January 7, 1998

Michael Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Petition to Ban Cornstarch Powder on Latex Gloves

Dear Dr. Friedman:

Public Citizen's Health Research Group and its Director, Sidney M. Wolfe, MD and Staff Researcher, Christine Dehlendorf, and Timothy Sullivan, MD, Professor of Medicine at Emory University School of Medicine and Head of the Subsection of Allergy and Immunology at the Emory Clinic hereby petition the Food and Administration (FDA) to immediately ban the use of cornstarch powder in the manufacture of latex surgical and examination gloves because of the serious and widespread dangers these gloves cause to medical personnel and to patients. An acceptable substitute, non-powdered gloves, is available and has already been implemented in many places. FDA's legal mandate to require such a ban is found in section 516 of the Food Drug and Cosmetic Act, 21USC 360(f). The continued use of powdered latex gloves is unacceptably harmful and the FDA must act to ban such dangerous products.

Introduction: Hospitals Which have Stopped Using Powdered Gloves

According to industry sales data, 26% of the U.S. surgical glove market is currently comprised of the sales of powder-free latex gloves. Following are three examples of hospitals which switched from cornstarch powdered gloves to powder-free gloves.

In 1993, Brigham and Women's Hospital, a Harvard teaching hospital in Boston, experienced a mysterious epidemic among operating room personnel, in which 12 to 14 employees a day were unable to complete their typical duties due to allergic reactions. An internal investigation, followed by the hiring of an environmental consultant, identified the source of the epidemic to exposure to latex -- especially to aerosolized glove powder, which bound the latex proteins (Appendix A). Following this experience, the hospital became powder-free. In other words, they no longer used powdered latex surgical gloves.

Ralph Nader, Founder
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In December of 1995, Jackson Memorial Hospital in Miami also chose to convert to low allergen, powder-free gloves, “after an epidemic of latex allergy, glove dermatitis and occupational asthma” (Appendix B). The number of complaints of reactions to latex plummeted after the switch was made.

Following the lead of these hospitals, Methodist Hospital in Indianapolis eliminated all powdered gloves from their facility in late 1995 and early 1996 after having more than 80 employees be identified as allergic to latex. As a result of the switch none of the allergic employees needed to leave their jobs (Appendix C).

The experiences of these hospitals are part of a rapidly growing recognition of problems with cornstarch powdered gloves. In addition to the link with latex allergies noted above, evidence also indicates that cornstarch causes surgical complications. In order to protect patients and health care workers from the risks of exposure to cornstarch, the FDA must follow the example of these hospitals by taking immediate action to ban its use as a lubricant for surgical and examination gloves.

In delineating the basis for urging the FDA to immediately implement this ban, this petition, following a brief discussion of the history of powdered gloves, details the serious medical problems associated with the use of cornstarch powder on surgical and examination gloves and addresses perceived barriers to the implementation of the proposed ban. This petition builds on Dr. Richard Edlich’s (distinguished Professor of Plastic Surgery and Biomedical Engineering, University of Virginia School of Medicine) previous contacts with the FDA requesting a ban on cornstarch. On December 7 and 14th, 1995, Dr. Edlich sent letters to the FDA requesting a ban on cornstarch (Appendix D & E), and included in his letter scientific studies indicating that cornstarch-powdered gloves caused toxic reactions to tissues. Six months later, on June 3, 1996, Carol J. Shirk, Consumer Safety Officer of the FDA, responded to his letter, and informed Dr. Edlich that the FDA was extensively investigating his request and that he would be advised of the outcome of the review once a policy was determined regarding cornstarch powdered gloves (Appendix F). On July 15, 1997, he was informed by the FDA that they had made no final decision regarding this issue. We are therefore demanding that the FDA immediately take action to address this widespread public health problem. The FDA regulation, which went into effect September 30, 1997, requiring latex-containing medical devices such as gloves to contain a warning that the product contains latex “which may cause an allergic reaction” is appropriate for those products for which there is no safer substitute. But for powdered latex gloves, anything short of a ban--such as merely this label--is a dangerous insult to the millions of patients and tens of thousands of health care workers whose lives and health are jeopardized by the continued use in health care settings of these powdered gloves.
History of Medical Gloves

When surgical gloves were introduced at the turn of the century, they were sterilized by boiling and could only be donned by pulling the rubber gloves over wet hands. Because the wet hands of the surgical staff became macerated under the occlusive cover of the rubber glove, predisposing to severe dermatitis, surgeons searched for a dry lubricant that would facilitate donning and prevent the gloves from sticking together during the pressurized steam sterilization process (autoclaving). An early lubricant, a powder made of Lycopodium spores (club moss) was identified as causing foreign body responses, including adhesions and granulomas. Talcum powder (hydrous magnesium silicate), a non-absorbable lubricant, was also implicated in the production of granuloma in tissues and adhesion formation in the peritoneal cavity. In the study in 1947, Lee and Lehman, in addition to verifying the increasing evidence that talcum powder was a dangerous disease-promoting factor in human surgery, identified what appeared to be an acceptable alternative to talc -- cornstarch powder. They found that cornstarch powder was completely absorbed from the peritoneum (abdominal cavity) without any demonstrated inflammation and it produced no adhesions whatsoever. Because it was a cornstarch powder, it was taken up by the peritoneum and metabolized like any ingested starch.

By 1952 a sample survey indicated that cornstarch had replaced talc in 60% to 90% of hospitals in the U.S., and currently is found as the lubricant on most surgical and examination gloves used by health care workers. However, experimental and clinical studies in the last 50 years have continually documented dangerous side effects of this absorbable lubricant. There has also been increasing evidence of a link between cornstarch and latex allergies. Likely in response to concerns about adverse effects caused by cornstarch, in 1971 the FDA required that manufacturers place warning labels on the glove packages which stated that glove users should remove cornstarch from the glove surfaces by wiping the gloves with a wet sponge, towel, or by using another effective method. In addition, realizing these serious dangers to the patients and health professionals, numerous manufacturers have developed powder-free surgical gloves, removing a barrier to the elimination of cornstarch powdered gloves. However, despite this recognition of the dangers of cornstarch and the existing technological advances in glove manufacturing, most hospitals continue to use powdered gloves.

Cornstarch-Induced Foreign Body Disease From Gloves

Most surgeons have an unfounded confidence in cornstarch and mistakenly believe that it is safe. Scientific experimental and clinical studies have confirmed that cornstarch promotes disease by two different mechanisms. First, it acts as a foreign body when deposited in the wound that elicits an exaggerated inflammatory response and interferes with the host's defenses against infection. When cornstarch contaminates soft tissues, it promotes the development of wound infection. The presence of small amounts of cornstarch promotes wound induration, bacterial growth, and wound infection. When cornstarch gains access to the peritoneal cavity, it can cause granuloma formation, adhesion formation and peritonitis. The development of cornstarch induced adhesions can produce intestinal obstruction, infertility, and pelvic pain.
Other documented adverse reactions to cornstarch include endophthalmitis, post-thoracotomy syndrome, meningismus after craniotomy, retroperitoneal fibrosis, and synovial inflammation.

It is important to recognize that simply warning health care workers to wash the cornstarch off gloves prior to use does not prevent the adverse effects discussed above. Jagelman and Ellis reported that washing with water reduced the number of starch granules, but left significant cornstarch on the glove that appeared to aggregate as clumps. They postulated that the development of clumps of cornstarch would promote a delay in absorption and an enhancement of the foreign-body reaction. In 1980, Tolbert and Brown provided further evidence that glove washing with a saline solution left a portion of the cornstarch on the glove surface.

The most effective method of washing the cornstarch from the gloves involves a one minute cleansing with 10 mL of povidone-iodine followed by a 30 second rinse under sterile water. This technique reduced the median number of starch granules per mm² of glove, as seen on microscopic examination, from 2,720 (when no attempt to remove the powder was made) to 0 (when the povidone-iodine method was performed). However, this technique is time-consuming, costly, and burdensome to the clinical staff and can not ensure that all powder particles have been eliminated.

Even if these procedures were completely effective, it would still be necessary to ensure that health care workers adhere to the washing guidelines if the cornstarch powder is to be removed. In a study conducted by Fay and Dooher, the surgical staff's compliance with glove washing to remove cornstarch lubricants was examined. Only 17% of the surgeons and 21% of the surgical nursing staff washed their gloves after donning. These investigators attributed the slightly higher levels of compliance among nurses to practices taught in nursing school and/or to references to the need for glove washing in nursing journals and textbooks. Information about glove washing might not be included in medical education.

It is also important to realize that some departments in the hospital use powdered surgical gloves in an environment in which they do not have easy access to sterile wash basins. For example, emergency physicians in Emergency Departments treat more than 10 million patients annually using sterile surgical gloves. During wound treatment, they usually do not have the benefit of a nursing assistant who prepares a sterile wash basin filled with sterile saline in which they can attempt to remove cornstarch from their gloves. Consequently, most emergency physicians use gloves lubricated with cornstarch during their wound closure techniques.

