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FDA Law Update

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PhRMA Revised Clinical Trial Principles

Pharmaceutical Research and Manufacturing of America ("PhRMA") has revised its Principles on Clinical Trials to further reflect its commitment to transparency in clinical trials and build upon FDAAA requirements. PhRMA's updated principles trial address four key issues: protecting research participants; conduct of clinical trials; ensuring research objectivity; and providing clinical trial information. The PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results take effect on October 1, 2009.

Key PhRMA recommendations made include the following:

- The timely registration (21 days after enrollment of first patient) of all interventional clinical trials involving patients, including some Phase 1 studies, on a public website (www.clinicalTrials.gov for FDAAA-required and voluntary registry of trials or, for those trials that are voluntarily registered on another public website such as www.clinicalstudyresults.org). For clinical trials subject to FDAAA, sponsors are instructed to list the data elements required by statute i.e. Descriptive Information, Recruitment Information, Location and Contact Information, and Administrative Data. However, PhRMA encourages sponsors to provide FDAAA data elements for all clinical trials without regard to whether they are subject to FDAAA.

- The timely submission (12 months after clinical trial ends or within 30 days after approval of drug) of all safety and efficacy results summaries on a public website for all clinical trials conducted involving the use of either an investigation or marketed product regardless of whether the investigational drug was approved or the study was discontinued and regardless of outcome. In addition, PhRMA principles include a commitment that sponsors will work with investigators to publish data determined to be of significant medical importance for any clinical trial.

- PhRMA has adopted the authorship standards of the International Committee of Medical Journal Editors (ICMJE), which requires that to be designated as an author a person must: (a) provide substantial contribution into conception or design of study, or data acquisition, or data analysis and interpretation; (b) write or revise the manuscript involving important intellectual content; and (c) have final approval of the revision to be published. PhRMA's principles further specify that acquisition of funding, collection of the data and/or general supervision of the research group alone does not justify authorship. Finally, all authors are to be provided with the

underlying statistical tables, figures, and reports supporting the publication.

- PhRMA also has adopted the contribution standards of ICMJE which require that contributions should be recognized appropriately in publications – either as an author or as a contributor depending on the level of contribution. Contributors that do not meet all three of the author criteria should be listed in the acknowledgements section and their role or contribution identified. In addition, authors should disclose any assistance received, and acknowledge any financial or material support.

- PhRMA has also adopted ICMJE disclosure standards for publication of a medical journal manuscript. Authors submitting manuscripts are instructed to disclose all financial or personal relationships that might present a conflict of interest and disclose names of anyone who has provided writing or other assistance. Authors are further instructed to describe the role of sponsors in designing the study, collecting and interpreting data, writing the report, and in the decision to submit the report for publication. If the sponsor had no involvement, the author should state that as well.

- Other publication issues addressed in the PhRMA principles include sponsor's right to review a manuscript, presentation or abstract prior to submission for publication and the sponsor's commitment to timely review and to work with authors to resolve through scientific debate any differences of opinion or interpretation of data that may arise. In addition, PhRMA principles provide that sponsors should agree to furnish clinical trial protocol information to a reviewing medical journal upon its request.

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