NPA Avoiding Conflict-of-Interest in Medicine Leadership Development Call Series Archive

One Doctor's Experience with Conflict of Interest and an Update on Physician Payment Sunshine Provisions of the ACA

August 29, 2012 CALL NOTES

1. Welcome and Introductions:

I am Rachel DeGolia, Executive Director, Universal Health Care Action Network & NPA Board member, and facilitator for this call. This Conflict-free Leadership call is hosted by the National Physician's Alliance as part of its Unbranded Doctor work, which has been expanded under the Partnership to Advance Conflict-free Medical Education (PACME) grant.

The PACME grant is the result of a state Attorney General settlement regarding the inappropriate marketing of the drug Neurontin. Partners for the grant include the National Physicians Alliance, American Medical Student Association, Community Catalyst and the Pew Charitable Trust, and staff from all these organizations are on this call.

The goal of the project is to reduce conflicts of interest created by the pharmaceutical industry in the medical profession and medical research. The organizations partnering on this grant promote a number approaches to raise awareness of the issue and to build leadership in the medical profession to eventually eliminate some conflicts.

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

Our first speaker tonight will be **Daniel Carlat, MD, Director of the Pew Prescription Project** . Dr. Carlat will describe his personal experience with COI as a well-meaning physician representing a drug company in educating prescribers about the benefits of a prescription drug and his current work in strengthening conflict-of-interest policies at medical schools and hospitals across the country. Links to several pieces written by Dr. Carlat's were included in the email about this call – his 2007 New York Times Magazine article, ***Dr. Drug Rep*** and his recent editorial in the Philadelphia Inquirer, ***Disclosure Can Address Doctors' Conflicts of Interest***

After time for a couple questions of Dr. Carlat, we will then hear from **Allan Coukell, Director of Medical Programs, Pew Health Group**. As Director of the Pew Health Group Medical Programs, Dr. Coukell oversees the work of the Pew Prescription Project, the Medical Device Initiative, the Drug Safety Project, the Antibiotics and Innovation Project and other PHG activities related to medical products and services. He actively participated in the development of federal and state policy to foster transparency of physician-industry relationships and in the creation of programs to encourage evidence-based prescribing. Allan will discuss the status of the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act.

Please email your questions throughout the call to Ann Woloson, NPA's Director of Education…. Ann.woloson@npallinace.net -- who will now provide a brief overview of the project.

2. Partnership for the Advancement of Conflict-free Medical Education (PACME) - Ann Woloson, Director of Education, National Physicians Alliance <ann.woloson@npalliance.net>

Ann: This call is part of a series of educational opportunities under the Partnership to Advance Conflict Free Medical Education. More information is posted on the Unbranded Doctor page on the NPA website at www.npalliance.org. Some announcements -- our second National Grand Rounds will be Oct. 12 from 4 – 5:30 pm in collaboration with AMSA's "Empowering Future Physicians Conference" in Florida. It will feature NPA member, Dr. David Evans, a professor in the Dept of Family Medicine at the University of Washington School of Medicine, who will speak about his personal experience as a physician in becoming "unbranded", as well as a couple speakers from Florida on improving transparency and improving their institutions' AMSA Conflict-Free Scorecard grades. Also, please fill out a short evaluation you will receive in the next couple of weeks regarding these calls to help us evaluate them and plan for future calls. Finally, NPA is developing presentations and slide sets on a variety of topics related to conflict-of-interest and pharmaceutical marketing strategies. Please let me know if you have interest in hosting an event in your local community.

3. Dan Carlat, MD, Director of the Pew Prescription Project

Dr. Carlat: I am a psychiatrist by training, although most of my work now is policy work and conflict of interest work. I've learned about this through being in the trenches experiencing conflicts of interest as a promotional speaker in a couple of venues. Even when you're aware of the potential for COI, it can be very hard to manage because it tends to affect your teaching. In 1995, doing my residency at Massachusetts General, most of the research was funded by the pharmaceutical industry and the expectation is that you would work in some way with the industry. I was asked by the Paxil representative to talk about social anxiety disorder and was told I could say whatever I wished. I wanted to talk about cognitive behavioral therapy, so I did, and what struck me is that the rep would not establish eye contact with me throughout the rest of the dinner. I realized I missed the expectation that I was supposed to really talk about the medication. I learned there is always a quid pro quo when you are accepting money from the industry. Six years later, in my private practice, seeing a lot of patients and a another rep asked me to talk about Effexor. I knew that if I was going to accept funds like this I would have to talk about the drug. Now, I knew that there was some evidence that it was more effective than other SSRIs, so this was big news if it was true. I thought that if I would honestly relay that information to the doctors that both they and the company would get something valuable. I started on a very slippery ethical slope – they flew me and my wife to a speakers' training with lots of perks. I listened to some of the biggest names in psychiatry, heard about specific things to say, and I continued to be impressed by the data. I quickly started getting calls from reps inviting me to do "lunch and learns" at primary care doctors' offices with the reps for which we provided sandwiches and I talked while they ate. My spiel was educational, at least at first, since I was talking about a large meta analysis of 2000 patients who had been randomly assigned to Effexor, other SSRIs or placebos – all depressed patients. Effexor had a higher remission rate than the others. At that point, very few companies had used remission rates (complete recovery) instead of response rates as a measure, so I explained the difference. These were primary care doctors, not psychiatrists, so they were not familiar with the nuances. I remembered the slides: remission rates were listed, and not the response rates. Later, after I quit giving the talks, I found out that the reason was there was hardly any difference in the response rates.

