



NATIONAL DIALOGUE FOR
Healthcare Innovation

National Dialogue for Healthcare Innovation Summit on Physician-Industry Collaboration

Executive Summary

October 4, 2010
Knight Conference Center
The Newseum, Washington, D.C.



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Abstract

The [Healthcare Leadership Council \(HLC\)](#), a coalition of chief executives representing all sectors of American healthcare, formed the [National Dialogue for Healthcare Innovation \(NDHI\)](#) in 2010 as an interactive forum for leaders from government, academia, industry, payers, providers, societies, and patient and consumer organizations to engage in constructive dialogue aimed at building better understanding and consensus around critical issues affecting healthcare innovation, and, ultimately, patient care.

NDHI's inaugural event, the NDHI Summit on Physician-Industry Collaboration, was held on October 4 in Washington, D.C. The meeting represented one of the first cross-disciplinary cooperative dialogues among leaders from stakeholder groups across the U.S. healthcare ecosystem.

At the Summit, 107 high-level representatives from key stakeholder organizations attended the day-long event, focusing on identifying areas of consensus and alignment, as well as raising divergent viewpoints and key issues surrounding physician-industry collaboration.

Areas of Consensus

At the conclusion of the Summit, consensus was established on the following points:

- Innovation in healthcare is critical, and collaboration is necessary for that innovation to continue.

- Public trust and communication are vital, and substantial work is needed to enhance trust in the collaboration model.
- Maintaining balance is important: continuing to collaborate and innovate, while maintaining public trust by educating the public on the process and becoming more transparent about the collaboration.
- Solving collaboration challenges is an economic imperative for the U.S.

Post-Summit Activities

Following the Summit, participants agreed to work within NDHI to continue engagement on this issue in the following areas:

- Guidelines & Principles
- Education & Outreach
- Improving Innovation

Toward that end, NDHI expects to engage smaller working groups beginning in late 2010, to make progress over the next year on these areas, in order to maximize trust and preserve innovation, both for the benefit of patients and for continued U.S. leadership in the critically important healthcare industry.





Background

In considering the breakthroughs and miracles of U.S. healthcare innovation over the past several decades, it's clear that very few of them would have been possible without close physician-industry collaboration, or more appropriately termed, cooperation, that drives innovation.

Healthcare professionals are often the best source of ideas about how to develop complicated drugs or bio-pharmaceuticals and medical devices like artificial joints, neurostimulators, and pacemakers. In turn, pharmaceutical or medical device companies have the expertise to engineer and manufacture the new products.

This close physician-industry collaboration, however, presents the potential for conflicts of interest, as many doctors who are paid to collaborate with companies to develop new drugs or products, and train and educate other doctors on their use, are often the same doctors who prescribe or implant them. These conflicts, both real and perceived, can affect patient and stakeholder confidence in clinicians, products, companies – and the entire industry.

Over the past several years, physician-industry collaboration in the U.S. has come under critical review, both as a result of increased media scrutiny and the budgetary constraints of healthcare payers, including federal, state, and local governments. This, in turn, has fueled increasing demands to ensure that healthcare decisions remain unbiased, and to preserve the integrity of the physician-patient relationship, and address conflicts of interest, both real and perceived.

Given the importance of physician collaboration in the pharmaceutical and medical device industries, many U.S. companies have already taken voluntary steps to make payments to physicians transparent to the general public. Congress this year passed transparency requirements that will establish a uniform set of federal disclosure requirements for physician payments for all drug and medical device industries in the United States. These requirements will help ensure that treatment decisions remain driven by patient needs and physician expertise.

As important as these voluntary and legislative steps are, transparency in physician payments forms only one part of the equation. Innovation consists not only of collaboration between industry and physicians, but also involves principled collaboration, with appropriate guidelines, and communication between a number of additional key groups: patients, payers, academia, consumer groups, physicians, government, and policy makers, all of whom work together to make innovation happen and optimize its value for patients.

On October 4, 2010, leaders from each of these stakeholder groups gathered in Washington, D.C., for the NDHI Summit on Physician-Industry Collaboration, an initiative of the HLC, a coalition of chief executives from all sectors of American healthcare.



Background (continued)

NDHI is a forum in which leaders from government, academia, industry, payers, providers, societies and patient and consumer organizations can share their diverse and sometimes conflicting views while working toward consensus on the most important issues affecting healthcare innovation. Co-chaired by David Barrett, M.D., CEO Emeritus of the Lahey Clinic, and Bill Hawkins, Chairman and CEO of Medtronic, NDHI brings together a broad spectrum of leaders and organizations involved in healthcare delivery and policy for discussions on subjects related to medical innovation in the United States, its importance and the opportunities and challenges affecting its progress.

