
CAPITOL FORUM REPORT

JANUARY 29-30, 2003



MEDICAL  TECHNOLOGY
LEADERSHIP FORUM

GIVING NEW MEANING TO THE FUTURE OF MEDICAL TECHNOLOGY

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

The Second Annual MTLF Capitol Forum was held on January 29-30, 2003. Our goals for the Forum were to take the political pulse in Washington, D.C. on issues of health policy and health politics, showcase the work of MTLF during the previous year, and continue to build and strengthen relationships between MTLF members and the key policy makers in the Capitol.

This year, our timing was extraordinary. The Forum took place the day after the President's State of the Union message. This key address by the President to a joint session of Congress provides insight into the White House legislative priorities for the year. Soon thereafter, the chief executive submits his budget to Congress and the political year is launched.

The sessions began with a stimulating dinner presentation by **David Broder**, senior reporter for the Washington Post. Broder noted that the overriding single fact of life, and the dominant factor in the State of the Union message, is the impending war with Iraq. The second overriding issue is the lackluster economy. The war and economic downturn are shaping the legislative environment for all of the issues including health care.

In his State of the Union address, the President set two health priorities; liability reform and Medicare reform with a prescription drug benefit. The following day, members of Congress were pressing for more details on the proposals and expressing concerns over rumors that were floating around Capitol Hill.

To assess the likelihood of action on these two issues, Broder commented on the political environment. He noted that Washington, D.C. had changed fundamentally after the election of 2002, in that the Republicans now can set the agenda for the next two years. However, they do not have the votes in the Senate to control the outcomes, as 51 votes is well short of control. Broder did state that the Capitol operates in terms of personal relationships, and for the first time in his memory, the leaders in both the House and the Senate have an interest in health care issues. The new Majority Leader Senator Bill

Frist, who is the only doctor in the Senate, and House Speaker Dennis Hastert have been insisting that the Congress engage on health issues. Broder believes that health is now becoming a business issue and business interests are mobilizing. However, the public is not prepared for trade-offs and has very unrealistic expectations.

Broder's observations rang true as we listened to **Representative Jim Ramstad (R-MN)**, a member of the Health Subcommittee of the Ways and Means Committee and **Senator Mike Enzi (R-WY)**, who serves on the Senate's HELP Committee.

Ramstad noted that the nation was riveted on the strong possibility of

war, but he asserted that it is important not to forget domestic policy, including Medicare. Bioterrorism has made national defense a health care issue as well. He urged that policy makers continue to work hard to reform Medicare, make technol-



DAVID BRODER
Washington Post

ogy advances available to all Americans, and to reform the liability system, all issues identified by the President in his address. Senator Enzi reiterated the importance of these issues, and noted that Senator Frist has the knowledge and ability to make sure that Medicare reform is addressed this year.

Tom Scully, the Administrator of CMS, arrived fresh from a three-hour grilling before the Senate Appropriations committee. He said that the Medicare reform plan announced by the President was still being written, that it was incredibly complicated to draft, and would be available soon. He praised the President for making Medicare reform his highest priority, but couldn't disclose any of the details at this time. **Doug Badger**, the White House Health Policy Advisor, was at the White House drafting and unable to keep his commitment to participate in MTLF.

In addition to the need to reform Medicare, Scully noted that physician payment needed to be fixed. Another priority was his quality project and he discussed his efforts to design standardized measures of clinical outcomes for nursing homes, home health agencies and hospitals.



TOM SCULLY, Administrator, CMS
DAVID DURENBERGER, MTLF President



KENNETH KELLER, University of Minnesota, MARK McCLELLAN, Commissioner, Food and Drug Administration

In summary, our speakers confirmed the Presidential priorities, but it is clear that focus on domestic issues will be challenging, and that some of the goals of Medicare reform will be very difficult to realize given the complexity of the policy and the volatility of the political environment.

We were fortunate to have the new FDA Commissioner **Dr. Mark McClellan** share his vision for the FDA in the

coming years. Dr. McClellan participated in last year's Capitol Forum in his role as White House Health Policy Advisor. He has been on the job at FDA for several months, and provided MTLF with an overview of his priorities and challenges.

Applying his prodigious talents as an economist and a physician, Dr. McClellan said that his three major areas of focus are to 1) conduct a root cause analysis of multiple review cycles,

2) establish quality systems in product review processes, and 3) develop clearer guidances. He expects to see significant changes at FDA in the months ahead, making regulation faster and at lower cost by applying the best techniques of risk management and biomedical knowledge.

