

### THE HEALTH INDUSTRY FORUM







### Informing innovative healthcare policy and practice

### CHAIRMAN'S LETTER TO OUR MEMBERS



The Health Industry Forum continued to solidify its role as an effective organization bringing together leading health plans, medical technology providers, policy analysts and government officials to address challenging U.S. health policy issues. Highlights include:

STUART ALTMAN, PhD Chairman and professor, Brandeis University

#### National policy conferences

We strive to engage senior health policymakers in discussions about improving the efficiency and effectiveness of the U.S. healthcare systems. This year many senior federal officials were able to

participate in our forums, including former Centers for Medicare & Medicaid Services Administrator Mark McClellan; FDA Deputy Commissioner Janet Woodcock; Agency for Healthcare Research and Quality Director Carolyn Clancy; and Wendell Primus, senior adviser to Speaker Nancy Pelosi.

#### **Congressional briefings**

We are pleased to be acknowledged as a reliable, unbiased source of information. We are able to provide pertinent and timely healthcare analysis to our nation's leaders in order to facilitate better discussions and decision-making.

#### **Technical workgroup**

We launched a new workgroup with its own conference to allow members and outside experts to drill down into important policy problems at a level of detail that is not possible in our regular, larger policy conferences. These groups will increase the number and quality of opportunities for members to participate in healthcare policy discussions.

#### Cosponsorship of conferences

Lending our expertise to other institutions makes it possible to increase our influence and effectiveness. This year we collaborated with the Personalized Medicine Coalition and with the University of Washington on *Roadmap for Integrating Genetic Testing into Health Care Delivery and Disease Prevention*.

#### New publications format

We worked hard this year to develop a new format for conference reports in order to more effectively capture, distill, and disseminate key elements of the discussions.



## **I** FORUMS

This year, the Health Industry Forum held three major policy conferences. These conferences were organized in roundtable format and purposefully kept small—forty-five to sixty participants each—in order to maximize interaction and debate.

### Developing an Effective Long-Term Strategy for Post-Marketing Surveillance of Medical Products (April 11, 2007)

This forum was organized in the wake of growing public concern about drug safety and prominent government reports criticizing the Food and Drug Administration's ability to identify and respond to emerging safety problems. There was broad agreement that the FDA's current systems for post-marketing surveillance were inadequate and that new systems, strategies, and resources were required. This discussion was important considering the FDA reauthorization bill then pending in Congress. Participants agreed that new "active" surveillance systems were necessary to detect safety signals more effectively and that these systems must be able to integrate and adjudicate large amounts of data from many different sources including health insurance claims and electronic health records. Rather than a system developed by the government, participants discussed a "federated data-sharing model" where multiple participants including the FDA would share information for specific monitoring and analytic activities.

### Implementing Comparative Effectiveness Research: The Value Proposition for Patients, Physicians, and the Healthcare System (July 25, 2007)

Following two previous forums on options for expanding comparative effectiveness research capacity in the United States, this conference focused on engaging future consumers of this research (physicians, patients, researchers, health systems, and payers) to identify key challenges and to examine specific examples of how this information could be used. Stakeholders were generally enthusiastic about expanding the availability of this research, but some concerns emerged. Patient advocates emphasized their desire for a meaningful role in priority setting and the need for investments in making this information more understandable and accessible to consumers. Physicians supported comparative effectiveness research for developing evidence-based guidelines but were concerned about how this information might affect coverage and payment policy. Payers expressed interest in reining in expensive medical technologies with only marginal clinical benefits but were unsure whether this research would be timely enough to help do so. All participants emphasized the need for a trusted source of governance and a transparent process for any new comparative effectiveness entity.



### Value-Based Pricing and Payment for Medical Technologies: Can We Establish Systems that Promote Affordability and Innovation? (October 2, 2007)

Economists identify medical technology as the major factor driving the real growth in healthcare spending. New medical technologies bring substantial clinical benefits for patients, but inappropriate use of medical technologies results in excess costs and unnecessary risks for patients. There is growing interest among purchasers and policymakers in developing "value-based" payment strategies that reflect the clinical and economic benefit of specific therapies. Challenges to value-based payment include a lack of research examining the comparative effectiveness of alternative medical technologies, as well as the complexity of establishing automated healthcare benefits management systems that can accommodate individual patient variation in response to therapies. Nevertheless, payers are experimenting with new models that include risk sharing with manufacturers, value-based benefit design, and financial incentives for evidence generation. The purpose of this meeting was to begin discussing key issues and to articulate future needs for research and policy development.

