issues Coordinating Committee directed activities of the Ethylene Oxide (EtO) Residual Task Force of the Medical and Scientific Section, chaired by Shirely Anderson (H.W. Anderson Products, Inc.) and the Legal and Regulatory task force on ethylene oxide, chaired by Michael Cole (Johnson & Johnson).

Following the Environmental Protection Agency's (EPA) initial action against EtO in January, 1978, the Coordinating Committee and staff prepared a comprehensive, 400 page compilation of information which supports EtO's continued use as a sterilant. The Coordinating Committee was also active in responding to the Food and Drug Administration's proposed regulation to severely restrict residual limits of EtO on devices, drugs, cosmetics, and other products. In late October, HIMA filed a detailed document disputing this proposed action.

Working with the American Industrial Health Council, HIMA provided both written comments and oral testimony requesting the Occupational Safety and Health Administration (OSHA) to withdraw its proposal to regulate suspected carcinogens by generic category.

HIMA defended the continued use of chlorofluorocarbons by the medical device industry. EPA's action on CFCs is still pending. Under the auspices of the Environmental Issues Coordinating Committee, a potential problem for manufacturers who use raw cotton was avoided. The final cotton dust regulation by OSHA provided an exemption for medical grade, washed and bleached cotton as requested by HIMA.



G. Briggs Phillips, Ph.D., Chairman
HIMA

Ronald Abrahams, Ph.D.
American Hospital Supply Corporation

Robert J. Gauthier, Ph.D.
Abbott Laboratories

Roger Ginger, Ph.D.
The Kendall Company
Research Center

Frank Halleck, Ph.D.
American Sterilizer Company

George E. Heinze
Johnson & Johnson

Jack Horman
Baxter Travenol Laboratories, Inc.

Raymond Murphy
Baxter Travenol Laboratories, Inc.

Robert L. Valentine, Ph.D.
Sherwood Medical

John L. Watters, M.D.
Becton Dickinson and Company

Long-Range Planning

The Long-Range Planning Committee, chaired by W. J. Howe (Becton Dickinson and Company), compiled in one comprehensive document, a chronicle of each HIMA Section, including major accomplishments since the Association's inception in November 1974.

The Committee, formed by the Board of Directors at the 1978 Annual Meeting, also obtained from each Section an outlook for future activities in order to structure Association plans to more readily identify and cope with member needs. The Committee was comprised of nine HIMA directors.



W. J. Howe, Chairman
Becton Dickinson and Company

A. J. Abbruzze
Johnson & Johnson

Harold O. Buzzell
HIMA

Theodore W. Eckels
Howmedica, Inc.

Lewis W. Lehr
3M Company

Robert H. McCaffrey
C. R. Bard, Inc.

William D. McGrath
Sybron Corporation
Medical Products Division

Charles V. Owens, Jr.
Miles Laboratories, Inc.

Richard N. Sarns
Sarns Inc.

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Medical Products Division

Charles V. Owens, Jr.
Miles Laboratories, Inc.

Richard N. Sarns
Sarns Inc.

Committees

Membership Committee

Directed by Thomas Tierney (The Kendall Company), the HIMA Membership Committee successfully recruited 40 new members in 1978. The new members manufacture devices and diagnostic products of all types, and the companies vary in size as well as in geographic location.

Most significant in 1978 was addition of several manufacturers of sophisticated diagnostic imaging and instrumentation products. These new members provide HIMA with a stronger and broader membership base, therefore increasing the Association's overall effectiveness.



Thomas E. Tierney, Chairman
The Kendall Company

George E. Blowers
Welch Allyn, Inc.

Dimitri V. d'Arbeloff
Millipore Corporation

J. Morgan
Zimmer · USA, Inc.

Charles V. Owens, Jr.
Miles Laboratories, Inc.

Nominating Committee

The Nominating Committee, chaired by Lewis Lehr (3M Company), met several times throughout the year to nominate candidates from the Official Representatives of active members to serve on HIMA's Board of Directors. The Committee also prepared a slate of nominees for elected officers (Chairman, Chairman-Elect, Treasurer) for 1979, giving special consideration to candidates who would assure adequate and fair membership representation.



Lewis W. Lehr, Chairman
3M Company

Robert A. Elliott
Shiley Inc.

W. J. Howe
Becton Dickinson and Company

J. Morgan
Zimmer · USA, Inc.

Richard N. Sarns
Sarns Inc.

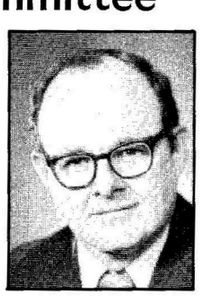
Robert A. Schoellhorn
Abbott Laboratories

Sales and Educational Training Committee

Under the guidance of the Sales and Educational Training Committee, chaired by John Hughes (Kendall Company), over 400 dealer sales persons received practice-oriented training in 5 different U.S. locations throughout the year.

Special highlights of 1978 included a seminar devoted exclusively to operating room salespersons, sponsored in conjunction with the Association of Operating Room Nurses. The Committee devoted a substantial part of the year to developing an effective 1979 sales training program. Included in 1979's plans are the following seminars:

March 17 Charlotte, North Carolina
March 24 Minneapolis, Minnesota
March 31 Los Angeles, California (home health care market)
August 5-10 Blue Mt. Lake, New York
October 19-20 Columbus, Ohio (specialty sales training)



John Hughes, Chairman
The Kendall Company

Allen Pearson, Vice Chairman
Don Kitzmiller
Russ Pennavaria

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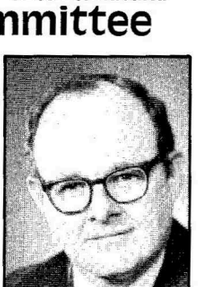

John Hughes, Chairman
The Kendall Company

Allen Pearson, Vice Chairman
Vernitron Medical Products

Don Kitzmiller
Midmark Medical

Russ Pennavaria
Puritan-Bennett Corporation

George Blowers, Board Liaison
Welch Allyn, Inc.

