

American Cancer Society – Institutional Research Grants 2013

“Counterfeit Avastin health policy and legal analysis to improve cancer patient safety and public health”

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This project addresses a key health policy and health services issue in a critical, ACS priority area: a examination of the case study of counterfeit versions of the angiogenesis inhibitor drug Avastin (Bevacizumab) detected in the U.S. drug supply chain in 2012. This project will critically examine the case study of counterfeit Avastin by first examining multiple sources in the peer-review literature, regulatory announcements, grey literature/media, and legal documents/filings in order to identify risk factors associated with the case and assess what measures could have been taken to prevent this critical failure in public health and patient safety. Furthermore, while identifying and describing the risk characteristics through this review, this study will also identify and produce a list of other cancer drugs that may be at risk for counterfeiting given their status as an FDA shortage drug and similar risk characteristics when compared to the counterfeit Avastin case. Finally, informed by the risk characteristics identified, the study will examine the role of physicians and other healthcare professionals in mitigating such risks through surveillance, education, and health promotion in order to develop a system to prevent counterfeit cancer drugs from reaching patients. This is a critical area of study, since counterfeit medicines have increasingly been detected in the U.S. drug supply chain. Yet the risk factors and a detailed assessment of how these dangerous products are marketed, sourced, distributed and dispensed has not been adequately researched. The case study of counterfeit Avastin provides an opportunity to describe key risk characteristics, identify cancer drugs at risk of counterfeiting, and exploring collaborative solutions with healthcare professionals to prevent counterfeit medicines from reaching patients.