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**Comments by Sidney M. Wolfe, Director, Public Citizen's Health Research Group,  
Concerning FDA's Proposed Regulation (7/30/99) on Powdered Latex Gloves  
Docket No. 98N-0313**

In January, 1998, Public Citizen and Dr. Timothy Sullivan, Professor of Medicine at Emory and Head of the subsection of Allergy and Immunology at the Emory Clinic, petitioned the Food and Drug Administration to ban powdered latex gloves because of their significant dangers and because of the fact that safer alternatives are available. At that time, FDA had already been studying this issue for at least two years. When FDA published the July 30, 1999 Federal Register notice announcing the reclassification of powdered latex gloves, the agency also rejected our petition to ban powdered latex gloves.

These comments will elaborate on the reasons why a ban on powdered latex gloves—one which would take effect, for example, 18 months from now—coupled with the proposed reclassification as Class II medical devices for all surgical and patient examination gloves, is the most health-responsive action the Agency could take. Our comments will also discuss what, according to the agency's own data, are the dangers of allowing the powdered latex glove industry essentially to dictate the pace of phasing out these unquestionably dangerous and unnecessary medical devices.

**Dangers of Powdered Latex Gloves**

"FDA has long been aware that MDR's [mandatory device reports] received by the agency may account for as little as one percent of the actual events (Ref. 37). If true, the reports received for allergic reactions associated with medical gloves could represent as many as 43,500 allergic incidents during the 12-month period [including 38,045 people with systemic respiratory problems such as asthma--10,272 of whom have problems with a duration of two months]. Because patients may often fail to connect an allergic incident to use of gloves, FDA believes that this estimate better reflects the true number of incidents associated with medical gloves." FDA Proposed Rule, 64 Fed. Reg. 41717. In the same one-year period, FDA estimated that 150 people would suffer allergic reactions serious enough to require very aggressive treatment and that about one-half of these people, 73 people a year, would exhibit long-term effects lasting two months.

"FDA has significant concerns about the role of glove powder as a carrier of airborne allergens, because NL [Natural Latex] allergens have been shown to bind to cornstarch. A number of published clinical and experimental studies support this conclusion (Refs. 10 to 14). In addition to the role of glove powder as a carrier of airborne allergens, FDA is also aware that glove powder contributes to a number of other adverse health effects. As particulate matter, it can cause foreign body reactions, resulting in inflammation, granulomas and adhesions of peritoneal tissues after surgery (Refs. 15 to 19). Glove powder may serve as an absorbent or adsorbent for

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unbound chemicals that may be irritants or chemical contact sensitizers. In addition, glove powder from nonsterile patient examination gloves may also support microbial growth and act as a carrier for endotoxins (Ref. 20)." FDA Proposed Rule, 64 Fed. Reg. 41710.

In a study published in the July, 1999 issue of the American Journal of Public Health (see attached), Dr. Timothy Sullivan (one of our co-petitioners in the January, 1998 petition to ban powdered latex gloves) and his co-authors reach conclusions even more grave than those of FDA as far as the damage done by the continued use of powdered latex gloves: "At a conservative 8% prevalence, 586,080 [American] health workers are sensitized to latex and are at risk for potentially serious and fatal allergic reactions. . . . Once a worker is sensitized and has an allergic reaction, continued exposure to latex antigens can result in progressive morbidity, increased sensitivity to other antigens, and possibly mortality from anaphylactic reactions. The only known treatment for latex allergy is cessation of exposure." Of the 8% of employees routinely exposed to latex glove use who would develop latex allergy, "2.5% of this number [14,652 health workers] would develop latex-related asthma." In calculating the costs of switching to a "latex-safe" environment, that is, banning the use of powdered latex gloves as well as other latex gloves, the authors found that even with very low rates of permanent disability from these gloves (1%) or low partial disability rates (2%), it was more cost-effective to protect workers by going to a latex-safe environment. They included diagnostic and permanent (but not temporary) disability costs in their calculations, based on a tertiary care hospital, a community-based hospital and an outpatient clinic in Georgia. They concluded that "health care facilities, regardless of size, are likely to benefit financially from becoming latex-safe even if latex-related disability levels are extremely low."

In our original petition, a copy of which is attached to these comments, we cited several examples of hospitals which had made this kind of decision, not only for the above economic reasons but because they were losing valuable, experienced employees:

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 be exposure to latex—especially to aerosolized glove powder, which bound the latex proteins. Following this experience, the hospital became powder-free. In other words, they no longer use powdered latex surgical gloves.

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." 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 more than 80 employees were identified as allergic to latex. As a result of the switch, none of the allergic employees needed to leave their jobs. "[M]ost of these [80 latex-allergic] employees [had] 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 lost their job.

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. To protect patients and health care workers from the risks of exposure to cornstarch, FDA must follow the example of these hospitals by taking immediate action to ban the use of cornstarch as a lubricant for surgical and examination gloves.

A recent review of latex glove allergy workers compensation cases, mainly involving health workers, confirms the seriousness of the injuries caused by such exposure. (Mealey's Litigation Report, December, 1999). As of June 30, 1999, 13 states had reported decisions in latex-related workers compensation cases and 21 of 30 cases (70%) were deemed compensable, a significant number of which involved total and permanent benefits to the claimants. The number of such claims is rapidly rising. In addition, because this workers' compensation remedy often falls far short financially, especially for those totally and permanently disabled, a growing number of product liability lawsuits, currently estimated to be more than 500, are being filed against glove manufacturers, suppliers and distributors of these latex products.

### **Foreign Body Disease in Patients From Gloves**

In addition to the problems which occur in health workers because of repeated exposure, patients also experience serious problems after exposure during surgery.

