HP 00-2

Latex Allergy New

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Citizen Petition

The Undersigned submits this petition under CFR. Part 1051, "procedures for petitioning for rulemaking" Latex allergy is a progressive allergy that has been recognized in the last ten years. Prior to that it was thought that a very small percent of the population had any kind of reactions or sensitization to Natural Rubber Latex (NRL) With the advent of Universal Precautions by OSHA and the CDCP that changed. There were changes made to speed up the production of NRL products, and this lead to the sensitization of a large percentage of the population.

The FDA recognized that there was a problem, and issued an alert as early as 1991, and now requires labeling on all products that contain NRL. The FDA only mandates the Medical Products need to be labeled. This ruling went into effect in September 1998. There was some question about whether to include consumer products, and it was felt that that was outside the jurisdiction of the FDA. That puts this problem in the hands of the Consumer Products Safety Commission.

A. Action Requested

1. Amendment of sec.1500.13, to add to list of "strong sensitizers, Natural Rubber Latex (NRL) and products containing NRL, and that said substance and products be labeled per sec. 1500.3(A)(2)(12),(13) and (14).

2. In accordance with sec.1500(b)(15)(i), re: "Banned hazardous substances", to require labeling of toys or other articles intended for use by children which may contain NRL under sec. 1500.3(b)(9).

B. Statement of grounds

1. Recent scientific findings indicate that NRL meets CFR criteria for a "hazardous substance" per sec. 1500.3(4)(i)(A), a "strong sensitizer" per sec. 1500.3(b)(9), a "banned hazardous substance" per sec. 1500.3(b)(15)(i) and sec. 1500.3(c)(5)(i) through (v), and sec. 1500.14(B)(9), that details the definition of sensitizers and strong sensitizers that qualify as hazardous substances.

2. The scientific findings described below clearly contradict concensus re: NRL when the list of "Strong sensitizers" in sec. 1500.13 was codified, per the attached page from a report, "Rubber sensitizers" by Susan E. Feinman, Ph.D., sent to Sandra Eberle, Chemical Hazards Program, OPM, on 29, December 1986. Introductory sub-paragraph (A), "Purpose of Report", states, "The purpose of this report is to evaluate whether certain rubber additives are bioavailable from consumer products in sufficient quantities to elicit allergic hypersensitivity responses and whether they should be labeled by the commission as strong sensitizers under the Federal Hazardous Substance Act. Subparagraph (c), "Rubber Sensitization, states, "Natural rubber poses no hazard as a contact allergen (Cronin, 1980)". The subparagraph concludes, "Thus consumers attributing allergic contact dermatitis to "rubber" are actually reacting to rubber additives"

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3 The above earlier conclusion re NRL is obsoleted by the preponderance of reputable research and clinical studies cited in the Food and Drug Administration Final Rule, effective September 30, 1998, 21CFR Part 801, "Natural Rubber Containing Medical Devices: User Labeling" which according to the FDA, "scientific studies and case reports have documented sensitivity to natural latex proteins found in a wide range of medical devices". Re-labeling of "nonmedical NRL gloves and other consumer products that contain natural rubber", the Final Rule states, "The regulation of such products is beyond the scope of this rule. FDA's authority under the act to impose labeling requirements is restricted to products that meet the definition of foods drugs, cosmetics, animal drugs, biologics, and devices, as those terms are defined under the act." The rules adds," FDA also does not agree with the suggestion that OTC Medical devices be exempted from the labeling"

4. The Journal of the Academy of Dermatology (Vol 39, No. 1, July 1998) article, "Latex Allergy", summary states: "Coined the next major health concern of the decade, allergy to natural rubber latex affects people routinely exposed to rubber products. Groups at highest risk include health care workers, rubber industry workers, and persons who have undergone multiple surgical procedures, especially those with spina bifida. Allergy to latex is a type I, immediate, IgE - mediated reaction, which can lead to anaphylaxis and death. Much of latex research is published in allergy journals." The attached Journal article pages 1, 3, 5, 6 and 7, describe common nonmedical household products containing NRL, prevalence of latex allergy in the general and occupational populations; and allergy "risk factors" per attached with reference citation. The prevalence of latex in the general population is probably less than 2%. However, the accompanying Table IV lists six authoritative sources for "percent of positive", using different methods of testing, and the range from 0.8% to 7.9%. Pages 5 and 6 and Table V cite studies reporting much higher latex sensitivity rates among certain populations: "Children with Spina Bifida: Currently 8 of 10 anaphylactic reactions occurring during surgery in all children are due to latex allergy" It adds, "a recent study demonstrated a rate of 65%".

5. The enclosed CPSC Consumer Product Incident Reports, obtained under the FOIA and/or "copied" to the Latex Allergy News, detail the everyday experiences of latex allergy sufferers; including the newspaper article description of 13-year-old Denise Rae Odenbreit's fatal allergic reaction to toy balloons, (per her attending physician, Paul Kubic, MD. / 612-220-6744, and her death certificate). The CPSC also received notice of the death of Sherry Fee Swineburg, 7/11/97, which was passed on to the FDA MedWatch system. (Rpt Page 562). Although there was no scientific evidence to link this event to latex allergy, it did mention that the patient had been diagnosed with a latex allergy, and the event did not have to be a work related death, the causative agent could have been a consumer product. The CPSC also released the enclosed Incident Report on the latex induced death of U.S. Navy Lt. Harold R. Henderson, as poignantly described by his mother, Mary Ann Henderson in her January 7, 1998 letter to the state of Wisconsin State Legislature.

6. The cover page of Mary Ann Henderson's letter mentions my name, Debra Adkins, in association with The Latex Allergy Information Service. I am Editor of "The Latex Allergy News", a newsletter with 10,000 subscribers and 942 daily visitors to its Web site (one of five or ten latex allergy related web sites). However my interest in latex allergy is personal as well as professional. Briefly, I was a health care worker for 22 years, before I developed a life threatening latex allergy. I have very limited access to health care, and have to be very aware of latex products wherever I visit. That is why I have to travel into New York City for any dental care, a distance of over 90 miles one way Any and all of my physicians are made aware of the implications, and reactions and schedule any of my appointments for early in the day, to try to insure my safety

There are so many products that contain NRL, but they may not be known. That is why we need the help of the CSPC. There is presently no "cure" for latex allergy; the only management is avoidance.

Latex Allergy New

C. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition 2/28/00

Sincerely

Debra M. Adkins

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Date: 3

From: Debi Adkins Latex Allergy Information Service

To: Sandy Dunn Sec. to Comm.

Fax number:

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Comments:

No. of pages to Follow: 4

If any portion of this is transmittal is unclear please call 860-482-6869

This is an updated petition. there were a couple of typo's and one stat. was wrong it had 69% instead of 65%

I mailed it out on Feb 29, and it was returned - I give up

Please respond by Fax

Thank you

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LATEX ALLERGY

FOR

Secretary
Office
Product Safety Commission
Westboard Ave
MD

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American Academy of
DERMATOLOGY
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CONTINUING MEDICAL EDUCATION ART 105 98

Latex allergy

Erin M. Warshaw, MD *Minneapolis, Minnesota*

Coined the next major health concern of the decade, allergy to natural rubber latex affects people routinely exposed to rubber products. Groups at highest risk include health care workers, rubber industry workers, and persons who have undergone multiple surgical procedures, especially those with spina bifida. Allergy to latex is a type I, immediate, IgE-mediated reaction, which can lead to anaphylaxis and death. Much of latex research is published in allergy journals. Dermatologists may not be aware of the prevalence, symptoms, risks, diagnosis, and treatment of latex allergy. These topics are the subject of this review. Research concerning antigenic proteins, as well as sources of latex alternatives, is also summarized. (J Am Acad Dermatol 1998;39:1-24.)

Learning objective: At the completion of this learning activity, participants should have a clear understanding of the history, biology, epidemiology, mechanism, clinical characteristics, diagnostic work-up, and treatment of latex allergy. Readers should also have a greater understanding of multiple potential allergenic latex proteins and their importance in preventing future latex-sensitization.

HISTORY OF RUBBER PRODUCTION

Pre-Columbian sketches depicting natural rubber religious offerings are probably the earliest documentation of the use of natural rubber latex (NRL). The first European explorers to visit Central America in the 15th century saw local people fashioning rubber shoes, balls, and bottles. Samples of these products were sent to Spain by the conquistadors. Rubber became an industrial product in Europe during the late 1700s after MacIntosh developed a waterproofing process.[1]

Unfortunately, early rubber products became brittle under cold conditions as well as sticky with age. These problems were solved in 1839 when Goodyear accidentally discovered vulcanization, a process that utilizes sulfur to stabilize the elastic properties of rubber. Dunlop invented the inner tube and hollow tire in 1888,[1] and the first pair of rubber gloves was made by the Goodyear Rubber Company in 1890 at the request of William Stuart Halstead of breast surgery fame.[2] In 1850, Wickham, a British rubber planter in Brazil, introduced rubber seeds into Asia, now the major supplier of raw latex.[3]

HISTORY OF RUBBER ALLERGY

Two types of allergic reactions to rubber products are now known: type I (immediate-type) and type IV (delayed-type hypersensitivity [DTH]) (Table I). The first case of an immediate reaction to NRL was reported in 1927 by Stern[4] who described severe generalized urticaria caused by a rubber dental prosthesis. Almost half a century later, Nutter[5] reported the first glove-related case of an immediate-type reaction, contact urticaria. Soon after, several researchers[6-10] established a link between NRL glove–induced symptoms and IgE mechanisms.

