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# **CAPITOL FORUM REPORT**

**JANUARY 23-24, 2002**



MEDICAL  TECHNOLOGY  
LEADERSHIP FORUM

GIVING NEW MEANING TO THE FUTURE OF MEDICAL TECHNOLOGY

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# **WHAT IS THE MEDICAL TECHNOLOGY LEADERSHIP FORUM?**

The Medical Technology Leadership Forum (MTLF) was founded in 1996 to educate its own members, policy makers, the general public, and the media about issues facing medical technology. MTLF has attracted an elite group of leaders from a wide spectrum of the medical technology community, including innovative bioengineers, physicians, research institutions and universities, manufacturers, and patient organizations. MTLF has held forums at leading institutions, including Duke University, the Johns Hopkins University, Indiana University, and Stanford University. 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.

# REPORT FROM THE CAPITOL FORUM

**T**he Medical Technology Leadership Forum held its Capitol Forum in Washington, D.C. on January 23 and 24, 2002. We set several goals for this meeting. We wanted to take the measure of the health policy leadership in the new Bush Administration and to acquire a clearer understanding of its health policy agenda for 2002. We also were interested in their views specifically related to medical technology policy. Finally, we wanted to dialogue with staff in the legislative and executive branch on two issues of specific interest to MTLF — coverage for clinical information technology (CIT) in Medicare, the topic of the Duke University Forum in Feb. 2001, and conflict of interest in the academic-industry interface of medical research, the subject of the Stanford University Forum in July 2001.

The Capitol Forum was extraordinarily productive and informative due in large part to the remarks of and discussion stimulated by two leading political commentators, **Norm Ornstein** of American Enterprise Institute and **David Broder**, senior reporter for the Washington Post as well as an array of important officials, including **Tom Scully**, Administrator of the Centers for Medicare and Medicaid (CMS), **Dr. Sean Tunis**, Director of Coverage and Analysis at CMS, **Tom Grissom**, Director of Medicare Management at CMS, **Dr. Mark McClellan**, a member of the President's Council of Economic Advisors. We also received insights from two Congressional staff members, **Liz Fowler** of the U.S. Senate Finance Majority and **Deb Williams**, on the Ways and Means staff of the U.S. House of Representatives and **Sheila Burke**, former chief of staff for Senator Bob Dole, former Secretary of the Senate and currently member of the

Medicare Payment Advisory Commission (MedPAC). We were also fortunate to have participation from **David Feigal**, who runs the FDA's Center for Devices and Radiologic Health, along with Congressmen **Mark Kennedy**, **Jim McCrery**, **Sherwood Boehlert**, and **Jim McDermott**. MTLF President **David Durenberger**, former United States Senator, presided over the discussions.

## 1. Insights regarding health policy and politics in 2002

AEI's **Norm Ornstein** and **David Broder** of the Washington Post both commented on the challenges presented by a Congress that is evenly divided on party lines almost in mathematical precision. This balance of power tends to make members in both parties cautious, with a low likelihood that either side will take any chances that might tip the balance in the other's favor in this congressional election year.

**Ornstein** also noted that while the Congress is evenly split between the two parties, there are wide ideological divides among the members. While sentiment in the country coalesces somewhere in the ideological middle, the Republicans in the Congress tend to be farther right and the Democrats farther left than the country at large, increasing the tendency to polarize on important issues, even when the nation is more likely to want to get things done rather than deadlock on ideology.

**Broder** commented on the increase in the power of trade and professional groups that often hold firmly to special interests and prevent compromise on their key issues. He stated



**NORM ORNSTEIN**  
American Enterprise Institute

that interest group influence is higher than it has ever been in the past. He cited the deadlock on the patients' bill of rights as a result of the refusal of the interest groups to compromise, holding their congressional supporters from negotiating a solution.

**CMS Administrator Tom Scully** also noted that members of Congress don't focus on the complicated issues of health policy in sufficient numbers, despite what he feels is the "death spiral" in health care, with rising costs and significant substantive health care issues as yet unresolved. Senate staff member **Liz Fowler** seconded the challenge of dealing with the complicated issues of health policy, particularly when other pressing issues confront members of Congress. Health is currently competing with the war on terrorism, homeland security, the Enron scandal, and the stimulus package to name a few. **Fowler** predicted that the Senate Finance Committee might not deal with any Medicare issues until March or April at the earliest.

