# AN INVESTIGATION INTO THE ADEQUACY OF EXISTING ADMINISTRATIVE PROCEDURES RELATING TO THE USE OF SURGICAL GLOVES AT CERTAIN HOSPITALS

By: Eric G. Freeman, LL.B

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This OCCASIONAL PAPER is somewhat different from the usual discourse which we have published in the past. It is a report of an Investigation completed by the Parliamentary Commissioner for Western Australia, Mr. Eric Freeman.

When Mr. Freeman recently visited me at the I.O.I. Offices in Edmonton we discussed this investigation and I suggested that it might be useful if the I.O.I. Members had the opportunity to read for themselves how the investigation had proceeded and been completed. I had in mind also how helpful it would be for Ombudsman Staff to have the opportunity to read the details of such an investigation. Mr. Freeman readily agreed and gave me the manuscript for distribution. I see no reason therefore to issue the usual disclaimer or to suggest that the contents might not be used without the permission of the I.O.I. Rather I view this Paper as more of an educational tool which may indeed be helpful to many.

We are indebted to Mr. Freeman and his Staff for their kindness in making this paper available for publication.

R.F.Ivany
Executive Director.

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## Explanatory Note

REPORT BY THE PARLIAMENTARY COMMISSIONER FOR ADMINISTRATIVE INVESTIGATIONS ON AN INVESTIGATION INTO THE ADEQUACY OF EXISTING ADMINISTRATIVE PROCEDURES RELATING TO THE USE OF SURGICAL GLOVES AT 84 HOSPITALS IN WESTERN AUSTRALIA.

The background to the investigation was that I received a complaint from a person concerning the standard of medical treatment that she had received from a surgeon while she was in hospital. At the surgeon's recommendation, the complainant underwent exploratory abdominal surgery. Complications from the operation required further surgery which was carried out at another hospital by a different surgeon. This operation was necessary to bypass an obstructing mass in the intestine which was found to have developed from a reaction to surgical glove powder in the first operation. The complainant claimed that both she and her husband had been told by the surgeon who performed the first operation that it was not his practice to wash his gloves for most surgery.

While I had jurisdiction over the hospital concerned, I did not have jurisdiction over the surgeon who was not an employee of the hospital. In these circumstances I did not commence an investigation of the specific complaint.

In the course of my preliminary inquiries (which were made with the co-operation of the Commissioner of Health) I noted that the problem of foreign-body reaction to surgical glove powder, although diagnosed infrequently, was well documented in medical literature both in Australia and overseas. I also noted that the envelope in which the most commonly-used gloves were wrapped contained the following notice-

WARNING

> Surface powder should be removed prior to undertaking operative procedures in order to avoid the risk of adverse tissue reaction.

I was of the opinion that the matter brought to my attention was of sufficient public importance to warrant an investigation into the adequacy of existing administrative procedures in relation to the using of surgical gloves. I accordingly commenced an investigation on my own motion pursuant to section 16 of the Parliamentary Commissioner

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Act. The terms of the investigation related to the procedures at the 84 hospitals within my jurisdiction in which surgery is performed. The relevant hospitals included 43 under the control of the Health Department of Western Australia and 41 administered by Hospital Boards.

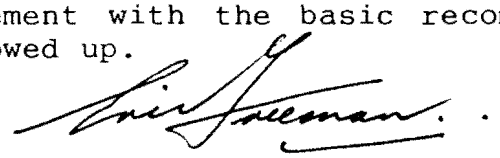
A survey of the administrative procedures in use at the relevant hospitals was conducted. I was concerned to discover that the majority of hospitals did not have established administrative procedures relating to the use of surgical gloves and only about half made specific provision for glove wearers to remove the surface powder from their gloves. It was evident that the pre-operation procedures followed by surgeons and assisting staff varied considerably.

In the light of these results I pursued my investigation further. I reviewed the medical literature, considered the legal position, observed the practices of surgeons and staff during a variety of operations and discussed the matter with surgeons and hospital administrators, including the Past President of the Royal Australasian College of Surgeons and the Commissioner of Health. I also inspected the production plant of a glove manufacturer and sought the views of its research staff.

I formed the opinion that, not only in the interests of the patients' welfare but also for the legal protection of the hospitals, surgeons and theatre staff concerned, there should be adequate procedures for glove powder removal.