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Journal of the American Academy of Dermatology
July 1998

Table I. Allergic reactions to natural rubber latex

Reaction	Mechanism	Antigens	Diagnosis
Immediate, type I	IgE	Small latex proteins	SPT, RAST, etc.
Delayed, type IV	Cell-mediated	Manufacturing additives	Patch testing

RAST, Radioallergosorbent test; *SPT*, skin prick test.

Immediate reactions may be life-threatening. By November 1992, more than 1000 reports had been received by the Food and Drug Administration (FDA) describing severe systemic allergic reactions to NRL medical devices. The majority were related to latex gloves and barium enema catheter tips.[11] The latter caused 15 deaths, prompting the FDA to recall a particular brand of barium enema catheter tip[12] and to publish a bulletin identifying the risk of anaphylaxis associated with NRL devices.[13]

NOMENCLATURE

Natural latex refers to the milky fluid produced by the *Hevea brasiliensis* tree. NRL refers to products, such as gloves, balloons, and condoms, which are made from water-based natural latex emulsions. Dry rubber latex refers to products made from processed, dried, or milled sheets of latex rubber (Table II).[14] Most immediate-type reactions result from exposure to NRL products.

BIOLOGY OF NATURAL RUBBER

Latex is actually the cytoplasm of *H. brasiliensis* laciferous cells. The nuclei and mitochondria are not expelled during collection, thereby enabling cell regeneration. Latex consists of four major components: rubber particles, lutoids, Frey Wyssling particles, and cytosol.

Rubber particles are the most numerous organelles in laciferous cells and consist of spherical droplets of *cis*-1,4 polyisoprene chains enclosed in a fine phospholipoprotein envelope.[15] Two proteins important in *cis*-1,4-polyisoprene synthesis were identified and sequenced in 1989. The first, *cis*-prenyl transferase (38 kd), is a hydrophobic membrane-bound enzyme, which catalyzes the addition of isoprene units, resulting in a polyisoprene chain several thousand isoprene units in length.[16,17] The second, rubber elongation factor, is a 14.6 kd stabilizing cofactor necessary for efficient function of *cis*-prenyl transferase.[18]

Lutoids are small vacuoles that comprise 10% to 20% of latex volume and are important for latex coagulation. Hevein (5 kd) and prohevein (20 kd) are major lutoid body proteins.[15] Hevein makes up 70% of lutoid proteins and has considerable structural homology with many plant agglutinins (lectins) such as those found in wheat, barley, rice, and potatoes.[19] Hevamines (29 kd) are lysozymes that demonstrate homology with lysozymes in other plants such as ficus and papaw.[20]

Frey Wyssling particles comprise 2% to 3% of latex volume; their biologic role has not been clearly defined. The remaining cytosol forms 40% to 50% of latex volume and contains soluble carbohydrates, organic acids, amino acids, nucleotides, and proteins important in isoprene synthesis.[15]

NATURAL LATEX GLOVE PRODUCTION

Many immediate-type I allergic reactions result from contact with NRL gloves. The process of glove production is important for understanding latex allergy and will be briefly reviewed. The steps in NRL production include collection, centrifugation, compounding, coagulation oven curing, vulcanization, and powder application.[14]

As reviewed by Hamann,[14] *H. brasiliensis* trees take 6 to 8 years to reach harvesting maturity, and an average tree yields enough latex to make approximately 10 pairs of gloves per week (1500 pairs per acre). Latex is harvested by cutting a spiral groove into the bark of the tree, a process termed tapping. The milky contents of the exposed articulated laciferous cells drain into a cup at the base of the tree. Latex coagulates on the tapping cut and seals the wound. The laciferous system then regenerates lost cell material before the next tapping, typically 2 to 3 days later. Autocoagulation, deterioration, and bacterial contamination occur rapidly in fresh latex unless preservatives and anticoagulants, such as ammonia, are immediately added. Anticoagulants convert the emulsion into approximately 60% liquid and 40% solid phases. Centrifugation removes liquid and concentrates solids.[14]

Approximately 5% of finished glove weight represents chemicals added during compounding. These chemicals are responsible for type IV DTH reactions and include accelerators, antioxidants, antiozonants, emulsifiers, stabilizers, extenders, colorants, retarders, stiffeners, biocides, UV light absorbers, and fragrances. Accelerators primarily control the rate, uniformity, and completeness of vulcanization; the most common include thiurams, carbamates, and mercaptobenzothiazoles. Antioxidants and antiozonants stabilize unsaturated isoprene bonds and prevent deterioration.[14]

Glove-shaped glass or porcelain formers are then dipped into the emulsion of compounded latex. Some formers are pretreated with coagulants such as calcium nitrate and/or releasing agents such as cornstarch powder. Formers are then pulled into a coagulation oven. After emerging from the oven, gloves are dipped into a water bath to leach excess chemicals and water-soluble proteins. The amount of time spent in leaching tanks and rate of water exchange are crucial variables that influence degree of protein removal.[14]

Vulcanization creates disulfide bonds that cross-link *cis*-1,4 polyisoprene chains to each other; the completeness and speed of this process depend on choice and concentration of accelerators added earlier during compounding. After vulcanization, cornstarch powder may be applied in a wet emulsion dip or as a dry aerosolized powder. Gloves are then removed from formers. An extra wash with chlorine yields powder-free gloves; although this additional wash reduces the amount of water-soluble proteins, it also accelerates glove deterioration.[14]

IMMEDIATE, IGE-MEDIATED REACTIONS TO LATEX

The contact urticaria syndrome, as defined in 1975 by Maibach and Johnson,[21] includes localized urticaria (stage 1), angioedema (stage 2), asthma (stage 3), and anaphylaxis (stage 4). Typical reactions occur within an hour of exposure as a result of IgE-mediated hypersensitivity to NRL proteins. Clinical manifestations depend on exposure route as summarized in Table III.[22] Immediate itching and urticarial wheals are the most common manifestations of allergy to NRL gloves.

Glove-induced asthma was first reported by Seaton, Cherrie, and Turnbull[23] who postulated

Table II. Common natural rubber latex and dry rubber latex products*

General medical
Gloves
Elastic bandage
Esophageal dilator
Face mask with elastic band
Hemodialyzer
Enema retention cuff
Syringe stopper
Medication stopper
Feeding tube
Tourniquet
Hot water bottle
Rubber sheet, pillow
Wheelchair tire
Blood pressure cuff
Electrode pad
Intravenous tubing
Catheter
Stethoscope tubing
Elastic support stockings
Obstetric/gynecologic
Cervical cap
Cervical dilator
Diaphragm
Condom
Dental
Dental dam
Bite block
Surgical/urologic
Implants
Urine bag and strap
Anesthesia
Endotracheal tube
Induction mask
Teeth protector
Breathing circuit
Ventilator tubing
Ventilator bellows
Household products
Gloves
Adhesive
Rubber toys
Balloons
Rubber bands
Shoes
Carpet backing
Underwear elastic
Baby bottle nipple
Pacifier
Raincoat
Swim goggles
Swim cap
Stamps
Shower curtain
Window insulation
Air mattress
Stretch textiles
Whoopee cushion

*Adapted from Hamann CP. Am J Contact Dermatitis 1993;4:4-21.

Table III. Immediate type I hypersensitivity reactions*

Route	Clinical manifestations
Cutaneous	Urticaria
	Dermatitis
	Pruritus
Airborne	Rhinitis
	Conjunctivitis
	Asthma
Mucosal	Anaphylaxis
	Tachycardia
	Angioedema
	Nausea
	Vomiting
	Abdominal cramps
	Hypotension

*Adapted from Sussman GL. Allergy Proc 1992;13 67-9

terpene vapor as the offending agent. In vitro and in vivo experiments have now produced convincing evidence that NRL proteins bind to cornstarch glove powder[10] and induce respiratory tract reactions through IgE-mediated mechanisms.[24-27] Both maize allergens in cornstarch powder[28,29] and ethylene oxide[30] used for sterilization have been suggested as etiologic agents, but have not been proven to induce asthma during specific inhalation challenge tests.[31]

Latex causes at least 10% of all intraoperative anaphylactic reactions.[32,33] Anaphylaxis has been reported from contact with baby bottle nipples,[34] baby pacifiers,[35] rubber vaginal vibrators,[36] Foley catheters,[37] condoms,[38-40] latex balloon tip catheters,[41,42] balloons,[43] dental cofferdams,[44] endotracheal tubing,[45] electrocardiographic pads,[45] squash balls,[46] air expelled from a whoopee cushion,[47] and food prepared with latex gloves.[48]

Hands most commonly come into contact with NRL products, but there are relatively few cases[49] of serious allergic reactions resulting from this exposure because an intact epidermis helps prevent absorption of allergenic proteins. Anaphylaxis to latex, therefore, occurs primarily when NRL products contact abraded mucosa[50] such as occurs during obstetric/gynecologic procedures,[44,47,51] rectal manometry,[52] and surgery.[53]