**Cornstarch: Facilitator of Serious, Life-threatening Allergic Reactions to Latex**

The second mechanism by which cornstarch on gloves causes disease is based on its role as a carrier for latex allergens. Reported reactions to latex include contact urticaria, rhinitis, asthma, and anaphylactic shock, and the development of reactions to latex.
exposure has been linked to people’s production of IgE antibodies to natural latex when exposed to the substance. In 1992 the FDA identified more than 1,000 combined Medical Device Reporting Program and Product Problem Reporting Program reports of allergic or anaphylactic reactions in conjunction with the use of plant-derived rubber or latex containing medical products. (Note that there is some overlap between these two reporting programs). More recently, according to an official at the FDA (SF Dillard, Center for Devices and Radiological Health), in the last year alone for which data are available (August 15, 1996-August 15, 1997), there were 305 reports to the FDA of allergic or anaphylactic reactions associated with the use of latex gloves.

Health care workers are especially at risk for this allergy due to occupational exposure to latex. A 1992 study found that 8.8% of dentists in the U.S. Army Dental Corps self-reported histories consistent with latex allergy. More recently, a 1996 study found that 5.5% of hospital personnel were positive for latex specific IgE antibody using a radioallergosorbent test. Two other studies, published in 1997, reported that 12.1% of health care workers and 21% of hospital nursing staff were sensitized to latex, as determined by skin prick tests.

This high prevalence of latex sensitization has staggering human costs, as trained health care workers who experience symptoms may require reassignment, or potentially can even need to discontinue their career in health care. Not only is this devastating to the individual, but society also loses the benefit of the training of these professionals.

A role of cornstarch in the development of latex allergy by health care workers was suggested by Beezhold and Beck, who identified a significant interaction between latex proteins and cornstarch powders. Further, Tomazic et al. showed that cornstarch binds latex proteins. This interaction between cornstarch and latex has been implicated as the major cause of airborne latex, as evidenced by the fact that work areas which use only powder-free gloves have been shown to have low or undetectable amounts of latex aeroallergens. These airborne cornstarch/latex particles have been shown to serve as an agent for exposure and sensitization of health care workers to latex protein through the release of latex/cornstarch particles into the air.

First, Tomazic et al. demonstrated through competitive inhibition and direct binding immunoassays that the latex-protein/starch particles are allergenic proteins. In addition, one study has demonstrated that sensitized people exhibit allergic symptoms such as rhinitis, cough, conjunctivitis or breathing problems when exposed only to airborne latex through the handling of cornstarch powdered latex gloves. Of 11 sensitized people, four developed shortness of breath, wheezing and had documented evidence of increased airway resistance. Another study showed that four sensitized female nurses experienced immediate bronchoconstriction (increased airway resistance) when handling powdered latex surgical gloves and that bronchial challenges with powdered latex surgical glove extracts resulted in more severe reactions than challenges with non-powdered latex surgical glove extracts. Therefore, the interaction between cornstarch and latex provides a route of exposure to the latex proteins which the absence of cornstarch would minimize.
Case reports in the literature support the role of cornstarch in latex allergy of health care workers. One hematology laboratory technician, who had experienced contact dermatitis, contact urticaria and anaphylaxis following contact with latex, continued to experience symptoms such as facial urticaria and rhinitis after she switched to vinyl gloves, and eventually stayed off work. She was able to return to work after her laboratory changed to powder-free gloves.\textsuperscript{39} Another report involved an intensive care nurse who immediately had asthmatic symptoms when powdered latex gloves were manipulated in front of her, but had no reaction to vinyl gloves.\textsuperscript{42}

The experiences of Jackson Memorial Hospital in Miami and Methodist Hospital in Indianapolis as well as the aforementioned situation at the Brigham and Women’s Hospital in Boston also indicate the role of powdered gloves in the development of latex allergy, and the effectiveness of a switch to powder-free gloves for the protection of workers. All three hospitals made the switch to powder-free gloves after discovering that latex allergies were a substantial problem among their staff, and were able to adequately address the problem by implementing the ban.

For example, Methodist reported more than 80 employees diagnosed as latex allergic, with “most of these employees [having] 10-20+ years of service with Methodist Hospital...[some] employees had such severe respiratory symptoms that they had to be removed from their current working environments until changes could be implemented.” Having identified the primary source of exposure as powdered latex gloves, the hospital eliminated the “latex laden powder.” As a result, none of the employees originally diagnosed as allergic was terminated. (Appendix C)

In 1994, Jackson Memorial also began having latex allergy problems, including “a clerk who was transferred from the gift shop to a lab clerk position, suffered anaphylactic shock and a full respiratory arrest after donning latex gloves...and was never able to work again” and “an OR tech who....began to have asthma attacks and hives every time she entered the operating room...She became so allergic she had reactions when she touched the phone, her underwear, the car steering wheel and even her child’s school paper when she had used an eraser...She could not work at all for over a year and almost lost her home.” In the first five months of 1995, the hospital was receiving five new complaints a week of glove dermatitis or other symptoms, and “by May, 1995, 95 employees had been treated for problems related to gloves...Each event required an average of two weeks off duty...many began to return with progressively more severe hives, facial edema and respiratory symptoms even though they were using non-latex gloves.” Following the switch to powder-free gloves the number of complaints decreased to no more than two a month, with no new cases of occupational asthma or respiratory events related to glove use. (Appendix B)

The positive experiences of these hospitals with the elimination of powder-free gloves indicate that a commitment to eliminating cornstarch powder is an invaluable tool against the growing problem of latex allergy among health care workers.
The link between increased exposure of health care workers to latex proteins due to the use of cornstarch powder in gloves appears to be well established by the literature and case reports presented above. The National Institute for Occupational Safety and Health (NIOSH) has recognized this link, and the danger that the continued use of these gloves poses to workers. A safety alert report released in June 1997, entitled “Preventing Allergic Reactions to Natural Rubber Latex in the Workplace,” not only alerted the public, employers, and safety and health officials to the increase in allergic reactions to latex, particularly among health care workers, but also recommended that “If latex gloves are chosen, provide reduced protein, powder-free gloves to protect workers from infectious materials”.

**Powder-Free Gloves are Effective and Cost-Efficient**

According to IMS America, powder-free surgical gloves made up 26% of the surgical glove market in the second quarter of 1997.1 This finding indicates that these gloves are being found to be acceptable by many surgeons. However, despite this and the developing understanding of the negative effects of the use of cornstarch powder on examination and surgical gloves, there is still resistance to the use of powder-free gloves based on questions about their ease of use and effectiveness, as well as about the cost of switching to powder-free alternatives. Below we will discuss the evidence regarding the use of powder-free gloves, as well as the experience of certain hospitals, all of which indicate powder-free gloves are in fact a viable alternative to cornstarch powdered gloves.

First, some surgeons are reluctant to use powder-free gloves because they perceive that they are more resistant to donning than powdered gloves. Dr. Edlich and his colleagues demonstrated that the glove-donning forces necessary for powder-free gloves and powdered gloves were comparable if the surgeon's hands were dry.43 When donned with wet hands, one brand of powder-free gloves tore in all trials and the tested brand of powdered gloves tore in 6 of 14 trials, while a third powder-free brand could be donned without ripping. Another study demonstrated that many different brands of powder-free gloves exist with donning forces using dry hands which were comparable to those of the powder-free gloves tested in the original study. In this same study, 11 of 13 powder-free brands were donned using wet hands without tearing in all 13 trials.44

Concerns about the potential for leaks of powder-free gloves are addressed by the FDA’s quality control testing of medical gloves. The FDA’s guidance manual for manufacturers of medical gloves (issued in the December 12, 1990 Federal Register) describes in detail the water leak method of testing used to ensure that all medical glove manufacturer’s meet a standard level of quality.45 Further, in contradiction to claims that powder-free gloves will be less effective than powdered gloves, polymer coated powder-free surgical gloves are particularly well suited for tape wound closure.46 The tested brand of powder-free gloves had adherence to wound closure tape which was comparable to that of powdered gloves when unwashed, and was significantly less subject to adhesion after both brands of gloves had been washed and dried. In addition, adhesion of wound closure tape to powdered gloves decreased the tape’s adhesion to skin by
61%, compared to only 28% with powder-free gloves.

One of the hospitals discussed above, Methodist Hospital, initially confronted resistance to the use of powder-free gloves due to concerns about effectiveness and ease of use. However, through providing a variety of gloves, the hospital succeeded in meeting the needs of its staff. This experience illustrates that with the increase in the variety of powder-free gloves available, concern about the effectiveness and ease of use of powder-free gloves are not substantial enough to override the benefit of their use.

In addition to concerns about the effectiveness of powder-free gloves, hospitals claim that making a switch to powder-free gloves would result in excessive costs, as the cost of one pair of surgical gloves purchased by a consumer in a pharmacy is around one and one-half to three fold greater than that of a glove lubricated with cornstarch. However, calculating the real cost of gloves is not as simple as comparing the cost of the two products.