He then discussed additional priorities, including prevention of avoidable adverse events in the products FDA regulates, provid-

ing more reliable and helpful information for the public relating to nutritional supplements and medical products, and responding to the new challenges and responsibilities in fighting terrorism. Bioterrorism threats have been a transforming experience at FDA. Where FDA once focused on food safety, it now focuses on food security. According to McClellan, FDA is also setting a high priority on medical countermeasures in response to biological attacks, and designing ways to reward innovators who develop treatments for counter-terrorism. This focus illustrates the ways that 9/11 and its aftermath have fundamentally influenced government at all levels.



PETER GOVE, St. Jude Medical
TOM SCULLY, Administrator, CMS

MEDICARE COVERAGE POLICY: BALANCE BETWEEN LOCAL AND NATIONAL POLICY

The goal of this session was to provide an overview of the MTLF report on Medicare coverage, and challenge a range of experts to comment on the report. Dan Mendelson, MTLF member representing Duke University and a D.C. based consultant, walked through the highlights of the June report (available at www.mtlf.org). Our four invited experts, **Dr. Sean Tunis**, the Acting Deputy Director of the CMS' Coverage and Analysis Group and the Acting Chief Clinical Officer at CMS, **Dr. Charlotte Yeh**, formerly Contractor Medical Director, **Dr. Douglas Wood** of the Mayo Clinic, and **Deborah Williams**, staff for Chairman Bill Thomas of the Ways and Means Committee, offered their

thoughts on the balance between local and national coverage.

Sean Tunis began his remarks with the Dartmouth Atlas map of variation in practice patterns around the country. He noted that there is little consensus about whether the variation in practice is “bad” (some physicians are making bad decisions, over and under-utilizing services) or “good” (there is not a lot of good evidence; physicians do the best they can with the evidence available). How one interprets these variations has a lot to do with response to variation in local decisions. He continued by explaining the way CMS evaluates technologies, stressing the benefits of solid evidence on decisions. He noted: “The quality of the decision is only as good as the quality of the evidence.”



SEAN TUNIS, Acting Deputy Director of Coverage and Analysis Group, CMS, and Acting Chief Clinical Officer, CMS

Tunis said that in both local and national decisions, CMS is looking for evidence of net improvement in health outcomes, although local decisions place greater weight on expert opinion and informal local input than at the national level. The tension between local and national in his view is between the inconsistencies in local coverage decisions and the greater flexibility and responsiveness to innovation in regional areas. He said that the current model allows controversies to “bubble up” to the national level in a reactive manner. He also noted that timeliness has less to do with the level of decision than with the consequences of an open process, allowing more opportunities to have input and various avenues at many levels to influence the outcome. He suggested that big, potentially disruptive technologies and technology supported by solid evidence should be subject to uniform national decisions.

Dr. Charlotte Yeh took the opportunity to explain in fascinating detail her experiences as a Carrier Medical Director in Medicare. She agreed that the more public input, the more the time frame is extended, noting that the local timeframe ranged from 6-9 months for uncontroversial decisions, to over a year (or never) for controversial ones. She provided several examples to illustrate the flexibility for responding at a local level. She also cautioned about using consumer involvement in the policy process, noting that the issues are very personal and you don’t want to make policy by anecdote. She justified some of the variation, explaining that local policy differs often because state laws, practice requirements, and expertise is often different from area to area. She



Rep. Jim Ramstad (R-Minn)

reminded the audience that just because there isn’t a policy doesn’t mean there isn’t access; CMDs do have discretion for individual determinations.

In relation to evidence, she stated that resources are limited at the local level. In her office, there were only two people devel-

oping technology assessments, and information on formal assessments was not available. She concluded with her view that national and local each have value and that the tension should be celebrated. She suggested that we need a methodology to balance scientific evidence with consensus opinion, and should consider how to convert local policies to national ones after a certain amount of diffusion. She recommended that there should be flexibility to modify national decisions if there are good reasons at the local level to do so.

Dr. Douglas Wood critiqued variation in the program as a burden on physicians, discrimination against some beneficiaries, and waste of

resources. Multiple policies don’t improve outcomes. The challenge, according to Dr. Wood, is to find a way to couple regulation, supervision and payment policy with research to get us the best information as quickly as possible. One solution is to make the decisions at the national level, and where we don’t have sufficient evidence, craft a payment policy that would be tied to research to get the evidence. CMDs could be used to make exceptions to the national decision for individual patients based on local needs, thereby eliminating the thousands of LMRPs.

