April 25, 2011

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.
Director, Center for Devices and Radiologic Health
Food and Drug Administration
Department of Health and Human Services
WO 66, Room 5442
10903 New Hampshire Avenue
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Dear Drs. Hamburg and Shuren,

Public Citizen, a consumer advocacy group representing more than 225,000 members and supporters nationwide, hereby petitions the Food and Drug Administration (FDA), pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 USC § 360f, and 21 CFR §§ 10.30 and 865, to immediately (a) ban the use of cornstarch powder on all surgeon’s and patient examination gloves, and (b) ban the use of all natural latex rubber surgeon’s and patient examination gloves, because of the serious threat posed by these products to patients and healthcare workers and the ready availability of widely used safer alternatives (i.e., powder-free synthetic gloves).

On January 7, 1998, Public Citizen and Dr. Timothy Sullivan, Professor of Medicine at Emory University School of Medicine and Head of the Subsection of Allergy and Immunology at the Emory Clinic, petitioned the FDA to immediately ban the use of cornstarch in the manufacture of latex surgeon’s and patient examination gloves because of the well-recognized serious and widespread dangers these gloves cause to both medical personnel and to patients and the availability of safer alternative.¹ In a July 30, 1999 Federal Register notice (64 FR 41790-41743, docket number 98N-0313), the FDA rejected our petition and instead proposed regulations to reclassify surgeon’s and patient examination gloves as class II devices requiring special controls.² The proposed special controls included new labeling that would warn users about possible allergic reactions to latex and the fact that glove powder is associated with adverse reactions.
More than a decade later, these proposed regulations have not been finalized (although promulgation of such regulations would not have been sufficient to address the dangers posed by powdered gloves). In response to FDA’s inaction, Dr. Richard Edlich and colleagues on September 28, 2006 and Dr. Wava Truscott on February 24, 2009 submitted separate petitions to the FDA requesting a ban on the use of cornstarch powder on surgical and patient examination gloves.

The FDA’s prolonged failure to take action eliminating the dangers posed by powdered surgeon’s and patient examination gloves demonstrates an astonishingly reckless and inexcusable disregard for the health and safety of patients and healthcare workers. The available scientific evidence and market circumstances today provide overwhelming and irrefutable justification for granting our petition.

I. BACKGROUND

A. Regulatory status of glove powder

Absorbable powder for lubricating a surgeon’s glove is a class III medical device (21 CFR § 878.44803, product code KGP). A person intending to market absorbable powder for lubricating a surgeon’s glove must submit a premarket approval application to the FDA prior to its introduction into interstate commerce (21 CFR § 878.4480(c)).

B. Regulatory status of surgical and patient examination gloves

Medical gloves, including surgeon’s and patient examination gloves, are used to prevent transmission of a wide variety of diseases to both patients and healthcare personnel. They are class I medical devices and are subject to general controls.

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner’s hand or finger to prevent contamination between patient and examiner. The product codes for patient examination gloves are LYY for latex glove, LYZ for vinyl (PVC) gloves, LZA for polymer gloves other than vinyl, LZB for finger cot gloves, and LZC for chemotherapy gloves.

A surgeon’s glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. This excludes the lubricating or dusting powder used in the glove. All surgeon’s gloves have the product code KGO.

II. STATEMENT OF GROUNDS

A. Risks of powdered surgical and patient examination gloves

The dangers posed by powdered surgical and patient examination gloves have been widely recognized throughout the medical profession and the world for many years and are indisputable. The evidence from the medical literature demonstrating these risks
was summarized in detail in our 1998 petition and in the subsequent citizen’s petitions submitted by Dr. Richard Edlich and his colleagues on September 24, 2008 (docket number FDA-2008-P-0531)\(^7\) and by Dr. Wava Truscott on February 24, 2009 (docket number FDA-2009-P-0117),\(^8\) and will not be reiterated here.

To summarize, when cornstarch is deposited in tissues at the time of surgery, it can result in foreign-body disease, resulting in the following harms to patients:

- Promotion of wound infections;
- Delayed wound healing;
- Granuloma formation in the peritoneal cavity, resulting in adhesions and peritonitis;
- Intestinal obstruction, pelvic pain, and infertility secondary to peritoneal adhesions;
- Endophthalmitis;
- Post-thoracotomy syndrome;
- Meningismus after craniotomy;
- Retroperitoneal fibrosis; and
- Synovial inflammation.