Tom Langer
The Burdick Corporation

Thomas Reider
Jewett Refrigerator Company

Committees

Annual Meeting Committee

The Annual Meeting Committee, chaired in 1978 by Dee d'Arbeloff (Millipore Corporation), assisted in planning business, educational, social and recreational aspects of the fifth HIMA Annual Meeting, scheduled for February 10-14 at the Boca Raton Hotel and Club, Boca Raton, Florida.

In developing details for the 1978 meeting, the Committee followed the popular format of previous years; concurrent early-bird breakfast sessions focusing on specific topics of industry concern and general sessions with nationally prominent featured speakers addressing broader issues. As in past years, the social and recreational program was planned to complement the business and educational aspects of the meeting.

The Fourth HIMA Annual Meeting, held February 12-15 at the Cerromar Beach Hotel, Puerto Rico, was attended by over 600 senior executives from member companies and their spouses.



Dimitri V. d'Arbeloff, Chairman
Millipore Corporation

Robert Beechner
Dart Industries
Health Care Sector

Gerald Bell
Lumex Inc.

George Blowers
Welch Allyn, Inc.

Con Sterling
The West Company

Robert Tucker
R. P. Scherer Corporation

Conventions & Exhibits Committee

The Conventions & Exhibits Committee, chaired in 1978 by Arthur H. Murphey (Simmons Company, Hausted), continued to work with numerous national hospital, medical specialty, and professional organizations. The Committee's work helped keep members informed of current meeting information and developments regarding national and international exhibits.



Arthur H. Murphey, Chairman
Simmons
Hausted

Robert L. Beechner, Board Liaison
Dart Industries
Health Care Sector

Robert T. Osterlund
Johnson & Johnson
Patient Care Division

Frank Reesby
American Sterilizer Company

Robert B. Sullivan
Parke, Davis & Company

H. J. (Bud) Witt
The Kendall Company

Credit Committee

Exploring methods to make the present credit-reporting system more effective and applicable to member companies' financial personnel was the predominant effort of 1978's Credit Committee. The Committee met monthly to analyze dealer information submitted by member companies and prepared over 750 Credit Experience Exchange Reports. The Committee also sponsored its Annual Credit Manager's Workshop in September in New York City. Topical items for this year's session included financial trends in the medical supply dealer community, creditor's rights and bankruptcy, and current foreign credit and account information.

Bob Weeks (Ethicon, Inc.) served as Chairman of this year's Committee. The first member company representative to serve the Credit Committee in this capacity, he replaced Frank Samuel, formerly HIMA's Vice President and General Counsel.



Robert L. Weeks, Chairman
Johnson & Johnson
Ethicon

William A. Baum, Jr.
W. A. Baum Company, Inc.

E. Douglas Bergen
Becton Dickinson and Company

Lawrence Cohen
Lumex, Inc.

Michael Hastings
C. R. Bard, Inc.

Warren R. Kendrick
James R. Kendrick Co., Inc.

John Sklar
J. Sklar Manufacturing Company, Inc.

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William A. Baum, Jr.
W. A. Baum Company, Inc.

E. Douglas Bergen
Becton Dickinson and Company

Lawrence Cohen
Lumex, Inc.

Michael Hastings
C. R. Bard, Inc.

Warren R. Kendrick
James R. Kendrick Co., Inc.

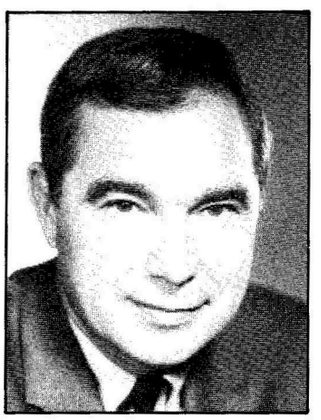
John Sklar
J. Sklar Manufacturing Company, Inc.

Counsel
Covington & Burling
Washington, D.C.

Accountant
Simon Akst, CPA
New York, New York



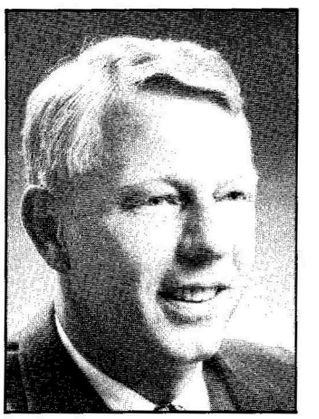
Dimitri V. d'Arbeloff
Millipore Corporation



Theodore W. Eckels
Howmedica, Inc.



Stuart Edgerly
Cordis Dow Corp.



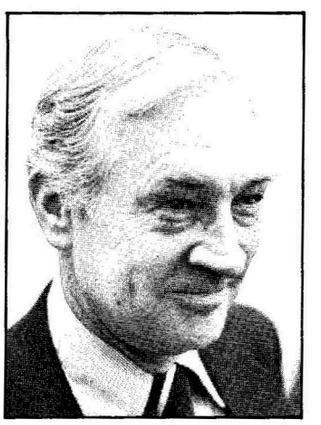
Frank A. Ehmann
American Hospital Supply Corporation



Vernon R. Loucks, Jr.
Baxter Travenol Laboratories, Inc.



