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Department of Health & Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: IRB Accountability RFI

Pfizer, a global research-based pharmaceutical company, submits the following comments in response to the Office of Human Research Protection (OHRP) notice of March 5, 2009 (74 Fed. Reg. 9578).

In the March 2009 notice, OHRP requested comment on whether OHRP should hold institutional review boards (IRBs) accountable for compliance with OHRP's human subject protection requirements. According to the notice, OHRP currently holds the sponsoring institution, which is required to have filed a federalwide assurance (FWA) to obtain government research funding, accountable. The notice reports that some research institutions have been reluctant to use external, central IRBs to review studies. This is reportedly due, in part, the fact that the sponsoring institution, rather than a central IRB, may be responsible for non-compliance with OHRP rules.

Since issuance of that notice, the Congressional Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee, has held hearings about the integrity of IRB oversight.¹ In addition, the *Protection for Participants in Research Act of 2009* was introduced by Congresswoman Degette, which would strengthen the integrity of IRB oversight.² These concerns reiterate many of the concerns identified in 2001 by the National Bioethics Advisory Commission, with regard to reliance on a decentralized system of IRB oversight.³

¹ http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1552&Itemid=95

² <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:h.r.01715>

³ <http://bioethics.georgetown.edu/nbac/human/oversumm.html>

Discussion

Pfizer is the sponsor of over 150 studies a year, involving over 10,000 sites around the world. In running those studies, we work with approximately 500 U.S. IRBs, as well as many cooperative groups and institutions that have an FWA on file with OHRP. We share responsibility with the investigators and IRBs in ensuring human subject protection and regulatory compliance for the trials that we sponsor.

Pfizer continues to supported voluntary accreditation and other measures to improve confidence in human subject protection. Last year, Pfizer adopted a policy of only using central IRBs that had received accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In addition, we recently benchmarked our own policies and operations, including our IRB review practices, against those set forth by AAHRPP and are the first pharmaceutical company to have obtained accreditation from AAHRPP (for our phase I research units).

With respect to OHRP's proposal to hold IRBs accountable for compliance with the human subject protection requirements, 45 CFR Part 46, we *support* this proposal. It is clear that vesting accountability in the IRB of record, for compliance with requirements for the IRB review, is reasonable and appropriate. In addition, the potential to facilitate the greater use of centralized IRBs would enhance the protection of public health.

OHRP should, like FDA, hold third-party commercial IRBs to the same standards as internal, local IRBs are held. Thus, even though FDA's statutory authority relates to the introduction of drugs into interstate commerce [21 USC 355(a)], FDA holds IRBs to "the same [FDA] oversight, scrutiny, and inspectional practices" -whether the IRB is internal to the sponsor or external to the sponsoring organization.⁴

Conclusion

Our previous proposal of September 29, 2008, for OHRP and FDA to formally unify their rules for IRB review, is also something that we believe would benefit human subject protection. In that proposal, we proposed unified training standards for human subject protection (including training of IRB members), Departmental support for voluntary certification and accreditation efforts, and that FDA and OHRP create and maintain a list of IRB members who have obtained certification from trusted third-party organizations. These initiatives could help improve trust in the oversight of human subject experimentation by both independent and local/internal IRBs.

⁴ See Testimony of Joanne R. Less, Ph.D., Director of the Good Clinical Practice Program at FDA, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce (March 29, 2009), posted at <http://www.fda.gov/ola/2009/irb032609.html>

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Thank you for providing us with the opportunity to comment on OHRP's regulation of human subject protection and enhancing IRB accountability. We look forward to working with OHRP and FDA, other regulators, and partners in the scientific, research, and patient advocacy communities, to strengthen human subject protection.

Sincerely,

/s

Marc Wilenzick

cc: Joanne R. Less, Ph.D.
Director, Good Clinical Practice Program
U.S. Food and Drug Administration