

The FDA Amendments Act of 2007 (“FDAAA”) was recently signed into law, becoming the first to mandate disclosure of clinical trial results through a publicly-available database.

Title VIII of the Act was designed to improve patient enrollment and provide a means by which the Department of Health and Human Services (“HHS”) can track the progress of clinical trials and ensure transparency of the trial results. The Act requires the Secretary of HHS, acting through the Director of the National Institutes of Health (NIH), to establish and administer through the Internet a clinical trial registry database and a clinical trial results database for drugs and devices.

The databases apply to both privately and publicly-funded clinical trials. The registry database includes all except Phase 1 drug studies and device trials comparing a device against a control (other than a small clinical trial to determine the feasibility of a device) and all pediatric post-market surveillance. The results database will apply to trials conducted on approved drugs and devices and those trials that primarily test efficacy.

The responsible party for submitting such information to the database is the “sponsor” of the Study, as that term is defined in the Code of Federal Regulations. In the case of an investigator-initiated study, the employing institution bears responsibility for compliance.

The sponsor is required to list in the registry database descriptive information about the trial including study design, eligibility criteria and sponsor details. The registry will also have a link to the results database.

The NIH will ensure that the results database list any FDA assessments of the trial results, any FDA advisories regarding the drug or device and citations to any publications focused on the study results. The NIH will also add detailed information about the patient sample, endpoints and outcomes and whether the sponsor and principal investigator have an agreement restricting the ability of the investigator to publish the results of the trial.

Sponsors will be required to submit data to the registry database for ongoing or new studies within ninety days after the date of enactment or 21 days after the first patient is enrolled, whichever occurs later. In the case of an ongoing study that is not of a serious or life-threatening disease or condition, sponsors have one year from the date the Act was enacted to comply.

The Act authorizes the Secretary to expand, by rulemaking, the database to require submission of additional information on trial results, including results for drugs not approved and devices not cleared.

The Act authorizes civil monetary penalties up to \$10,000 per day for noncompliance with registration or results reporting requirements.

To maintain data integrity and ensure compliance with these new standards, Sponsors are advised to re-evaluate their policies and procedures regarding clinical trial data collection and closely monitor and audit sites conducting the trials. Sponsors will also need to establish new policies addressing the submission of data to the databases.

If you have any questions regarding this Client Alert, please contact:

**Cathy J. Frankel**

(212) 554-7848

[cfrankel@mosessinger.com](mailto:cfrankel@mosessinger.com)

**Linda A. Malek**

(212) 554-7814

[lmalek@mosessinger.com](mailto:lmalek@mosessinger.com)

**Jill E. Anderson**

(212) 554-7836

[janderson@mosessinger.com](mailto:janderson@mosessinger.com)

**Samuel J. Servello**

(212) 554-7872

[sservello@mosessinger.com](mailto:sservello@mosessinger.com)

## MOSES & SINGER LLP

MOSES & SINGER LLP has served its clients skillfully and decisively since 1919. We provide cost-effective and result-focused legal services in the following primary areas:

- Banking and Finance
- Business Reorganization, Bankruptcy and Creditors' Rights
- Corporate Securities and M & A
- Employment and Labor
- Entertainment, Advertising, IP and Internet/Technology
- Healthcare
- Hotel and Hospitality
- Litigation
- Matrimonial
- Private Funds
- Legal Ethics & Law Firm Practice
- Real Estate
- Tax
- Trusts and Estates and Wealth Preservation

The Chrysler Building  
405 Lexington Avenue  
New York, NY 10174-1299  
Tel: 212.554.7800  
Fax: 212.554.7700

2200 Fletcher Avenue  
Fort Lee, NJ 07024  
Tel: 201.363.1210  
Fax: 201.363.9210  
Abraham Y. Skoff, Esq.,  
Managing Attorney for New Jersey

**Disclaimer**

Viewing this or contacting Moses & Singer LLP does not create an attorney-client relationship. This is intended as a general comment on certain legal issues. It does not contain a complete legal analysis or constitute an opinion of Moses & Singer LLP or any member of the firm on the legal issues herein described. This contains timely information that may eventually be modified or rendered incorrect by future legislative or judicial developments. It is recommended that readers not rely on this general guide in structuring or analyzing individual transactions but that professional advice be sought in connection with any such transaction. To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. tax advice contained in this communication is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

**Attorney Advertising**

It is possible that under the laws, rules or regulations of certain jurisdictions, this document may be construed as an advertisement or solicitation.

Copyright © 2007 Moses & Singer LLP  
All Rights Reserved