Scientific experimental and clinical studies confirm that cornstarch promotes disease in surgical patients by two different mechanisms. First, when deposited in the wound, it acts as a foreign body 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.

### **Why We Favor a Ban on Powdered Latex Gloves in Addition to Restrictions on Latex Protein Content**

As stated in our original petition, we strongly favor a ban on powdered latex gloves, which could be announced now—already four years after FDA started looking into this matter— but become effective in 18 months. The 18 months would, according to FDA's own reasoning, allow manufacturers adequate time to switch from manufacture of powdered to non-powdered gloves. 64 Fed. Reg. 41718. We also favor, but with a shorter time for implementation, FDA's proposal to reduce the permissible amount of latex allergen in latex gloves. FDA offers no reason why the

time-frame for implementation of this aspect of its proposal should be two years, rather than one. Moreover, 1200 micrograms of latex protein per glove does not appear to be based on any safe scientific health assessment. Rather, it appears to be based on the analytical sensitivity of one particular test (not at all the most sensitive test) for measuring latex protein. Yet it is clear that much lower amounts of latex protein per glove can cause a reaction in latex-sensitized people. (J.All. Clin. Immunol. 1996;98:872-83)

It is quite extraordinary that one branch of the Department of Health and Human Services (HHS), the National Institute for Occupational Safety and Health (NIOSH), has taken a much stronger stand on this issue than is reflected in the weak proposal of FDA. NIOSH has recognized 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 "[i]f latex gloves are chosen, provide reduced protein, powder-free gloves to protect workers from infectious materials." For this NIOSH recommendation to be effective in protecting already sensitized workers from debilitating and life-threatening injuries and to prevent new workers from becoming sensitized, FDA must not only significantly reduce the latex protein content in these gloves but also ban powdered gloves entirely.

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

"A ban of all powdered medical gloves has been requested in a citizen petition submitted to FDA. FDA considered banning powdered gloves because that action would meet the stated objective of eliminating airborne powder and greatly reducing exposures 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 NL [natural latex rubber] allergens from medical gloves with high levels of NL 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."

Elsewhere, FDA stated that another reason for rejecting our petition was that an immediate ban might cause a disruption in the supply of medical gloves.

The stated reasons for rejecting our request for a ban are insufficient. First, although a ban on powdered latex gloves would not address exposure to NL allergens through non-powdered gloves, FDA offers no reason why a ban on powdered gloves could not be implemented in conjunction with a rule reducing the permissible amount of NL allergens in non-powdered gloves. Neither action would be exclusive of the other.

Second, a September 1997 FDA bulletin from the Center For Devices and Radiological Health (CDRH), entitled "Medical Glove Powder Report," considered various alternatives for addressing the problem of powdered latex gloves. Alternative #2 was:

Ban powdered medical gloves at some predetermined time in the future. Require manufacturers to convert to powder-free production or provide safety data, including foreign body and airborne allergen concerns, by a certain date.

Pro: Should not precipitate market shortage. Requires no education effort.

Offers a greater degree of protection from airborne natural latex allergens than Option 1. (Option 1. was providing information to consumers.)

Con: Conversion date would have to be negotiated with industry to avoid market shortage. The effect of powder-free gloves on user preferences and needs for qualities such as tactile sensation, etc. are largely unknown. Would most likely result in increased costs to the U.S. health care system. It is not clear that the amount of particulates need to be reduced to the "powder-free" level in order to offer an acceptable level of protection from adverse health effects. Does not address natural latex protein level. Would require a new regulation.

Thus, more than two years ago, FDA concluded that a ban, implemented at a predetermined date, would not lead to a shortage of supply. The agency's 1997 conclusion is supported by the commentary accompanying the July 1999 Proposed Rule, which suggests no reason why a ban made effective with an 18-month lead time would disrupt the supply of gloves.

In addition, each of the "cons" listed by FDA in 1997 is negated today by the widespread use of powder-free gloves; current estimates of the overall cost balance (such as worker disability), not just the increased cost of powder-free gloves; FDA's decision to add protein content to the standard, and FDA's decision to promulgate a regulation. In fact, in the July 1999 Proposed Rule, FDA states: "FDA is also considering a future requirement that all surgeons' and patient examination gloves marketed in the United States be powder-free."

### **Conclusion**

We agree with the Agency that a standard addressing the level of protein in latex gloves should be implemented. We question the standard proposed in the July 1999 Proposed Rule, as it does not seem to be based on a scientific assessment of a safe level. Most importantly, for the reasons stated in these comments and in our January 1998 petition, we again urge FDA to ban the use of powdered latex medical gloves. Based on the findings discussed in the Proposed Rule, such a ban should become effective 18 months after publication of a final rule. Finally, we urge FDA to issue a final rule as soon as possible.

# Health Care Worker Disability Due to Latex Allergy and Asthma: A Cost Analysis

## ABSTRACT

**Objectives.** The reported prevalence of occupational allergy to natural rubber latex is 8% to 17%, and that of latex-induced occupational asthma is 2.5% to 6%. Conversion of medical facilities to "latex-safe" can reduce employee sensitization, impairment, and disability. The purpose of this study was to determine the cost of a latex-safe approach, compared with that of continued latex glove use, and to identify the level of worker disability required to make the latex-safe approach financially preferable to a health care institution.

**Methods.** The costs of 2 strategies—latex-safe vs the status quo—were calculated from the perspective of 3 health care institutions. A break-even point was calculated for each facility.