The October Summit on Physician-Industry Collaboration was the first in a series of planned NDHI forums on topics of importance to innovation in healthcare. The Summit was conceived as a unique, interactive forum in which thought leaders with diverse perspectives could discuss, and then continue to work on, the issue of collaboration in improving patient care, identify best practices and gaps in physician-industry collaboration, and strengthen patient and public confidence by minimizing perceived or real conflicts of interest.

At the Summit, 107 high-level representatives from academia, providers, institutions, societies, government, payers, patient and consumer advocacy groups, and industry attended the day-long event, focusing on identifying areas of consensus and alignment, as well as raising divergent viewpoints and key issues surrounding physician-industry collaboration.

Moderated by Susan Dentzer of the journal *Health Affairs*, the Summit program consisted of interactive sessions in which thought leaders identified

opportunities and challenges presented by physician-industry collaboration, and began the process of answering some fundamental questions, such as how to determine when collaboration is necessary and appropriate, how compensation is structured, how to minimize conflicts of interest, how to facilitate collaboration and innovation while maintaining healthcare affordability, and how the relationships between industry and collaborating physicians should be appropriately regulated.

The sessions were as follows:

- Framing the Discussion
- Collaboration Opportunities and Challenges
- Current Practices and Gaps
- What Collaboration Means for the Patient
- Role of Government and Other Payers in Physician-Industry Collaboration
- Lessons Learned and Next Steps

The significant level of engagement and discussion from thought leaders across stakeholder groups illustrated a firm desire across disciplines to work together to protect physician-industry collaboration in order to drive innovation and most importantly, advance patient care. The Summit has set the stage for ongoing dialogue and work over the next year ultimately to forge consensus across all stakeholder groups on shared principles and guidelines to guide collaboration, as well as how collaboration produces tangible benefits to public health.

Following is a summary of the key points raised in each session.



Framing the Discussion

The introductory panel laid out the agenda from the day, and featured senior leaders from a sampling of the stakeholder groups at the Summit, including:

- Government – [U.S. Senate Committee on Finance](#)
- Physician inventors – [Fogarty Institute for Innovation](#)
- Pharmaceutical industry – [Pharmaceutical Research and Manufacturers of America \(PhRMA\)](#)
- Medical device industry – [Advanced Medical Technology Association \(AdvaMed\)](#)
- Patient advocate community – [Friends of Cancer Research](#)
- Payers – [Blue Cross and Blue Shield Association \(BCBSA\)](#)
- Medical Societies – [American Osteopathic Association \(AOA\)](#)
- Providers – [Walgreens](#)

The panelists came to consensus on several top-line observations about the collaborative process in healthcare:

- Innovation is critical to improving patient care, and collaboration between industry and the commercial sector is vital to innovation, to training of doctors, including continuing medical education.
- Maintaining public trust is vital to preserving collaboration for the benefit of patients, and that trust has eroded due to a variety of factors.
- Much work needs to be done on balancing the two: continuing to collaborate and innovate, while maintaining public trust by educating the public on the process and becoming more transparent about the collaboration, ultimately to eliminate misunderstandings and negative perceptions on conflicts of interest.



Collaboration Opportunities and Challenges

This panel explored the benefits and challenges of collaboration and how guidelines should be developed and maintained to ensure acceptable standards of collaboration while maintaining forward progress in medical innovation.

The panelists included senior leaders from the following stakeholder groups and institutions:

- Providers – [Cleveland Clinic](#)
- Patient community – [Society for Women's Health Research \(SWHR\)](#)
- Pharmaceutical industry – [Pfizer](#)
- Medical device industry – [Medtronic](#)
- Academia – [University of Virginia](#), [Stanford](#), [Duke](#)
- Providers/Industry – [Fresenius Medical Care North America](#)

Following the panel discussion, a number of thought leaders participated in the discussion, from institutions including:

- Academia – [Vanderbilt](#)
- Pharmaceutical research – [Quintiles](#) (representing Association of Clinical Research Organizations)
- Physician inventors – [Fogarty Institute for Innovation](#)
- Group purchasing organizations (providers) – [MedAssets](#)
- Pharmaceutical industry – [Merck & Company](#)

The participants agreed on the following key points:

- There is value in innovation and the partnerships between healthcare providers and industry are critical; all of this is clearly good for the economy.
- Patient groups, in particular, rely on industry for information and resources that enable them to educate stakeholders in government and advocate for cures and research funding, and also in educating patients about how to manage their treatment. This information also must be clear and understandable for patients.
- Public trust has been eroded, as real and perceived conflicts of interest in episodes of physician-industry collaboration have come to light. Communication with the public about appropriate collaboration is essential. Multiple guidelines and standards for collaboration have been developed, but there are gaps and inconsistencies. There is a need for a cross-stakeholder group such as NDHI to work collaboratively across stakeholder groups to develop consensus-based shared principles to guide appropriate and ethical partnerships.
- Part of the necessary education and outreach is an unbiased history of the extent to which industry/healthcare professional/biomedical research scientist interactions have resulted in therapies – unique drugs or advanced medical devices – that have improved and saved the lives of patients.