MECHANISM OF IMMEDIATE REACTIONS

Reactions to latex probably follow the typical sequence of events seen in other immediate reactions.[14] Briefly, first exposure to NRL may induce sensitization. This occurs when a new antigen, through a series of steps, induces plasma cells to produce NRL-specific IgE or IgG4 antibodies that bind to high-affinity surface receptors on mast cells. On reexposure, elicitation of an allergic reaction occurs when these bound antibodies are cross-linked by NRL antigens. Mediators such as histamine and arachidonic acid metabolites are immediately released from mast cells, causing increased vascular permeability, vasodilatation, and bronchoconstriction expressed as urticaria, hypotension, and asthma.[54] Type I, late-phase reactions are mediated by low-affinity receptors and occur 6 to 12 hours after exposure.[55]

POTENTIAL ROLE OF ENDOTOXIN

Mechanisms other than those in immediate-type hypersensitivity may play a role in latex protein reactions. Endotoxin is a potent proinflammatory agent produced by gram-negative bacteria. It has been linked to irritation of skin,[56] eyes, and lungs.[57,58] Clinical symptoms range from skin erythema and respiratory distress to fever, malaise, and shock. Williams and Halsey[59] found that endotoxin was a highly significant contaminant of some latex gloves. The highest levels of endotoxin were found in powdered examination gloves caused by heavy bacterial contamination of cornstarch slurries used during manufacturing. These researchers found that endotoxin was not physically associated with powder (as are latex proteins) but instead was released in association with tiny respirable particles.[60] These findings suggest that endotoxin may be responsible not only for skin irritation, but also for enhancement of allergic reactions to NRL products, especially powdered gloves.

DELAYED-TYPE HYPERSENSITIVITY TO LATEX

Many allergic reactions to rubber are DTH reactions to chemicals added to NRL during manufacturing. These DTH reactions and allergens are not the subject of this review, and readers are referred elsewhere[61-64] for such information. There are few reported cases of DTH to raw latex without added chemicals.[65,66] Wilkinson and Beck[67] patch-tested 822 patients to ammoniated latex applied in Finn Chambers. Ten patients had positive patch tests to latex, half of these were also prick test positive to

Table IV. Latex sensitivity in the general population

Author(s)	Population	Sample size	Test	% Positive
Turjanmaa[69]	Consecutive allergy clinic patients	130	Scratch	0.8
Moneret-Vautrin et al.[70]	Allergy clinic patients without risk factors	272	SPT	0.4
Turjanmaa[34]	Consecutive preoperative patients	800	SPT	0.13
Porri et al.[71]	Patients seen for annual check-up	365	SPT/RAST	2.3
Ownby et al.[72]	Blood donors	1000	RAST	6.5
Merrett et al.[73]	Blood donors	1436	RAST	7.9

RAST, Radioallergosorbent test; *SPT*, skin prick test.

latex. These rare DTH reactions to latex should be interpreted cautiously because chemicals such as 1,2-benzisothiazolin-3-one, a recognized cause of DTH allergic contact dermatitis, may be added to raw latex in the country of origin.[65] Patch testing with glove pieces should also be interpreted with caution because ingredients of glove powder, such as epichlorhydrin and sorbic acid, may cause DTH.[68]

PREVALENCE OF LATEX ALLERGY

General population

Prevalence of latex sensitivity in the general population is probably less than 2% (Table IV).[34,69-71] Studies analyzing serum samples from blood donors[72,73] indicate higher rates of sensitization probably because health care workers, known to be at risk for latex allergy, are more likely to donate blood.

Importantly, not all persons who show evidence of sensitivity by testing have or will have clinical symptoms. Study design obviously affects reported prevalence rates; people without symptoms are less likely to answer questionnaires and undergo testing.[74]

Atopic patients

Predisposing risk factors for the development of latex allergy are summarized in Table V. Studies of atopic persons indicate latex sensitivity rates of 3% to 9%, whereas rates in atopic children without other risk factors are 2% to 4%.[70,71,75] This lower rate in atopic children compared with atopic adults probably stems from less exposure to NRL products with high allergen content such as gloves.

Spina bifida

The first cases of latex-induced anaphylactic shock during surgery in children with spina bifida were reported in 1989 and 1990[30,77], many more followed.[53,78,79] In 1991, the Centers for Disease Control (CDC) alerted the medical community to this high-risk group.[80] Currently 8 of 10 anaphylactic reactions occurring during surgery in all children are due to latex allergy. The risk of anaphylaxis to latex in children with spina bifida has been estimated to be 500 times greater than the general population, probably because of the need for multiple surgeries.[81,82] Most studies have found latex-sensitivity rates of 30% to 51%,[70,83-89] although a recent study demonstrated a rate of 65%.[90] Lower sensitivity rates have been reported from mostly questionnaire studies.[91-94] Of course, not all of these children have clinical symptoms.

Table V. Risk factors for development of latex allergy*

- *Occupational exposure to latex*
  - Health care workers
  - Rubber industry employees
  - Janitorial workers
  - Food handlers
- Multiple surgical procedures
  - Patients with spina bifida
  - Patients with congenital abnormalities
- Frequent mucosal exposure to NRL products
  - Dental
  - Contraceptive
  - Daily urinary catheterization
  - Manual fecal disimpaction
- Preexisting hand eczema
- Atopy
- Female gender
- Fruit allergy

*Adapted from Barrth EC. Nurse Pract 1993;18:54-8

Occupational

As summarized in Table VI,[95-115] most studies estimate latex sensitivity in health care workers

Table VI. Occupational prevalence of latex sensitivity

Author(s)	Population	Sample size	Test	% Positive
Berky, Luciano, James[95]	Dental workers	1043	Questionnaire	14
Rankin, Jones, Rees[96]	Dental school staff	526	Questionnaire	15
Tipirneni et al.[97]	HCWs	1526	Questionnaire	33
Katelaris, Widmer, Lazarus[98]	Dental school staff	177	Questionnaire	33
Kujala and Reijula[99]	HCWs	534	Questionnaire	44
Turjanmaa[69]	Hospital employees	512	Scratch	3
	OR nurses	71	Scratch	6
	OR doctors	54	Scratch	7
Salkie and Chir[100]	Laboratory technologists	230	RAST	1
Akasawa et al.[76]	HCWs	601	RAST	2
Wrangsjo et al.[101,102]	HCWs	202	SPT/RAST	4
Kaczmarek et al.[103]	HCWs	504	RAST	6
Eriksen et al.[104]	HCWs	200	RAST/LHRT	17
Harfi et al.[105]	HCWs	128	RAST	21
			SPT	19
Capriles-Hulett et al.[91]	1st yr dental students	43	SPT	0
	OR HCWs	80	SPT	3
Beaudouin et al.[106]	Hospital employees	907	SPT	3
Arellano, Bradley, Sussman[75]	Anesthesiologists	101	SPT	10
Lagier et al.[107]	OR nurses	197	SPT	11
Sussman and Liss[108]	HCWs	1351	SPT	12
Yassin et al.[109]	HCWs	224	SPT	17
Charous[110]	Symptomatic HCWs	39	RAST	49
Jones et al.[111]	Symptomatic HCWs	41	SPT	68
Bubak et al.[112]	Symptomatic HCWs	49	SPT	69
van der Walle and Brunsveld[113]	Hairdressers with rubber glove exposure	48	Scratch	10
Tarlo et al.[114]	Glove factory workers	81	SPT	11
Moneret-Vautrin et al.[70]	Occupational exposure	31	SPT	29
Heese et al.[115]	Occupational exposure	39	SPT/RAST/Use	33

HCWs, Health care workers; *LHRT*, leukocyte histamine release test; *OR*, operating room; *RAST*, radioallergosorbent test; *SPT*, skin prick test.

without symptoms to be 2% to 17%. Similar rates of sensitization are found in other workers who are regularly exposed to NRL gloves, such as glove factory workers (11%)[114] and hairdressers (10%).[113] When health care workers with symptoms are tested, up to 69% show evidence of sensitivity.[112]

In addition to contact urticaria, persons occupationally exposed to powdered NRL gloves are at higher risk for the development of rhinoconjunctivitis and asthma. There have been numerous reports of health care workers disabled in the workplace from respiratory symptoms, which were subsequently linked to aerosolized latex proteins.[116-118] A large study of occupational asthma confirmed by skin prick tests (SPTs), as well as inhalation challenge tests, indicated a prevalence of 2.5%.[119] Smaller and less well-designed studies have shown prevalences as high as 38%.[27,99,103,114,120]

Other risk factors

Presence of multiple risk factors increases the incidence of latex sensitivity. More than half of latex-sensitive health care workers in one study reported a history of hand dermatitis before the development of contact urticaria and systemic reactions. More than three fourths of Taylor and Praditsuwan's series[121] of predominantly female, occupationally exposed, latex-allergic persons had current or prior hand eczema. Arellano, Bradley, and Sussman[75] found that atopic physicians were 19 times more likely to be SPT positive to latex than nonatopic physicians and nine times more likely to be SPT positive than atopic control subjects who were not occupationally exposed.[75]

Moneret-Vautrin et al.[70] investigated risk factors of atopy and exposure in 569 subjects and found that these factors were not just additive, but synergistic. Latex SPT positivity was 0.4% for neither risk factor, 6.9% for exposure alone, and 9.4% for atopy alone. Atopy and exposure together, however, increased the positivity rate to 36%.