**Results.** In all facilities, the cost of using nonlatex gloves exceeded the cost of using latex gloves. In all 3 facilities, however, 1% or fewer of those at risk would have to become fully disabled or fewer than 2% would have to become partially disabled for the continued use of latex gloves to exceed the cost of the latex-safe approach.

**Conclusion.** Health care facilities, regardless of size, are likely to benefit financially from becoming latex-safe even if latex-related disability levels are extremely low. (*Am J Public Health* 1999;89:1024-1028)

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Occupational latex allergy was initially reported in US health care workers in 1992. Prevalence estimates over the last 5 years have varied from 8% to 17%.<sup>1-5</sup> At a conservative 8% prevalence, 586 080 health care workers are sensitized to latex and are at risk for potentially serious and fatal allergic reactions.<sup>6</sup> Sensitization to latex is primarily mediated by direct contact with latex gloves and by latex antigens aerosolized with glove powders in the donning and doffing process.<sup>7-12</sup> Once a worker is sensitized and has an allergic reaction, continued exposure to latex antigens can result in progressive morbidity, increased sensitivity to other antigens, and possibly mortality from anaphylactic reactions.<sup>1,13</sup> The only known treatment for latex allergy is cessation of exposure.

Data on latex allergy are scarce because of its recent recognition, but latex allergy and asthma are believed to be similar to other immunoglobulin E (IgE)-mediated occupational sensitizers.<sup>14</sup> Studies have documented that occupational asthma, arising from exposure to several substances, can lead to permanent impairment.<sup>15</sup> However, the extent of disability caused by such impairment is currently unknown.

Disability technically results when an individual's earning capacity is compromised by work-related impairment.<sup>16</sup> Impairments can be temporary, permanent, full, or partial. Only persons who lose income because of an acquired impairment are eligible for compensation. Disability from occupationally induced allergies is compensable under workers' compensation law.

Patients are also susceptible to the same latex-related risks as health care workers. Both workers and patients can be protected from the potential risk of latex exposure by the conversion of medical facilities to what is known as "latex-safe," defined here specifically as the use of nonlatex gloves. Moving to a latex-safe environment has met with con-

siderable resistance because of concerns about the cost of nonlatex gloves,<sup>17</sup> their protective features,<sup>18-20</sup> and their tactile quality as reported by surgeons.

The Centers for Disease Control and Prevention<sup>21</sup> has addressed the safety of nonlatex gloves. It does not favor one glove type but stresses that barrier protection should be appropriate for the risks anticipated. Cost and tactile quality issues remain unresolved. The purpose of this study was to determine the cost of a latex-safe approach, compared with that of continued latex glove use, and to identify the level of worker disability required to make the latex-safe approach financially preferable to a health care institution.

## Methods

We did a cost analysis of 2 strategies—latex-safe vs the status quo—from the perspective of the health care institution. Three different types of facilities in Georgia were chosen for the study: a tertiary-care hospital, a community hospital, and an outpatient internal medicine clinic. Data on glove costs and purchasing patterns were collected from the purchasing department at each facility. No data were available to estimate the number of sensitized employees who would actually develop serious, sustained impairment or qualify for disability. Therefore, we calculated the per-

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centage of those at risk for disability who would have to become permanently fully or partially disabled for a latex-safe approach to be less costly than the status quo. Periods of liability and levels of disability payment were varied in a sensitivity analysis.

#### Glove Cost and Use

Facilities reported the type, quantity, and manufacturer of gloves purchased. Nonsterile nonlatex alternatives are vinyl and nitrile gloves; nitrile offers superior durability. Sterile nonlatex alternatives are polymer or synthetic rubber surgical gloves. Prices were obtained from manufacturers, distributors, and the Internet. The unit price for the comparable nonlatex alternative was substituted for the latex glove price and was used to calculate the health care facilities' annual glove costs in the latex-safe setting. The price for nonsterile gloves was a weighted average of costs for vinyl and nitrile, used in the laboratory and surgery areas. The average price per pair was used for sterile nonlatex gloves.

#### Latex Sensitization and Disability Risk

We assumed, on the basis of documented prevalence rates, that 8% of the employees routinely exposed to latex glove use would develop IgE-mediated latex allergy, with 2.5% of this number also developing latex-related asthma.<sup>1,22-24</sup>

#### Diagnostic Costs

Data to determine treatment paths and costs for allergic reactions to latex are not available. Insurance also complicates the question of who bears treatment costs. Therefore, only the cost of diagnosis was included in the analysis. Latex allergy may be diagnosed after an evaluation by an allergist, serum latex-specific IgE antibody testing, and skin-prick tests. Skin-prick tests are used to identify other associated allergies present and to test for latex allergy in cases in which medical centers have developed their own antigens. Diagnosis of latex-related occupational asthma also requires pulmonary function testing and a chest x-ray. Charges for these procedures were converted to actual costs based on our institution's standardized cost-to-charge ratio of 0.715.

#### Disability Costs

In Georgia, most health care institutions self-insure for workers' compensation. Workers who qualify for permanent total disability receive wage replacement benefits equal to two thirds of their average weekly wage (\$300 maximum) for 400 weeks. Workers who qualify for

TABLE 1—Medical Facility Description and Comparison

Facility Features	Tertiary-Care Hospital <sup>a</sup>	Community-Based Hospital <sup>b</sup>	Outpatient Clinic <sup>c</sup>
No. of beds/rooms	894	523	22
Average daily census	659	314	67
Total personnel	5800	2750	24
Exposed personnel	5521	2600	22
Prevalence-based estimate of workers with latex allergy (8%)	442	208	2
Prevalence-based estimate of workers with latex-induced asthma (2.5%)	138	65	1

<sup>a</sup>Large, nonprofit, county-owned teaching hospital with Level I trauma center.