I have accordingly recommended that appropriate routine procedures for the use of surgical gloves be formulated and brought to the attention of all those involved in operating theatres at the hospitals concerned.

Both the Commissioner of Health and the President of the Royal Australasian College of Surgeons have indicated agreement with the basic recommendations, which are being followed up.



E.G. FREEMAN,
Parliamentary Commissioner for
Administrative Investigations.

8th September, 1987.

# AN INVESTIGATION INTO THE ADEQUACY OF EXISTING ADMINISTRATIVE PROCEDURES RELATING TO THE USE OF SURGICAL GLOVES AT CERTAIN HOSPITALS

By Eric G Freeman LL.B
Parliamentary Commissioner for
Administrative Investigations
Western Australia

## Introduction

I received a complaint from a person concerning the standard of medical treatment that she had received from a surgeon while she was in hospital.

At the surgeon's recommendation, the complainant had undergone exploratory abdominal surgery. Complications from the operation required further surgery which was carried out at another hospital by a different surgeon. This operation was necessary to by-pass an obstructing mass in the intestine which was found to have developed from a reaction to surgical glove powder following the first operation. The complainant claimed that both she and her husband had been told by the surgeon who performed the first operation that it was not his practice to wash his gloves for most surgery.

While I had jurisdiction over the hospital concerned, I did not have jurisdiction over the surgeon, who was not an employee of the hospital. In these circumstances I did not commence an investigation of the specific complaint.

In the course of my preliminary inquiries (which were made with the co-operation of the Commissioner of Health) I noted that the problem of foreign-body reaction to surgical glove powder, although diagnosed infrequently, was well documented in medical literature. I ascertained that most types of surgical glove used in Western Australian hospitals under my jurisdiction were coated with a fine powder and that pre-operation procedures followed by surgeons and assisting staff varied considerably between hospitals. The washing of gloved hands was by no means a universal practice despite the fact that the envelope in which the most commonly used gloves were wrapped contained the following notice -

WARNING
Surface powder should be removed prior to undertaking operative procedures in order to avoid the risk of adverse tissue reaction

I was of the opinion that the matter brought to my attention was of sufficient public importance to warrant an investigation into the adequacy of existing administrative procedures in relation to the use of surgical gloves. I accordingly commenced an investigation on my own motion pursuant to section 16 of the Parliamentary Commissioner Act.

I am aware that surgical gloves have wide application outside the operating theatre. They are used for example when treating lacerations requiring sutures, for dressing burns and other wounds, for the removal of skin lesions and for oral, rectal and vaginal physical examinations. They are also used to create barriers against the transmission of infections such as AIDS and Hepatitis B.

I limited my investigation however to the operating theatre procedures at the 84 hospitals within my jurisdiction in which surgery is performed. The relevant hospitals included 43 under the control of the Health Department of Western Australia and 41 administered by Hospital Boards.

## Summary of the investigation

During my investigation I obtained information from the following sources -

* A review was made of most of the known papers published on the subject. These included case studies of foreign-body reactions to surgical glove powder, research work into the problem and methods proposed to alleviate the complication. A number of medical compendia, text-books and manuals for surgeons and nurses were perused. The legal position was also studied.

* A survey was conducted of the administrative procedures in use at the relevant hospitals. Each hospital provided written responses to a series of questions regarding the types of glove made available, and the administrative and other procedures, if any, for the donning, washing and use of surgical gloves.

* With the co-operation of the hospitals and the

surgeons concerned, I attended several operating theatres and observed the practices of surgeons and assisting staff immediately prior to and during a number of operations. On each occasion I was accompanied by my Senior Investigating Officer.

* Informal discussions were held with surgeons and hospital administrators (including some from hospitals not subject to my investigation). These persons expressed their personal views regarding the frequency of starch foreign-body reactions, the need to wash surgical gloves, the best procedures for removing glove powder, the desirability of procedures being established by hospitals for removing powder from gloves and their likely effectiveness, and related matters.

* I visited the Melbourne plant of the manufacturer of the gloves most frequently used at the hospitals under review and inspected the production process. I also had helpful discussions with the manufacturer's executives and research and development staff.

* The matter was discussed with a representative of the supplier of disposable glove wipes.

* Helpful discussions were held with the Commissioner of Health. He also sought the views of Fellows of the Royal College of Surgeons in Edinburgh.

