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Subject: PhRMA Comments on Revised Peer Review Guidelines

PhRMA Comments
to OMB (5.18.20...

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PhRMA

May 18, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
New Executive Office Building
Room 10201
Washington, DC 20503

Re: Revised Information Quality Bulletin for Peer Review

Dear Dr. Schwab:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") submits these comments in response to the revised peer review guidelines announced by the Office of Management and Budget (OMB) on April 15, 2004.

In December of 2003, PhRMA submitted comments in response to OMB's original draft, observing that its language seemed to indicate that the peer review requirements would not apply to information submitted by sponsors and relied upon by the Food and Drug Administration (FDA) in granting approval for the marketing of new drugs, biologics, and Class III medical devices. PhRMA's comments also explained why this exemption represented good public policy.

Upon reviewing the revised draft, PhRMA was pleased to learn that OMB agrees with our original comments. In the new draft, OMB explains that the peer review guidelines do not "cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) and likely to have precedent-setting influence on future adjudications or permit proceedings." *Revised Bulletin*, page 26. According to OMB, "[t]his exclusion is intended to cover, among other things, licensing, approval and registration processes for specific products . . .." *Id.* PhRMA's original comments explained why FDA decisions to approve drugs, biologics, and devices would certainly qualify as "adjudications," "permit proceedings," or "licensing," and perhaps all of these.

PhRMA submits these additional comments to point out that the final sentence of the paragraph quoted above could be misinterpreted as qualifying the assurance provided in the opening sentences. Specifically, the last sentence provides that "if a Department or agency plans to disseminate information supplied by a third party (i.e., using this information to support decisions, thereby adopting this information as an official dissemination), the requirements of the Bulletin apply, assuming the dissemination is

'influential.'" *Id.* at 27. This sentence could inadvertently undercut OMB's main message that information relied on in agency adjudications or permit proceedings is not subject to the peer review guidelines. Although FDA does not, in the literal sense, "disseminate" sponsor information to the public, it does base approval decisions primarily upon information supplied by product sponsors, and language in the revised bulletin seems to equate reliance with dissemination.

The qualification that the third-party information must be "influential" in order for the peer review requirements to apply does not remove this tension. According to the revised bulletin, "influential scientific information" means "scientific information the dissemination of which the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." *Id.* at 9. The sponsor information upon which FDA bases approval of drugs and devices would qualify as "influential," since many, perhaps most, such decisions have a "clear and substantial impact" upon patient treatment, health care costs, and the commercial prospects of product sponsors.

PhRMA believes that OMB's goal in the revised proposal is to exempt agency disseminations "that arise in adjudications and permit proceedings" from the peer review requirements. In order to avoid any misinterpretation, PhRMA respectfully requests that OMB, in the final peer review bulletin, qualify the discussion of third-party information so as to leave no doubt about its position.

Sincerely,

Erika Lietzan

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