<sup>b</sup>Medium-sized, nonprofit, nonteaching hospital.

<sup>c</sup>Residency program-affiliated internal medicine outpatient clinic.

permanent partial disability also receive wage replacement benefits equal to two thirds of their average weekly wage (\$192.50 maximum) for 350 weeks. The largest group of health care workers affected by latex allergy is registered nurses; at their pay levels, they would qualify for the maximum payment. We calculated the present value of 400 weeks of permanent total disability wage replacement payments and 350 weeks of permanent partial disability payments at the maximum payment level. We used the recommended discount rate of 3.0%.<sup>25</sup>

#### Excluded Costs

Latex allergies likely involve a range of other costs, such as increased sick leave, increased employee turnover, and decreased on-the-job productivity caused by mild allergic reactions. These costs, along with medical care costs for disabled employees and the costs of diagnostic tests for exposed workers without allergy or asthma, were excluded because they are impossible to quantify with accuracy. In addition, costs associated with patients who were allergic to latex were not taken into account. Excluding these costs results in an underestimate of the total cost of continuing latex glove use in the workplace.

However, neither the costs of developing and implementing policies for avoiding latex use nor the costs of in-service training of staff on latex-safe procedures were included in the analysis. Excluding these costs results in an underestimate of the total cost of converting to a latex-safe work environment.

#### Sensitivity Analysis

Our calculations were based on Georgia's workers' compensation payment rules. Most states also pay wage replacement benefits equal to two thirds of the weekly wage, but the maximum payment and duration of payments vary by state. We did a sensitivity analysis of the level and duration of disability

payments. In addition, we explored the effect on costs if (1) latex produced impairment rates similar to those of other occupational sensitizers and (2) nitrile was the required nonlatex substitute.

#### Results

Table 1 shows descriptive data on the 3 health care facilities. Identification of employees commonly exposed to latex was based on 3 factors: the requirement to attend blood-borne pathogen training, the employee's job title, and the employee's actual work location. With these criteria it was determined that 92% of the clinic employees, 95% of the community-based hospital employees, and 95% of the tertiary-care hospital employees were exposed to latex.

When a conservative prevalence-based estimate (8%) was used, 442 people in the tertiary-care hospital would be at risk for latex-related disability, whereas 208 and 2 would be at risk in the community-based facility and the clinic, respectively.

Latex and nonlatex glove prices are shown in Table 2. In this market, prices are negotiated on an annual basis and vary by glove type, manufacturer, and volume purchased. Table 3 shows the annual glove use and costs for each facility. The tertiary-care facility uses 7.2 million pairs of gloves annually, whereas the community-based hospital uses 3.5 million and the clinic uses 10 620. Nonsterile gloves constitute 96%, 98%, and 99% of the gloves used in the tertiary-care facility, the community hospital, and the clinic, respectively, whereas nitrile gloves account for 12%, 22%, and 0% of nonsterile glove use. The cost of purchasing the same number and mix (sterile and nonsterile) of nonlatex gloves is shown. The total costs for nonlatex gloves exceed those for latex gloves in all settings.

The costs for diagnosis of latex allergy were those accrued for an appointment with a

**TABLE 2—Glove Price Range, in Dollars, in the 3 Health Care Settings**

	Tertiary-Care Hospital	Community-Based Hospital	Outpatient Clinic
Nonsterile (100-count box)			
Powdered latex	3.99	4.01	5.95
Unpowdered latex	5.43	6.86	8.39
Powdered vinyl	3.65	...	5.95
Unpowdered vinyl	...	4.27	...
Nitrile	11.25	11.25	...
Sterile surgical (pair)			
Powdered latex	0.30–1.58	0.32–1.14	0.50
Unpowdered latex	1.73–2.59	1.27–3.33	...
Powdered nonlatex	2.50–3.00	2.50–3.00	3.95

Note. Data provided by each facility's purchasing department for gloves currently in use. Costs of non-latex substitutes not currently in use by a facility were obtained from manufacturers, distributors, and the Internet. "... " = not available.

**TABLE 3—Annual Glove Use and Cost in the 3 Health Care Settings**

	Tertiary-Care Hospital	Community-Based Hospital	Outpatient Clinic
Glove type			
Nonsterile (100-count box)	139 128	68 440	210
Sterile (pair)	288 932	79 544	120
Latex annual cost, \$			
Nonsterile	592 466	391 697	1 616
Sterile	339 952	106 269	60
Latex total cost, \$	932 418	497 966	1 676
Latex-safe annual cost, \$			
Nonsterile	653 644	396 688	1 250
Sterile	794 563	218 746	474
Latex-safe total cost, \$	1 448 207	615 434	1 724

physician trained in allergy and immunology (\$122), skin-prick testing (\$50), and radio-allergosorbent IgE serum testing (\$21), for a total of \$193 per latex-allergic employee. The costs for diagnosis of latex-induced occupational asthma also included pulmonary function testing (\$127) and chest x-ray (\$75), for a total of \$395 per employee with latex-induced asthma.

Table 4 shows the number of workers needed to become permanently fully or partially disabled for the cost of continued latex glove use to equal that of converting to latex-safe. The present value of total disability wage replacement payments for the maximum period for 1 employee with latex allergy or latex-induced asthma is \$108 917. The present value of partial disability payments for the maximum period for 1 employee is \$61 988. Diagnostic tests cost, on average, \$241 per person at risk for disability. Because of the additional cost of converting a facility to latex-safe, the break-even point for the tertiary-care facility is 4.73 (1.07%) of those at risk for full disability and 8.29 (1.88%) of those at risk for partial disability. The

break-even point is lower for the community-based facility. When the marginal cost of converting to latex-safe and the size of the disability payments are taken into account, the break-even point for the clinic is close to zero, and the clinic should become latex-safe.

