

NPA Bimonthly Conflict-free Leadership Call
Dealing with Conflicts of Interest in Academic Medical Centers
Partnership for the Advancement of Conflict-free Medical Education (PACME)
hosted by the
National Physicians Alliance (NPA)
April 18, 2012

Selected notes from call. [Link to full call recording at NPA Conflict-Free Leadership Calls – Archive](#)

1. Welcome and Introduction

Rachel DeGolia, NPA Board Member and Executive Director, UHCAN, and facilitator for this call

Rachel: This call is being hosted by the National Physician's Alliance as part of its Unbranded Doctor <www.npalliance.org/integrity-trust-in-medicine> work which has been expanded under the Partnership to Advance Conflict-free Medical Education (PACME) grant. The grant is the result of a state Attorney General settlement regarding the inappropriate marketing of the drug Neurontin. Partners under the grant include the National Physicians Alliance, American Medical Student Association, Community Catalyst and the Pew Charitable Trust.

The goal of the project is to reduce conflicts of interest created by the pharmaceutical industry in the medical profession and medical research. Partners are promoting and working on a number approaches to bring awareness to the issue and to build leadership in the medical profession to eventually eliminate some conflicts.

This call is the second of a series which will take place on a bi-monthly basis over the next three years, and will highlight specific steps being taken to reduce industry conflicts. Watch your email for an invitation to the next call, which will take place in mid-June.

According to our pre-registrations, we have people on this call from CT, FL, KY, MA, MD, NJ, NY, OH, PA, RI, TN and WA, including members of AMSA, the NPA and other faculty and physicians.

Our featured speakers tonight are:

- **Guy Chisolm, PhD**, Vice Chair, Lerner Research Institute, and Director, Innovation Management and Conflict of Interest Program at the Cleveland Clinic. Dr. Chisolm played a key role in the development of Cleveland Clinic's current COI policies. Cleveland Clinic was the first AMC in the country to disclose publicly their faculty's industry ties. He will provide an overview of Cleveland Clinic's approaches to COI policies, public disclosure, benefits and risks associated with industry-academic relationships and management of potential conflicts.

- **Stephen Smith, MD, MPH**, Brown University, Professor Emeritus of Family Medicine. Dr. Smith served as associate dean at the Warren Alpert Medical School of Brown University for 25 years and was a founding member of the National Physicians Alliance. He serves as the physician consultant to Community Catalyst, which is working with medical schools and AMCs to develop strong COI policy through the Partnership to Advance Conflict-free Medical Education. He will use some case studies to illustrate the ethical dilemmas that institutions face when developing COI policies.

2. Overview - Partnership for the Advancement of Conflict-free Medical Education

Ann Woloson, Director of Education, National Physicians Alliance

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Ann: Thanks to everyone on the call. This work is an expansion of the NPA's Unbranded Doctor campaign, which is a network of doctors working to reduce undue industry influence in their practices and academic medical institutions. We encourage physicians and medical students to get involved in their communities and their institutions to reduce conflicts of interest. We are excited by the degree of interest and look forward to working with all of you over the next three years of this project.

3. Guy Chisolm, PhD, Vice Chair, Lerner Research Institute and Director, Innovation Management and Conflict of Interest Program at the Cleveland Clinic

Guy: I will discuss four topics: (1) Disclosure and transparency; (2) Conflict management and how to create COI management plans to mitigate bias; (3) benefits to society and risks coming from AMC having ties to industry, and (4) brief mention of selected new NIH rules.

(1) One way to control conflicts of interest by faculty or employees is to disclose them. Disclosure of financial interests can be looked at two ways – internally within the institution, and externally, with the public, and these are often confused. As to internal disclosure, our faculty and providers must disclose to the institution all their outside financial interests that relate in any way to their institutional activities or their professional competence – consulting, speaking, commercialization efforts, royalties, etc. My office monitors all this information. The Cleveland Clinic philosophy is that we need to know this in order to understand our faculty's relationship to the industry and we were the first AMC to put all this on our website easily accessed – since 2008. This is on each faculty members' web page along with all their other professional information. We do not list amounts of money. Many AMC's have followed suit, and some companies now also post what they contribute, but there is no standardized way of reporting so it's difficult to make comparisons. In 2013 the public govt website under the Sunshine Act, part of health care reform, will be set up and all the companies will have to report on this federal website what they give to all the physicians and institutions nationally. Most people believe transparency is best practice.

(2) Conflict of interest management plans – Disclosure of COIs doesn't do anything to minimize bias. A COI management plan is a list of rules imposed on a conflicted

individual to minimize bias, in addition to disclosure. One way is for the conflicted investigator to have read-only access to data so he/she cannot change out of it. Another way is to send the data to an independent group and have them do the raw data analysis. If the research involves human subjects, one can set up an independent position of equal rank to verify that subject selection is appropriate, and take the prospective subjects through the consent process. One can also set up independent groups to monitor the research and audits take place. Another element can be that the investigator can be removed from any purchases related to the company's project. The point of a COI management plan is to build a firewall between the money and the validity of the data, well-being of the subjects, and validity of the research product.