Collaboration Opportunities and Challenges (continued)

- There is a need for consistency across disclosure guidelines among industry and academia in order to provide a level of transparency that is understandable to the public/patients who are ultimately making decisions about their own healthcare.
- Consideration should be given to reaching consensus around the guidelines that academic medical centers have in place in order to maintain public trust (such as the divergence on policies with respect to participation in speakers' bureaus, or the difference between treatment of adjunct vs. full-time faculty).
- Collaboration is important in ensuring patient safety because of the need for physicians to work with industry in educating and training healthcare professionals on the safe and effective programming or implantation of products.

Important additional perspectives included:

- In developing principles and guidelines, the "point-of-care" needs to be as objective as possible, must include the perspective of all stakeholders, and should be owned by those domains where patient care and innovation occur.
 - Trusted collaboration will occur when an educated public and government develop an understanding of and cultural tolerance for the existence of inherent conflicts that are managed through principled guidelines. There is also a need for monitoring and accountability around these guidelines.
- The development of guidelines should allow for discussion of five areas: transparency, communication that separates the perception from the reality of the relationships, the need for objective measures for the efficacy of products, an understanding that core research and development can sometimes involve marketing pressures, and an appreciation that applying standards that are unnecessarily and overly restrictive can stifle innovation and lead to an exodus of scientific talent from the United States.
 - A key question in developing guidelines is the threshold at which a physician inventor or discoverer needs to remove him/herself from patient-facing care or evaluation because of his or her financial conflict.
 - Conflicts can arise from indirect collaborations as well as direct ones, such as from industry sponsorship of professional societies.
 - Industry needs to acknowledge excesses that have occurred, and develop lessons learned, as part of enhancing public trust. Collaboration must demonstrate added value for patients and the healthcare system, and not exist solely for financial gain.



Current Practices and Gaps

The second panel examined the policies and standards that currently govern collaboration between physicians and industry, and whether patients/consumers are well served by the status quo. Most important, it focused on how to optimize collaboration to maximize innovation.

The panelists included senior leaders from the following stakeholder groups and institutions:

- Academia – [Vanderbilt](#)
- Medical Societies – [Association of American Medical Colleges \(AAMC\)](#), [American College of Cardiology \(ACC\)](#)
- Providers – [New York-Presbyterian Hospital](#)
- Pharmaceutical industry – [Eli Lilly](#)
- Medical device industry – [Johnson & Johnson](#)

Following the panel discussion, a number of thought leaders participated in the discussion, from institutions including:

- Patient advocate community – [Society for Women's Health Research \(SWHR\)](#)
- Providers – [Cleveland Clinic](#)
- Medical device industry – [Medtronic](#), [ResMed](#)
- Medical Societies – [Council of Medical Specialty Societies \(CMSS\)](#)
- Physician inventors – [Fogarty Institute for Innovation](#)
- Academia – [Stanford](#)

The participants agreed on the following key points:

- Healthcare stakeholders have all been very active in developing their own sets of guidelines and principles regarding collaboration and conflicts of interest, resulting in great variability and inconsistency.
- A first step toward developing a unified, cross-disciplinary set of guidelines, principles and best practices would be to compile a comprehensive inventory of the existing standards that have been developed by various stakeholder groups.
- Once the inventory is established, there is a need to examine them closely and establish actual best practices and gaps that exist.
- Healthcare is in the midst of a major transformation, driven by rapidly developing new scientific technologies, demographic change resulting in an older and more diverse population, and the necessary insistence by public and private payers for evidence that innovation delivers value. Technological and scientific convergence will require more collaboration, not less, in order to achieve the innovation needed to benefit our healthcare system.
- As a result, healthcare stakeholders need to drive innovation in the process for collaborating, by bringing minds together across groups in an open way, such as with regular forums, and sabbaticals for physicians with industry.
- Optimizing collaboration is as much about alignment of interests always for the benefit of patients as it is about eliminating conflict.



Current Practices and Gaps (continued)

- Academic medical centers especially have a responsibility to encourage this sort of principled and optimized collaboration.
- Developing cross-stakeholder guidelines is essential to getting this done.

