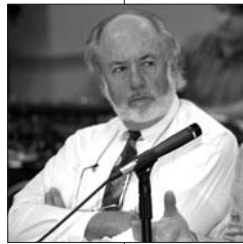

MTLF

2002 Annual Report



MEDICAL  TECHNOLOGY
LEADERSHIP FORUM

GIVING NEW MEANING TO THE FUTURE OF MEDICAL TECHNOLOGY

MESSAGE FROM THE PRESIDENT

MTLF was conceived at a leadership retreat in the Fall of 1996. Based on the Jackson Hole model of dialogue and consensus development, MTLF has convened leaders from the wide spectrum of the medical technology community in order to become more informed about market-based and policy-driven realities, and has undertaken analysis of change.

Each year since our founding in 1996, we have provided our members and the medical technology community with an annual report on leadership in medical technology policy development. MTLF prides itself on its ability to anticipate the needs of policy makers, informing them, and reporting the consequences of our work.

MTLF has identified key themes confronting the medical technology community and has explored these issues in a variety of ways and in a variety of settings. Our Chair, Ken Keller, is an expert in technology policy. He has testified before Congress on the challenges facing innovators on several dimensions. Increasingly innovation is taking place at the interface of previously discrete disciplines – such as information technology, materials science and molecular and cell biology. We have explored how public policies often do not keep pace with innovation in science and technology, creating barriers to the flow of new technologies into the health care system. Some of these barriers have led to the fact that there is a growing gap between medical and scientific discovery and medical practice.

In 2002, our major public policy forum explored the challenging regulatory issues involved in tissue engineering, a field that represents the confluence of many scientific disciplines. Top officials and innovators from the United States and Europe provided each other an opportunity to better understand the potential patient benefits and the policy innovation required to meet those needs.

We hope to pursue this theme in 2003 at Harvard University Medical School in April where we will look at barriers to and

creative responses to multi-disciplinary research in the university / academic research settings. We will also follow up on our study of regulation at the interface of science and technology at the University of Minnesota in July of 2003.



MTLF has also continued its theme of Evidence of Value, which it has looked at since its first meetings in 1997. This year we explored the balance between local and national coverage policy in a conference in Washington, D.C. in June. MTLF has made valuable contributions in this policy area, and has been recognized by CMS (formerly HCFA) leaders for its efforts.

MTLF has kept the pulse of medical technology policy in its now annual Capitol Forums. We took the measure of the new Bush Administration in January of 2002, and will return to D.C. in early 2003. These policy forums provide MTLF with an opportunity to interact with the policy leaders in Washington and to showcase our work through discussion of our reports.

In my six years as President of MTLF, I have been convinced that the MTLF model really works to inform decision makers and the public about the challenges facing medical technology, a key component of the health care system. Informed decision making is the key. This Annual Report explains how we have contributed to a different and better future.

A handwritten signature in black ink that reads "Dan Dooling". The signature is written in a cursive, flowing style.

2002 ACTIVITIES

CAPITOL FORUM – JANUARY

The first meeting of MTLF in 2002 was our Capitol Forum in Washington, D.C. We met on January 23-24, during the week of the President's State of the Union message. We had several goals for the meeting. First, we wanted to take the measure of the health policy leadership in the new Administration and its health policy agenda for 2002. Many of the key Administration health officials participated, including Dr. Mark McClellan, of the President's Council of Economic Advisors, Tom Scully, Administrator of the Centers for Medicare and Medicaid Services (CMS), Dr. Sean Tunis, Director of the Coverage and Analysis Group at CMS and Tom Grissom, Director of Medicare Management Group at CMS.



MARK McCLELLAN, President's Council of Economic Advisors

A second goal was to dialogue with elected legislators and their staff on general health care issues. Members of Congress attended the reception and dinner, including Rep. Mark Kennedy (R-MN) and Rep. Jim McCrery (R-LA). In a roundtable discussion the following day, Rep. Jim McDermott (D-WA), Sherwood Boelert (R-NY) and Mr. McCrery joined the discussion. Several staffers, including Deb Williams of the House Ways and Means Committee staff, and Dr. David Bowen of the U.S. Senate HELP Committee also participated.

Well-known political pundits, Norm Ornstein of the American Enterprise Institute and David Broder, Senior Reporter for the Washington Post, rounded out the political discussion.

