Public Citizen

July 14, 1977

Dr. Donald Kennedy
Commissioner
Food and Drug Administration
200 C St. S.W., Room 6815
Washington, D.C. 20204

Dear Dr. Kennedy:

This letter urges you to recall approximately 6000 plastic intraocular lenses (used to replace natural lenses removed because of cataracts) because of serious eye disease they have caused.

In addition to recalling these not-yet implanted lenses, approximately 1000 patients--in whom the lens has already been implanted--should be notified so that they can be examined by their physicians to determine whether their eyes have been damaged by the lens.

We have learned that:

(1). The lens was first marketed in April 1976 by the Surgidev Corporation (lens is called Surgidev style 8 anterior chamber lens).

(2). Sales accelerated in summer and fall of 1976.

(3). Early spring of 1976 the company first learned of adverse reactions to the lens.

(4). Surgidev notified FDA May 19, 1977 (see attachment 1) that one doctor alone had been forced to surgically remove lenses from 5 patients in whom they had been implanted because of severe inflammation, bleeding and/or glaucoma which "he was unable to get under control."

(5). As of June 21, 1977 the company had reported to FDA 98 instances of significant adverse effects occurring in patients in whom the lens had been implanted. In about 30 cases, surgical removal of the lens was necessary and in a number of patients, decreased vision occurred as a result of the lens implant (about 7000 lenses have been shipped and about 1000 implanted).

Health Research Group • 2000 P Street, N.W., Washington, D.C. 20036 • (202) 872-0320

SURGIDEV CORPORATION

ATTACHMENT #1

19 May 1977

Doctor James Dillon (HFK 470)
Bureau of Medical Devices
and Diagnostic Products
Division of Compliance
8757 Georgia Avenue
Silver Springs, Maryland 20910

Dear Doctor Dillon:

A doctor reported to us and the Implant Society that he had removed five of our style 8 lenses (anterior chamber lens) from several months post-operative patients. He stated that the patients exhibited increased intraocular pressure, uveitis, and/or hyphema, which he was unable to get under control.

As a result of this complaint, the implant society sent notices to their entire membership, and Surgidev sent Western Union Mailograms to 625 doctors, hospitals, and clinics, who are our customers for the style 8 lens. A copy is attached.

We have been unable to obtain serial numbers from the doctor until his office provided three numbers May 18, 1977. We are still waiting for the other two numbers.

We did initiate a telephone survey May 13th to doctors using the style 8 lens and we are continuing this survey.

The initial doctor suggested "warped footplates" as the probable cause, other surgeons with considerable experience state that the nature of the problems more likely relates to improper lens length selection and/or technique.

As soon as we have sufficient data, we will provide a statistical analysis. In the meantime, the following comments may be in order:

(1) Doctor originating complaints reported removing five lenses.

(cont/...)

(2) Another doctor since reported having ten patients with varying degrees of uveitis, increased pressure and recurring hyphema, all of whom were being closely watched and treated.

(3) A third doctor indicated he had experienced about eleven cases of mini-hemorrhages (hyphema) since he had started, and seems to be under control.

(4) Three other doctors report removing one lens each for similar reasons.

In addition to the above doctors, we have conferred thus far with over 40 surgeons, representing about 900 style 8 surgeries --- including lenses from the original complaint batch (related by production batch numbers). They report satisfactory results and consider our product quality to be good.

One doctor that had removed a lens, replaced it immediately with a shorter one, thereby eliminating all three problem conditions, resulting in a "quiet" eye.

This letter is an attempt to provide an overview of the present status of our investigation. Please call collect at any time for information: Office (805)965-1085 and at home (805)969-0768.

Sincerely yours,

Mike Lippman

Myron E. Lippman
President

MEL:tac

copies:
Doctor Kenneth J. Hoffer, American Intra-ocular Implant Society
Mr. Robert Hubbell, Intraocular Lens Manufacturing Association
Doctor David M. Link, Division of Compliance
Mr. Lee Matthews (HFK 113), Division of Compliance

SURGIDEV CORPORATION

ATTACHMENT #2

24 June 1977

IMPORTANT DEVICE ADVISORY:

RE: SURGIDEV STYLE 8 ANTERIOR CHAMBER LENS

Previous communications from Surgidev Corporation and the American Intraocular Implant Society have alerted you to instances of uveitis/iritis, hyphema, and/or elevated intraocular pressure after implantation of the Surgidev Style 8 Anterior Chamber Intraccular Lens. It has been reported that in some cases, the onset of these symptoms have occurredfour to five months following implantation.

