PUBLIC CITIZEN

Buyers Up ☐ Congress Watch ☐ Critical Mass ☐ Health Research Group ☐ Litigation Group

November 9, 1988

Frank Young, M.D., Ph.D.
Commissioner, Food and Drug Admisistration
5600 Fishers Lane
Rockville, Md. 20857

Dear Dr. Young,

We have obtained internal Dow Corning and FDA documents, that contain information already well known to you, which clearly demonstrate that silicone gel, currently being implanted in 130,000 women a year in the form of breast implants, causes highly malignant cancers in over 23% of the animals tested. According to one of the FDA memos, "while there is no direct proof that silicone causes cancers in humans, there is considerable reason to suspect that it can do so."[1] As you well know, animal evidence of carcinogenicity is regarded as posing a risk of cancer in humans. In light of this evidence, I urge you to halt immediately the use of silicone gel materials for implantation into the human body.

In addition, I urge you to implement immediately recommendations made almost three months ago by one of the many concerned FDA scientists who has studied this serious problem, namely that:

" 1. a medical alert be issued to warn the public of [the] possibility of malignancy development in humans following long-term implant of silicone breast prostheses.

2. mandatory leaflet information regarding adverse reactions and risks of silicone prostheses be given to past, current and

---

[1] Memo entitled "Analysis of Dow Corning Data Regarding Carcinogenicity of Silicone Gels", from Acting Chief, Health Sciences Branch, Center for Devices and Radiological Health, FDA, Dr. M.E. Stratmeyer. August 9, 1988.

future patients"[2] [if silicone gel is banned, there will be no future users]

FDA should also promptly investigate why the detailed records of the Dow Corning study (Dow is the main producer of silicone gel) which show silicone gel to be carcinogenic were apparently not promptly sent to FDA but were obtained during an FDA inspection of Dow in December, 1987.

Finally, you must explain why six and one-half years elapsed before finalizing the FDA's January 19, 1982 proposal to require Dow and other companies making silicone gel breast implants to submit safety data on this product because, as stated in 1982, it "presents a potential unreasonable risk of injury".[3] Your agency negligently did not finalize this regulation until June of this year and, as presently planned, you are giving industry until 1991 to submit data justifying the continued marketing of these carcinogenic implants, a task which is not possible for them given the findings of their own study.

EVIDENCE FOR THE CARCINOGENICITY OF SILICONE GEL IMPLANTS

In the memo previously referred to, by FDA pharmacologist Dr. Luu [2], she stated that "gel implant associated malignant tumors... were found only in the treated rats".

The 2-year rat carcinogenicity study which was done by Dow Corning to see if silicone gel caused cancer involved three groups of animals, each with 50 males and 50 females. The first group (the controls) developed no malignant fibrosarcoma tumors similar to the ones seen in the silicone-treated animals. One of the other two groups was implanted with a silicone gel used before 1976 and 20% of the females and 22% of the males developed fibrosarcomas at the injection site. Even more worrisome, 21% of the animals with these tumors had evidence of metastases, including spread to lungs, kidney, adrenal, skin, thymus and liver. The third group was implanted with the silicone gel currently in use and in this group, 23% of the females and 26% of the males developed gel-associated fibrosarcomas with 18% of those animals with sarcomas having metastases to distant organs including the heart, lung, liver, pancreas, stomach and thymus.

---

[2] Memo from FDA pharmacologist Dr. H.M.D. Luu (a member of FDA Task Force which has analyzed the evidence concerning the carcinogenicity of silicone gels) to the file, August 15, 1988.

[3] Federal Register, January 19, 1982, pages 2820-1. The reasons stated for requiring safety data submissions included "possible migration of silicone from the interior of the prostheses to adjacent tissue... and possible long-term toxic effects of the silicone polymers from which the prostheses are fabricated."