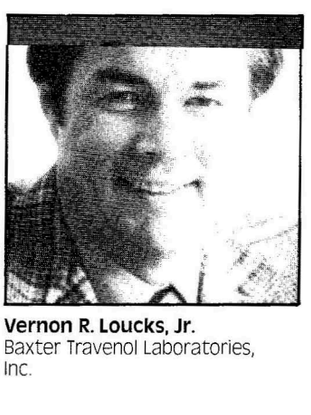
Robert H. McCaffrey
C. R. Bard, Inc.



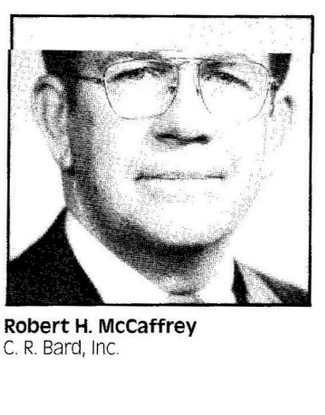
William D. McGrath
Sybron Corporation
Medical Products Division



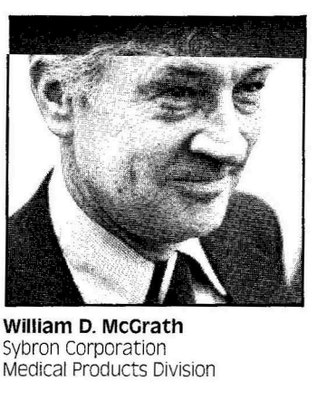
J. Morgan
Zimmer · USA, Inc.



Vernon R. Loucks, Jr.
Baxter Travenol Laboratories, Inc.



Robert H. McCaffrey
C. R. Bard, Inc.



William D. McGrath
Sybron Corporation
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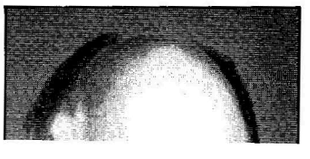








HIMA Board of Directors Executive and Finance Committees



Donald James Bentley
Bentley Laboratories, Inc.
Executive Committee



George E. Blowers
Welch Allyn, Inc.



Robert M. Collins
Cobe Laboratories, Inc.
Finance Committee



Paul Creager
Warner-Lambert Company
Hospital Products Division
Executive Committee



Robert A. Elliott
Shiley Inc.
Finance Committee



Henry E. Fish
American Sterilizer Company
Executive Committee



W. J. Howe
Becton Dickinson and Company
Executive Committee



Lewis W. Lehr
3M Company



Charles V. Owens, Jr.
Miles Laboratories, Inc.



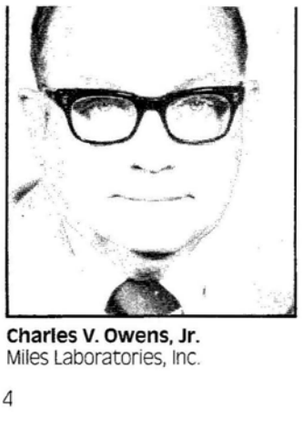
John E. Robson
G. D. Searle & Company



Richard N. Sarns
Sarns Inc.



Robert A. Schoellhorn
Abbott Laboratories
Executive Committee



Charles V. Owens, Jr.
Miles Laboratories, Inc.



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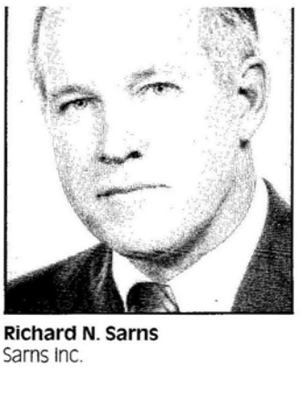
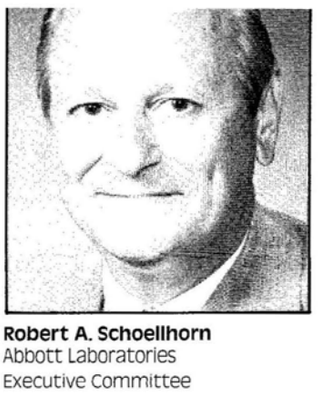


Richard N. Sarns
Sarns Inc.



Robert A. Schoellhorn
Abbott Laboratories
Executive Committee

HIMA Board of Directors and Officers

The Board of Directors, representing a cross-section of HIMA's diverse membership, is the Association's major policy-making body. In 1978, the Board was chaired by John C. Baum (W.A. Baum Company, Inc.). Kenneth A. Marshall (Sherwood Medical) served as Chairman-Elect.

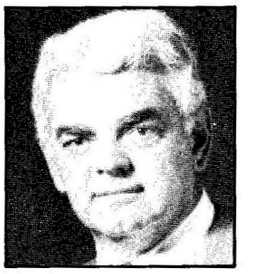
The 1978 Board included 29 Official Representatives in addition to the HIMA President. Directors, who serve three-year terms, are selected by members at the Association's annual business meeting.

The Executive Committee exercises the Board's authority between Board meetings and is composed of seven directors at-large, elected officers, the President, and the immediate-past Chairman. As HIMA Chairman, John Baum chaired the 1978 Executive Committee.

The Finance Committee, chaired by the Association's Treasurer Daniel Mayworm (Tower Products, Inc.), advises the President and the Board of Directors on the Association's budget and financial planning. The HIMA Chairman, President, and three additional Directors serve on the committee with the Treasurer.



