

# **The Medical Technology Leadership Forum's First Two Years and Plans for the Future**

## **The Lansdowne Challenge**

In 1995, a small group of device company CEOs decided to explore the viability of a new organization to focus on challenges facing medical technology. The group contacted former United States Senator David F. Durenberger to help them define the need and structure the response. They agreed on several key points:

- 1] there was an intellectual void of analysis and understanding about the impacts of changing markets and public policy on medical technology innovation; and
- 2] there was a need for the broad medical technology community to share their mutual interests and concerns.

The group was attracted to the Jackson Hole Group model. Led by Dr. Paul EILwood, the Jackson Hole Group consisted of leaders in health care and top academics who gathered periodically to discuss how to effect change in the health care delivery system. The papers produced by the discussions had a profound impact on how policy makers and others thought about the health care system and its potential for change. Like the Jackson Hole Group, medical technology leaders were looking for ways to lead, not just react, to the changing environment.

Having identified the challenges and a model for addressing them, the Inaugural Meeting of the MTLF, sponsored by Medtronic, Inc., the Mayo Clinic Foundation, St. Jude Medical, Inc., and the Cleveland Clinic Foundation, was held in October 1996. The goal of the sponsors was to determine if their enthusiasm for the concept could spread to a distinguished group that had responded to the invitation.

Hosted by William George, Chair and CEO of Medtronic, Inc., and led by Dr. Sam Thier, CEO of Partners Healthcare System, Inc. and former President of the Institute of Medicine, the group identified the dilemmas that face all stakeholders in the medical technology community. The following day, two dialogues explored in greater depth the major changes in the marketplace and the public policy arena. True to the Jackson Hole model, the speakers served as catalysts for discussion rather than lecturers. Finally, the group participated in a Roundtable discussion on how to structure and govern the organization. The MTLF was born.

During the winter of 1996 and spring of 1997, a governing board was recruited, articles of incorporation filed, and paperwork was completed to launch the enterprise. Public Policy Partners, under the direction of David F. Durenberger and his partner Susan Bartlett Foote, a well-known author and analyst of technology issues, agreed to manage the Forum's activities.

The new Board determined that our initial activities would focus on developing critical issues to discuss and building the membership base. We agreed to sponsor two Forums a year. We felt that additional activities would grow out of the Forum discussions.

### **1997 ~ Development of Themes**

In 1997, we held two very successful Forums and began to construct a design for dialogue and debate that met the needs of the group. The theme for 1997 was Evidence of Value -- the challenge of designing scientific standards of evidence required to show value that are appropriate to the fast pace and technologically diverse technology industry. Copies of the Forum programs are attached for new or potential members who have not participated in our forums.

#### Cleveland Clinic Foundation ~ June, 1997

In Cleveland, Ohio, we examined the dynamic medical technology environment and its interaction with managed care. The members engaged in lively dialogue with top leaders in managed care organizations, including Stephen F. Wiggins, Chairman of Oxford Health Plans, Inc., David M. Lawrence, Chair and CEO of Kaiser Foundation Health Plans, Inc., and Dr. Kenneth Kizer, the Under Secretary for Health at the United States Department of Veterans Affairs.

We then engaged in issue identification with the help of leading national analysts. The group agreed to pursue the theme of Evidence of Value in two specific follow-up activities - a look at the industry and its innovations in order to help design a new paradigm of evidence, and a review of the specific concerns relating to coverage of technology in the Medicare program.

#### The Summer Task Force Meetings

In the summer of 1997, MTLF gathered the top national experts in Medicare policy for a task force on Medicare coverage. Under the leadership of Candace L. Littell, an independent consultant, the small group of MTLF members and outside experts identified core issues relating to coverage. Susan Bartlett Foote developed a draft White Paper entitled, *Medicare Coverage: Time for a Public Policy Dialogue*.

Dr. Bryan R. Luce, another well-known consultant, led the Evidence of Value Task Force. Using the model of member and expert interaction, the lively discussion was also reduced to a White Paper draft, entitled: *Evidence of Value: Designing a New Paradigm*.

