NATIONAL PHYSICIANS ALLIANCE

THE UNBRANDED DOCTOR

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

The Latest Drug Settlement: New Opportunities to Correct Misinformation

November 1, 2012

NOTES

1. Welcome and Introductions:

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 for 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 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 visit the NPA Unbranded Doctor website at http://npalliance.org.

Our featured speakers will each give 10-minute presentations on the call, with time for a couple questions in between and again in the last 10 minutes of the call. Given the # people on this call, we invite you to email your questions as they occur to you to Ann Woloson, NPA's Education Director, at ann.woloson@npalliance.net and we will make sure they are either asked during the call, or you receive a response following the call if we run out of time.

Our first speaker tonight will be:
Adriane Fugh-Berman, MD is an Associate Professor in the Department of Pharmacology and Physiology, Department of Family Medicine at Georgetown University Medical Center and Director of *PharmedOut*. **Dr. Fugh-Berman** will present on how the pharmaceutical industry uses medical science liaisons and key opinion leaders to promote drugs off-label and will discuss off-label promotion in the recent $181 million settlement between Johnson & Johnson and the Department of Justice.

After time for a couple questions of Dr. Fugh-Berman, we will then hear from:

Wells Wilkinson, J.D., Director of the Prescription Access Litigation (PAL) project and staff attorney with Community Catalyst. **Mr. Wilkinson** will present on opportunities industry settlements present to fund independent prescriber education (academic detailing) as an appropriate remedy for illegal 'off-label' drug promotion.

2. Partnership for the Advancement of Conflict-free Medical Education (PACME) - Ann Woloson, Director of Education, National Physicians Alliance <ann.woloson@npalliance.net>
Ann: A couple of quick updates – this is the fifth of a series offered by NPA as part of the PACME. Past calls are archived at <www.npalliance.org> by clicking on "Conflict-free Medical Education" from the home page. NPA is offering CME-accredited, nationally webcast Grand Rounds as part of this project. The next one is Nov. 10th at 1:15 pm during NPA's national conference in Alexandria, VA - the title is "Selling Drugs: PHARMA's Evolving Strategies." This will include information about the pharmaceutical industry's use of technology and coupons to market products. Information is posted on NPA's website as well.

Since Adriane has not joined the call, we start with Wells.

3. Wells Wilkinson, J.D., Director of the Prescription Access Litigation (PAL) project and staff attorney with Community Catalyst.
Wells: The Prescription Access Litigation (PAL) project was founded in 2001 to try to use litigation to confront unfair practices of the pharmaceutical industry and to promote access to affordable pharmaceutical treatments for patients, especially generic drugs, and to confront rampant marketing that obstructs good treatment. We've launched 32 class action lawsuits that have resulted in 17 settlements that have resulted in over $1 billion in settlements. PAL does not receive funds from these private sector settlements, but rather has been funded by foundations. We've seen over past 8 years 23 settlements over off-label promotion of drugs and are becoming increasingly concerned about this widespread conduct. Nearly all major manufacturers have plead guilty or admitted to off label promotion which violates the law. While some off-label uses of drugs are justified, analysis shows that 70% of off-label use of drugs are not based on any real evidence of the drug being effective.

We are also concerned that even after a settlement, the behavior continues and no measures are taken to correct the misinformation has been spread. We have proposed earmarking some settlement funds to finance independent prescriber education efforts, or academic detailing, to pay a medical professional to go into the field and meet with doctors to explain best practices and therapeutic treatments in each class. Attorneys are only solving half the problem. The settlements go back to the Medicaid programs, which is good, but only represents less than 5% of the money made on the off-label promotion of these drugs. That's not enough of a deterrent for these large manufacturers. If the government held out to go to litigation, they risk having to pay the costs if they lose, so these settlements are understandable.

