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# MTLF

## Forum Report

4th Annual Capitol Forum

# A New Era in Medical Technology Policy: Medicare Modernization Act Meets the Nation's Fiscal Reality

February 16 & 17, 2005  
Capitol Hill  
Washington, DC



Medical Technology  
Leadership Forum

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# What is the Medical Technology Leadership Forum?

The Medical Technology Leadership Forum encompasses a broad spectrum of the medical technology community, including clinicians, manufacturers, health plans, medical specialty societies and consumer groups. It is a forum for breaking down barriers and enhancing discussions of medical technology issues. Our White Papers and Forum discussions have made a significant contribution to the development of public policy on issues of concern to the medical technology community.

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**Medical Technology  
Leadership Forum**

# A New Era in Medical Technology Policy: Medicare Modernization Act Meets the Nation's Fiscal Reality

The Medical Technology Leadership Forum held its fourth annual Capitol Forum on February 16 and 17, 2005 in Washington, D.C. Each year, MTLF's Capitol Forum takes the measure of the Administration and the Congress, with a focus on the impact of prospective legislative issues on health policy generally and medical technology in particular. MTLF attracts an impressive lineup of national policy experts and Capitol insiders who offer insights on health policy prospects for the upcoming Congressional session.

The 2005 Forum was designed to predict the challenges facing the second President Bush term and the potential impact on medical technology policy. This year's reality included the big election victory for the President, the solid Republican majority, the mandate to implement the Medicare Modernization Act (MMA), deficits of record proportion, and a Congress committed to tax cuts and a war in the Middle East. It is against this backdrop that MTLF members engaged in dialogue with political and policy leaders.

## An Inside View of the Proposed Federal Budget

At the time of the Forum, the President had just sent his proposed budget to Congress. Our budget experts included Honorable Don Young, Assistant Deputy Secretary, Office

of Health Policy, U.S. Department of Health and Human Services, who presented an overview of the President's proposed \$642 billion budget for Health and Human Services. Because the largest single item in that budget is Medicare at \$394 billion, followed by Medicaid at \$193 billion (which is only the federal share), and with estimates of the cost of the new drug benefit at \$59 billion, it's clear that cuts in health care spending at the federal level are likely.

Dr. Young explained other presidential priorities including expanding private health coverage through tax incentives, grants to states to develop purchasing pools, expanding community health centers, and support for electronic medical records and research on quality.

The longer term budget issues, and the relationship of health care spending to those larger budget questions, were addressed by two long-time budget experts in the Congress. Bill Hoagland, Policy Advisor, Office of the Senate Majority Leader, noted that there is pain in this year's budget. But, the real problem is what lies beyond the current budget cycles.

Honorable Don Young: "The President's 2006 Health and Human Services budget proposal would spend \$642 billion. That's 42.8 billion for every minute of my speech."



While he expressed concern that Social Security is expected to go broke in 2040 to 2050, the Social Security problem is small compared to the coming crisis of Medicare and Medicaid. If we can't find a solution in Social Security, how will we ever solve the crisis in Medicare and Medicaid?

Bill Dauster, Democratic Deputy Staff Director and General Counsel, Senate Finance Committee, expressed intense concern about the federal budget situation. He asked how cuts could be made in programs for the elderly and disabled. He expressed dismay about the fact that Congress is not seriously working on these issues. As he put it, "Don't just do something, stand there!" seems to be Congress' battle cry.

During the question period, both Hoagland and Dauster agreed we need a bipartisan solution. Sooner or later, a summit of the leaders will be needed to find enough common

ground to fashion a solution. "It's math, not politics," said Hoagland. In terms of predictions, Hoagland believes that Social Security reform efforts will prevent committees from focusing on anything else. He also believes that Congress will probably do a five-year budget instead of a ten-year because of uncertainty in the longer term. While Dauster noted that the governors seem to be working in a bipartisan way to find solutions, the politics of this issue remain challenging. Both Republican and Democratic perspectives, represented by these two budget experts, reflect the conclusion that the nation faces monumental federal budget deficits due in part to continued rapid growth of Medicare and Medicaid, but that no solutions are in sight.