#### The Johns Hopkins University Forum ~ October 1997

The growing MTLF membership met in October in Baltimore, Maryland, hosted by Johns Hopkins University President William R. Brody, a physician, inventor, and academic who personally embodies the leadership principles that MTLF stands for. Following the Jackson Hole model once again, we engaged in dialogue with a diverse group of former Administrators of the Health Care Financing Administration [HCFA], whose observations about the changing role of Medicare over its thirty year history provided invaluable perspective on the nature of the Medicare program. Our moderator was Dr. Donald A. Young, whose many years at HCFA and the Prospective Payment Assessment Commission [ProPAC] gave him a unique perspective on changes in the Medicare program.

The following day, the members turned to a group discussion of the two White Papers. The process was intense and many editorial changes were suggested and debated.

### **1998 ~ Making a Difference**

At the January 1998 meeting of the Board of Directors, it was decided that the fledgling Forum was ready to launch the fruits of the labors – the two White Papers – and seek greater visibility and impact in the public policy arena. The Board also met with Dr. John M. Eisenberg, the new Administrator of the Agency for Health Care Policy and Research [AHCPR], the government body where most of the evaluative expertise resides. He expressed interest in and enthusiasm for our work.

### **United States Capitol Forum ~ April 1998**

This Forum provided us an opportunity to showcase our work and interact with the policy makers who can benefit from it. Our theme was reform of Medicare coverage and our White Paper was the starting point. We began our D.C. odyssey with a challenging presentation by William A. Cook, Chief Executive Officer of the Cook Group, Inc., and a man whose contributions to medical technology innovation as an inventor/executive are unmatched in the world.

The following morning, we were pleased to have key Administration officials and members of Congress participate, including Nancy-Ann Min DeParle, Administrator of HCFA, Dr. Gail R. Wilensky, former HCFA administrator and current Chair of the Medicare Payment Assessment Commission [MedPAC], and Dr. John M. Eisenberg, AHCPR Administrator, skillfully moderated by United States Senate staff veteran, Sheila Burke, now Executive Dean at the John F. Kennedy School of Government at Harvard University. The group was also enlightened by presentations from Senators Daniel Patrick Moynihan [D/New York] and John Breaux [D/Louisiana], Chair of the Bipartisan Commission on the Future of Medicare. He was joined by his Administrative Chairman William Thomas [R/California], who also serves as Chair of the House of Representative's Ways and Means Health Subcommittee.

This Forum was the first major exploration of the issue of Medicare coverage of technology for many years. MTLF members had an opportunity to interact with these key leaders and decision makers. The discussion was so valuable that MTLF produced an edited transcript for widespread circulation.

### Methods Summit ~ July 1998

In July, MTLF sponsored a Methods Summit to explore the themes raised in the second White Paper, *Evidence of Value: Building a New Paradigm*. Under a contract with Dr. Clifford S. Goodman of The Lewin Group, MTLF assembled sixteen world-class experts from the public and private sector to discuss issues related to evidence of value. The discussion was so engaging that all our panelists, including HCFA official Dr. Grant Bagley and AHCPR Administrator Dr. John M. Eisenberg, participated for six hours. At the University of Minnesota Forum, MTLF members discussed the draft and identified specific areas for future work. The report, *MTLF Summit Meeting: Evidence of Value for Medical Devices*, is available from the MTLF office.

### Measuring MTLF's Impact

Our goal in 1998 has been to make a difference in the marketplace of ideas that impact medical technology. Early on, we knew that the professional demands on our membership meant MTLF itself had to show "evidence of value" as an organization. We had to offer more than just another conference, more than just another organization placing demands on members' time.

MTLF has matured as an organization this year and have begun to make an impact. Our White Papers, which were widely circulated and continue to have value, were the foundation for the Forum and the Summit. Policy makers responded with their time and their attention.

On the issue of Medicare coverage reform, MTLF set the stage for a real reform debate. We believe that our articulation of the issue in the White Paper and the impact of the Forum discussion helped to turn HCFA from its previous position that the issue was not sufficiently important, to a prominent place on their already-crowded agenda.

Thanks to public relations assistance provided by Medtronic, Inc. and St. Jude Medical, Inc., we had good trade press coverage of the United States Capitol Forum. Interest was reflected in a marked increase in calls to the MTLF officers.

MTLF ideas were featured in the background paper -- *Medicare Coverage and Technology Diffusion: Past, Present, and Future* -- produced by The George Washington University's National Health Policy Forum on July 9, 1998. At that meeting Dr. Jeffrey L. Kang, HCFA's Chief Clinical Officer and Director of Clinical Standards and Quality who

attended MTLF's Capitol Forum, revealed HCFA's heretofore unanticipated proposal for reform.

