FDA’s Proposed Rule Will Require Sponsors to Promptly Report Falsified Data

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Introduction

All sponsors and investigators of clinical trials take heed! The U.S. Food and Drug Administration (FDA) recently proposed a new rule that would require sponsors of clinical trials involving human and animal subjects to promptly report any information that may indicate a person has, or may have, falsified data in connection with the regulated clinical trial.¹ Pursuant to the proposed rule, a sponsor must file a report within 45 days of discovering the falsified data and the sponsor’s duty to report will continue both before and after clinical studies are completed.² A failure to timely report confirmed or possible falsifications may carry consequences, including potential criminal and civil penalties.³ This proposed rule would amend the ambiguous regulations currently governing reporting requirements for sponsors.⁴

The purpose of the proposed rule is two-fold: (1) to ensure the integrity of data submitted to the FDA, and (2) to protect the rights, safety, and welfare of human and animal subjects in clinical trials.⁵ Because the FDA relies on the data it receives, any unwitting reliance on falsified data could lead to clinical testing of unsafe products, subsequent approval of ineffective or unsafe products, and marketing of products with false or misleading claims.⁶ Simply put, falsified data, if undetected, can undermine the underlying basis for FDA decisions, and more importantly, undermine the regulatory protections for research subjects.⁷

The FDA’s intent behind this proposed rule is consistent with the federal government’s new policy of “transparency”⁸ – open communication and accountability – to gain public trust in all areas of government, including those agencies overseeing public health and

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¹ This proposed rule is published in 75 Fed. Reg. 7412 (Feb. 19, 2010).
³ What are the Consequences of Not Reporting Confirmed or Possible Falsification?, 75 Fed. Reg. 7413 (Feb. 19, 2010); see also 21 C.F.R. §§ 301(e), 302, 303, 307; 18 U.S.C. § 1001.
⁵ Why FDA is Proposing this Rule, 75 Fed. Reg. 7414 (Feb. 19, 2010).
⁶ Id.
safety.\(^9\) Through its own Transparency Initiative,\(^{10}\) the FDA is seeking to promote early
and open communication about emerging safety issues concerning FDA-regulated
products and agency decisions on pending product applications.\(^{11}\) This proposed rule, if
it becomes final,\(^{12}\) should by its own terms create “trickle-down transparency” among
sponsors and their investigators, and thus improve levels of sponsor and investigator
accountability and provide greater protections for the rights, safety and welfare of
research subjects.

**Background History Leading to FDA’s Proposed Rule**

The FDA reportedly discovers falsified data at study sites and in submitted applications
on an annual basis.\(^{13}\) Quite often, the falsified data found at one study site may lead to
the discovery of false information in another study at the same site or at another site.\(^{14}\)

In the mid-to-late 1990’s, the FDA discovered some egregious cases of falsified data
created by clinical investigators.\(^{15}\) In one case, an investigator falsified data that
extended across studies in 91 applications submitted to the FDA by 47 different
sponsors.\(^{16}\) In an effort to determine why this falsified data was so widespread, and yet
never reported, the FDA appointed an internal task force to evaluate the effectiveness of
the current reporting requirements for sponsors.\(^{17}\) The task force found ambiguous
language in several areas of the current regulations, such as: (1) whether sponsors had to
report possible falsification of data to the FDA, (2) what information the sponsors should
report when an investigator’s participation is terminated, (3) what falsified data must be
reported, and (4) the time frame for when such falsified data should be reported.\(^{18}\)

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\(^10\) FDA Comm. Hamburg launched the Transparency Initiative in response to the Obama Administration’s
Open Government Initiative. She announced the formation of the FDA Transparency Task Force to
develop recommendations for making useful and understandable information about FDA activities and
decisions more readily available to the public in a user-friendly format. See Asamoah, supra note 10.

FDATransparencyTaskForce/default.htm; see also Asamoah, supra note 10.

\(^12\) This proposed rule is pending public comment until May 20, 2010. The FDA has proposed the final rule
will become effective 90 days after it is published in the Federal Register. See 75 Fed. Reg. 7412, 7418
(Feb. 19, 2010).

\(^13\) See Background, supra note 8, at 7414.

\(^14\) Id.

\(^15\) Id.

\(^16\) Id.

\(^17\) Id.