For healthcare workers, the major risk is allergic reactions to latex, some of which can are serious and life-threatening. For many healthcare workers, sensitization to latex and subsequent allergic reactions results from exposure to aerosolized cornstarch powder bound to latex proteins which have been released from latex gloves. These allergic reactions include:

- Contact dermatitis and urticaria;
- Rhinitis;
- Conjunctivitis;
- Asthma; and
- Anaphylactic shock.

While allergic skin reactions to latex gloves most frequently result from direct contact between the glove and the skin in a latex-sensitized individual, the other types of allergic reactions result from exposure to aerosolized cornstarch powder bound to latex allergens in a latex-sensitized individual. As a result, serious allergic reactions can occur in healthcare workers even when they avoid wearing powdered latex gloves because other workers may be wearing such gloves. Likewise, allergic reactions can occur in patients exposed to aerosolized cornstarch powder from latex gloves in the environment of healthcare facilities.

Because of FDA’s failure to ban powdered latex gloves in response to our 1998 petition, untold numbers of preventable serious injuries have continued to occur to both patients and healthcare workers exposed to these extremely dangerous products.
B. Risks of powder-free latex gloves

Even powder-free latex gloves pose risks of serious allergic reactions, including contact dermatitis, urticaria, rhinitis, and anaphylaxis, to healthcare workers and patients sensitized to latex, some of which are life-threatening. In some cases, these allergic reactions may be due to previous sensitization to latex from exposure to aerosolized cornstarch powder bound to latex allergens.

Our review of the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database reveals that since 2005 FDA has received the following reports of serious allergic reactions in nine healthcare workers and one patient exposed to powder-free latex gloves:

- Seven reports of serious allergic skin reactions in healthcare providers;\(^9,10,11,12,13,14,15\)
- One report of allergic rhinitis and conjunctivitis in a healthcare worker;\(^16\)
- One report of a serious allergic skin reaction with anaphylaxis in a healthcare provider;\(^17\) and
- One report of a patient undergoing surgery who died from intraoperative anaphylaxis.\(^18\)

Given that latex allergy has been widely recognized for many years, it is likely that many incidents of allergic reactions secondary to latex gloves, including powder-free latex gloves, go unreported and are not captured by the FDA’s MAUDE database.

C. The FDA’s reasons for rejecting our petition to ban powdered latex gloves

In its July 30, 1999 Federal Register notice, the FDA provided the following three reasons for rejecting our prior petition:

1. A ban would not address exposure to natural latex allergens from medical gloves with high levels of natural latex proteins;
2. A ban of powdered gloves might compromise the availability of high quality medical gloves; and
3. A ban might greatly increase the annual costs by almost as much as $64 million over the alternative approach proposed by the FDA.\(^19\)

These reasons for rejecting our petition were not valid in 1999, and, as discussed below, additional evidence has accumulated which invalidates these arguments definitively.

Regarding the first reason presented by FDA, elimination of cornstarch powder from surgeon’s gloves would eliminate the occurrence of foreign-body disease due to cornstarch powder in patients undergoing surgery and other invasive medical procedures. A ban would have also eliminated most allergic reactions, particularly the
most serious such as allergic asthma and many cases of anaphylaxis, which result from exposure to aerosolized cornstarch powder bound to latex allergens.

We agree with the FDA that simply banning the use of cornstarch powder in surgeon’s and patient examination gloves would not address the serious allergic reactions that can still occur in patients and healthcare workers who are exposed to powder-free latex gloves. Therefore, given the serious risks posed by powder-free latex gloves, we are also now petitioning FDA to ban the use of all latex gloves as well.

D. Many hospitals have transitioned successfully to powder-free and/or non-latex gloves

In our 1998 petition, we noted that three hospitals – Brigham and Women’s Hospital in Boston (1993), Jackson Memorial Hospital in Miami (1995), and Methodist Hospital in Indianapolis (1995-1996) – successfully transitioned to powder-free gloves in response to epidemics of allergic reactions among their healthcare workers due to use of powdered latex gloves.

Since the time of our petition, the number of hospitals in the United States (U.S.) that have switched to powder-free gloves has dramatically increased. Jackson et al in 2000 reported identifying 70 hospitals in 21 states that had transitioned to powder-free gloves. Additional major medical centers and healthcare systems that have eliminated the use of powdered latex gloves because of risks to their patients and employees include Kaiser Permanente, which has multiple hospitals across the country, Legacy Healthcare System in Washington and Oregon, and Geisinger Medical Center in Pennsylvania. For many of these institutions, the transition to powder-free gloves likely involved increased use of gloves that were non-latex as well.

Several hospitals also have transitioned to using only latex-free surgeon’s and patient examination gloves, including the Johns Hopkins Bayview Medical Center, the Johns Hopkins Hospital in Baltimore, and the Cleveland Clinic. In the case of the Johns Hopkins Bayview Medical Center, only powder-free synthetic gloves are used.