For the sensitivity analyses, we gathered data on workers' compensation benefit programs from across the nation. The lowest values for the duration of and level of benefits offered in the United States for permanent total and partial disability payments were used to calculate the break-even point for the 3 health care facilities.<sup>26</sup> For permanent total disability, 257 weeks is the minimum duration, and \$271 per week is the lowest payment level. The minimum permanent partial disability package is 200 weeks at \$126 per week. These figures indicated that 7.82 people, or 1.77% of the impaired population, would have to become fully disabled for the cost of the latex-safe option to equal that of the status quo for the tertiary-care facility; 4.70% of the population would have to become permanently partially disabled.

The lowest estimate of sustained impairment from studies of IgE-mediated occupational asthma is 29% of the exposed population.<sup>27</sup> If latex allergy follows a similar impairment pattern and if all impairment translates into permanent partial disability, the cost of workers' compensation would rise to \$7.9 million for the tertiary-care facility. If durable nitrile is the required non-latex substitute, converting to latex-safe would cost \$1.4 million more than the status quo for the tertiary facility. However, only 3% of those at risk would have to become disabled for the latex-safe option to remain preferable financially.

## Discussion

When only glove costs were considered, our data indicated that a latex-safe approach was more expensive for each facility than was continued latex glove use. Additional glove costs were highest for the tertiary-care hospital, which used the most sterile gloves. Although institutions may not have identified latex-allergic workers at this point in time, existing data indicate the presence of individuals with early stages of disease.<sup>1</sup> The impairment and disability that may accompany latex allergy introduce disability costs into the financial decision about whether an institution should become latex-safe.

Partial disability costs may arise as workers with a diagnosis of occupationally induced latex allergy or asthma move to jobs that minimize their contact with latex. If these jobs pay less, workers will be eligible for workers' compensation. In other cases, workers may become so sensitized to latex that employment is not possible because of the ubiquitous nature of latex. Catastrophic anaphylactic reactions are also possible.

At present, the former scenario of partial disability and job change seems more likely than the latter ones involving total disability. Both types, however, are possible and would entail significant expense for the health care institution. From a financial standpoint, the institution must determine whether the known increased expense of the latex-safe approach is preferable to possible disability payments.

Data here indicate that the break-even points for the 3 health care institutions are at extremely low rates of permanent disability. For the tertiary-care facility, if more than 1.07% of those at risk (5 people) become fully disabled or more than 1.88% (9 people) become partially disabled, the latex-safe approach would be cost saving.

These results were based on Georgia's very conservative workers' compensation benefits. Evidence from 3 types of facilities

**TABLE 4—Break-Even Analysis for the Costs of Disability Due to Latex Allergy and Asthma From Continued Latex Use Compared With the Costs of Converting the Facility to be Latex-Safe**

	Tertiary-Care Hospital	Community-Based Hospital	Outpatient Clinic
Additional costs of becoming latex-safe, \$	515 789	117 468	48
At-risk pool of workers	442	208	2
Average diagnostic costs per worker, \$	241	241	241
Total disability wage replacement and diagnostic costs per worker, \$	109 158	109 158	109 158
Partial disability wage replacement and diagnostic costs per worker, \$	62 229	62 229	62 229
Break-even no. of people on total disability	4.73	1.08	0.0004
Percentage of at-risk pool	1.07	0.45	0.02
Break-even no. of people on partial disability	8.29	1.89	0.0008
Percentage of at-risk pool	1.88	0.78	0.04

in Georgia and the sensitivity analysis showed that very low levels of disability are required to make the latex-safe approach financially preferable even in cases in which benefits are limited. In states with more generous benefits, converting to a latex-safe environment would be financially advantageous at even lower disability levels.

Many other costs that would favor the latex-safe conversion were excluded. In particular, possible patient-related liability costs were not included. Excluded costs would be offset, to some degree, by the transaction costs of changing practices within a facility. However, a few institutions have made the transition to latex-safe environments. Their experiences could help others reduce transition costs.<sup>12</sup>

The costs of temporary disability were not included in the current analysis. Latex-allergic workers must be removed from exposure. Resulting job changes are likely to be permanent, not temporary. Excluding any costs associated with temporary disability increases the degree to which the costs of the status quo are underestimated.

A few institutions have partially converted their facilities by making the areas that use nonsterile gloves, primarily nonsurgical areas, latex-safe. Our data indicate that 96% to 99% of glove use involves nonsterile gloves and suggest that conversions that focus on nonsterile gloves can greatly affect levels of latex antigens in the environment.

Others have advocated a switch to powder-free latex gloves only.<sup>29</sup> In the community hospital, substituting powder-free nonsterile latex gloves for powdered gloves would increase annual glove costs by \$73 000. Using powder-free gloves would significantly reduce the amount of latex antigen in the environment. However, it would increase the cost of converting to a latex-safe environment and would not protect patients or those already sensitized to latex, or prevent continued sensitization.

This study found that 3 health care facilities of varying size and orientation are likely to benefit economically from becoming latex-safe by using nonlatex gloves. Latex allergy appears to be a rare case in which primary prevention will likely prove to be cost saving. The applicability of these findings is limited by the effect of state-to-state variability in workers' compensation laws and by whether the facility self-insures. For those facilities that self-insure, the calculations presented here can be easily reproduced with data from their purchasing departments and the parameters established by their states' workers' compensation laws. □

### Contributors

V.L. Phillips and M.A. Goodrich together planned the study, collected and analyzed the data, and wrote the paper. V.L. Phillips revised the paper several times. T.J. Sullivan contributed to discussions about the study and commented on several drafts of the paper.