Additional perspectives included:

- Guidelines should consider providing an oversight mechanism in order to ensure accountability.
- In developing guidelines, stakeholders need to work together in a spirit of accountability and trust.
- If the goal is restoring public trust, any guidelines developed should be analyzed to ensure that they are actually accomplishing that goal.
- Transparency in payments absent context actually can confuse the issue and diminish trust, particularly for patient advocacy organizations that receive support from industry.
- A climate of mistrust regarding collaboration exists among many, especially faculty, driven by unclear or overlapping guidelines, media scrutiny, and lack of context, and this has already diminished collaboration and innovation.
- There are precautions that can be taken to ensure conflicts are managed. For example, some societies have required that board members who vote on scientific conclusions regarding a new therapy or product have no involvement or payments whatsoever with and from industry.
- Outcomes registries can be very helpful in driving collaboration and innovation, by encouraging the adoption of best practices and therapies, and driving evidence-based conclusions.
- Stakeholders are judged as a group, viewed as either physicians or industry, and that is even more incentive to working across disciplines to solve issues related to collaboration.
- In developing principles and guidelines that work across disciplines, it might help to leave the actual specific standards to the individual stakeholders to establish.
- One example of encouraging collaboration that results in innovation is Stanford's successful SPARK program that brings together pharma, biotech, graduate students, venture capital, and faculty regularly to talk about opportunities for transfer of knowledge from academic-developed discoveries into industry.
- Executives in industry and leaders in academic medical centers would rather have their colleagues come to them and ask, "How can I get this done?" as opposed to, "What are the rules that keep me from interacting?"
- CMSS has developed a [code](#) governing interactions between industry and specialty societies that divides those relationships into two camps—direct financial relationships between physicians and industry, and the commercial support of continuing medical education.
- Getting collaboration right is not just about innovation, it's about the role that the U.S. is going to play in that process.



What Collaboration Means for the Patient

During lunch, Summit participants heard firsthand stories on the importance of collaboration from a patient perspective, first from a top leader of a patient advocacy organization, the [Parkinson's Action Network \(PAN\)](#), who made the following central points:

- The patient interest in collaboration is having access to newer treatments faster in terms of the drug development and biomedical research pipeline, as well as better quality of care in terms of ensuring that physicians have access to the greatest amount of and newest information, whether about devices or drugs, so that they can give their patients the best care possible.
- Patients have an expectation, whether realistic or not, that their own physicians, in fact, have access to the best information, and clinical medical education is part of that process.
- There is little public understanding that collaboration in fact does benefit patients.

- Conflicts are unavoidable, the question is how to manage them, and the three keys are disclosure, coupled with guidelines and education of the public, because context is important.
- Industry needs to be honest that profit-making is a significant motive, though clearly not the only motive. Public will not trust industry if it is not honest about this motive.

Subsequently, participants heard from two patients, who described in personal terms the benefits that they have received from innovative products and therapies in treating chronic illnesses.



Role of Government and Other Payers in Physician-Industry Collaboration

The Summit's third session focused on the government's expectations and current areas of concern of payers, with respect to physician-industry collaboration, and how payers, providers and industry can work together to ensure collaboration results in improved patient outcomes.

The panel included senior leaders representing the following stakeholder groups and organizations:

- Government – [Centers for Medicare and Medicaid Services \(CMS\)](#), [Office of the Inspector General of the Department of Health and Human Services \(HHS OIG\)](#), the [U.S. Senate Special Committee on Aging](#), and a former prosecutor from the [U.S. Department of Justice \(DOJ\)](#)
- Payers – [Aetna, Health Care Service Corporation \(HCSC\)](#)
- Pharmaceutical industry – [Novo Nordisk](#)

Following the panel discussion, a number of thought leaders participated in the dialogue, from institutions including:

- Academia – [Institute of Medicine \(IOM\)](#), [Vanderbilt](#), [Stanford](#)
- Medical Societies – [Association of Perioperative Registered Nurses \(AORN\)](#), [Care Continuum Alliance \(CCA\)](#)
- Pharmaceutical industry – [Merck & Company](#), [Iktaria](#)
- Medical device industry – [Johnson & Johnson](#)
- Pharmaceutical research industry – [Quintiles](#) (representing Association of Clinical Research Organizations)

- Medical device industry – [Medtronic](#)
- Payers – [Blue Cross and Blue Shield Association \(BCBSA\)](#)
- Providers – [Walgreens](#)
- Providers/Industry – [Fresenius Medical Care North America](#)

The following central perspectives were offered by panelists and thought leaders:

- Government is deeply skeptical of collaboration, including the financial impact on patients, as well as the conflicts and possible fraud to which it can lead.
- Government is aware of the large public perception problem on the issue of collaboration, and it is feeding demands for more regulation, or an outright ban, despite some positive steps that industry has taken in a short time on issues of conflicts-of-interest. Some regulators and enforcement officials share that view.
- Government as a payer is interested only in collaboration that will advance the “triple aim”: better health, better care, at a better cost, and in improved integration of care and alignment of incentives across stakeholder groups.
- Government and private payers are very interested in promoting collaboration that leads to integrated and coordinated care that delivers better outcomes at lower costs, and integrating and aligning the delivery system to drive quality, affordability, and access.