Health policy changes are further challenged this year because of the dramatic reduction in federal resources due to the recession, the tax cut, and war on terrorism and other homeland security priorities. Many of the high profile health issues, like adding a prescription drug benefit to Medicare or expanding access to insurance for the uninsured, are expensive programs. In the



**DAVID BRODER**  
**Washington Post**

words of **Broder**, "there does not appear to be the political will or the resources to deal with health care problems in a systemic way."

These factors all weigh in on the side of gridlock or inaction on larger health issues this session. However, public opinion appears to be arrayed on the side of action now. **Broder** cited the recent "Battleground Poll" which found that, contrary to views right after September 11th, both Republican and Democratic pollsters find that the public now ranks the economy twice as high as terrorism as their number one concern. And, looking deeper into that statistic, pollsters have found that rising health care costs rank highest among the economic concerns and are of deeper concern to more people than retirement security or job loss. In addition, **Broder** also noted that the recent responses to terrorism in this country have raised the public confidence in government, which increases the demands for government action. Both commentators felt that this confluence of factors could give rise to a Harris Wofford candidate, referring to the one term U.S. senator from Pennsylvania elected in a special election in 1991 by making health reform his signature issue.

None of our experts felt there were any easy answers to our health care problems even if Congress could be persuaded to



**DAVID DURENBERGER, MTLF President**  
**TOM SCULLY, Centers for Medicare and Medicaid**

act. Political solutions to issues such as the problems of the uninsured, Medicare funding, designing a Medicare drug benefit are elusive. In fact, **Broder** noted that much of what needs to be done must come from inside the health care delivery system - among

providers and patients – rather than from mandates or regulations from the federal government.

Observers of the political scene should be heartened by the fact that Bush Administration officials, in particular **Tom Scully** and **Mark McClellan**, are pragmatists not ideologues. If anything can be done in the political environment described above, it is an Administration committed to action not ideology. Both Scully and McClellan made pleas for pragmatism over ideology in addressing health care issues. Scully lamented that philosophical debates and intellectual barriers need to be broken down so we can get to the point of doing something. In relation to technology issues, McClellan noted that there is not one single dominant approach, but rather there are lots of promising ideas out there and that all approaches have some limitations.

Our political pundits recognized that the President has enormous political capital and that he learned from his father that he must carefully “use it or lose it.” It appears that the President’s advisors have a pragmatic, let’s get it done approach, but are faced with a cautious election-year Congress that is showing early signs of partisanship and ideological rigidity. It remains to be seen if this President will be willing to use some of his formidable capital to pursue important health reform issues in this election year.

## 2. Insights on Medical Technology Policy

The five most important Administration officials who deal with medical technology policy – **Scully**, **Tunis**, **Grissom**, **McClellan**, and **Feigal** – all provided us with some insights

into their views on medical technology issues. Through their prepared remarks and the interaction with MTLF members, we have elicited their opinions and approaches on a wide range of technology policy issues. It behooves all of us to consider carefully the perspectives of these key government policy makers.

**TOM SCULLY, ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID (CMS)**



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

Tom Scully described in some detail his priorities for the renamed CMS. He is motivated to create a culture change in CMS, so that employees will be more open with all the stakeholders of the agency. He has two important goals — education of Medicare beneficiaries and improvement of relations with providers. He is also committed to improving internal staff relations because insiders have also been frustrated with the

agency’s responsiveness to their concerns. He noted that Administration priorities in the legislative arena include Medicare prescription drug coverage through Medicare reform, and designing ways to increase access to health care through refundable tax credits.

On issues specific to medical technology policy, Scully shared the following views:

**OPPS** - He believes that the technology pass-through in the Out-Patient Prospective Payment System (OPPS), an on-going issue for medical device companies and hospitals is, in his words, “the worst public policy in 18 years.” He said the solution advocated by the device industry is a short-term fix for them with “disastrous” consequences in the long term. He believes that the pressure to impose the pass-through has slowed down the outpatient regulation and damaged the entire program. Scully did recognize, however, that the real

issue for the industry is the fact that innovators cannot get reasonable and timely approval of new technology from CMS, and pledged to work toward that end. (House Ways and Means Committee staffer **Deb Williams** subsequently disagreed with Scully's conclusions, stating that it was data flaws not legislative design that caused the problems with the pass-through).