For the present, we have temporarily discontinued the distribution of the Surgidev Style 8 Anterior Chamber Lens, and request that you discontinue the implantation of the Surgidev Style 8 Anterior Chamber Lens until you are further advised by Surgidev Corporation.

Surgidev Corporation and the United States Food and Drug Administration are currently investigating these reported conditions. Surgidev Corporation will advise you of the results of this investigation shortly. In the meantime, we recommend that you closely monitor all patients in whom the Surgidev Style 8 Lens has been implanted.

Although you may have provided similar reports in the past, Surgidev Corporation and the United States Food and Drug Administration request that you complete the attached form and return it in the enclosed self-addressed pre-paid postage envelope as soon as possible.

We appreciate your assistance in this investigation.

Myron E. Lippman

Myron E. Lippman
President

SURGIDEV CORPORATION

ATTACHMENT #3

24 June 1977

Mr. Lee Matthews
Division of Compliance
Bureau of Medical Devices
FOOD AND DRUG ADMINISTRATION
8757 Georgia Avenue
Silver Spring, Maryland 20907

Dear Mr. Matthews:

We appreciate your making yourself and other members from the staff of the Food and Drug Administrator's Bureau of Medical Devices available for meetings with us at your offices on June 21 and 22, 1977. We believe, and trust that you concur, that these candid meetings were both informative and productive. At the conclusion of these meetings, it was mutually agreed that Surgidev Corporation would send the enclosed letter and attachments via certified mail to each consignee of the Surgidev Style 8 Anterior Chamber Intraocular Lens. This letter, as you will recollect, was approved by yourself and Larry Pilot, Director of Compliance for the Bureau of Medical Devices.

However, the distribution of the enclosed letter is not an admission by Surgidev Corporation that the Surgidev Style 8 Anterior Chamber Lens is in violation of any provisions of the Federal Food, Drug and Cosmetic Act. As we stated during our meetings, we believed, and continue to believe, that the Food and Drug Administration request to recall all Surgidev Style 8 Anterior Chamber Intraocular Lenses, that have not been implanted is unwarranted. In addition, we feel that the investigations which are currently being conducted by Surgidev Corporation and the Food and Drug Administration will confirm this belief.

Sincerely,

Joe W. Utt
Director of Compliance
SURGIDEV CORPORATION

MEDICAL DEVICES
JUN 29 1977

JWU:tac

cc: Larry Pilot, Director of Compliance, Bureau of Medical Devices
Joseph P. Hile, Associate Commissioner for Compliance
Food and Drug Administration
Jay H. Geller, Attorney at Law

TESTIMONY OF SIDNEY M. WOLFE AND ANITA JOHNSON
PUBLIC CITIZEN'S HEALTH RESEARCH GROUP
ON
MEDICAL DEVICE LEGISLATION
BEFORE
HOUSE SUBCOMMITTEE ON HEALTH
July 28, 1975

ATTACHMENT #4

Chairman Rogers and members of the Subcommittee, thank you for the invitation to present testimony on the pending medical devices legislation.

The ability of the government to control medical devices now, in 1975, is largely comparable to its ability to control drugs in 1906. The public is justifiably outraged by the endless succession of medical devices such as IUDs, pacemakers, cardiac resuscitation equipment and the like which, not having been adequately tested before marketing, fail to work properly and kill or injure thousands of people each year.

This need to bring medical devices from the earlier to the later part of the 20th century by regulation comes, however, at a time when many are questioning the need for certain kinds of regulation.

The experiences with the ICC and CAB, in which cartels are being protected from the public should not be confused with consumer protection statutes such as the Food, Drug & Cosmetic Act, Occupational Safety and Health Act, Consumer Product Safety Act and other legislation which more clearly intend to prevent harm to the public.