Role of Government and Other Payers in Physician-Industry Collaboration (continued)

- Law enforcement continues to emphasize removing potential conflicts of interest and preserving unbiased clinical decision-making, and see effective compliance programs and transparency programs as going a long way to achieving these goals.
- Continued areas of concern are payments that camouflage kickbacks, fraud and abuse in CME, and financial conflicts in research.

Additional perspectives included:

- Comparative effectiveness research is an important tool in defining the highest quality and most cost effective ways of delivering care.
- Some payers are driving effective integrated care by establishing well-articulated common goals for treatment, demanding transparency of results, identifying aligned incentives, and successfully integrating advances in health information technology.
- One way industry can address the public perception problem on collaboration is by making technological innovation a more patient-centered process that is integrated across disciplines.
- Many in Washington D.C. are questioning why corporate executives and doctors are not being individually sanctioned when hundreds of millions of dollars in fines are imposed for fraud.
- Some U.S. attorneys want to concentrate on criminal healthcare fraud, and leave “off-label” promotion to the FDA and other regulatory agencies.
- The IOM issued a report last year concluding that disclosure is a necessary floor for providing information to patients, but it is not enough, and there is a need for more research around evidence, and how to calibrate the risk of different types of collaboration in the innovation space.
- IOM has held a number of forums and roundtables on collaboration that have produced summaries of proceedings that can be mined to catalogue and develop best practices around collaboration.
- The healthcare reform law establishes a loosely-defined Accountable Care Organization that might provide a body that can examine how to optimize collaboration from a value perspective.
- Four keys to collaborating to achieve the “triple aim” at the point of care are the leadership role of the physician, the education and empowerment of the patient, the capacity, expansion and infrastructure resources that population health management organizations can bring to the physician office, and developing scientifically based guidelines on best practices.
- Government and payers need to be careful not to confuse cost with value and improvement of care to patients. If the focus is too much on cost at the expense of value, it will strangle innovation, and that will have an adverse impact on both patients and the economy. The emphasis should be on cost-effectiveness rather than cost.



Role of Government and Other Payers in Physician-Industry Collaboration (continued)

- Some providers have implemented effective, value-based purchasing practices by innovating in at least four areas: in services and methods based on comparative effectiveness research, in effective information technology integration, in achieving population management through accountably delivered care, and in aligning payers and providers around payment systems that drive integrated care and better outcomes.
- Collaboration occurs in several different areas: innovation, research, and education and training. A separate area of collaboration involves the promotion of products, which have been known to involve physicians in marketing and the untoward promotion of therapies that aren't evidence-based; this is the form of collaboration that has garnered much public scrutiny and negativity from the public.
- The divergent institutions of the federal government need to develop a unified position on legitimate collaboration, including recognition of the different types of collaboration, to provide clarity on what collaboration is allowed.



Summary and Next Steps

The Summit's final session involved a free-flowing discussion among leaders who contributed as panelists or participants in each of the sessions.

They emphasized many of the earlier points above, and established consensus around the day's key points:

- Innovation in healthcare is critical for both the well-being of patients and the sustainability of the healthcare system, and collaboration is necessary for that innovation to continue.
- Public trust and communication are vital; and substantial work is needed to enhance trust in the collaboration model.
- Maintaining balance is important: continuing to collaborate and innovate, while maintaining public trust by educating the public on the process and becoming more transparent about the collaboration.
- Solving collaboration challenges is an economic imperative for the U.S.

Following the Summit, participants agreed to work within NDHI to continue engagement on this issue in three areas:

- Guidelines & Principles
 - Assemble a thorough inventory of current guidelines and best practices by stakeholder group.
 - Work toward consensus and alignment around clear, cross-disciplinary principles and guidelines on collaboration and transparency.
 - Drive consistency in transparency disclosures across disciplines, such as those mandated by the Sunshine Act.

- Education & Outreach
 - Assemble an honest, neutral, and credible history of successes showing benefits and risks.
 - Conduct research to define and prove the value of collaboration in innovation.
 - Develop a plan for effective public education around collaboration process and benefits to address skepticism and mistrust.
- Improving Innovation
 - Develop innovation in the collaboration/innovation process.
 - “Spark” program as model
 - Sabbaticals of physicians in industry
 - Encourage broader, proactive collaboration across stakeholder groups in a neutral/non-competitive space to work on specific areas of research (the “democratization of innovation”).

