



NATIONAL DIALOGUE FOR  
Healthcare Innovation

# *Healthcare Innovation and Progress in a Sunshine Era: Establishing Principles for 21st Century Collaboration*

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



An Initiative of 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



# 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

November 20, 2011 12:00 am

## HARVARD LAW SCHOOL

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

October 04, 2011



Financial Ties Bind Medical Societies to Drug and Device Makers

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



Critics rap delay in doctor-payment reporting rules  
Nov. 14, 2011.



Million-dollar payments to surgeons raise questions

Oct 24, 2011 5:20pm EDT



Piercing the Veil, More Drug Companies Reveal Payments to Doctors

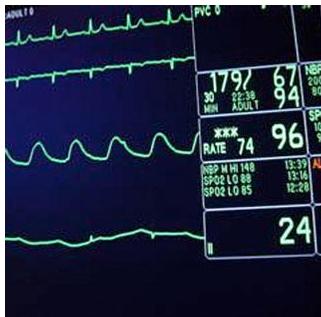
Sept. 7, 2011, 4:31 p.m.

# How Physician-Industry Collaboration Transformed Our World



Penicillin (1939)

Heart and lung bypass machine (1953)



Pacemaker (1963)

Benzodiazepines (1960)

Fluorouracil (1962)

Implantable Cardioverter-Defibrillators (1985)



Coronary stent (1987)

Deep brain stimulation (1987)



Cervical disc (2007)



Neupogen (1991)

Statins (1971)

# 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)
- 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 20<sup>th</sup> 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 21<sup>st</sup> 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 21<sup>st</sup> Century Collaboration for Healthcare Advancement

*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 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 Snydeman, M.D. (Duke University School of Medicine)
- Bruce Wilkoff, M.D. (Cleveland Clinic)

# In Closing

**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**





NATIONAL DIALOGUE FOR  
Healthcare Innovation

# Q & A

An Initiative of the



# Healthcare Innovation and Progress in a Sunshine Era: Establishing Principles for 21st Century Collaboration

## 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 Col ]

# 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 4<sup>th</sup> 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: 

# 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

# Autonomic Technologies

Cluster headache is one of the most painful types of headache. Associated with excruciating pain typically in the area of one eye.

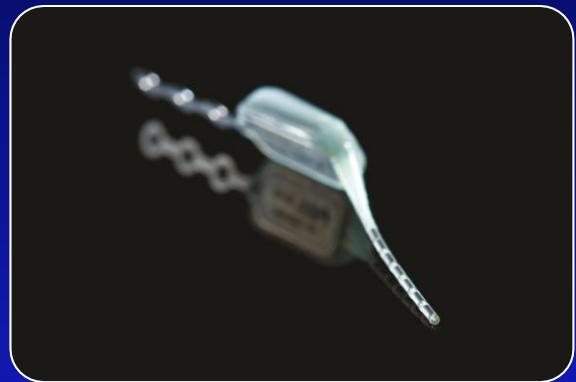
"Current preventive treatments are often ineffective, and in many patients acute and preventive treatments may not be tolerated or are contraindicated." (Prof. Dr. Jean Schoenen, Prof Functional Neuroanatomy and coordinator of the Headache Research Unit at University of Liege in Liege, Belgium)

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



# Autonomic Technologies: ATI Neurostimulation System

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

# NYT – Conflict of Interest Article

“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,...

## The New York Times

WEDNESDAY, DECEMBER 3, 2008



Dr. Viktor Krebs telling a patient, Sara Schwab, of his business ties to a product he will be using in her knee operation.

## Doctors Show Their Hand

### Cleveland Clinic Takes Steps to Disclose Conflicts of Interest

BY REED ABELSON

The Cleveland Clinic plans to announce this week it has begun publicly reporting the business relationships that any of its 1,800 staff doctors and scientists have with drug and device makers.

The clinic, one of the nation's most prominent medical research centers, is making a complete disclosure of doctors' and researchers' financial ties available on its Web site, [www.clevelandclinic.org](http://www.clevelandclinic.org).

It appears to be the first such step by a major medical center to disclose the industry relationships of individual doctors. And it comes as the nation's doctors and hospitals are under increasing pressure to address potential financial conflicts of interest that can occur when they work closely with companies to develop and research new drugs and devices.

The Cleveland Clinic's Web postings are the most recent part of a multi-front effort at the clinic after some of its leading doctors came under fire last year when the news media disclosed some of their financial links.

“They are breaking a new path here,” said Dr. David J. Rothman, the president of the Institute of Medicine as a Profession, a nonprofit group based in Columbia University that studies potential conflicts of interest.

In American medicine, doctors' links to industry are often hidden from public view. And critics argue that those relationships can hurt the integrity of clinical research and patient care. In one of the most recent controversies, a highly regarded and influential psychiatrist at Emory University, Dr. Charles B.

#### Out in the Open

Doctors and researchers at the Cleveland Clinic are disclosing their ties to medical companies to avoid hidden conflicts of interest.

Cleveland Clinic staff doctors and researchers

Receive more than \$5,000 a year from at least one company

400  
280  
1,600

#### COMPANIES WITH THE MOST RELATIONSHIPS

	Clinic Doctors
Pfizer	24
Sanofi-Aventis	21
Merck	20
Novartis	19
Medtronic	16
GlaxoSmithKline	12
Stryker	10
Wyeth	10

THE NEW YORK TIMES

Nemecoff, drug executive in October for failing to disclose at least \$1 million in consulting fees from drug makers.

Senator Charles E. Grassley, Republican of Iowa, has brought Congressional scrutiny to the issue and introduced legislation that would require drug and device makers to divulge the payments they make to doctors. In a statement, Sena-

Continued on Page 8

# CONFLICT OF INTEREST

## *Sample Col 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

# Healthcare Innovation and Progress in a Sunshine Era: Establishing Principles for 21st Century Collaboration

*Ryan M. Hohman, JD, MPA*

*Managing Director, Friends of Cancer Research*



# National Dialogue for Healthcare Innovation

*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 \**

\*Yale Journal of Medicine and Law, April, 2009 Vol. VII, Issue 2