

Managing Industry Interactions with Academic Medicine

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Conflict of Interest and Medical Innovation:
Assuring Integrity while Facilitating Innovation

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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 now Col]

Why a Commercial Focus?

- Improve the lives of patients
- Make Cleveland Clinic more innovative
- Recruit, retain and reward the highest performing staff
- Secure resources to enable reinvestment
- Aid economic renewal of Cleveland

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:



Factors driving innovation in academia...

- An innovative faculty
- Leadership support for innovation
- Leadership support for Col management
- ‘Buy in’ from faculty for Col management
- Col program with a ‘service’ mentality

Process for identifying, addressing Col...

- Examine every funded grant for Col
(aims, investigators, companies)
- Work directly w/ each investigator
(define regs, policies; create CMP)
- Take some of the burden of compliance
from faculty

Management of identified, approved Col...

Goal: Separate the possible influence of industry \$\$ from...

- the integrity of data,
- the validity of research decision-making and
- the well-being of research subjects

Management of identified, approved Col...

- Broad disclosure
- Reassignment of data analysis
- Read-only access to data; other restrictions
- Independent data audit
- Indep approval of subject selection, consent
- External DSMB
- Purchasing restrictions
- Trainee protection
- Authorship limitations

New NIH regulations: pros and cons for innovation

Pros: The institution decides FCOIs; Public Disclosure

Cons: Extra work and resources for uncertain benefit (lower threshold; monitoring industry-sponsored travel)

AAMC: gathering metrics to measure the impact

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, salaried physicians
- 1,400 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



June 6, 2013

CHRIS COBURN, GUY CHISOLM

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

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.”

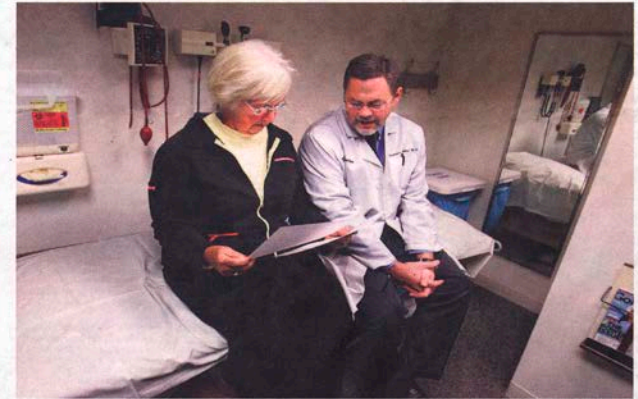
--Senator Charles E. Grassley, R-Iowa

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.

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 mounting 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.

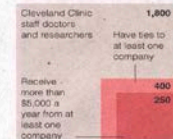
The Cleveland Clinic's Web postings are the most recent part of a conflict-of-interest effort at the clinic after some of its leading doctors came under fire several years ago when the news media disclosed some of their financial links.

"They are breaking a new path here," said Dr. David J. Rothman, the president of the Institute on Medicine as a Profession, a nonprofit group based at 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 such relationships can taint the integrity of medical 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.



Source: Estimates by the Cleveland Clinic

COMPANIES WITH THE MOST RELATIONSHIPS	
Company	Clinic Doctors
Pfizer	24
Sanofi-Aventis	21
Merck	20
Novartis	19
Medtronic	16
GlaxoSmithKline	12
Stryker	10
Wyeth	10

THE NEW YORK TIMES

Neimoff, drew criticism 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-

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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...