Bill Dauster: "We're heading toward a train wreck of diminishing social security surpluses and growing Medicare costs."

Bill Hoagland: "We have a problem right here in River City."

## Medicare Modernization Act: The Implementation

The macro budget issues set the stage for a focus on implementation of the Medicare Modernization Act (MMA). Mark McClellan, M.D. PhD., Administrator of the Centers for Medicare and Medicaid Services, provided impassioned support for the MMA. He argued that MMA represents a new direction in Medicare to reward better quality and lower costs. “Existing barriers and incentives reward more services and complications, not better care.”

He also argued that under the MMA, Medicare beneficiaries will have greatly expanded access to reliable health plans through Medicare Advantage. He also noted that Medicare fee-for-service will be taking the same new direction toward creating quality and performance-based incentives. He also stressed that moving Medicare toward quality and efficiency requires evidence. CMS will be leading and supporting efforts to gather better evidence through initiatives and by improving and making more transparent the process used to make Medicare coverage decisions. How Medicare implements these new directives will have a major influence on the medical technology community.

Sean Tunis, M.D., MSc, Chief Medical Officer, Centers for Medicare and Medicaid Services, focused his remarks on initiatives to improve quality and reduce variation in medical practice to improve value and reduce costs. The evidence gaps to affect decisions about quality are systematic and widespread; existing clinical research expertise will not correct the problem. One solution is through Medicare coverage decisions.

However, Tunis reminded us that there are challenges in evidence-based decision making. Most importantly, it is often viewed as interfering with physician/patient relations. Additionally, the current payment system appears to impede innovation — it does not promote promising but unproven high value technologies in order to gain evidence of their effectiveness.

The core strategy for CMS will be to improve evidence for decision making by linking coverage of emerging technologies and treatments to prospective data collection. If there is adequate evidence of benefit and potential value, it should be covered in an appropriately designed study to



Dr. Mark McClellan: “There is no business case for quality.”



Dr. Sean Tunis: To get to evidence-based decision making, “we need decision-based evidence making.”

measure effectiveness. Tunis argued that the benefits of this approach include:

1. It addresses economic barriers to emerging treatments;
2. Payers can promote innovation and access while supporting better value;
3. It creates a strategy to establish a clinical research agenda oriented to decision makers;
4. Demand can be channeled to improve evidence; and
5. The policy discussion will be focused around evidence.

Challenges that will be faced include how to move from the current ad hoc approach to a systematic one, how to set priorities, defining roles and governance, and funding.

Two academicians responded to the Tunis presentation. Peter Neumann, Sc.D., Associate Professor of Policy and Decision Sciences, Department of Health Policy and Management, Harvard School of Public Health, reported on the results of his recent study of national coverage determinations (NCDs) in Medicare. He found that NCDs are consistent with the evidence in most cases, but the quality of the evidence is often poor. When the evidence is poor, Medicare seeks to cover with conditions. The implications are that we need better evidence, a good process for coverage decisions,



Peter Neumann found that national coverage determinations are consistent with the evidence in most cases, but the quality of the evidence is often poor.

and value-based reimbursement. Dr. Neumann also observed that “we need cost-effectiveness analysis, but this is not likely due to political sensitivity.”

Susan B. Foote, J.D., Director, Division of Health Service Research and Policy, University of Minnesota, described her work on local coverage decisions (LCDs) that account for the vast majority of CMS decisions. She noted that the MMA raises implications for local and national decisions because it is moving the program towards a more consolidated regional structure. Her research has shown that local contractors have few resources to do evidence-based technology assessments. She asked that CMS focus on how to integrate the current local decision-making processes into their vision for a regionalized, evidence-based coverage process.

There was lively debate about the direction that CMS plans to take in relationship to coverage and the use of evidence. It is clear that more dialogue among the medical technology community and CMS needs to occur as this area of coverage policy unfolds.



