Case Study 7

Case Study 7: Inadequate use of public information leads to costly study requirements

Challenge: A Biotech company could not afford the time and expense to conduct the studies recommended by its consultant and agreed upon by the FDA.

Background: The Biotech company had previously initiated product development discussions with the FDA through a regulatory consultant that used existing 505(b)(1) guidance. The result of their first Pre-IND meeting was a strategy with concurrence from the FDA to conduct significant clinical trials estimated to cost $25 million and take longer than three years. The company couldn't afford the plan and sought Camargo's assistance to rescue the project.

Solution: Through analysis of the product's scientific and medical viability, Camargo identified a possible alternate solution. In their previous FDA meeting, the client and the original consultant had not made sufficient use of data from outside sources – a unique possibility in the 505(b)(2) pathway. Using Camargo's proprietary search methods, Camargo researchers identified key publications to support the 505(b)(2) development plan. After arming the sponsor with this new information and following Camargo's recommendations on how best to approach the FDA, the company contracted with Camargo to request and conduct another Pre-IND meeting with the FDA.

Outcome: After a thorough and detailed scientific argument presented by Camargo, the Agency reversed its decision and required only a bioequivalence study, which reduced the initial 3-year clinical trial plan to mere months. Through their unique understanding of the nuances of published guidance, Camargo helped reduce the client's projected development cost to within 10% of the original $25 million estimate and increased the speed to market by more than 2 years, a significant win for the client.