First, it is important to realize that the purchasing power of the hospital is quite different from that of the individual consumer. In a wholesale marketplace, hospitals purchase so many thousands of surgical gloves that they can effectively barter regarding glove price. They can use a variety of innovative strategies to lower the purchase price of surgical gloves. For example, at the Mayo Clinic, a new innovative strategy to purchase gloves that markedly reduced the cost of powder-free gloves was developed. They used the research data of Dr. John Yunzinger, an internationally recognized allergist at the Mayo Clinic, on the allergen protein content to select surgical gloves. Since December 1993, Mayo Clinic has only used gloves with a low-latex allergen protein content. From 15 to 16 different kinds of gloves, the Mayo Clinic now uses only 10 types from 5 manufacturers. The use of low latex allergen gloves has actually saved the Mayo Clinic money as they purchased only a few brands of gloves with low latex allergen content because, by buying from only a few manufacturers, they were able to negotiate for better prices. They also corrected inappropriate uses of the gloves.47

In addition, related costs, such as the cost of extra equipment, worker’s compensation and the loss of skilled workers must also be taken into account. The cost associated with washing procedures for cornstarch dusted gloves was determined by adding basin costs that contained the solution, solution cost, and unit wiping materials together and dividing by the number of team members. The direct cost of washing materials averaged $0.46 per glove with a range between $0.26 to $1.25 per glove, depending on the materials used and the level of washing required20

The experiences of Jackson Memorial Hospital and Methodist Hospital indicate how important the cost of worker’s compensation and the loss of skilled employees can be in choosing whether to use powder-free gloves. For example, Jackson Memorial Hospital reported four worker’s compensation claims related to latex allergy, and two EEOC claims. Two workers compensation settlements alone exceeded $100,000 each, plus ongoing expenses (one of the cases has already cost at least $370,000). Further, the hospital notes that there were additional costs of replacing employees with overtime, and defending against the claims. Having compared
these costs to estimates that having a powder-free facility would cost $300,000 a year, it was found that the actual increase was only $200,000 a year but that an additional $250,000 a year could be saved by other changes in glove utilization in the hospital. An administrator at the hospital stated that, although “It has not been easy going powder-free in today’s economic environment...However, the satisfaction of seeing lives destroyed and then put back together...has been a rewarding experience. I would challenge any manager trying to make this difficult decision in today’s medical financial arena to listen to the medical facts, talk to allergic employees and remember why we are in the health care business. The answer will be obvious and cost justifiable.” (Appendix B)

The OR project coordinator at Methodist Hospital reported similar findings with respect to the cost of switching to powder-free gloves, stating that “Latex allergies tend to strike the health care professionals with the most experience, and that is more costly than any additional expenses to a glove budget...For the price of commitment and persistence we were able to keep our tenured employees -- really a pretty good deal!” (Appendix C)
Conclusion

The evidence of the adverse effects of cornstarch and the growing problem of latex allergies, especially among health care professionals, indicate that the continued use of this powder on surgical and examination gloves is of major concern. It is clear that alternatives which are effective and well established in the market exist, and that, if the cost of powdered gloves are adjusted to include the cost of wash basins required to remove the powder, extra gloves, workers’ compensation claims, and the loss of the experience of health care workers, there is no economic justification for failing to halt the use of cornstarch on gloves. We therefore urge the FDA to take immediate action to ban the use of surgical and examination gloves with cornstarch lubricants.

We expect a prompt response to this urgent petition.

Sincerely,

[Signature]

Sidney M. Wolfe, M.D.
Director

[Signature]

Christine Dehlendorf,
Researcher

Public Citizen’s
Health Research Group

[Signature]

Timothy Sullivan, MD, Professor of Medicine, Emory University
School of Medicine and Head of the Subsection of Allergy and Immunology at the Emory Clinic
1. IMS Hospital Supply Source Index, 2nd Quarter 1997. For that quarter, the total sales of surgical gloves was $170 million, with $44.2 million for powder-free latex gloves.


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APPENDIX A

BRIGHAM & WOMEN'S HOSPITAL

Boston, MA
Latex Allergy Epidemic: Crisis Management or Proactive Decision Making?

To the Editor:—Our modern hospitals are marked by towering buildings that have a self-contained, carefully controlled environment. These contemporary health care centers are designed to be ideal places to work, tailored to human comfort. Patients treated in these modern facilities have the expectation that they will receive the physical and emotional support that is needed to effectively care for their conditions. The dedicated hospital personnel take special precautions to prevent transmission of the patients' illnesses. With the building regulation codes, neither the patients nor the hospital personnel would believe that the environment in the hospital could make them ill.

On Thursday, July 29, 1993, Richard Saltos, a reporter for the *Boston Globe* newspaper, wrote an article titled “Five Brigham operating rooms close due to faulty ventilation” that described a mysterious epidemic that sent operating room (OR) employees home with headaches and fatigue. This epidemic followed 5 months of complaints from OR personnel who reportedly had a wide range of symptoms, including rashes, hives, respiratory irritation, nausea, and heart palpitations. Saltos indicated that “an internal investigation, which officials say is widening, has traced some of the symptoms to allergic reactions to latex ... used in surgical gloves and other equipment.”

In that article, Margaret Hanson, clinical vice president of Brigham and Women’s Hospital, stated not only that the problem was sapping morale, but also that on any given day, 12 or 14 OR employees were unable to work or were reassigned to desk jobs because of their allergic reactions. Hanson reported “None of us are happy about this. People are impatient, and I don’t blame them. We all just want to find out what the answer is.” Hanson noted that Occupational Safety and Health Administration investigators had visited several times, that environmental experts from Harvard School of Public Health were looking into the cause of the symptoms, and that 9 senior hospital administrators were working on the problem almost full time.

On December 26, 1995, WGBH Educational Foundation aired its *NOVA* show titled “Can Buildings Make You Sick?” This insightful documentary detailed the investigation of the “sick-building syndrome” in a diversity of settings as well as at Brigham and Women’s Hospital. Sherwood Burge of the Birmingham Heartlands Hospital, an international expert in health problems caused by buildings, defined the sick-building syndrome as a concurrent set of “very common complaints which are more common in some buildings than in others, and which get better when people go away from that building.”

The *NOVA* documentary provided an update on the Brigham and Women’s Hospital at Boston, where the hospital administration took action after the sick-hospital syndrome worsened through the winter of 1993. Subsequent to closing down the 5 ORs in July 1993, Brigham and Women’s Hospital administration enlisted the expertise of an environmental consultant, John McCarthy.

McCarthy found that a number of people who had experienced difficulties on the job had developed rashes and also had complained of various type of allergic reactions. The affected staff members worked in the ORs during shifts that spanned all periods in the day and under many different circumstances. It took McCarthy months of effort to check out an enormous number of potential culprit causes. He searched anything and everything brought into the OR. After a series of investigations that involved looking at particulates in the air, considering chemicals used in the workplace, examining equipment, and finally, scrutinizing the products used by nurses and physicians in their care of patients, he identified that, for a large number of employees, sensitivity to the latex gloves used in ORs caused illness associated with the sick-building syndrome at Brigham and Women’s Hospital.

The occurrence of this epidemic of latex allergy coincided with the institution of universal precautions, in which hospital personnel took extra precautions when contacting patients. In an effort to prevent the spread of the HIV in the hospital, there was a staggering rise in the use of latex gloves, so much so that the need for latex gloves exceeded the manufacturers’ production capabilities. Some manufacturers took shortcuts to keep up with the demand. Speeding up the rinse cycle in glove manufacture prevented the latex-sensitizing proteins from washing off the gloves.

Unexpectedly, the source of latex exposure was not just from skin contact. When the gloves were donned or removed, the powder used on the glove to aid in glove donning was released into the air. These powders, it turned out, bound tightly to the allergenic latex proteins, and remained airborne for hospital employees to breathe in. Each time anyone donned or removed surgical gloves, more powder was liberated into the environment. The powder lodged itself on the anesthetists’ gowns, formed a thin coat on flat surfaces throughout the room, fell to the floor where it could later be re-aerosolized again and again, and electrostatically adhered to surgical sutures and instruments.

Once McCarthy understood the source of the sick-building syndrome, he instituted a vigorous cleaning program for all gurneys, beds, hospital supplies, walls, ceilings, and the ventilation system. It took months of meticulous cleaning to remove the powder, but the hardest task was making sure that the latex aerosolized-laden levels were controlled.

John Gaida, vice president, Brigham and Women’s Hospital, emphasized the magnitude of the problem by pointing out “most hospitals could use as many as 10 different brands of gloves in their operation, from exam gloves, to surgeons’ gloves, to procedure gloves, all different kinds of gloves. We took this step that
outraged basically all kinds of gloves except for the ones that we felt were the very absolute lowest in latex. It was a very tough step for us to take. It was a tough move just to get the other ones out of the institution. There was a few hundred thousand dollars of new expense that we had to bear because of the...the situation with latex. The latex was a huge issue that, I think, hit the fan overnight to us, as well as to other hospitals."

Brigham and Women’s Hospital was widely recognized for its efforts to control the problems associated with latex allergies. It is somewhat ironic that a hospital that is dedicated to public health and to improving people’s health problems could be the source of life-threatening illnesses. In light of these experiences, Brigham and Women’s Hospital has been forced to make dramatic changes in its health care facility. The hospital’s involvement in a multimillion dollar renovation of its existing facility illustrated its commitment to avoiding the problems of the past.

