6 Prescription Drugs That Aren't as Safe as the Government Claims

Adding to the problem is the fact that the nominee to head the FDA is steeped in Big Pharma money.

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What stands between Big Pharma's desire for blockbuster drug sales and drug safety? In addition to the FDA, it is often medical journal editors who see, evaluate and publish early research. In fact, the benefits of drugs in the "pipeline" that have not been approved yet are sometimes floated in medical journals to "preposition" the marketing and brand the drug candidate. For example, five years before the recent approval of the drug flibanserin for low female sex drive, the British journal Women's Health published research titled "Flibanserin: a potential treatment for Hypoactive Sexual Desire Disorder in premenopausal women." Just trying to get a jump on things.

A quick look at drugs or drug uses that later turned out to be risky shows a disturbing trail of "bought" science in major medical journals—"support" from the drug company that is actually making the drug is not disclosed.

Vioxx

Awareness of bought science crystalized after Vioxx, a pain drug advertised by Dorothy Hamill, the former Bruce Jenner and other celebrities was eventually linked to more than 27,000 heart attacks and sudden cardiac deaths. The drug was pulled from the market in 2004. Much of Vioxx's perceived safety stemmed from an article published in the New England Journal of Medicine in 2001 that downplayed its actual heart risks. When the enormity of the dupe

became apparent, Jeffrey Drazen, then NEJM editor, said the authors of the article, who included Merck employees, had deliberately buried data. Why would paid employees of a for-profit drug company do that?

"This was an episode where it was clear people had taken data and not reported it fully," said Drazen. "I have now learned we need to be much more careful."

SSRI Antidepressants

Soon after the Vioxx revelation, the Journal of the American Medical Association began to have its own scandals. Doctor authors who had defended the use of antidepressants during pregnancy in a 2006 JAMA article had ties to antidepressant manufacturers. Oops. Lee Cohen, lead author of the antidepressants study, declared in a followup letter to JAMA that, "We did not view those associations as relevant to this study," and listed 76 other financial relationships the nine physician authors had with Pharma.

Three years later another JAMA author was found to have undisclosed financial links to SSRI makers. Robert Robinson, who wrote about the drug Lexapro, had failed to report lecture fees he received from its manufacturer.

The SSRI Paxil also benefitted from Pharma money. Martin Keller, former professor emeritus of psychiatry at Brown and lead author of a now discredited Paxil study, admitted that GSK had given him tens of thousands of dollars during and after the study.

Statins

AlterNet recently covered how Big Pharma got statins—especially Lipitor and Crestor—into millions of US medicine chests. During the same year JAMA had undisclosed funding from antidepressant makers, Harvard's Paul Ridker (whose research put the statin Crestor on the map) also apologized to JAMA for omitted financial disclosures. For his article about cardiovascular clinical trials, he thought he only had to report funding for the "study at hand" and did not mention funding from AstraZeneca, Bayer, Novartis, Roche, Sanofi-Aventis and five other pharmaceutical companies.

Immune Suppressing Drugs

Weeks after Ridker's disclosure, another apology letter appeared in JAMA referring to a paper that had been published the previous year looking at cancer risks in patients taking infliximab (Remicade) and adalimumab (Humira) for rheumatoid arthritis. Author Eric L. Matteson, a professor of medicine at the Mayo Clinic and other Mayo researchers didn't tell the journal they had received $25,000 from Enbrel-maker Amgen. ("The stipend was not linked to the study or systematic review of TNF-alpha antibodies") Nor did the researchers tell JAMA they had let Abbott Laboratories, then the maker of Humira (now made by AbbVie), review the paper before it was published.

AlterNet has covered the dangers of immune suppressing drugs like Humira, prescribed for rheumatoid arthritis and other conditions, for years. The drugs can be beneficial for people with serious conditions, but for people with mild conditions the risks, which include cancer, are hard to justify. In fact, some are speculating the pneumonia and intestinal conditions that took the life of the Eagle's Glenn Frey in January were exacerbated by the RA drugs he took which invite opportunistic infections.

Various Anti-Stroke Drugs

There were more missed disclosures at JAMA. The same year as Ridker's mea culpa, doctor authors who said patients with migraines that included auras were at risk of cardiovascular disease and stroke also disclosed financial links to cardiovascular medication manufacturers.

"While we believe that we have no financial interests, relationships, or affiliations that would be relevant to our describing a biological link between migraine and cardiovascular disease," wrote Tobias Kurth, lead author in a followup letter to JAMA, "we are disclosing all nonfederal relationships of every coauthor." Kurth goes on to list 53 financial relationships the six physician authors had with drug companies.

Five years later in the American Heart Association's magazine Circulation, Kurth was among authors who were still making the stroke risk claim, this time with Pharma disclosures.

Risperdal and Other Pediatric Antipsychotics

Is the last few years, Pharma has led the "science" that proclaims children can and do suffer from depression and psychosis (in addition to their widespread attention deficit problems). Leading the claim is Joan Luby, who was forced to write in the Archives of General Psychiatry that she had not disclosed lectures she gave for AstraZeneca and other industry ties when writing about the problem of childhood depression "because they were not relevant to the subject of the article."

If anyone doubts there is money in psychiatric pediatric drug sales consider this: an entire "Pediatric Mood Disorders" program was founded at the University of Illinois Chicago by a Pharma-funded doctor to "intervene" in such childhood problems.

Courts Increasingly Defend Pharma Marketing "Speech"

You might think courts would side with the public against Big Pharma's desire to hide risks and increase benefits to sell drugs. But the opposite is occurring. Last year US District Judge Paul A. Engelmayer ruled that the First Amendment covers Big Pharma messages including when the industry floats uses for its drugs that have not been approved by the FDA, called "off-label marketing." The FDA cannot block such speech, said the court. The ruling pertained to the triglyceride-blocking drug Amarin, only applies to the 2nd US Circuit Court of Appeals (which includes New York, Connecticut and Vermont) and is likely to be appealed.

But in 2011, the Supreme Court struck down a Vermont statute that blocked Pharma from mining doctor prescribing information to better sell drugs, also calling it speech. Six Supreme Court Justices said the law limited Pharma's free speech—previously known as "marketing."

Does Disclosure Even Matter?

The medical journals' "disclosure-gates" reveal that doctors have more Pharma financial links than anyone thought, and that some doctors think they have the ability and the right to decide which ones are “relevant.” Remember when politicians and officials would step down over merely the appearance of conflicts of interest or wrongdoing?

And there is another irony. The medical community and public may not even care. Since medical disclosure rules were rolled out more than five years ago, I have been to medical conferences where presenters post disclosure slide after disclosure slide which clearly shape their pro-drug presentations, yet doctors in the audience do not seem to blink an eye. Is it a case of, "Hey Mom, all the kids are doing it"?

More disturbing is the fact that the current FDA Commissioner nominee, Duke researcher Robert Califf, is so steeped in Pharma money, some have said it amounts to a handover of the drug safety organization to the drug industry. A disclosure statement on the website of the Duke Clinical Research Institute where Califf directed research lists 25 drug companies Califf receives funding from, including drug giants Johnson & Johnson, Lilly, Merck, Schering Plough and GSK. Duke itself was steeped in scandal after a major research fraud that resulted in terminated grants, retracted papers and a 60 Minutes special.

Califf was instrumental in the Duke drug trial of the blood thinner Xarelto, and was an early cheerleader despite medical experts’ objections to its approval and 379 subsequent deaths.

Califf defended Pharma financial ties on National Public Radio, saying, “Many of us consult with the pharmaceutical industry, which I think is a very good thing. They need ideas and then the decision about what they do is really up to the person who is funding the study.”

Senator Bernie Sanders says he opposes the confirmation of Califf. "Instead of listening to the demands of the pharmaceutical industry and their 1,400 lobbyists, it is about time that the FDA and Congress started listening to the overwhelming majority of the American people, who believe that medicine is too expensive," he said in a news release.

Senator Lisa Murkowski of Alaska blocked the January vote for Califf’s confirmation, ironically not because of the FDA’s drug duties but because of its food responsibilities. According to the New York Times, the senator said she would block Califf’s candidacy because of the FDA’s 2015 approval of a genetically engineered salmon that threatens her state’s salmon industry. (AlterNet looked at the new GE salmon in December.)

Still, few doubt the Pharma-friendly Califf will be the next FDA Commissioner, and some say if that is the case, why even have an FDA?

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