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FDA Proposes to Expand the Scope of Clinical Investigator Disqualifications

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The Food and Drug Administration (FDA) has issued a proposed rule which, if finalized, will expand the scope and consequences of clinical investigator disqualifications.[1] Under the proposed rule, issued April 13, an investigator disqualified from receiving specified test articles (i.e., investigational drugs (including biologics) and devices and new animal drugs) will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods (including dietary supplements, infant formulas, food, and color additives), and tobacco products. FDA is accepting comments on this proposed rule through July 12, 2011.

Under the current rules, FDA may consider the disqualification of a clinical investigator for repeatedly or deliberately failing to comply with the requirements for conducting a clinical investigation or submitting false information in a required report to the FDA or investigational sponsor.[2] Should the investigator be disqualified, he or she may no longer receive the particular type of test article involved in the disqualifying study. Thus, under the current rule, if an investigator is disqualified as a result of a drug study, he or she may no longer receive investigational drugs. The investigator may, however, receive investigational devices.

Further, if the investigator is disqualified, FDA only examines the approved research and marketing applications pertaining to the kind of test article from which the investigator was disqualified.[3] This is done to determine whether the investigator submitted unreliable data in support of an application. Any data deemed to be unreliable is eliminated from the application. After this data elimination, if FDA determines that it is no longer safe for subjects to continue an investigation, the investigation may be terminated.[4] Moreover, if continued marketing approval can no longer be justified, FDA will withdraw the approval.[5] Thus, under FDA's current regulations, if an investigator is disqualified during a drug study, the disqualification would only affect drug studies and drug marketing. The disqualification would not affect any device studies in which the investigator was involved.

1. Disqualification of a Clinical Investigator, 76 Fed. Reg. 20575 (Apr. 13, 2011). The proposed rule is available online at http://edocket.access.gpo.gov/2011/pdf/2011-8786.pdf.

2. 21 C.F.R. §§ 312.70(a), 511.1(c)(1), 812.119(a).

3. *Id.* §§ 312.70(c), 511.1(c)(3), 812.119(c).

4. *Id.* §§ 312.70(d), 511.1(c)(4), 812.119(d).

5. *Id.* §§ 312.70(e), 511.1(c)(5), 812.119(e).

FDA's proposed rule, however, would bar disqualified investigators from receiving any investigational articles of any kind, regardless of the basis for their disqualification.[6] The investigators would also not be able to conduct any clinical investigation supporting a research or marketing application.[7] If an investigator is disqualified, all applications for which the investigator submitted data will be reconsidered, not just those involved in the disqualified trial.[8] This could result in terminated investigations and withdrawn marketing applications, without consideration of the basis for the disqualification. According to FDA, "an investigator who repeatedly or deliberately violates the regulations or who repeatedly or deliberately submits false information would not be considered a qualified expert with experience required to conduct investigations of FDA-regulated articles."[9]

The agency's decision to propose this regulatory shift was prompted, in part, by a September 2009 Government Accountability Office (GAO) report, which recommended that FDA extend disqualification decisions to include ineligibility to receive drugs, biologics, and medical devices.[10] According to the GAO, "It is critical for FDA to take action—and to have the authority to take action—to prevent clinical investigators, sub-investigators, and study coordinators who engaged in serious misconduct from doing so again, whether in research that involves drugs, biologics, or devices."[11]

The proposed rule is also consistent with FDA's expanding efforts to address the issue of data integrity. These efforts include a proposed rule requiring sponsors to report suspected data falsification, and the investigation and Department of Justice charging of a prominent investigator for data falsification.[12]

If finalized, this proposed rule would require research sponsors to be even more diligent in their quality assurance efforts to screen investigators against disqualification lists. Sponsors would be well advised to screen investigators both at the preclinical and clinical stages, and throughout the duration of the trial. Failure to do so could mean the discontinuation of studies and a loss of marketing approval. Sponsors should also consider screening investigators used as experts in other contexts, such as meetings with FDA or panel presentations, as FDA has stated that investigators who violated the regulations would not be considered qualified experts.[13]

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact its authors, **Phoebe Mounts** (202.739.5898; pmounts@morganlewis.com) and **Jacqueline R. Berman** (202.739.5057; jberman@morganlewis.com).

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6. 76 Fed. Reg. 20,577.

7. *Id.*

8. *Id.* at 20,580.

9. *Id.* at 20,582.

10. *Id.* at 20,577.

11. Government Accountability Office, Oversight of Clinical Investigators 43 (2009), *available at* http://www.gao.gov/new.items/d09807.pdf (last visited Apr. 13, 2011).

12. *See* Reporting Information Regarding Falsification of Data, 75 Fed. Reg. 7412 (Feb. 19, 2010); *see also* U.S. Attorney's Office District of Massachusetts, *Springfield Anesthesiologist Charged with Falsifying Medical Research* (Jan. 14, 2010), *available at* http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Jan2010/ReubenScottPR.html (last visited Apr. 13, 2011).

13. 76 Fed. Reg. 20,582.

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