



Controversies

Citizen's Petition to Food and Drug Administration to ban cornstarch powder on medical gloves: Maltese cross birefringence

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Abstract

Background: During the last 25 years, scientific experimental and clinical studies have documented the dangers of cornstarch powder on examination and surgical gloves because the cornstarch promotes wound infection, causes serious peritoneal adhesions and granulomatous peritonitis, and is a well-documented vector of the latex allergy epidemic in the world. Realizing the dangers of cornstarch on examination and surgical gloves, Germany's regulations of personal protective equipment banned the use of surgical glove powder cornstarch in 1997. In 2000, the Purchasing and Supply agency for the United Kingdom ceased to purchase any gloves lubricated with cornstarch.

Discussion: Realizing the dangers of cornstarch-powdered gloves, many hospitals and clinics in the United States have banned the use of cornstarch-powdered examination and surgical gloves. Hospitals that have banned cornstarch in their examination and surgical gloves have noted a marked reduction in the latex allergy epidemic in their facilities. Realizing the dangers of cornstarch-powdered examination and surgical gloves, Dr Sheila A. Murphey, branch chief, Infection Control Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices Office of Device Evaluation, Center for Devices and Radiological Health of the Food and Drug Administration (FDA),

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recommended that a Citizen's Petition be filed to the FDA to ban cornstarch on surgical and examination gloves.

Conclusion: The 12 authors of this report have attached the enclosed petition to the FDA to ban the use of cornstarch on all synthetic and latex examination and surgical gloves used in the United States.

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1. Introduction

This Citizen's Petition has been sent on September 24, 2008, to Andrew Von Eschenbach, MD, commissioner, Food and Drug Administration (FDA), 5600 Fishers Ln, Rockville, Md 20857, and Daniel G. Shultz, MD, director, Center for Devices and Radiological Health, FDA, 9200 Corporate Blvd, Rockville, Md 20850.

This Citizen's Petition is entitled "Maltese cross birefringence" because pathologic contamination of tissue under polarized light microscopic observation reveals a Maltese cross appearance of individual cornstarch granules. The Maltese cross is identified as the symbol of an order of Christian warriors known as the Knights Hospitaller or Knights of Malta. Selecting this title is a method for the authors of this Citizen's Petition to commemorate the thousands of individuals who have been seriously injured or died of cornstarch-coated gloves that produced wound infection, peritoneal adhesions resulting in intestinal obstruction, cornstarch granulomatosis, as well as latex allergic reactions. Banning the use of cornstarch-coated gloves would eliminate the need of searching for Maltese cross birefringence in microscopic examination of tissue containing cornstarch granules.

We hereby petition the FDA to ban the use of cornstarch powder on natural rubber latex (NRL) and synthetic surgical and examination gloves because of the serious and widespread dangers that these powdered gloves present to medical personnel and patients. Safer powder-free gloves are available and have already been implemented in many hospitals in our country. The FDA's legal authorization to impose such a ban is found in Sec 516 (21 USC 360f) Banned Devices of the Food Drug and Cosmetic Act. The continued use of powdered medical gloves is unacceptable, and the FDA must act to ban these dangerous products.

2. Statement of grounds

Powdered latex gloves aerosolize more latex proteins into the air than any other medical product in a medical facility. Latex proteins bind with glove powder and are aerosolized when gloves are removed from their package and when they are donned or doffed from the hands. Aerosolized latex antigens can remain in the air, on clothing, or on surgical instruments and equipment many hours after powdered gloves are donned or doffed. Research shows that areas in which powdered latex gloves were used had up to 300 times more aerosolized latex protein than when only powder-free, low-allergen latex gloves were used [1]. In addition to the

potential for aerosolizing latex proteins, powder can contaminate recovered transplant tissue and may lead to adverse reactions or rejections of the tissue by the recipient, among numerous other potential complications that are discussed within this petition.

This request to ban the use of glove powders is also based upon a number of clinical and research studies reporting that cornstarch on surgical gloves can reduce tissue resistance to infection, enhance the development of infection, cause granuloma and adhesion formation, act as a carrier of NRL proteins from NRL products, and serve as a potential source of occupational asthma.

Glove powder can also cause foreign body reaction, resulting in inflammation, granulomatosis, and adhesions of peritoneal tissues after surgery. Cornstarch represents a growth source for bacteria, and it also can act as a carrier of endotoxin, which can play a role in enhancing both delayed and immediate hypersensitivity [2].

