

Caveat oncologist: clinical findings and consequences of distributing counterfeit erythropoietin in the United States.

Abstract:

Counterfeit pharmaceuticals pose risks domestically. Because of their cost, cancer pharmaceuticals are vulnerable. We review findings from a domestic counterfeiting episode involving erythropoietin and outline anticounterfeiting recommendations for policy makers, patients, and health care professionals. Information was obtained on patients who received counterfeit erythropoietin, its distribution, and criminal investigations into counterfeiting networks. Interview sources included a physician, an attorney, employees of the Florida Department of Health and Human Services and the US Food and Drug Administration's (FDA) Office of Criminal Investigation, manufacturers, and wholesalers. Other sources included the book "Dangerous Doses," LexisNexis (search terms "counterfeit" and "erythropoietin") and the FDA database. Counterfeit product consisted of 2,000 U vials with counterfeit labels denoting 40,000 U. The counterfeiters, in collaboration with a Miami pharmacy, purchased 110,000 erythropoietin 2,000 U vials and affixed counterfeit labels to each vial. Products were then sold via the pharmaceutical "gray market" to wholesalers, then pharmacy chains. Investigations by Florida government officials implicated 17 persons, all of whom were found guilty of trafficking in counterfeit pharmaceuticals. Despite the large size of the operation, the FDA received reports of only 12 patients who had received counterfeit erythropoietin and detailed information for only two individuals. A 17-year-old liver transplant recipient and a 61-year-old patient with breast cancer experienced loss of efficacy after receiving counterfeit erythropoietin. Wider use of FDA anticounterfeit initiatives, limiting pharmaceutical suppliers to reputable distributors, and educating providers and patients about signs of counterfeit drugs can improve the safety of cancer pharmaceuticals.