The challenge of designing appropriate changes now falls on those who work directly with Congress and the Administration. However, our paper contributed to the issue and help define the problem for all the stakeholders. Our follow-up work on evidence of value will also contribute to science-based and technology appropriate solutions.

In summary, our activities in the first half of 1998 helped to launch MTLF as an important player in the policy arena.

### *University of Minnesota Forum ~ October 1998*

True leadership means the ability to have a vision of the future and to help lead others down the road to a better world. After considerable discussion, the Board agreed that a crucially important theme for the 1990s and beyond is: The Role of Information in Health Care Decisionmaking. Information is a rich and complex topic, and MTLF can mine many of its veins. We began that task in Minnesota with the role of the media in defining, describing, and communicating new innovations to the public. Participants in the first session include Dr. Arnold S. Relman, Editor-In-Chief Emeritus of *The New England Journal of Medicine*, Tim J. McGuire, Editor of *The Star Tribune* and Joe Palca, Science Correspondent with National Public Radio.

In February, 1997, the Speaker of the House of Representatives asked the House Science Committee to conduct a review of our nation's science policy and develop a long-range science and technology policy. Staff for Representative Vernon J. Ehlers [R/Michigan], a physicist and educator, addressed the Forum about a recently released Congressional study ~ *Unlocking Our Future: Toward a New National Science Policy*.

The second day was devoted to a discussion of new innovations on the horizon and the policy issues that they may raise. Are we ready for new breakthroughs? What hurdles might they encounter as they move through scientific discovery to research, development and production to the bedside? These panels uncovered problems which can be explored and solutions proposed.

### ***1999 MTLF Agenda ~ Expanding MTLF's Reach***

We have an ambitious agenda for 1999. Based on our previous experiences and member impact, we have identified five different activities and products. In putting together our agenda, we have been challenged by the task of balancing the enthusiasm for engagement in issues with the resource constraints of a fledgling organization and our firm commitment to make significant and lasting contributions to technology policy and public understanding of the values of medical technology.

- Forums - Formal conference/dialogue-style meetings focusing on select issues in a two day format.
- Summits - Less formal but structured meetings which include government officials and experts exploring a focused issue in a one day or half day format.
- Task forces - Small, informed dialogue with select experts and MTLF members exploring issues through debate and discussion in half day sessions.
- Reports - Interested members prepare commentary in writing, circulate to the membership for review and publication under MTLF imprimatur.
- MTLF FAX - MTLF staff and officers communicate about key issues and trends in medical technology, update MTLF events and members.

### **Task Force - Evidence of Value: Defining Criteria for Coverage**

January, 1999

Washington, D.C.

White Paper on Criteria, Spring 1999

While there is a growing consensus that evidence-based medicine defines the future, further work is necessary on what the appropriate criteria are to measure value. The task force will discuss the criteria currently used by Medicare and private sector assessment programs, and compare them to recently published Guidelines in the American Journal of Managed Care. This discussion will include consideration of such controversial topics as cost-effectiveness as a coverage criterion, definition of terms, and the hierarchy of evidentiary standards.

### **Report- Comment on House Science Committee Report**

February, 1999

(in progress)

The House of Representatives, Committee on Science issued a Report to Congress on September 24, 1998 entitled "Unlocking Our Future: Toward a New National Science Policy. MTLF staff and interested members are drafting a comment on the Report for circulation to the MTLF membership.

### **Report- Role of NIH in Biomedical Engineering/Medical Technology Basic**

Research

March, 1999

(under consideration)

It is well-documented that the National Institutes of Health spend very few of their resources on basic bioengineering and medical technology research. MTLF is considering drafting a report summarizing the history and scope of the issue and outlining potential solutions to the problem of support.

### **Summit: Evidence of Value - Conditional Coverage of Technologies**

April, 1999

Washington, D.C.

White Paper on Conditional Coverage, Summer, 1999

Research scientists and innovative clinicians have long been concerned about providing access to promising but not completely proven new technologies and procedures. If a technology diffuses too rapidly, we lose the opportunity to learn more about its value in a controlled setting; if we wait until more is known, do we deprive patients of access of life-saving options? While the problem is well-recognized, there appear to be institutional barriers to collaboration on ways to provide “conditional” coverage under prescribed circumstances. This Summit would bring together the key players from government, payers, and innovators to develop consensus on principles for new policy design.