John C. Baum, Chairman
W. A. Baum Company, Inc.
Executive Committee
Finance Committee



Kenneth A. Marshall, Chairman-Elect
Sherwood Medical
Executive Committee



Daniel E. Mayworm, Treasurer
Tower Products, Inc.
Executive Committee
Finance Committee



Harold O. Buzzell, President
HIMA
Executive Committee
Finance Committee



Michael F. Cole, Secretary*
HIMA



Betty J. Seward, Assistant Treasurer*
HIMA



Daniel E. Mayworm, Treasurer
Tower Products, Inc.
Executive Committee
Finance Committee



Harold O. Buzzell, President
HIMA
Executive Committee
Finance Committee



Michael F. Cole, Secretary*
HIMA



Betty J. Seward, Assistant Treasurer*
HIMA





Message from the Chairman and President

In many ways, 1978 was a year of significant events and expanded activities for HIMA; we experienced substantial growth in membership, interacted with regulatory agencies on many fronts, expanded our programs to facilitate early involvement in developing issues, and enjoyed an extraordinary degree of support from our members.

Formed four years ago in anticipation of the 1976 Medical Device Amendments, the Association was understandably preoccupied with this legislation. Our initial years were spent commenting and reacting to proposed regulations, meeting with FDA officials, and generally interpreting regulatory actions. We took a cooperative attitude toward FDA when cooperation was desirable and productive, and stood firm when our differences with the Agency were significant. HIMA's constructive working relationship with the Agency assured industry a role in implementing the Device Amendments.

Substantial involvement with FDA's implementation of that law continued in 1978. However, in response to a rapidly changing regulatory and legislative environment, HIMA significantly broadened both its range and type of activity. By addressing new areas of concern and becoming active before new legislation or regulations were proposed, the Association articulated the concerns of manufacturers and helped shape the opinions of government decision-makers.

In a broad sense, all HIMA activities can be defined as representation and education. These have not changed since the Association's inception; they remain our basic goals. What is changing is the depth and breadth of the services members need and request. More and more, industry realizes the need for representation that influences developing issues as well as reacts to proposed regulations. More and more, the need is recognized for detailed member education in a greater variety of subjects. It is within the context of these broad goals that this Annual Report provides an account of 1978 accomplishments—most extensively in the special feature on page 14. Several actions of particular note are listed below. In 1978 HIMA:

(1) Assumed the industry lead in responding to government regulatory initiatives to ban or restrict the use of ethylene oxide for medical device sterilization.
(2) Commented extensively on other proposed FDA regulations and testified before the GMP Advisory Committee on the economic impact of GMP regulations, and before Agencies concerned with environmental and workplace safety regulations.
(3) Established an active Congressional monitoring program and testified before Congressional Committees on health planning legislation.
(4) Established Medmarc, Ltd., a captive insurance company to help HIMA members obtain stable product liability insurance coverage at a reasonable cost.
(5) Helped prevent passage of hospital cost containment legislation by participating in the Voluntary Effort with the American Medical Association, American Hospital Association, Federation of American Hospitals, and Blue Cross/Blue Shield.
(6) Continued to provide a number of financial services to members through periodic Credit Experience Exchange Reports, a program paid for only by those members using the service.
(7) Gave special attention to the needs of small companies through work on product liability insurance problems, and by coordinating closely with the Bureau of Medical Devices and other government agencies concerning the economic impact of regulatory controls.
(8) Significantly expanded HIMA educational services by publishing more than 15 HIMA reports, and sponsoring over 30 educational seminars, regional GMP workshops, and dealer training seminars.

It became clear in 1978 that government influence, true to earlier predictions, is no longer limited to direct product regulation; it now extends to indirect economic or marketplace regulation and environmental issues. Entering 1979, we face a dynamic regulatory and legislative environment characterized by four distinct areas:

(1) *Product Safety*—The 1976 Medical Device Amendments have been, and will continue to be, our primary focus. The Consumer Product Safety Commission may require attention in product areas where devices are also direct consumer items. This area continues to be HIMA's major mission in 1979, and requires significant work. We must assure that the industry has appropriate influence with government agencies to produce workable regulations and fair implementation. Furthermore, the membership must be provided with educational opportunities to help them interpret and comply with regulations.
(2) *Environmental*—Numerous workplace issues exist such as those related to ethylene oxide, chlorofluorocarbons and carcinogenic chemicals, which are primarily generated by the Occupational Safety and Health Administration and the Environmental Protection Agency. It is clear that these and other similar issues will be with us in 1979, and will require our attention.
(3) *Economic*—At present restricted to Medicare/Medicaid issues, for example, renal dialysis, CT scanner and durable medical product reimbursement, this area of concern will grow as HEW expands its activities in this area. The government will probably attempt to achieve hospital cost containment goals even without legislation.
(4) *Utilization*—Existing health planning and technology assessment legislation will be the basis for further regulation of our industry. Directly affected products are: (a) major capital equipment such as CT scanners and sterilizers; (b) high technology items such as cardiac monitors and dialysis equipment and supplies; and (c) products that are dependent on hospital construction or modernization such as beds and installed equipment.

These concerns demand attention and compel us to expand activities beyond traditional preoccupation with direct product regulatory issues. As HIMA begins its fifth active year in this evolving climate, we look back at the accomplishments of that short period with satisfaction. We look forward with some apprehension, but much confidence, to the issues and problems still facing us. We approach this challenge with an experienced and vigorous Association of nearly 300 corporate members. Moreover, HIMA's own growth continues, providing the necessary financial and personnel resources to address expanding regulatory and legislative intervention in the health care industry.

To echo last year's message, we remain optimistic about the industry, and the Association's ability to serve you. Preserving and improving the vitality of our industry is our constant watchword and we seek your continued support and involvement toward these ends.

John C. Baum
Chairman

Harold O. Buzzell
President



John C. Baum, W. A. Baum Company, Inc. and Harold O. Buzzell, HIMA's Chairman and President, respectively.

through periodic Credit Experience Exchange Reports, a program paid for only by those members using the service.
(7) Gave special attention to the needs of small companies through work on product liability insurance problems, and by coordinating closely with the Bureau of Medical Devices and other government agencies concerning the economic impact of regulatory controls.
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John C. Baum, W. A. Baum Company, Inc. and Harold O. Buzzell, HIMA's Chairman and President, respectively.