* I discussed the basis for my findings at a meeting with the President of the Royal Australasian College of Surgeons who expressed his substantial agreement with the approach taken. The President also made a number of valuable comments which have been incorporated in this report.

## Background to the problem

As I understand the position surgical gloves made from rubber were first introduced in the late 1890's to protect the hands of nurses from the strong antiseptic solutions used. As well as acting as protective barriers, the aseptic advantages of surgical gloves were noted and their use soon became widespread.

There were many advantages in using rubber for the manufacture of surgical gloves. For example its high surface friction enabled users to take a firm grip on

surgical instruments. There were however certain difficulties -

- in the manufacturing process, when the rubber tends to stick to the formers on which gloves are moulded;
- in packaging and storing, when gloves in direct contact with each other tend to stick together; and
- in donning, when it is difficult for wearers to slip hands into the gloves.

For many years, surgical gloves were supplied without a coating of donning lubricant. In an attempt to overcome the donning problem, liquids such as water or weak alcohol solutions were originally used as lubricants. These however allowed the hands to slip around inside the gloves. Dusting powders (mainly lycopodium and talc) were substituted. The powders were provided by the hospitals and/or by the glove suppliers enclosed in sachets. Powder was applied to the hands as the users required. Gloves were used many times over, being washed, patched where necessary, and sterilized between each operation. Subsequently, single use, disposable gloves coated with powder during production were introduced and achieved widespread acceptance.

There was however a problem in that particles of the dusting powders for surgical gloves, if released into tissue areas, could cause the formation of granulomas and adhesions. Granulomas consist of nodules, which form as a result of the inflammatory process initiated by glove powder or other stimulant. Adhesions are areas of attachment of tissue, such as part of the intestine to another part of the intestine or to the abdominal wall. These can interfere with normal function. In the case of abdominal adhesions, obstructions can occur which prevent the peristaltic action of the intestine and which lead to granuloma peritonitis.

Tissue reactions to glove powder have been observed in most body organs and cavities. Peritoneal granulomas appear to be the most common and cause the most concern. The clinical features of glove powder granuloma peritonitis are well-established. Some 2 to 6 weeks after an apparently uncomplicated operation the patient becomes unwell, with a low-grade fever and abdominal pain. Physical examination indicates intra-peritoneal inflammation or bowel obstruction. The erythrocyte sedimentation rate is often high. If a re-exploration of the abdomen is performed, characteristic free straw-coloured fluid, peritoneal nodules and adhesions are observed. Biopsy and examination of

a nodule under a polarizing microscope reveals the "Maltese cross" appearance of the powder particles.

In 1947, after it had become known that talc powder from surgical gloves was particularly hazardous because it was insoluble in tissue fluids, an alternative powder was introduced by some manufacturers. The powder consisted of modified cornstarch with approximately 2% magnesium oxide and lesser amounts of some other substances. It was considered to be both suitable and safe because it was not toxic and could be absorbed into tissue fluids.

Within a few years however cases were reported of granuloma, adhesions and peritonitis caused by starch powder. It was realized that, although treated starch is eventually absorbed, it produces a foreign-body reaction as long as it is present in tissue in aggregated form. Patients usually recover spontaneously unless there are secondary complications. These are relatively rare.

It has however been suggested that the frequency of glove powder reactions may be much higher than is generally recognized. The reason is that in many cases the symptoms (such as abdominal pain, fever and vomiting) are characteristic of other abdominal conditions and cause relatively minor post-operative discomfort. The nature of the syndrome may not be recognized unless there are complications and a second operation is performed.

A report concerning five documented and two suspected cases of starch granuloma peritonitis known to have occurred at the Mayo Clinic during a 12-month period when 4965 intra-abdominal procedures were performed indicated that the frequency might be as high as 1 in 1000 (refer report by Sternlieb and others, Arch. Surg. (1977), vol. 112, pp. 458-61). In another study conducted over a 6-month period it was found that 10 out of 20 patients who underwent a second laparotomy following a single abdominal operation had starch granulomas (refer report by Cooke and Hamilton, Br. J. Surg. (1977), vol. 64, pp. 410-2).

While the exact nature of the starch-tissue interaction is not known it does appear that in some cases it is an allergy-type reaction by particularly-sensitive patients stimulated by a minute amount of powder.

