

Rezulin

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Press Accounts

NIH Director Calls for Review of Scientist's Ties to Firm December 16, 1998

Los Angeles Times

By David Willman

Rezulin: Questions arise after top diabetes researcher enters consulting agreement with company whose drug was chosen for use in study he helped oversee.

WASHINGTON- The director of the National Institutes of Health said Tuesday that he has requested an internal review of the financial ties between the federal government's top diabetes researcher and a major pharmaceutical company.

Dr. Harold E. Varmus, the NIH director, said he wants the institutes' office of inspector general to examine "whether any violation of law and/or regulations occurred."

Varmus called for the review after a Los Angeles Times series disclosed the ties between the government's top diabetes researcher, Dr. Richard C. Eastman, and the New Jersey-based Warner-Lambert Co.

The Times reported on Dec. 7 that Eastman--while maintaining what he termed "overall global responsibility" for the government's largest study of diabetes--entered a consulting arrangement with Warner-Lambert.

The company's pill, Rezulin, was one of two drugs chosen in mid-1996 for use in the study.

The \$150-million Diabetes Prevention Program is ongoing. NIH officials withdrew Rezulin from the study in June after the liver failure and death of a volunteer participant, a 55-year-old high school teacher from East St. Louis, Ill., who had been taking the drug.

"I am concerned about the questions that have been raised regarding NIH staff responsible for the oversight of the diabetes prevention study," Varmus, an appointee of President Clinton, said in a written statement.

It is "critical" Varmus added, "that NIH officials who oversee these studies adhere to the highest scientific and ethical standards."

Varmus said he also wants the inspector general's office to examine whether Eastman's superiors "correctly applied" conflict-of-interest guidelines in approving the arrangement.

Eastman and one of his bosses, Deputy Institute Director L. Earl Laurence, declined in interviews last month to say how much money Eastman has received from Warner-Lambert or from a separate group funded by the company, the National Diabetes Education Initiative.

Eastman, 52, told The Times that he has received "thousands" of dollars both from the company and from the other group, which he said continues to pay him at an hourly consulting rate of more than \$150 an hour.

Eastman's government salary is in excess of \$122,000. He is director of NIH's division of diabetes, endocrinology and metabolic diseases.

Eastman entered a formal consulting arrangement with Warner-Lambert on Nov. 1, 1995.

As recently as late 1997, he was listed in company records as one of 11 members of the "faculty" of the Rezulin National Speakers Bureau. He delivered the group's keynote address at a meeting on Sept. 7, 1997, in Dallas.

Varmus, 58, until Tuesday had not spoken publicly about Eastman's simultaneous consulting for Warner-Lambert and oversight of the government's \$150-million diabetes study.

"The public counts on the NIH to provide science-based information on new ways to prevent, diagnose and treat diseases, so it is critical that our studies are objectively designed and carried out," Varmus said.

Moreover, Varmus said Tuesday that his staff is reviewing whether NIH's conflict-of-interest guidelines "need clarification."

Beyond Eastman's receipt of income from Warner-Lambert, Varmus said he is seeking to determine the nature and extent of other arrangements between senior NIH researchers "and private sector companies."

Laurence last month said that he would quickly provide copies of any authorization granted Eastman--plus financial-disclosure documents showing the amounts of money the diabetes researcher has received.

To date, however, NIH officials have not provided the relevant records, saying that they first must be reviewed to protect Eastman's privacy.

In his defense, Eastman has said that he abstained in 1996 from at least one final vote that resulted in the selection of Rezulin for the NIH study.

Yet, Eastman also has acknowledged that he participated in a continuum of deliberations and decisions--from 1994 through mid-1998--concerning the drug.

After Rezulin was selected for the study and the volunteer participants began taking the drug, Eastman participated in discussions about its safety, The Times reported.

Indeed, once the first liver-failure deaths of patients in the general population were disclosed in the fall of 1997, NIH officials repeatedly reevaluated whether to keep the drug in the government study.

As of Dec. 4, Rezulin had been linked to the liver-failure deaths of at least 33 people in the United States and Japan, according to the U.S. Food and Drug Administration.

Federal law makes it a crime for an official to participate "personally and substantially" in government matters that affect an outside employer.

And, ethics guidelines at NIH prohibit an official from entering into a consulting arrangement if it would "interfere in any way" with the official's public responsibilities.

