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## Case Studies

### ADVERSE EVENT LINKED TO OTC PRODUCT

A pharmaceutical company retained THE WEINBERG GROUP to audit the results of a FDA-requested, industry-sponsored case-control study that linked their over-the-counter (OTC) product and several others with a serious, life-threatening adverse event. There was a substantial concern from the FDA based on reports of adverse events that use of these OTC products would present a public health problem. The study was commissioned to answer the question of risk with a controlled investigation. According to the study investigators, the results of the study showed a strong association between these products and a severe, life-threatening adverse event. Epidemiologists at THE WEINBERG GROUP led experts and consultants to some of the other affected OTC companies, in an effort that included a reanalysis of the raw data from the case-control study, and an assessment of the study's methodological flaws. The unique ability of the experts at THE WEINBERG GROUP to combine their expertise in epidemiology and biostatistics with strategic thinking enabled them to lead the pharmaceutical company's effort in their dispute with the FDA.

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