Because of the problem caused by the use of starch powder a number of procedures have been devised in attempts to remove powder from the external surfaces of surgical gloves. These include procedures for washing or rinsing with sterile

water or with saline, detergent or antiseptic solutions (e.g. 1% Cetrimide or chlorhexidine). Washing and rinsing operations are commonly carried out in sterile basins (splash bowls) containing the appropriate solution. Another procedure is for wiping the gloves with sterile dry towels or with wet sponges or glove wipes which are impregnated with antiseptic solution.

It does not appear that any of these procedures has gained universal acceptance because of the general belief that the glove starch granuloma problem is rare and because the procedures have been shown to have shortcomings. Several studies have concluded that even vigorous washing, rinsing and/or wiping is unlikely to remove all the surface powder from surgical gloves. This view was also expressed by surgeons when I discussed the problem with them.

Several studies, using scanning electron microscopy techniques, have demonstrated that even after repeated washing and wiping loose aggregated clumps of starch are left on the outside of gloves (refer for example to report by Jagelman and Ellis, Br. J. Surg. (1973), vol. 60, pp. 111-4). One study found that vigorous procedures appeared to exacerbate the clumping and that the aggregated clumps took longer to absorb than finely-dispersed particles. A conclusion reached was that contamination in abdominal surgery is inevitable when starch-coated surgical gloves are used.

It has also been suggested in a report by Campbell and others (Aust. N.Z. J. Surg. (1984), vol. 54, pp. 559-63) that washing several pairs of gloves in the one solution (for example, in a splash bowl) may increase the hazard. This is because much of the powder washed from gloves floats and some returns to the gloves as the hands are withdrawn from the solution.

Of at least as much concern is the danger of relatively large deposits of concentrated starch powder from the inside of gloves being directly implanted in localized areas in wound sites when gloves not uncommonly fail during operations, for example as a result of being accidentally punctured, cut or torn by surgical instruments.

In an attempt to overcome the problem of starch powder granuloma a recent innovation has been the production and distribution by some manufacturers of non-powdered single use, disposable surgical gloves. This is referred to later in this report.

## Survey of hospitals

In the light of my research on the subject it was interesting to note the responses to my questionnaire from the 84 Western Australian hospitals the subject of my investigation.

* The majority of the hospitals concerned did not have administrative procedures relating to the wearing of surgical gloves.
  Six hospitals stated that procedures used were as defined in the "Western Australian School of Nurses Notes on Theatre Technique".
  Three hospitals relied on the procedures recommended in the "Manual of Guidelines for Nursing Procedures".
  One hospital provided me with an extract of the relevant section from its Theatre Manual. This provided procedures for donning gloves but had no reference to powder removal. The section describing procedures for nurses assisting others to gown and glove included an instruction -
  "Powder or cream envelope is opened and powder poured on doctor's hands <u>if required</u>."
  The Manual would appear to be in urgent need of revision!
  One hospital maintained a card index in which the preferences and requirements of individual surgeons were recorded.

* Most of the hospitals used one particular type of surgical glove powdered on both surfaces with a cornstarch preparation during manufacture. The gloves were packaged with the following warning on the inner wrapper -

  WARNING
  Surface powder should be removed prior to undertaking operative procedures in order to avoid the risk of adverse tissue reaction

* Nearly one-fifth of the responding hospitals that reported using the most common type of powdered glove stated that there was no warning on the glove wrappers! The reason for this may be that the surgeons are often helped into their gloves by assisting staff.

* Two hospitals expressed the opinion that the printed warning on the inner wrapper was almost illegible.

I referred this matter to the manufacturer concerned.

* Only 54% of the hospitals made specific provision for glove wearers to remove surface powder from surgical gloves. Most of these provided a basin containing one of a number of sterile solutions. A few hospitals provided sterile wet or dry towels or pre-packaged disposable wipes.

* Only three hospitals stocked the non-powdered surgical gloves, although several reported having tried them. In some cases the non-powdered gloves had not been taken into regular use either because of their cost (approximately double that of the corresponding powdered type) or because they had been rejected by surgeons. This was usually on the grounds either that the gloves were difficult to don (especially if the hands were not completely dry) or that they did not feel as comfortable as the powdered variety.