Susan Foote’s research has shown that local contractors have few resources to do evidence-based technology assessments.

## View from the Congress

Four members of Congress addressed MTLF over the course of the Forum: Two Republicans, Congressman Jim Ramstad (R, MN-3rd) Ways and Means Committee, Subcommittee on Health and Senator John Ensign (R-NV), Senate Budget Committee and Senate Health, Education, Labor and Pensions Committee and two Democrats, Congressman Jim Cooper (D, TN-5th) House Budget Committee and Congressman Pete Stark (D, CA-13th), House of Representatives Ways and Means Committee, ranking member of the Subcommittee on Health. These four leaders revealed dramatically different perspectives on the Congress and on priorities for health care policy.

Senator Ensign expressed concern about the growing costs of health care, noting that health care problems dwarf Social Security issues. While he stressed that action was imperative, his three pillars of health reform — (1) medical liability reform; (2) put the patient back into the accountability loop; and (3) coordinated care and best practices — did not involve tinkering with Medicare or Medicaid, the spending

cost drivers. These solutions are consistent with the majority party's priorities. Congressman Ramstad shared the concerns about the deficit and crisis in Medicare, but took a more optimistic tack on the prospects for remedial action. However, he did not provide a roadmap for how this partisan Congress can get there. In regards to medical technology, he noted that many in Congress still view it as a big cost driver; education is necessary to show how technology can save money.

The view from the House Democrats is quite different from their Republican colleagues. Congressman Stark told us that government must save Medicare by using its financial clout to negotiate lower drug prices and mandate standards for system improvements in quality and efficiency. Government must require the data that is needed to know what we are buying. The real issue is the underlying push to privatize Medicare and rely on market forces to control health care costs. According to Stark, "In the health care system, the free market doesn't work."



Congressman Ramstad: "What we really need is a paradigm shift in Medicare that rewards improvement in value."



Senator John Ensign: "There is no way our country can exist if nothing dramatic is done."

Congressman Cooper offered a more pessimistic view about the institution of Congress and its ability to solve policy problems. He believes that Congress has lost its way in a morass of political rhetoric and campaign sound bites. He noted that the institution of government is moving away from the traditions of our country's founders who valued free discourse, checks and balances and compromise. "The real danger is raising a generation of public servants who don't know what a real debate is, what a real vote is."

In relation to health care, Cooper believes that it is off the table because the Republicans exhausted themselves on the MMA and the President has thrown all his chips on the table for Social Security reform. The current situation is dire, yet the leaders seem unwilling to return to a spirit of healthy debate, bipartisanship and compromise to do the right thing for the country. "If we don't move away from politics as usu-

al, we'll have a sad time telling our grandchildren what we did for them."

When asked about ways to change the current situation, Cooper suggested that the private sector needs to get together and do something before Congress does something rash. Cooper would repeal the Medicare drug benefit because it is an unfunded liability. "If you don't pay your bills, don't spend the money."



Congressman Pete Stark: "Higher premiums, higher deficits. That's not the best way to preserve Medicare."



Congressman Jim Cooper: "We've got to solve the Medicare problem or we are going to lose our status as the greatest nation in the history of the world."

## A View from the Streets: The “Real” Crisis

Susan Dentzer, Health Correspondent for PBS’ *The NewsHour*, provided a bit of a reality check by offering her insights as a health reporter. Ms. Dentzer drew upon her years of experience to provide candid comments on the real versus perceived state of the nation in health care. The real crisis is dire, yet the political rhetoric and media coverage too often defaults to a discussion of perceived problems which divert us from the real issues. Her example of a perceived crisis is the cost of medical malpractice insurance. Many politicians tout tort reform as a cornerstone of solutions to the rising cost of health care, when in fact the “problem” to the extent there is one, is isolated in certain areas such as OB-GYN and neurosurgery, and reforms will do little to stem the tide of rising costs.