Female gender increases the incidence of latex sensitivity. Tomazic et al.[50] found a female predominance of 3:1 in a review of 145 cases of latex-induced systemic allergic reactions. This female predominance may be attributable to the fact that more women are employed in high-risk professions. Other factors, however, may also play a role. For example, it is known that female hormones enhance histamine release.[122,123]

Although attention to high-risk groups may help screen persons for latex sensitivity, it is important to remember to ask all patients about sensitivity. Diaz et al.[124] described three women without risk factors in whom anaphylaxis developed from latex gloves worn by obstetricians during the delivery of their children.

WHY INCREASE?

The CDC published a report on Aug. 21, 1987 that came to be known as "universal precautions." It emphasized the need for all health care workers to routinely use appropriate barrier precautions, such as gloves, when contacting body fluids. To meet this demand, new inexperienced glove manufacturers produced poorly compounded, inadequately leached products. These gloves contained unprecedented concentrations of protein allergens, which sensitized thousands. Annual glove imports rose dramatically from less than 1 billion gloves to about 11 billion by 1992. During the late 1980s, a glove glut ensued, prices plummeted, and many new manufacturers folded. However, a newly sensitized population continued to have problems, even with previously used, high-quality products.[125] Today, despite pleas from the FDA to manufacturers for tighter regulations, allergen levels in gloves can vary 40-fold from batch to batch.[126]

DIAGNOSIS

Fig. 1 outlines a reasonable approach to diagnosing latex allergy. As with any diagnosis, a detailed history and thorough clinical examination are essential. Evidence of risk factors and history of immediate symptoms should prompt an evaluation. DTH to rubber additives and immediate reactions to latex proteins may coexist; therefore both patch testing and evaluation for latex antibodies may be necessary.[121] A clinical examination showing patchy or diffuse eczema or urticaria (or both) on an exposed body part is classic. Hands can transfer allergens to other body parts, especially the face, resulting in unusual presentations.

Table VII. Diagnostic tests

Research	Clinical
Cytometric assay	SPT
Radioimmunoassay	RAST
Basophil histamine release test	Latex allergosorbent test
Flow cytometry	Use test
Immunoblots	Rub test
ELISA	Scratch chamber test
	Intradermal test
	Inhalation tests
Cross and rocket immunoelectrophoresis	Open and closed patch tests
Reverse enzyme immunoassay	Latex-specific antibody assays

ELISA, Enzyme-linked immunosorbent assay

As summarized in Table VII, multiple tests have been developed to detect latex allergy. Most experts feel that SPT with diluted latex antigen extracts is the most sensitive and, therefore, the standard for detecting latex allergy. Unfortunately, although commercial, unstandardized extracts are available in Europe (Stallergenes) and Canada (Bencard), the FDA has yet to approve a skin testing latex extract for use in the United States.[127] As a result, clinicians often resort to skin testing with office-made extracts.

SPT

Glove brands vary greatly in allergenicity. Turjanmaa et al.[128] found that prick test positivity of solutions made from 19 brands of NRL gloves among 40 sensitive persons varied from 8% to 87%, and relative concentrations of total protein in gloves ranged 3000-fold. Therefore a known allergenic brand should be chosen to make prick solutions, and ideally concomitant testing of three different brands is recommended.[74]

Most investigators prepare prick solutions by stirring twenty 1 cm^2 (1 gm) glove squares in 5 ml of sterile saline for 15 minutes. Glove pieces are then removed and the solution is stored in a sterile

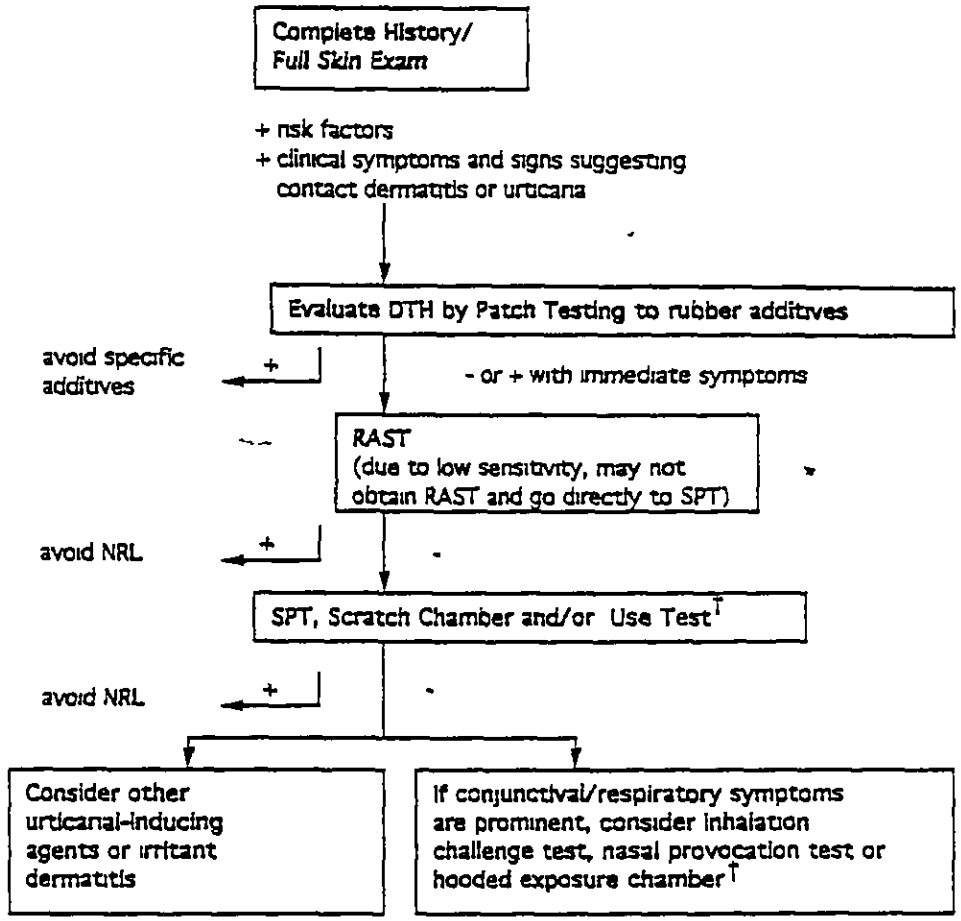

Fig. 1. Diagnosis of latex allergy *Dagger.* Epinephrine and resuscitation equipment are recommended if these diagnostic tests are performed. *DTH,* Delayed-type hypersensitivity; *NRL,* natural rubber latex; *RAST,* radioallergosorbent test; *SPT,* skin prick test. (Modified from Hamann CP Am J Contact Dermatitis 1993;4 4–21)

bottle. No preservatives are needed if the test material is refrigerated and replaced monthly [74] The stock solution may be diluted in saline 1 1,000,000, if no reaction is noted at 15 minutes, then subsequent increasing concentrations (e.g , 1.100,000, 1 10,000) are tested.[87] Histamine dihydrochloride (10 mg/ml) and saline are used as positive and negative controls, respectively [74]

Testing is done by placing a drop of diluted antigen solution on the skin and gently pricking the skin with a lancet. The remaining solution is gently wiped away with blotting paper. Fifteen minutes after application, the wheal is measured by adding the two largest perpendicular axes and dividing the sum by two. A positive reaction is defined as a number equal to or greater than half the value of the histamine control. The risk of sensitization after skin prick testing is unclear [74]

Although anaphylactic risk during prick testing is minimized by initially using very diluted solutions, physicians should be prepared with resuscitation equipment and epinephrine.[129 130] As summarized in Table VIII,[131-136] most studies indicate SPT sensitivity and specificity rates of at least 90%

Radioallergosorbent test

A radioallergosorbent test (RAST) is an in vitro test in which solid phase allergen is incubated with serum to induce specific antigen-antibody reactions. Radiolabeled anti-IgE antibodies are mixed with solid-phase allergen-antibody complexes, and bound radioactivity is measured [137]

At least two RASTs are available in the United States, AlaSTAT by Diagnostic Products Corporation and ImmunoCap by Upjohn-Pharmacia. As summarized in Table VIII, although

specificities range from 80% to 87%, sensitivities are low (50% to 90%), making these poor screening tests. A negative RAST does not exclude latex sensitivity. Latex-sensitive persons with documented positive RASTs who avoid latex products for several years have subsequently developed negative RASTs.[43] Presumably, in the absence of allergen exposure, specific IgE concentration decreases over time. Nonetheless, because it is easy to perform and carries no risk of anaphylaxis, RASTs remain a diagnostic option,[138] and there is evidence that sensitivities of latex RASTs are improving. Jaeger et al.[27] found a correlation of 82% between IgE-RAST and latex SPT. The latex allergosorbent test (LAST) is similar to RAST, but avoids radioisotopes. It can be performed in less than 6 hours and correlates well with latex RASTs.[139]

Use test

A use test involves applying a latex glove directly to a wet hand; a vinyl glove serves as a control. First, one wet finger is exposed to a glove finger for 15 minutes. A positive test is defined as two to five urticarial wheals. If no reaction is observed, the entire glove is applied to a wet hand for an additional 15 minutes. If no wheals are noted, exposure can be lengthened to several days. This test carries a risk of anaphylaxis.[74,140]

Rub test

The rub test is a modification of the use test in which latex fluid, a glove piece, and/or glove powder are repeatedly rubbed into the volar aspect of the forearm. A positive reaction is defined as one or more wheals. This test also carries a risk of anaphylaxis.[141]

Scratch chamber test

A scratch chamber test is performed by using a lancet to create a 6 mm scratch on the volar aspect of the forearm. A small piece of latex glove moistened with saline is placed in a Finn Chamber and applied over the scratch for 15 to 20 minutes. A positive reaction is defined as in prick testing. This test carries a risk of anaphylaxis, and false-positive reactions are well documented.[69]

Intradermal test

Intradermal testing involves injecting diluted antigenic solutions directly under the skin. Reports of anaphylaxis[142,143] advocate against this test, five deaths occurred from intradermal testing in a 42-year study period.[130]

Basophil histamine release test

The basophil histamine release test is an in vitro test in which donor-washed leukocytes are incubated with diluted latex antigen. Histamine release by basophils is measured directly by fluorometric, enzymatic, or immunologic methods or indirectly by enumerating degranulated basophils. It is a time-consuming and expensive test but carries no risk of anaphylaxis and has a sensitivity rate comparable to SPTs. Turjanmaa et al.[136] studied 15 patients with latex contact urticaria and found that the basophil histamine release test was positive in 93% compared with a commercial RAST positivity of 60%.

