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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Draft Guidance for Clinical Investigators, Industry and FDA Staff: Financial Disclosure by Clinical Investigators

The Food and Drug Administration (FDA) issued draft guidance on May 24 describing its current thinking on the disclosure of financial interests of clinical investigators[1] updating the prior decade-old guidance issued on the subject. The new draft guidance is notable in that it provides more information regarding the sponsor's responsibility to collect the required disclosure information, provides more information about the due diligence expected of an applicant in collecting the information required in a marketing application, and provides detail regarding how FDA will review and perhaps disclose the financial information it receives. Electronic or written comments on the draft guidance should be submitted by July 25, 2011.

Sponsor's Collection of Required Disclosure Information

The draft guidance notes that the sponsor of a covered study is in a unique position to both obtain the financial information that may be needed if or when the study is submitted years later. Furthermore, the financial information collected may serve to alert the sponsor of potential conflicts of interest and thus allow it to minimize any potential for study bias. Under the regulations, any clinical investigator who is not a full-time or part-time employee of the study sponsor must provide the sponsor with sufficient and accurate financial information to allow for complete disclosure or certification and to update the financial information if any relevant changes occur either during the study or for one year after its completion.

FDA notes that it is Agency policy to review financial disclosure information provided to a sponsor by a clinical investigator during a bioresearch monitoring (BIMO) inspection, and that it is entitled to access and copy supporting documentation.

Due Diligence Expected under 21 C.F.R. Part 54

Under 21 C.F.R. Section 54.4, an applicant must exercise "due diligence to obtain the information required in this section" and if unable to obtain the information "the applicant shall certify that despite the applicant's due diligence in attempting to obtain the information, the applicant was unable to obtain the information and shall include the reason." FDA's prior March 20, 2001, guidance simply referred to due diligence and provided a brief discussion. In contrast, the new draft guidance provides specific detail regarding FDA's recommendations for the certification of due diligence: "FDA recommends that sponsors and/or applicants try to locate the clinical investigator through at

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least two telephone calls and make written memoranda of their calls and any telephone conversations." Applicants should also follow up these calls in writing and send at least two certified letters to locate missing investigators. FDA expects the applicant to request contact information for the investigator if he/she is no longer at the institution where the study was conducted, to contact professional associations, and to conduct internet searches to locate the investigator. An applicant must exercise due diligence whether a covered study was conducted domestically or internationally.

FDA Review of Financial Information and Potential Disclosure

The draft guidance sheds additional light on how the financial disclosure information will be reviewed and used by FDA. When evaluating the information disclosed, FDA will assess the level of concern raised by the amount and nature of the specific financial interest. For example, it noted that payments that may be affected by the outcome of the study elicit the highest level of concern. The most common financial interests disclosed by investigators are equity interests and significant payments of other sorts (SPOOS). In determining whether action is indicated due to the financial interests, FDA may consider factors such as the number of investigators used, the total number of subjects and investigators, the number and percentage of subjects enrolled by the disclosing investigator, and whether the investigators are blinded to the randomization allocation. FDA reviewers may also compare the study results from more than one investigator and re-analyze the data, excluding the results from the disclosing investigator to determine if results can be replicated. Importantly, FDA stated its reviewers will consider the description of steps taken by the sponsor to minimize the potential bias of study results from disclosed financial interests submitted on Form FDA 3455.

Another notable distinction in the draft guidance from FDA's prior guidance is with regard to public disclosure of financial interests. The prior guidance indicated that clinical investigators' equity interests "would be protected from public disclosure unless circumstances relating to the public interest clearly outweigh the clinical investigator's identified privacy interest" and stated that "only rarely" would an investigator's privacy interest be outweighed by public interest. The draft guidance reflects a change not only at FDA but also in industry generally. It states that multiple entities "including federal and state governments, institutions, companies, and other organizations, are developing and implementing policies on public disclosure of industry financial arrangements." FDA acknowledged the growing interests in clinical investigator equity interests and noted that much of this information is already in the public domain. Stating that it is currently developing its transparency policy, FDA noted that the policy may affect what information, and in what manner, it publicly discloses the financial interests and arrangements of clinical investigators. FDA is seeking comments on the various options for disclosure, including whether the information disclosed should be a summary of information, a listing of interests and arrangements without identification of the investigator, or a listing that identifies the investigator.

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King & Spalding will continue to monitor this draft guidance. Please contact us if you would like further information or assistance preparing comments to the draft guidance.

[1] Accessible at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM256525.pdf.