**FDA/CMS Collaboration** – Scully believes that FDA and CMS have different goals. FDA's goal is to evaluate safety and efficacy, but it is not an insurance company and can't decide what to pay for. "There are a lot of things that are safe and effective, but are not a good investment for the taxpayers and that we are just not going to pay for." However, he did note that CMS and FDA could coordinate more effectively, which is one of the Secretary's goals for HHS.

**Local Medical Review Policy** - Scully has worked hard to get contractor reform in the Medicare program, which requires legislation to amend the existing contracting structure. However, he showed little sympathy to the local coverage process, which is coverage policy set by the local Medicare contractors, referring to it as "forum shopping."

**DR. SEAN TUNIS, DIRECTOR OF COVERAGE AND ANALYSIS GROUP, CMS**

**Dr. Tunis** implements coverage policy at CMS. He stated clearly the current CMS view on criteria for coverage in Medicare. He noted that the agency is increasingly trying to implement a more explicit, evidence-based standard for what gets covered in Medicare. The criterion "is a reasonable quality of evidence" that the technology "improves clinical outcomes." The agency is looking to see if the benefits exceed the risks as demonstrated through some sort of objective evaluation. His view is that the program is moving to a policy based on clinical effectiveness. The bottom line: "if you have a good

technology and you can prove it, we'll find a way ...that the program can ultimately pay for it."

**Dr. Tunis** also noted the difficult challenge of evaluating new technologies with incremental benefits and huge price tags. He noted these challenges arise with several new technologies in the pipeline, including a new drug for sepsis, new medications for macular degeneration, and the left ventricular assist device (LVAD).

**TOM GRISSOM, DIRECTOR OF MEDICARE MANAGEMENT GROUP, CMS**

**Tom Grissom** oversees Medicare payment policy. In a similar vein, he made a plea for the measurement of value in new technologies. He urged that we find true ways to measure cost and measure value based on outcomes. He also noted that CMS does not have the resources or the capacity to do all the tasks that it is expected to do.

**DR. MARK McCLELLAN - PRESIDENT'S COUNCIL OF ECONOMIC ADVISORS**

**Dr. McClellan** gave us both good news and bad news about medical technology in the health care system. The good news is that when medical technology has been studied for a

host of medical conditions, it has shown to be worth the investment. The bad news, according to McClellan, is that medical technology is responsible for about one-half of the increases in costs in health care, and that it appears that costs of health care will be rising as far as we can see in the future. He did note promising opportunities for technology to improve outcomes and he advocated more consumer involvement and patient control. He also said that there is no single dominant approach to answer the challenges of rising health care costs, but that there are promising ways to use technology more efficiently.



**MARK McCLELLAN**  
**President's Council of Economic Advisors**

As a former practitioner, **McClellan** noted also that Medicare is good at making binary decisions to cover or not to cover new technologies. He noted that the real question from a clinical perspective is: do patients benefit enough from the treatment in a specific case? We need to do more to help providers to use the treatments more appropriately at the patient level.

In summary, all these officials addressed in some way the need to improve our ability to measure the value of new technologies and to use these new technologies appropriately in clinical settings to improve outcomes. In the exchanges with MTLF members, we all wrestled with, but did not solve, the looming questions of rising costs of health care colliding with the challenges to the private and public sectors to pay for care.

### 3. Presentation of MTLF Reports

A final goal of the Forum was to showcase the MTLF Reports on Clinical Information Technology (CIT) and Conflict of Interest. We brought MTLF participants together with Washington-based policy makers to share views and to get updates on the potential for policy reform from Administration officials and Congressional staffers.