Inhalation tests

Several tests detect mucosal sensitivity to latex. The workplace challenge test involves measuring spirometry in workplace and nonworkplace environments.[120] The inhalation challenge test involves measuring spirometry at 15- to 30-minute intervals while subjects handle latex gloves; vinyl gloves are used as controls.[119] The nasal provocation test consists of applying a substance on a cotton swab to the nasal mucosa for 5 minutes. Responses are monitored with anterior rhinoscopy, rhinomanometry, and measurement of nasal secretions. Sensitivity and specificity of this test have yet to be determined.[144] The hooded exposure chamber system produces a precise and reproducible NRL allergen-cornstarch particle cloud of uniform size that simultaneously challenges the eyes, nose, and bronchi.[145]

Latex-specific IgG

Latex-specific IgG has been reported as an indicator of latex sensitivity. Higgins et al.[146] found that control subjects had low levels of latex-specific IgG antibodies, whereas those known to be latex-sensitive demonstrated much higher levels. A Japanese study found that latex-specific IgG was at least nine times more common than IgE in atopic children and six times more common in hospital workers.[76] Alenius et al.[147] found eight latex antigens common to both IgG4 and IgE antibodies, which suggests that IgG4 antibodies may play a role in the pathogenesis of latex allergy.

The presence of IgG4 antibodies in the sera of

Table VIII. Sensitivity and specificity of diagnostic tests

Author(s)	Sample size	Skin prick test	
		Sensitivity (%)	Specificity (%)
Rueff, Thomas, Przybilla[131]	63	NRL solution 91 NRL sap 100	92-95 74
Turjanmaa, Reunala, Rasanen[132]	15	NRL solution 100 NRL sap 80	NR
Ebo et al.[133]	83	95	100
Kadambi, Field, Charous[134]	33	NR	NR
Blanco et al.[135]	50	NRL extract 98 Glove extract 72-96	Both extracts 96-100
Pecquet, Leynadier, Dry[33]	17	NR	NR
Turjanmaa et al.[136]	15	NR	NR
Beaudouin et al.[106]	907	100	99

AlaSTAT, RAST produced by Diagnostic Products Corporation, *BHRT*, Basophil histamine release test; *ImmunoCap*, RAST produced by Upjohn-Pharmacia; *NR*, not reported.

latex-allergic patients may be due to prolonged and intense antigen exposure.[148] In vitro evidence shows that interleukin-4 upregulates both IgE and IgG4 production,[149] and this may explain the concomitant occurrence of IgE and IgG4 antibodies in latex, food,[150] and insect sting allergies.[151] The significance of allergen-specific IgG antibodies is controversial and, as the aforementioned studies indicate, not particularly specific.

DIFFERENTIAL DIAGNOSIS

If tests are negative and suspicion for type I allergy remains, evaluation for other types of urticaria should be considered. Nonimmunologic urticaria occurs without previous sensitization and can be caused by chemicals that directly induce degranulation of mast cells. Sorbic acid, found in some glove powders, can induce nonimmunologic contact urticaria.[152]

Immediate-type allergic reactions to rubber additives (which usually cause DTH) have been reported. Fuchs and Wahl[153] described two patients with urticarial patch test reactions to tetramethylthiuram disulfide, mercapto mix, and *p*-phenylenediamine mix. Helander and Makela[154] reported a kitchen worker with contact urticaria to rubber gloves who had negative immediate and delayed patch tests to standard rubber allergens and gloves. Scratch tests, however, were positive to zinc diethyldithiocarbamate, an accelerator, as well as a glove piece. Belsito[39] described three patients with rubber contact urticaria with positive scratch tests to mercaptobenzothiazole, carba mix, and black rubber mix. Wrangsjo, Mellstrom, and Axelsson[155] described a RAST-positive and scratch test–positive patient who also had an urticarial response to two accelerators, zinc pentamethylene dithiocarbamate and zinc dibutyl dithiocarbamate. The significance of these immediate reactions to rubber additives is uncertain, well-designed large studies are needed to rule out false-positive tests caused by contaminants.

Although granulomatous responses to cornstarch are well described,[156,157] there have also been several reported cases of contact urticaria to cornstarch in gloves.[28,39,158,159] Most researchers, however, believe this immediate hypersensitivity is due not to cornstarch itself but rather to contamination by latex protein allergens.[10] Pure powder supplied by manufacturers, in several cases, did not induce urticarial reactions,[29,112,128] and no maize-specific IgE antibodies were identified. Milk allergy may also masquerade as latex allergy because casein may be added to powder during manufacturing.[160]

VARIABLES IN ANTIGEN DETERMINATION

Identification of major latex allergens is important for two major reasons. First, diagnostic accuracy will greatly improve, enabling the development of standardized extracts of well-characterized latex allergens. Second, once antigens are characterized, their source (biologic vs industry) can be determined and eliminated.[161]

RAST		Other tests
Sensitivity (%)	Specificity (%)	Sensitivity (%)
89	87	NR
53	NR	Scratch 86 Use test 92
ImmunoCap 97	83 33	NR
54	NR	SPT/Use test 78
ImmunoCap 86	80	NR
AlaSTAT 84	80	
76	NR	NR
60	NR	BHRT 93
NR	NR	NR

Unfortunately, there are multiple variables that make detection and characterization of latex allergens difficult. Different proteins are produced by *H. brasiliensis* during different seasons and by different plant hybrids. Variations in collection, preservation, and compounding of latex can lead to chemical hydrolysis resulting in different protein profiles. Haptenization with various compounding chemicals may alter bioavailability and antigenicity. Modifications can also result from different isolation detection methods.[162] Finally, nuances of individual immune systems can produce different reaction patterns when challenged with identical proteins.

The source of NRL (crude nonammoniated latex [NAL], high or low ammoniated latex [AL], rubber tree leaves, dry rubber, or latex-containing end products such as gloves) used for extraction and testing is still under debate.[163,164] Hamilton et al.[165] found that glove extracts were more sensitive in detecting latex allergy than NAL or AL. Jones, Scheppmann, and Yunginger[166] found that extractable latex allergen levels varied 500-fold among 27 medical latex gloves and 6- to 40-fold in the same brand sampled at different times. Turjanmaa and colleagues[128,167] performed skin tests with extracts from 17 brands of latex surgical gloves and 16 brands of latex condoms and similarly found that allergenicity varied widely. Yunginger et al.[168] reported a cross-sectional study of 71 glove brands and found that the latex allergen level varied over 3000-fold

Some investigators have suggested that ammoniation of latex can result in formation of new antigens.[169] Lu et al.[170] investigated this question and found that ammonia treatment alters latex proteins but does not create new antigens with novel epitopes. Makinen-Kiljunen et al.[171] found that AL and NAL shared at least 10 common antigens, but a surgical glove extract had only six of these antigens. The surgical glove extract also demonstrated one allergen not found in natural rubber, suggesting that rubber proteins may be altered and/or created during glove manufacturing.

Geographic differences can result in different antigenic profiles. Kurup et al.[172] compared Finns and Americans for reactivity to gloves from their respective countries and to raw latex from Malaysia and India. The results showed that persons are more likely to react to extracts made from products distributed in their country of origin. As expected, raw latex extracts were more sensitive (29 of 45 subjects [64%]) than glove extracts combined (22 of 45 subjects [49%]).

Different patient populations produce antibodies that recognize distinct latex peptides. In one study by Alenius et al.,[173] 46 of 57 allergens were identified by patients with spina bifida, 19 of 57 by health care workers, and 8 of 57 by both groups. It is unknown whether sensitivity among different risk groups is due to different modes of exposure or if immune responses are modified by medical conditions such as spina bifida.

ANTIGEN IDENTIFICATION

As summarized in Table IX,[143,147,174-183] immunoblotting studies show that IgE from sera of latex-allergic patients binds heterogeneously to many different proteins ranging from 4 to 200 kd. Identification of one or two major allergens is a daunting task.

