

# PHARMACEUTICAL AND BIOTECHNOLOGY UPDATE

HOGAN &  
HARTSON

## NIH Public Meeting on Expansion of Clinical Trial Registry and Results Data Bank

On April 20, 2009, the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS) hosted a public meeting to solicit input on the expansion of the clinical trial registry and results database at ClinicalTrials.gov. NIH held this public meeting to discuss a number of issues raised by Section 801 of the Food and Drug Administration Amendments Act (FDAAA).<sup>1</sup> Participants and commenters at the meeting included representatives from industry trade associations, generic manufacturers, consumer advocacy groups, and medical journals. A videocast of the meeting is available online.<sup>2</sup>

NIH is also soliciting electronic comments from interested stakeholders at Docket No. NIH-2009-0002.<sup>3</sup> The docket will be open until June 22, 2009. NIH will rely upon the feedback from the meeting and the public docket as it conducts the rulemaking process required by FDAAA.

In addition to describing the critical issues considered at the April 20 public meeting, this Update also outlines a new wrinkle in the application of Maine's clinical trial registry and results reporting requirements.

### Background

Since September 2008, sponsors and other "responsible parties" have been required to submit "basic results" information for "applicable clinical trials" for which the products have been approved under relevant sections of the Federal Food, Drug, and Cosmetic Act (FDCA) or Public Health Service Act (PHSA). FDAAA also requires NIH to expand ClinicalTrials.gov via regulations promulgated by September 2010.<sup>4</sup> This expansion will require responsible parties to submit both lay and technical summaries, if they can be included without being misleading or promotional. Responsible parties will also have to post the full trial protocol or other information on the protocol that NIH deems necessary to evaluate the results.

As part of this expansion of ClinicalTrials.gov, NIH is directed to consider whether to require sponsors to submit results for applicable drug clinical trials of unapproved products, which NIH would post on ClinicalTrials.gov. The statute also requires NIH to consider lengthening the results submission deadlines to as much as 18 months after trial completion, among a number of other issues.

<sup>1</sup> 42 U.S.C. § 282(j).

<sup>2</sup> Click here to view [videocast](#).

<sup>3</sup> Click here to view [Public Docket](#).

<sup>4</sup> 42 U.S.C. § 282(j)(3)(D).



### **Key Issues Regarding Expanded Results Requirements**

Despite the large number of issues that the statute directs NIH to consider, comments during the April 20 meeting suggest that the following topics are of greatest interest to stakeholders:

#### ***Posting Results for Studies of Unapproved Drugs***

Numerous stakeholders discussed the relative merits of requiring submission of results information for certain unapproved products. Industry trade association representatives indicated support for limited expansion of the database to include results of certain clinical trials discontinued for safety reasons. For example, Jeffrey Francer, Assistant General Counsel at Pharmaceutical Research and Manufacturers of America (PhRMA), discussed PhRMA's recently revised *Clinical Trial Principles*,<sup>5</sup> which calls for the voluntary submission of results summaries for all medicines whose research programs are discontinued. Generic representatives, including Howard Rutman of Taro Pharmaceuticals, urged NIH not to require submission of clinical bioequivalence studies submitted by generic companies. Finally, a consumer advocacy group representative pushed for the submission of results for clinical trials of all unapproved products. Although it is difficult to predict with any certainty, we believe that it is likely that the final results posting regulations will require some level of disclosure for discontinued studies of unapproved drugs. This is a critical issue for sponsors and manufacturers, which bears further monitoring. The open docket for comments is an important opportunity for sponsors and manufacturers to provide input that could affect NIH's decisions about the forthcoming regulations.

#### ***Narrative Summaries of Results Data***

Industry representatives expressed reservations about including narrative summaries with results data without clear guidance from the FDA. Sponsors required to submit such information for both technical and lay audiences would be faced with the dilemma that the FDA could consider the summaries "promotional." This risk is particularly great for studies that involve off-label uses for approved drugs, according to Jeffrey Francer of PhRMA. Edward Campion, Senior Online Editor at the *New England Journal of Medicine*, recommended that NIH not mandate narrative summaries, for fear that they would introduce an element of subjectivity to the data and otherwise lead to misinterpretation. Government officials at the meeting were noncommittal about industry members' concerns. To dissuade NIH from requiring sponsors to submit results summaries, industry may need to advance more compelling arguments.

#### ***Other issues***

Among the other issues proposed for consideration, one that received significant comment from stakeholders was whether NIH should require posting of the full trial protocol. A representative from the Consumers Union supported the required submission of "key" portions of the protocols, with the full protocol available at researchers' request. Lisa Vincent, on behalf of AdvaMed, took the position that a required submission of the full protocol would not be in harmony with the confidential protection afforded such information under the FDCA. A second issue raised by a number of the commenters was the adverse event reporting requirements. If NIH does not promulgate regulations describing adverse event reporting requirements by September 2009, FDAAA provides default

---

<sup>5</sup> Click here to view the [Clinical Trial Principles](#).

provisions requiring the submission of serious and frequent adverse events. Numerous commenters sought further guidance from NIH on this issue.

### Conclusion

The expansion by regulation of the clinical trials registry will no doubt have a significant effect on sponsors and manufacturers of clinical trials. As NIH works to develop these new requirements, interested parties have an opportunity to help shape the federal government's clinical trial disclosure policy and the forthcoming regulations through the public docket. Manufacturers affected by the proposed expansion will want to closely monitor the progress of the federal rulemaking process and be ready to revise their disclosure policies in response to future changes, such as the posting of data from clinical trials of certain unapproved products.

\*\*\*\*

### Maine Issues an Advisory Regarding the 30-Day Requirement in Section 1.03-5

On March 30, 2009, the State of Maine released an advisory regarding clinical trials results reporting.<sup>6</sup> Current Maine law requires manufacturers to report to the State when trial results submitted to ClinicalTrials.gov are not posted within 30 days, if the deadline for posting has passed.<sup>7</sup> Recognizing that delays are caused by the volume and complexity of submissions, Maine is considering amending this requirement. Until then, the informal advisory extends Maine's reporting deadline. Thus, a manufacturer will have to notify the State when submitted results are not posted after 90 days, if the deadline for posting has passed.

**If you would like Hogan & Hartson to assist you in drafting or submitting written comments to the federal public docket, or if you have questions about federal, state, and other clinical trials registration and results posting requirements, please contact one of the authors listed below.**

**ROBERT F. CHURCH**  
[rfchurch@hhlaw.com](mailto:rfchurch@hhlaw.com)  
310.785.4646  
Los Angeles

**MICHAEL N. DRUCKMAN**  
[mndruckman@hhlaw.com](mailto:mndruckman@hhlaw.com)  
202.637.5635  
Washington, D.C.

*Special thanks to George A. O'Brien for his contributions to this update*

This Update is for informational purposes only and is not intended as basis for decisions in specific situations. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship.

Copyright © 2009 Hogan & Hartson LLP. All rights reserved. Hogan & Hartson LLP is a District of Columbia limited liability partnership with offices across the United States and around the world. Some of the offices outside of the United States are operated through affiliated partnerships, all of which are referred to herein collectively as Hogan & Hartson or the firm.

[www.hhlaw.com](http://www.hhlaw.com)

<sup>6</sup> Click here to view the [Maine advisory](#).

<sup>7</sup> See 10-144-275 ME. CODE R. § 1.03-5.