#### A. MEDICARE COVERAGE OF CLINICAL INFORMATION TECHNOLOGY

**Dan Mendelson** of Health Strategies Consultancy, adjunct professor at Duke University and organizer of the MTLF Summit there in February, presented the findings of the Duke Report. The goal of the report was to identify barriers to the diffusion of promising technologies built around information

technology. **Mendelson** noted that there is pending legislation addressing CIT issues, the Rockefeller-Snowe bill, and also discussed the value of forms of disease management (DM) in addressing new and creative ways to treat chronic disease.

A lively discussion ensued. Moderator **Sheila Burke** noted that legislation should be approached cautiously. "Beware of what you ask for," she said, "legislation should always be the last resort." In her experience, you never can assume going in that you will get what you want coming out. Both Hill staffers, **Deb Williams** and **Liz Fowler**, concurred. They commented

that lack of technical expertise, the press of deadlines, and the unpredictable nature of the process, can always lead to drafting problems in legislation.

**Sean Tunis** noted that several CIT technologies had received positive coverage decisions since the Duke report was issued, but sounded a cautionary note. He said: "even if you pass legislation allowing us to pay for forms of CIT in Medicare, it doesn't

necessarily mean that Medicare would pay for it." He warned that all technologies must meet an explicit, evidence-based standard that they improve clinical outcomes. CIT must meet that test.

**Tom Grissom** expressed concern that demonstration projects are not always the most effective ways of testing new technologies, commenting that often private enterprise and academic institutions are more appropriate than the federal government. Federal demonstrations often slow down the process of evaluation and adoption. He insisted that all technologies must show value and improved outcomes in order for them to be paid for by Medicare.



**LAWRENCE COHN, Partners Healthcare, and DAVID DURENBERGER, MTLF President**

U.S. Senate Finance Committee staff member, **Liz Fowler**, noted that the Senate calendar is quite full, and that advocates of any legislation must work hard to get support from all members of the Committee. **Deb Williams** described many of the priorities of the Ways and Means Committee, also communicating the challenge of getting on the priority list for legislation on a crowded legislative agenda.

#### B. CONFLICT OF INTEREST IN ACADEMIC/INDUSTRY RESEARCH

In the summer of 2001, MTLF met at Stanford to discuss the challenges presented to academic research institutions and industry innovators by the increasing federal debate about conflict of interest in clinical trials. A report detailing MTLF's conclusions was circulated to policymakers. Following the Stanford conference, many associations of academic research institutions and university groups focused on research protections, and the GAO had studied how universities deal with conflict of interest situations. In addition, some members of Congress had expressed interest in further legislation in this area.

The policy challenge is to balance the goal to promote innovation and innovative research while protecting the research integrity of individuals and institutions and protecting patients from unreasonable risks of participation in clinical research studies. The challenge is to develop and improve public policy to protect the balance of these two goals.

Our panelists reflected many perspectives. **Kendra Dimond**, partner in the law firm of Epstein, Becker & Green, moderated the panel. **Susan Bartlett Foote**, professor at the University of Minnesota and MTLF Policy Director presented the MTLF Stanford Report. GAO Health Care Group Director



**STEVE UBL, AdvaMed, Rep. JIM McCRERY (R-LA) and SUSAN BARTLETT FOOTE, University of Minnesota**

**Janet Heinrich** presented the findings of the GAO Report, "Biomedical Research: HHS Direction Needed to Address Financial Conflict of Interest." **Richard Turman** of the American Association of Universities (AAU) presented the views of his organization.

**Dr. David Bowen**, staff to Senator Ted Kennedy, presented the Senator's concerns on this issue. Senator Kennedy has been involved in research ethics since his early involvement in

the 1970s following the Tuskegee Institution experiments. He noted the similarities in recent controversies to earlier ones, and spoke to the need to create new rules for a new generation of researchers.

It is clear that much work needs to be done in order for the policy environment to find the

right balance in this area. MTLF will continue to work on these issues at the Harvard/Partners Forum in July of 2002.

#### 2002 MTLF PROGRAMS

APRIL 21-22

**"Defining a Regulatory Process for Combination Products: The Emergence of Tissue Engineering"**

Petit Institute for Bioengineering on Bioscience  
Georgia Tech  
Atlanta, Georgia

JULY 21-22

**"Breaking Down the Barriers: How to Make the New Science Happen"**

Harvard Medical School/Partners Healthcare  
Boston, Massachusetts

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