Currently, there is no consensus on which proteins are most important. Some authors believe that proteins of 14.6 kd (rubber elongation factor, Hev b 1),[175-177,180,184-187] 20 kd,[176] 22 and 23 kd,[183] and 27 kd[88,176,188] are particularly important in spina bifida. Others believe that hevein (4.7 kd)[189] and prohevein (20 kd)[178,179,190] may be important antigens. Several other potential antigens have recently been identified with molecular weights of 10,[174] 16,[191-193] 18,[181] 21,[147] 23,[181] 25,[181] 30,[44,194] 36,[188] and 66 kd.[181]

Table IX. Identified latex antigens

Author(s)	Molecular weight of identified antigen(s) (kd)*											
	0	5	10	15	20	25	30	35	40	45	50	> 50
Turjanmaa et al.[128]	2*	5					30					
Morales et al.[143]			10			24		35				100
Turjanmaa and Reunala[167]		3———	10									
Turjanmaa et al.[10]			10									
Alenius et al.[169]		4———		14———	21							70
Alenius et al.[147]				14	21		29				53	
Chambeyron et al.[174]			10	15	18 20	25	30	35				60
Fuchs and Wahl[153]						28						
Jäeger et al.[27]				14			30	———		45		
Slater and Chhabra[175]				14	20							
Tomazic et al.[50]	0	———			20 (AL)							
		4	———									200 (NAL)
Alenius et al.[176]				14	20		27					
Czuppon et al.[177]				14.6								58 (tetramer of 14.6)
Alenius et al.[173]				14			27					
Alenius et al.[178]				14	—— 20	———						200
Slater and Trybul[88]				14.3		26.7						
Alenius et al.[179]					20		30	36				
Aamir et al.[180]				14		24					46	
Chiu et al.[181]				14	18 23	25						66
Eriksen et al.[104]				14	21		30	——35		44		
Nieto et al.[182]			11 12 13				27	32				
Yeang and Ward[183]					22-23							

AL, Ammoniated latex. *NAL*, nonammoniated latex.
*Boldface type indicates major antigen.

LATEX ALLERGENS IN AIR POLLUTION

Small particles suspended in polluted air are significantly linked to hospital admissions for asthma, particularly in young children.[195] Many of these particles originate from abrasion of rubber tires on road surfaces. Williams et al.[196] analyzed these respirable particles by optical microscopy, chemical solubility tests, and mass spectrometry and found them to be consistent with those observed from latex gloves. Antibody inhibition assays demonstrated that six of seven sera samples from latex-sensitive persons were inhibited equally by rubber tire and latex glove extracts. Therefore latex antigens from respirable tire fragments may be immunologically active, contributing to asthma and other respiratory problems.[196] In a further study by Williams et al.,[197] immunoblots tentatively identified a 50 kd protein in rubber tire fragments. Respirable latex allergens may also act as specific adjuvants for IgE responses by enhancing reactions induced by unrelated allergens.[198]

CROSS-REACTIONS

Allergies to multiple foods and plants are associated with allergy to NRL (Table X)[40,199-202] and allergens common to both latex and food have been identified.[191,192,203-206] Preincubation with latex extracts has been shown to inhibit binding of food-specific antibodies and vice versa.[207,208] Other studies have not supported the association between latex and food allergy.[209,210] It may be important to test fresh food extracts because commercial extracts have yielded false-negative tests.[211]

It is unclear whether latex sensitization predisposes persons to food allergy or vice versa. Eades, Keane, and Cullom[212] studied 11 latex SPT-positive persons and found that food sensitivity

appeared concurrently with latex sensitization. It may be that similarity of epitopes in food and latex allergens is responsible for this observation. It is possible, therefore, that anaphylaxis in latex-sensitive patients is due to cross-reactivity among food and latex antigens rather than to specific sensitization with latex.

Fruit-latex cross-reactivity may be due to ethylene, a gas used to hasten commercial ripening. When forced to ripen quickly under high ethylene concentrations, plants produce allergenic wound-repair proteins that are similar to wound-repair proteins made by *H. brasiliensis*.[213] There are reports of cosensitization to latex and items sterilized by ethylene.[30,214]

Reported cross-reactions of latex with inedible plant proteins include reactions to profilin, an allergen present in many plant species,[215] and ficin, a protease found in the sap of the ficus tree, *Ficus glabrata*.[216,217] Because ficin is utilized in many pharmaceutical, textile, and cosmetic products, it may be an important cross-reactant and/or cosensitizing agent.

Table X. Food allergies associated with latex allergy

Avocado*
Banana*
Chestnut*
Kiwi
Passion fruit
Peach
Mango
Pineapple
Fig
Cantaloupe
Apple
Papaya
Pear
Melon
Cherry
Wheat
Turnip
Spinach
Potato
Celery
Tomato

*Highest association.

PREDICTING ANAPHYLACTIC REACTIONS

Anaphylactic reactions occur between 1 in 1500 and 1 in 5000 operations; approximately 5% to 10% of patients die as a direct result.[218] It is estimated that latex allergy is responsible for at least 10% of all intraoperative anaphylactic reactions.[32,33] The rate of anaphylaxis in patients with spina bifida is approximately 13.5%.[219] As these numbers demonstrate, we need reliable and accurate predictors of anaphylaxis.

Unfortunately, preoperative evaluation has not predicted anaphylaxis.[89] Kelly et al.[219] authored a large study that specifically addressed historical, lifestyle, and immunologic risk factors for anaphylaxis caused by latex. Of 7389 surgical procedures done in children, 11 (10 with spina bifida and one with a congenital urologic abnormality) experienced 12 anaphylactic reactions. Risk factors that reached statistical significance included history of anaphylaxis, history of immediate reactions to rubber products, food allergy, and daily rectal disimpaction. The most important predictive immunologic evaluation was total IgE level, a nonspecific indicator; latex SPT, enzyme-linked immunosorbent assay, and RAST alone or in combination were not statistically significant.[219]

In the same study, univariate analysis determined that the following variables were sensitive but not very specific: latex sensitivity, history of asthma, history of immediate reactions to rubber products, food allergy, or rash caused by adhesive tape. The most specific, but not very sensitive, variable was the need for daily rectal disimpaction. Anaphylaxis was best predicted by a combination of the following three factors: RAST or SPT positivity to latex, history of immediate clinical symptoms to rubber products, and daily rectal disimpaction. The authors concluded that although SPT, ELISA, and RAST are helpful for identifying patients who are sensitive to latex, these tests lack specificity for predicting anaphylactic reactions. Clinical history in combination with total serum IgE was a more sensitive and specific predictor of patients at risk for anaphylactic reactions.[219]

PRECAUTIONS

Multiple educational resources are available (Tables XI and XII). Patients and physicians can take precautions to prevent serious reactions (Tables XIII[220,221] and XIV). Prevention of sensitization is an ideal goal, especially for those at high risk. Many hospitals now have latex-free operating rooms used specifically for children with spina bifida and other congenital anomalies

Table XI. Latex allergy sources

Organizations

ALERT, Allergy to Latex Education and Resource Team, Asthma/Allergy Center #795, PO Box 1997, Milwaukee, WI 53201 (414-677-9707)

ELASTIC, Education for Latex Allergy Support Team and Information Coalition, 176 Roosevelt Ave., Torrington, CT 06790 (800-482-6869)

Spina Bifida Association of America, 4590 MacArthur Blvd., NW, Suite 250, Washington, DC 20007-4226 (800-621-3141 or 202-944-3285)

Publications

The ABC's of Latex Allergy, patient education pamphlet, Asthma and Allergy Foundation of America, 1125 15th St., NW, Suite 502, Washington, DC 20005 (202-466-7643)

The Alternative Resource Catalog, latex-free products for daily living. Nicci D Paris, RN, President, Alternative Resource Catalog, 145 Wetzel Rd., Pittsburgh, PA 15209-1127 (800-618-3129)

Latex Allergy: Protect Yourself, Protect Your Patients, American Nurses Association, Workplace Information Series, 600 Maryland Ave., SW, Suite 100W, Washington, DC 20024-2571 (800-274-4ANA)

Natural Rubber-containing Medical Devices; User Labeling, Department of Health and Human Services, Food and Drug Administration, Docket No. 96N-0119, 21 CFR Part 801, Federal Register, Vol. 62, No. 189, Sept. 30, 1997 For more information contact Donald E. Marlowe, Center for Devices and Radiological Health (HFZ-100), Office of Science and Technology, Food and Drug Administration, 12725 Twinbrook Parkway, Suite 217, Rockville, MD 20852 (301-827-4777)

Guidelines for the Management of Latex Allergies and Safe Latex Use in Health Care Facilities, American College of Allergy, Asthma and Immunology, 85 W Algonquin Rd., Suite 550, Arlington Heights, IL 60005 (847-427-1200)

Latex Allergy News, information-sharing vehicle of ELASTIC, 176 Roosevelt Ave., Torrington, CT 06790 (800-482-6869)

Immunology and Allergy Clinics of North America, February 1995, Vol. 15. Guest Editor Jordan N. Fink, MD Entire issue devoted to latex allergy

Other

Medic Alert (to obtain allergy alert ID bracelet): 2323 Colorado Ave., Turlock, CA 95382

Med Watch (to report problems with products to the FDA): Food and Drug Administration, Med Watch Office, Room 1765, 5600 Fishers Lane (HF2), Rockville, MD 20857 (800-332-1088)

