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FDA guidance on investigator financial disclosures needs more work, says WLF

CLINICAL NEWS | AUGUST 04, 2011

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Proposals from the US Food and Drug Administration to strengthen requirements for financial disclosure by clinical investigators in cases where conflicts of interest may arise need to show more clarity, transparency and sensitivity to privacy rights, argues the Washington Legal Foundation.



The WLF is a non-profit law and policy centre based in Washington and focused on promoting policies consistent with a free-market economy, while "defending the rights of individuals and businesses to go about their affairs without excessive intervention from government regulators".

The Foundation was responding to draft guidance for clinical investigators, industry and agency staff issued by the FDA in May. The proposed guidelines would revise and replace the Guidance for Industry: Financial Disclosure by Clinical Investigators published by the Food and Drug Administration in 2001.

Changed landscape

The landscape around conflict of interest issues in clinical research has changed in a number of ways since that time.

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The bar for public disclosure of records has been raised through various 'sunshine laws' at US state and federal level. Moreover, organisations such as the Association of Academic Medical Centers have published more stringent guidelines on conflicts of interest in biomedical research, and there has been increased attention to these issues in Congress and the media.

OIG report

A report by the US Department of Health and Human Services' Office of Inspector General (OIG) in January 2010 said the FDA needed to step up its efforts to ensure clinical trial sponsors were properly disclosing investigators' financial interests and to minimise any potential conflicts of interest.

An OIG review of financial forms, attachments and accompanying FDA review notes for all 118 marketing applications approved by the agency in fiscal year 2007 found, for example, that only 1% of the clinical investigators listed in the forms had disclosed at least one financial interest, with almost all of these investigators disclosing only one interest.

Moreover, the OIG discovered, 42% of the FDA-approved marketing applications were missing financial information and in 28% of cases sponsors had used the



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due diligence exemption to indicate they were unable to provide complete financial information.

Lack of transparency

In formal comments filed in response to the agency's 24 May Federal Register notice, however, the WLF urged the FDA to revise its draft guidance on financial disclosure by clinical investigators, arguing that the proposed guidelines lack transparency on how the agency uses financial information submitted with marketing applications at the end of a clinical trial programme.

The proposed guidance is also "vague" about what constitutes an inappropriate financial interest warranting concern that an investigator's participation in a clinical trial, as the guidance puts it, raises a "serious question about the integrity of the data" in that study, the Foundation complained.

"FDA has been unclear on this issue for over a decade since the regulations and first Guidance were released," commented WLF litigation attorney Michael Wilt.

"This newly-proposed Guidance does little to clarify what FDA actually does with this financial information and fails to give a concrete standard by which sponsors of clinical trials and those who seek to market new drugs and devices can evaluate potential researchers."

The WLF comments argue that the "purpose of a guidance should be to clarify and explain not only what FDA wants from an applicant but also why they want it and how the information will be used."

Early disclosure

The Foundation did commend the FDA for not taking up the OIG's recommendation that the required financial disclosure information should be filed to and reviewed by the agency before a clinical trial even starts.

"Implementing such a policy would require industry to continuously monitor investigators' financial arrangements for the duration of the study and to submit that information to FDA, and FDA correctly notes that this would burden the agency as well," the WLF said.

But it took exception to the draft guidance's proposed 'recommendations' to industry on the measures applicants should take to ensure due diligence when seeking disclosure of financial information from clinical investigators.

"FDA recommends that applicants take a lengthy series of steps, such as phone calls, certified mail, and internet searches," the Foundation noted.

"WLF argued that providing a list of actions to take in this fashion abandons what is a common-sense understanding of a term – due diligence – in favour of what may be treated as a benchmark rather than a mere recommendation."

Privacy rights

The WLF also insisted that any disclosure to the general public of information on clinical investigators' financial interests risked violating the privacy rights of investigators and their families.

The draft guidance suggested a number of different ways in which information could be disclosed to the public, including releasing a summary of the financial interests, a specific listing, or even the names of investigators and their relationship to specific interests, the Foundation pointed out.

"While FDA should keep these private financial records private, anything more than a general summary released to the public would be inappropriate," Wilt commented.

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