A final goal was to showcase MTLF's policy work during 2001 on two specific topics – coverage for clinical information technology (CIT) in Medicare, the topic of our Forum at Duke University, and conflict of interest in the academic-industry inter-

face, the subject of the Stanford University Forum. The Duke and Stanford reports, and our summary of the Capitol Forum discussion, are available on our website and in hard copy at MTLF's offices (see page 8 for order form).

The Capitol Forum was so successful that MTLF plans to host similar events on an annual basis.



NORM ORNSTEIN
American Enterprise Institute

GEORGIA TECH SUMMIT– APRIL

A continuing theme at MTLF has been a focus on the intersection between advances in technology and institutions in the public policy arena. The most promising innovations in medical technology over the next few decades are likely to involve or occur at the intersection of the biological sciences, materials science, and information technology. Since each of these disciplines is rapidly changing, promoting hybrid technologies that involve at least two and often all three of these fields is a challenge for researchers and regulators. Tissue engineering is one of the most important examples of a new field that combines aspects of these merging sciences and was an appropriate starting point for addressing these complexities.

In April of 2002, MTLF convened at the Parker A. Petit Institute for Bioengineering and Bioscience at the Georgia Institute of Technology in Atlanta. Our goal was to examine the interface between tissue engineering and public policy, with a particular emphasis on FDA regulation. Many of our members and guests are innovators in the area of tissue engineering. FDA leaders Dr. Kathryn Zoon, Director of the Center for Biologics Evaluation and Research, Dr. David Feigal, Director of the Center for Devices and Radiological Health, and Mark Kramer, Director of Combination Product Initiatives at FDA participated in the workshop.

In addition, congressional staff and representatives from the European Community (EC) joined the discussion. Our host was MTLF member Dr. Robert Nerem, Director of the Georgia Institute of Technology's Parker H. Petit Institute. Two of the participating companies, Organogenesis and Advanced Tissue Sciences, created some of the first tissue-engineered products approved by FDA.

Given our collective experience in science and public policy over the last three decades, and given the good will and collaborative spirit exhibited by all the participants, MTLF believes that the present scientific and regulatory challenges can be overcome. The Report provides a series of recommendations, which we hope to explore further at the Capitol Forum in 2003 and subsequent MTLF programs. To order copies of the Georgia Tech report, see page 8.

MEDICARE COVERAGE POLICY-JUNE

In June, MTLF held a forum entitled "Medicare Coverage Policy: The Balance Between Local and National Decision-Making." The Society for Thoracic Surgeons hosted the meeting in its Washington, D.C. offices, and Dan Mendelson, formerly of the Office of Management and Budget in the Clinton Administration, served as moderator.

How the health care system evaluates new technologies and procedures for purposes of deciding whether or not to cover them is a critically important decision for patients. While the Medicare coverage processes affect millions of Medicare beneficiaries, little is known about how these decisions are made. The purpose of the meeting was to explore the local and national Medicare coverage processes from a variety of perspectives.

The conference included perspectives of a variety of stakeholders, including patient representatives, physicians, industry representatives. We also heard the views of CMS officials, including Dr. Sean Tunis and Dr. Tom Grissom. Local decisions are made by private contractors. Two Carrier Medical Directors from a contracting organization also shared their opinions.

In the final discussion, congressional staff and health policy analysts provided perspective on options for change.



Rep. MARK KENNEDY (R-MN) and TERRY SHEPHERD, CEO, St. Jude Medical

FDA ROUNDTABLE-SEPTEMBER

On September 10, 2002, MTLF hosted a conference call with Dr. Lester Crawford, the acting commissioner of the FDA. Board members Dave Durenberger and Ken Keller participated in the offices of the Commissioner. Over 28 individuals from MTLF member organizations joined in the call. Dr. Crawford shared

his views on many issues, including risk assessment, risk management, GMPs, gender issues in research, and tissue engineering challenges. As this annual



DAVID FEIGAL, Center for Devices and Radiological Health, LINDA SUYDAM, U.S. Food and Drug Administration, and KATHRYN ZOON, Center for Biologics Evaluation and Research

report goes to press, Dr. Mark McClellan is being confirmed as the FDA Commissioner. It is expected that Dr. Crawford will serve as Deputy Chairman.