Table XII. Latex allergy information on the Internet

Organization/Topic	Web site
Latex Allergy Links	*http://www.netcom.com/~nam1/latex_allergy.html*
The LAIR (Latex Allergy Information Resource)	*http://medisww.cwru.edu/dept/anesth/lair/lair.htm*
Latex Allergy Help	*http://www.latexallergyhelp.com*
Foundation for Latex Allergy Research and Education (FLARE)	*http://www.flare.org*
Allergy to Latex Education and Resource Team (ALERT)	*http://www.execpc.com/~trukaras/ALERT/*
Latex-Allergy Home Page	*http://allergy.mcg.edu/physicians/ltxhome.html*
Federal Register Notice: Latex-containing Devices; User Labeling	*http://www.fda.gov/cdrh/fr6241xf.html*
PALS (Physicians Against Latex Sensitization)	*http://www.pals.net/*
ELASTIC (Education for Latex Allergy/Support Team and Information Coalition)	*http://www.netcom.com/~ecbdmd/elastic.html*
NIOSH (National Institute for Occupational Safety and Health	*http://www.cdc.gov/niosh/latexall.html*

Table XIII. Providing a latex-safe hospital environment for patients allergic to latex*

1. Use nonlatex examination and sterile gloves.
2. Remove all latex products from patient's room.
3. Do not inject or withdraw fluid through rubber ports of intravenous lines.
4. Substitute polyvinylchloride, silicone, and/or other nonlatex alternatives for medical supplies such as endotracheal tubes, adhesive bandage strips, bulb syringes, airways, ventilator bellows.†
5. Shield direct exposure from certain dry-rubber equipment. Blood pressure cuffs can be used over clothing. Stethoscope tubing can be covered with a stockinette.
6. Utilize single-dose ampules for parenteral medication rather than multiple-dose vials.

*Modified from Pasquariello CA, Lowe DA, Schwartz RE. Pediatrics 1993;91:983-6
†Extensive list in Latex Allergy News 1997; introductory issue: 5-9

Table XIV. Precautions for physicians

1. Consider placing information sheets and signs about latex allergy in waiting room.
2. Use nonlatex gloves for all mucosal examinations
3. Consider using nonlatex gloves for all contact with patients.
4. If latex gloves are to be used, choose powder-free and low allergen gloves to decrease aerosolized antigen in workplace.
5. Screen patients for latex allergy at each clinic visit and hospital admission. "Latex allergic" label should be designated for all those patients with a clinical history. All high-risk patients (myelodysplasia, multiple congenital anomalies, or history of multiple operations) should be labeled "latex alert."
6. Create awareness within hospital, clinic, and community.
7. Urge development of latex-free operating rooms, especially for high-risk patients.
8. Report incidents to the FDA (800-638-6725).

Meeropol et al.[94] found that 7 of 16 Shriners children's hospitals surveyed had latex-free operating rooms.

SURGERY FOR LATEX-SENSITIVE PERSONS

When surgery is necessary, prophylactic medication (Table XV[222]) is recommended in addition to latex avoidance. Although this is beneficial in some cases of latex sensitization,[83,220] allergic reactions still occur.[223-225] Although some authorities[83,226] do not advocate switching to latex-free medication vials and syringes, there have been reports of reactions to latex in these sources.[227-230] A detailed anesthesia protocol describing equipment, set-up, and management for surgical latex-sensitive patients has been developed at the Cleveland Clinic and is posted on the Internet.[231]

LATEX SUBSTITUTES

For sources of nonlatex surgical and examination gloves, low allergen latex gloves, and DTH allergens in gloves, several excellent references are available.[14,115,232-235] Lists of latex-safe alternatives to many products found in hospital and home environments are also available.[221] Five major glove alternatives are briefly discussed below

Polyvinylchloride (vinyl) gloves are probably the least expensive and most widely used nonlatex examination glove alternative. Their main disadvantages are inflexibility and permeability to fluids and infectious agents.[226,237] One study found that 63% of vinyl gloves versus 7% of latex gloves leaked after repeatedly attaching and removing a needle from a syringe.[238] Vinyl gloves may also contain colorants and formaldehyde, which may produce DTH allergy, accounting for approximately 1% (5 of 542) of occupational allergic glove dermatitis in one series.[61]

Polychloroprene (neoprene) gloves may similarly contain allergenic accelerators such as isodiphenylthiourea, carbamates, and mercaptobenzothiazoles. Heese et al.[141] reported a latex-sensitive person in whom anaphylaxis developed after wearing polychloroprene gloves. Prick and patch tests to polychloroprene were negative. On inquiry of the manufacturer, it was discovered that an inner coating of NRL (not declared on the glove box label) had been added to minimize costs.

Carbamates may be found in both sterile and nonsterile examination gloves made of styrene butadiene block polymers (elastyren).[232] Nonsterile acrylic nitrile butadiene polymer (nitrile) examination gloves can also contain added chemicals such as mercaptobenzothiazoles and dyes (Allerderm product information). Sterile and nonsterile triblock copolymer (polystyrene-b-[ethylene-cobutylene]-b-polystyrene) gloves (Tactylon) were found to be safe in patients with immediate[239] and DTH to NRL. Lahti et al.[240] found one positive reaction in 156 persons patch tested to Tactylon.

Table XV. Preoperative regimens for latex-sensitive persons*

Start 24 hr preoperatively and continue for 24 hr postoperatively:	
Diphenhydramine	1 mg/kg q 6 hr IV/PO (max 50 mg)
Alternative	Terfenadine 30-60 mg q 12 hr PO
Methylprednisolone	1 mg/kg q 6 hr IV/PO (max 125 mg)
Alternative	Prednisone 0.5 mg/kg/dose q 12 hr PO
Cimetidine	5 mg/kg/dose q 6 hr IV/PO (max 300 mg)
Alternative	Ranitidine 1-2 mg/kg/day divided q 8 hr IV or 3-4 mg/kg/day divided q 12 hr PO

IV, Intravenous, *max*, maximum; *PO*, orally, *q*, every

*Modified from Meeropol E, Frost J, Pugh L, Roberts J, Ogden JA. J Pediatr Orthop 1993;13:1-4; Kelly KJ. Immunol Allergy Clin North Am 1995;15:139-57 and Kwittken PL, Becker J, Oyefara B, Danziger R, Pawlowski NA, Swenberg S. Allergy Proc 1992;3:123-7

Availability of nonlatex contraceptive products is important because severe reactions have been reported from mucosal exposure to latex condoms.[38,40] Condoms made of processed lamb cecum do not protect against transmission of HIV[241] and therefore are not practical for many persons. Fisher[242] recommended that NRL-sensitive men wear a lamb cecum condom under an NRL condom and that this layering be reversed if the partner is sensitive to NRL. Unfortunately, wearing two condoms has little appeal.

Polyurethane male and female condoms are now available.[243] Polyurethane condoms prevent not only pregnancy but also transmission of viral diseases such as herpes and HIV.[244,245]

It is expected that a new male condom made of Tactylon will also be available soon.[246] A clinical trial has already demonstrated that the breakage rate of Tactylon condoms is as low as NRL condoms.[247] Tactylon condoms prevented passage of a small bacteriophage (27 nm) as effectively as NRL condoms when tested as a surrogate for HIV (80 to 100 nm).[248] Tactylon condoms have the added benefit of possessing no unsaturated bonds and therefore are unaffected by conditions that cause NRL to deteriorate, such as contact with petrolatum products and ozone.[246]

LATEX PRODUCT LABELING

Manufacturers use various labels to describe NRL products. The term *hypoallergenic* refers to reduced DTH allergen content and does not imply latex-free. The FDA restricts the use of this label to products that do not induce DTH during a modified Draize test involving 200 humans. Hypoallergenic gloves can still contain latex and therefore are not appropriate for persons who are latex-sensitive.[168] Such labeling causes confusion; a latex-sensitive nurse developed anaphylaxis to sterile surgical gloves labeled "specially formulated for hands allergic to latex."[249] The manufacturer used this phrase to refer to the removal of antioxidants that cause DTH.[250] Incidences such as this have prompted the FDA to ban the term *hypoallergenic* on labels of products containing NRL. In the same ruling, the FDA also mandated that labels of NRL medical devices must state "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", dry natural rubber medical devices must be labeled "This Product Contains Dry Natural Rubber." Similar labeling will be required for nonmedical devices containing NRL that contact humans, such as NRL adhesives used in adhesive bandage strips. These rulings go into effect Sept. 30, 1998.[251] The FDA, industry, and the European glove standard are also developing regulations for "powder-free" latex medical devices.[125,235]

EFFORTS TO DECREASE ALLERGEN CONTENT

Efforts to minimize and remove allergens causing type I reactions depend on identification of responsible proteins. As the role of specific allergens has yet to be clarified, current aims at eliminating allergens have focused on decreasing total amounts of protein produced during manufacturing. Ammonia, added to fresh latex during collection, decreases extractable protein levels. Centrifugation halves total protein levels, and double centrifugation reduces protein levels by another 25% to 30%. During compounding, however, addition of detergents or potassium hydroxide can actually increase levels of extractable proteins. Water leaching is critical. 5 minutes of wet gel leaching removes 60% of extractable protein from postvulcanized films and 85% from prevulcanized films. As much as 90% of extractable protein can

be removed by combining wet gel and dry film leaching.[252]

