

Transcript of Pharma Insider I

(A video by PharmedOut.org released on October 22, 2007)

Douglas Melnick, MD MPH, a preventive medicine physician, worked for a major pharmaceutical company for more than five years. He is currently a consultant to PharmedOut.org.

Adriane Fugh-Berman, MD, is an associate professor in the Department of Physiology and Biophysics in the Georgetown University Medical Center and principal investigator of PharmedOut.org.

Dr. Melnick: A medical liaison is supposed to be – similar to my job – a medical consultant within the company, to educate marketing if a customer were to call. I would meet with the customers – but these medical liaisons are out in the FIELD. So if the company is located in Chicago, but the doctor's in Oregon...well, the company could send letters, which they often do, to Oregon. But, if they really want to share information with that doctor, then they're going to send this representative: the PharmD, the MD, the PhD – some of them might be nurses (I would say those are the three most common degrees) to talk to the doctor about the use. Now, there definitely is cause for abuse.

...Let's just say you have a drug and you don't have an indication in a certain disease. So your drug reps cannot talk about it. You might, as a company, send your drug reps in, to get information about that condition – without mentioning the drug – to “learn.” You want your reps to “learn” about this new disease. So your rep will go in and meet with the doctor – let's say it's a gastroenterologist – “Doctor, I'm a drug rep from the company. You know me for this other drug, this other indication. I want to learn now about tummy rash. Can you tell me everything about tummy rash because I don't know anything about it?” Or ... stomach noises. That would be your new—you have a drug for...”

Dr. Fugh-Berman: “Borborygmi”—stomach rumbling.

Dr. Melnick: Yeah – I'm just inventing a disease. So you have a drug that works for rash. But now you've got to get an indication for borborygmi. So you send reps in to talk to the GI doctor—“I don't know anything about borborygmi.” So the doctor starts explaining and then after a few minutes he says, “Well, didn't I read in the Wall Street Journal that you have a new drug in this area?” Ding. OK. “Doctor, we may have something. I can't mention or discuss it with you. However, if you'd like, I can have the company contact you.”

Dr. Fugh-Berman “...there's not a distinction made between on-label and off-label sales. So it's certainly to the drug reps' advantage in terms of their bonus to promote off-label use, but they are not supposed to—and in fact can get fired for promoting off-label use.

Dr. Melnick: Now, I'm not saying all off-label use is necessarily bad.

Dr. Fugh-Berman... Right. We don't have a lot of clinical trials in children, but we have to treat them when they get sick. So that can be an appropriate off-label use. There are appropriate off-label uses. However, the medical literature and the medical information environment is sometimes tainted by information that's from companies that are really promoting off-label uses. And that's a problem.

Dr. Melnick... See, there's a risk-benefit reward. Within the company they will ask themselves, "Gee. If we're making a billion dollars a year on this drug off-label – if we find out it doesn't work, we're going to lose that billion dollars." So they'll calculate. They may say, "Well, we've sort of maximized. Even if we get the indication, the doctors aren't going to use any more of it because we've so successfully marketed it. They can't really spend more than a billion (or maybe they'll spend another hundred million) but if we really study it in enough patients and it proves to be either ineffective or, worse – dangerous – we're going to lose the whole billion. And we don't want to take that risk."

Dr. Fugh-Berman: So it's a disincentive to testing for that indication.

Dr. Melnick: It's a disincentive. And the company will say we have no reason to test this. "You – the general medical community – go ahead and study it on your own."

Dr. Fugh-Berman: The oncologists are the biggest users—off-label users—of drugs. So a lot of drug use in oncology is off-label.

Dr. Melnick: Right.

Dr. Fugh-Berman: So in the Physician's Desk Reference (the PDR) you only have the labeled uses, but in compendia you can have labeled and unlabeled uses.

Dr. Melnick: Right, that's my understanding. There might be six or eight major compendia. And you might have off-label uses discussed. Once it's in that compendia, then the payers (who are the insurance companies and others) will start paying. Medicaid and these other payer sources, will start paying for these expensive medications. So it's very useful for a company to have a relationship with compendia. The best practice that I've seen – the most effective way for a company to work with compendia – is have a single contact who gets – usually a pharmacist-type person, somebody with a degree – who gets to know the writers of the compendia (who often are pharmacists, drug information-type people), builds up a relationship. And then as we were discussing, abstracts and papers, those things can be sent in a package to the compendia. Because you have got to realize, it's a lot of work to analyze a new drug and then, if it's in the compendia, there might be a celebration because now your drug is going to be paid for off-label.



PharmedOut (<http://www.pharmedout.org>) is an independent project funded through the Attorney General Consumer and Prescriber Education grant program that educates physicians on how pharmaceutical companies influence prescribing.