Clinical experience suggests that powder on natural rubber latex gloves, in addition to its role in type I allergy, may contribute to the development of irritant dermatitis and type IV allergy. Irritant skin reactions have been observed in association with frequent exposure to glove powder. Compromised skin barrier properties resulting from such reactions may permit penetration of allergens and other substances into the skin, thereby, increasing chances for the development of both type I and type IV allergies [3].

In addition, the aerosolized, latex allergen-laden powder from natural rubber latex gloves can cause respiratory problems and episodes of bronchial spasms in hospital employees and patients. In fact, glove powder has been implicated in the clinical reports based on medical histories of individuals presenting with symptoms, positive skin tests, positive tests for the presence of antibodies to NRL allergens in blood, and in some cases, on positive inhalation challenge tests. A number of published clinical and experimental studies support these conclusions.

Binding of NRL proteins to cornstarch was demonstrated in laboratory studies, which support a causal relationship between asthmatic reactions in individuals with NRL allergy and the exposure to airborne particles from NRL products [4,5].

The level of exposure and the severity of the reactions depend on both the amount of powder and the amount of NRL protein allergens on the finished products. Measurements of airborne particle levels in environments where NRL gloves were used frequently demonstrate that the level of airborne allergen is directly related to the frequency of powdered NRL glove use in particular areas and to the level of allergen and/or powder on the gloves used [6,7].

Direct evidence that NRL protein allergens, bound to the glove powder particles, provoke respiratory allergic reactions and asthma-like attacks has been documented by bronchial provocation tests with powders on NRL gloves. The tests were performed by having allergic individuals inhale the extracts from powder-free surgeon's gloves, from powdered surgeon's gloves, and from cornstarch powder not exposed to NRL. The studies show that cornstarch powder not exposed to NRL did not cause any reaction in sensitized subjects, whereas nebulized powdered NRL surgeon's glove extract induced bronchoconstriction in tested subjects [8].

Additional complications associated with the use of powdered surgical gloves include granuloma formation, hand dermatitis, adhesion formation, transport of allergens, starch conjunctivitis after eye surgery, transport of potentially infectious microorganisms, delayed wound healing, erroneous test results, increased scar formation, increased risk of infection, and loss of employee work days.

3. Background of previous actions

During the past 15 years, the FDA and other federal agencies received numerous requests to ban the use of glove powder. It has been suggested that experimental and clinical studies demonstrate that glove powder on medical gloves can enhance foreign body reactions, increase infections, and act as a carrier of natural latex allergens. The following is an account of actions related to the ban of powder on surgical gloves.

In October of 1995, Dr Richard Edlich sent letters to the FDA requesting a glove cornstarch ban. Included in the letters were scientific studies indicating that cornstarch-powdered gloves cause toxic tissue reactions [9]. Six months later, on June 3, 1996, Carol J. Shirk, consumer safety officer of the FDA, responded that the FDA was extensively investigating the request. Dr Edlich was later informed by the FDA that no final decision had been reached on the request.

On January 7, 1998, Public Citizen's Health Research Group and its director, Sidney M. Wolfe, MD; staff researcher, Cristine Dehlendorf; and Timothy Sullivan, MD, petitioned the FDA to immediately ban the use of cornstarch in the manufacture of latex and synthetic surgical and examination gloves because of the potential dangers these gloves cause to medical personnel and to patients. It pointed out that an acceptable substitute, nonpowdered gloves, was available [9].

In the July 1999 Federal Register Notice, FDA discussed alternatives to the proposed regulation and, with respect to Dr Wolfe's petition, said the following:

"A ban of all powdered medical gloves has been requested in a citizen's petition submitted to FDA. Food and Drug Administration considered banning powdered gloves because that action would meet the stated objective of eliminating airborne powder and greatly reducing ex-

posures to airborne allergens associated with the use of medical gloves. However, FDA did not select this alternative because a ban would not address exposure to NRL allergens from medical gloves with high levels of NRL proteins. Moreover, such a ban of powdered gloves might compromise the availability of high-quality medical gloves and greatly increase the annual costs by almost as much as \$64 million over the selected alternative [10]."

4. Changes since submission of the 1998 Citizen's Petition

Since 1998, there have been a number of advances in the surgical and examination glove industry. These changes satisfy each of FDA's concerns for not accepting the 1998 petition. The FDA reply to the 1998 Citizen's Petition contained 3 concerns:

- (1) a ban would not address exposure to NRL allergens,
- (2) a ban might compromise the availability of high quality medical gloves, and
- (3) a ban would greatly increase the annual cost of medical gloves by nearly \$64 million.

