

## Conflicts of interest

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### **An Accidental Health Reporter**

I'm a medical reporter with the *Milwaukee Journal Sentinel* ([www.jsonline.com/sideeffects](http://www.jsonline.com/sideeffects)) and with MedPage Today (<http://www.medpagetoday.com>). I'm actually a former business reporter who never wanted to be a health reporter, then they merged the two newspapers in Milwaukee in 1996 so suddenly I was covering health. I had a new job and it turned out it was a great career move. For years I've been what you would call a traditional medical reporter. I went to a lot of the medical meetings and covered the latest presentations. I monitor the medical journals for the latest developments.

Then in 2008 I got a disk that contained the disclosure statements of several hundred doctors who practised at the University of Wisconsin School of Medicine. These disks were essentially statements of their outside income. Money that they had been getting from drug or medical device companies for being speakers, or for royalties. I did a two-part series on this. I examined all of the disclosures and talked to a lot of people and I found there were dozens of doctors who were moonlighting for drug companies and earning tens of thousands of dollars a year or more.

The stories ran in early January 2009. Really I had no plans to continue working as an investigative medical journalist, but to pretty much go back to doing what I was doing which was more traditional medical reporting. About 2 weeks after that series ran the US Senate Committee on Finance which had been investigating payments by drug companies to doctors came out with a report that said that among other things that there was a spine surgeon at the University of Wisconsin who was earning \$4 million a year from the device firm Medtronic for royalties. That's when it became obvious to me that this was something that needed more attention. I started looking into these issues a bit more and getting tips from people. I was being told what rocks to look under. Since then it's been a full-time job for me, that's basically all I write about – conflicts of interest in medicine.

My stories in the *Journal Sentinel* can be found on our website, there's a landing page for them, JS online ([www.jsonline.com/sideeffects](http://www.jsonline.com/sideeffects)). They also run in Medpage Today, which we've had a partnership with since 2010. You can also follow me on Twitter (@fauber\_mjs). Every year I do maybe six or seven investigative pieces with some follow-ups.

### **Big Pharma: The Source of the Conflict**

There is a common theme in a lot of this reporting in that drug companies are really skilful at spending a lot of money to gain an advantage to sell more of their products. While this may be good for them it isn't good for the patients, some of whom can actually be harmed by this activity.

Often it works like this. There's first a buzz created about a potential new therapy. Then research, often by doctors with financial ties to a drug company is presented to the FDA for approval of a product for a very specific use on a very narrow group of people. Once the product gets on the

market, other uses are promoted for it and articles and presentations given by doctors with financial links to the drug company.

I'm going to talk about some of these conflicts, focusing on five of them which come up quite often in my reporting.

### **Promotional Speaking**

The first is promotional speaking. This is one of the more common forms of conflict of interest in medicine. It basically involves drug companies engaging prominent doctors who are key opinion leaders who can give talks to other doctors about a disease or condition. Often these doctors are academics at a university. It works something like this.

A drug company sales rep will go out into the community and find a few doctors, usually practice doctors, family medicine doctors, and ask them if they are interested in seeing a presentation. They often go to restaurants, usually hire restaurants, they tend to prefer steak-houses. The doctor will settle, the speaker will give the talk. The speaker is usually paid somewhere around \$1000 but is could be as much as \$5000. If it works out the way the drug company would like, some of these doctors will leave the presentation and eventually put some of their patients on the drugs of the company that funded the talk.

This is successful in part because I think in the USA direct consumer advertising is allowed. If you watch the evening news, cable news in the Unites States you will be bombarded with ads for all kinds of drugs. Patients see these ads and go to their doctor who often doesn't have much time to dissuade them from going on an expensive brand name drug instead of maybe going on a generic or even having no treatment at all. This system has been fairly successful for drug companies in that regard. But it's also been an embarrassment for a lot of medical schools.

A lot of schools have gotten bad publicity because their doctors are essentially acting as promoters for drug companies. Several leading medical schools in the USA have actually banned the practice. The University of Wisconsin came out a few months after the stories that I did and told its doctors they could no longer do promotional speaking for drug companies.

So drug companies are now using more private practice physicians who are not necessarily subject to the code of ethics of universities and medical schools. I don't know whether promotional speaking is declining; my sense is that it is somewhat, although I still think it's a fairly common practice. Some drug companies have stopped doing it.

### **Continuing Medical Education (CME)**

This topic is related to promotional speaking: it's a more sophisticated and acceptable sibling of promotional speaking, which is continuing medical education. Doctors, in order to maintain their licences, have to update them continually with credit. They can do this through various courses they are offered. Drug company funding of CME courses is a pretty big business still. These kinds of programmes are usually done under the auspices of an accreditation system. So the money doesn't

go directly from the drug company to the doctor, it often flows through a shadowy third-party organisation known as the medical education/communication company. They will engage the speakers, prepare the course materials, and take over the role of working between the drug company and the doctors to give the presentations for these CME courses.