The “real” crisis is a health care system that has many things wrong with it and we don’t know where it is going. The real issue is the underlying push to privatize Medicare and rely on market forces to control health care costs. Dentzer provided examples: forty million Americans do not have health insurance, health care costs are skyrocketing out of control, and the safety net is at risk, to name a few. And in spite of all the money we spend on health care, we don’t know if what we are buying is effective, safe and high quality. The public is feeling lots of pressure, but the politicians seem unable to do anything to fix the problem.

Susan Dentzer: George Carlin once said, “There’s no problem so big that Americans, if they set their minds to it, will roll up their sleeves and ignore it.”



## Reflections from MTLF President David Durenberger, Former U.S. Senator (R-MN)

The MTLF Forum in Washington, D.C., this February could not have been better timed. This summary of the presentations speaks for itself. However, because of my service as a Medicare Payment Advisory (MedPAC) Commissioner and on three other national health commissions, as well as my experience as a United States Senator, I'd like to add some of my observations about the impact of the present policy environment on the future of health care.

The combination of rising health care costs and patient needs, innovation in technology and the proliferation of what has come to be called "the medical arms race," and the partisan polarization around complex health policy challenges does not bode well for the future solutions. We saw federal budget deficits rising on my watch in the 1980s, but never like the magnitude of today's deficits. Cost drivers like the new Medicare Prescription Drug benefit and the privatization of Medicare through extra payments to Medicare Advantage Plans and deficit-drivers like making tax cuts permanent are serious challenges to the solvency of Medicare and its commitment to providing access to all beneficiaries.

Both public and private payers, as well as consumers and patients, have raised the level of urgency of some way to contain costs to new heights. Em-

ployers are demanding the same value for their medical expenditures as their customers demand from them in their businesses. As we learned at the Capitol Forum, Congress has directed the Medicare program to demand evidence of value and pay for performance. The medical technology community is being asked to rise to the challenge. We believe that the commitment of MTLF to raise the level of understanding of the policy environment and open dialogue between the technology community and the policy makers is essential to meeting the challenges of today and of the future.



Senator David Durenberger: "The partisan polarization around complex health policy challenges does not bode well for future solutions."

# Conference Agenda

## Wednesday, February 16

Washington Court Hotel

5:30-7:00 pm (EST) — Social Hour/Reception

7:00 pm — Dinner

7:45 pm — Welcome

**Dr. Kenneth Keller**, Board Chairman, Medical Technology Leadership Forum, Charles M. Denny, Jr. Professor, Technology & Public Policy, University of Minnesota

Presenter —

**Ms. Susan Dentzer**, Health Correspondent and Head of the Health Policy Unit, The NewsHour with Jim Lehrer on PBS

## Thursday, February 17

G-11 Dirksen Senate Office Building

7:30 - 8:30 am — Continental Breakfast

7:45 - 8:00 am (EST) — MTLF Annual Membership Meeting

**Dr. Kenneth Keller**, Board Chairman, Medical Technology Leadership Forum; Charles M. Denny, Jr. Professor, Technology & Public Policy, University of Minnesota

8:00 - 8:05 am — Welcome

**Hon. David Durenberger**, President, Medical Technology Leadership Forum

8:05 - 9:30 am — Medicare Modernization Act: The Implementation

*Presenter:* **Mark McClellan**, M.D., Ph.D., Administrator, Centers for Medicare & Medicaid Services

*House of Representative Ways and Means Health Subcommittee Respondent:*

**U.S. Congressman Pete Stark** (D, CA-13th), Ways and Means Committee, Ranking Member of the Subcommittee on Health

9:45 - 11:30 am — An Inside View of the Proposed Federal Budget

*Presenter:* **Hon. Don Young**, Assistant Deputy Secretary, Office of Health Policy, United States Department of Health and Human Services

*Reactor Panel:*

**Bill Hoagland**, Policy Adviser, Office of the Senate Majority Leader

**Bill Dauster**, Democratic Deputy Staff Director and General Counsel, Senate Finance Committee

11:30 am - Noon — Health Policy and Health Reform Ten Years After “Clinton Care”