The total number of hospitals that have made the transition to using only powder-free and/or latex-free gloves during the past decade is certainly much larger than the number of institutions reported in the medical literature.

In addition to actions taken by individual hospitals in the U.S., as well as in other foreign countries, Germany in 1998 banned the use of powdered latex gloves and any latex gloves with high allergen content throughout the country. The actions taken by many individual hospitals and by Germany reflect the near-universal recognition of the dangers posed by cornstarch powdered gloves. They further demonstrate that high-quality powder-free surgeon’s and patient examination gloves are readily available on a large scale and adequate for all medical care activities requiring the use of gloves.

As we noted in our 1998 petition, according to IMS America, powder-free surgical gloves made up 26 percent of the surgical glove market in the second quarter of 1997.
Given the large number of hospital facilities that have transitioned to powder-free gloves since our 1998 petition to the FDA, the percent of the surgical glove market must have expanded significantly over the past 14 years. The number of companies making powder-free gloves also has likely increased. Glove manufacturers clearly recognize that healthcare facilities in ever greater numbers have transitioned to powder-free gloves and have adjusted production accordingly.

Furthermore, even the FDA, in estimating the compliance costs for its July 30, 1999 proposed rule, stated the following:

...industry comments suggest that even in the absence of this regulation, the market share of powder-free gloves is expected to increase from 35 percent to about over 80 percent over a 4-year period. With regulation, this trend will be accelerated.

Given the above information, it seems highly unlikely that a ban on the use of cornstarch powder as a lubricant for surgeon's and patient examination gloves would compromise the availability of high quality medical gloves, even had it occurred in 1999. Thus, the FDA's second reason for rejecting our 1998 petition to ban powdered latex gloves – "A ban of powdered gloves might compromise the availability of high quality medical gloves" – is clearly not valid today, nor was it valid in 1999. Furthermore, it is likely that the market can provide sufficient supplies of synthetic gloves if FDA bans the use of all latex gloves.

Of note, multiple glove manufacturers opposed many of the proposed additional controls and requirements on surgeon’s and patient examination gloves in the FDA’s July 30, 1999 notice of proposed rulemaking. In contrast, more recent FDA docket established for comment on the risks and benefits of powdered gloves and on the more recent citizen’s petitions from Dr. Edlich and his colleagues and from Dr. Truscott (76 FR 6684, docket number FDA-2011-N-0027) as of 4:00 PM EST today had no comments posted from glove manufacturers.

One comment to the docket for Dr. Edlich’s 2008 petition (docket number FDA-2008-P-0531) submitted by the Malaysian Rubber Export Promotion Council opposed a ban on powdered latex gloves.

To protect patients and healthcare workers from the risks of exposure to cornstarch, FDA must finally follow the lead of these hospitals and German officials by taking immediate action to ban cornstarch as a lubricant for surgical and patient examination gloves.

E. When hospitals transition to powder-free gloves, workers compensation claims decrease, saving money

The third reason given by the FDA for rejecting our 1998 petition to ban powdered latex gloves was that such a ban might greatly increase the annual costs by almost as much
as $64 million over the alternative approach proposed by the FDA. Such projected costs are likely no longer valid today given the transition of many hospitals to powder-free and/or latex-free gloves. Furthermore, multiple studies have shown significant benefits to the occupational health and safety of healthcare workers resulting in decreased worker compensation claims.\textsuperscript{31,32,33,34} Thus, any costs due to the greater expense of powder-free synthetic gloves are likely to be more than offset by decreased costs from lower worker compensation claims, employee sick days, occupational health clinic visits, and early retirements due to permanent disability from latex allergies.

For example, Canadian researchers looked at the number of claims allowed for occupational asthma due to latex exposure by the Ontario Workplace Safety and Insurance Board before and after implementation of educational programs designed to limit latex exposure and transition to powder-free latex gloves at Ontario Hospitals. The researchers found a dramatic drop in the number of allowed asthma claims for healthcare workers after the transition to powder-free gloves.\textsuperscript{31} In a related study, these same investigators showed that following implementation of an education program and transition to low-protein, powder-free latex gloves, the number of latex allergy diagnoses, including asthma and anaphylaxis and the number of visits to the occupational health department for perceived latex allergy illness decreased dramatically. They also reported that there was no increased in glove costs with the transition as a result of consolidated glove purchases.\textsuperscript{32}

