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Clinical study of epilepsy drug may have been purely promotional

June 27 2011

Yale School of Medicine researchers have found that a clinical trial of the epilepsy drug gabapentin may have been a "seeding trial" used by a pharmaceutical company to promote the drug and increase prescriptions, according to a report in the June issue of *Archives of Internal Medicine*.

As described in the study by Yale assistant professor of medicine Joseph Ross, M.D., and his colleagues, a seeding trial is a clinical trial conducted primarily for marketing purposes and intended to promote the drug and increase prescribing by exposing physician-investigators to it.

Ross and co-authors reviewed all documents relating to the clinical trial "Study of Neurotonin: Titrate to Effect, Profile of Safety (STEPS)." These documents included company internal and external correspondence, reports, and presentations, as well depositions elicited in legal proceedings of Harden Manufacturing v. Pfizer, and Franklin v. Warner-Lambert.

"We found that STEPS was a seeding trial posing as a legitimate scientific study," said Ross. "The trial itself, not trial results, was part of a marketing strategy used to promote gabapentin and increase prescribing among investigators without informing trial patients or investigators."

Although seeding trials are not illegal, Ross said they are unethical, because of the promotional nature of the trials and because participants and physicians may not be told the true purpose of the studies.

According to the authors, STEPS' stated purpose was to study dosing of gabapentin among 2,759 patients who were enrolled by 772 investigators. Although two articles based on the results of the study appeared in journals, Ross and his colleagues note that two outside sources questioned the uncontrolled, unblinded study design and that "data quality during the study was often compromised." They also cite documents that appear to suggest that marketing personnel were involved in data collection, and that marketers viewed the trial (and not just the trial results) as a vehicle for promoting gabapentin.

Ross said that although STEPS was conducted 15 years ago, the ethical breaches it illustrated is relevant in today's debates over the limits and consequences of pharmaceutical industry sponsorship of Phase IV post-marketing clinical trials.

"The current Institutional Review Board (IRB) system needs to be reformed, and better clinical trial practice needs to be promoted in the human subjects research community in order to prevent further seeding trials by the pharmaceutical industry," said Ross.

More information: Study: *Arch. Intern. Med.* 2011;171[12]:1100-1107.
Commentary: *Arch Intern Med*. 2011;171[12]:1107-1108.

Provided by Yale University