**Operating theatre and other observations**

I observed several operations at various hospitals in the Perth metropolitan area with my Senior Investigating Officer. They included abdominal (removal of a section of cancerous intestine), cardiac (heart valve by-pass) and eye (corneal graft) surgery, hysterectomy, laparoscopic sterilization and dilatation and curettage procedures. The procedures of the surgeons and assisting staff with respect to their use of surgical gloves, both prior to and during the operations, were noted. The procedures were also discussed with the surgeons, a number of assisting staff and with the hospital administrators concerned.

The result was a wide range of procedures, responses and attitudes regarding the use of surgical gloves, which are summarized below -

* While the surgeons were aware of the potential hazard of surgical glove powder the majority considered that the probability of patient reaction to starch was so rare that no special precautions were needed for general surgery.

* It was acknowledged that particular care should be taken for operations involving especially sensitive organs or tissues (for example the eye and ear) and for procedures which do not include frequent washing and irrigation of exposed tissue areas. Some eye

and ear surgeons were already using non-powdered gloves.

* Some surgeons used splash bowls to wash powder from gloves. The bowls contained either sterile water, a warm 1% saline solution or a detergent or antiseptic solution (Cetavlon, Cetrimide, chlorhexidine).

* Some surgeons stressed that the presence of splash bowls within sterile areas of operating rooms is predominantly for the removal of blood and other material from surgeons' gloves during operations rather than for the removal of powder from gloves. Although I observed the solutions in the splash bowls being changed at intervals during operations the timing of such changes appeared to be a matter of personal judgement for the relevant theatre assistant.

* One senior surgeon who had taken a particular interest in the glove powder problem made the point that he required there to be two splash bowls containing appropriate solutions. The first was for removing powder from gloves and was discarded as soon as this procedure was completed. The second was for removing blood and other material from gloves during operations.
He also emphasized that glove washing and wiping actions should be gentle.
In addition this surgeon referred to another potential source of starch implantation in wound areas, namely from the lower sleeves of surgeons' gowns, adjacent to the area of contact with the gloves. This was a result of surgeons holding the arm cuffs of their gowns as they slipped their hands into the gloves.

* Other surgeons regarded the use of splash bowls as a source of potentially greater risk, either from starch or because of the possibiity of the washing solution splashing onto gowns and then acting as a channel for the transfer of organisms both between patient and surgeon and surgeon and patient.

* Some surgeons used glove wipes impregnated with an antiseptic solution to remove powder.
(I was subsequently informed by the local supplier of a brand of glove wipes used in Western Australia that they had been withdrawn from the market. The reason for this was that it had been found that in the sterilization process the wipes deteriorated and became prone to linting, thereby creating a

potential problem at least as serious as that from glove powder.)

* Sterile dry towels are used as a final step in powder removal by some surgeons.

* Other surgeons do not wash or wipe their gloves at all.

* Another view expressed to me was that glove rinsing was expensive and inefficient.

* None of the operating theatres that I visited displayed any notices giving procedures for glove powder removal. In contrast one hospital had notices giving procedures for scrubbing up.

* In two of the operations which I observed the gloves were punctured (which I understand is not uncommon). In the first the surgeon concerned noticed the puncture and immediately changed the glove outside the sterile area. He then gave the new glove a wash in a splash bowl before returning to the patient. When I examined the punctured glove I noted that powder from inside the glove had come through the puncture to the outer surface.
In the other case the surgeon became aware of the puncture at the conclusion of the operation.

* Some surgeons who had tried non-powdered gloves stated that they were difficult to don, especially if the hands were slightly damp, and that they were uncomfortable to wear. (One surgeon stated that he had never heard of non-powdered gloves.)

* A research scientist associated with an in vitro fertilization (IVF) programme informed me that starch powder was extremely hazardous in IVF procedures since it is toxic to embryos. On the programme concerned all workers used non-powdered gloves. They report having no problems with them except donning difficulty if the hands were not completely dry.

## Inspection of glove manufacture

I visited the plant which produces the surgical gloves used in most Western Australian hospitals. These gloves are manufactured by a process in which hand-shaped formers

are dipped into rubber latex. A release agent (a powder) and latex gelling agents are placed on the surface of each former prior to dipping it into the latex to facilitate removal of the glove. The gloves are turned former side out when removed. The release agent is accordingly on the outside glove surface.

