

The Emergence of Institutional Gift Bans and Disclosure Requirements

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2nd Annual Summit on Disclosure, Transparency and Aggregate
Spend for Drug, Device and Biotech Companies

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My focus for today's remarks...

Approaches to transparency at Cleveland Clinic

Public disclosure of faculty-industry ties by government, industry and academia

Value and risks of disclosure

What is the pattern of infractions cited for industry-academia ties?

A dominant theme...

-- failure to disclose --

A case in point: NEJM: disclosure discrepancies in physicians' presentations at 2008 annual meeting of the American Academy of Orthopaedic Surgeons

“The most notable finding of our study, however, was the high rate of nondisclosure. A total of 20.7% of directly related payments and 50.0% of indirectly related payments received during the 2007 calendar year were not disclosed, despite instructions directing each participant to make a disclosure “if he or she has received something of value from a commercial company or institution, which relates directly or indirectly to the subject of their presentation.”⁴⁰ The size of these undisclosed payments was substantial: the 43 directly related payments that were not disclosed totaled \$4,320,563, and the 16 indirectly related payments that were not disclosed totaled \$7,772,105.”

Okike, K, et al. Accuracy of conflict-of-interest disclosures reported by physicians. NEJM 362:1466-74, 2009

Disclosure Websites...

- Federal -- US Att'y Gen'l's settlement with 5 device mfgs
- Federal -- Grassley & Kohl's "Sunshine Act"
- States -- Massachusetts, Minnesota, Vermont...
- Companies -- Eli Lilly, Merck, Pfizer, Edwards, GSK, Medtronic, AstraZeneca...
- AMCs -- Cleveland Clinic (went live, 10/08)
U of Pennsylvania (8/09), Stanford (8/09), U of Iowa (10/09), others?

Go to www.clevelandclinic.org

Click on 'FIND A DOCTOR'

“Search by Doctor's Last Name”

(TIP: Try just the first few letters.)

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- * Industry Relationships

Biographical Sketch

- **Current Positions:** Dr. Chisolm is currently Vice Chairman of the Lerner Research Institute of Cleveland Clinic, where he is a Professor of Cell Biology. He also holds active secondary professorships in the Cleveland Clinic Lerner College of Medicine (CCLCM) of Case Western Reserve University, Kent State University and Cleveland State University. He is also Director of Cleveland Clinic's Innovation Management and Conflict of Interest Program.
- **Education:** He received a BS from the University of Pennsylvania (Philadelphia), PhD from the University of Virginia (Charlottesville) and postdoctoral research training from the Karolinska Institute (Stockholm) and Massachusetts Institute of Technology (Cambridge).
- **Research:** Dr. Chisolm has published over 110 scientific articles, most on vascular biology and the cell biology of atherosclerosis. His work and contemporaneous studies from others led to the theory that oxidation of low density lipoprotein, LDL, accelerates atherosclerosis.
- His laboratory continues to study oxidized LDL's influence on gene expression, programmed cell death, cell proliferation, pro-coagulation processes and "foam cell" formation. His research funding has come predominantly from multiple grants from the NIH, the American Heart Association and the pharmaceutical industry. Dr. Chisolm received the Research Merit Award from the American Heart Association's Ohio Valley Affiliate (2001) and a Special Recognition Award for Vascular Biology Research from the AHA's (national) Council on Arteriosclerosis, Thrombosis and Vascular Biology (2006).
- **Cleveland Clinic (institutional leadership, service, education):** Dr. Chisolm has served on Cleveland Clinic's Board of Governors and Board of Trustees. He is actively involved in numerous aspects of Cleveland Clinic's new medical school, the CCLCM. He is co-director of the school's Basic Science Curriculum and sits on the Admissions, Faculty Appointments and Promotions, Student Promotion and GI Curriculum committees. He is recipient of the 2007 Lerner Research Institute Award for Excellence in Education.
- **Conflict of Interest:** Dr. Chisolm is Director of Cleveland Clinic's Innovation Management and Conflict of Interest Program, Chairman of the IM&Col Committee and a member of the Clinic's Board of Trustees Col Committee. He played an active role in crafting the Clinic's current Col policies. He is on the Steering Committee for the Association of American Medical College Forum on Conflict of Interest in Academe and in 2006 hosted at Cleveland Clinic the annual national meeting of this organization and another national summit on Col (9/06). He has been on the program planning committees for the Forum's national meetings sponsored by Johns Hopkins University School of Medicine (9/07) and Mayo Clinic (9/08). He was a member of the joint AAMC-AAU Advisory Committee on Conflicts of Interest in Human Subjects Research that recently published updated Col guidelines. He is a member of CWRU's Col Committee and CWRU's President's Committee on Col Policy Development.
- **American Heart Association:** Dr. Chisolm has served the AHA at the regional and national level in numerous committees, task forces and as an officer. He has, for example, served as a member of the Board of Trustees and Board of Directors of regional affiliates, as the President of the regional affiliate, on multiple research peer-review study sections, including as chairman, at the regional and national level. He is an active member and recent officer of the AHA's Council on Arteriosclerosis, Thrombosis and Vascular Biology.
- **NIH and Other National Committees:** He has served on multiple NIH committees, including the NHLBI Study Section for Program Projects (Chair), the Metabolism Study Section, and the Data Management and Safety Board for the "Arterial Disease Multiple Intervention Trial". He is a member of multiple professional societies.
- **Editorial Boards and manuscript review:** Dr. Chisolm has served as Associate Editor or on the Editorial Board of American Journal of Physiology: Heart and Circulatory Physiology, Arteriosclerosis, Thrombosis and Vascular Biology, and Journal of Biological Chemistry. He has been an ad hoc reviewer for over forty scientific journals.