Since 1998, the latex protein levels of NRL gloves have decreased in most latex surgical glove brands. In addition, there are now new standards and guidelines that recommend using gloves with aqueous soluble protein content no higher than 200 $\mu\text{g}/\text{dm}^2$ of glove material. Currently, gloves are available in the marketplace with protein levels as low as 50 $\mu\text{g}/\text{dm}^2$. The Emergency Care Research Institute believes that hospitals should use NRL gloves with the lowest possible protein levels.

Also since 1998, major glove manufacturers have introduced a variety and an ample supply of high-quality, customer-preferred, powder-free NRL and synthetic gloves. Today, more than 90% of examination gloves and more than 60% of surgical gloves used in hospitals are powder-free. Medical glove manufacturers have increased the availability and manufacturing capacity of powder-free gloves significantly since the last Citizen's Petition. Those powder-free gloves are of high enough quality to have replaced most powdered gloves, yet powdered gloves with all of their documented potentially harmful effects still persist.

Lastly, since 1998, the average price of powder-free latex surgical gloves has declined by as much as 44% for some brands, and the 1998 estimated \$64-million increase in annual costs can be reduced. The price declines are the result of increased availability and competition of powder-free medical gloves since 1999. In addition, as mentioned in the previous paragraph, most hospitals are now using powder-free gloves, which significantly reduce the number of hospitals used to calculate total costs.

Despite 2 decades of voluntary customer education (as suggested by FDA), the successes of glove manufacturers'

production, the quality of powder-free gloves, and the continued reports of the harmful effects of glove powder, the U.S. marketplace continues to use powdered medical gloves. Therefore, a ban of such powder is necessary for the protection of health care professionals and their patients.

5. 2008 Citizen's Petition

Finally, in a series of correspondence between Dr Richard Edlich and Dr Sheila A. Murphey, branch chief, Infection Control Devices Branch, Division of Anesthesiology, General Hospital, Infection Control and Dental Devices, Office of Device Evaluation, Center for Devices and Radiological Health, the following advice was provided:

"Food and Drug Administration does not disagree that there are some risks associated with the use of cornstarch powder on latex gloves. However, as we noted, there are limits on our regulatory authority, imposed by Congress. Due process must be used to invoke a measure as sweeping as a "ban" on the use of glove powder. The proper mechanism for addressing such a change would be to submit a "citizen's petition." Please note that information on how to file a citizen's petition was emailed to you, at your request, on July 15, 2008, by FDA."

"As noted in my earlier email, FDA agrees with Occupational Safety and Health Administration and with the American College of Surgeons that the education of health care professionals and institutions is critical in assisting all interested parties to choose safe and appropriate protective gloves for use in the operating theater and elsewhere."

On the basis of the advice and comments from Dr Sheila A. Murphey, the 12 authors of this report are filing a Citizen's Petition to ban the use of cornstarch on examination and surgical gloves.

This Citizen's Petition is intended to provide overwhelming evidence that cornstarch is an unnecessary, and in rare cases deadly, hazard to health care providers and patients, which should be banned from medical gloves. The sections below include the following:

- overview of scientific studies on glove powder,
- organizations highlighting the dangers of glove powder,
- hospitals abandoning glove powder, and
- countries abandoning glove powder.

6. Overview of scientific studies on glove powder

The following section is an overview of scientific studies related to the dangers of cornstarch on surgical and examination gloves.

6.1. Influence of glove cornstarch on wound closure techniques

Tape closure is ideally suited for lacerations because it avoids the use of foreign bodies (eg, sutures, staples, tissue adhesives) in the wound that can damage host defenses and invite the development of infection. Consequently, contaminated wounds closed by tape exhibit the lowest incidence of infection as compared to staples and the least reactive suture. Despite the obvious benefits, tape closure has had limited use in many emergency departments because many emergency physicians use sterile, cornstarch-coated surgical gloves. In the study by Pavlovich et al [11], they examine the magnitude of tape adhesion to a dry powder-free skin compared to that of a dry glove covered by cornstarch. In addition, they examine the influence of temporarily wetting and then drying the glove surfaces on the adhesion of the tape to the glove. This study showed that the skin closure tapes adhered aggressively to cornstarch-coated latex gloves. Consequently, it was difficult to separate the tape from the glove and apply the tape to the skin. The advent of a new powder-free glove allowed emergency physicians to handle the tapes and accomplish successful tape wound closure.