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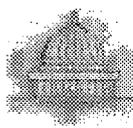
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Joan Claybrook, President

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.<sup>1</sup> 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.

1

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.



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## FAX MESSAGE

**From:** Sid Wolfe

**To:** Richard Hamilton, Ph.D.

**Date:** 7/6/95

**Fax No.** 410-570-2030

**No. of pages, including cover** 15

**Message:**

Ralph Nader, Founder

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## **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.<sup>2</sup> 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.<sup>3,4</sup> In the study in 1947,<sup>4</sup> 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.,<sup>5</sup> 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.<sup>6</sup> 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.<sup>7,8</sup> When cornstarch gains access to the peritoneal cavity, it can cause granuloma formation, adhesion formation and peritonitis.<sup>9,10,11,12</sup> The development of cornstarch induced adhesions can produce intestinal obstruction, infertility, and pelvic pain.

Other documented adverse reactions to cornstarch include endophthalmitis,<sup>13</sup> post-thoracotomy syndrome,<sup>14</sup> meningismus after craniotomy,<sup>15</sup> retroperitoneal fibrosis,<sup>16</sup> and synovial inflammation.<sup>17</sup>

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<sup>18</sup> 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<sup>19</sup> 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.<sup>20</sup> This technique reduced the median number of starch granules per mm<sup>2</sup> 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,<sup>21</sup> 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,<sup>22,23,24,25,26,27,28,29,30,31</sup> 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.<sup>22-29</sup> 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.<sup>32</sup> (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.<sup>33</sup> More recently, a 1996 study found that 5.5% of hospital personnel were positive for latex specific IgE antibody using a radioallergosorbent test.<sup>34</sup> 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.<sup>35,36</sup>

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,<sup>37</sup> who identified a significant interaction between latex proteins and cornstarch powders. Further, Tomazic et al. showed that cornstarch binds latex proteins.<sup>38</sup> 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.<sup>39</sup> 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.<sup>38</sup> 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.<sup>40</sup> 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.<sup>41</sup> 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.<sup>39</sup> 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.<sup>42</sup>

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.<sup>1</sup> 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.<sup>43</sup> 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.<sup>44</sup>

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.<sup>45</sup> 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.<sup>46</sup> 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 Yunginger, 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.<sup>47</sup>

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 required.<sup>20</sup>

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)

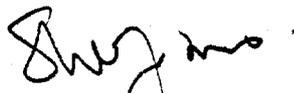
The OR project coordinator at Methodist Hospital reported similar findings with respect to the cost of switching to powder-free gloves, stating that "Latex allergies tend to strike the health care professionals with the most experience, and that is more costly than any additional expenses to a glove 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,

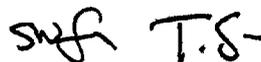


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Medicine, Emory University  
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the Emory Clinic

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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.<sup>1</sup> 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?"<sup>2</sup> 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 aeroallergen 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

outlawed 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.<sup>3</sup> 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 allergenic latex proteins.<sup>4</sup> Latex proteins are easily absorbed to the cornstarch powder, and are aerosolized at levels comparable to those of other occupational respiratory allergens.<sup>5-7</sup> 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.<sup>7</sup> When all coworkers have switched to powder-free latex gloves, health care 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,<sup>8</sup> 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.<sup>9</sup> 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.

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**—APPENDIX B**

**JACKSON MEMORIAL HOSPITAL**

**Miami, FL**



1611 N.W. 12th Avenue  
Miami, Florida 33136-1094

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## 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.

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 reoccurrence 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 anaphylatic 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 \$1600 and each event involved at least two weeks of lost time. Two workers compensation settlements exceeded \$100000 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 \$250000 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 todays 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 todays 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 M. Breeden, R. N. COHN-S  
Assistant Administrator  
Employee Health Services

ABwdos/latex2

**FACSIMILE COVER SHEET**

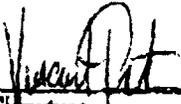
**TO:** Anna Maxine Patton  
Interactive Media Specialist for Medical Products and Education

**TEL#:** 804 924 0424/ 804 973 6085

**FAX#:** 804 973 0767

**FROM:** Mr. Vincent Petri  
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 web site to be located at <http://www.deadlydust.com>.

  
\_\_\_\_\_  
Signature

Director of Public Affairs  
\_\_\_\_\_  
Title

7/11/97  
\_\_\_\_\_  
Date

**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

*7-8-97*

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 25<sup>th</sup> 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 powderfree 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 of our 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 environments 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 powderfree 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 powderfree 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 Maxxim 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 powderfree 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 to 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 2:00am, a group of people from the Latex Safe Task Force came in to 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 powderfree 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 Maxxim 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 nailed 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!

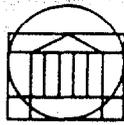
In conclusion, I would encourage you to communicate, communicate, communicate, before you implement, and then once you implement your changes, communicate some more, because there will still be people who have never heard about latex allergies. Also, to this day, I still find latex powdered gloves that come out of the woodwork. For the price of commitment and persistence, we were able to keep our tenured 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*

Rhonda Anders, RN  
OR Product Coordinator  
Methodist Hospital of Indiana

UNIVERSITY OF VIRGINIA



HEALTH  
SCIENCES  
CENTER

DEPARTMENT OF PLASTIC SURGERY

—APPENDIX D—

December 7, 1995

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

Dear Mr. Kroehling:

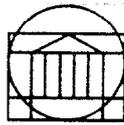
The toxic affects of cornstarch lubricants on surgical gloves are well known to the Food and Drug Administration. Repeated clinical and experimental studies have demonstrated that the cornstarch lubricants on surgical gloves can cause peritonitis, adhesions, and granulomas. Our recent studies have demonstrated 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

*Appendix*

UNIVERSITY OF VIRGINIA



HEALTH  
SCIENCES  
CENTER

DEPARTMENT OF PLASTIC SURGERY

December 14, 1995

—APPENDIX E—

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.