## II CONGRESSIONAL BRIEFINGS

The Health Industry Forum is periodically asked to provide briefings for congressional staff focusing on issues of current legislative importance. As a neutral, academic entity, we can represent the viewpoints of multiple stakeholders. We held two such briefings this year.

#### Assessing the Value of New Drugs, Devices, and Biologicals: Is There a Better Way? (February 14, 2007)

Experts from across the healthcare industry discussed how to better assess the value of new drugs, devices, and biologics at a briefing for congressional staff in Washington. This event was cosponsored by Kaiser Permanente and America's Health Insurance Plans and was webcast on Kaisernet. This briefing received attention in the press, including coverage in an article in *The British Medical Journal*.

#### Setting Priorities for Comparative Effectiveness Research (November 29, 2007)

This congressional briefing provided an overview of how a national comparative effectiveness research entity might work and the potential benefits for the U.S. healthcare system. Health system leaders and federal officials from AHRQ, the National Institutes of Health, and Congress also discussed research priorities and opportunities for collaboration across agencies. This briefing was also webcast on Kaisernet, and is available for viewing via our Web site.



## **III** WORKGROUP MEETINGS

The Health Industry Forum has established policy workgroups to analyze key issues in greater detail, increase opportunities for member participation, and expand our breadth of high-quality meetings and discussions.

#### **EVIDENCE WORKGROUP**

We initiated an evidence work group charged with developing strategies for improving the availability of clinical evidence to support decision-making for patients, physicians, payers, and manufacturers. The first evidence workgroup meeting held in October 2007 examined options for collecting data to inform medical policy under Medicare's Coverage with Evidence Development program.

#### Optimizing Information under Coverage with Evidence Development (October 24, 2007)

The purpose of the meeting was to begin to assess whether Coverage with Evidence Development (CED) can generate sufficient evidence through observational research—in particular through prospective clinical registries—for payers to refine coverage policies. Four case studies were presented (implantable cardioverter defibrillators, lung volume reduction surgery, autologous bone marrow transplants, drug-eluting stents) and used to discuss practical considerations for CED. Participants concluded that while CED provides an important alternative to yes/no coverage decisions, registry data collected through CED should be used to complement, rather than replace, randomized clinical trials. Further work is necessary on a wide range of policy issues regarding use of clinical registries for CED including funding, design, and methodology.

The evidence workgroup will hold its second meeting in spring 2008:

## Generating Evidence on Clinical Safety and Effectiveness from Electronic Medical Records, Registries, and Integrated Claims Databases

Policymakers are now discussing the potential to generate evidence for decision-making through clinical and administrative data systems. Called the "learning healthcare system" by supporters, this approach would supplement clinical trial data by generating information rapidly about treatment outcomes in large patient populations. Despite its conceptual appeal, the current and near-term capabilities of delivery systems to generate this type of information are not well understood. This meeting will examine the following questions: 1) What are current capabilities of leading delivery systems to develop evidence of effectiveness and safety for drugs, devices, and medical procedures? 2) Can these systems generate evidence to address specific clinical questions of importance to providers, payers, and the policy community? (e.g., how many ICDs implanted during a specific period failed to fire properly?)

3) Could these systems be designed to support coverage with evidence development or pharmaco vigilance?

#### INNOVATION WORKGROUP

The Forum initiated planning for an innovation workgroup that will develop strategies for promoting more effective innovation in healthcare—both in medical science and in health services delivery.

The innovation workgroup will hold an inaugural meeting in spring 2008 focusing on innovation and policy:

#### Framework for evaluating innovation and policy.

The Forum's planning group on innovation identified a need to examine the role of innovation in healthcare more systematically and to begin establishing definitions and a framework that would support a coherent discussion across stakeholder groups (e.g., consumer, provider, payer, manufacturer, policymaker). As a general premise, this group believes that public policy should support both technology and organizational innovation but that there has not been a clear articulation of what type of innovation we want and how to best promote it. This initial workgroup meeting will focus on establishing definitions and a preliminary framework for discussion and articulating different stakeholder views. Subsequent meetings will examine payment policy and regulatory issues.

## IV COSPONSORED CONFERENCES

In addition to regular Health Industry Forum conferences, we have partnered with other organizations to hold events on issues of importance for our members.

