
March 11, 2013
Noon – 1:30 p.m. ET
U.S. Capitol Visitor Center (HVC 201)
Washington, DC
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
Under Critical Review & 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

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

Harvard Law School
At HLS, former investigator questions the relationship between physicians and pharmaceutical industry
October 04, 2011

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.
How Physician-Industry Collaboration Transformed Our World

- Penicillin (1939)
- Benzodiazepines (1960)
- Pacemaker (1963)
- Heart and lung bypass machine (1953)
- Fluorouracil (1962)
- Statins (1971)
- Deep brain stimulation (1987)
- Coronary stent (1987)
- Neupogen (1991)
- Implantable Cardioverter-Defibrillators (1985)
- Cervical disc (2007)
Why Collaboration is Important

**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)
- 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
Panelists

- David Caraway, MD, PhD, St. Mary’s Medical Center

- Guy Chisolm, PhD, Director, Innovation Management and Conflict of Interest Program, Cleveland Clinic

- Ryan M. Hohman, JD, MPA, Managing Director, Policy & Public Affairs, Friends of Cancer Research
A Joint Statement on 21st Century Collaboration for Healthcare Advancement

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:
A Joint Statement on 21st Century Collaboration for Healthcare Advancement

Four principles to guide appropriate collaboration:

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**Additional Endorsements:**

- Alliance for Aging Research
- American Association of Neurological Surgeons
- American College of Cardiology
- 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)
Principled Physician-Industry collaboration is important to patient-centered innovation

Patients and the economy benefit from this collaboration

We are building consensus around preserving principled collaboration

Patient-centered innovation requires principled collaboration, relationship transparency, focus on patient benefits

Sunshine provisions are a starting point and should be monitored; they may require refinement to maintain principled collaboration and medical innovation
Q&A

Physician Perspective

David L. Caraway, M.D., Ph.D.
St. Mary’s Regional Medical Center
Huntington, WV

"Life is like riding a bicycle. To keep your balance you must keep moving." - Albert Einstein
Physician – Industry Interactions

“Constructive collaboration”

- Innovation
- Education
- Research
- Safety
- Support
- Access
Physician – Industry Interactions

Education

• Direct instruction by KOL
  • FDA regulatory compliance
• Indirect by disseminating studies /updates
  • Content development
• Unrestricted grants for CME

IMPROVED OUTCOMES
Physician – Industry Interactions

Research
• Development, coordination and support of high level evidence
• Clinical Trials, IIT
  • Efficacy/Safety
• Regulatory
• Publication
Physician – Industry Interactions

Safety

• Development and participation in reporting mechanisms such as registries.
• Improved Techniques
• Patient Selection
Physician – Industry Interactions

Characteristics of physicians who participate in beneficial collaborations with Industry:

• Knowledge of the disease state
• Reputational, personal stake in the field
• See development, teaching and success of a product as key to improving patient care
Industry Interactions with Academic Medicine

Guy M. Chisolm, III, Ph.D.

Vice Chair, Lerner Research Institute
Director, Innovation Management & Conflict of Interest Program
Professor, Department of Cellular and Molecular Medicine
Cleveland Clinic
Challenges facing academic biomedical science

• Low payline at NIH

• Need at Universities for new avenues of funding
  [ eg, commercialization of IP, more aggressive philanthropy, … ]

• Intensification of government regulatory activities
  [ radioisotopes, recombinant DNA, carcinogens, biohazards, viral constructs, drugs, animals, human subjects, effort reporting, expense validation, and CoI ]
Cleveland Clinic

• Founded 1921 as one of world’s 1st non-profit group practices
• $6 billion annual revenue
• 42,000 employees
• Over $10 billion in economic impact to the State of Ohio
• 4.3 million clinical visits
• 2,800 employed physicians
• 1,100 residents/fellows
• $250 million research activity
• More than $660 million in state and local taxes
• Ranked 4th best hospital in the U.S*

* according to U.S. News Report
Innovation @ Cleveland Clinic

February 24, 2015

CHRIS COBURN, GUY CHISOLM
Cleveland Clinic Innovations

- Top 4 in world in Healthcare Corporate Venturing*
- Top 5 most innovative companies in HealthCare**
- 1800 patent applications, 425 issued patents in portfolio
- 450 product licenses
- 55 spin-off companies
- 65 FTEs – One of the largest in the US
- More than $650M in equity investment
- $160M commercialization grants
- Nearly 1000 jobs created

* Source: Global, Corporate, Venturing

** Source: Fast Company
Why a Commercial Focus?

• Improve the lives of patients
• Make Cleveland Clinic more innovative
• Recruit, retain and reward the highest performing staff
• Aid economic renewal of Cleveland
Cluster headache is one of the most painful types of headache. Associated with excruciating pain typically in the area of one eye.

