

STATISTICS COLLOQUIUM

THURSDAY, OCTOBER 30, 2008

Talk: 4:00 PM – *Science Center 309*

Reception: 5:15 PM – *Science Center, 7th Floor*

“Statistical Issues in Drug Safety: The Curious Case of Antidepressants, Anticonvulsants,....., and Suicide”

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ABSTRACT

In 2003, the U.S. FDA, MHRA in the U.K., and European union released public health advisories for a possible causal link between antidepressant treatment and suicide in children and adolescents ages 18 and under. This led the U.S. FDA to issue a black box warning for antidepressant treatment of childhood depression in 2004, which was later extended to include young adults (18-24) in 2006. Following these warnings, rather than observing the anticipated decrease in youth suicide rates, record increases in youth suicide rates were observed in both the U.S. and Europe. In this presentation, we review the data and statistical methodology that led to the public health advisories and black box warning, and the data that led to the record increases in youth suicide rates and discuss their possible relationship. New statistical and experimental design approaches to post-marketing drug safety surveillance are developed, discussed and illustrated.