Deb Williams reported that Chairman Thomas believes in technology and wants to support it. She was pleased to listen to the discussion about balance that is often missing in policy debates. She said that it is important to bring more logic to the local process and to make the national coverage process stronger, so people feel that it is fair and open.

All the medical speakers expressed interest in mechanisms to reimburse in exchange for gathering information. Often called conditional coverage, it would require some post-coverage authority to review and monitor studies. Concerns were raised about who pays for the studies and how quickly they could be done given the iterative and dynamic nature of device innovation. Tunis commented that the rapid development of information technology could make the gathering of clinically relevant, standardized data in real time a possibility.

The discussion among these experts and MTLF members elicited creative responses to the tension between local and national coverage decisions. This issue is clearly ripe for policy changes given the strong interest in Medicare reform, as well as the equally strong interest in simplifying regulation and reducing complexity in the Medicare program.

UPDATE TO THE GEORGIA TECH SUMMIT

MTLF Chair Ken Keller moderated our discussion of the FDA. The MTLF Summit at Georgia Tech in April, 2002 looked at the challenges facing combination products in terms of science, economics, and regulation (available at www.mtlf.org). **Dr. Bob Nerem**, our host at Georgia Tech, began the discus-

sion with an update on the combination products generally, and tissue engineering specifically, in the last year. Dr. Nerem



TOM SCULLY, Administrator, CMS

noted that the science is still emerging, funding issues present challenges, payment issues create delays and barriers, and clinical acceptance can be slow. His data indicated that while the number of companies is growing, growth is slowing, some firms have gone out of business, the pipeline of tissue-engineered products is “threadbare,” and the industry needs a real success story.

At the Georgia Tech conference, MTLF focused on changes at FDA to facilitate the combination product challenges. Among the MTLF recommendations at the Summit, were calls for procedural redesign at FDA. Since the meeting, FDA has established an Office of Combination

Products, and directors of the two key centers, **Dr. David Feigal** of the Center for Devices and Radiological Health (CDRH) and **Dr. Jesse Goodman**, newly appointed at the Center for Biologics Evaluation and Research (CBER) joined us to explain their views on combination products and answer questions from the MTLF members.

Dr. David Feigal frequently attends MTLF events and was an active participant in the Georgia Tech Summit. He noted that FDA has begun to identify combination products and to track them to assess performance expectations. The two key problems for combination products are what center will regulate and what is the product? These questions matter because the legal requirements, including enforcement and standards, differ if the product is a device or a biologic.

Since the Atlanta meeting, the centers have worked together to develop agreements on how to interact. They are moving from consulting relationships to true collaboration. He supports using a single review team where it makes sense working together in a single location. He noted that one model is the way FDA handles blood, categorically and programmatically, all reviewed by the same team in a single review group. The team uses a variety of regulatory tools to accomplish the goals.

He concluded by saying that combination products are here to stay and that FDA and its centers need to keep developing strategies to address them.

Dr. Jesse Goodman reiterated a commitment to make collaborative reviews work. He said that he, Mark McClellan, and David Feigl all share a common vision on this point. He noted that we need the regulatory agency to be a more permeable membrane, with more collaboration and dialogue with outside experts.

MTLF members challenged our FDA friends to envision a continuous system that accommodates feedback loops, parallel paths of development, and the multi-directional interactions between scientific progress and technological innovation. We hope that the expertise of these key FDA leaders and their commitment to innovation will propel them to reduce regulatory barriers and focus on mechanisms to continuously evaluate scientific advances. We invite them to participate in the University of Minnesota Summit in July where we will look at ways to reconceptualize regulation to address the challenges of multi-disciplinary innovation.



DANIEL MENDELSON, Health Strategies Consultancy, SUSAN BARTLETT FOOTE, University of Minnesota, CHARLOTTE YEH, National Heritage Insurance, DOUGLAS WOOD, Mayo Foundation

UPCOMING MTLF PROGRAMS

April 27-28
“Breaking Down the Institutional Barriers to Multi-Disciplinary Research”

Harvard Medical School / Partners Healthcare
Boston, Massachusetts

This program will gather together leading experts in national policy, the academy and industry to identify organizational inhibitors of innovation and to explore ways to break down the barriers to achieving the promise of the new science.

July 17 – 18
“Facilitating the Continuum from Experimental to Clinical Use: Designing Alternative Methods”

University of Minnesota
Minneapolis, Minnesota

Innovation in medical technology is iterative, not linear. The purpose of this conference will be to think about alternatives to the current regulatory system of gates and hurdles as new technologies progress from experimental to clinical.

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