On the basis of the Brigham and Women’s Hospital experience as well as hundreds of well-controlled experimental and clinical trials, we now know that some patients as well as hospital personnel are at high risk for symptomatic latex sensitivity. While it is agreed that the latex proteins are the responsible allergens, it is well accepted that cornstarch-powdered glove lubricants play an important role as a vector for the allergic latex proteins. Latex proteins are easily absorbed to the cornstarch powder, and are aerosolized at levels comparable to those of other occupational respiratory allergens. Respiration of these latex protein-powder aeroallergens has been proposed as a major mechanism for the sensitization to latex. Complete removal of powdered latex gloves from the OR environment has lowered the level of airborne latex allergens to below detection. When all coworkers have switched to powder-free latex gloves, healthcare workers with latex sensitivities have been able to return to their workplace. The antigenic protein level on latex rubber devices can be reduced to prevent further sensitization. Low-allergen latex gloves are now available. As these low-latex-allergen gloves are used, the incidence of new sensitization and the number of adverse reactions are expected to decline.

Despite overwhelming evidence of the dangers of powdered glove lubricants, of high-latex-allergen-content gloves and the frightening experience at Boston’s Brigham and Women’s Hospital, hospitals across the United States persist in a crisis management policy rather than a proactive stance that would protect their patients and their employees. Hospitals continue to use powdered surgical gloves and gloves that contain high contents of latex allergens, an invitation to continuing the epidemic of life-threatening allergic reactions. Currently, a wide range of powder-free surgical gloves are available with low levels of latex allergens. With uncompromising leadership, physicians and administrators should band together to promote the exclusive use of powder-free surgical gloves with low levels of latex allergens.

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Key words: latex gloves; allergy; latex allergy; administration; occupational health.

REFERENCES
-APPENDIX B -

JACKSON MEMORIAL HOSPITAL

Miami, FL
Jackson Memorial Hospital

Dr. Richard Edlich  
Department of Plastic Surgery  
University of Virginia School of Medicine  
Box 332  
Charlottesville, Virginia 22908

Subject: Powderfree Glove Program

Dear Dr. Edlich:

Jackson Memorial Hospital (JMH) made the decision to become powderfree in December 1995 after an epidemic of latex allergy, glove dermatitis and occupational asthma. By June 1996 most of the cases were resolved and most have had no further problems. There was an significant initial cost for converting to low allergen, powderless gloves. However, the reduction in workers' compensation claims, lost productivity, and human suffering has made the initial cost seem minimal and justifiable.

JMH is a large urban public teaching medical center affiliated with the University of Miami Medical School. Approximately 7600 employees operate a 1200 bed hospital and trauma center, a 100 bed satellite maternity hospital, clinics with over 300000 visits a year, three residential care facilities, home health and correctional health care in for the county jail facilities. Funding is provided by a 1/2 penny sales tax in addition to traditional resources.

The first latex allergy problems began to surface in 1994. A clerk who was transferred from the gift shop to a lab clerk position, suffered anaphylactic shock and a full respiratory arrest after donning latex gloves the second day on the job. She had never worn latex gloves before and was never able to work again. An OR tech who had been switched to non-latex gloves because of glove allergy in the past began to have asthma attacks and hives every time she entered the operating room. She became so allergic, she had reactions when she touched the phone, her underwear, the car steering wheel and even her child's school papers when she had used an eraser. She could not work at all for over a year and almost lost her home. A nurse developed asthma while she was pregnant with her first child. The attacks were more severe whenever she worked and improved on her days off. She attributed the problem to the physical demands of her pregnancy and took an early leave. Her symptoms resolved completely. When she returned to work, she had an anaphylactic reaction that required emergency treatment and three months additional leave to control her asthma. During the first five months of 1995 approximately five new cases of glove dermatitis or other symptoms associated with glove use were reported each week. By May 1995, 95 employees had been treated for problems related to gloves. Each event required an average of two weeks off duty. Most cases were resolved by returning the employee to work with non-latex or low latex protein gloves. However, many began to return with progressively more severe hives, facial edema and respiratory symptoms even though they were using non-latex gloves. All filed for workers' compensation and demanded payment for lost time and alternative jobs. An attempt was made to place two employees in non-direct care jobs in medical records and finance areas.

AN EQUAL OPPORTUNITY EMPLOYER
Even though they were not in the clinic treatment areas, they both continued to have severe allergic reactions when they worked with the charts or entered the clinic buildings. When a new jail was built, powdered latex gloves were not allowed. We were able to place two nurses in the new jail clinic with no further adverse health problems. Since downsizing reduced available non-direct care nursing jobs and workers' compensation claims were still pending, others decided to try to continue working even though they were symptomatic rather than face the financial consequences. One worked all day with a respirator mask in order to minimize her attacks. Two filed EEOC claims stating that the hospital failed to accommodate their disability.

By then research had confirmed that latex is aerosolized on glove powder and that prolonged exposure through skin contact and inhalation of particles contributes to the development of allergy. Additional information also implicated glove powder in increased wound infections, wound adhesions and nosocomial infections. Based on our mounting human resources costs and our experiences with our struggling employees, we decided to eliminate glove powder and purchase low protein, low allergen medical gloves in spite of the additional cost.

The first powderfree gloves were put on the units in December 1995. By June 1996, all except two employees with latex allergy had returned to work in their original units with no new symptoms. Two employees received large settlements from workers' compensation and two are pending. Today the number of persons presenting for glove problems has decreased to no more than two a month. The new complaints are usually related to dermatitis and are resolved with a change of gloves. There have no new cases of occupational asthma or respiratory events related to glove use. In the latter part of 1996, the hospital had another "restructuring experience". Employees were "bumped" to jobs all over the hospital. Two of the nurses who had been returned to work in the latex free clinic, were now able to transfer back to inpatient units without allergy symptoms. Now our biggest challenge is maintaining a powder free work place in light of cost containment pressures in the health care industry. In 1997, two latex allergic nurses began to experience a recurrence or symptoms when they floated to certain units. Investigation revealed that other staff were using powdered gloves from a catheter kit that had been purchased by that floor to cut costs. Another nurse who had been asymptomatic for two years suffered a severe anaphylactic reaction when she was transferred to a unit who receives the postpartum patients. She has not been able to return to work and will probably never be able to work as a nurse again. Investigation revealed that powdered gloves were purchased off bid in the labor and delivery unit and latex was being carried to post partum when the patient was transferred.

Estimating the cost effectiveness of changing to powderfree gloves was tedious but not difficult. The medical cost of one dermatitis event was estimated at $1800 and each event involved at least two weeks of lost time. Two workers compensation settlements exceeded $100,000 each plus ongoing medical and retraining expenses. One of the claims has already been estimated to have cost at least $370,000 and there are three cases pending settlement from early 1995. This does not take into account the cost of replacing the employee with overtime and agency help as well as defending EEOC claims and labor disputes that arise. We also considered the impact of the studies implicating glove powder in the transfer of MRSA and TB infections and readmissions for wound adhesions.
When we investigated the cost of going powderfree, we discovered that not all glove purchases and costs were accounted for by the institution. Many units were buying gloves direct from vendors at much higher prices than could be negotiated with bulk buying. Others were using more expensive surgeons gloves in situations that called for sterile exam gloves at a cost difference of $65 a box just to avoid dermatitis outbreaks. The original estimate showed that with better glove management, it would only cost about $300,000 a year to go powder free. When the financial and human impact of not taking action was considered the choice was difficult but justifiable.

Today the program is focused on cost containment and maintenance of a powderfree environment. A committee consisting of nursing, operating room, materials management, purchasing, infection control and employee health oversees all glove purchases and monitors the program. A nurse has been assigned to focus on reducing inappropriate glove use throughout the medical center. A recent cost analysis shows the actual increase in glove costs from 1994 to 1996 has only been about $200,000 per year in spite of an overall increase in latex prices during that time period. We also discovered that our medical gloves costs represent only 6% of the entire supply budget, a figure we plan to use as a benchmark for monitoring costs in the future. A survey of current glove use indicates that an additional $250,000 a year can be saved by changing the type of sterile gloves used in some units and enforcing the use of utility gloves for cleaning. Further savings have been identified by changing some nursing procedures so that less expensive gloves can be used. The Purchasing Department is also experimenting with alternative purchasing agreements such as capitation.

It has not been easy going powderfree in today's economic environment. However, the satisfaction of seeing lives destroyed and then put back together by the teamwork of management, occupational health and the glove industry has been a rewarding experience. I would challenge any manager trying to make this difficult decision in today's medical financial arena to listen to the medical facts, talk to allergic employees and remember why we are in the health care business. The answer will be obvious and cost justifiable. I hope your institution will take this opportunity to join other hospitals in pioneering efforts to challenge the glove industry to make safer gloves an industry standard. If I can be of any further assistance as you make this transition, please feel free to contact me at any time.

Sincerely,

Alma Breeden

Alma M. Breeden, R. N. COHN-S
Assistant Administrator
Employee Health Services

ABwdoslatex2
FACSIMILE COVER SHEET

TO: Anne Maxine Patton
Interactive Media Specialist for Medical Products and Education

TELE: 804 924 0424/ 804 973 6085

FROM: Mr. Vincent Petrini
Director, Public Relations
Brigham and Women's Hospital

The signature below indicates that Brigham and Women's Hospital uses only powder-free surgical and examination gloves and that the institution can be listed as such on the website to be located at http://www.deadlydust.com.

