

GlaxoWellcome

December 17, 1999

VIA AIRBORNE EXPRESS

Dockets Management Branch  
H FA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room IO-61  
Rockville, MD 20857

Re: Docket Number 99D-4396;  
Draft Guidance for Industry on Financial Disclosure by Clinical  
Investigators

Dear Sir or Madam:

Glaxo Wellcome Inc. is engaged in the research, development, manufacture, and sale of prescription drug products and is the sponsor of many new drug applications that have been or will be subject to FDA's regulations concerning financial disclosure by clinical investigators. We appreciate the opportunity to comment upon the draft guidance that FDA announced in the Federal Register on October 26, 1999. More generally, we thank the agency for its willingness, since the final financial disclosure regulations were published in February 1998, to consider and respond to the legitimate concerns of industry.

At a November 1, 1999 workshop sponsored by the Drug Information Association ("DIA"), representatives of Glaxo Wellcome took advantage of the opportunity to voice comment on certain aspects of the draft guidance, in the presence of FDA officials who have taken part in its development. In this letter, we would like simply to reiterate and emphasize two points we raised at the meeting.

Travel Reimbursements

We respectfully suggest that the guidance be modified to provide that reimbursements for travel expenses (e.g., meals, lodging, transportation, etc.) that are incurred in the course of providing personal services to a study sponsor do not fall within the defined category "payments of other sorts" (see 21 C.F.R. § 54.2(f), which defines, "significant payments of other sorts").

99D-4396

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Although the draft guidance does not focus specifically on the status of travel reimbursements, the question was raised from the floor at the DIA workshop. FDA representatives at the meeting reacted initially to the question by voicing an opinion that reimbursed travel expenses do fall within the category of "payments of other sorts."

Subsequently, representatives of Glaxo Wellcome Inc. rose to urge reconsideration. We expressed the view that reimbursement for travel expenses simply serves to make service-providers whole, rather than to enrich them. While any speaking fees or other payments for services rendered do unquestionably represent a net "gain" to recipients, and thus deserve to be counted against the total of "payments of other sorts," reimbursed travel expenses do not represent a "gain." Rather, they serve as "loss prevention," i.e., as a means of sparing recipients the consequence of having to absorb travel expenses that they would not have incurred had they not rendered services at a location remote from their homes. This "loss prevention" function is clearly outside the policy purposes of the financial disclosure regulations because it does not realistically represent a source of conscious or unconscious bias on the part of clinical investigators.

In support of the view we expressed, we pointed to the tax treatment of reimbursed travel expenses, which is entirely consistent with the "no enrichment" (i.e., "no potential bias") perspective. Clinical investigators who provide services (non-study-related) to sponsors typically do so in the capacity of independent contractors. Independent contractors who adequately account to their clients for travel expenses incurred in connection with the performance of services, i.e., who meet IRS "substantiation" requirements, can exclude travel reimbursements from gross income (technically, under such circumstances, the reimbursements have the status of excludible "working condition fringes"). See Sections 132, 162, 167, and 274 of the Internal Revenue Code, and implementing regulations, particularly Treas. Reg. § 1.274-5T(h). This tax treatment of reimbursements paid to a contractor generally parallels that of expense reimbursements paid to an employee, which are also excluded from the employee's gross income, and not reported as wages or other compensation on the employee's Form W-2, provided that they are paid under an "accountable" plan. See Sections 62 and 274 of the Internal Revenue Code and implementing regulations, particularly Treas. Reg. § 1.62-2.

On an administrative level, treating sponsor-financed travel costs as within the category "payments of other sorts" raises significant practical problems. Not uncommonly, such costs are direct-billed to the sponsor, or to a vendor coordinating an event for a sponsor. Typically, in such circumstances, financial accounting systems are not equipped to associate payment on the related

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invoices with the individual service-provider(s) who incurred travel costs. For example, if attendees at an expert advisory board meeting stay at a hotel that directly bills the sponsor who convened the meeting, and the sponsor subsequently pays a lump sum to the hotel, a search through company financial records will not identify that payment in relation to the individual consulting experts. Likewise, in such circumstances, the individual consulting experts will be unable to report on such direct-billed costs, if they are asked via questionnaire to report on "payments of other sorts." Even if the travel costs are not direct-billed, and are reimbursed, the individual consulting experts would be hard pressed to report accurately on them, because (as discussed above) reimbursement of properly accounted-for travel expenses is excluded from income, and therefore not reported to independent contractors on Form 1099-MISC.

For the reasons reiterated above, we renew our suggestion that reimbursements for travel expenses incurred in the course of providing services ought not be treated as within the defined category "payments of other sorts." We respectfully suggest that language be added to the guidance in accordance with this understanding.

#### Acceptability of investigator questionnaires to collect "other payment" information

At the November 1, 1999 DIA workshop, FDA representatives clarified that the agency will accept the use of questionnaires to investigators as a satisfactory and complete approach to collecting (and if need be, disclosing) information about "payments of other sorts." Understandably, agency representatives tempered their acceptance with the caution that investigators need to be adequately instructed concerning the information collection exercise. We agree that companies collecting "other payment" information via questionnaires need to furnish clear, specific instructions to investigators.

Although the answer to Question 8 in the draft guidance broadly states, on the subject of relying on questionnaires to collect "other payment" information, that "[c]ompanies have the flexibility to collect the information in as efficient and least burdensome manner as possible," the need for clarification arises from some arguably conflicting language in the answer to Question 28. That language seems to suggest, apparently inadvertently, that information furnished from investigators can serve as sufficient documentation only of "equity interest" holdings, and that for the defined category of "payments of other sorts," only financial records gathered internally can suffice. We therefore respectfully suggest that the answer to Question 28 be modified, to eliminate any future confusion, particularly on the part of persons who are not privy to the oral clarification that agency representatives gave at the DIA workshop.

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To be specific, we suggest that the first and second sentences in the answer to Question 28 be replaced in their entirety by the following three sentences:

*To the extent that applicants have relied on investigators as the source of information about potentially disclosable financial interests in any of the four categories, the underlying documentation -- e.g., copies of executed questionnaires returned by investigators, correspondence on the subject of financial disclosure, mail receipts, etc. -- should be retained. Likewise, to the extent that applicants that did not sponsor a covered clinical study have relied on information furnished by the sponsor, the underlying documentation -- including all relevant correspondence with and reports from the sponsor -- should be retained. To the extent that applicants have relied upon information available internally, all appropriate financial documentation regarding the financial interests or arrangements in question should be retained (for example, in the case of "payments of other sorts," and not by way of limitation, check stubs, canceled checks, records of direct electronic financial transactions, receipts of certified mail deliveries, etc.).*

Thank you again for your willingness to respond to the concerns of industry on this important topic. We look forward to publication of a final guidance.

Sincerely yours,

William M. Zoffer

William M. Zoffer  
Senior Counsel

A handwritten signature in black ink, appearing to read "William M. Zoffer", written in a cursive style.

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W. ZOFFER 3-4286

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