\(^18\) Id.
Sponsors’ Role in Clinical Studies

According to the FDA, sponsors are responsible for ensuring the integrity of study data.\textsuperscript{19} The FDA believes sponsors are in the best position to discover possible falsification of data through their monitoring, auditing, and review processes.\textsuperscript{20}

Through its internal review, the FDA learned that sponsors were somewhat unclear regarding the extent of their reporting duties because of the ambiguous, confusing language in some of the regulations.\textsuperscript{21} Thus, in an effort to clarify those ambiguities and to eliminate any confusion, the FDA drafted the proposed rule with two purposes in mind. First, the FDA wants to ensure the integrity of all data submitted to it, thus giving it confidence in all data from studies conducted by, or on behalf of, a sponsor or relied upon by a sponsor for product approvals or authorizations of labeling claims.\textsuperscript{22} Second, the FDA wants to protect the rights, safety and welfare of research subjects by making it less likely that the persons who falsify data will be able to continue to conduct studies, come in contact with research subjects, or jeopardize the safety and welfare of such subjects with unsound scientific practices.\textsuperscript{23}

What Should be Reported Under the Proposed Rule and When?

As proposed, sponsors would be required to report to the appropriate FDA center all information indicating that any person has, or may have, engaged in the falsification of data in studies conducted by, or on behalf of a sponsor, or relied upon by a sponsor.\textsuperscript{24} This includes reporting on any falsification of data during the course of reporting study results, or during the course of proposing, designing, performing, recording, supervising, or reviewing data.\textsuperscript{25} The reporting requirements would apply to clinical investigations, nonclinical laboratory studies, and clinical studies in animals, any or all of which may be relied upon by a sponsor to support product approvals, new dietary ingredient notifications, or authorizations of labeling claims, including nutrient content claims and health claims.\textsuperscript{26}

As defined in the proposed rule, the term “falsification of data” means creating, altering, recording, or omitting data in such a way that the data do not represent the accurate facts of what occurred.\textsuperscript{27} Unintentional errors, such as typographical errors and transposed numbers or characters, should not be reported.\textsuperscript{28}

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\textsuperscript{19} Why FDA is Proposing this Rule, supra note 6.
\textsuperscript{20} Id.
\textsuperscript{21} Id.
\textsuperscript{22} Id.
\textsuperscript{23} Id.
\textsuperscript{24} Description of the Proposed Rule, 75 Fed. Reg. 7414 (Feb. 19, 2010).
\textsuperscript{25} Id.
\textsuperscript{26} Id.
\textsuperscript{27} Id.
\textsuperscript{28} Id.
Sponsors would be required to report falsification by any person, whether it is the individual responsible for conducting the trial or his or her colleague or subordinate.\textsuperscript{29} Moreover, sponsors would be required to report not only confirmed falsification, but also possible falsification of data.\textsuperscript{30} This means the sponsor would be required to report information that suggests the person engaged in falsification regardless of the amount of evidence, if any, the sponsor may have.\textsuperscript{31}

Under this proposed rule, sponsors would be required to report the following information by mail, electronic mail, telephone or facsimile: (1) the name and address of the person who has, or may have, falsified data, (2) the identification number of the affected study, and (3) the information suggesting falsification occurred with a description of the false data.\textsuperscript{32} Although the FDA wants sponsors to report promptly, the proposed rule allows a 45-day reporting window from the time the sponsor first becomes aware of the falsification or possible falsification.\textsuperscript{33} The FDA proposes to put some “teeth” in this reporting requirement, by imposing criminal and civil penalties for failure to report.\textsuperscript{34}

What Will the FDA Do with Sponsors’ Reports of Falsified Data?

The FDA intends to compile sponsors’ reports for purposes of identifying patterns or indications of investigator-related misconduct.\textsuperscript{35} This information will be used to conduct further investigations, which may lead to administrative and enforcement actions, such as excluding a clinical trial, disqualifying an investigator, or pursuing criminal actions.\textsuperscript{36}

Conclusion

While the consuming public may expect all clinical trial investigators should possess integrity and adhere to ethical principles when conducting clinical trials, the FDA has reason to know otherwise. Consistent with the FDA’s new policy of “transparency,” and through this proposed rule, the FDA is seeking to impose accountability on all sponsors and investigators as a means to protect the rights, safety and welfare of research subjects.

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\textsuperscript{29} Description of the Proposed Rule, supra, note 25.
\textsuperscript{30} Id.
\textsuperscript{31} Id.
\textsuperscript{32} Id.
\textsuperscript{33} Id.
\textsuperscript{34} What are the Consequences, supra note 3.
\textsuperscript{35} Why FDA is Proposing this Rule, supra note 5.
\textsuperscript{36} Id.
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