Researchers in Germany studied the impact of the 1998 German regulation banning powdered latex gloves by assessing the development of occupational skin disease caused by latex gloves in healthcare workers at facilities insured by the German statutory accident insurance company, which covered 1.8 million insured healthcare workers. They compared trends in the number and type of latex gloves purchased in acute care hospitals to trends in the annual number of reported suspected cases of latex-induced occupational allergies (mainly contact urticaria). The number of suspected cases increased until 1998 as did the number of latex gloves purchased. After 1998, with legally required transition to powder-free latex gloves, the number of suspected cases of latex allergy decreased 80 percent from 1998 to 2002.\textsuperscript{33}

Finally, researchers at Geisinger Medical Center in Danville, Pennsylvania examined trends in workers’ compensation claims for latex-related illness during the five years before and five years after transition to powder-free latex gloves at their medical center. The claim incidence per 1,000 workers at risk was 2.92 before the transition and 0.92 after the transition; the average yearly incidence was 3.16 times higher before the transition (95 percent confidence intervals, 1.87-5.34; p=.001). The mean annual payment to claimants was $34,789 before the transition and $2,505 after.\textsuperscript{34}

These studies indicate that healthcare facilities are likely to benefit financially by transitioning to powder-free, latex-free surgeon’s and patient examination gloves as the result of decreased workers’ compensation claims, employee sick days, occupational health clinic visits, and early retirements due to permanent disability related to latex allergies.
F. Widespread support for a ban on powdered surgeon's and patient examination gloves

Since the time of our initial petition in 1998, there has been widespread support in the medical and patient communities for a ban on the use of powder as a lubricant in surgeon's and patient examination gloves. The major opposition to such a ban had previously come from glove manufacturers, although even they more recently seem to realize the time has come for such a ban.

A review of the comments submitted to the FDA between February and August of 1998 in response to our petition (FDA docket number 1998P-0008) reveals that more 700 individual consumers strongly supported an immediate ban of powdered latex gloves, whereas only a handful of commenters voiced opposition.\(^{35}\)

Likewise, most individual consumers and several organizations representing a variety of healthcare professionals who submitted comments to FDA in response to its July 30, 1999 notice of proposed rulemaking regarding surgeon's and patient examination gloves (76 FR 6684, docket number FDA-2011-N-0027) strongly supported restrictions, if not a complete ban, on the use of cornstarch powder in gloves, whereas glove manufacturers, with a few exceptions, opposed such actions or wanted to see more limited action.\(^{36}\) The following are excerpts of these earlier comments made by professional organizations:

- **The American College of Surgeons:**

  The FDA is considering a future requirement that all surgeons' and patient gloves marketed in the U.S. be powder-free. The College agrees with the recommendation and believes there is no reason to continue the use of powdered gloves. Indeed, the elimination of powdered gloves will significantly lower the risk of allergic reactions. By making powder-free gloves the standard, the FDA will reduce the incidence of allergic reactions from airborne protein particles carried to the medical staff using them and to the patient.

- **Task Force on Latex Sensitivity of the American Society of Anesthesiologists’ Committee on Occupational Health:**

  FDA is considering a future requirement that all surgeon's and patient examination gloves marketed in the United States should be powder-free. The Task Force agrees that this is a desirable goal for protecting the health of both patients and healthcare providers.

- **The American College of Allergy, Asthma & Immunology:**

  Every year some 15,000 new medical students and 70,000 nursing students enter medical training environments we now know will sensitize a
significant fraction. Some 6 million health care personnel already work in such environments. These same current work environments can cause significant, sometimes career ending occupational allergic diseases. As documented in the petition and as summarized in the recent CDC review of latex allergy among health care personnel, a minimum of 300,000 health care personnel are now allergic to natural rubber latex. A conservative estimate of the prevalence of latex powder-induced occupational asthma among health care personnel is 120,000. Definitive steps must be taken to end this epidemic.

The 1997 NIOSH ALERT – Preventing Allergic Reactions to Natural Rubber Latex in the Workplaces – states, "If you choose latex gloves, use powder-free gloves with reduced protein content." [Emphasis in original].

- American Nurses Association:

  FDA should require all surgeon's and patient examination gloves marketed in the U.S. be powder-free and limit the amount of protein to 600 micrograms per glove.

- Emergency Nurses Association (ENA):

  ENA believes FDA's goal should be to eliminate the use of powder on gloves, and to do so as soon as possible. After more than two decades of exhaustive research, the literature is replete with studies that document adverse health effects of powder, namely, allergic sensitization and reactions, foreign body reactions, irritation, and infection. It is ironic that powder-free gloves are used for the assembly of sensitive computers, but not for use inside the bodies of human beings.

