Case Study 8

Case Study 8: Inadequate use of public information leads to clinical holds

Challenge: A Biotech company had its drug development efforts placed on hold by the FDA by following the advice of a consultant not experienced in the nuances of the 505(b)(2) pathway.

Background: The Biotech Company looking to go public used a clinically-focused consulting company for its Pre-IND meeting, and after progressing to the IND stage, the FDA put the program on clinical hold. There are several reasons for holds being issued including those due to deficiencies or problems with data related to patient safety, design of the trial, and factors in the expected market for the drug. Due to the hold being issued, the Company was in need of expert guidance in the 505(b)(2) approval pathway to allow their product development efforts to continue.

Solution: As Camargo was engaged to review the FDA clinical hold ruling, they worked with the Company to understand the initial submission to the FDA and to uncover why the filing hold was issued. From this review, Camargo identified that the Biotech provided information in the Pre-IND meeting that was deficient with respect to the nonclinical components. Specifically, the FDA put the company on clinical hold due to the lack of toxicological data. Camargo noted that public information was not utilized to cover the sponsor's nonclinical toxicology program. Since the correct questions about this part of the program were not included in the Pre-IND meeting materials, the FDA was silent regarding toxicology requirements and a FDA hold followed.

Outcome: Through an application of a thorough feasibility assessment, Camargo's toxicology specialist (a specialty unavailable at the original consulting firm) found information on the public domain to cover much of the toxicology requirement. Camargo also determined that the client needed to conduct a small study to cover some additional data to determine whether the product would irritate the stomach lining of patients, as there was nothing in the public domain on this aspect. In this case, Camargo helped to get the clinical hold removed by rapidly identifying and addressing the gaps in the toxicological data, allowing the client to move their product development project forward and complete its public offering.