*Appendix*

Ms. Mary Brady  
Page 2  
December 14, 1995

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

—APPENDIX F

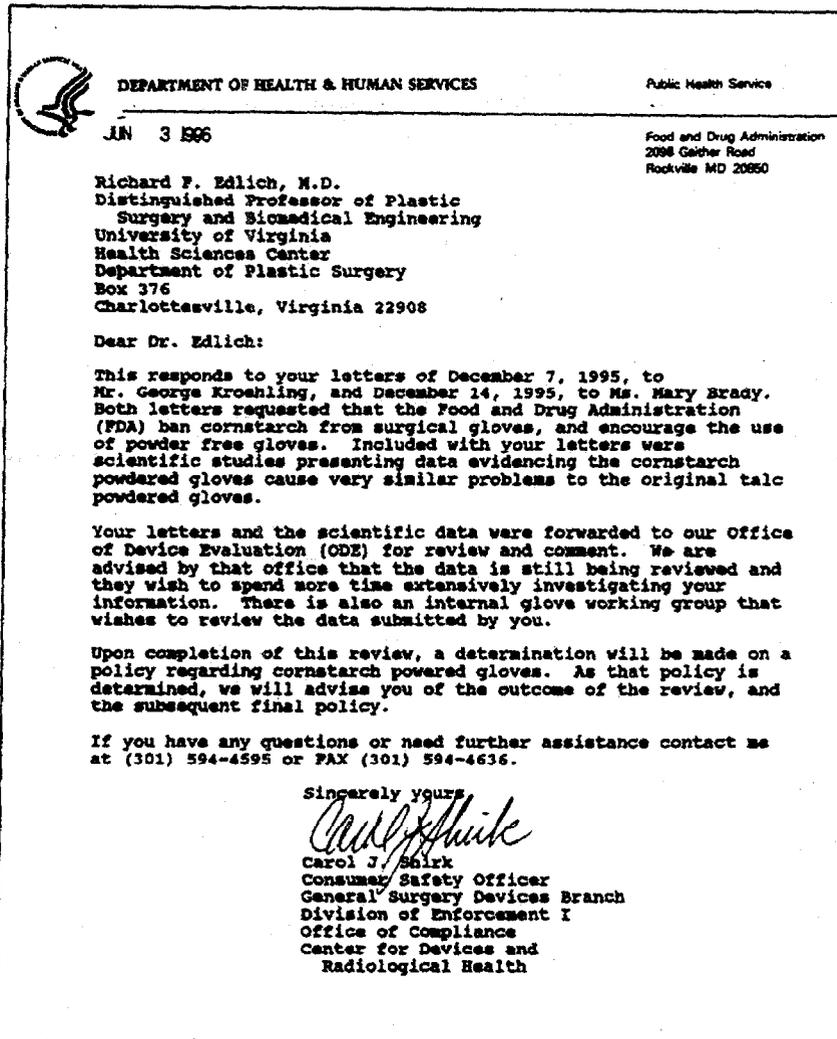


Figure 8.1 Letter from Carol J. Shirk, Consumer Safety Officer of the Food and Drug Administration, June 3, 1996.

Appendix

# Public Citizen



## NEWS RELEASE

Embargoed Until:  
11 am EST January 7, 1998

Contact: Dr. Sidney Wolfe 202 588-1000  
or Brian Dooley 202 588-7703

### **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 the 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.*

NEW YORK (CNNfn) - Dow Corning Corp. Tuesday proposed a new \$4.4 billion settlement to compensate its creditors and the thousands of women allegedly injured by silicon-gel breast implants.

However, the proposal -- which still needs the approval of U.S. Bankruptcy Judge Arthur Spector, who oversees Dow Corning's nearly three-year-old bankruptcy -- received mixed reaction and could potentially cause a row between the creditors and the female plaintiffs, collectively known as the tort claimants.

Under the plan, the Midland, Mich.-based Dow Chemical Co./Corning Inc. venture proposed to put up its own equity to finance the tort group's claims. The latest offer tops an August offer by at least \$640 million.

The proposal also would split up the tort claimants into two groups: those women who wish to settle and those who wish to litigate. The plan would establish a litigation trust -- financed with the help of Dow Corning's equity value -- as well as a settlement trust, with \$3 billion targeted primarily at resolving breast implant claims.

About \$1.4 billion of the \$4.4 billion would be used to satisfy the claims of commercial creditors, a group that is encouraged by the proposal.

"I'm very encouraged because I think this is a serious proposal that warrants a serious response from the [tort] claimants and it represents a substantial step forward in the case," said Donald Bernstein, a lawyer at Davis Polk & Wardwell, who represent a key group of creditors.

Creditors were evaluating the proposal and declined to issue an official comment.

However, the proposal received harsh criticism from the tort claimants. Based on initial evaluations, the plan would pay most of the women \$10,000 or less if they choose to settle, a spokeswoman said. In addition, final payment could take as much as 10 years.