Toward that end, NDHI expects to engage smaller working groups beginning in late 2010, to make progress over the next year on these three areas, in order to maximize trust and preserve innovation, both for the benefit of patients and for continued U.S. leadership in the critically important healthcare industry.



Appendix

1. [Summit Agenda](#)
2. [List of Participating Organizations](#)
3. [HLC Members](#)
4. [Resource Materials list](#)



Summit Agenda

Sunday October 3

6:00 – 7:00 p.m. Welcome Reception and Pre-registration (Hamilton Crowne Plaza Hotel)

Monday, October 4

8:00 – 8:30 a.m. **Breakfast - Welcome and Background**

8:45 – 9:30 a.m. **Framing the Discussion**

Strategic Questions:

- How will the day progress?
 - Why is the issue important?
 - What is the definition of collaboration for purposes of the day's discussion?
 - How will everyone be given the opportunity to participate and why is it important that they do?
 - What are the critical dimensions that should be covered today?
-

9:30 – 10:30 a.m. **Session I – Collaboration Opportunities and Challenges**

Strategic Questions:

- Is collaboration necessary?
 - What are the benefits of collaboration to patients?
 - What are the challenges involved in collaboration?
 - What are some real-world examples of collaboration making a difference in outcomes in patient care?
 - How should guidelines be developed and maintained to ensure acceptable standards of collaboration while maintaining forward progress in medical innovation?
-

10:45 – 11:45 a.m. **Session II – Current Practices and Gaps**

Strategic Questions:

- What policies/standards currently govern collaboration between physicians and industry?
 - Is the patient/consumer being well served by the status quo?
 - What are currently the main unresolved issues regarding physician-industry collaboration?
 - What is currently being done to update or upgrade standards?
 - What are the agreements/disagreements in proceeding to optimize collaboration principles?
 - What role should different sectors – industry, professional societies, payers, government – play in ensuring or encouraging adherence to collaboration principles?
 - What are the conflicts or perceived conflicts that arise from collaboration?
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Summit Agenda (continued)

Noon – 12:45 p.m. Lunch - What Collaboration Means for the Patient

1:00 – 2:00 p.m. Session III – Role of Government and Other Payers in Physician-Industry Collaboration

Strategic Questions:

- What are the expectations of government as a payer, with respect to physician-industry collaboration?
- Is collaboration vital to medical innovation and should it be encouraged?
- How should payers, providers and industry work together to ensure collaboration results in improved patient outcomes? What do payers see as areas of concern?
- What is working well in physician-industry collaboration and what are current areas of concern?
- How can current government efforts be leveraged to address ongoing concerns?
- Are there specific “best practices” taking place that payers and/or regulators would like to see replicated?

2:15 – 3:30 p.m. Session IV – Lessons Learned from the Day and Next Steps

3:30 – 4:00 p.m. Closing Remarks

** All sessions are open discussion. In addition to designated moderators and contributors, participation by all thought leaders in attendance is encouraged.*



Participating Organizations

-A-

- AdvaMed
- Aetna
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American College of Cardiology
- American College of Surgeons
- American Osteopathic Association
- American Psychiatric Association
- America's Health Insurance Plans
- Amerinet, Inc.
- AmerisourceBergen
- Arnold & Porter LLP
- Association of American Medical Colleges
- Association of Clinical Research Organizations
- Association of Community Cancer Centers
- Association of periOperative Registered Nurses
- Avenue Solutions

-B-

- Baylor Health Care System
- BlueCross BlueShield of Tennessee
- Blue Cross Blue Shield Association

-C-

- Cardinal Health
- Care Continuum Alliance
- Centers for Medicare and Medicaid Services
- Cleveland Clinic
- Coalition for Healthcare Communication
- Cook Medical
- Council of Medical Specialty Societies
- CVS Caremark

-D-

- Davidson College
- Duke Clinical Research Institute
- Duke University Medical Center

-E-

- Edwards Lifesciences
- Eli Lilly and Company

-F-

- FasterCures
- FMOL Health System
- Fogarty Institute for Innovation
- Fresenius Medical Care North America
- Friends of Cancer Research

-H-

- Health Affairs
- Health Care Service Corporation
- Healthcare Leadership Council
- Heart Rhythm Society

-I-

- Ikaria
- Institute of Medicine of the National Academies

-J-

- Johnson & Johnson

-L-

- Lahey Clinic





Participating Organizations (continued)

-M-

MedAssets, Inc.

Medtronic, Inc.

Men's Health Network

Merck & Company, Inc.