It's a great system for the drug companies and for doctors because doctors essentially get free credit to help maintain their licences and drug companies often get very favourable mention of their products in these CME courses.

I don't think all CME is corrupt. I think some of it is very useful. But in 2007 the US Senate Committee on Finance, which had been investigating pharmaceutical firms, found that they had essentially taken control of these programmes to get favourable presentations of their products to grab market share for expensive brand-name drugs, and to encourage doctors to write prescriptions for off-label use.

This kind of drug-company funding of CME once was about a billion dollars a year in the USA. I think it's now probably several hundred million but it's still a fairly common thing. I've done a number of stories about drug company funded CME.

The very first one that I did was a piece that was on a \$12 million programme that the drug company Wyeth had created (Wyeth has since been purchased by Pfizer). They had a programme that they started in 2002 after getting some devastating news from a national randomised trial on hormone therapy replacement products for women. Those products were found to actually increase the risk of breast cancer and heart disease and stroke and blood clots. Wyeth was trying to stop the bleeding and created this programme called the hormone education council, which was run through the University of Wisconsin Medical School. For 6 years this programme essentially gave doctors CME credit. Most of the course materials downplayed the risks of hormone therapy and over-stated the benefits.

The hormone education council had 40 members on it; 34 of them had financial ties to Wyeth. Some of the materials that had been put up for CME credit actually had been ghost written by agents for Wyeth, who found academics to put their names on the papers. This research material reached about 128,000 doctors. For its part the university got about \$1.5 million essentially to put their name on the programme. The day after we enquired about the programme they took the materials down from the web, which had been out there for nearly 6 years.

I've done other stories about drug industry funded CME. The Singh University thinking that's what good for women is also good for men, decided to put their name on a CME course on testosterone therapy for men. These drugs are very unproven and potentially dangerous and are actually a pretty good example of how drugs get on the market for a very narrow use and the big money is getting people to use them for other things. Testosterone therapy has been around for a long time and it's always been a treatment for a very small number of men who don't produce testosterone or who produce very little of it.

Then somebody got the great idea that maybe with all the testosterone levels declining as you get older, if you could start selling it men as they aged there was a big market there. If you watch the news in the USA in the evening you will see ads almost every night pushing testosterone therapy. It's very unproven and potentially dangerous.

I've done stories about a smoking cessation class that promoted another dangerous drug, another course on restless leg syndrome, and another on premenstrual dysphoric disorder in women.

## Medical Societies and Organisations

The next area is a very fertile one for drug company spending. Non-profit medical societies and organisations who get significant funding from drug companies. These are groups in the USA like the American Geriatric Society or the American Academy of Allergy, Asthma and Immunology. Some of them get a very high percentage of their funding from the pharmaceutical industry and as a result they can be very friendly in their messages, and what they tell patients, towards the drug companies.



Figure 1

Figure 1 is a graphic that ran with the story that I did 2 years ago. It was about a bunch of non-profit groups that advocate for treating pain. These are groups that took millions of dollars over the years from companies that make narcotic pain killers, opioids. The story with opioids is they are very accepted and well established for treating acute pain, the kind of pain you might get after having

surgery or if you were in an accident or even if you were getting a root canal and you needed something to lessen the pain for a day or two. They are also well established and acceptable for cancer pain and end of life care.

Where they aren't proven or effective is in chronic, non-cancer pain, the kind of pain that can go on for many months or years: low-back pain, fibromyalgia, migraine. The drug companies knew that there was a huge market for chronic pain. In the late 1990's to early 2000's they started funding a lot of these organisations hoping that they would deliver a message that said that opioids were great for treating private pain, and they did. As a result we have a real opioid epidemic in the USA today.