"Instead of real compensation to these women, Dow is offering token payments years down the road," said Ed Blizzard, plaintiffs' counsel. ▀

-- by staff writer Robert Liu



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Message Printout Requested by Benita Adler at 2/17/98 12:43 pm

Date Sent: Friday, February 06, 1998 10:55 AM  
From: BERNICES@SMTP (Samuels, Bernice) {BerniceS@bdg10.niddk.nih.gov}  
To: BADLER@CITIZEN (Benita Adler)  
Subject: Women's Health Information Center

Dear Benita - A possibly helpful website for your work. Bernice

-----  
FORWARDED FROM: Samuels, Bernice  
Microsoft Mail v3.0 (MAPI 1.0 Transport) IPM.Microsoft Mail.Note  
From: HHS News  
To: NIH-STAFF@LIST.NIH.GOV  
Subject: Women's Health Information Center  
Date: 1998-02-04 22:51  
Priority: 3  
Message ID: 3D4DA348E09DD111869D00805FEACCE5  
-----

NEW NATIONAL WOMEN'S HEALTH INFORMATION CENTER NOW  
OPEN FOR TESTING!

1-800-994-WOMAN or <http://www.4woman.org>

The U.S. Public Health Service's Office on Women's Health (PHS OWH) invites you to test our new National Women's Health Information Center, (NWHIC) during the month of February! Through a toll-free phone number and the Internet, the NWHIC acts as a federal "Woman's Health Central" for the public, health care professionals, educators, researchers and women in the military. By organizing the vast array of health information for women to a single point of entry, the PHS OWH hopes that women will have easier access to information from Federal Health Clearinghouses within the DHHS, and hundreds of private sector organizations. ?

If you have a question about women's health in general or about a specific program, concern, or disease, you can call 1-800-994-WOMAN. Our specially trained health information specialists will be happy to provide the information to you. You can also access our website at <http://www.4woman.org>.

Once you have made the connection with our new service, we would like to hear your feedback! Were the specialists helpful? Were you able to get your questions answered? Is the web-site user-friendly? Do you have any suggestions on how we can improve the service? You can give us feedback by e-mailing us via our FEEDBACK option on the website, or by calling the PHS OWH office at 202-260-9275. We hope this pre-test period will give the PHS OWH the information it needs to make this a truly useful service for women, as well as help us assess the impact of the service on other federal health agencies.

We would like to officially launch this new service in March/April. Please help us reach that goal by testing and letting us know how it works.

The National Women's Health Information Center (NWHIC) is a joint project of the U.S. Public Health Service's Office on Women's Health, within the Department of Health and Human Services, and the Department of Defense Women's Health Research Program.

PLEASE GIVE IT A TRY AND LET US HEAR FROM YOU!

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](http://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 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 air borne. 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 some one 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 powdered 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 aeroallergens 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**

**Center for Devices and Radiological Health**

[\[Go Back To Results\]](#) [\[Previous Doc\]](#) [\[Next Doc\]](#) [\[New MDR Search\]](#)

**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:**

[\[Go Back To Results\]](#) [\[Previous Doc\]](#) [\[Next Doc\]](#) [\[New MDR Search\]](#)

**Center for Devices and Radiological Health**

[\[Go Back To Results\]](#) [\[Next Doc\]](#) [\[New MDR Search\]](#)

**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.

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**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.

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**Access Number:** M381542

**Date Received:** 04/12/93

**Product Description:** MICROTOUCH LATEX SURGICAL GLOVES

**Manufacturer Code:** JOHNJOHNPROD

**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 PHYSIOLOGICAL 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.

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**Access Number:** M711384

**Date Received:** 05/19/95

**Product Description:** MICRO-TOUCH LATEX MEDICAL GLOVES

**Manufacturer Code:** JOHNJOHNPROD

**Manufacturer Name:** JOHNSON & JOHNSON MEDICAL, INC.

**Address:** 2500 ARBROOK BLVD. P.O. BOX 90130

**City:** ARLINGTON

**State:** TX

**ZipCode:** 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.

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**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

**ZipCode:** 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 REPIRATORY 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.

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**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

**ZipCode:** 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.

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**Access Number:** M407776

**Date Received:** 08/30/93

**Product Description:** PERRY LATEX SURGICAL GLOVES

**Manufacturer Code:** SMITNEPHPERR

**Manufacturer Name:** SMITH & NEPHEW PERRY

**Address:** 1875 HARSH AVENUE SE

**City:** MASSILLON

**State:** OH

**ZipCode:** 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.

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**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

**ZipCode:** 60085

**Report Type:** MALFUNCTION

**Model Number:** NA

**Catalogue Number:** 2Y1504

**Panel Code:** GENERAL HOSPITAL

**Product Code:** LYY

**Event Type:** FINAL

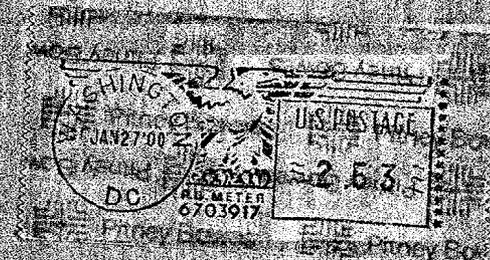
**Event Description:** GLOVE USER DEVELOPED A RASH ON BOTH  
HANDS AFTER WEARING GLOVES THAT WERE MADE IN  
MALAYSIA. THE GLOVE USER HAD WORN THIS TYPE OF GLOVE  
THAT WAS PREVIOUSLY MADE IN THE USA WITHOUT INCIDENT  
FOR SEVERAL YEARS. THE USER CHANGED TO A POWDER FREE  
GLOVE THE RASH CLEARED UP AND 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.

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