6.2. Cornstarch-induced peritoneal adhesion formation

In 1977, Cooke and Hamilton [12] examined the significance of cornstarch powder contamination in the etiology of peritoneal adhesions. In their study, they examined the presence or absence of starch granulomas on the peritoneal surface or within peritoneal adhesions in 20 patients subjected to a second laparotomy. They presented evidence to show that cornstarch granuloma formation is common in the early months after operation and that adhesions associated with starch granulomas cause intestinal obstruction. They pointed out that although starch is usually absorbed within 2 years, associated band adhesions may persist. Consequently, glove powder contamination of the peritoneal cavity may be a common cause of band adhesion intestinal obstruction.

In a report by Luijendijk et al [13] in Göteborg, Sweden, they studied the presence of foreign material and post-operative adhesions. Cornstarch granulomas were found in 14 (5%) of 309 patients with a history of being operated on with cornstarch-coated gloves. The authors concluded that intraabdominal contamination with foreign material, such as cornstarch, should be minimized.

In 2001, van den Tol et al [14] performed an experimental study that demonstrated that cornstarch glove powder promotes adhesion formation and facilitates tumor cell adhesion and growth. They developed a reproducible model that allowed semiquantitative scoring of adhesion formation or tumor load in rats. On the basis of these studies, they found that application of cornstarch on minimally and

severely traumatized peritoneum gave rise to significantly greater adhesion formation and intraabdominal tumor load than peritoneal trauma alone. On the basis of this experimental study, the authors concluded that starch-induced peritoneal trauma led not only to more adhesion formation but also to increased adhesion and growth of tumor cells. Because good quality powder-free surgical gloves are available, they believe that there is no longer any justification for the use of cornstarch-powdered gloves during intraabdominal surgery.

6.3. Glove cornstarch-induced granulomatous peritonitis

In 1976, Berkow [15] discussed granulomatous peritonitis due to cornstarch from surgeon's gloves. Berkow [15] indicated that granulomatous inflammation of the peritoneal surfaces resulting from exposure to cornstarch granules from surgical gloves produces a syndrome of abdominal pain, adynamic ileus, fever, peritonitis, variable white blood cell count, and inflammatory ascites. Berkow [15] indicated that symptoms developed 3 to 4 weeks after a routine abdominal surgical procedure. It was pointed out that recognition of this entity by nonsurgical means is necessary to avoid reoperation. Paracentesis with examination of the fluid by polarized light offers the best method of nonsurgical diagnosis. Berkow [15] recommended treatment with steroids or indomethacin or conservative measures. To prevent this disease, gloves coated with cornstarch must be washed effectively before starting the operation. When this article was reported, it is important to emphasize that there were no commercially available powder-free surgical gloves.

In 1994, Giercksky et al [16] describe patients with multiple cornstarch powder granulomas that were assumed to be peritoneal carcinomatosis. In their report, they registered 10 cases of multiple powder granulomas, believed by the surgeon to represent tumor dissemination, but diagnosed by the pathologist as glove powder granules with the typical Maltese cross pattern viewed under polarized light. The authors concluded that routine pathologic documentation of all peritoneal nodules appearing to be tumor dissemination should be undertaken. If the results influence the surgical procedure, frozen sections should always be performed. To minimize the risk of powder-induced complications, the authors recommended the use of powder-free sterile surgical gloves for all operative procedures in the abdominal cavity.

In 2001, Winkler et al [17] evaluated the use of magnetic resonance imaging in a differential diagnosis between cornstarch and fecal peritonitis. They reported that magnetic resonance imaging of the starch peritonitis was remarkable for a diffuse pathologic process with enhancement of the omentum and the peritoneum after gadolinium injection. In contrast, the magnetic resonance imaging of the fecal peritonitis group showed a localized process with no diffuse enhancement of the peritoneum. This initial study was done

in rats. They are currently investigating the use of magnetic resonance imaging in suspected starch peritonitis in humans. The obvious solution is to ban the use of cornstarch on surgical gloves.