Signature

- Director of Public Affairs

Date 7/11/97
FACSIMILE COVER SHEET

TO: Ann Maxine Patton  
Interactive Media Specialist for Medical Products and Education

TEL#: 804 924 0424/ 804 973 6085

FAX#: 804 973 0767

FROM: Ms. Conchita Ruiz-Topinka  
Director, Public Relations  
Jackson Memorial Hospital

The signature below indicates that Brigham and Women's Hospital uses only powder-free surgical and examination gloves and that the institution can be listed as such on the web site to be located at http://www.deadlydust.com.

Conchita R. Topinka
Signature

Dir. Public Relations
Title

7-9-97
Date
—APPENDIX C —

METHODIST HOSPITAL

Indianapolis, IN
March 26, 1997

Dr. Richard Edlich
Professor of Plastic Surgery
University of Virginia School of Medicine, Box 332
Charlottesville, Virginia 22908

Dear Dr. Edlich,

I enjoyed speaking with you on March 25th regarding the changes made at Methodist Hospital in response to employees with latex allergies. The following paragraphs outline the stages that we went through to get to where we are today—a latex powder-free hospital. Please note that we consider our institution latex safe, rather than latex free.

As most of the literature on “How to create a latex safe environment” recommended, the first step that we took was to form a multi-disciplinary team to look at the problems associated with latex allergies in our hospital. Chairing the committee was our hospital attorney who also happens to be an RN. Other members of the committee included the manager from the employee health department, the manager of the pharmacy, a clinical nurse specialist representing the critical care units, the manager of the laboratory, the director of materials management, and me, the Product Coordinator from the operating room. It was apparent from the very beginning that we had a problem with latex allergies.

Methodist Hospital purchased an Alastat machine that enabled us to test employees for latex allergies in our own lab. We did not do a massive screening, but rather a massive communication effort was made to make the staff aware of the potential for latex allergies, and also the existence of a diagnostic tool which was at their disposal free of charge. Many people responded, and before we knew it, we had 80+ employees diagnosed as latex allergic. Most of these employees had 10-20+ years of service with Methodist Hospital, making them invaluable members of our staff. Depending on the individual’s type and severity of reaction, some employees were allowed to return to work with the agreement that they would stop wearing latex gloves, and would protect themselves from handling anything containing latex. Other employees had such severe respiratory symptoms that they had to be removed from their current working environment until changes could be implemented to make the environment safe for them. Immediately identified as the primary source of latex exposure were powdered latex gloves.

We were using powdered latex gloves in virtually every department in the hospital. Each time a pair of these gloves was donned or removed, latex protein laden powder became aerosolized, putting our employees and patients at risk! For the next year, our Latex Allergy Task Force looked at all of the varieties of non-latex gloves, and powdered free latex gloves that were on the market. Our goal was to eliminate latex gloves wherever
possible. When it was impossible to eliminate the latex gloves, we agreed that we would institute powder-free latex gloves. We looked at both exam gloves and surgeon's gloves. The entire time that we were looking at the varieties of gloves on the market, a massive communication effort was underway to let the Medical Staff and all employees know of the change that was coming.

On December 18, 1995, Methodist Hospital converted all exam gloves to Sensicare exam gloves by Maxxam Medical, a synthetic glove. With the assistance of the Material Management department, a sweep was made of the entire hospital, and all latex exam gloves were collected and removed. (They were later donated to a mission group in Africa.) For the first several months, we answered many concerns about the barrier quality of synthetic gloves. We also had a lot of education to do in regards to the donning and removal of these gloves, as synthetic gloves do not have the stretching qualities that made latex gloves so appealing. We brought in both the powdered and powder-free versions of Sensicare because powder was only a concern to us if it was combined with a latex product.

This first step with the removal of the latex exam gloves, was a good place to start, but it was not enough to allow us to bring our latex sensitive employees back to work. Something had to be done about the surgeon's gloves as well. It was agreed that any attempt to eliminate all of the latex surgeon's gloves would be an exercise in futility. The goal was to eliminate all powdered latex surgeon's gloves. On February 14, 1996, at 2:00 am, a group of people from the Latex Safe Task Force came into the hospital to make a sweep through the building and collect all of the powdered latex surgeon's gloves. I went through each operating room suite and replaced the existing gloves with three types of surgeon's gloves from Reagent: Biogel M, Sensor, and Reveal. These three gloves were selected because it was thought that they would satisfy most of the concerns that had been expressed by the surgeons during the communication phase. Biogel M is a textured glove. Many of the surgeons were concerned that powder-free gloves would be too slippery, thus we did not select the standard Biogel. Sensor is a thinner glove for surgeons that require increased fingertip sensitivity, as in ophthalmology and cardiovascular areas. The Reveal glove is a double gloving system in one package: a green glove that goes on first, with a neutral colored glove over the top. It was thought that this glove would be suitable for Orthopaedic surgeons as it had the two layers that would be much more tear resistant. We soon discovered, however, that these three gloves did not meet everybody's needs.

Some surgeons continued to complain of slipperiness with the new gloves. Our medical director, Dr. William Turner, asked me to do whatever necessary to meet the surgeon's needs as they adjusted to our new glove policy. I brought in a glove from Boston Medical called Guards that has a "patented slip-resistant finish", and for most, this solved the problem. The Orthopaedic surgeons were not satisfied with the Reveal glove, as it did not prove to be tear-resistant enough for their procedures. Again, in the interest of trying to resolve conflict during the adjustment phase of this conversion, I brought in two additional gloves: Perry Encore and Perry Encore UltraThick. The UltraThick glove
worked great and eliminated the complaints in regards to durability. Finally, for employees or patients with latex sensitivity, we selected the Neolon glove from Maxxium Medical. It is a synthetic surgeon's glove with powder. Once the glove conversion was complete, we had one more step to take prior to bringing back our latex sensitive employees. The latex laden powder had to be removed!

Throughout the hospital, terminal cleaning procedures were implemented. Every surface that was scraped down was wiped clean, then every movable piece of furniture or equipment was also wiped clean. From there, all ceiling vents or filters that could possibly be changed were changed. All curtains from patients rooms were taken down and washed or replaced with new ones. It was a massive effort which took about 3 weeks to complete, but when it was done, most of the latex sensitive employees were able to go back to their original units to work. Some of our latex allergic employees who had found temporary positions within the hospital while we were cleaning up the environment, opted to stay where they were. No one was terminated because of their allergy. In surgery, we felt so fortunate to get our staff members back. Latex allergies tend to strike the health care professionals with the most experience, and that is more costly than any additional expenses to a glove budget!

In conclusion, I would encourage you to communicate, communicate, communicate, before you implement, and then once you implement your changes, communicate some more, because there will still be people who have never heard about latex allergies. Also, to this day, I still find latex powdered gloves that come out of the woodwork. For the price of commitment and persistence, we were able to keep our teared employees—really a pretty good deal! Good luck, and if there is anything that I can do to help you, please call me at 317-929-8187.

Sincerely,

Rhonda Anders, RN
OR Product Coordinator
Methodist Hospital of Indiana
December 7, 1995

Mr. George Kroehling
General Surgery Branch
Chief
Food & Drug Administration
2098 Gaither Road
Rockville, MD 20850

Dear Mr. Kroehling:

The toxic affects of cornstarch lubricants on surgical gloves are well known to the Food and Drug Administration. Repeated clinical and experimental studies have demonstrated that the cornstarch lubricants on surgical gloves can cause peritonitis, adhesions, and granulomas. Our recent studies have demonstrated that cornstarch on surgical gloves can damage tissue's resistance to infection and enhance the development of infection. The Food and Drug Administration has mandated warning labels on glove packets recommending removal of the cornstarch before use. Surgical studies have demonstrated that efforts to remove cornstarch from surgical gloves using washbasins and wet cloths are unsuccessful. Consequently, many surgeons do not wash their gloved hands before surgery. With the development of eight different types of powder free gloves, we recommend that the Food and Drug Administration abandon the use of cornstarch on surgical gloves. I have enclosed with this letter four pertinent articles on this subject for your review. Because many surgeons do not routinely remove cornstarch from their gloves before surgery, do you feel that this omission becomes a regulatory problem. However, the simplest solution is to ban the use of cornstarch on surgical gloves.

Very truly yours,

Richard F. Edlich, M.D.
Distinguished Professor of Plastic Surgery
and Biomedical Engineering
December 14, 1995

Ms. Mary Brady
Acting Branch Chief
HFC-520
1350 Piccard Dr.
Rockville, MD 20850

Dear Ms. Brady:

I appreciated talking to you about the complications of glove lubricants. As you know, glove lubricants were first used by the manufacturer to release the latex glove from the mold. The dusting powder or lubricant has also been used to coat the latex gloves to facilitate donning of the surgical glove.

Talc, a non-absorbable powder, was first used as the glove lubricant. Numerous scientific studies demonstrated that talc caused peritonitis, adhesions, granuloma, as well as increased the incidence of infection.

In 1955, cornstarch, an absorbable powder, was introduced to replace the talc. Early reports confirmed that cornstarch was less toxic than talc. Consequently, the Food and Drug Administration banned the use of talc on surgical gloves.