Education & Fellowships

Fellowship:	Karolinska Institute , Stockholm, Sweden
Fellowship:	Massachusetts Institute of Technology , Cambridge, MA
Other Education:	(Doctorate) University of Virginia , Charlottesville, VA
Other Education:	(Masters) University of Virginia , Charlottesville, VA
Other Education:	(Undergraduate) University of Pennsylvania , Philadelphia, PA

Specialty Interests

Lipoprotein oxidation, vascular diseases, lipoprotein-cell interactions, atherosclerosis.

Research & Publications

[Click through to [PubMed](#)]

Industry Relationships

Cleveland Clinic physicians and scientists report if they have any collaborations with the pharmaceutical or medical device industries as part of the Cleveland Clinic's procedures. The Cleveland Clinic publicly discloses payments for speaking and consulting of \$5,000 or more per year, and any equity, royalties, and fiduciary relationships in companies with which they collaborate. In publicly disclosing this information, the Cleveland Clinic tries to provide information as accurately as possible about its doctors' connections with industry and those of their immediate family members. **As of 6/26/2008, Dr. Chisolm has reported no financial relationship with industry that is applicable to this listing. Patients should feel free to contact their doctor about relationships with industry** and how the relationships are overseen by the Cleveland Clinic. To learn more about the Cleveland Clinic's policies on collaborations with industry and innovation management, go to our [Integrity in Innovation](#) page.

Consulting. Dr. Chisolm receives fees of \$5,000 per year or more as a paid consultant or speaker for the following companies:

None listed

Royalty Payments. Dr. Chisolm has the right to receive royalty payments for inventions or discoveries related to the companies shown below:

None listed

Equity. Dr. Chisolm owns stock or stock options from the following companies for activities as a founder, inventor, or consultant:

None listed

Fiduciary Role. Dr. Chisolm serves in a fiduciary capacity, such as an officer or director, for the following companies:

None listed

Inventor Share. Dr. Chisolm may receive future financial benefits from the Clinic for inventions or discoveries related to the companies shown below:

None listed

What were we thinking...?

Our patients...well, we thought at least some of them...want to know

No reason to hide our innovation efforts or the fact that our faculty members are thought leaders who are asked to consult

The website should change for the better faculty attitudes and behavior

We could refer to the website in disclosures to patients in IRB consent forms

We could refer to the website in our disclosures in manuscripts, and grant proposals; show slide of webpage in presentations

Our doctors could hand out a printout of this to their patients

Most of the publicized infractions have been failure to disclose

Another effort at transparency ...

We invited a reporter to attend our
Col Committee meeting

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

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.

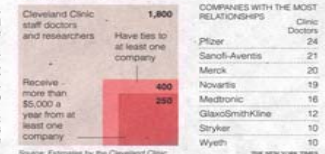
The Cleveland Clinic's Web postings are the most recent part of a conflict-of-interest effort at the clinic after some of its leading doctors came under fire several years ago when the news media disclosed some of their financial links.

"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

Nemeroff, 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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Reed Abelson, NYT, 12/3/08

Col Article on Cleveland Clinic

New York Times, 2010

- Generated 1,300 positive stories over 12 days
- Reached 400 million people

(data source: Cleveland Clinic Corporate Communications)

What were we thinking...?

We believe the public wants to know that academic medical centers...

- Take conflicts of interest seriously
- Require internal reporting of industry ties of their physicians and scientists
- Scrutinize the internal reports for possibilities of causing bias
- Deliberate and discuss the issues and the individual and institutional relationships
- Make strong efforts to eliminate, limit or manage conflicts of interest in efforts to reduce the chance of bias

Arguably, disclosure is for the benefit of our patients?

Do patients even care to know their doctors' ties to industry?



Conflict of Interest

Online Survey with Cleveland Clinic Patient Panel

Guy M. Chisolm, Ph.D.
Vice Chair, Lerner Research Institute

In collaboration with Michelle Bolek, Michelle Frietchen, Jacqueline Nemeth, and Maya Wolpert
Cleveland Clinic

Research Objective

Objective

- To gauge patient perceptions of conflicts of interest due to physician relationships with industry

Methods

- Online survey of the **Cleveland Clinic Patient Panel**. A total of 2,319 panel members (Cleveland Clinic employees excluded) were invited to participate.
- Cleveland Clinic Patient Panel consists of current patients of Cleveland Clinic who have volunteered to assist the organization by participating in surveys that address topics related to healthcare.