In considering this legislation, then, the question needs to be asked, will it significantly reduce the mounting toll of medical device-caused injuries and deaths or will it simply further the cartel status of the largest companies which control this multi-billion dollar per year industry? Will we continue to see dozens of deaths, hundreds of injuries and thousands of units "voluntarily" recalled as with pacemakers, IUDs and other devices -- the extent of whose dangers have not yet been made known to the public? Will this legislation prevent these tragedies or will it merely institutionalize and even legitimize their further occurrence?

I will cite several examples of serious problems associated with medical devices which illustrate the need for mandatory authority to regulate devices more like drugs than like office furniture, as the present bill might allow.

INTRA-OCULAR DEVICES

Intra-Ocular Devices (IODs) are plastic lenses which are surgically implanted in the eyes of people whose natural lenses have had to be removed, usually because of cataracts. Although these lenses have been in use for more than 20 years as an alternative to wearing glasses after cataract surgery, many ophthalmologists think they have never been properly tested in animals or clinically investigated by multiple ophthalmologists under carefully controlled protocols.

As a result, the implantation of IODs has resulted in serious damage to the eyes of many patients including glaucoma, severe corneal disease, inflammation and infection. In a large number of cases, many known to the FDA, it has become necessary to re-operate to remove the plastic lens because it has become displaced forward or backward from its original location.

More alarming are a very large number of cases, mostly never published -- or reported to the FDA -- of people who have had to have their entire eye removed because of complications resulting from the lenses. The one published study of such complications reports on 17 people whose eyes had to be removed because of IOD-induced glaucoma, severe corneal damage and other complications.[1]

1. Arch. Ophthal. 82, 726, 1969

At a recent meeting (April 3-4, 1975) of the FDA Ophthalmic Devices Advisory Committee, Dr. Richard Troutman, a noted ophthalmologist from the Manhattan Eye and Ear Hospital in New York, revealed the following:

> 1) One of the earlier lenses, the "Strampelli" lens, was eventually discontinued because 80% of those implanted had to be removed, 20% of these causing sight-destroying complications.
>
> 2) 10-15% of a series of 261 patients who had a "Copeland" IOD implanted suffered retinal damage (cystoid maculopathy) which may be irreversible and lead to decreased vision.
>
> 3) The placement of lenses in younger (than 67) patients results in uniformly poor results.
>
> Conservative ophthalmologists* do not implant lenses in patients under 67 years of age or in more than 10% of cataract patients and then only in one eye (because of the possibility of serious bilateral complications).
>
> Two West Coast ophthalmologists, on the other hand, place the lens into about 90% of their cataract operation patients, often in both eyes, in young patients and at a rate that may be as high as 100 lenses per week.

Dr. Troutman further told the FDA advisory committee about his concern that "in the United States lenses were used which had not been clinically proven" and that "statistically significant results on implants which had been placed for 5 to 7 years were not available."

He expressed serious concern about the bioincompatibility between the plastic lens and the eye which he felt to be the primary cause of the problem.

Finally, in response to being asked if he would have an intra-ocular lens implanted, Dr. Troutman stated

> "If I were more than 75 years of age and if I had a signed death certificate indicating that I would die in seven or less years, than I would have it."

We have subsequently learned, via sources in the industry, that the Copeland lens alone is being produced at a rate exceeding 3,000 in 1974 and estimated at over 5,000 for 1975. At more than $1,000 per operation, this amounts to a $50 million dollar annual industry.

Like the IUD, the IOD, or intra-ocular lens is a plastic device for long-term implantation in the human body without adequate pre-market testing before what was and is mass-marketing for both. Both have yielded millions of dollars for their producers and for the doctors who put them in. Both have had severe adverse effects on health with death from septic abortions from the IUD, loss of eyes and vision from the IOD.

In the absence of mandatory pre-market testing for all such devices, more disasters are bound to occur.