2

HIMA is

The Health Industry Manufacturers Association is a trade association serving domestic manufacturers of diagnostic products and medical devices. The industry's dominant characteristic is the critical role it plays in contributing to health care in this country. The Association's membership is characterized by a wide variety of products and companies. Over 75 percent of the Association's 270 members have device and diagnostic sales of less than $10 million, and the industry's products run the gamut from relatively simple to exceedingly complex.

The illustrations that appear on the front cover and throughout this report allude to activities and concepts which comprise the daily work of the Association.

Contents

2 Message from the Chairman and the President
3 HIMA Board of Directors/Officers/Executive and Finance Committees
Committees
6 Annual Meeting
6 Conventions and Exhibits
6 Credit
7 Membership
7 Nominating
7 Sales and Educational Training
Special Committees
8 Cost Containment
8 Environmental Issues
8 Long-Range Planning
Sections
9 Legal and Regulatory
10 Manufacturing, Engineering and Quality Assurance
11 Medical and Scientific
12 Public and Professional Relations
13 Standards
14 Issues Report: 1978
18 Educational Services
20 Publication Services
21 Membership
25 HIMA Staff 1978

7 Nominating
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14 Issues Report: 1978
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21 Membership
25 HIMA Staff 1978

PROGRESS REPORT ON A STUDY OF PUBLIC JUDGMENTS REGARDING ETHICAL ISSUES IN BIOMEDICAL RESEARCH

Glen D. Mellinger, Mitchell B. Balter*,
Carol L. Huffine, and Dean I. Manheimer

PS 7819
August 1978

Adapted from a paper presented at the Meetings of
The New Clinical Drug Unit Evaluation Program
Key Biscayne, Florida
May 21, 1977

*Dr. Balter is with the Psychopharmacology Research Branch, NIMH, Rockville, MD. The other authors are with the Institute for Research in Social Behavior, Berkeley, CA. This research is jointly funded by the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, under grant number MH27337.

CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Department of Pharmacology & Toxicology
University of Rochester Medical Center
Rochester, New York 14642
Phone: (716) 275-3832

CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Department of Pharmacology & Toxicology
University of Rochester Medical Center
Rochester, New York 14642
Phone: (716) 275-3832

PROGRESS REPORT ON A STUDY OF PUBLIC JUDGMENTS REGARDING ETHICAL ISSUES IN BIOMEDICAL RESEARCH

Rationale Underlying the Research

In the studies we are going to describe, our immediate goal is to develop household interview procedures for obtaining reasonably informed public judgments about ethical issues in biomedical research. These studies are being conducted with cross-section samples of the general population.

The project grew out of two convictions: first, that the general public is one of many parties that have an important stake in current efforts to revise ethical standards and regulations in biomedical research; and second, that the public can and should be consulted as one important resource in this process.

As we all know, some groups are urging increasingly stringent safeguards to protect human subjects. Others fear that these safeguards could stifle therapeutic progress. Proponents of both views sincerely believe that they are acting in the public interest. It is obvious, moreover, that regulatory decisions made on behalf of the public will have profound effects on the benefits the public will or will not gain from medical research, on the risks to which subjects drawn from the general public will be subjected and, ultimately, on the extent to which the tax-paying public will view the scientific enterprise favorably or unfavorably.

risks to which subjects drawn from the general public will be subjected and, ultimately, on the extent to which the tax-paying public will view the scientific enterprise favorably or unfavorably.

Until now, public sentiments and pressures have been channelled almost exclusively through special interest groups or individual spokesmen whose views do not necessarily represent the whole range of public values, beliefs and judgments. Our hope is that the kinds of data we are obtaining will help to clarify the issues under debate and will lend balance and a broader social perspective to the process of evolving ethical standards in research.

We want to emphasize that our surveys are not intended as plebiscites. Nor are we asking the person on the street to make technical and scientific judgments regarding the potential risks and benefits of particular research procedures. Rather, we are presenting our respondents with a broad range of hypothetical (but reality-based) risk/benefit dilemmas that arise in research and we are asking them to judge the ethical acceptability of various courses of action.

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presenting our respondents with a broad range of hypothetical (but reality-based) risk/benefit dilemmas that arise in research and we are asking them to judge the ethical acceptability of various courses of action.

One of the most important things we hope to gain is some understanding of the factors that influence how people make these ethical judgments. Another is to establish the feasibility limits of consulting the public on such complex issues. To the extent that we find some segments of the population either uninter-

Our studies also have obvious implications regarding the feasibility limits of comprehension in the realm of the patient package inserts issues.

Issues

In its present form, our interview schedule addresses six distinct types of issues.

First, there is the basic risk/benefit issue, i.e., what levels of risk or cost can one justifiably impose on human subjects in order to achieve specified levels of benefit for the subject himself, for society, or for both.

The second type of issue arises in connection with design of the research -- e.g., research that requires either withholding or withdrawing from patients a standard effective treatment, or maintaining a patient on a treatment that is not effective.

The third issue is informed consent: under what conditions must it be obtained? How complete and detailed must the information be? To what extent does insistence upon informed consent vary with the level of risk involved?

Fourth, there is the issue of confidentiality, i.e., the need to maintain the anonymity of human subjects. This issue often involves the use of previously collected data.

The fifth issue arises when the characteristics or special circumstances of the subjects themselves limit their freedom or

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The fifth issue arises when the characteristics or special circumstances of the subjects themselves limit their freedom or

capacity to give fully informed consent -- as with children, the elderly, the mentally infirm, and prisoners.

The sixth issue has to do with institutional safeguards, or "trade-offs", including review and regulatory processes. These safeguards may provide protection for human subjects, but may also impede or prevent worthwhile research. The question here is: how much medical progress is one willing to sacrifice in order to protect human subjects? How much flexibility is desirable?