In another case report by Juaneda et al [18], they described a 54-year-old woman admitted with abdominal pain, fever, and an unusually prolonged ileus in the postoperative period after a laparotomy. Conventional hysterectomy was undertaken 3 months before. At admission, exploratory video laparoscopy was undertaken, in which the distal jejunum was accidentally perforated that required laparotomy for enterorrhaphy. One month later, she was subjected to another laparotomy due to the persistence of ileus. Granulomatous peritonitis was confirmed by histopathologic examination. Endovenous hydrocortisone was given during 2 weeks and changed to oral prednisone during 4 weeks with gradual diminution until suppression. The authors concluded that prevention was crucial and would not have occurred if the surgeons had worn cornstarch-free surgical gloves.

6.4. Wound infection

In an experimental study reported in 1994, Ruhl et al [19] performed experimental studies that evaluated the damaging effects of cornstarch on local tissue defenses in contaminated wounds. They found that in contaminated wounds, cornstarch enhanced the growth of bacteria and elicited exaggerated inflammatory responses as measured by wound induration.

In another experimental study undertaken in 1998, Odum et al [20] studied the damaging effects of both cornstarch and calcium carbonate in experimental wounds. This experimental study documented that these glove powders significantly potentiated bacterial growth and enhanced the wound's inflammatory response.

In a 1999 report by Dave et al [21] from the United Kingdom, they provide documentation that powdered glove wearers have an increased risk of latex allergy, and there is circumstantial evidence that the examination and surgical glove powders may increase bacterial environmental contamination. They also noted that cornstarch glove powder promoted infection in animal models. The authors concluded that infection control teams need to be aware of this evidence and should support switching from the use of powdered to powder-free gloves.

6.5. Cornstarch-induced latex hypersensitivity

In 1997, National Institute for Occupational Safety and Health published a working document on preventing allergic reactions to natural rubber latex in the workplace [22]. In their document, it is emphasized that workers exposed to latex gloves and other products containing natural rubber latex may develop allergic reactions such as rashes; hives; nasal, eye, or sinus symptoms; asthma; and (rarely) shock.

They made the following recommendation: If you have a latex allergy, consult your physician regarding the following precautions: avoid contact with latex gloves and products and avoid areas where you might inhale the powder from latex gloves worn by others.

In 1999, the American Dental Association Council on Scientific Affairs wrote a landmark report on latex hypersensitivity [23]. The report summarizes the signs and symptoms of natural rubber latex protein allergy, allergic contact dermatitis, and irritant dermatitis. It also offers information on the means to diagnose these conditions definitively and suggests means of reducing occupational exposure to the causative allergens and irritants in the dental office. In their report, they pointed out that latex antigens can bind to cornstarch, and aerosolization of cornstarch powder when donning or removing gloves can precipitate a heightened latex protein exposure. In addition to the use of synthetic or powder-free latex gloves, dental personnel can further reduce occupational exposure by using low-protein, powder-free latex gloves.

In 2002, Truscott [24] of the Kimberly-Clark Corporation, Roswell, Ga (USA) wrote another important article on glove powder reduction and alternative approaches. Her superb article addressed the role of glove powder in facilitating allergic reactions to natural rubber latex and to the chemical additives in synthetic gloves, as well as its role in eliciting postsurgical complications. She pointed out that various dusting powders have been used historically to prevent gloves from sticking to each other, to facilitate donning, and that all glove powders have manifested adverse consequences for health care professionals and patients. She presented important manufacturing methods for powder elimination from gloves and reviewed the American Society for Testing and Materials methods for the measurement of powder on powder-free and powdered gloves along with the new American Society for Testing and Materials maximum powder limits for all medical gloves. Her most important message was that it is imperative to eliminate powder from any surgical and examination glove.

In another report published in 2002 in Sweden, Edelstam et al [25] reviewed glove powder in the hospital environment. The authors made the following strong recommendations: "It is not acceptable to use powdered medical gloves within health care. In spite of the risk of allergy and impairment of the working environment from powdered gloves, there is still only a minority of hospitals working according to a strict general powder-free policy in Sweden." The study further pointed out that the reduced cost resulting from fewer absences due to sickness further adds an argument for omitting glove powder and justifies the higher cost of using powder-free medical gloves.

In another study by Barbara et al [26], they pointed out that cornstarch powder present in medical gloves plays an important role in latex-induced hypersensitivity as an allergen carrier either by the inhalation route, by skin contact, or by direct contact with mucous membranes. Their study demonstrated that cornstarch powder enhanced anti-

gen-induced bronchoconstriction and antibody production. This role of immunoadjuvant is not antigen-specific. The authors concluded that cornstarch powder used as a donning agent in latex gloves is an allergen carrier, and it can enhance latex-induced hypersensitivity.