-N-

National Organization for
Rare Disorders

New York-Presbyterian Hospital

Novartis

Novo Nordisk

-O-

Office of the Inspector General,
Department of Health and Human
Services (HHS OIG)

-P-

Parkinson's Action Network

Pfizer, Inc.

Pharmaceutical Research and
Manufacturers Association
(PhRMA)

Premier Healthcare Alliance

-Q-

Quintiles

-R-

Research!America

ResMed

Rockpointe

Ross Group, The

-S-

sanofi-aventis

SCAN Health Plan

Society for Women's
Health Research

Stanford University
School of Medicine

-U-

U.S. Senate Committee on Finance

U.S. Senate Special Committee
on Aging

University of Virginia

-V-

Vanderbilt University

VHA, Inc.

-W-

Walgreens

Within3





Members of the Healthcare Leadership Council

-A-

Abbott
Aetna
Amerinet
AmerisourceBergen
Aptuit
Ascension Health
AstraZeneca, US

-B-

Baylor Health Care System
BlueCross BlueShield of Tennessee

-C-

Cardinal Health
CareFusion
Cleveland Clinic Foundation
Covidien
C.R. Bard
CVS Caremark

-E-

Eli Lilly and Company

-F-

Franciscan Missionaries of Our Lady
Health System, Inc.
Fresenius Medical Care

-H-

Health Care Service Corporation
Healthways

-I-

Ikaria

-J-

Johnson & Johnson

-L-

Lahey Clinic

-M-

Marshfield Clinic
Mayo Clinic
McKesson Corporation
MedAssets, Inc.
Medtronic, Inc.
MemorialCare Health System
Merck & Company, Inc.

-N-

New York-Presbyterian Hospital
NorthShore University
HealthSystem
Novartis Pharmaceuticals
Novo Nordisk, Inc.

-P-

Pfizer, Inc.
Premier, Inc.

-R-

ResMed

-S-

sanofi-aventis
SCAN Health Plan
SCHOTT North America

-T-

Texas Health Resources
Theragenics

-V-

Vanderbilt University
School of Nursing
VHA, Inc.

-W-

Walgreens





Resource Materials

Note: *These materials were submitted by participants in the Summit as recommended resources on the topic of physician-industry collaboration. In the event others would like to recommend additional articles, please email Debbie Witchey at dwitchey@hlc.org.*

Medical Research and Innovation

- [Measuring the Gains from Medical Research: An Economic Approach](#) by Kevin M. Murphy and Robert H. Topel
 - A preview of the first 45 pages of the book is available on Google Books (see link)

Codes

- [American College of Cardiology Industry Relationships and Code of Ethics](#)
 - [Principles for Relationships with Industry](#)
 - [Code of Ethics](#)
 - [Partnership Policies for the CardioSmart National Health Initiative](#)
- [Accreditation Council for Continuing Medical Education \(ACCME Policies\)](#)
 - [ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities \(“SCS”\)](#) (updated 2004)
 - [ACCME® Accreditation Policies including Information for Provider Implementation](#)
- [AdvaMed Issues & Advocacy Materials](#)
 - [AdvaMed’s Board-Approved Disclosure Positions](#) – Physician Payment Disclosure Legislation
 - [AdvaMed’s Sunshine One-Pager](#) – Physician Payment Disclosure Legislation
 - [Code of Ethics on Interactions with Health Care Professionals](#) (July 1, 2009)

- BIO Press Release and Statement in Support of PhRMA’s revised Code on Interactions with Healthcare Professionals (February 19, 2009)
 - [BIO Encourages Its Members to Adopt Code of Conduct to Govern Interactions With Healthcare Professionals. Members Should Maintain “Highest Standards” For Ethical Business Practices Related to Interactions](#)
- [Council of Medical Specialty Societies Policies and Positions](#)
 - [AMA CEJA I A 10 CMSS Comments](#) (June 9, 2010)
 - [Code for Interactions with Companies](#)
 - [Ethics Statement](#)
- [PhRMA Principles and Guidelines](#)
 - [Revised Clinical Trial Principles Reinforce PhRMA’s Commitment To Transparency and Strengthen Authorship Standards](#)
 - [Principles on Conduct of Clinical Trials: Communication of Trial Results](#)
 - [Code of Interactions with Healthcare Professionals](#)

Conflicts of Interest

- [ACRE Response to NIH Proposed COI and Transparency Policy](#) (posted by Thomas Sullivan as published on Policy and Medicine, July 22, 2010)
- [AHA Ban on Industry Posters and Presenters: Conflict of Interest Run Amuck?](#) (posted by Thomas Sullivan as published on Policy and Medicine, June 17, 2010)





Resource Materials (continued)