(3) The implication is that the institution and individual need to decide if there is a benefit from the relationships with the industry other than the financial interest, and whether it's in the best interest of the institution for the researcher to participate in these relationships. A basic consideration includes that if there are discoveries coming from an institution, to benefit society, there has to be a partnership with industry. At a high-end AMC there are clinicians and scientists with whom industry would like to consult for particular expertise and is willing to pay for it. The Cleveland Clinic and other innovative institutions encourage the innovative steps one can take in partnering to commercialize discoveries or to share expertise with industry the way we do with other AMCs.

(4) The new NIH rules came out Aug. 25th and go into effect on Aug. 24th, 2012, and some are game-changers. I will speak to a handful of the more compelling ones – there are tens of pages more. They define what is a “significant financial interest,” such as having equity in a non-publicly traded company, or having fees for services like consulting and speaking that are in excess of \$5,000/year from a single company – which is reduced from the old rule's threshold of \$10,000. Our work in scrutinizing this has tripled. We have to determine if the interest is related to an NIH grant, and then we have to determine if the financial interest actually creates bias or is actually a financial conflict of interest, which is defined as whether or not it could have a significant and direct effect on the conduct of the research. These must be reported annually, and also on a public website, or, if the institution does not want to post it, they must agree to respond within 5 business days to any inquiries.

Q: Does the Cleveland Clinic ever get push back when information about financial relationships is required?

A: We had an internal vetting process, which included a visit from myself and the Chief of Staff to a staff meeting of the Orthopedics Institute when these regs were first proposed. There was a lot of discussion, but in the course of answering questions that were posed by fellow faculty members, most were supportive. A straw vote was suggested at that meeting and the faculty was also supportive. We also had a process

that took place over several months in which we asked people to consider their financial relationships with the industry and give them time to change or drop, but none did.

Q: If I were a drug company and wanted to appear to be equally involved with all members of the faculty wouldn't it be smart to give a small amount of funds to all members since dollar amounts are not revealed?

A: I didn't talk about gifts from pharmaceutical companies and device manufacturers, and we and AMSA and NPA have common ground on this. The question implies there is a way to distribute money and curry favor with all the institution's physicians, and we would not allow that. We are discouraging gifts, and in the future we will discourage talks that promote specific products, and establish criteria for what an academician's talk should fulfill. I do not agree we should eliminate all relationships between academia and industry – that will not be beneficial to patients and is short-sighted.

4. Stephen Smith, MD, MPH, Brown University, Professor Emeritus of Family Medicine and physician consultant to Community Catalyst on conflict of interest of policies for medical schools and academic medical centers

Steve: In my 25 years as Assoc. Dean at Brown for medical education, my main goal was trying to develop among the students a sense of being a socially responsible physician – to put the interest of your patients and society above your own. Whenever there are forces or influences that exist that compromise the fiduciary duty to one's patients or society, this represents a conflict of interest.

- I first became aware of COIs as a 2nd year medical student when I did a project in rural Appalachia. I noticed a disjunction between what I learned at school and saw in practice. The physician I was working with was using broader spectrum antibiotics than I was taught was appropriate – he was a wonderful physician – but he was seeing drug representatives who were promoting this. He was not aware of how he was being sold on their new products.
- I saw more of this in residency – we were supplying a brand of ampicillin that was the most expensive available. The drug company provided it at a discount to the hospital pharmacy which got residents used to writing prescriptions for it later when it had to be bought at a more expensive price.
- A third example – when my partner and I purchased a new EKG machine, I found I was prescribing more EKGs to try to pay it off quickly. I did not have a financial stake, but it was a subtle COI. There are many other situations like these. When I retired from Brown, and was offered this opportunity to work with Community Catalyst, I saw this as an opportunity to focus again on professionalism and address the erosion of public trust in medicine. Over the years, medicine has allowed self-interest to trump the patient's and society's best interest – society is simply the plural form of patient.

A couple case studies – this is not black-and-white – there are pluses and minuses to relationships with industry.

