Kidney dialysis patients received misbranded drugs

By Brian Dulle, Kansas First News

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TOPEKA, Kan. – A pharmacist from Tennessee has pleaded guilty to substituting a cheaper drug imported from China for the iron sucrose that the Federal Drug Administration has approved for kidney dialysis patients, U.S. Attorney Barry Grissom said today. The misbranded drug was administered to kidney dialysis patients in Kansas.

Robert Harshbarger, Jr., 53, Kingsport, Tenn., who was doing business as American Inhalation Medication Specialists, Inc., pleaded guilty to one count of distributing a misbranded drug and one count of health care fraud. In his plea, he admitted that as a result of the fraud kidney dialysis patients treated by Kansas Dialysis Services, L.C., received iron sucrose that had not been certified by the FDA to meet quality and safety standards.

Although there were no reports of harm to patients, the crime put patients at risk because the FDA cannot assure the safety and effectiveness of products that are not FDA approved and come from unknown sources or foreign locations.

Harshbarger admitted that health care benefit programs paid more than \$848,000 for the misbranded iron sucrose he distributed from 2004 to 2009. Harshbarger misrepresented the iron sucrose drug as Venofer, which is the only iron sucrose drug approved by the FDA for both pre-dialysis and post-dialysis patients.

Harshbarger purchased iron sucrose from Chinese companies including Qingdao Shenbang Chemical Company in Qingdao, China, and Shanghai Rory Fine Chemicals Co., Ltd., in Shanghai, China. The iron sucrose from China was cheaper than purchasing Venofer.

Sentencing is set for Nov. 4. Both parties have agreed to recommend a sentence of 48 months in federal prison, restitution of approximately \$848,504, a criminal fine of \$25,000, and a forfeiture judgment of \$425,000 to be paid prior to sentencing.

Grissom commended the Food and Drug Administration, the Dept. of Health and Human Services, Office of Inspector General and Assistant U.S. Attorney Tanya Treadway for their work on the case.