

Innovation in the Interest of Society

Institute of Medicine

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www.hlc.org



What is in the Patient's Best Interests?

- Continuous improvements in medical treatments and technologies
- Constant evaluation of safety and efficacy of drugs and devices
- Physicians apprised of new healthcare innovations
- Knowing the relationships between physicians and industry
- Understanding the context, benefits of those relationships



The Impact of Physician-Industry Collaboration



Implantable Cardioverter-Defibrillators (1985)

Pacemaker (1963)



Coronary stent (1987)



Cervical disc (2007)

Benzodiazepines (1960)

Penicillin (1939)

Heart and lung bypass machine (1953)



Statins (1971)

Fluorouracil (1962)

Neupogen (1991)



Deep brain stimulation (1987)

Decades of Health Improvement

Patient Benefits: Reduction in deaths & disease

- 40% decline in mortality resulting from coronary heart disease (1980 and 2000)
- 30% decline in the overall hospitalization rate for heart failure (1998-2008)
- 50% reduction in U.S. AIDS deaths (1995-1996)
- 55% reduction in hospital mortality from acute myocardial infarction (1975-1995)
- 90% reduction in Hib-related meningitis and other diseases in the U.S. (1975-1995)

Economic Benefits

- 30-year gain in life expectancy (age 46 versus age 76) over the 20th century is worth more than \$1.2 million per person in the current population
- From 1970-2000, gains in life expectancy added \$3.2 trillion per year to national wealth
- A 10% reduction in all cause mortality over 30 years has a value of over \$18.5 trillion



Physician-Industry Relationships Receive Scrutiny

The New York Times

Payments to Doctors by Pharmaceutical Companies
Raise Issues of Conflicts

Published: November 24, 2011

The New York Times

Health Guideline Panels Struggle with Conflicts of
Interest

Published: November 2, 2011

**Billings
Gazette**

Payment debate: Health care workers defend
their payments from drug companies

November 20, 2011 12:00 am

HARVARD LAW SCHOOL

At HLS, former investigator questions the
relationship between physicians and
pharmaceutical industry

October 04, 2011

**American Medical
Association
News**

Critics rap delay in doctor-payment reporting rules

Nov. 14, 2011.



REUTERS

Million-dollar payments to surgeons raise
questions

Oct 24, 2011 5:20pm EDT



Piercing the Veil, More Drug Companies
Reveal Payments to Doctors

Sept. 7, 2011, 4:31 p.m.



Financial Ties Bind Medical Societies to
Drug and Device Makers

May 5, 2011, 8:48 p.m.

The Next Stage in Transparency: Sunshine Act

- August 1, 2013:
 - Manufacturers begin collecting, tracking data
- By March 31, 2014:
 - Manufacturers report data to CMS
- September 30, 2014:
 - CMS releases data to public on website



The Critical Importance of Context

- Payment data without context can lead to:
 - Negative presumptions about payments to physicians
 - Fewer physicians engaging in clinical trials, educational conferences, scientific advisory board meetings
 - An impact on dissemination of medical information
 - A ‘witch hunt’ for highest physician payment levels



Are Patients Well Served When...

- ...sharing of information is restricted because of concerns over potential conflicts?
- ...academic institutions wall themselves off from relationships with industry?
- ...the potential of research is limited by avoidance of any conflict of interest?



The National Dialogue for Healthcare Innovation

- Convened Summit on Physician-Industry Collaboration
 - More than 100 high-level representatives from across healthcare sector
- Achieved consensus on the following:
 - Innovation is critical, and collaboration is necessary for innovation to continue
 - Substantial work needed to enhance trust in the collaboration model
 - Continuing to collaborate and innovate, while maintaining public trust and becoming more transparent is important
 - Solving collaboration challenges is an economic imperative for the U.S.
- Formed two cross-sector working groups to:
 - Draft consensus statement on Principles to guide collaboration
 - Develop outreach & education plan to educate key stakeholders



The Keys to Principled Collaboration

Four principles to guide appropriate collaboration:

The Benefit of Patients

Collaborations must aim to benefit patients and put patients' interests first

Autonomy of Healthcare Professionals

Free to assess independently multiple sources of information and treat each patient in a manner consistent with the patient's needs and best medical practice

Transparency

Reasonable access to relevant and meaningful information about how academic institutions, researchers, healthcare professionals and medical products companies engage in collaborative relationships.

Accountability

All participants across healthcare must be responsible for their actions; internal self-regulation with recurrent training and communication is essential.

Developed and endorsed by the following organizations:



The Keys to Principled Collaboration

Four principles to guide appropriate collaboration:

**The Benefit of
Patients**

**Autonomy of
Healthcare
Professionals**

Transparency

Accountability

Additional Endorsements:

- Alliance for Aging Research
- American Association of Neurological Surgeons
- American College of Osteopathic Neurologists and Psychiatrists
- Association of Clinical Research Organizations
- College of Neurological Surgeons
- Federation of State Medical Boards
- Johnson & Johnson
- Kansas Association of Osteopathic Medicine
- Men's Health Network
- Merck & Co.
- Pfizer
- Society for Women's Health Research
- South Carolina Osteopathic Medical Society
- Stryker
- Vanderbilt University School of Nursing
- WomenHeart

Individual Endorsements:

- Dennis Ausiello, M.D. (Harvard Medical School and the Massachusetts General Hospital)
- Eugene Braunwald, M.D. (Harvard Medical School and Brigham & Women's Hospital)
- William N. Kelley, M.D. (University of Pennsylvania School of Medicine)
- Ralph Snyderman, M.D. (Duke University School of Medicine)
- Bruce Wilkoff, M.D. (Cleveland Clinic)

Moving Forward

- It is in society's interest to encourage healthcare innovation
- Physician-industry collaboration is critical to medical progress
- Transparency in physician-industry relationships is essential
- Information must be provided with context as to patient, healthcare system benefits



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