In the current climate, with state budgets hurting, the monies coming back to Medicaid program from these settlements are badly needed to just help the programs keep going. Since 2004, that comes to $8.6 billion. So, we need to figure out a new strategy to educate physicians and patients who have been victimized by having these drugs prescribed to them. They need to know what information they received was false, and what the alternatives are that can be more effective. In the Neurontin settlement, the Attorney General earmarked $28 million which is funding the PACME project and Consumer Reports' Best Buy Drugs – that is the one example of using settlement monies to re-educate doctors or consumers. The only other example is the requirement in the Seroquel settlement requested by the Department of Justice that the company send a letter to all the prescribers informing them about it. However, that's not nearly enough to counteract the impact of weekly promotion over two years. Programs to educate prescribers do exist in some states, but they are desperate for funds. The curriculum is already created, so start-up costs would be low.

Discussion

Wells: Have any of you on this call ever seen corrective information after any of these settlements over off-label promotional activities, and do you talk with your fellow physicians about this?

Mark Ryan (Richmond, VA): I usually do not hear this in an organized way from anybody. I only hear about it from grants that have resulted from the settlements, or in a journal article. It would be good if companies

advertising their products at conferences had to include disclaimers in the program with this information that they've misled prescribers for years.
Wells: That's a great idea.

Q: Are there existing academic detailing programs utilizing off-label promotion settlement funds?
A: I am not aware of any to educate prescribers. There are examples of some to educate consumers, such as around vitamins, but with small amounts.

Q: How would an existing or new program access settlement funds?
A: It's a political problem, largely. When Medicaid recovers funds from one of these settlements, they really need the money just to keep their programs going. The way to make this happen is to create pressure on Attorneys General to understand that this re-education is needed and has to be funded separately from the payments to Medicaid. Most political leaders and people have trouble understanding that physicians do not know when the use of a drug is actually off-label. The world of medicine is complex and there are so many drugs that it is unreasonable to expect physicians to know all this, and there are too few good resources to help physicians select the best treatments. We also need to try to engage the patients as well who continue to be prescribed the off-label use of a drug – they have the right to know their use is the result of illegal promotion by the drug manufacturers in a concerted way. That might help reinforce to Attorneys General that they need to address this by generating funds for academic detailing.

Ann: To follow-up what Well's said, we have a small but effective academic detailing program in Maine administered by the Maine Medical Association. They have requested from the Attorney General that a small portion of the funds from the recent Johnson and Johnson settlement be set aside to help fund it. I am willing to share this proposal with people from other states. It's clear that academic detailing – independent prescriber education – is allowable under the wording of the settlement.
Wells: Agrees and this is a great opportunity.

Q: What is the chance that we will ever see an end to direct-to-consumer-advertising for drugs?
A: There are new rules likely to come out soon from the FDA which will require stronger, clearer descriptions of the risks of drugs in a way that is understandable with no distracting images on the screen. I'm more concerned about the marketing targeting the prescribers – the drug industry spends 4-5 times as much on that. There are 85,000 drug salespersons, at least 1 for every 10 doctors. If you take out the doctors who don't see them, that means there is really one salesperson for every 5 doctors. Their only full-time job is to get 5 doctors to do something different every week, so that is a lot of attention. They know every prescription doctors write and almost in real time – whether they are from competing companies or generics. This makes it easy to manipulate doctors.

Q from Wells: We have seen that drug companies will engage and hire different doctors who are key opinion leaders to speak on behalf of their drug products and go out and talk within the medical community about how effective a drug is. A peer-to-peer education model. Is there a model for an academic detailing program that is a peer group model that allows doctors to talk with each other about cost effective therapeutic alternatives?
Mark Ryan: I work at an academic medical center and we don't deal with drug reps, so we avoid a lot of that influence or call it out when we see it. I don't know that we do as well in preparing our medical students how to handle this when they go out into the world and encounter it. I have an idea for a service-learning project that would bring together our pharmacy and medical students on academic detailing.

Lisa Primate (Seattle, WA): One source I have participated in are Pharmacy and Therapeutic Committees, including one with organizations like Group Health Cooperative, and another at Madigan Medical Center, that are very interested in being cost-effective and evidence-based. Both of these have tight formularies. We were really able to deal with this problem. We did not allow drug reps to either facility. I don't know what happens with the P&T Committees in private practice situations. An active P&T Committee is good way information to

put out and provide some physician education. We are able to apply rational decisions to the formulary and to give good information to doctors.