Study Description	
Survey Timeline	June 19, 2009 – July 5, 2009
Panel Members Invited	2,319
Completed Surveys	1,367
Completion Rate	59%
Median Survey Time	9 minutes
Participation Incentive	Raffle of (25) \$50 USD Checks

Summary of patient survey findings

- 92% were familiar with “conflict of interest” in healthcare, but few (10%) had sought information on their physicians’ industry ties
- 69% found it OK for physicians to have industry ties, depending on the nature
- 75% and 64%, respectively, wanted limits placed on amount of money received for consulting & the number of business relationships of a physician
- 87% were likely to seek physician-industry information if available online
- 84% viewed the institution more favorably when informed of public website.
- Some made suggestions for disclosure clarification & other information wanted
- 96% wanted to know institutional (distinct from individual physicians’) industry ties

Possible Goals of disclosing researchers' financial relationships to potential research participants: *

- promoting informed decision making,
- respecting participants' right to know,
- establishing or maintaining trust,
- minimizing risk of legal liability,
- deterring troubling financial relationships, and
- protecting research participants' welfare.

* Weinfurt KP et al. Disclosure of financial relationships to participants in clinical research. NEJM 36:916-21, 2009

Does public disclosure have a downside?

- It's expensive! (months of concentrated efforts)
- Risks of revealing your faculty's and the institution's business interests (media, malpractice,...)
- Faculty resistance
- Discrepancies between your disclosure and others';
how to promote uniform disclosure?

Col Disclosure Website Working Group Cleveland Clinic, March 27, 2009

Host:	Guy M. Chisolm, Ph.D.	Cleveland Clinic
Moderator:	Susan Ehringhaus, J.D.	AAMC
State Government:	James Daniel, MPH	State of Massachusetts
Device Industry:	Christopher White, Esq. Bruce P. Garren Kathy E. DiGiorno	AdvaMed Edwards Lifesciences Corp Medtronic
Pharma Industry:	Jack Harris, M.D. Geralyn S. Ritter Cathryn M. Clary, M.D., MBA Jeffrey Paden	Eli Lilly Merck & Co., Inc. Pfizer, Inc. GSK
Public AMCs:	Raymond Hutchinson, M.D. Deborah Biggs, J.D. Neal Cohen, M.D., MPH, MS Barry D. Burgdorf, J.D. Lynn Zentner	University of Michigan Medical School UNC Chapel Hill School of Medicine UCSF School of Medicine The University of Texas System University of Minnesota
Private AMCs:	Ross McKinney, M.D. Claudia Adkison, JD, PhD Julie Gottlieb, M.A. Marianne Hockema Christopher Clark, J.D. Glen Gaulton, Ph.D. Harry Greenberg, M.D.	Duke University School of Medicine Emory University School of Medicine Johns Hopkins University School of Medicine Mayo Clinic Partners Health Care (B&W, MGH, Harvard) University of Pennsylvania School of Medicine Stanford University School of Medicine

Some organizing principles for public disclosure

- Construct disclosures to offer patients what they want to know
- Present the faculty in broad professional context; not just industry ties
- Give the rationale for industry partnerships
- Indicate how the institution handles CoIs
- Define clear, uniform categories for disclosure

disclosure, disclosure, disclosure,...

By all means let's all disclose,

But after we're all naked,

let's at least stop and think if that's the main
issue

BIAS!

Current national standards (AAMC)...

- No human subjects research related to a company while you have consulting/speaking > \$10K, any amounts of royalties or equity
- Exceptions: “compelling circumstances,” & “management” of the Col
- **Col Management:** *disclosure!!!*; data analysis; subject selection; subject consent; multi-center; alternate principal investigator; external data & safety monitoring; no phase III, etc...

Like many other academic medical centers...

- We consider ourselves to be an innovative organization
- We believe you bring discoveries to the benefit of patients by industry partnerships
- We're committed to doing so effectively and ethically; disclosure is an essential step

What's coming nationally?

- Col is a moving target; things will continue to change
- Media attention: will continue to press these issues
- Government attention continues to increase
- NIH regulations
- Disclosure: more websites, rigid rules, journal crackdown
- Gifts: much more restrictive guidelines
- Consulting: fair market value; appropriate for services rendered; documentation
- AMCs are developing policies on Institutional Col, Col in Education, Col in Clinical Practice
- Consequences for noncompliance
- Col research: more rigorous data are needed on bias

TRANSPARENCY...

Acknowledgments

- **Cleveland Clinic Webpages--**

Mike Meehan, Bridget Cougevan, Eileen Sheil,
Stephanie Orszak, Kelly Selep

- **Patient Survey--**

Maya Wolpert, Michelle Bolek, Michelle Frietchen,
Jackie Nemeth, Rob Coulton

- **Disclosure Website meeting--**

"Pudge" Henkel, Marleina Davis, Gina Petredis,
Chris Coburn