Over the past 20 years, there have been literally hundreds of scientific studies that have demonstrated the toxic affects of cornstarch. Cornstarch also causes peritonitis, adhesions, granuloma, and increases the incidence of infection. In 1971, the Food and Drug Administration required that warning labels be placed on each glove packet. It indicated that the surgeon should remove the cornstarch from gloves before surgery. Later studies have shown that washing surgical gloves in saline is ineffective in removing the cornstarch and causes aggregation of the particles that causes more serious problems.

Realizing the dangers of the cornstarch lubricant on latex gloves, every leading manufacturer of surgical gloves has developed powder-free surgical gloves. The cost of the gloves is approximately twice that of the powdered gloves. However, it is important to point out that the cost for the washbasin is approximately $8.00, which makes powdered gloves more expensive than powder free-gloves.
Studies of the biomechanical performance of powder-free gloves demonstrate that they are superior to powdered gloves. First, surgeons can don powder free gloves more easily than powdered gloves. Second, tape aggressively adheres to powdered gloves, while tapes have limited adherence to powder-free gloves. Consequently, surgeons must remove their powdered gloves to perform tape wound closure. In addition, many powdered gloves exhibit glove expansion during surgery, while the powder-free gloves maintain their elasticity and fit uniformly on the surgeon's hand. Finally, the resistance to needle puncture and tactile discrimination of powder-free and powdered gloves do not differ significantly.

Consequently, I would strongly urge the FDA to ban cornstarch from surgical gloves. The superb manufacturers of latex gloves in our country are prepared to provide a superior powder-free glove that will be safe for the surgical patient and have excellent performance characteristics for the surgeon. I have enclosed copies of many scientific articles for your review. Thanking you in advance for your immediate consideration of this important request.

Sincerely,

Richard F. Edlich, M.D.
Distinguished Professor of Plastic Surgery
and Biomedical Engineering

RFE/jf

Enclosures
Richard P. Edlich, M.D.
Distinguished Professor of Plastic
Surgery and Biomedical Engineering
University of Virginia
Health Sciences Center
Department of Plastic Surgery
Box 376
Charlottesville, Virginia 22908

Dear Dr. Edlich:

This responds to your letters of December 7, 1995, to
Mr. George Kroehling, and December 14, 1995, to Ms. Mary Brady.
Both letters requested that the Food and Drug Administration
(FDA) ban cornstarch from surgical gloves, and encourage the use
of powder free gloves. Included with your letters were
scientific studies presenting data evidencing the cornstarch
powdered gloves cause very similar problems to the original talc
powdered gloves.

Your letters and the scientific data were forwarded to our office
of Devices Evaluation (ODE) for review and comment. We are
advised by that office that the data is still being reviewed and
they wish to spend more time exhaustively investigating your
information. There is also an internal glove working group that
wishes to review the data submitted by you.

Upon completion of this review, a determination will be made on a
policy regarding cornstarch powered gloves. As that policy is
determined, we will advise you of the outcome of the review, and
the subsequent final policy.

If you have any questions or need further assistance contact me
at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,

Carol J. Shirk
Consumer Safety Officer
General Surgery Devices Branch
Division of Enforcement I
Office of Compliance
Center for Devices and
Radiological Health

Figure 8.1 Letter from Carol J. Shirk, Consumer Safety Officer of the Food
and Drug Administration, June 3, 1996.
POWDERED LATEX GLOVES POSE SERIOUS RISK TO PATIENTS AND HEALTH WORKERS

CALL FOR BAN ON DANGEROUS SURGICAL AND EXAMINATION GLOVES MANUFACTURED WITH CORNSTARCH POWDER COATING

Millions of patients and tens of thousands of health workers throughout the country are at serious risk from latex gloves powdered with cornstarch, said Public Citizen’s Health Research Group in a petition to the Food and Drug Administration (FDA) today to ban such gloves.

The group, joined by co-petitioner Timothy Sullivan, MD, an allergist/immunologist from Emory University School of Medicine and an expert on latex allergy, called for an immediate ban by FDA on the use of cornstarch powder on latex surgical and examination gloves because of the serious dangers these gloves have caused medical personnel and patients. Cornstarch can inflame wounds and promote infection, and cornstarch-induced adhesions can produce intestinal obstruction, pelvic pain and infertility in patients operated on by medical personnel wearing cornstarch-powdered surgical gloves, said the group.

One of the most widespread dangers occurs because cornstarch also acts as a carrier for latex protein/allergens—these allergens becoming combined with the cornstarch during the manufacturing process. Well-documented and frequently reported adverse reactions to latex include rhinitis, asthma, and life-threatening anaphylactic shock, often caused by breathing in the cornstarch powder in the air. Many health care workers have experienced such serious reactions to latex they have been forced to give up work.

“These powdered latex gloves are a serious, unnecessary menace in hospitals and other health care facilities all over the country,” said Dr. Sidney Wolfe, MD, Director of Public Citizen’s Health Research Group. “Safer alternatives such as powder-free gloves are easily and currently available, but too many hospitals are willing to cut corners and risk the health of their patients and employees. As of last year, 26% of surgical gloves used in the United States were powder-free proving that this safer alternative is quite feasible.”

Labels warning that powdered gloves should be washed—to remove cornstarch—before use
are routinely ignored by the vast majority of health workers. A 1992 study found that only 17% of surgeons washed their gloves after donning. Most emergency physicians use gloves lubricated with cornstarch during their wound closure techniques.

Several major hospitals have already switched to powder-free gloves, including Harvard’s Brigham and Women’s Hospital in Boston and Miami’s Jackson Memorial Hospital. At the Brigham and Women’s, one of the leading hospitals in the United States, as many as 12 to 14 operating room hospital workers a day were unable to work or had to be reassigned to desk jobs because of their allergic reactions. Jackson Memorial began experiencing problems with latex allergies in 1994 and by May 1995, 95 employees had been treated for problems related to the gloves.

Between August 1996 and August 1997 alone the FDA received over 300 reports of allergic or anaphylactic reactions associated with latex gloves (it is estimated that at most one out of ten adverse reactions which actually occur are reported to the FDA so the number during that last year is likely in the thousands or more), and a 1997 study showed that up to 21% of hospital nursing staff were sensitized to latex.

Apart from the human cost, sticking with powdered latex gloves can be expensive for hospitals, says Public Citizen. Latex allergies tend to strike health care professionals with the most experience, leading to costly absences and compensatory claims. At Jackson Memorial Hospital, two workers compensation settlements exceeded $100,000 each, and the ongoing expense in one case has already cost over $370,000.

“These powdered gloves are expensive for hospitals, dangerous for their patients and a serious occupational hazard for their employees. The FDA should act immediately to prevent further damage to the public’s health,” said Dr. Wolfe. “The current FDA regulation, which went into effect on September 30, 1997, requires labels on all medical devices containing natural latex warning that the product contains latex ‘Which may cause allergic reaction’. Whereas this is an admission of the problem, it is grossly inadequate compared with the additional action of banning powdered latex gloves which we are requesting today. If the FDA is to perform as a public health agency it must more definitively protect the millions of patients and tens of thousands of workers already allergic to latex. Unless definitive action is taken, not only will those people already allergic to latex continue to suffer serious, often life-threatening reactions, but the number of affected people will continue to rapidly increase as more and more exposure to airborne, latex-laden glove powder occurs.”

Copies of the petition to the FDA are available on request.
Statement for press release on January 7, 1997

My name is Barbara Zucker-Pinchoff, MD. I am an anesthesiologist, in practice for 13 years before becoming disabled by latex allergy 11 months ago. In response to the loss of my beloved career, I founded a not-for-profit corporation, Physicians Against Latex Sensitization (PALS). The primary goal of PALS (www.PALS.net) is to prevent the continuing growth of this epidemic, so that others need not experience the tragedy of becoming disabled, and unemployed.

I wish to make three points about latex allergy, and why it should be of concern to the press and the public. First, latex allergy afflicts millions of Americans. Up to 17% of the healthcare work force has been sensitized to latex, as well as an estimated 6% of the general population. Second, this allergy can cause significant suffering, occupational asthma, career loss, permanent disability, and death. Last, it is treatable and, most important, preventable if appropriate steps are taken.

I will tell you a bit about my own history, not because it is unique, but because it is a typical one. My first catastrophic reaction occurred on April 15, 1988, during the cesarean deliver of my second child. About 10 minutes into the surgery, I began to go into anaphylactic shock, indicating that I had been sensitized earlier. Thanks to the prompt and excellent care I received from my startled anesthesiologist, both the baby and I survived. We were all baffled by what had caused the reaction, and blamed it on a drug reaction, since no one involved in my care, including myself, had ever heard of latex allergy. I then had a very rough year and a half, with frequent anaphylactic episodes which no one could diagnose. My specialty was obstetric anesthesia, and one day I was taking care of a lovely woman having a baby, and when she told me that her husband was an allergist/immunologist, I fell into conversation with him, since by that time I was at my wits end, looking for a diagnosis. He listened carefully to my story, and said he thought I was allergic to latex. I was incredulous. Unfortunately this is a common response among physicians, “If I haven’t heard of it, it doesn’t exist.” But being desperate, I listened to him. He became my doctor, and after several more months with anaphylactic episodes as often as once a week, we finally determined that in addition to severe latex allergy, I had the common related food allergies, although little was known about them at that time. In addition to latex, I am anaphylactic to bananas, avocados and papayas. When I stopped putting latex gloves on my hands (actually, I had had to stop some time before, without understanding why), and avoided the foods I was allergic to, the frequent episodes stopped, and my life settled down considerably.