- New York State Nurses Association (NYSNA)

  In response to the FDA's Specific Request for Comments, NYSNA would support a requirement that all surgeon and patient examination gloves be powder-free and the proposed recommendations on powder and protein limits becoming requirements.

The following comments from some glove manufacturers suggest that even some glove manufacturers recognize the dangers of powdered gloves:

- London International Group, Inc.:

  Recently we have participated in a HIMA group of medical glove companies drafting comments to the FDA on the proposal to reclassify medical gloves from Class I to Class II devices. HIMA will be sending
these comments to FDA this week. These comments by HIMA represent a consensus of the participants and not unanimity of opinion of HIMA's members....There are many points in the HIMA comments with which we agree.... We cannot, however, agree with the extreme position taken by HIMA in its comments regarding the safety of gloves powder. As has long been our position, Regent Medical believes that there is a significant body of scientific evidence regarding the contribution of starch powder to postoperative complications and latex allergies.

- Reichhold, Inc.:

In item #8, the FDA states the objective of reducing adverse health effects by controlling the levels of water-extractable protein and glove powder on natural latex gloves, and requests comments on feasible alternative approaches to achieve these objectives. Reichhold submits that feasible alternatives exist, namely powder free synthetic gloves, and more specifically, powder free nitrile gloves. Nitrile gloves have elastomeric and barrier properties similar to, or superior to natural latex gloves for medical use. We recommend that the FDA promote the use of synthetic nitrile gloves for medical glove applications. [Emphasis in original]

It is also interesting to note that Ansell Healthcare Products, Inc., a major manufacturer of medical gloves in the U.S., opposed many provisions of the FDA’s July 30, 1999 proposed regulations, but more recently issued a document describing 10 good reasons to use powder-free gloves. 37

Finally, in reviewing the public comments submitted in response to the FDA’s request for comments on the petitions submitted by Dr. Edlich et al and by Dr. Truscott, the FDA asked if there were any unique benefits provided by cornstarch powdered gloves. Our review of the literature and the public comments submitted in response to FDA’s FR posted in docket number FDA-2011-N-0027 reveals no arguments of any unique benefit provided by cornstarch powdered gloves.

III. SUMMARY OF REQUESTED ACTIONS

Public Citizen hereby petitions the FDA, pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 USC § 360f, and 21 CFR §§ 10.30 and 895, to immediately (a) ban the use of cornstarch powder on all surgeon’s and patient examination gloves, and (b) ban the use of natural latex rubber surgeon’s and patient examination gloves, because of the serious threat posed by these products to patients and healthcare workers and the ready availability of widely used safer alternatives (i.e., powder-free synthetic gloves).

The time has finally come for FDA act in the interests of public health, rather than the interests of cornstarch powdered and latex glove manufacturers, and take action to protect the health of patients and healthcare workers by banning the use of cornstarch
powder on surgeon's and patient examination gloves, as well as by banning all latex surgeon's and patient examination gloves. Given the serious threat posed by these products, it is not reasonable for FDA to rely upon the marketplace as the mechanism for removing them from use in the healthcare system.

We also note that FDA has proposed placing a warning on the packaging of powdered latex gloves. Such an action is grossly inadequate for dealing with this problem and likely would have little to no impact on this serious problem which is already widely recognized throughout the medical profession. Furthermore, the warning would not be visible to most users of gloves in the healthcare setting. Such a proposal would be laughable if the problem were not so serious for patients and healthcare providers alike.

IV. ENVIRONMENTAL IMPACT STATEMENT

Nothing requested in this petition will have an impact on the environment.

V. CERTIFICATION

We certify that, to the best of our knowledge and belief, this petition includes all information and views on which this petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen Health Research Group

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16 Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of allergic rhinitis and conjunctivitis reaction on March 13, 2007 associated with use of Cardinal Health TXT
Positive TCH Latex Powder Free Examination Gloves.
Accessed April 25, 2011.

Accessed April 25, 2011.

Accessed April 25, 2011.


Dr. John Harmon. The Johns Hopkins Bayview Medical Center. Personal communication.

Patient safety: Johns Hopkins, Cleveland Clinic ban latex gloves from ORs. OR Manager. 2008;24:1, 12-14.


IMS Hospital Supply Source Index, 2nd Quarter 1997. For that quarter, the total sales of surgical gloves was $170 million, with $44.2 million for powder-free latex gloves.


Food and Drug Administration. Docket number FDA-2011-N-0027.

http://www.regulations.gov/#/searchResults.dct=N+PS:cp=O+C;rpp=50;so=DESC;sb=postedDate;po=0;s =fda-2011-n-0027. Accessed April 25, 2011 at 4:00 PM EST.