CENTER FOR DISEASE CONTROL

# MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

November 26, 1976 / Vol. 25 / No. 46



*Epidemiologic Notes and Reports*

## Endophthalmitis Associated with Implantation of Intra-ocular Lens Prosthesis — United States

Eight patients in a Minnesota hospital who had cataract surgery and implantation of an intra-ocular lens prosthesis on November 10 or 11, 1976, developed endophthalmitis. All patients had received lenses from a single lot of a single manufacturer. *Pseudomonas aeruginosa* was subsequently isolated from 2 patients' eyes and from unused lenses of the same lot. The manufacturer has voluntarily recalled all lenses released after November 5, 1976.

Disease became apparent between 24 and 48 hours following operation and was characterized by brown pupillary light reflex, corneal clouding, and, in 4 patients, by coagulum or hypopion in the anterior chamber. No patient complained of increased pain, and the maximum temperature of any patient was 100 F. Needle aspirations obtained from vitreous fluid of 2 patients grew *P. aeruginosa* sensitive to gentamicin, tobramycin, colistin, and carbenicillin.

An epidemiologic investigation revealed that all 8 lenses were from lot # 76-285 produced by the Copeland Lens Company, New York City. Two control groups of uninfected patients were evaluated: (1) 15 other patients receiving Copeland lenses October 24-November 8, 1976, and (2) 21 patients operated on in the same period receiving prosthestic lenses from other manufacturers. No other patients received lenses from lot # 76-285. Six of 8 affected patients were operated on by a single surgeon, but that surgeon inserted approximately half of all Copeland lenses in the insitution ($p = 0.2$). Other than exposure to lenses from lot # 76-285, there were no significant differences between the case and control groups in terms of underlying illnesses, age, sex, or types of preoperative, intraoperative, or postoperative care.

Patients were initially treated with topical and systemic antimicrobials and corticosteroids. When the identity of the infecting microorganism was discovered, gentamicin was administered parenterally, and by either subconjunctival or sub-tenon injection. In addition, parenteral carbenicillin and high dose prednisone therapy was initiated. One lens had to be removed to control infection, but 7 patients are improving on chemotherapy. At least 5 of the 8 patients are expected to suffer no impairment of vision.

Four unopened lenses from the suspect lot were available in the hospital. Three lenses were aseptically removed from their containers and cultured; each grew *P. aeruginosa* with the same antimicrobial susceptibility pattern as that causing disease. The fourth lens was subsequently cultured by the Food and Drug Administration and was found to be contaminated with *P. aeruginosa.*

Distribution records of the suspect lot were obtained from the manufacturer. Of 97 lenses in the lot, all were recovered except 12 that already had been implanted: 8 in the patients described above, 3 in Florida, and 1 in Connecticut. Close clinical evaluation of the Connecticut and Florida patients has revealed no signs of infection. However, on November 15, an ophthamolgist in California noted *P. aeruginosa* endophthalmitis in a patient who had had implantation of a Copeland lens from a different lot.

The manufacturer has voluntarily recalled all lenses released after November 5, 1976, and reports that lenses released before that date have already been implanted.

*Reported by H Bauer, BS, L Ozols, BS, and B Poley, MD, Abbott-Northwestern Hospital, Minneapolis; D Gerding, MD, Minneapolis Veterans Administration Hospital; JS Andrews Jr, MD, Acting State Epidemiologist, and J Washburn, Minnesota State Dept of Health; G Stambaugh, MD, West Palm Beach, Florida; EWP Smith, MD, Acting State Epidemiologist, Health Program Office, Florida State Dept of Health and Rehabilitative Services; CF Chambers, MD, Ridgefield, Connecticut; JN Lewis, MD, State Epidemiologist, Connecticut State Dept of Health; J Chin, MD, State Epidemiologist, California State Dept of Health; U.S. Food and Drug Administration; and Bacterial Diseases Div, Bur of Epidemiology, CDC.*

**Editorial Note:** This incident represents the second outbreak of endophthalmitis associated with implantation of lenses reported to CDC. The first outbreak, involving 11 cases of ocular infection with *Paecilomyces lilacinus* associated with lenses from a different manufacturer, occurred in late 1975. While some lens prostheses are sterilized by ethylene oxide, each of these reported outbreaks was associated with implantation of lenses disinfected with sodium hydroxide.

*Reference*

1. MMWR 24(52):437, 1975

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