

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

August 28, 2013

How I Sold Low-T: Guarding against Industry Influence

Call Notes

Welcome and Introductions:

Welcome to this bi-monthly Conflict-free Leadership call hosted by the National Physicians Alliance as part of its Unbranded Doctor project which takes place under the Partnership to Advance Conflict-free Medical Education, PACME, grant. I am Rachel DeGolia, facilitator for this call and a board member of the National Physicians Alliance. In my day job, I direct the Universal Health Care Action Network.

A little background on the PACME project under whose auspices this call is taking place. 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. The goal of the project is to reduce conflicts of interest created by the pharmaceutical industry in the medical profession and medical research. The partners 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, please visit the NPA Unbranded Doctor Website at: npalliance.org/conflict-free

We have a terrific speaker for tonight's call who will share with us his personal experience and expertise around drug company influence in the arena of consumer and physician education regarding the drugs they sell.

Stephen Braun, a medical writer from Amherst, Massachusetts, has worked for nearly 30 years as a journalist, most recently as a freelance medical writer. During the past 10 years, Stephen has written and developed physician and consumer educational materials and he is going to describe for us tonight how drug companies often pay for the creation of seemingly objective physician or consumer education media products while obscuring or minimizing their role and/or the identity of the actual writers or producers of the products. In the announcement for this call we included a link to a recent article by Steve published in JAMA, "Promoting Low-T: A Medical Writer's Perspective." Steve let us know that he welcomes further communication from any of you listening in tonight via email following this call – his email is <braun.writer@gmail.com>.

Now a few words from Ann Woloson, Education Director for NPA, and then we'll get right to our speaker.

Ann:

Thank you for joining us tonight. A few announcements. First all of the recordings and notes from these calls, as well as our Grand Rounds, are archived on our website at www.npalliance.org under the "Unbranded Doctor" tab. Our next National Grand Rounds will be webcast and takes place during NPA's annual conference in DC, "Challenging the Selling of Sickness – A New Partnership Movement of Professionals and Advocates" on Oct. 19th.

One of our partners, Community Catalyst, has created a toolkit with model policies and other resources to help address ghostwriting – Google "Community Catalyst Conflict of Interest Toolkit" to download it (free).

Steve Braun:

It is a pleasure to be here in this virtual space – a great way to get the word out. I fully endorse NPA's efforts to disentangle medicine from company money at all levels. Starting with a broader context, there have been a lot of recent efforts to encourage greater transparency – for example, the Physician Payment Sunshine Act – which will be in place soon. It will require many companies to report items of values and payments they give physicians and hospitals. That's great, but a lot of loopholes remain. A quote from the NEJM earlier this year – "Many types of indirect payments, such as those made through intermediary organizations that host CME conferences, will be exempt from the national reporting requirement which raises the possibility of some undetected payments." So drug companies can still funnel money through the AMA or state professional associations to fund physician training programs and not report that. They can also hire public relation agencies which then hire ghost writers, such as myself. They can hire medical education companies to produce unbranded patient education publications. They can fund "consensus panel meetings" and the publications that come out of that. They can pay for the creation of CME programs. These are powerful means of influencing patients and providers and are loopholes that have to be closed eventually.

I chose low testosterone as an example for this presentation because there has been a lot of attention to that lately. I could have focused on opioids or other drugs, too. Hormone replacement therapy for women was a big issue some years ago and it wasn't until after a long-term study that raised serious concerns that prescribing began to diminish. The point is that we've *been* here before. Hormone replacement therapy was being sold for years without a strong evidence base at all and the same thing is happening now with low testosterone. More generally you see disease-mongering activity by drug companies – making a disease state where there wasn't one before – ie, we've seen that with human growth hormones, among other examples.

As an example of all this – In 2009 I participated in this development of Low-T as a disease state. I was hired by a drug company that made Androgel after they contacted a public relations firm, which sought out a doctor I worked with to ask him to write articles for women's magazines. This doctor, who is a very good doctor, asked me to write some of these articles. He forwarded to me the points that Abbott wanted made to get women to educate themselves about the symptoms of Low-T and educate the men in their lives about it. A clever approach since guys don't tend to go to the doctor and talk about this stuff. The drug companies are not crass about this. They engage in self-censorship, but direct the writer to craft the message in a certain way. I was paid by the physician who was being paid

by Abbott, and the articles were neutral and did not mention any specific product by name. As I look back on it, this was a totally unskeptical approach with no dissenting voices or any mention of weaknesses in the data on the basis of which this was based.

A few years later I was hired by a medical communications company – there are lots of them primarily funded by drug companies – to write a consumer booklet about Low-T. It was funded again by Abbott and was unbranded and was under my name. This is an example of how you can tell the truth, but not the whole truth, and exactly builds the paradigm the drug company wants. They don't say things that are untrue, they aren't necessarily hiding, they use words like "may" in referring to what the medication can do (ie, restore your sexual energy), but influences what people believe about this drug being a cure-all. The booklet was handed out by sales reps to doctors to give their patients.

My last example – I was hired last year by another state professional organization which is in the business of producing CMEs. Many of these companies are funded by drug companies. I was hired to write a consensus statement about hypogonadism by a meeting of experts entirely funded by Abbott. All the speakers had served as consultants, researchers or speakers for Abbott or other companies that were involved. The funder was not invisible, but there were no skeptics of low-T on the panel. By this time I realized there were skeptics and the evidence on which basis these claims were being made was thin, so I included some reports on clinical trials that contradicted the paradigm into the draft for the monograph. The panel members took out some of this in the editing. This was the straw that broke the camel's back for me that motivated me to start writing and talking about this issue. The consensus can be contrived by careful selection of panel members, and by lack of involvement by them – many do nothing to impact the outcome. There was self-censoring on my end, but also their end. Physicians believe they can take money and this will not influence their opinions – there is a lot of evidence to contradict this. Doctors are as human as anyone else.

