



Case Studies

SUPPORT TO DRUG MANUFACTURERS

The Food and Drug Administration proposed cancellation of a registered new drug. Cancellation requires an administrative hearing. THE WEINBERG GROUP was retained by two manufacturers of the drug under attack, to define strategy for the administrative hearing, identify the experts to be used in the continued support of the drug; assist in the preparation of the experts for written testimony, analysis of the testimony of experts for the Food and Drug Administration, and preparation for oral cross-examinations and preparation of the summary brief. This led to an extensive process with a written appeal from the first decision to the Commissioner and leading to 10 additional years of sales prior to the ultimate cancellation of the drug.

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