Q: Can pharmacists be required to give out corrected information to patients taking these drugs?
A: Not sure how to require them to do that since they don't have a direct connection to the companies making the drugs. You might be able to require companies to provide free materials to pharmacists to distribute to patients – that's a fantastic idea! It would be hard to make sure it actually happened. Pharmacists are increasingly overworked, but there might be ways to do that. You might be able to do the same thing via physicians and give them information to provide their patients to whom they are prescribing these drugs.

Q: Since Medicaid programs and AGs are concerned about funding going directly back to Medicaid, and Medicaid knows who is prescribing these drugs, why can't Medicaid programs use some of those funds to provide education to prescribers to correct misinformation.
A: The Medicaid programs are all worried about their sustainability. Some are discussing limiting their patients to only 2 prescriptions, which makes no sense whatsoever. The policymaking is not always guided by the best therapeutic practices.
There are states where the political leadership does as little as they can to provide a good Medicaid program, providing none of the optional benefits even when the federal govt is picking up most of the cost.
Q: If doctors are prescribing drugs that don't work or may be harmful because they were marketed fraudulently, and the Medicaid is paying for it, and therefore ends up with sicker people because of that, isn't there a cost-effectiveness argument here?
A: Yes, there is a penny wise-pound foolish argument here. I also think that some Medicaid programs may not be aware of this at all – it's just not on their radar. They are struggling just to keep up and they're up against PhRMA which is very powerful and trying to prevent restrictions on these drugs. The disease groups are recruited to advocate for no restrictions on these drugs at all.

Q: How easily can academic detailing programs be set up in areas where they don't already exist?
A: Community Catalyst got funds from PEW Charitable Trust, and with grants from $50-100,000 we engaged some medical organizations to pilot these programs – a small amount of seed money is all that is needed. There are very good resources already developed that can be used. Just need to hire nurses, pharmacy assistants, doctors – people with some credibility to present the info to practices. The costs are not high, the logistics are not that challenging, but one hurdle for Medicaid programs to surmount is to not be perceived as sending in the "prescription drug police." Once they have real dialogue, the resistance by medical professionals can be overcome.

Q: As gratifying as these settlements are, are they large enough to dissuade these practices?
A: With one exception, they are not. The $1.4 billion settlement with Eli Lilly over off -label promotion of Ziprexa amounted to about 5% of the gross revenue they made selling it. That's just the cost of doing business. When Pfizer was forced to pay $2.3 billion for promotion of 4 drugs, that was about 14% of their gross revenue from those drugs, that was better. I haven't done the analysis of Depakote – that was a $1.6 billion. If one state attorney general in Arkansas decided not to accept the settlement over Risperdal and sought damages under false claims statute ($10,000 fee per false claim) and they won a $2 billion settlement at the state court level. If every state did the same thing, we'd be looking at $100 billion for settlements for that one manufacturer. That settlement is an exception that might be sufficient deterrent. Unfortunately, that decision will be appealed and it will be 5-7 years before it's settled. This could be a game changer, however.

Ann: I suggest folks call their attorney general offices in their states, find out who has worked on those settlements (assistant AGs), and get copies of these settlements. There have been a lot of great suggestions on this call as to what we could do as a group. We could work on writing a letter to the AG, that associations or others could use to ask that some of the funds be used to re-educate providers and consumers about this settlement.

To get in touch with Wells: wwilkinson@communitycatalyst.org

Ann, your idea is great – get in touch with AGs now, coming from physicians who are concerned about the quality of their prescribing and that of their colleagues would be kind of compelling. I've written a memo on this that I will share with everyone on this call. I may also be able to help connect people to specific AGs in some states – the junior level staff are very sympathetic and might advise as to the best way to weigh in.

Ann: If there are states without programs that want to start one, the National Resource Center for Academic Detailing has lots of information.

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, FL, KY, MA, MD, MI, NC, NY, OH, OR, PA, VA, WA

NPA is a proud partner in the Partnership to Advance Conflict-free Medical Education (PACME). This partnership and related materials were made possible by a grant from the state Attorney General Consumer and Prescriber Education Grant Program which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.