Research Method and Strategy

The interviewing strategy we are using to address these issues is specifically designed to elicit informed rather than naive judgments. Achieving this goal requires a step-by-step educational sequence of questioning that may be briefly summarized as follows. After some introductory questions pertaining to health care, we tell the respondent that we will be talking about testing medicines, drugs and other kinds of treatments "to make sure they're safe and really work". We note that all drugs in-

issues is specifically designed to elicit informed rather than naive judgments. Achieving this goal requires a step-by-step educational sequence of questioning that may be briefly summarized as follows. After some introductory questions pertaining to health care, we tell the respondent that we will be talking about testing medicines, drugs and other kinds of treatments "to make sure they're safe and really work". We note that all drugs in-volve some risk and some benefit, and we cite aspirin and its more common side effects as an example. The interviewer then

numbers of people first...Even doctors and other experts sometimes find it hard to decide what to do in some situations, but someone has to decide and for the purpose of this interview let's say that the decision is up to you."

The interviewer then goes on to present a series of experimental situations in the form of brief vignettes.* Each vignette names a disease, describes its major symptoms in simple terms, and usually gives some indication of its prevalence. We then describe an experimental procedure (often a new drug) and indicate the risks it entails for subjects in the research. The respondent is asked whether he or she thinks it is OK or not OK to do that research. In one series of questions we ask whether or not informed consent should be required. The following sample vignette was presented to respondents after a brief explanation (accompanied by a visual aid) of the use of placebos in research.

"An example of the use of placebos is this research on rheumatoid arthritis. This is a condition that does not kill people but it can be very painful, can cripple people and may get worse as time goes by. There's no cure for it but there's a new drug that researchers believe will relieve arthritis pain, and keep the disease from getting worse. In order to test the drug, the researchers need to compare it over a long period of time with a placebo. They would give the new drug to one group of arthritis patients, and a placebo to another group. The test would last one year. If the new drug

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- 5 -

is as good as the researchers think, most of the people taking it would no longer be in pain and their arthritis would not get worse. Most of the people taking the placebo would continue to have pain and their arthritis would steadily get worse. The patients would be told that they are in a study involving placebos, but they would not be told which they are getting -- placebo or new drug. In this study then, the possible benefits of the new drug would be withheld from half the subjects for one year. But if the study is successful, a more effective drug would be available for all arthritis sufferers.

*Do you think it is OK or not OK to do this study?"**

An important virtue of the vignettes is that respondents find them inherently interesting. In addition, this mode of questioning is specifically suited to our objectives for two reasons. First, it makes it possible to systematically vary level of risk, level of benefit, and other dimensions of interest. Second, the vignette mode lends itself to an educational sequence of questioning in which respondents are presented first with relatively simple issues and then, step by step, with more complex issues that build upon the definitions and concepts established in earlier questions. Thus the sequence of questioning begins with relatively simple issues involving risk/

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benefit ratios, and then proceeds with more complex issues and concepts involving research design (e.g., control groups, the

use of placebos in drug research, and "wash-out" designs), with issues of informed consent, confidentiality, the use of special subgroups in research (children, prisoners, etc.), and finally, institutional safeguards and regulations.

Several aspects of our research strategy are worth noting. Obviously, the major methodological problem we face is to develop an interview schedule that will elicit meaningful judgments from as broad a segment of the general population as possible. For this reason we have done even more pretesting of our questions than we usually do, and much of the pretesting has been concentrated among persons with relatively little education. Each vignette goes through many revisions until we are reasonably confident that it can be understood by most respondents. At this point we also submit the vignettes to our medical colleagues and consultants to be sure they are credible from a medical viewpoint.

Early in pretesting we began using a visual aid to help the interviewer explain the use of placebos and control groups. Although we have not yet perfected that device, we have found that it does help some respondents understand these concepts. More recently we have also found that another visual aid, early in the interview, seems to help overcome the difficulty that some of our less sophisticated respondents have in understanding the concepts of risk and benefits.

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- 7 -

Findings to Date

Thus far we have completed three pilot studies, in addition to extensive pretesting. One pilot study was conducted with 104 persons in a suburban area near Berkeley. Most of these persons had at least some college education, and the major purpose of the study was to evaluate our questioning procedures under optimal conditions. The second pilot study was conducted with 159 residents of a socioeconomically marginal area in Oakland. The main objective of this study was to evaluate our ability to convey these ethical issues in a way that could be comprehended by persons with relatively little education.*

We should emphasize that these samples were small and were not probability based, although we did select respondents systematically to represent a broad range of socioeconomic characteristics. In any case, the findings have to be regarded as preliminary and tentative.

1. Even though it is quite clear from the first two pilot studies that most persons have not given a lot of thought to these ethical issues in research, most re-

not probability based, although we did select respondents systematically to represent a broad range of socioeconomic characteristics. In any case, the findings have to be regarded as preliminary and tentative.

1. Even though it is quite clear from the first two pilot studies that most persons have not given a lot of thought to these ethical issues in research, most respondents find the interview interesting and recognize the

issues being discussed as important.