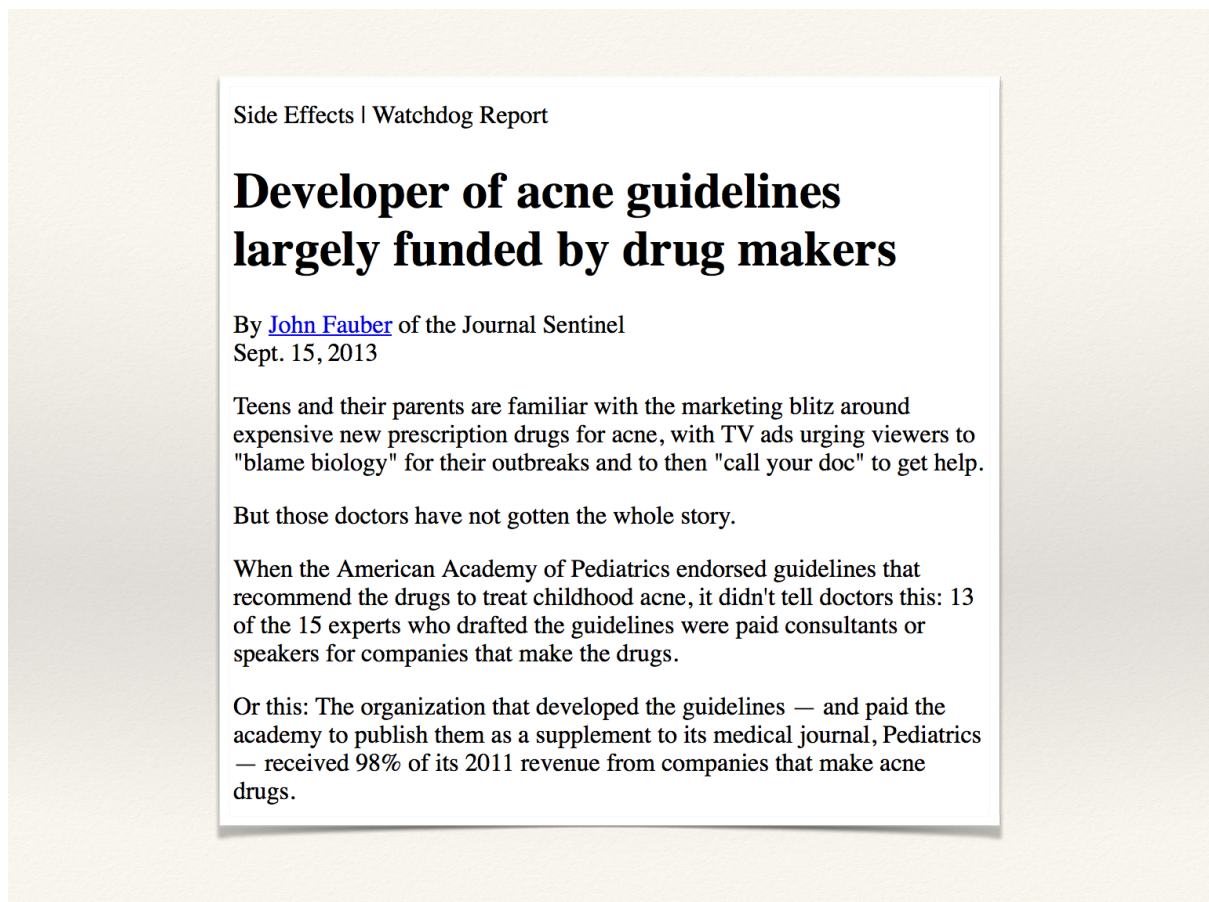


Figure 2

Another story I did (Figure 2) had more to do with a more obscure organisation, the American Acne and Rosacea Society. This is a group that gets 98% of its revenue from companies that make prescription acne products. Two of its top officers when I did the story last year were paid speakers and consultants for acne drug companies, including one that is their biggest corporate contributor. Early last year I did a story on some treatment guidelines that the American Acne and Rosacea Society issued for treating acne in children. It's probably not a surprise that these treatment guidelines recommended a product that's made by their leading funder. This product costs about \$2500 a year and it was treated very favourably in their guidelines.

None of these conflicts were exposed and to a make it even worse the guidelines that the society issued were picked up by the American Academy of Pediatrics and published in their journal. The

American Academy of Pediatrics had information showing that the 13 of the 15 doctors who drafted the guidelines were paid speakers or consultants to drug companies but they also failed to disclose that.

### **Clinical Treatment Guidelines**

Intertwined with these medical societies and organisations are clinical treatment guidelines. This is another area where you see drug company money spent quite a bit. These guidelines are essentially standards of care and they are for treating a variety of diseases and conditions and there could be a lot of money riding on national treatment guidelines. In the USA they are often issued by non-profit organisations. They can also be issued by government entities like the national institutes of health. I believe in the UK they are issued by the National Institute for Health and Care Excellence (NICE).

In 2012 I was trying to figure out how to come up with a fair and systematic way to take a look at conflicts of interest and clinical treatment guidelines. I remembered that line from *All the President's Men* – follow the money. So I got a list of the 25 top-selling drugs in the USA for 2011 and these are drugs that produce sales of \$94 billion that year. Then I went to the FDA and found out when each of these drugs was first approved and for what conditions they were approved for – high cholesterol or asthma or depression. From there I found the list of clinical guidelines that were immediately after the first approval of these drugs. I found 20 sets of guidelines that were applicable to these 25 drugs. These guidelines were in total were created by a group of 293 experts, mostly doctors and specialists in their fields.