The next seven years were a long struggle to suppress the symptoms of my allergy. Denial plays a large role in allergy for all professionals. In general, we love our careers, we worked long and hard to achieve them, and don’t wish to perceive anything which may interfere with them. For example, for many years my eyes would become red, itchy, and swollen at work. It did not occur to me that this was related to my latex allergy. In fact, I remember going to the Department of Environmental Safety at the institution where I worked, asking in bewilderment what in the air could be causing my eye problems. This was in part because I knew so little about aeroallergens.

Aeroallergens play a significant role in latex allergy. These are proteins which cause allergy (allergens) which become airborne. Many latex products, especially latex gloves, are powdered in order to make them easier to slip on and off. The powder itself is
seldom a cause of allergic problems, but the latex allergens adhere to the powder particles, and are spread into the air. From there they spread to every surface in a hospital: clothes, charts, hair, elevator buttons, surgical instruments, etc. And more significantly, the particles are of a size which can easily be inhaled. It may be via this inhaled route that many individuals are sensitized to latex. It is undoubtedly a major cause of occupational asthma in those who are already sensitized.

I had occupational asthma for many years without realizing it. I knew that I had become more asthmatic over the years, but I accepted this as inevitable. For many years, I took a variety of antihistamines, and inhaled medications on a daily basis. The nights that I was on-call in the hospital I required bronchodilating medications in addition to inhaled steroids in order to get through the night. I just assumed I was allergic to "something" in the on-call room, and really avoided thinking much about it. Again, this is typical of the physicians and nurses I have talked to. The hazards of inhaled latex are not well known or publicized, and we just keep on working, with our itchy eyes, runny noses and wheezing lungs without questioning or understanding the cause, and the doctors who treat us are often only concerned with controlling symptoms, rather than understanding that they may have a preventable source.

About 16 months ago I began to have increasing symptoms at work. I broke out in hives just from walking onto the labor floor. One day I developed hives on my arm and an episode of wheezing which required intravenous benadryl. Another day, shortly before I was due to go home, I developed angioedema (severe swelling) of both eyelids, to the point where one eye was swollen shut by the time I got home. I then had pneumonia, possibly related to the chronic asthma.

The day I returned to work, in the afternoon, I was taking care of a patient having a forceps delivery. Things were a bit urgent at the time of the delivery, so that about 5 people, nurses, obstetricians and pediatricians, popped latex gloves out of a box, one after the other. Within a few minutes, I realized I was in trouble. I left the room, and fortunately a colleague saw me and immediately realized I needed help. I was bright red, and a bit confused. My colleagues put me in a treatment room. I was flushed, with a very fast heart rate. My hands and feet were beginning to tingle and itch, an early sign of swelling. My lower lip was beginning to swell, and my soft palate was starting to tingle as well. All of these are signs and symptoms of anaphylaxis. I was given two injections of epinephrine, and I took the potent antihistamines and steroids which I carry with me at all times. I was kept under observation in a latex-free environment for a few hours, and then sent home, since the worst place for someone with latex allergy is an emergency room, or hospital. I have not worked as an anesthesiologist since that day.

I wish to reiterate that my story is not unusual. As I stated, as many as 17% of healthcare workers have some degree of latex allergy. This is an epidemic. I believe that workers in other industries, where cheap highly powderied latex gloves are in constant use, are being sensitized at a similar rate. Take a look the next time you eat at a restaurant or delicatessen at whether gloves are being used, and if so what kind. Good data on the incidence of clinically significant latex allergy is hard to come by. This is in part because individuals with latex allergy may be unaware of the cause of their problems, some may have been misdiagnosed, and some are reluctant to have their status known. They fear that they will experience job discrimination, that they will be fired, or that they will have difficulty finding employment. These are realistic fears, as all of these have been reported. The number of cases of latex allergy is increasing rapidly. The FDA, through the CDC or
NIOSH must develop a program to track this epidemic. It is critical to know how many cases there are, and to document new cases so that strategies designed to stop the sensitization can be assessed.

That latex allergy causes suffering, occupational asthma, career loss, permanent disability, and death is known. It changes your life forever. I recently experienced an anaphylactic episode while eating in a restaurant. Why? I finally realized that they used powdered latex gloves to prepare the salad I ate. Now wherever I go, I have to inquire whether latex gloves are used to prepare the food I may eat. I have a colleague who has recently lost his career to latex allergy. He anaphylaxed while attending a children’s birthday party. Why? Powdered latex balloons. Some latex allergic individuals react to the latex in the elastic used in clothing, especially underwear, bras and bathing suits. Condoms are disastrous for us. I couldn’t take my children to my pediatrician’s office because so many latex gloves were used there, until they recently switched to non-latex gloves. I had to find a dental office where latex is not used. And on, and on.

Why do I say that latex allergy is treatable? The treatment is avoidance. Since I have been out of the hospital environment, my asthma has practically disappeared. I require no chronic medications. This is usually the case, although some individuals have developed severe asthma and heart problems from chronic latex exposure which do not entirely resolve. The vast majority of people with latex allergy can lead normal, productive lives as long as they avoid latex.

The best option to treat and prevent latex allergy, is not to use it. Alternative materials can be used for almost all the applications in which latex is now used.

Two reasonable interim steps are to ban all powdered latex, and to limit the protein content of latex products (since it is the proteins which act as allergens). Institutions which have taken these measures have shown a marked decrease in the number of new cases of sensitization. In addition, when it comes to gloves, banning powder means that only the person wearing the gloves is exposed to latex. At present, when powdered gloves are used, the aerallergens expose everyone in the environment. These first steps, a ban on powdered latex and a limit on protein content, should be taken immediately. There is no excuse to continue to sensitize workers to latex, nor to place workers and patients who are already sensitized at risk for reactions which include asthma and death.

In order to entirely prevent allergic reactions to latex, it will have to be replaced. Industry must be encouraged to continue to perfect alternative materials. Some have questioned the ability of non-latex gloves to function as well as latex. For example, vinyl gloves may be more permeable to viruses than latex. Since the main purpose of gloves in the healthcare industry is protection against bloodborne pathogens such as HIV or hepatitis, this issue is an important one. A multitude of new synthetic materials are now being used for gloves. These have not been fully tested in this regard. Since those in industry may have a strong interest in the outcome, the government must fund the appropriate studies. These studies should compare gloves based on properties including protection against infectious diseases, tactile properties, resistance to chemicals, mechanical strength under the conditions in which they are used, and allergenicity. Cost is obviously a significant factor as well, but one that will play itself out in the marketplace, once standards are set. It is not necessary or prudent to continue to expose large segments of our population to a potentially toxic substance such as latex, when other good alternatives are available.
EXAMPLES OF ADVERSE REACTIONS INVOLVING LATEX GLOVES