2. Respondents in both pilot studies were more willing than we expected to approve the research situations described in the vignettes, even when the risks to normal adult subjects were quite high. In no case did the percentage of persons rejecting a study exceed 40 percent. We should add, however, that all of the vignettes we wrote for these first two studies described situations in which the benefits to be gained from the research were substantial and more or less commensurate with the risk. We have developed a new series of vignettes, a few of which are designed to test the limits of majority acceptance by describing situations in which the risk is high relative to the probability and degree of the potential benefit.
3. As one might expect, our survey respondents were more "protective" (i.e., more inclined to say the research should not be done) when the subjects were children or mentally retarded persons. Even here the majority of persons were willing to condone such research, provided that the vignette offered some rationale for conducting the research with subjects of this type. (In other words, the research had to be relevant to the disease or clinical state of the subjects.) The one instance

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in which we did not offer a specific rationale to using a particular subject population was overwhelmingly rejected when the subjects were children or mentally retarded. However most respondents accepted doing the same research with various types of adult non-retarded subjects. This is just one of many instances in which our lay respondents seemed to be both willing and able to make reasonable and discriminating judgments regarding the situations presented to them.

4. It is interesting that protectiveness with respect to using children in research did not extend to two other special population groups, namely, prisoners and persons on welfare.

5. In this connection, one of the most striking results was the very high degree of protectiveness we found among nonwhite respondents, most of whom were black residents in Oakland. Nonwhites were much more likely than whites to judge particular research situations as unacceptable, and they were much more likely to favor institutional safeguards (including legislation and governmental regulations) for protecting human subjects. Among the nonwhites, women, younger persons,

very high degree of protectiveness we found among nonwhite respondents, most of whom were black residents in Oakland. Nonwhites were much more likely than whites to judge particular research situations as unacceptable, and they were much more likely to favor institutional safeguards (including legislation and governmental regulations) for protecting human subjects. Among the nonwhites, women, younger persons, and better educated persons were more likely than others to adopt a protectionist stance on these issues. It may be no

especially following disclosure of the Tuskegee experiments.

6. The willingness of our survey respondents to approve conducting research contrasts sharply with their protectiveness when it comes to informed consent. Consistently large majorities insisted that informed consent should be required in medical research, even when the vignette specified that this requirement would make it difficult to conduct research with high potential benefit. There were only two situations in which the majority of persons were willing to forego informed consent. One involved the collection of data anonymously from computer records. The other specified three conditions: the benefit was quite high, the risk and cost to subjects (a urine test) was essentially nil, and we specified that it would be impossible (not just difficult) to conduct the research if informed consent were required. Only under such conditions as these do we find the majority of persons willing to forego informed consent. Thus many persons appear to rely heavily on informed consent as the primary means of protecting human subjects; many seemed reluctant to accept the possibility that fully informed consent may sometimes be difficult to achieve. Some respondents explicitly verbalized the opinion that it is permissible to do anything to a human subject so long as he agrees.
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underlying the ethical judgments made by our respondents. We elicited this information by asking respondents to explain their judgments regarding selected vignettes. In many cases, judgments focussed specifically on the level of risk to subjects. Reactions based on level of benefit or on the ratio of risk to benefit were less frequent. The most frequently occurring value orientation associated with approval of research was one that expressed a high regard for science and the importance of medical progress. Less frequently, respondents referred either positively to their faith in the ethical behavior of physicians and scientists, or negatively to doubts about physicians, scientists or the use of drugs in medicine. Not infrequently respondents mentioned some personal experiences or concern with the medical disorder described in the vignettes. Still another value underlying judgments favorable to research was altruism -- the belief that human subjects can make a valuable contribution to society by taking part in research.

Following are some actual responses illustrating these points. One vignette described a hypothetical test of a new drug for con-

medicine. Not infrequently respondents mentioned some personal experiences or concern with the medical disorder described in the vignettes. Still another value underlying judgments favorable to research was altruism -- the belief that human subjects can make a valuable contribution to society by taking part in research.

Following are some actual responses illustrating these points.

One vignette described a hypothetical test of a new drug for controlling hypertension. The new drug, it was postulated, will

drug for two weeks in order "to be sure that their high blood pressure is not temporary". One respondent (a 26-year-old female college graduate) said it would be proper to do this research,

> *"because there are so many people with high blood pressure. My mother sometimes gets really depressed and she has high blood pressure. If they can do a study on people to find a drug with fewer side effects, then they should do it -- especially since these few people could help so many others."*

A 46-year-old male with some college education approved the research because,

> *"(the subject) wants to get well and if they haven't got the medicine to cure him, then it's to his advantage. They don't know, so (the doctors) are going to have to search. That's what research is -- searching -- trying to find out better things."*

A 52-year-old-female high school graduate explained her answer in the following way:

> *"Well, because, getting back to these drugs that have had bad side effects...because I had one (for arthritis) that did it to me and I know what it's like. If this experiment is done under the careful, watchful eye of a doctor, and if it's not for a long time without medicine, I think it's worth taking the risks."*

The Problem of Respondent Comprehension

A major objective of these studies is to test the feasibility of obtaining informed public judgments about ethical issues in biomedical research. Respondent interest and comprehension have been major issues throughout the instrument development and pretesting phases. From the outset we alerted our interviewers

ity of obtaining informed public judgments about ethical issues in biomedical research. Respondent interest and comprehension have been major issues throughout the instrument development and pretesting phases. From the outset we alerted our interviewers

- 13 -

to be on the lookout for any evidence of misunderstanding in spontaneous comments by respondents or in answers to open-ended questions. We made a special effort to include among our pretest respondents a substantial number of older persons with relatively little education.

We assess comprehension in various ways, each of which has inherent virtues and limitations: 1) We instruct interviewers to indicate, after the interview is completed, whether the respondent seemed to understand the questions and answer readily or whether s/he seemed to have trouble answering and understanding. 2) We code and analyze spontaneous comments and responses to open-ended (free answer) questions that suggest a comprehension problem. 3) We construct indices which count the number of times respondents replied "don't know" to the questions posed. 4) We use the Guttman Scaling procedure to count the number of times a respondent's sequence of answers to two or more questions ran counter to the prevailing trend of answers and to the "ethical logic" of the questions. A "reversal" of this kind would be illustrated by a pair of answers in which the respondent was more protective regarding a vignette situation involving little risk than in one involving a higher degree of risk -- holding benefit constant. Re-

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vignettes. Included in each set is one rationale that is either illogical or inconsistent with the premises of the vignettes. A respondent's willingness to endorse these false rationales provides a direct test of comprehension.

Results of our early pilots lead to the following conclusions:

1. Almost all respondents (regardless of educational level) are very interested in the subject matter and issues presented and are willing to participate in the study, even though the interviews frequently exceed one hour in length.
2. Most respondents who have at least a high school education appear to comprehend the questions and to provide meaningful answers.
3. Among respondents with less than a high school education (especially those who are older) we find evidence of difficulty in comprehending some of the issues and dilemmas. However, relatively few persons display consistent comprehension problems across many or all of the vignettes.
4. Persons with relatively little education appear to have difficulty primarily with some of the more complex and abstract vignettes. And, among these persons, our preliminary evidence suggests that the visual materials are quite effective as aids to comprehension. There are some respondents, of course, for whom these ethical issues appear to be totally beyond comprehension, but such persons can be readily identified in our

suggests that the visual materials are quite effective as aids to comprehension. There are some respondents, of course, for whom these ethical issues appear to be totally beyond comprehension, but such persons can be readily identified in our

analyses.

5. It is encouraging that willingness to approve research varies systematically (as it should) with level of risk and level of benefit. Equally important, the majority of persons are able to make meaningful and consistent discriminations among the vignettes. We find this to be the case even among persons with less than a high school education, provided that we use visual aids in the interview.
6. Although responses to the open-ended questions are generally logical and rational, we occasionally find responses suggesting that the judgments people make regarding the ethical dilemmas are based on considerations and values that might not be anticipated.

This last point is illustrated by responses to a vignette similar to the one described earlier. This research project would test the effectiveness of another new drug that is expected to be more effective than existing drugs in relieving the pain of arthritis. Subjects in the research would be subject to some risk of incurring gastric ulcers. One respondent said he would not

not be anticipated.

This last point is illustrated by responses to a vignette similar to the one described earlier. This research project would test the effectiveness of another new drug that is expected to be more effective than existing drugs in relieving the pain of arthritis. Subjects in the research would be subject to some risk of incurring gastric ulcers. One respondent said he would not condone the research, not because he was concerned about the risk to subjects, but rather because he himself has arthritis and does

did not approve of offering prisoners reduced sentences in return for participating in research. His answer was based, however, not, on the view that such inducements constitute undue pressure, but rather on his fear of releasing "dangerous criminals" into society.

These examples are instructive in two respects. First, they demonstrate that it is sometimes difficult to distinguish lack of comprehension from idiosyncratic value orientations in assessing free-answer responses. Thus it is necessary to seek various ways of assessing the level of comprehension. Second, the examples cited above illustrate the diversity of values that the general public may bring to bear in judging the benefits and risks of biomedical research. In this respect they lend broader perspective to the policy issues currently under debate -- perspectives that should not be discounted readily even though they do not always coincide with our own. The examples cited above also demonstrate the care that must be exercised in formulating questions in this area, and in interpreting the results. Simple polling-type questions would not reveal the diversity of perspectives described above and could lead to very misleading conclusions.

Discussion

We began by observing that the general public has an important stake in the process of evolving a practical research ethic. The public provides the pool from which volunteers for research are drawn; it is the ultimate beneficiary of research; and it

We began by observing that the general public has an important stake in the process of evolving a practical research ethic. The public provides the pool from which volunteers for research are drawn; it is the ultimate beneficiary of research; and it

provides a substantial share of the resources which support biomedical research. On these grounds alone it would seem that the public is entitled to express its views.

We suggest further that it would be a serious mistake to ignore public sentiments in these issues. In any realm of public policy, decisions cannot always correspond exactly with public preferences, informed or otherwise. Such preferences, however, represent important boundary conditions, and policies that consistently violate these conditions ultimately lose their viability and become vulnerable to unreasoned attack.

We also believe that taking account of public preferences in the process of evolving a practical research ethic is in the best interest of all parties concerned. For the research scientist, data derived from cross-section sample surveys can afford protection against overly zealous proposals that are made on behalf of the public, but that go farther than informed public preferences would desire. For the human subject, such data can afford protection (in a way that informed consent cannot) by clearly establishing which research procedures are generally acceptable

interest of all parties concerned. For the research scientist, data derived from cross-section sample surveys can afford protection against overly zealous proposals that are made on behalf of the public, but that go farther than informed public preferences would desire. For the human subject, such data can afford protection (in a way that informed consent cannot) by clearly establishing which research procedures are generally acceptable

under specified conditions, and which are not. For those involved in formulating ethical standards or regulations, the same data

The strategy and methodology of the research we have described provides a way of defining the boundary conditions and the normative structure of ethical values within which viable policies for biomedical research can evolve.

At the same time the results of these studies must be interpreted judiciously. The kinds of judgments we elicit in our studies cannot be particularized to real life research situations; the vignettes we present to respondents are, of necessity, greatly simplified and represent the ethical essence of issues that in reality can be highly technical and complex. Even at this level, there is no doubt that elements of irrationality occasionally find their way into some of the judgments made by our respondents -- as they sometimes do even in the judgments and decisions of scientists. It is also clear that some survey respondents are uninterested in these issues or fail in varying degrees to understand the ethical issues involved. The same is true of the body politic when it comes to complex matters of political and economic policy. The solution, however, lies not in disenfranchising the uninformed and disinterested, but rather in striving for more enlightened participation. It is our hope that the results of the research described here will contribute to that goal by encouraging the public to think about ethical issues in research within a realistic framework of costs, risks and benefit.

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- 19 -