2003 PROGRAMS

Capitol Forum January 29 & 30

Modeled on the highly successful 2002 Capitol Forum, this meeting will focus on presentations by top administration officials, and will showcase MTLF's work in 2002. Specifically, the forum will focus on the FDA's response to our tissue engineering combination products report and inform MTLF members on the progress made to date. We will also encourage discussion of Medicare coverage issues, focusing on our most recent forum on balancing local and national approaches to coverage.

The evening reception will include newly elected members of Congress, along with Finance Committee, HELP, Ways and Means, and Commerce members and staff. MTLF's growing reputation as a place where thoughtful and insightful dialogue occurs continues to draw top policy makers to our events.

Harvard/Partners Summit April

Breaking Down the Barriers: Making the New Science Happen

This program will provide MTLF an opportunity to explore the challenges that the emerging interdisciplinary fields of science present for the traditional organization of public and private research institutions. This program continues MTLF's focus on new interdisciplinary developments and the impact of these new areas on institutions and public policy. The Georgia Tech Summit focused on a specific field – tissue engineering – and the barriers created by FDA's regulatory structures. At Harvard/Partners, leading experts from cutting edge institutions will discuss ways to break down the institutional barriers that limit the potential of interdisciplinary research.

University of Minnesota Forum July • Annual Meeting

Breaking Down the Barriers: Can Regulatory Form Follow Scientific Function?

This Forum will focus on the "gold standard" for scientific evidence – the randomized controlled clinical trial (RCT) and potential alternatives. Experts will look at the problems related to RCTs, including ethical and economic issues, and alternative methodologies that would produce acceptable results. The University of Minnesota is known for research on stem cells and the combination of engineered and biological research. FDA leaders, industry scientists, clinical researchers, NIH, technology assessment experts will participate.

NIH Roundtable October

Roundtable discussion with Roderic Pettigrew, MD, director of the National Institute for BioImaging and Bioengineering

The NIBIBE is the newest NIH Institute. Its challenge is to strengthen NIH's commitment to bioengineering research. Many MTLF members have worked for years to rectify NIH's lack of support for bioengineering research. As Dr. Pettigrew undertakes the organization of this Institute, MTLF members will have the opportunity to provide input, hear his views, and discuss the potential of NIBIBE to advance the field. An option would be to combine the roundtable with Dr. Pettigrew into a larger program on restructuring NIH. This would fit well into our "breaking down the barriers" themes and allow for some discussion of the barriers created by public research institutions.

2002 MEMBERS

Distinguished Innovators

Louis Sullivan, MD, former Secretary of HHS
Dr. Thomas Fogarty, Stanford University

Corporate Technology Innovators

3M
Boston Scientific
The Cook Group
Medtronic
Neothermia
Organogenesis
Sapient Capital
Smith & Nephew, Wound Management Division
St. Jude Medical
SurModics

Consumer/Research Organizations

Alliance for Aging Research
Society for Women's Health Research

Research/Academic Organizations

Alton Oschner Medical Foundation
Duke University
Georgia Institute of Technology
Partners Healthcare System
Permanente Federation
Regenstrief Institute
Stanford University
University of Minnesota
Harvard University Medical School

Professional/Trade Associations

AdvaMed
AIMBE
American Academy of Orthopaedic Surgeons
American Association for Thoracic Surgery
American College of Cardiology
California Health Care Institute
International Society for Cardiovascular Surgery/Society for Vascular Surgery
National Electrical Manufacturers Association
Society of Cardiovascular Interventional Radiology
Society of Thoracic Surgeons
Regulatory Affairs Professionals Society

MTLF also wishes to thank: the Parker H. Petit Institute for Bioengineering and Bioscience at Georgia Tech, Smith & Nephew, Edwards Lifesciences, Genzyme, Boston Scientific, and Medtronic for their generous support of MTLF programmatic activities.

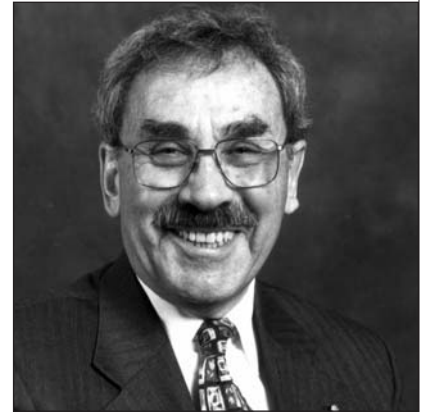
THE CHAIRMAN'S MESSAGE

There are many ways to think about how and why we have seen such extraordinary progress in medical technology over the past half century, but three factors strike me as particularly important: the rapid and simultaneous rate of progress in several different fields of science and engineering; the successful collaborations that promoted multi-disciplinary approaches, bringing the advances in individual fields to bear in understanding the nature of various morbidities and in engineering diagnostic and therapeutic tools to cope with them; and the recognition that progress in coping with problems in complex systems requires that the interaction of the parts be considered at every stage.