Sixteen of the 20 guidelines had disclosure statements – things that they bury at the very end in fine print. From there I was able to establish that 66% of the doctors who drafted the guidelines had financial ties to drug companies such as working as speakers or consultants. More importantly, these panels sometimes recommended drugs that were not proven to make a real meaningful difference in treating a disease. One panel recommended narcotic painkillers to treat chronic pain. Another recommended a dangerous and expensive drug for chronic kidney disease patients. In 2007 the National Heart and Lung Blood Institute put out a set of guidelines to treat asthma. Fifteen of the 18 members of that panel had financial ties to Glaxo and Kline or other companies that make asthma drugs including the market leader, Advair. This panel had recommended Advair and other similar drugs known as long-acting beta agonists as the preferred treatment to inhaled steroids for adults and children over the age of 12. Never mind that these drugs had been linked to fatal asthma s in thousands of people and that they were already vastly over-prescribed.

# Clinical Treatment Guidelines

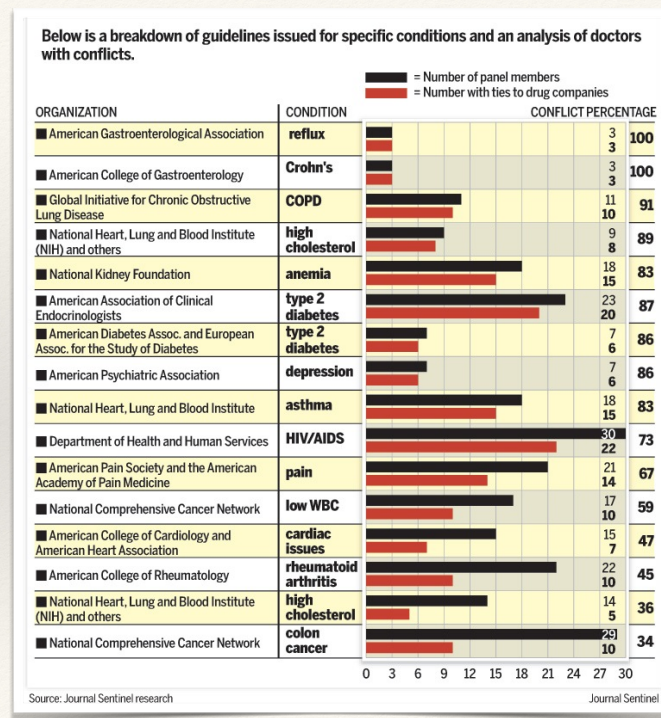


Figure 3

Figure 3 shows the conflicts of interest in various conditions.

## Medical Device Royalties

I've written a lot about this. If you are lucky enough to get them these are essentially the mother lode of conflict of interest money. In the last 5 years I've reported quite a bit about the device company Medtronic and its spinal fusion product known as Infuse. Infuse is used in spinal fusion and it's actually a combination device. It combines a piece of hardware with the very powerful biologic drug BMP2 (bone morphogenetic protein 2). This device was approved in 2002 as an alternative to traditional spinal fusion surgery that often required harvesting a small amount of the patient's own hip bone to obtain a fusion.

Thanks to a very small group of prolific spine surgeons who had authored several papers on the BMP2 it soon became a block buster or near block buster drug. Its sales hit near \$800 million a year and 80% of its use was off label. These spine surgeons were actually getting millions of dollars every year in royalty income from Medtronic from other spinal products that it made. Much of this was not disclosed.

More importantly, there was a problem with much of their research papers that they published. These papers systematically failed to link BMP2 to a variety of serious complications including cancer, growth of unwanted bone on the spine and a condition that could cause sterility in men.

Eventually it was revealed that over the course of 15 years Medtronic had paid \$210 million to these 13 surgeon authors. Also that Medtronic executives had been secretly drafting and editing many of the papers that they wrote. So this is playing out now. I had a few stories this year about how Medtronic is now being sued by thousands of back patients who were harmed after getting BMP2, after getting some type of off-label surgery.

### **Conclusions for Health Journalists**

I don't think that conflicts of interest are necessarily a bad thing or should be banned. They can lead to in some cases medical innovation. But they can also lead to some real bias when it comes to medical news and research. It's something that if you are a health reporter, you always need to look for.

I spend 2 months sometimes working on a story, so I can do these. A lot of reporters in health don't have that kind of time. So they can't do these types of investigations. But the one thing I think you can do is whenever you do write something about a new drug or a treatment, look to see if there are conflicts and point them out. It's the least that you can do. Disclosing a conflict doesn't eliminate it but at least it puts people on notice that it does exist.