In another study reported in *Morbidity and Mortality Weekly Report*, the authors made the following comment: "because of the role of glove powder in exposure to latex protein, National Institute for Occupational Safety and Health recommends that if latex gloves are chosen, health care personnel should be provided with reduced protein, powder-free gloves" [27]. They also pointed out that nonlatex (eg, nitrile or vinyl) powder-free and low-protein gloves are also available.

In the landmark book written by Dr Richard F. Edlich, Dr Julia A. Woods, and Dr Mary Jude Cox entitled, "Medicine's Deadly Dust: A Surgeon's Wake-Up Call to Society [28]," cornstarch was described as the deadly menace that lurks in America's hospitals. They emphasized that cornstarch is a substance recognized by all surgeons, doctors, nurses and hospital administrators. It is a substance that has outlived its benefits. It is a substance that should be eliminated immediately by the FDA.

This information should be included in all health care professionals' training until the FDA bans the dangerous cornstarch powder from examination and surgical gloves that risk the lives of patients and health care workers. It is a crisis in health care that can be easily stopped by banning the use of powder on surgical and examination gloves. In conclusion to the overview of scientific studies, the authors of this petition believe the scientific evidence supporting the need to ban the use of glove powder for the protection of all Americans is overwhelming and indisputable. We call upon the FDA to take immediate action to exercise its authority and end the menaces of cornstarch.

7. Organizations highlighting the dangers of cornstarch powder

In this section, we have highlighted comments from several nationally recognized organizations that support the ban of cornstarch powder on synthetic and latex gloves.

7.1. American Academy of Allergy, Asthma, and Immunology; and American College of Allergy, Asthma, and Immunology

"Only powder-free latex gloves should be purchased and used. This will reduce latex rubber aeroallergen levels and exposure [29]."

7.2. American College of Surgeons

"...only powder-free gloves should be used in the operating room [30]."

7.3. The American Nurses Association

“Following guidelines in a joint statement of the American College of Allergy, Asthma, and Immunology and the American Academy of Allergy, Asthma, and Immunology, the American Nurses Association (ANA) is calling for the elimination of powdered latex products and the implementation of low-allergen, powder-free latex gloves in all health care settings [31].”

8. Hospitals in the United States that have stopped using cornstarch-powdered gloves

The University of Virginia Health System was the first to ban cornstarch from all of its surgical and examination gloves in the United States. The basis for this decision was outlined in a published collective review of the hazards of powder on surgical and examination gloves [32]. In addition, a team of scientists documented that powder-free latex gloves have been designed so that they have the same donning forces as gloves with cornstarch [33].

Some major hospitals, including Johns Hopkins Hospital in Baltimore (MD) and the Cleveland clinic's network of 9 hospitals, have switched to synthetic surgical gloves. These 2 health care facilities converted their hospitals and clinics entirely to powder-free, nonlatex surgical and examination glove facilities [34].

In 2000, Jackson et al [35] conducted a global inventory of hospitals using powder-free gloves. Their study, using a global Internet search, identified 70 hospitals in the United States that use only powder-free gloves. The survey did not include the Legacy Healthcare System in Washington and Oregon, which in 2001 banned the use of cornstarch gloves in their hospitals and hospice under the leadership of Dr William B. Long III, Director of Trauma Specialists LLP, Legacy Emanuel Hospital, Portland, OR (USA).

In 2008, Dr Wendy Huber (Oakland, CA) confirmed that all Kaiser Permanente clinics and hospitals in our country use only powder-free latex or synthetic examination and surgical gloves.

An extensive survey by GHX Market Intelligence in Louisville, CO (USA), of the second quarter 2008 market research data of gloves used in the United States showed the following for total examination glove market (physician offices, surgery centers, and hospitals): Powder-free examination gloves (units) 94.4%; powdered examination gloves (units) 5.6%. In the second quarter 2008 market research data showed the following for total surgical glove market: Powder-free surgical gloves (units), 64.6%; and powdered surgical gloves (units), 35.4%. After the successful development of technology to produce powder-free examination and surgical gloves, the United States has sufficient resources for all physicians and health care workers to use powder-free examination and surgical gloves.