After a multi-step cleaning process the integrity of each free glove is electronically tested. To render the gloves "hypoallergenic" they are then boiled in water to release from the latex water-extractable substances which might cause allergic reactions to wearers.

Donning powder is then applied. The composition of the powder which is purchased by the manufacturer conforms to the standards set in the prescriptions given in the British and United States pharmacapoiea respectively. The resulting gloves have from 300 to 500 mg of powder on the inside and a maximum of 50 mg of powder on the outside surface. I understand that these levels are the result of extensive trials and are the minimum amounts which still enable gloves to be donned easily.

Gloves are packaged such that the printed warning on the inner wrapping of each glove is visible. The gloves are sterilized after packaging.

During detailed discussions with the manufacturer I was informed that the non-powdered surgical gloves, which were produced outside Australia, were manufactured in a similar process except that instead of passing through the powdering stage the inner surfaces were chemically treated with chlorine in a manner which changes the nature of the surface layer of rubber. The resulting surface has lower friction so that it becomes easier to slip hands into the gloves.

It was clear from my discussions with the manufacturer (which is a subsidiary of a large company) that it was aware of the glove powder problem. It had been involved in considerable research into the subject and papers had been published and presented at conferences. The company can be expected to produce both powdered and non-powdered surgical gloves as long as there is a demand for such products.

## Discussion

The terms of my investigation concern the adequacy of existing hospital administrative procedures relating to

the use of surgical gloves. Implicit in these terms are questions of whether hospitals should have such procedures and whether they can be so devised to be both reasonable and effective in minimizing the risk of surgical glove powder entering sensitive areas of patients during operations.

My inquiries have been characterized by the lack of definitive scientific results in the research on the subject and by the widely-differing views expressed both in the published literature and by hospital surgeons and staff in Western Australia. I am also conscious of the practical need to maintain a co-operative balance between the responsibilities and authority of those administering hospitals and the traditional and necessary independence and autonomy of surgeons in the operating theatre.

Nevertheless two points need to be made -

> No matter how rare the problem of foreign-body reaction to starch from surgical gloves might be thought to be, it exists and can be the precursor of potentially-grave complications, as was demonstrated not only by the complaint I received but also from the medical literature. Glove powder granulomas and adhesions result from surgical intervention. The syndrome does not exist in the patient prior to operation. If it can be avoided relatively simply there can be no medical or legal justification for its occurrence.
>
> The use of non-powdered gloves, which are now available (and which are being increasingly used in at least one of the teaching hospitals in Western Australia), would prevent the problem occurring.

The main objections of surgeons to the use of non-powdered gloves are that they are difficult to don and that they diminish finger sensitivity.

I have been informed that tests have shown that the difficulty of donning non-powdered gloves can be overcome by ensuring that the hands are completely dry.

The reduced sensitivity of touch through non-powdered gloves is attributed by many surgeons to the gloves being thicker. In point of fact this was shown not to be the case when the thicknesses of powdered and non-powdered gloves were measured by the manufacturer using a micrometer screw gauge. The sensation of increased thickness is apparently due

to the rubber on the inside of the non-powdered gloves having a lower modulus of elasticity because of the chemical modification it undergoes during manufacture.

Unless side effects become evident, the use of non-powdered gloves appears to represent a solution to the surgical glove powder problem. I believe however that it would be quite inappropriate for me at this time to recommend that their use should be required at the hospitals that are the subject of my investigation. I say this because the glove powder problem must be seen in perspective. There is no such thing as a foolproof surgical procedure. Little would be achieved if the use of non-powdered gloves, because of their sub-optimal tactile sensitivity, resulted in mistakes, for example with fine thread, which in turn led to complications more serious than those caused by glove powder.

## Legal ramifications

The liability of hospitals and surgeons to patients for complications from glove powder granulomas and adhesions should not be overlooked.

By way of illustration, during my research on this topic I considered the case of Simms v. Southwest Texas Methodist Hospital, and others (535 South Western Reporter, 2d series, 192-201 (Texas Cr. App. 1976)). In that case a patient who suffered complications from foreign-body granulomatous peritonitis sought compensation by suing in the District Court the surgeons, the hospital and the glove manufacturer concerned.