From Food and Drug Administration Files
Access Number: M720115
Date Received: 06/22/95
Product Description: LATEX EXAM GLOVES
Manufacturer Code: PHARMASEAL
Manufacturer Name: PHARMASEAL DIV. BAXTER HEALTHCARE CORP.
Address: 1500 WAUKEGAN RD, BLDG K
City: MCGAW PARK
State: IL
ZipCode: 60085
Report Type: SERIOUS INJURY
Model Number: NA
Catalogue Number: 8858
Panel Code: GENERAL HOSPITAL
Product Code: LYY
Event Type: FINAL
Event Description: AFTER DONNING THE ABOVE REFERENCED GLOVE, REPORTER EXPERIENCED DIFFICULTY BREATHING AND SWALLOWING. REPORTER WAS TAKING TO THE HOSP'S ER, AND WAS GIVEN IV INJECTIONS OF SOLU MEDROL AND BENADRYL. REPORTER SUSTAINED NO PERMANENT DAMAGE FROM THIS EVENT AND HER SYMPTOMS DISSIPATED AFTER BEING TREATED. REPORTER HAS WORN THESE GLOVES IN THE PAST AND HAS NEVER EXPERIENCED THIS TYPE OF EVENT IN THE PAST. THE ER DOCTOR ATTRIBUTED THE REACTION TO THE POWDER IN THE GLOVE.
Closeout Text:
Access Number: M349269
Date Received: 10/14/92
Product Description: LATEX MEDICAL GLOVE
Manufacturer Code: ALADAN
Manufacturer Name: ALADAN CORP.
Address: 630 COLUMBIA HIGHWAY
City: DOThan
State: AL
ZipCode: 36304
Report Type: SERIOUS INJURY
Model Number: NI
Catalogue Number: NI
Panel Code: GENERAL HOSPITAL
Product Code: LYY
Event Type: FINAL
Event Description: "AN RN WHO HAD PREVIOUSLY REPORTED AND ALLERGIC REACTION TO THE CONVENTIONAL POWDERED LATEX GLOVE, USED A NONPOWDERED GLOVE WITH ONLY MINOR IRRITATION. AWAY FROM HIS NORMAL WORK AREA DOING A VERY SHORT PROCEDURE, THE EMPLOYEE USED THE CONVENTIONAL POWDERED GLOVE AND SUFFERED A SEVERE LIFE-THREATENING REACTION. THE EMPLOYEE IS OK AND TESTING IS UNDERWAY TO DETERMINE THE EXACT SOURCE OF THE REACTION, THE LATEX GLOVE OR THE POWDER IN THE GLOVE." NO OTHER INFO IS AVAILABLE AT THE PRESENT TIME. (SEE DEN M57163.)
Closeout Text: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP, AND/OR OTHER ACTION IS INDICATED.
Access Number: M297369
Date Received: 06/30/92
Product Description: SIME LATEX EXAMINATION GLOVE
Manufacturer Code: SIMEHEAL
Manufacturer Name: SIME HEALTH LTD.
Address: 1200 SIXTH AVENUE SOUTH
City: SEATTLE
State: WA
ZipCode: 98134
Report Type: SERIOUS INJURY
Model Number: 10002
Catalogue Number: 10002
Panel Code: GENERAL HOSPITAL
Product Code: LYY
Event Type: FINAL
Event Description: THE DR WAS USING THE GLOVES AND HE EXPERIENCED AN ALLERGIC REACTION TO THE CORNSTARCH IN THE POWDER OF THE GLOVES. DR BROKE OUT WITH TERRIBLE RASH ONHANDS.
Closeout Text: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
Access Number: M381542  
Date Received: 04/12/93  
Product Description: MICROTOUCH LATEX SURGICAL GLOVES  
Manufacturer Code: JOHNOHPROD  
Manufacturer Name: JOHNSON & JOHNSON MEDICAL, INC.  
Address: 2500 ARBROOK BLVD P.O. BOX 130  
City: ARLINGTON  
State: TX  
ZipCode: 76004  
Report Type: DEATH  
Model Number: NA  
Catalogue Number: 5865  
Panel Code: GENERAL AND PLASTIC SURGERY  
Product Code: KGO  
Event Type: FINAL  
Event Description: PT DEVELOPED BRONCHOSPASM AND THEN CONTINUED INTO A CARDIOVASCULAR ARREST PRESENTING AS HYPOTENSION. PT RESPONDED TO RESUSCITATIVE EFFORTS. AN ALASTAT WAS DRAWN AND WAS POSITIVE TO AN ALLERGY TO LATEX. SUBSEQUENT INFO OBTAINED INDICATES PT DIED 5 DAYS FOLLOWING INCIDENT. (SEE DEN #M58332.)  
Closeout Text: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY PHYSIOLICAL OR PROCEDURAL FACTORS. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
Access Number: M711384
Date Received: 05/19/95
Product Description: MICRO-TOUCH LATEX MEDICAL GLOVES
Manufacturer Code: JOHNSON & JOHNSON Prod
Manufacturer Name: JOHNSON & JOHNSON MEDICAL, INC.
Address: 2500 ARBROOK BLVD. P.O. BOX 90130
City: ARLINGTON
State: TX
Zip Code: 76004
Report Type: SERIOUS INJURY
Model Number: NA
Catalogue Number: 5741
Panel Code: GENERAL HOSPITAL
Product Code: LYY
Event Type: FINAL
Event Description: THIS INDIVIDUAL HAS A KNOWN SENSITIVITY TO LATEX PRODUCTS WHICH HAS PROGRESSIVELY BECOME MORE SEVERE. SHE HAS BEEN USING VINYL GLOVES WITHOUT DIFFICULTY, BUT IN JULY OF LAST YR, SHE BEGAN EXPERIENCING ECZEMA ON HER FACE, PALPITATIONS, SWEATING AND CHEST TIGHTNESS WHEN SHE WAS IN A ROOM WHERE LATEX GLOVES WERE BEING USED BY OTHER INDIVIDUALS. INDIVIDUAL'S ALLERGIST HAS OFFERED THE OPINION THAT THESE SYMPTOMS ARE RELATED TO AEROSOLIZED GLOVE PROTEINS BEING CARRIED IN THE AIR FROM THE GLOVE POWDERS. AT THE TIME THAT THESE SYMPTOMS OCCURRED, THE OTHER INDIVIDUALS IN THE ROOM WERE USING LATEX MEDICAL GLOVES, HOWEVER, INDIVIDUAL BELIEVES THAT ANY POWDERED LATEX GLOVES WOULD HAVE RESULTED IN THE SAME DIFFICULTIES. TREATMENTS FOR THE SYMPTOMS INCLUDED PREDNISONE AND INSTRUCTIONS TO AVOID ANY LATEX PRODUCTS. INDIVIDUAL HAS FILED WORKMAN'S COMPENSATION CLAIMS AND IS NOW ON DISABILITY.
Closeout Text:
Access Number: M348405
Date Received: 10/29/92
Product Description: LE PETIT/PERRY ORTHOPEDIC SURGICAL GLOVES
Manufacturer Code: SMITNEPHPERR
Manufacturer Name: SMITH & NEPHEW PERRY
Address: 1875 HARSH AVENUE SE
City: MASSILLON
State: OH
Zip Code: 44646
Report Type: SERIOUS INJURY
Model Number: 823
Catalogue Number: 21713
Panel Code: GENERAL AND PLASTIC SURGERY
Product Code: KGO
Event Type: FINAL
Event Description: A 40-YEAR-OLD SURGEON EXPERIENCED DERMATITIS ALONG WITH BRONCHIAL SPASMS AND SEVERE RESPIRATORY PROBLEMS AND HAD TO LEAVE THE OPERATING THEATER. TREATMENT CONSISTED OF CORTISONE AND DECONGESTANT SPRAY. THE SURGEON BELIEVED THE PROBLEM WAS CAUSED BY LATEX GLOVES. HE HAS PREVIOUSLY EXPERIENCED ADVERSE REACTIONS RELATED TO LATEX GLOVES.
Closeout Text: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
Access Number: M350583
Date Received: 11/13/92
Product Description: TRIFLEX SURGEON'S GLOVE
Manufacturer Code: PHARMASEAL
Manufacturer Name: PHARMASEAL DIV. BAXTER HEALTHCARE CORP.
Address: 27200 N TOURNEY RD
City: VALENCIA
State: CA
Zip Code: 91355
Report Type: SERIOUS INJURY
Model Number: NA
Catalogue Number: 2D7253
Panel Code: GENERAL AND PLASTIC SURGERY
Product Code: KGO
Event Type: FINAL
Event Description: DR HAD AN ANAPHYLACTIC REACTION AFTER WEARING LATEX GLOVES. REACTOR WAS KNOWN TO BE ALLERGIC TO LATEX.
Closeout Text: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
Access Number: M407776
Date Received: 08/30/93
Product Description: PERRY LATEX SURGICAL GLOVES
Manufacturer Code: SMITNEPHEPERR
Manufacturer Name: SMITH & NEPHEW PERRY
Address: 1875 HARSH AVENUE SE
City: MASSILLON
State: OH
Zip Code: 44646
Report Type: SERIOUS INJURY
Model Number: UNK
Catalogue Number: UNK
Panel Code: GENERAL AND PLASTIC SURGERY
Product Code: KGO
Event Type: FINAL
Event Description: FEMALE LPN-CST, 38-YR-OLD, HAS A HISTORY BEGINNING IN 2/90, OF ALLERGY PROBLEMS (HIVES, SWELLING OF FACE AND HANDS AND DIFFICULTY BREATHING) WHICH SHE FEELS IS RELATED TO "LATEX DUST" FROM GLOVES SUPPLIED BY THREE DIFFERENT MFRS. THE EVENTS WERE TREATED BY ADMINISTRATION OF BENADRYL AND EPINEPHRINE. REPORTER HAS BEEN A NURSE FOR 22 YRS AND IS CURRENTLY ON WORKMEN'S COMPENSATION AND LEAVE WITHOUT PAY FROM HER 14 YR NURSING JOB.
Closeout Text:
Access Number: M811124
Date Received: 06/12/95
Product Description: MULTI-FLEX CLEAN PROCESS LATEX GLOVE, NON-STERILE
Manufacturer Code: PHARMASEAL
Manufacturer Name: PHARMASEAL DIV. BAXTER HEALTHCARE CORP.
Address: 1500 WAUKEGAN RD
City: MCGAW
State: IL
Zip Code: 60085
Report Type: MALFUNCTION
Model Number: NA
Catalogue Number: 2Y1504
Panel Code: GENERAL HOSPITAL
Product Code: LYY
Event Type: FINAL
Event Description: GLOVE USER DEVELOPED A RASH ON BOTH HANDS AFTER WEARING GLOVES THAT WERE MADE IN MALAYSIA. THE GLOVE USER HAD WORN THIS TYPE OF GLOVE THAT WAS PREVIOUSLY MADE IN THE USA WITHOUT INCIDENT FOR SEVERAL YEARS. THE USER CHANGED TO A POWDER FREE GLOVE THE RASH CLEARED UP AND WAS NO LONGER PRESENT ON THE HANDS. THERE WAS NO INJURY AND NO MEDICAL OR SURGICAL INTERVENTION WAS REQUIRED AS A RESULT OF THIS EVENT.
Closeout Text: