Busted! Big Pharma Epilepsy Study Rigged to Push Drug Gabapentin

By S. L. Baker, NaturalNews

If you think being concerned over natural health issues means you automatically dismiss everything that mainstream medicine has to say - think again. Not only are many mainstream researchers coming up with evidence that nutrition and other natural therapies really are effective but now comes a report published in none other than *Archives of Internal Medicine,* a Journal of the American Medical Association (JAMA), that blows the lid off an unethical Big Pharma practice.

Specifically, the article shows how drug pushing - not science - appears to have been the motivation behind a study that supposedly was testing the drug Neurontin (gabapentin), currently widely used to treat nerve pain. The test was allegedly designed to document how various doses could treat epilepsy. ***But it turns out the trial was set up to "seed" the results in order to sell the drug, much like a card shark might stack a deck of cards in order to cheat at a game of poker.***

According to the just published article, when researchers are involved in so-called seeding research, they are conducting clinical trials primarily as marketing tools so the drug can be promoted and sales pushed by doctors. Bottom line: these are promotional trials used for selling drugs and research subjects and physicians may not be told the true purpose of the studies.

Surely, promoting a study as true scientific research when it is really a ploy used to market drugs must be illegal, right? According to the new report, Big Pharma is allowed to get away with seeding studies under the current law. However, the authors (Samuel D. Krumholz, B.A., David S. Egilman, M.D., M.P.H., and Joseph S. Ross, M.D., M.H.S., who are consultants at the request of plaintiffs currently suing Pfizer Inc. over the gabapentin seeding study in the U.S.), report the practice is clearly unethical.

To prepare their report, entitled "Study of Neurontin: Titrate to Effect, Profile of Safety (STEPS)", the researchers investigated whether the study was a seeding trial by looking into documents related to the marketing, sales practices, and product liability litigation of Neurontin (gabapentin), prescribed for epilepsy. Because the authors were consultants to the plaintiffs in a lawsuit involving the drug, they had access to depositions and the document database. ***And that meant they were able to get their hands on damning correspondence, clinical research reports and market research analyses for a look inside the workings of Big Pharma's pushing of the drug.***

What did they discover? Although the trial's supposed purpose was to study dose-titration of gabapentin among 2,759 patients enrolled by 772 investigators, the study was uncontrolled and unblended. In other words, it didn't meet the basic criteria for a sound drug study.

However, articles based on the results of this anything-but-gold-standard-science study managed to be published in two journals - even though the sloppy study design was

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questioned by two outside sources and that "data quality during the study was often compromised."

But here's even more compelling evidence something was not on the up and up: the authors cite documents that strongly suggest drug company marketing personnel were involved in collecting the trial data. What's more, the Big Pharma marketing heads viewed the trial (and not only its results) as a way to push sales of gabapentin.

This involvement of the marketing team and the failure to disclose the study's real purpose from both research subjects and collaborators are the "smoking guns" that mark the STEPS study as a seeding trial, according to the authors. They are calling for institutional review boards (IRBs) to finally take a strong stance in discouraging these types of marketing-over-science trials. "Reform of the current IRB system," they wrote, "as well as promoting better clinical trial practice in the human subjects research community, are necessary to prevent continued conduct of seeding trials by the pharmaceutical industry."

In an accompanying commentary to the study, G. Caleb Alexander, M.D., of the University of Chicago, noted that seeding trials negatively affect scientific knowledge and clinical care. "The biomedical enterprise depends on good science for its foundation, and good science requires transparency of methods and integrity of purpose," he wrote.

He pointed out the evidence presented by Krumholz and colleagues "strongly supports the conclusion that STEPS meets key criteria of seeding trials." Dr. Alexander also stated that these unethical seeding trials can detract from the legitimate value of well-designed and well-conducted phase 4 studies of pharmaceutical drugs.

"Although the road is long and the hill steep, these and other changes offer the promise of incrementally improving and safeguarding the integrity of the biomedical enterprise. One can only hope that the report by Krumholz et al will contribute to this evolution," he concluded.

Let's be blunt here: the new report in the *Archives of Internal Medicine* shows that Big Pharma's research results cannot always be trusted and may place more importance of skewing data to promote and push drugs on the public than in coming up with true scientifically sound data.

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http://archinte.ama-assn.org/curren...