"Current preventive treatments are often ineffective, and in many patients acute and preventive treatments may not be tolerated or are contraindicated." (Prof. Dr. Jean Schoenen, Prof Functional Neuroanatomy and coordinator of the Headache Research Unit at University of Liege in Liege, Belgium)

The ATI Neurostimulation System -- a novel, miniaturized device implanted using oral surgery, no externally scars. When patients feels cluster attack beginning, they hold a remote controller to their cheek to begin the neurostimulation therapy.

SOURCE: ATI Website
Autonomic Technologies

- Migraine & Cluster treatment device
- $57 million raised
- European sales underway
- US trials start 2013

- $5 M series A financing
  - KP

- Full operations

- $20M Series B
  - KP, Versant, InterWest, CC

- First in man

- $32M Series C
  - Novartis, Aberdare
  - 55 FTEs
Pain relief at 15 minutes was achieved in 67.1% of treated attacks compared to 7.4% of sham treated attacks (p<0.0001)

Pain freedom at 15 minutes was achieved in 34.1% of treated attacks compared to 1.5% of sham treated attacks (p<0.0001)

The average number of cluster attacks per week was reduced by 31% (p=0.005), and 43% of patients experienced an average reduction of 88% in the number of attacks suffered

64% of patients experienced clinically significant improvement in headache disability (HIT-6)

75% of patients experienced clinically significant improvements in quality of life (SF-36v2 physical and/or mental component scores)

Acute rescue medications were used in only 31.0% of treated attacks compared to 77.4% of sham treated attacks (p<0.0001), a reduction of 60%

The ATI Neurostimulation System was well tolerated, and side effects were comparable to other similar surgical procedures and tended to be transient
With Industry collaborations comes obligations to mitigate bias

In 2005, we crafted robust policies to identify, disclose and manage conflicts of interest

We instituted web-based transparency …

In 2008, we created public disclosure webpages to reveal industry ties of our ~3,000 physicians and scientists
“Patients deserve easy access to information about their doctors’ relationships with drug companies, and the Cleveland Clinic is making that possible.”

--Senator Charles E. Grassley, R-Iowa

Generated 1,300 positive stories over 12 days

--NEJM, Lancet, Science, Nature,…
CONFLICT OF INTEREST
Sample CoI Management Plan Elements

- Disclosure in manuscripts & presentations
- Disclosure in informed consent forms
- Independent research subject selection/consent
- Independent data audit
- Data collection, analysis limitations
- External data safety monitoring
- Purchasing restrictions
- Compliance with the plan & periodic review
- Other prohibitions, limitations…
A few bottom line issues for Cleveland Clinic...

• We wish to continue to be an innovative organization

• We know we can bring discoveries to benefit patients by partnering with industry

• We’re committed to doing this effectively and ethically

Ryan M. Hohman, JD, MPA
Managing Director, Friends of Cancer Research
Good policy regarding the suitability of communication and collaboration needs to begin with the desired impact on the end user: patients and their physicians and the decisions being made at the point of care.
Collaboration Across All Sectors is and Always Will be Vital to Getting *Patients* the Best Treatment

- At the point of diagnosis there is so much that a patient has to deal with for the first time in their life ...

- Making sure they have the best evidence-based information to support make these life changing decisions upon is critical.

- Collaboration = Education
NDHI Principles for 21st Century Collaboration

• Broad and diverse composition of the group and the process for developing.

• Promote broadly the importance of collaboration for patients and for life-enhancing treatments.

• Important to all sectors represented by our initial group including the patient advocacy community.

• This set of principles on physician-industry collaboration, emphasizes the critical importance of patient-centeredness, transparency and independence.
A Unique Model to Advance Biomedical Research

• Each year Friends of Cancer Research (Friends) convenes conferences, forums and working groups, to address critical issues in the research, development and delivery of new drugs.

• These annual venues bring together leaders from federal health and regulatory agencies, academic research centers, patient advocacy organizations and the private sector to propose consensus solutions and develop a clear path forward on critical issues surrounding the development and regulation of drugs and therapies.

• Through our unique collaborative model, we have created a path to better drug development and approval through scientific, cultural, regulatory and legislative solutions.
“I’m optimistic that, working in partnership with the private sector, we can create a new paradigm that will provide the public with new and more effective treatments far faster than we do now. We simply cannot sit around and wait for the next blockbuster drug.”

- Dr. Francis Collins, Director, National Institutes of Health *