- I met a student who was ecstatic about a wonderful dinner his doctor had invited him to join and all they had to do was listen to this person talk about a drug. He had no idea that the dinner was paid for by a drug company – he had no idea and was indignant when he discovered it. What should medical schools’ policy be for volunteer clinical faculty based in the community who are involved in medical education? Should the same policies that apply to paid faculty apply to them?
- Another example – I first started to meet with pharmaceutical reps when I was in practice and thought I could learn from them, but discovered quickly they were working from a script. I stopped talking to them. A question has arisen – should not we be training medical students how to deal with these guys in a way that makes sure it’s educational?
- Most medical schools require faculty who have a financial interest with industry to reveal that to their students. But what about faculty involved in clinical rounds? That’s harder to monitor. How do we deal with that? No answer yet.
- I have a colleague who owns stock in a generic drug company. We are always encouraging use of generic drugs instead of brand name drugs. Should he be required to disclose this on rounds, and if so, how should his students interpret that?
- I was at a meeting with the board who oversees the medical school at Brown and we were discussing how to get our faculty to do more invention and entrepreneurial activities and bring Brown in on the resulting royalties. One suggested that Brown buy a red Ferrari for the first physician to bring in a \$1 million contract and park it in the faculty parking lot! I was aghast, but it raises the question of conflict of interest at the institutional level. The NIH rules focus on conflict of interest for the individual. What kinds of provisions should we make when the institution itself is in a position to derive financial benefits from the outcome of research? We have not paid enough attention to this. I think the PACME project is a terrific venture. I hope I have stimulated some interesting thinking with these scenarios.

5. Discussion and Questions and Answers

Q: What do you see as the role or benefits of industry reps in providing samples for patients to medical practices?

A: Steve - In my practice in RI, pharmaceutical samples were the only way we could provide some things to our patients that they could not otherwise afford. I agonized over this, but my mentor told me that he was least concerned about me because I was the lowest down on the totem pole. However, these samples create a nefarious situation – it’s a marketing strategy to get doctors to give a few samples to patients for expensive drugs that really aren’t necessary and then get them hooked on those drugs. I would say it’s not necessary, but in cases where these samples are provided altruistically and are really helping people, we can create arrangements where the companies are held at arms length by providing them to a central distribution center.

Guy – The Cleveland Clinic banned free samples years ago. They go to a central dispensing center and not dispensed through our physicians when they come in. This is true at a lot of AMCs. That being said, there is a larger question re the role that pharmaceutical reps play in our medical institutions. We have strict restrictions as to where they can go and who they see. We need ways to communicate with drug companies. What I'm pushing for is new ways to communicate with the companies that do not go through their marketing departments, but rather through the R&D side.

Q: As a medical student, what is the best way to start or continue a discussion at my school where the AMSA grade is low?

A: Steve – It depends on the institution. If the Dean is accessible, then start there because that's where the power is. If that's not true, look for a faculty member or faculty-student committee that's looking at professionalism issues. These are issues of professionalism so this is an appropriate place to bring it up. If none of those work, every institution has someone like Guy, who is the primary lead for performance with regard to NIH rules – find that person and talk to them and they are likely to be very open.

Guy- This happened at a medical school with which I am affiliated and the students went to the Dean and got a response that improved their COI policy. The medical school at the Clinic is fairly new, and I started a seminar on COI at the school a few years ago. You might suggest to the Dean that they include COI seminars at your school. I think this should start in year 1, and continue in the upper levels as well. It is healthy when students question their faculty about COI policies.

Ann – NPA will be holding a series of ten national Grand Rounds – the first at U of Connecticut on May 31st at noon and will feature Dr. Eric Campbell who has done a lot of research in this area. You all will be receiving information about that.

Q: It appears that the Physician Sunshine Payment rules as part of the ACA are really geared toward the drug and device companies and what they have to report, and the NIH rules are geared toward researchers as to what they have to report for an NIH grant. Will these two be melded in some way? Is there a way to simplify the reporting processes?

A: Guy- Those two sets of rules address two different things. The Sunshine rules simply put out in the public domain all the funds doctors are getting – they are informative. The policies coming from NIH are about protecting research aims from the influence of those monies because they have such a low dominium of \$5,000. It would be great I all the agencies that have a dog in this fight, and funding agencies like National Cancer Society, could establish some uniformity as to all the rules and regs we are all subjected to in using that kind of money. It's not happening yet. There is a task force at IOM that is trying to figure out a template for uniform reporting and disclosure under the

Sunshine Act. If that happens, then the Cleveland Clinic would be glad to put the report on our website because there would no longer be inadvertent discrepancies with what the companies report.

Rachel: The next call will be two months from now – watch your email for the notice. Additional questions arising from this call can be emailed to either of our speakers:
Steve Smith <Stephen_R_Smith@brown.edu>
Guy Chisholm <chisolg@ccf.org>

For more information about the National Physicians Alliance and PACME, visit NPA Unbranded Doctor Website at: <http://npalliance.org/integrity-trust-in-medicine/>

To view the AMSA PharmFree Scorecard, visit <http://www.amsascorecard.org/>

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For more info on NPA's COI-Free Leadership Calls, the Unbranded Doctor Network or the PACME Project please email Ann Woloson, NPA Director of Education at ann.woloson@npalliance.net

*NPA is a proud partner in the Partnership to Advance Conflict-free Medical Education ([PACME](#)).
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