Review: Reports on Pfizer drug studies misleading

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(AP) -- Analysis of a dozen published studies testing possible new uses for a Pfizer Inc. epilepsy drug found that reporting of the results was often fudged, indicating the medicine worked better than internal company documents showed.

According to the report, when a company-funded study's primary finding wasn't favorable, that result was usually buried and something else positive was highlighted, without disclosing the switch.

The documents used in the review were obtained by lawyers suing Pfizer for refunds on prescriptions paid for by insurers and consumers. The lawyers, who are seeking class action status for the cases, claim Pfizer concealed evidence the epilepsy drug Neurontin didn't work for those unapproved uses, including nerve pain, migraines and bipolar disorder.

One of the report's authors is an expert witness for the plaintiffs; another has received fees from the lawyers.

Pfizer disputes the report's conclusions, saying the company never "attempted to mislead the medical community about the effectiveness" of the drug for certain uses.

"We believe the review suffers from significant bias, insufficient data, poor methodology, and cannot pass the threshold of credible scientific research," Pfizer said in a statement.

The report, by researchers at the University of California at San Francisco and the Johns Hopkins Bloomberg School of Public Health, comes two months after Pfizer was fined a record $2.3 billion - including an unprecedented $1.2 billion criminal fine - for illegally marketing other blockbuster drugs.

The report appears in Thursday's New England Journal of Medicine.

Dr. Sidney Wolfe, head of health research at consumer group Public Citizen, called it the first comprehensive look "at studies in which a company and people working for it so maliciously manipulated the data to make a drug look more effective than it actually was."

"In every instance, the published article made the drug look better than it would have," said Wolfe, a member of the Food and Drug Administration's drug safety advisory committee. "This results in harm."

Neurontin was approved by the FDA a decade ago for treating seizures and later for pain caused by shingles - but not for other conditions. Its potential side effects include suicidal tendencies and depression.

While doctors can prescribe drugs for unapproved, or off-label uses, drug companies are legally barred from promoting their products for such uses. Drugmakers often test drugs for additional conditions and publicize the results. But they don't always seek approval for those new uses, particularly if the new findings aren't convincing.

Experts believe most Neurontin sales were for off-label uses - the ones in the reviewed studies. Sales peaked at $2.7 billion in 2004, when Pfizer paid $430 million in government fines to settle allegations it improperly marketed the epilepsy drug for unapproved uses. By last year, Neurontin sales fell to $387 million due to cheaper generic versions sold as gabapentin.

For the new review, the researchers examined 20 patient studies funded by New York-based Pfizer and its Parke-Davis unit on use of Neurontin for preventing migraines or treating nerve pain or bipolar disorder. The studies were published in medical journals or presented at conferences, mostly over the last decade.

In eight of the 12 published studies, the main outcome listed in internal documents differs from the one later given in the published report. In half the cases, a new primary outcome was substituted and in others, the original main outcome was instead reported as a secondary measure or wasn't disclosed at all.

The authors cited some limitations to their review, including not knowing who made the changes.

"We cannot be certain that selective reporting was a decision made by employees of Pfizer and Parke-Davis, since the authors of the published reports included nonemployees," the researchers wrote.

Arthur Caplan, director of the University of Pennsylvania's Center for Bioethics, called the report "one of the most ethically disturbing papers I've read in some time" and "an indication that people have been playing fast and loose with studies," particularly industry ones.

Caplan said the FDA should have the power to audit industry drug studies. Wolfe said there should be bigger fines and jail terms for manipulating study data, plus tougher rules for studies being published in journals.

Medical journals in recent years have required that studies be listed on a federal Web site, www.clinicaltrials.gov , to be eligible for publication. That move was made partly to make it harder for industry to hide studies on products that don't pan out and only publish those with good results.

The study descriptions also list their primary and secondary outcomes.

Pfizer said it now has 1,245 company-sponsored studies listed on the Web site.

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