My favorite quote about using statistics to tweak the data: Statistics are like bathing suits … what they reveal is suggestive. What they conceal is the vital. When you are being paid by the company, even if you are not conscious of it, you end up using data in this way. I gave about 30 talks, at first I enjoyed them, I was making $750 for each of the talks, but gradually I began to wonder if I was providing education or really just being a marketing agent for the company. The distinction is not easy to be aware of when giving these talks. I realized I was beginning to sound more like a drug rep than an educator. I knew future invitations depended on making the reps happy with what you're saying. I realized I was not making false claims, but leaving out nuances of the statistics, which was too easy to do when talking to primary care doctors. When they asked me to give the talk to a group of psychiatrists finally, I was questioned by one who challenged me that what I was saying was not his experience. It made me realize that the slide provided by the company was only one way of cutting the data and I was compromising my integrity. So, I decided to be completely honest in future talks and I was more forthcoming about the limitations of the data – that it was short-term data – and the drug reps present were not happy. They asked if I was sick (!) so that was when I decided to stop doing the talks for any companies. AS I look back on it, that experience taught me that even though I was acutely aware that I had a COI and disclosing

that to my audience and trying to guard against that affecting my judgment, that it was very hard to have it not affect the content of your talks and your judgment. If anyone out there gets an invitation to be on a speakers panel from a drug company, I suggest you think about that very carefully before you say yes.

Now, I am the Director of the PEW Prescription Project which is the part of the PEW Health Group involved with medical COIs. I am working on the PACME Project to advance stronger COI policies in medical centers around the country. I also am involved in urging rapid implementation of the Physician Payment Sunshine Act, which is part of the Affordable Care Act, which would require all insurance companies to disclose all their payments to physicians and hospitals on a publicly available website.

Q: Why do you think you were specifically asked by the company to give these talks? Were you an expert in the field, or were your prescribing patterns being monitored?
A: I think it was combination of the fact that I had written a textbook on psychiatric interviewing and was somewhat known by residents, and possibly my prescribing patterns because I was prescribing Effexor. I became friendly with the reps and they began to fax me messages about pushing fellow physicians that were not prescribing much Effexor. I had no idea they had that degree of prescribing detail on physicians, so they obviously had it on me.

Q: The PEW Dollars for Docs Reporting series notes that doctors who are recruited to speak about drugs to other doctors also start prescribing more themselves. Did you see this trend in your practice?
A: It's hard for me to know. I asked for information about my own prescribing, but the reps would have charged a lot for it. It's inevitable that this happens because in order to give these kinds of talks you have to go over and over it and become more convinced in your own mind that it's true. This probably does happen.

4. Allan Coukell, Director of Medical Programs, Pew Health Group
Dr. Coukell: PEW has a fairly long-term involvement in looking at physician-industry relationships and policies around them and long-standing relationships with NPA and AMSA. I will mainly talk about the Sunshine Act (PPSA) – its history, the details of what it does, how it fits with other disclosure programs and requirements that are out there, and finish with ways to become involved.

The PPSA is a federal law that requires drug and device companies to publicly disclose gifts and payments to physicians and teaching hospitals. The first version was introduced in 2007, when PEW became involved, and nobody thought it had a chance of becoming law. By 2010, when it passed, the world had changed, COI interest had become very high profile. We had first person accounts like Dan Carlat's article in the NYT Magazine that were very influential, high profiles by leaders of the profession in medical journals saying we needed a new ethical framework for relationships with the industry, we had almost weekly settlements with companies involving payments to physicians, high profile reports calling for change from professional organizations, we had calls from the leadership of a lot of schools, often pushed by AMSA and NPA, saying we needed new COI policies. We also had state laws requiring industry disclosure of payments to physicians – this helped create a catalyst for a national law because the industry hate having to comply with different laws in different states.