**U.S. Congressman Jim Cooper**, (D, TN-5th) House Budget Committee

Noon - 1:00 pm — Lunch

**U.S. Congressman Jim Ramstad**, (R, MN-3rd) Ways & Means Committee, Subcommittee on Health

1:00 - 1:30 pm — National Medical Liability Reform: Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005

**U.S. Senator John Ensign**, (R-NV), Senate Budget Committee, and Senate Health, Education, Labor and Pensions Committee

1:30 - 3:00 pm — Pricing Value in Medical Device Technology: Coverage by Protocol

*Presenter:* **Sean Tunis**, MD, MSc, Chief Medical Officer - Centers for Medicare & Medicaid Services

*Reactor Panel:*

**Peter Neumann**, Sc.D., Associate Professor of Policy and Decision Sciences, Department of Health Policy and Management, Harvard School of Public Health

**Susan B. Foote**, J.D., Associate Professor and Division Head, Division of Health Services Research & Policy, University of Minnesota School of Public Health

3:00 - 3:45 pm — Summary and Next Steps on Evidence of Value

# Attendees/Program Participants

**Dr. Susan Alpert**

*VP, Chief Quality and Regulatory Officer, Medtronic*

**Ms. Susan Bartlett Foote, JD**

*Associate Professor and Division Head, Division of Health Services Research & Policy, University of Minnesota School of Public Health*