9. Countries that have banned cornstarch-coated gloves

In December 1997, Germany's regulations of personal protective equipment banned the use of surgical glove powder (cornstarch). Dr Henning Allmers, Director of the Department of Occupational Medicine, Head of the Occupational Medicine Laboratory at the Department of Dermatology, Environmental Medicine and Health Sciences at the University of Osnabruck in Germany described the educational and regulatory measures in the German health care system to prevent natural rubber latex allergy through education and intervention [36].

“In December 1995, an interdisciplinary work group from the departments of dermatology, allergy, and occupational medicine of 7 German universities met in the Berufsgenossenschaftliches Forschungsinstitut für Arbeitsmedizin (BGFA), Bochum, Germany, to decide on recommendations concerning the prevention of natural rubber allergy in health care workers and allergic patients. Those guidelines for hospital administrators and personnel were published in several scientific journals³⁴ and were also distributed by the BGFA.”

Recognizing the dangers of natural rubber latex allergy, a regulation banning powdered natural rubber latex gloves was implemented in Germany in 1998 [37]. A study by Allmers et al [38] assessed the effects of this regulation on the development of occupational skin disease caused by natural rubber latex in health care personnel working in facilities insured by the German statutory accident insurance company covering some 1.8 million insured health care workers. They reviewed the annual numbers of reported suspected cases of natural rubber latex-induced occupational allergies (mainly contact urticaria) from 1996 to 2002, as well as the number and type of gloves purchased in acute care hospitals from 1986 to 2002. They reported that the number of purchased non-sterile examination gloves increased by 1387% from 1986 to 2002. The purchase of powder-free natural rubber latex examination gloves exceeded that of powdered gloves in 1998. The incidence of suspected cases increased until 1998 and has since decreased by 79.9%. They reported that most suspected cases (67.9%) were identified as occupationally caused. The authors concluded that reducing the purchase of powdered natural rubber latex gloves is associated with a decrease in suspected and proved cases of occupational contact urticaria caused by natural rubber latex. Furthermore, development of occupationally caused contact urticaria by natural rubber latex can be significantly reduced by banning the use of powdered natural rubber latex gloves.

In addition in 2000, in response to the enormous scientific information about the dangers of cornstarch on gloves, the Purchasing and Supply Agency, responsible for purchasing health care supplies to be used in the National Health Service of the United Kingdom, ceased to purchase any gloves

lubricated with United States Pharmacopeia cornstarch (ie, all gloves in the National Health Service of the United Kingdom became powder-free). John Spashett has worked for BM Polyco Limited, a major United Kingdom glove producer for 9 years. During this time, he has performed chemical, physical, and microbiological testing as well as giving lectures in Malaysia, Thailand, and mainland Europe. With the formation of BM Polyco's Medical Division, he became a Technical Manager, responsible for the regulatory compliance of the entire product range. In this role, he has become a United Kingdom representative to the CEN/TC205/WG3 committee responsible for the preparation of various standards including the EN455 series for medical gloves. Mr Spashett contacted Dr Edlich on August 23, 2008, to inform him that no United Kingdom hospital has used United States Pharmacopeia-modified cornstarch powder for nearly a decade. This decision was made because of the high rates of adhesions, granulomas, and similar wound complications. This legislation was enacted by the Department of Health of the United Kingdom [39].

10. Conclusion

On the basis of this extensive review, the FDA must immediately ban dangerous cornstarch-powdered surgical and examination gloves. This review has cited studies that demonstrate the hazards of cornstarch powder on medical gloves related to numerous complications, including the following:

- wound closure
- adhesion formation
- granulomatous peritonitis
- wound infection
- latex hypersensitivity

All of these potential complications are painful, dangerous, and potentially deadly for patients and health care workers that are affected by them. As stated above, numerous organizations and hospitals in the United States recognize the significance of these complications and support the use of powder-free gloves only. It is time for a change. Although the market may not have been in a position to handle the ban when requested in prior petitions, it has now handled latex allergen, cost, and supply issues previously raised by FDA. The only remaining issue to address is the availability of dangerous cornstarch glove powder and only FDA can ban it. Evidence of the harm to health care workers and their patients by cornstarch glove powder is overwhelming and ignoring it is unjustifiable—particularly when profound evidence from individual facilities and other countries demonstrated comprehensive advancements in health care with the banning of cornstarch glove powder. The 12 coauthors hereby petition the FDA to

protect the health and safety of our beloved patients and their dedicated health care workers and ban the use of cornstarch powder on all surgical and examination gloves used in the United States.

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