

Panel Discussion: Conflicts of interest

John Fauber (JF) (Chair: John Lister (JL))

(Barry Turner) The ghost-writing issues and the off-label prescribing practice frequently cross the line into fraud. I've been involved in a couple of key actions in the United States against medical device companies. Why isn't there more of that?

(JF) I think the big problem is that in the United States it's illegal for drug companies to promote their drugs for off-label uses but doctors can prescribe them without any kind of sanction. There's no restrictions on doctors for prescribing off label. So for instance with CME. CME courses can bring up off-label uses of drugs and doctors will listen to these things and these presentations and maybe do it. As long as it's not the drug company that's doing the promoting it's entirely legal.

(BT) But it's not difficult. In the cases I've been involved in it's not very difficult to link alleged CME training to direct marketing. If that happens that's a key issue.

(JF) It is a fact that there are law suits that occur. There are a number of drugs where that has happened. There are whistleblower actions that occur when patients are harmed and lawyers find out that there was some effort to promote the drugs off label. Not only that but every year there's several huge criminal investigations that take place with the US Justice Department, who go after drug companies, prosecute them and extract what sounds like a really big settlement: a billion dollars. Some of them have been caught several times doing it. It looks like they are really coming down hard on them but in reality people think it's just the cost of doing business. If you look at how much money they pay in fines versus what the sales of the drugs are it makes perfect sense for the drug companies.

(BT) Some colleagues and I went after two – Eli Lilly and Pfizer. We were involved in the \$1.6 billion fines they got. What we had in the background, we wanted to damage their stock value sufficiently to go after them through the Securities and Exchange Commission. But they demonstrated their financial power. Their stock value rallied within 3 days after a \$1.6 billion fine. But if there was more of it, if the press hammered it more and more it's then clear the stock value would be damaged. The reason we were doing that is because they are not concerned slightly by paying corporate fines. But the CEO or the CFO is concerned about going to gaol.

One final point. If Pfizer was a person rather than a corporate personage, it would be banned from entering the UK because of its felony convictions, never mind being allowed to buy a British-Swedish drug company.

(JF) This happens everywhere. The huge financial crisis, the world-wide financial crisis in 2008. In the United States there were blatant examples of people breaking the law and the term is 'too big to fail'. They didn't want to prosecute big banks and insurance companies. They were worried that it would cause things to get worse so no individuals were prosecuted as a result of that. It's very seldom that individuals with drug companies get prosecuted for illegal promotion of their products. Occasionally it will happen but it's rare.

(BT) You could get them for an SEC violation if it was a knock-on effect.

(Unattributed) John, you are obviously building up a reputation as an investigative journalist. Have you suffered professionally by companies or governments or anyone refusing to speak to you because of who you are?

(JF) The way I do my stories is I get a snowball effect, I eventually figure out there's a story. I start building up research and coming to conclusions and things that I want to put into the story. I go to the drug companies at some point more towards the end of my research to say 'what do you have to say about this? What's your side of it?' It's not to their advantage to say nothing. Occasionally they won't, some individuals won't speak, but drug companies are pretty smart. They know what the story is going to be about and they are smart enough to realise that to say nothing just makes it look worse. So they provide their side of it. Sometimes they have a very good side but what usually happens is they don't refuse to respond but they usually refuse to talk to me so I have to submit questions, I have to e-mail them questions that they will respond to in e-mail. There's no interchange, there's just an exchange of e-mails. Sometimes their responses are really not responses but it's what they are providing. They generally always say something through a spokesperson.

(Harry Dugmore) Again, not wanting to be sensationalist and alarmist. These practices you've described are world wide. Speakers fees in some of the countries the companies have now foresworn they won't do any more. The lavish trips, the continuing education. It strikes me that getting away with this in the USA with their regulatory finesse and these large fines is something that they are prepared to take on. In other words they are behaving in quite terrible ways. These are deeply unethical practices that have real consequences for people's lives in the USA. It would seem to me that in all probability their behaviours are even worse when it concerns the developing world: the lower regulatory environments, lower enforcement. Which is a lot for the media and journalism to take on. I wonder if there's not again a watchdog rather than journalism because we shouldn't be putting more pressure not so much on the companies because they are big and they've got PRs and lawyers; but on regulatory agencies like the World Health Organisation.

I don't know who the WHO is beholden to, maybe also the same pharmaceutical companies, but maybe they should be helping both the Americans, the Europeans and also in the developing world take these guys on and expose these practices which have life and death consequences.

(JF) One of the things we're doing now in the third world is moving in on clinical trials, so they have regulations that there have to be trials, they have to go to institutional review boards, and you have to conduct these trials a certain way. I think they are finding a more relaxed environment in third world countries and they can get their research done quicker and without much oversight. But you are right, it's going on all over the place.

(JL) On that last point, I think it would be worth going back to our colleague in Oxfam, who is going off to the World Health Organisation Assembly in Geneva in the next few days and maybe suggest that that might be a strand that people might like to investigate as to how the WHO can step up and play a more significant role. Admittedly they are not playing it as much with the American

administration and haven't for a very long time but it's worth looking at what could actually be done to try to add weight to those who do want to make a stand on these questions.