### Roadmap for Integrating Genetic Testing into Healthcare Delivery and Disease Prevention (October 2007)

This two-day workshop focused in greater depth on many of the issues discussed during our October 2006 meeting on coverage and reimbursement for genetic testing services. The University of Washington organized this meeting with partners that included the Health Industry Forum, Centers for Disease Control, National Institutes of Health, the Center for Medical Technology Policy, and the RAND Corporation. This meeting focused on the substantial need for better evidence to support the clinical utility of new genetic testing. In addition, participants analyzed strategies for creating viable business models. One area of discussion included using multi-stakeholder consortia to formulate recommendations about the levels and types of evidence necessary to support introduction of genetic tests into clinical practice.

#### Twenty-First Century Medicine: Personalized and Evidence-Based (September 18–19, 2007)

This Washington-based meeting hosted by the Personalized Medicine Coalition and Georgetown University examined opportunities and barriers to promoting healthcare systems that are both more evidence-based and more personalized. The two-day workshop focused in greater depth on many of the issues discussed during our conference in 2006.

# V PUBLICATIONS AND MEDIA

Through benchmarking and discussions with our members, we determined that our written documents needed some improvements in order to effectively summarize and analyze key elements of the forum discussions. In addition, we needed to develop a more efficient method for distributing our publications.

As a result, we developed more useful and functional publications, while, at the same time, established more deliberate distribution methods for Health Industry Forum publications. Our new format for reporting on conference findings is both comprehensive and easy to read; we published five conference reports this year. We also have developed a series of companion policy briefs that summarize key forum findings more concisely. Policy briefs are available for our fall conference and evidence workgroup.

Additionally, we have redesigned our Web site to provide more effective access to these reports. You will find that both of our congressional briefings have been recorded for video webcasting, and are posted on our Web site. For more widespread circulation of our publications, we have adopted a new process to send a broadcast e-mail to all friends of the Health Industry Forum with links to our conference reports and policy briefs.

In order to extend the value of our conferences, we will continue to focus on developing and enhancing our publications in 2008.

#### **MEMBERSHIP**

#### **CHARTER MEMBERS**

AETNA INC. ASTRAZENECA PHARMACEUTICALS INC. EMBLEMHEALTH INC. JOHNSON & JOHNSON KAISER PERMANENTE LIFEMASTERS SUPPORTED SELFCARE INC. MERCK & COMPANY, INC. PFIZER INC.

#### MEMBERS

BLUE CROSS AND BLUE SHIELD ASSOCIATION BLUE CROSS AND BLUE SHIELD OF MASSACHUSETTS BOSTON SCIENTIFIC CORPORATION BRISTOL-MYERS SQUIBB MEDTRONIC INC. NOVARTIS PHARMACEUTICALS CORPORATION PARTNERS HEALTHCARE SYSTEM INC. SANOFI-AVENTIS WYETH PHARMACEUTICALS

#### **ADVISORY BOARD**

STUART ALTMAN, PHD, Sol C. Chaikin Professor of National Health Policy, The Heller School for Social Policy and Management, Brandeis University

CATHERINE BONUCCELLI, MD, Vice President, AstraZeneca, Inc.

TROYEN BRENNAN, MD, MPH, Senior Vice President and CMO, Aetna Inc.

KATHY BUTO, MPA, Vice President, Johnson & Johnson

KAREN IGNAGNI, MBA, President, America's Health Insurance Plans

JACK MAHONEY, MD, Corporate Medical Director, Pitney Bowes

NEWELL MCELWEE, PHARMD, Vice President for Outcomes Research, Pfizer Inc.

ELIZABETH MCGLYNN, PHD, Associate Director, Rand Health

DANIEL T. MCGOWAN, MS, President, Emblem Health Services BARBARA MCNEIL, MD, PHD, Professor of Healthcare Policy, Harvard Medical School

ROBERT REISCHAUER, PHD, President, Urban Institute

MURRAY ROSS, PHD, Director, Kaiser Permanente Institute for Health Policy, Analysis & Research

JOHN ROWE, MD, Professor, Columbia University

KEVIN SCHULMAN, MD, Professor of Medicine and Business Administration, Duke University

CHRISTOBEL SELECKY, MA, Executive Chairman, LifeMasters Supported Self Care Inc.

STEVEN TEUTSCH, MD, MPH, Executive Director, US Outcomes Research, Merck & Co., Inc.

KAREN WILLIAMS President, National Pharmaceutical Council





#### **BRANDEIS UNIVERSITY**

The Heller School for Social Policy and Management 415 South Street Waltham, MA 02453

781-736-8479 781-736-3306 Fax healthforum@brandeis.edu

www.healthforum.brandeis.edu