- [Association of American Medical Colleges](#) (link to AAMC's list of publications)
 - [In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making](#) (June 2010)
 - [Protecting Patients, Preserving Integrity. Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research](#) (February 2008)
 - [Protecting Subjects, Preserving Trust, Promoting Progress II](#) (October 2002)
 - [Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research](#) (December 2001)
- [ASCO Requests Changes to the NIH Proposed Conflict of Interest Rules: Unrealistic to Request Investigators to Reduce or Eliminate all COI's](#) (posted by Thomas Sullivan as published on Policy and Medicine, August 25, 2010)
- [Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers](#)
 - The Journal of the American Medical Association (JAMA. 2006; 295: 429-433)
 - Authors: Troyen A. Brennan, M.D., M.P.H.; David J. Rothman, Ph.D.; Linda Blank; David Blumenthal, M.D., M.P.P.; Susan C. Chimonas, Ph.D.; Jordan J. Cohen, M.D.; Janlori Goldman, J.D.; Jerome P. Kassirer, M.D.; Harry Kimball, M.D.; James Naughton, M.D.; Neil Smelser, Ph.D.
- [Institute of Medicine of the National Academies, Conflict of Interest in Medical Research, Education and Practice](#)
 - Released on April 21, 2009
 - Authors Bernard Lo and Marilyn J. Field, Editors
 - Link to online report: http://books.nap.edu/openbook.php?record_id=12598
- [Is the Campaign on Conflict of Interest In Medicine an Attack on Patient Rights?](#) (posted by Thomas Sullivan as published on Policy and Medicine, August 19, 2010)
- [Managing Financial Conflict of Interest in Biomedical Research](#)
 - Author: Sally J. Rockey, Ph.D. and Francis S. Collins, M.D.
 - Published in the Journal of American Medical Association (May 24, 2010)
- [University of Minnesota: Conflict of Interest Policy in Patient Care](#) (posted by Thomas Sullivan as published on Policy and Medicine, August 6, 2010)

Industry Collaboration

- Activities Concerning the Interactions between Private Industry and Medical Practice, Medical Education and Medical Innovation
 - Author: Thomas P. Stossel – includes list of writings on this topics



Resource Materials (continued)

- [Partners Commission on Interactions with Industry – Report, April 2009](#)

- Partners Healthcare, Founded by Brigham and Women's Hospital and Massachusetts General Hospital

Federal Policy, Legislation and Congressional Testimony

- [Examining the Relationship between the Medical Device Industry and Physicians: Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs](#)

- Office of Inspector General, Department of Health and Human Services
- February 27, 2008, 10:30 a.m., 628 Dirksen Senate Office Building

- [Final Health Care Reform Sunshine Language](#) – Transparency Reports and Reporting of Physician Ownership or Investment Interests

- [“Physician Payments Sunshine Act of 2009”](#) – text of Sens. Grassley-Kohl Bill

- [The Role of Medical Liability Reform in Federal Health Care Reform](#)

- The New England Journal of Medicine (NEJM, 361;1 - July 2, 2009)
- Authors: Michelle M. Mello, J.D., Ph.D., M.Phil., and Troyen A. Brennan, M.D., J.D., M.P.H.

- A Comprehensive Case Management Program to Improve Palliative Care

- Authors: Claire M. Spettell, Ph.D., Wayne S. Rawlins, M.D., M.B.A., Randall Krakauer, M.D., Joaquim Fernandes, M.S., Mary E.S. Breton, B.S., J.D., Wayne Gowdy, B.S., Sharon Brodeur, R.N., B.S., M.P.A., Maureen MacCoy, B.S.N., M.B.A., and Troyen A. Brennan, M.D., M.P.H.
- Published in Journal of Palliative Medicine (Volume 12, Number 9, 2009)

- Opportunities to Improve the Quality of Care for Advanced Illness: An Aetna Pilot Program Shows How It Can Be Done

- Authors: Randall Krakauer, Claire M. Spettell, Lonny Reisman, and Marcia J. Wade
- Published in Health Affairs, Perspective: Quality (Volume 28, Number 5)

- Translating Research into Practice: Transitional Care for Older Adults

- Authors: Mary D. Naylor Ph.D., R.N., Penny Hollander Feldman Ph.D., Stacen Keating Ph.D. R.N., Mary Jane Koren M.D. M.P.H., Ellen T. Kurtzman M.P.H. R.N., Maureen C. Maccoy M.B.A., R.N. and Randall Krakauer M.D. FACP FACR
- Published in Journal of Evaluation in Clinical Practice (July 15, 2009)

Case Studies – Patient Care

- [Case Study: Aetna's Embedded Case Managers Seek to Strengthen Primary Care](#)

- Author: Martha Hostetter
- Published in Quality Matters, August/September 2010