

Govt. altered records on possible hazards of implant, paper says

By Nicholas Regush
Montreal Gazette

MONTREAL — Officials in the federal Department of Health and Welfare ordered the destruction of some key government records and the modification of others relating to the hazards of a popular type of breast implant.

Federal documents reveal a trail of altered records that played down health concerns about the safety of the silicone-gel implant used by women to increase their bust size.

The implant, called Meme, has a foam coating that contains a cancer-causing chemical, according to University of Florida researchers. Medical studies show that the coating can break down, become entangled with breast tissue and promote infection.

The *Gazette* has obtained more than 200 pages of government documents on the implant.

One document orders the destruction of a scientific report calling Meme "unfit for human implantation."

In another case, a "memo recall" wiped out all mention in official files of a recommendation by Health Department scientists that the implant be temporarily withdrawn from the market.

The modification of documents occurred at the Health Department's bureau of radiation and medical devices, which regulates about 300,000 types of medical devices on the market.

Bureau director Ernest Letourneau said records are modified only to correct errors in scientific information, or perhaps when "people have egg on their face and want to make changes themselves."

Bureau policy on Meme is to wait for the Canadian distributor, Real Laperriere Inc. of Montreal, to voluntarily supply proof of the implant's safety and efficacy.

The firm sold about 7,500 pairs of implants in Canada in four years without notifying the government of the product, as required. Last fall it complied with federal law and registered Meme with the Health Department.

In 1986, senior bureau scientist Pierre Blais wrote an article raising questions about Meme's tendency to break apart and the lack of data on its long-term effects on the body.

On Feb. 20, Blais, a 14-year bureau veteran, wrote a memo to his boss, Irwin Hinberg, warning that Meme is "unfit for human implantation," partly because its chemical products could be released in the body.

(Researchers at the University of Florida have identified a highly toxic chemical - 2,4-toluene diamine - in Meme's foam coating. The chemical causes liver cancer in rats and mice, and is suspected of causing cancer in humans. But Robert Helbling, president of Surgitek Inc. of Wisconsin, Meme's manufacturer, has said there is no evidence the implant would break down in the body the same way it would under laboratory conditions.)

Blais sent copies of his memo and report to bureau chief Letourneau and to Hinberg's boss, David Johnson.

Johnson edited the documents, and Hinberg returned the edited versions to Blais on March 3, ordering him to make the alterations.

Blais complied on March 6, but he wrote Hinberg that "in my opinion, the content of the original documents is significantly altered."

On March 9, Hinberg ordered Blais in writing to destroy his original memo and report, as well as his March 6 memo stating his concern about making the changes.

(Distributed by Scuttham News.)

documents were part of my ATI requests responded to months later Ken Ruben

Irwin Hinberg Ph.D.

Research and Development Section
Research and Standards Division

Chief
Bureau of Development
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Bureau of Radiation and Medical Devices
Division of Research on Health

(913) 954-0000

*received
March 11/89
by [unclear]*

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Dr. Blais

DATE

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*Please destroy all
copies of the
attached.*

*Obtained by Ken Rubin
Under the Access Act
From Health Canada*

MEMORANDUM FOR THE SERVICE

Dr. P. Blais

Dr. J. Hinberg
Head
Research and Development Division
Research and Standards Division

March 23, 1989

Urgent ATI Requests

This is to remind you of my request that you "immediately respond to attached ATI requests referring to the ATI requests I am [unclear] by preparing copies of the relevant documents for my review."

A memo attached to the ATI requests warned that Mr. Ken Rubin has lodged a complaint to the Information Commissioner concerning the delay in receiving some records requested. You were assigned the job of collecting these records.

It is essential that you provide me with these records by 4:00 p.m. today.

J. Hinberg

cc: Dr. E. G. Litwinski
Dr. David L. Johnson

