Section 120 of Food and Drug Administration Modernization Act of 1997
21 U.S.C. 355(n)(4)
Amendment of Section 505 of FD&C Act

This document is the 505(n)(4) waiver for:

Name: Dr. Daniel Scharfstein
Institution: Johns Hopkins Bloomberg School of Public Health
Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: December 15, 2005

Topic: The Committee will hear presentations and make recommendations on the safety and efficacy of a Zoster vaccine manufactured by Merck.

Summary of 505(n)(4) Requirements

A. The requirement refers only to those Advisory Committees that provide expert scientific advice and recommendation to the agency regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 of the Food, Drug, and Cosmetic Act or Section 351 of the Public Health Service Act.

B. The requirement applies only to the review of particular matters relating to clinical investigations and approvals of drugs and biologics (e.g., NDA, PLA/BLA, efficacy and labeling supplements). It focuses uniquely and distinctly on a given product/manufacturer with a predictable rather than a speculative effect on a financial interest.

C. The requirement applies only when the member or the member's immediate family has a financial interest in the matter at hand. Immediate family is defined as spouse and minor children. Absent a waiver, no member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary (e.g., a member owns stock in the sponsor or a competing firm or the member receives salary support from a research grant/contract for research on the same or competing product).

D. The requirement applies only to voting. A member may be granted a waiver if the member affords the Committee "essential" expertise.

E. The requirement, however, unequivocally excludes the vote of any member who has personally conducted research in the product before the Committee.

The following applications of this Act for Dr. Scharfstein are checked as follows.

X A. The Committee is a CBER Committee.

X B. The issues before the Committee are a particular matter: safety and efficacy of a Zoster vaccine.

__X__ C. The member or the member's immediate family has a financial interest in the product or competing product. The interest is as follows:

Dr. Scharfstein has a current financial involvement with a competitor. He reported that since November 2004 he has been a member of the NIAID Safety Monitoring Board for AIDS vaccines clinical trials. Dr. Scharfstein receives approximately $800 per year.

In addition, Dr. Sharfstein owns [_____] stock valued at approximately $3,000.

__X__ D. The individual's expertise has been considered and deemed essential by the Center (CBER), the Agency Ethics Branch and the Office of Operations (Office of the Commissioner). See below or refer to 18 U.S.C. 208 waiver, if appropriate.

Dr. Scharfstein is an Associate Professor with the Department of Biostatistics at the Johns Hopkins Bloomberg School of Public Health. He is a renowned expert in biostatistics focusing on the development of statistical methods for analyzing studies with informative missing or censored data. Dr. Scharfstein also specialized in causal inference, longitudinal data analysis, survival analysis, group sequential clinical trials, and semiparametric models.

__X__ E. The member's own scientific work is not under consideration by the Committee.

DECISION:

Accordingly, Section 505(n)(4) waiver

__✓__ is granted.

_____ is denied.

J.W. Bardsley for 11.30.05

Sheila Dearybury Walcoff, Esq. Date
Associate Commissioner for External Relations
Food and Drug Administration