The Sunshine Law passed as part of the ACA, it was to be implemented in 2011, but the Administration missed that deadline. We are still awaiting the final rule that will give the companies the information they need to begin collecting the data. The first public reports will be 2014 at the earliest.

What the Act does – it requires reports from the industries of any gift more than $10, and for anything over $100/year. It does not require the doctors to do anything. It covers cash, in-kind, food, entertainment, all kinds of transfer of value which have to be described and categorized. A few things are exempt, such as pharmaceutical samples and educational material for patients. Our position is that we do need academic medicine to be involved in drug development and device testing, so there is a need for some financial relationships that do need to be managed. The Act does not prohibit anything, but increases transparency. Payments for research are reported, but the law allows a two-year delay before the data becomes public

because it recognizes the proprietary interest of the companies while developing the product so as not to undermine their competitiveness. There are fines for violations.

We have a lot of companies disclosing their financial relationships with doctors now, some voluntary, some as the result of lawsuits around their marketing practices. The limitations include that there are still a lot who are not reporting, and those who do use different criteria as to what they report and where it's reported making it of limited utility. As a patient, it's not easy to find out about all the financial relationships your doctor has. Different institutions and publications have different requirements for disclosure. The reality is that the Sunshine Act won't fully address this problem. For one thing, the data will always be a year out of date, and more for payments for research, so it can't be a complete cross-check on the relationships an author or faculty member will have. For the time being, we will see multiple disclosure programs because they have different reasons for being.

The Obama Administration has been slow in getting the rule for the Sunshine Act out. By the time it passed, it did have the support of Pharma and other trade associations. It would be helpful if they hear from doctors that they want the rule to be issued soon. I have some fear that there might be some physician backlash when the first reports come out, so whatever NPA and other organizations can do to inform physicians that it's coming, the better the response will be to the Act. So, we've come a long way in five years but there is still a great deal of work to do.

Q: Do you have specific suggestions as to how medical students or doctors use the PPSA information once it becomes available?
Allan: For students becoming involved with AMSA, there's a huge role to play in advocating for change in the profession and in your teaching environment. Similarly, NPA is a catalyst for change through it's Grand Rounds and other activities. We have had incidents where medical students were surprised at relationships their faculty had that affected their teaching that were not disclosed, so this is one area for students to address by lobbying for policy change.

Q: How would you respond to a prescriber that appears on the list and says they are not doing anything illegal?
Allan: Nothing we talk about here is illegal. The point of the Sunshine Act is transparency. It will let everyone make their own decisions. Some patients might like having their doctors work for a drug company, and others will want to know that their doctor's decisions will be made solely based on a good reading of the evidence. Everyone will bring their own values to the data.

Q: In addition to MA, VT, and MN, what other states are considering Sunshine-type legislation.
Allan: None, the federal Act preempted state laws. States are still free to require disclosure, but for the time being, the core of the state laws have not been preempted. This was part of the trade-off to gain industry support for the Sunshine Act. There was legislation filed in up to 20 states, and WV and DC also had laws on the books, but did not make the data they collected public as MA, VT and MN did.

Q: What has been the overall feedback from physicians on the Sunshine Act?
Dan: The organizations, like AMA, while they supported it there are some provisions they are concerned about. They want to make sure that payments to doctors doing research are accurately disclosed so that patients don't get an incorrect sense of how much the doctor is personally getting. There is also concern re whether CME payments will be reported as income. These are reasonable concerns.

Q: How do you respond to doctors who say they only speak about drugs they truly believe in?
Dan: I've heard this and it's something I thought originally. The danger is that when you begin speaking for a drug, that may be an accurate description. However, there are new studies coming out all the time and the problem is that new information becomes available that forces you to decide to either be honest about it or stop talking about it. In my situation, during the time I was talking about Effexor, data emerged that once patients stopped it they had terrible side effects.

Q: How useful is disclosure of COI in all of this? Does it not normalize the conflicts when they are so prevalent? Dan: It's very hard to argue against disclosure either even though there is some data that sometimes when you disclose your financial relationship you feel you can be trusted even more. We think that disclosure should raise the red flag. In this day and age, there is so much money involved that it's hard to argue against transparency and disclosure.

To get in touch with our speakers via email: Dcarlat@pewtrusts.org and acoukell@pewtrusts.org

Rachel: Our next Conflict-Free call will be in approximately two months – watch your email for the date and information. Again, for more information about NPA and this project, visit the NPA Unbranded Doctor website at: <www.npalliance.org>. For more information on the AMSA PharmFree Scorecard, visit http://www.amsascorecard.org/

A recording of this call will be available on NPA's website within 24 hours.

Participants from the following states were included on this call: CT, DC, MA, ME, NJ, OR, PA, TN TX, VA, VT, WA

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