The plaintiff had initially been operated on for the removal of an ovarian cyst. Some 10 days later she was re-admitted to the hospital having developed symptoms of an obstruction of the bowel. A second exploratory operation revealed extensive abdominal adhesions. A large part of the woman's small intestine was removed. As a result her bowel control was permanently impaired. The plaintiff claimed that the complication resulted from the presence of starch on the surgical gloves used by the surgeons who operated on her. Neither the glove manufacturer nor the hospital concerned issued warnings of the danger or instructions regarding removal of glove powder. Those involved washed their gloved hands in splash basins.

Although it was conceded that cornstarch had been introduced into the patient's abdominal cavity during the ovarian

cyst operation the defendant argued that the sole cause of the complications which arose was talc granuloma arising from an earlier operation performed when talc was used as a dusting powder for surgical gloves.

The trial jury found that the absence of a warning of the danger and instructions concerning removal of the powder rendered the gloves unreasonably dangerous. The case was lost however on the grounds that it had not been established that "such dangerous condition was a producing cause of the plaintiff's injuries".

The plaintiff appealed to the Court of Civil Appeals against the glove manufacturer on the basis of breach of implied warranty of merchantability. She contended that the manufacturer's failure to warn of the danger and to inform users of the gloves of the proper procedure to eliminate the danger rendered the gloves unreasonably dangerous and therefore unfit for the ordinary purposes for which such gloves were used. The Appellate Court however dismissed the appeal since it failed to find any error in the Trial Court's decision that the plaintiff had failed to demonstrate from a preponderance of the evidence that the injury to the patient was most likely caused by cornstarch.

In a review of the case by Regan (AORN Journal 1976 Vol. 24, pp. 1130-4) the following comment is in my view particularly pertinent -

> "If it could have been demonstrated in the law suit reported above that the hospital and its OR [operating room] staff knew or should have known of the potential danger of cornstarch and nevertheless failed to adequately cleanse the gloves, the outcome of this case might have been radically different."

It is interesting to note that, subsequent to the plaintiff's operation -

(1) The hospital issued a memorandum concerning the establishment of a "written policy for sterile gloving". It warned that the introduction of starch into an open wound might cause granuloma and contained instructions for the cleaning of gloves prior to surgery.

(2) The manufacturer commenced packaging its surgical gloves in a wrapper bearing a warning and instructions for removing starch from the gloves.

(3) The Federal Drug Administration adopted a regulation which required that packages containing surgical gloves which had been sprayed with starch bear a warning statement and instruction for removing the powder.

I understand that the British Standard Specification for single use, sterilized surgical rubber gloves adopted in Great Britain also requires that the inner wrapper of gloves be legibly marked with a warning that surface powder be removed prior to undertaking operative procedures. Although no similar requirement exists in Australia the manufacturer of the surgical gloves most commonly used by the hospitals concerned follows the relevant British Standard.

Having regard to the above comments I am of the opinion that, not only in the interests of the patients' welfare but also for the legal protection of the hospitals, surgeons and theatre staff concerned, there should be adequate procedures for glove powder removal.

**Recommendations**

1. I recommend that the Commissioner of Health, in conjunction with representatives of the Hospital Boards concerned, the Royal Australasian College of Surgeons and the Royal Australian Nursing Federation formulate appropriate routine procedures for the use of surgical gloves and bring them to the notice of all those involved in operating theatres.

   It is not for me to formulate those procedures. They should however be acceptable to surgeons and theatre staff as being effective and not seen as an unnecessary bureaucratic requirement.

2. Shortly after my investigation commenced the Commissioner of Health took action to make non-powdered surgical gloves available on request to surgeons operating within Government hospitals. I recommend that the Hospital Boards the subject of my investigation also make non-powdered surgical gloves available to those surgeons who wish to use them.

3. I recommend that immediate steps be taken to increase the general degree of awareness of the glove powder problem in the medical and nursing professions.

4. I recommend that, if not already the case, medical students and nursing students, as part of their training course, be made aware of the problem of patient contamination by surgical glove powder and the precedures to endeavour to overcome it.

5. I recommend that representations be made by the Commissioner of Health to the manufacturer and relevant Australian research groups to encourage further research directed towards the production of non-powdered gloves with improved tactile sensitivity that would be readily accepted by surgeons.

E.G. Freeman
Parliamentary Commissioner for
Administrative Investigations