

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 Andrew C. Leon, Ph.D., a member of the Psychopharmacologic Drugs Advisory Committee.

Summary of 505(n)(4) Requirements

A. The requirement refers only to those Advisory Committees that provide expert scientific advice and recommendations 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 Andrew C. Leon, Ph.D., are checked as follows.

- X A. The Committee is a CBER or CDER committee.
- X B. The issue before the Committee is particular matter.
- 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:

Andrew C. Leon, Ph.D., owns a nominal amount of stock in _____, subsidiaries of _____

_____ make competing products to Methypatch (Methylphenidate Transdermal System, MTS), sponsored by Noven Pharmaceuticals, Inc., and Shire Pharmaceutical Group plc, proposed indication for the treatment of Attention Deficit Hyperactivity Disorder. Methypatch is

the product to be discussed at the December 2, 2005, Psychopharmacologic Drugs Advisory Committee meeting.

X

- D. The individual's expertise has been considered and deemed essential by the Center for Drug Evaluation and Research, the Agency's Ethics and Integrity Staff, and the Associate Commissioner of External Relations.

Andrew C. Leon, Ph.D., is Professor of Biostatistics in Psychiatry and Professor of Public Health at the Cornell University Weill Medical College. He has extensive experience in evaluating quantitative methods in mental health research and issues in psychometrics, and collaborating in clinical trials and epidemiological studies. Dr. Leon's current research projects include (1) adjusting for missing data in randomized controlled clinical trials, (2) psychometric analyses of mental health assessments, and (3) a mixed-effect propensity adjustment for evaluating treatment effectiveness in longitudinal, observational studies. Dr. Leon's expertise in biostatistics in psychiatry is essential to the committee's discussions and deliberations and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

X

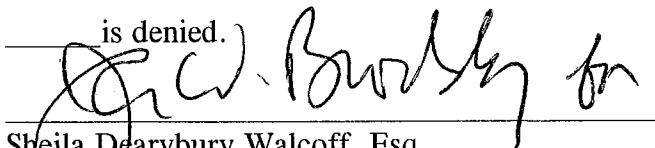
- E. The member's own scientific work is not under consideration by the Committee.

DECISION:

Accordingly, Section 505(n)(4) waiver

is granted, contingent upon public disclosure of the financial interest as required by Section 505(n)(4) of FDAMA.

is denied.



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

11-18-05
Date