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New Clinical Trial Registry Databank

The recently enacted Food and Drug Administration Amendments Act of 2007 ("FDAAA") adds new section 402(j) to the Public Health Services Act (21 U.S.C. § 282(j)), which requires the Director of NIH to create and operate a publicly available on-line data bank of information on clinical trials conducted on certain drugs and devices. These provisions expand upon the existing data bank of information concerning clinical trials for drugs to treat serious or life-threatening diseases and conditions, currently published at www.clinicaltrials.gov. Initially, only basic information about covered clinical trials need be submitted, but eventually, sponsors of clinical trials will be required to submit a great deal of information concerning covered trials and the results of those trials. The first submissions called for by the new provisions will be due as early as December 26, 2007.

Applicability

The new provisions apply to both drug and device trials. Specifically: (a) a controlled clinical investigation of a drug subject to section 505 of the Federal Food, Drug and Cosmetic Act ("FFDCA") or to section 351 of the Public Health Services Act, other than a phase I investigation, and (b) a prospective clinical study of health outcomes comparing an intervention with a device subject to the FFDCA against a control, other than a study to assess only the feasibility of a device, and (c) a pediatric postmarketing device surveillance, as required under new section 522 of the FFDCA¹ (collectively referred to as "applicable clinical trials").

Based on our analysis of the new provisions, we believe that the definition of "applicable clinical trials" includes drug bioavailability and bioequivalence trials, whether conducted under an IND or exempt from IND requirements and regardless of whether conducted in support of an NDA or ANDA filing. Similarly, with the exception of "feasibility studies," device studies appear to be included within the scope of the definition regardless of whether they involve significant-risk or non-significant-risk devices, whether they are covered by a submitted IDE or a deemed-effective IDE, or whether they are conducted in potential support of

¹ Section 307 of the Food and Drug Administration Amendments Act of 2007 amends section 522 of the FFDCA to enable FDA to order postmarketing surveillance of any class II or III medical device that is expected to have significant use in the pediatric population. The legislation requires the Secretary of the Department of Health and Human Services ("Secretary") to issue guidance by September 27, 2008 describing how the requirements of these provisions apply to pediatric postmarketing surveillance requirements that are not clinical trials.



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a PMA, a 510(k) notification, or an exempt device.² In contrast, the pre-FDAAA requirement to submit studies for posting on www.clinicaltrials.gov applied only to studies, conducted under FDA's IND regulations, testing the effectiveness of drugs for serious or life-threatening diseases or conditions.³

Basic Clinical Trial Information to be Submitted and Published by December 26, 2007

As initial disclosures, the sponsor⁴ of an applicable clinical trial must submit four categories of information, as follows:

- (1) a description of the study (e.g., a summary, the primary purpose, the study design and type, intervention name and type, disease/condition to be studied, anticipated start and completion dates, target number of subjects, and primary and secondary outcome measures);
- (2) recruitment information (e.g., eligibility criteria, including age and gender, overall recruitment status, individual site recruitment status, and for trials of unapproved drugs, information on any access under Section 561 of the FDCA for those not eligible to participate in the trial);
- (3) sponsor contact information; and
- (4) administrative information (e.g., any applicable protocol identification numbers).

This information must be submitted for applicable clinical trials that are initiated after September 27, 2007 (the date of enactment of the FDAAA) or that are ongoing on December 26, 2007 (90 days after the date of enactment). A trial is considered "ongoing" on a particular date if one or more patients have been

² The resulting broad scope of the newly-required disclosures indicates that the resulting database, particularly in the case of drugs, may advance significantly the point in time when firms become aware of products in their competitors' pipelines.

³ In guidance discussing these pre-FDAAA obligations, FDA broadly interpreted the phrase "trials for serious or life-threatening disease or condition" to include studies in HIV/AIDS, Alzheimer's disease, angina, heart failure, and cancer, as well as chronic illnesses that can have serious outcomes, such as inflammatory bowel disease, asthma, rheumatoid arthritis, diabetes, systemic lupus erythematosus, depression, and psychoses. See *Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions*, March 2002, available on FDA's website at: <http://www.fda.gov/Cder/guidance/4856FNL.PDF>.

⁴ The obligations under these provisions fall to the "responsible party" defined as the sponsor or the principal investigator if so designated and if certain preconditions are met. For brevity, this summary will use the term "sponsor."