### **MTLF Forum- Information and Informatics in Medical Technology**

May 24-25, 1999

Stanford University

Follow up sessions on information are expected in the fall of 1999 and the year 2000.

We will take advantage of the depth of expertise at Stanford University to explore our theme of information in greater depth. MTLF member Dr. Paul G. Yock, a well-known inventor-physician, and Dr. Ted Shortliffe, CEO of Informatronics, will headline the program. The accuracy and accessibility of information on outcomes will have a direct effect on the consistency and quality of medical care. The information revolution is changing the way health care is delivered and consumed. As we explore this issue, we will identify areas where MTLF’s combination of real world experience and policy expertise can move this issue forward.

### **Summit: Patient/Disease Group Seminar**

Summer, 1999

Washington, D.C.

Many patient groups and disease groups do not fully understand the consequences that barriers to innovation may pose for access to important technologies. MTLF plans to host a seminar on Capitol Hill to provide information and the opportunity to discuss the policy issues, including regulation, lack of NIH research support, FDA hurdles, payment barriers and product liability. This outreach to the patient and disease advocacy community will allow MTLF to build relationships with a wide variety of groups, identify potential new MTLF members, and enhance the understanding of technology issues among important stakeholders.

## **Task Force - Roundtable Discussion on the Role of Media**

Fall, 1999

East Coast (Boston and New York under consideration)

We began our exploration of the role of the media in medical technology policy and public awareness of technological innovations at the University of Minnesota forum. The lively discussion was the tip of the intellectual iceberg. Summaries of the Minnesota dialogue, supplemented by additional materials, will provide background for a follow up discussion with key national science and health media.

### **1999 ~ Growing MTLF**

#### Outreach

Almost all leaders participating in MTLF are also leaders in much larger professional associations and institutions. They can help demonstrate the educational value of MTLF on the public and policy world plus the ability to define tomorrow's issues in ways associations cannot. In 1999, MTLF hopes to reach out to these groups more widely.

We plan to look for opportunities to reach the public on issues of medical technology. We will try our hand at opinion-editorials pieces, articles, and other media outlets. With the sponsorship of Medtronic, Inc. *The Role of Scientists, Physicians, and the Media in Explaining Advances in Medical Technology* session at the University of Minnesota Forum was available for approximately thirty days on the world wide web through a webcast at [www.mpr.org](http://www.mpr.org).

#### Membership

For our first two years, we have sustained our programmatic and organizational activities through membership dues. In 1997, MTLF had seventeen members, representing academic research institutions, consumer health organizations, medical professional societies and technology innovators. We are proud to say that we increased membership to thirty-three in 1998, and we already have 1999 interest from an additional group. A complete list of members for 1998 is attached.

MTLF is seeking leaders, not high volume members. The Board has determined to keep the membership limited to individuals and organizations, who want to actively participate in substantive discussions, and are willing to work together to make a difference. While we do have room to grow, we want to ensure that our mission is maintained. This policy, however, limits the budget by definition.

#### Sponsorship

Therefore, we have begun seeking out other organizations to sponsor specific activities or to underwrite costs, including foundations, law firms, investment banking, consulting, and venture capital firms. These firms are integral to the future of medical technology development. The individual experts can contribute much in ways that are different and important. Conversely, we have much to offer them in the way in which we think about, define, and influence the future, especially in health policy.

The next three years provide a special opportunity for MTLF. We foresee divided government at the national level, turmoil in world financial markets, and debate over budget surplus, Social Security and tax reform. In health care, the prices are going back up, the number of uninsured is rising and the effectiveness of the 1990's price-stabilizer -- managed care -- is in question. Medical technology continues to get editorial heat for cost of care problems. But a Congress, which a couple of years ago sought to eliminate "outcomes" research agencies, like the AHCPH, this year provided research investment dollars for "tell us what works, for whom, and why."

MTLF is poised to be the leadership forum in medical technology. The concept upon which MTLF is based is sound. The membership is diverse, motivated and growing. The need MTLF fills is great, and the ability to contribute is high.

Attachments:

- Cleveland Clinic Foundation Forum Schedule
- The Johns Hopkins University Forum Agenda
- United States Capitol Forum Agenda
- Methods Summit Agenda
- University of Minnesota Agenda