

Leawood expert on drug regulation wins \$4 million whistleblower award

January 9

By GREG HACK

The Kansas City Star

A local expert on drug regulation, Cynthia Kirk, has won a nearly \$4 million award for pointing out potential violations by a California pharmaceutical company in its marketing of ChloroPrep, an antiseptic drug developed by a Leawood company.

Her award under the False Claims Act whistleblower law is part of a \$40.1 million payment the company, CareFusion, has made in a final settlement announced Thursday by the Department of Justice.

CareFusion faced two separate allegations — that it improperly marketed the drug for “off-label” uses not approved by the Food and Drug Administration and that it paid and concealed kickbacks to a physician who could influence standards for the drug’s use.

Kirk, who holds a doctorate in pharmaceutical sciences and is certified by the Regulatory Affairs Professionals Society, formerly worked for a business unit of CareFusion in its Leawood office as vice president of regulatory affairs.

An attorney for Kirk, Carrie Brous of the Brous Horn firm in Overland Park, said Kirk had alleged that CareFusion misused federal and state funds by marketing ChloroPrep off-label to doctors. As a result, the claims for the off-label uses were submitted to Medicare, Medicaid, Veterans Affairs and other health programs.

“Although doctors can use medications on patients during surgeries and for injections in ways not approved by the FDA,” Brous said, “it is illegal for pharmaceutical companies to market their drugs to doctors for any uses that are unapproved, or off-label uses.”

Brous said Kirk’s award was a reward for offering the information that resulted in the off-label portion of the settlement. Such whistleblower settlements are rare, especially those of this size, Brous said.

The Justice Department, in a news release, said CareFusion or its predecessor company also allegedly paid a physician to promote sales of ChloroPrep in 2008 in violation of the Federal Anti-Kickback Statute. The physician was a co-chair of a committee for the nonprofit National Quality Forum, which “endorses and recommends standardized health care performance measures and practices,” according to the Justice Department.

“When companies pay kickbacks to doctors, especially doctors involved in setting standards for the health care industry, they undermine the integrity of the health care system,” said Stuary F. Delery, an assistant U.S. attorney general.

The settlement, under which CareFusion avoids any prosecution, was worked out in principle last year. The final settlement in U.S. District Court in Kansas City, Kan., was announced Thursday.

In a statement, CareFusion chairman and CEO Kieran Gallahue said: “We are pleased to resolve this matter and are confident we have strong practices, processes and controls in place. We have made significant investments during the past several years to improve our quality and compliance systems, including our sales and marketing practices.”

ChloraPrep, which is chlorhexidine-based, won FDA approval in 2000 for some uses and was hailed as an improvement on iodine-based skin preparations for killing bacteria before surgeries and injections. Its maker, Medi-Flex, was based in Leawood but eventually changed its name to Enturia and was sold to Cardinal Health, a national health care conglomerate. Cardinal Health formed CareFusion, based in San Diego, by spinning off its division that sold ChloraPrep.

Read more here: <http://www.kansascity.com/2014/01/09/4739443/local-expert-on-drug-regulations.html#storylink=cpy>