It was also found that in 85% of all of the animals with fibrosarcomas, the tumor caused the death of the animal.[2]

Another FDA memo, from Robert Sheridan, Acting Director of the Office of Device Evaluation [4], states that:

"Dow Corning agrees that silicone gel is sarcomagenic [can cause sarcomas]. However, this sponsor contends that induction of sarcoma in rats is due to solid-state carcinogenesis (Oppenheimer Effect). This is uniquely a rodent phenomenon. Therefore, that it is of no human health consequence, as solid-state cancer in man has not been documented. In support of these contentions an epidemiological study by Deipan, et al., has been cited and shows no increased incidence of cancer in breast implant recipients."

" FDA staffers, on the other hand, noted the following:

* Solid-state tumor has been reported in rats, mice, chickens, rabbits, and dogs. <u>It is biologically unconvincing that man is a uniquely resistant species.</u> (emphasis supplied)

* The cited [by Dow] epidemiological study is severely flawed. The major deficiency of the study is that mean follow-up time is about five years which is nowhere near the two-thirds of life time required for tumor induction in rats.

*The sarcomas in the rat study are at variance with several classical characteristics of solid-state tumor. They are highly metastatic, lethal and show no variation between sexes.

* Asbestos, when administered through proper route (s/c-[subcutaneously]) induces sarcoma at the site.

* The event of induction of sarcoma in 25% test animals is a very important observation as it is lethal in 85% of the sarcomatous animals. This should be viewed in the context that sufficient time has not elapsed to record epidemiologically significant increase in human malignancies. "

Other documents show that even though the silicone gel is encased in a silicone envelope when used in breast prostheses, there is good evidence that silicone gel "bleeds" through the envelope and can thus get to other places in the body. "Silicone gel-filled breast implants all allow slow diffusion of gel through the silicone elastomer shell into surrounding tissues.... Many investigators have reported on the finding of silicone in lymph nodes and an associated lymphadenopathy [inflammation of the lymph nodes] in women who had undergone mammoplasty with

---

[4] Undated (date covered over in the copy we have obtained) memo from Robert Sheridan to Arthur Norris, Deputy Director of FDA's National Center for Toxicological Research.

silicone, either by injection or by placement of a gel-filled prosthesis." [5]

SCOPE OF USE OF SILICONE GEL IMPLANTS

According to the same FDA memo, "130,000 silicone gel breast prostheses are currently being implanted annually, and there are approximately 2 million implanted women to date. Of the breast prostheses implanted, 85% are for augmentation (cosmetic) purposes, and the remainder are for breast reconstruction following mastectomy." [5] This means that there are, on the average, 356 women per day (2500 per week or 10,833 per month) who are being implanted with these breast prostheses. Other uses of silicone gel implants are for testicular prostheses.

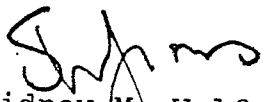
In summary, evidence more than a year old shows that silicone gel is highly carcinogenic. In the more than one year since Dow Corning had results showing sarcomas with metastases in animals in whom silicone gel had been implanted, over 130,000 more women have had breast implants. It is time for FDA to take action to stop further implants of this harmful material and to make sure that all women who already have these breast implants (and men with testicular implants) are warned about the possible dangers they face. Every week of delay in FDA action to stop the use of silicone gel implants means 2500 more women are subjected to this carcinogenic material.

It is a disgrace that FDA, even before it had knowledge of the carcinogenicity study, did not finalize its proposed requirement for safety testing of silicone gel implants based on its assertion, in 1982, that the gel presents "a potential unreasonable risk of injury."

As long as companies such as Dow Corning are as reckless as they appear to be with the health of the public, FDA needs to increase, not decrease its vigilance over these companies.

I look forward to a prompt response to this urgent issue.

Sincerely,



Sidney M. Wolfe, M.D.
Director, Public Citizen
Health Research Group

cc John Dingell, Henry Waxman and Ted Weiss

---

[5] Memo from Ronald J. Lorentzen, Ph.D., Executive Secretary, Cancer Assessment Committee, FDA. dated September 29, 1988.