Dr. Harold Varmus
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Varmus:

I am writing to inquire into the facts underlying an article, “Drug Maker Hired NIH Researcher,” published in today's *Los Angeles Times*. The article cites potential conflicts of interest raised by the relationship of the prescription drug company, Warner-Lambert, with NIH employee Richard C. Eastman, M.D

According to public records, Dr. Eastman is director, Division of Diabetes, Endocrinology and Metabolism, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr. Eastman is also principally responsible for the NIDDK Diabetes Prevention Program (DPP) multi-center clinical trial of pharmacological interventions to prevent or delay the onset of type 2 diabetes. Warner-Lambert is the manufacturer of Rezulin (troglitazone), one of the products initially selected for study in the DPP trial.

According to the article, Dr. Eastman served as a "faculty" of Warner-Lambert's "Rezulin National Speakers Bureau" and as an "advisor" to Warner-Lambert's efforts to obtain Food and Drug Administration (FDA) approval of Rezulin while key decisions were made at NIDDK regarding the selection of Rezulin for the DPP trial, its continuing study as regulatory authorities worldwide received increasing reports of adverse hepatic reactions and deaths related to Rezulin, and the institute's decision to remove Rezulin from the DPP trial.

18 U.S.C. 208(a) prohibits an officer or employee of the executive branch from participating in an official capacity in particular matters in which he has a personal financial interest, or in which certain persons or organizations with which he is affiliated have a financial interest. The Ethics in Government Act of 1978 also limits the outside income that senior employees may earn and requires annual disclosure of such income.

I would appreciate information regarding the following issues:

- 1.Under NIH policies, an employee may not receive compensation for outside activities that relate to his/her official duties and responsibilities as an NIH employee. I understand, however, that a determination by an NIH Deputy Ethics Counselor that "the financial interest is not 'so substantial as to be deemed likely to affect the integrity of the services the Government may expect' from the employee" may result in "a waiver granting permission to participate in the official matter."

Did the NIH grant Dr. Eastman such a waiver to work with Warner-Lambert? On what factual basis was such a waiver granted, given Dr. Eastman's supervision of the DPP trial? Was this waiver ever subject to reconsideration or revision by NIH or NIDDK?

- 2. Please specify the decisions and other official acts in which Dr. Eastman participated relating to the inclusion of Rezulin in the DPP trial.
- 3. How much compensation has Dr. Eastman received from Warner-Lambert in 1995, 1996 and 1997? Please make available all relevant financial disclosure records filed by Dr. Eastman under the Ethics in Government Act.
- 4. Was Dr. Eastman's arrangement with Warner-Lambert disclosed publicly? Were participants or principal investigators in the DPP trial aware of Dr. Eastman's compensation by Warner-Lambert? Is the NIDDK or NIH concerned about the public reaction to such disclosures?
- 5. Please provide any precedents or examples of NIH officials of comparable seniority and responsibility who have had comparable financial arrangements with pharmaceutical companies.
- 6. A June 11, 1996 Warner-Lambert press release quotes Dr. Eastman as characterizing the selection of Rezulin for the DPP trial as follows: "The group of investigators conducting the study... felt it [Rezulin] had a favorable safety profile, few side effects and it corrects the underlying cause of diabetes -- insulin resistance."

Did Dr. Eastman make this statement? If not, has the NIDDK or NIH corrected this statement publicly?

- 7. A December 3, 1997 *Wall Street Journal* article quotes Dr. Eastman as characterizing the risk of adverse reactions to Rezulin as follows: "Doctors should be concerned, they should monitor patients, and if they do that, the risk seems to be very minimal."

Is this sentiment consistent with the NIDDK's June 4, 1998 announcement that it would discontinue the Rezulin arm of the DPP trial?

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The issues raised by the *Los Angeles Times* article are serious and implicate the health and safety of the participants of the DPP trial, as well as of Americans with diabetes. I appreciate your attention to these matters and look forward to your response.

Sincerely,

HENRY A. WAXMAN

Member of Congress