**Ms. Ashli Carpi**

*Washington Counsel, St. Jude Medical, Inc.*

**Mr. Chris Cerone**

*VP, Government Affairs, Zimmer Holdings, Inc.*

**Mr. Blair Childs**

*EVP, Strategic Planning and Implementation, AdvaMed*

**Ms. Alexandra Clyde**

*VP, Health Policy & Payment, Medtronic, Inc.*

**Mr. Steve Cole**

*Director, Public Policy & Gov't Relations, Kaiser Permanente*

**Mr. Thomas Connaughton**

*Vice President, Cook Group Inc.*

**Rep. Jim Cooper (D-TN)**

*House Budget Committee*

**Mr. Mitchell Dann**

*Principal, Sapient Capital*

**Mr. Bill Dauster**

*Democratic Deputy Staff Director and General Counsel, Senate Finance Committee*

**Ms. Susan Dentzer**

*Health Correspondent, The NewsHour with Jim Lehrer on PBS*

**Hon. David Durenberger**

*President, Medical Technology Leadership Forum*

**Sen. John Ensign (R-NV)**

*Senate Budget Committee, Senate H.E.L.P. Committee*

**Dr. Art Erdman**

*Professor, University of Minnesota*

**Dr. Neal Farnot**

*President, Cook/MED Institute*

**Mr. Stephen Ferguson**

*Chairman of the Board, Cook Group, Inc.*

**Ms. Jori Frahler**

*Policy Director, Medical Device Manufacturers Association*

**Dr. Jim Gardner**

*Vice President, Reimbursement, Cook Group, Inc.*

**Mr. Peter Gove**

*Vice President, Corporate Relations, St. Jude Medical, Inc.*

**Ms. Phyllis Greenberger**

*President and CEO, Society for Women's Health Research*

**Dr. Robert Hauser**

*Senior Consulting Cardiologist, Minneapolis Heart Institute*

**Mr. Bill Hoagland**

*Policy Adviser, Office of the Senate Majority Leader*

**Dr. Kenneth H. Keller**

*Denny Professor of Sci., Technol. & Public Policy, University of Minnesota*

**Ms. Carol Kelly**

*EVP, AdvaMed*

**Mr. Pete Lauer, CAE**

*Executive Director, Society of Interventional Radiology*

**Mr. Mark Leahey**

*Executive Director, Medical Device Manufacturers Association*

**Ms. Nancy Loving**

*Executive Director, WomenHeart*

**Mr. Michael Mabry**

*Assistant Executive Director, Society of Interventional Radiology*

**Dr. John Mayer**

*Sr. Associate in Cardiac Surgery, Children's Hospital Boston*

**Dr. Mark McClellan, M.D., PhD.**

*Administrator, Centers for Medicare & Medicaid Services*

**Rep. Jim McCrery (R-LA)**

*House Ways & Means Committee, Subcommittee on Health*

**Dr. Robert Nerem**

*Director, Georgia Institute of Technology*

**Dr. Peter Neumann, Sc.D.**

*Associate Professor of Policy and Decision Sciences, Harvard School of Public Health*

**Ms. Susan Paquette**

*Technology Assessment Director, 3M Health Care*

**Mr. Dan Peterson**

*Vice President Industry & Government Affairs, Cook Group Inc*

**Rep. Jim Ramstad (R-MN)**

*Ways & Means Committee, Subcommittee on Health*

**Mr. Murray Ross**

*Director, Health Policy Analysis and Research, Kaiser Permanente*

**Mr. Michael Scandrett**

*Public Policy Director, Halleland Lewis Nilan & Johnson*

**Dr. Ann Schmierer**

*Georgia Tech, Industry Relations, Georgia Institute of Technology*

**Mr. Tom Scully**

*Senior Counsel, Alston & Bird*

**Ms. Valori Seltz**

*Director, Industry Relations & Communications, 3M*

**Mr. Peter Slone**

*Vice President of Government Affairs, Medtronic, Inc.*

**Rep. Peter Stark (D-CA)**

*House Ways & Means Committee, Ranking Member Subcommittee on Health*

**Dr. Sean Tunis, M.D., M.Sc.**

*Chief Medical Officer, Centers for Medicare & Medicaid Services*

**Ms. Betsey Urschel**

*Consultant, Baylor University Medical Center*

**Dr. Harold Urschel**

*Professor of Cardiovascular & Thoracic Surgery, Baylor University Medical Center*

**Ms. Susan Walker**

*Director, Reimbursement Policy, St. Jude Medical, Inc.*

**Hon. Don Young**

*Assistant Deputy Secretary, Office of Health Policy, U.S. Department of Health and Human Services*

*Note: Presenter names are shown in bold type*

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## Previously Published MTLF Reports

“The Search for Quality and Value in Healthcare: Implications for Medical Technology; Part II: The Future of Healthcare from a Community Perspective” October 2004\*

“Innovative Approaches to the Regulation of Combination Products & New Science: Options for Policymakers” July, 2004\*

“The Search for Quality and Value in Healthcare: Implications for Medical Technology” February, 2004\*

“Facilitating the Continuum from Experimental to Clinical Use: Designing Alternative Models” July, 2003\*

“Breaking Down the Institutional Barriers to Multi-Disciplinary Research” April 28, 2003\*

“MTLF Capitol Forum Report” January, 2003\*

“Medicare Coverage Policy: the Balance Between Local and National Decision Making” June 28, 2002\*

“Defining a Regulatory Process for Combination Products: The Emergence of Tissue Engineering” April 21-22, 2002\*

“MTLF Capitol Forum Report” January, 2002

“Risks and Rewards in Medical Technology: Innovation and Conflict of Interest at the Academic/Industry Interface” July, 2001\*

“Reimbursement for Clinical Information Technologies” July, 2001\*

“Medicare Coverage Criteria II: Task Force Summary” December, 2000

“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

“Priorities and Challenges in Developing Information Technology in the National Healthcare System” September, 1999\*

“Conditional Coverage of Investigational Technologies” July, 1999\*

“Medicare Coverage Criteria: Task Force Summary” April, 1999

“1997-1998, the First Two Years — 1999 and Beyond, Plans for the Future”\*

“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

\* Indicates that the report is available on-line at [www.mtlf.org](http://www.mtlf.org). All other reports are available by contacting the MTLF business office at (651) 962-4637.



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