

Human vaccines and TSE agents: A case study in risk evaluation and risk management

William Egan, PharmaNet Consulting

In March, 2000, the Office of Vaccines Research and Review (OVR) became aware that CBER's policies for the sourcing of bovine products used in the production of vaccines was, in at least one example, not being followed. In response to this finding, OVR conducted a general survey of licensed products and uncovered additional examples in which these policies were not followed. CBER's response to these findings, in terms of risk estimation, risk management, and risk communication will be discussed in this presentation.