My last point is that this monograph was turned into a CME-accredited PPT and given out to many physicians, so this is another example of how the drug companies get their message out in a way that seems rigorous but is not the whole truth. It illustrates the fundamental problem of having drug company money involved in physician education at all. It simply should not be allowed.

Thus, despite progress, drug companies are still free to pursue these activities and we have to always guard against these influences. We have to do our own research and stay skeptical about all claims they make.

Questions & Answers:

Steve will be happy to communicate directly with anyone after this call – email him at <braun.writer@gmail.com>.

Q: Do you have any thoughts about the industry's use of social media and technology to push products?

A: I have not yet been hired to do a Twitter-feed or Facebook posting, although I'm sure they are finding ways to use those. I do frequently embed QR codes everywhere to encourage people to use their smart phones to go directly to websites.

Q: Who is ultimately responsible for marketing pieces produced by medical writers? Especially in cases where the physician pays you for it.

A: The responsibility for what is the first question? For fairness and accuracy, I'd like to say the physicians are. I am, too, because I am directed to the literature and look through it as part of writing the article. I continue to try to be more independently minded when I write these things. Just this week I have been asked to write a monograph about the treatment of depression and it's funded by a company that produces a drug to treat it. The professional organization involved asked me to write about this and I will write what I think is the truth and they can remove it if they wish. I don't think the drug companies are responsible to be fair-minded. I think they are just trying to do everything they can to make a buck.

Q: Are medical marketing materials held to the same standards about citing risks as TV commercials are? If not, how can we change that?

A: If a piece is unbranded – that is, it does not include named brands – it does not have to include any of that elaborate information on risks and possible side effects as if you were writing a direct-to-consumer ad for a specific drug. The rules are different for unbranded things – that's why the drug companies like them. They don't get to mention their drug, but that's fine with them as long as the bigger message is being conveyed. How to change that unbranded loophole is a difficult question. I think they should be prevented from funding physician or education products even if they are labeled because it subverts the process of education.

Q: Were you aware of how doctors were compensated on the consensus panels in which you participated? Were you aware of the relationships they had with the industry?

A: Yes, the doctors were candid about talking about their industry relationships and everyone was being paid for the time at, I suspect, a very good rate (they didn't mention amounts). That is fairly common. We do need to convene panels of doctors to take a hard look at the evidence and develop clinical guidelines, but we just should not have them being paid anything by the drug companies. It should be funded by the government or by the money they can make from providing CMEs.

Stephen Braun – I have a question. I would like to know if anyone has had an experience with prescribing testosterone to guys without a good work-up or full understanding of what they are getting into. Was it easy to get off it once they realized what it was doing to their bodies? I've heard anecdotal stories I suspect we are going to hear more of them. I have heard that as many as 1/3 of those being prescribed it are not having their levels checked.

Steve Smith – I am a family physician in CT and I had a patient who came in asking for testosterone because his sister, who is a nurse, urged him to come in for it and told him to tell me he didn't need a blood test to get it. I tested him and his levels were normal and I did not prescribe it. It shows how effective the drug companies' marketing is.

Stephen Braun – I certainly don't feel good about some of the things I've written. I have not lost all my clients, but I am happy to get work writing for groups that are not on the dole.

Q: Can you mention the names of some of the physician organizations who co-branded the articles you wrote that were the result of these consensus panels?

A: Email me to ask that question. I am not able to mention them publicly. There are a lot of organizations co-branding with drug companies and it's not all evil, but any means because some of them do push back on the drug companies' message. This will be a long haul to stop this intrusion of the drug companies into medicine and we have to start pushing that now. I suspect it will take court and legislative action.

Q: How much material is now being produced that hides or shields the drug industry funding?

A: We don't know. There is no reporting requirement. We don't know how much money is being shifted from direct-to-consumer ads to other forms of marketing that are not under the same restrictions. We will see with the influence of the Sunshine Act and the efforts of groups like Propublica that publicize what doctors are being paid that the money will shift from that to other forms of influence that are not as direct. It will shift to organizations that then pay the doctors.

Q: A medical student asks what the next step is after the Sunshine Act?

A: A lot of medical schools are on the forefront of tightening up the rules for faculty, although they are not always being followed. First, check what the policy is at your institution as to receiving drug company money. Propublica is a group that has helped people find out what funds individual doctors are getting – check out their website at www.dollarsfordocs.org and look up your faculty member or doctor. I don't have a good answer for the next step other than to say that the FDA could be given more funds to enforce the rules they already have on misleading marketing practices. I'm not a policy expert, just a humble medical writer, but I hope that there are people working on this. This is an example of where we need more government, not less, regarding what drug companies can do.

Q: At this point don't the medical journals have sufficient restrictions to prevent ghost-writing in a medical journal?

A: We have made progress. You have to say if you've hired a writer and state their affiliations. Drug companies have some of their own staff on the writing teams. The rules are specific to each journal. There is still a ton on undue influence allowing us to rely totally on drug companies to conduct these evaluations of their own products. We need a national institute for drug trial research, as Marcia Angell has called for.

Rachel: Thank you, Steve. This has been a terrific call. Our next Conflict-Free call will be in approximately two months – watch your email for the date and information. Recordings and notes of past calls are archived online at <http://npalliance.org/conflict-free/>

Again, for more information about NPA and this project, visit the NPA Unbranded Doctor website at: npalliance.org/conflict-free . For more information on the AMSA PharmFree Scorecard, visit <http://www.amsascorecard.org/>