New understanding, multi-disciplinary approaches, systems analysis—these have been the keys to technical success. In a sense, the work of the Medical Technology Leadership Forum is an extension of this formula for success to the broader arena in which technical success is turned into better health care and an improvement in people's lives. For in truth, the "system" in which we all work is all of society, with its institutions, its policies, and its values, and each part affects every other part. MTLF considers this whole system, and its programs foster a multi-disciplinary approach, bringing together the stakeholders and the experts to better understand all parts of the system and to find ways to make the parts work together more smoothly.

One of the things we have learned is how important it is for the institutions and policies of government to be fine-tuned to match and mesh with the way technology development takes place, both to protect the public interest and to assure that people understand and benefit from new technologies in a timely way. This means anticipating what issues the new technologies will give rise to—in the minds of the public, in the practice of medicine, in regulatory processes, and in coverage decisions. It means developing strategies for dealing with those issues by bringing together the people who understand each of those parts of the whole puzzle.

In the six exciting years of its existence, MTLF has used this approach to consider coverage questions, evidence of value, the promise and challenge of e-medicine and tele-medicine, conflict-of-interest issues in clinical studies, and newly



emerging areas such as tissue engineering. Its meetings have been times of teaching and learning for its participants. Its reports have received wide circulation and have been influential not because they have been issued with any formal authority, but because they have contained sensible analyses and offered practical strategies.

As we look to the future, we see an increasing emphasis in MTLF on the newly emerging areas of biomedical technology—combination products, nanotechnology, the ever-increasing role of information technology at every level from product design to patient care, genomics and proteomics—each with its own special issues in research, technology transfer, product introduction, clinical use, and public understanding. We also see a much greater emphasis on creating a set of public policies and governmental institutions that enable and support a seamless process of development from research idea to clinical benefit, encouraging creativity, guiding the prudent introduction and appropriate use of new technologies.

The agenda is exciting, the need is great, and we believe the product is important. We are grateful to those many institutions and individuals who have contributed to MTLF's work over these past years and look forward to a continuing and productive collaboration.

A handwritten signature in black ink, appearing to read "Kenneth Keller". The signature is fluid and cursive, with a long horizontal stroke at the end.

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PUBLICATION ORDER FORM

The following publications are available from MTLF offices for distribution. Check all that apply.

- Medicare Coverage: The Balance Between Local and National Decision-making, June 2002
- Defining a Regulatory Process for Combination Products: The Emergence of Tissue Engineering, April 2002
- Capitol Forum, Washington, DC, January 2002
- Stanford University Summit: Risk and Rewards in Medical Technology, Innovation and Conflict of Interest at the Academic/industry Interface, July 2001
- Duke University Summit: Reimbursement for Clinical Information Technologies, July 2001
- Medicare Coverage Criteria II : Task Force Summary, December 2000
- Patient Confidentiality: An Examination of the Issues and Their Impact on the Development and Use of Medical Technology, October 2000
- Indiana University Forum: How Information Technology is Revolutionizing Medical Device Innovation: Implications for Medicine and Public Policy, July 2000
- Enhancing Patient Access to New Medical Technologies: Implications for Public Policy, October 1999
- Stanford University Forum: Priorities and Challenges in Developing Information Technology in the National Health Care System, September 1999
- MTLF Summit: Conditional Coverage of Investigational Technologies, July 1999
- Medicare Coverage Criteria: Task Force Summary, April 1999
- Methods Summit: Evidence of Value for Medical Devices, December 1998
- Evidence of Value: Building a New Paradigm, March 1998
- Medicare Coverage: Time for a Public Policy Dialogue, March 1998

Name _____

Title _____

Organization _____

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The 2001-2002 reports can be downloaded from the Medical Technology Leadership Forum web site at www.mtlf.org.

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