Vulcanization selectively favors build-up of water-soluble proteins on the inside glove surface. Perhaps because of this migration phenomenon, postprocessing chlorination appears to be the most effective method of reducing protein content, not only by rendering remaining surface proteins insoluble, but also by leaching additional extractable proteins. Chlorination is a necessary step in producing powder-free gloves and may explain why some latex-sensitive persons are able to tolerate powder-free gloves. Autoclaving and application of silicone to NRL surfaces can further reduce protein migration.[253]

Although these techniques reduce allergen content, benefits must be balanced against both increases in production costs and changes in physical properties of the finished product. For example, chlorination has several disadvantages. First, it increases a production facility's rejection rate by 7% to 20%. Second, it creates a slippery surface disliked by many clinicians. Third, it cleaves isoprene chains, which decreases stretch and strength of NRL films and reduces shelf life.[246] Experimental types of latex, such as enzymatically treated or pasteurized latex, may play a larger role in preventing latex allergy in the future.[252]

ALTERNATIVE SOURCES OF NATURAL RUBBER

There are several rubber-producing species other than *H. brasiliensis*. The rubber particles in the common North American desert shrub, guayule *(Parthenium argentatum)*, contain *cis*-isoprene that is virtually identical to *Hevea* rubber.[254] Recently, researchers have developed hypoallergenic rubber from guayule, which was tolerated by persons allergic to *Hevea* latex and demonstrated superior resiliency, strength, and elasticity. This technology has been patented, and guayule rubber medical supplies will soon be available.[255]

Immediate-type allergy to guayule has not been described; however, rarely DTH may develop.[256] Rodriguez, Reynolds, and Thompson[257] isolated the sesquiterpene cinnamic acid ester, guayulin A, from dried guayule leaf extract and determined that it was a potent elicitor of DTH. Other species of *Parthenium* contain sesquiterpene lactones that are cytotoxic and produce allergic skin reactions.[258] This DTH sensitization could be a potential problem for persons exposed to guayule rubber products.

Ficus elastica, the common ornamental rubber plant, produces relatively low-molecular-weight rubber proteins and is another potential alternative rubber source. Carey et al.[259] found that seven *H. brasiliensis*–sensitive health care workers all had negative SPTs to *F. elastica*.

MANAGEMENT

Avoidance of direct contact with latex products may not be sufficient.[260] Swanson et al.[261] collected air samples from 11 medical areas where powdered latex gloves were frequently used and found that latex aeroallergen concentrations were up to 115 times greater than in areas where powdered latex gloves were never or seldom used. Use of a laminar flow glove changing station in one work area did not reduce latex aeroallergen levels. Use of powder-free gloves appears to be more effective in reducing aeroallergen levels, as demonstrated by Tarlo et al.[262] who showed that the asthmatic and anaphylactic reactions of a hospital laboratory technician could be controlled by her coworkers' use of powder-free gloves. Vandenplas et al.[263] similarly found that latex gloves with lower protein and powder contents significantly reduced the risk of development of asthmatic reactions in eight health care workers who showed latex-induced occupational asthma during inhalation challenge tests.

Treatment of symptoms with topical steroids and oral antihistamines has been the mainstay of treatment for latex allergy. Hyposensitization has not been successful. Immunotherapy, although still experimental, holds promise for future therapy. Slater et al.[264] found vaccines with cloned Hev b 5 DNA sequences inhibited IgE responses to Hev b 5 in mice sensitized to this antigen. These results suggest that DNA vaccines with encoded allergens may offer a new mode of allergen immunotherapy for persons with latex allergy.

FUTURE ISSUES

Latex awareness is growing. National television has aired exposés such as ABC's *20/20* "Latex Allergies." A recent fictional drama, NBC's *ER*, depicted a medical student having an anaphylactic reaction to latex gloves. Many hospitals and organizations such as the National Institute of Occupational Safety and Health and the American

Academy of Dermatology have already formed latex task forces. These committees not only deliberate on issues regarding education and development of latex-safe areas, but also address potential legal implications. The Americans with Disabilities Act and the Federal Rehabilitation Act of 1973 may require accommodation (e.g., lowering allergen levels and special protective equipment) of employees with latex allergy.[265] Lawyers are already advertising for clients on latex Web sites, and there are at least two class action lawsuits in the United States filed against manufacturers of NRL gloves.[266] Bills entirely banning powdered latex gloves in health care facilities have been introduced in Oregon, Minnesota, and New York.[267] Implications of these heated legal debates are far-reaching and affect whom, how, and with what tools medicine is practiced.

SUMMARY

Latex allergy affects thousands of people in several major risk groups. Although progress has been made during the past decade in identifying responsible antigens, much research is needed to develop safe, accurate, and reliable tests for detecting latex allergy. Almost 50% of hospital products contain NRL, eliminating these sources of sensitization and educating those persons at risk without causing irrational public responses are ongoing goals.

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221 Product list. Latex Allergy News 1997;introd issue, 5-9

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224 Setlock MA, Cotter TP, Rosner D Latex allergy: failure of prophylaxis to prevent severe reaction. Anesth Analg 1993;76 650-2.

225. Gold M, Swartz JS, Braude BM, Dolovich J, Shandling B, Gilmour RF Intraoperative anaphylaxis: an association with latex sensitivity J Allergy Clin Immunol 1991,87 662-6

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227 Vassallo SA, Thurston TA Kim SH, Tradres ID

CME examination

Identification No 898-107

Instructions for Category I CME credit appear in the front advertising section. See last page of Contents for page number.

Questions 1-31, Warshaw EM. J Am Acad Dermatol 1998;39:1-24.

Directions for questions 1-15: Give single best response.

1. A mature *Hevea brasiliensis* tree produces sufficient latex to make approximately how many pairs of gloves per week?
   a. 1
   b. 10
   c. 100
   d. 500
   e. 1000

2. Accelerators such as thiurams, carbamates, and mercaptobenzothiazoles are important for controlling the rate and completeness of what step in glove production?
   a. Centrifugation
   b. Compounding
   c. Coagulation oven curing
   d. Vulcanization
   e. Powder application

3. What process discovered by Goodyear in 1839 creates disulfide bonds that cross-link *cis*-1,4 polyisoprene chains to each other?
   a. Centrifugation
   b. Compounding
   c. Coagulation oven curing
   d. Vulcanization
   e. Powder application

4. What are the two crucial variables that influence degree of protein removal during the post–oven leaching bath in glove production?
   a. Temperature and detergent
   b. Detergent and time
   c. Temperature and time
   d. Detergent and rate of water exchange
   e. Time and rate of water exchange

5. Clinical manifestations of type I immediate hypersensitivity to latex may include
   a. urticaria and pruritus
   b. nausea and vomiting
   c. rhinitis and conjunctivitis
   d. *a* and *c* only
   e. *a*, *b*, and *c*

6. Anaphylaxis caused by latex allergy has been reported after contact with
   a. squash balls
   b. food prepared with latex gloves
   c. air expelled from a whoopee cushion
   d. *a* and *c* only
   e. *a*, *b*, and *c*

7. Each of the following statements regarding endotoxin is true *except*
   a. it can cause irritation of skin, eyes, and lungs.
   b. high levels have been found in containers used for collecting raw latex.
   c. it is produced by gram-negative bacteria.
   d. it is physically associated with tiny respirable particles.
   e. high levels have been found in powdered latex examination gloves.

8. The prevalence of latex sensitivity in the general population is approximately
   a. 0% to 2%
   b. 3% to 5%
   c. 9% to 10%
   d. 13% to 15%
   e. 18% to 20%

9. Risk factors for development of latex allergy include each of the following *except*
   a. preexisting hand eczema
   b. atopy
   c. fruit allergy
   d. male gender
   e. history of multiple surgical procedures

10. The risk of anaphylaxis to latex in children with spina bifida is estimated to be how many times greater than in the general population?
    a. 10
    b. 50
    c. 100
    d. 500
    e. 1000

11. Persons in which of the following occupations are at high risk for development of latex allergy?
    a. Health care
    b. Hairdressing
    c. Latex glove manufacturing
    d. *a* and *c* only
    e. *a*, *b*, and *c*

12. Formation of a wheal is considered a positive reaction in each of the following tests *except*
    a. radioallergosorbent test (RAST)
    b. skin prick test
    c. use test
    d. scratch chamber test
    e. rub test

13. Variables that make detection and characterization of latex allergens difficult include

a. haptenization of latex proteins with compounding chemicals
b. variations in latex proteins produced by different hybrids of trees
c. seasonal variations in latex proteins produced by the same trees
d. *a* and *c* only
e. *a*, *b*, and *c*

14. Food allergies thought to be important in cross-reacting with latex include each of the following *except*
a. avocado
b. banana
c. chestnut
d. fish
e. kiwi

15. Each of the following types of gloves is safe for latex-allergic persons *except*
a. hypoallergenic
b. polyvinylchloride (vinyl)
c. polychloroprene (neoprene)
d. styrene butadiene block polymers (elastyren)
e. nitrile butadiene polymer (nitrile)

Directions for questions 16-25: For each numbered item choose the appropriate lettered item.
a. True
b. False

16. Allergen levels from a specific glove brand are fairly constant when tested at different times.

17. Delayed-type hypersensitivity (to rubber additives) and immediate-type hypersensitivity to natural rubber latex products may coexist.

18. Latex-specific RAST is considered the standard for detecting latex allergy

19. At least two Food and Drug Administration–approved commercial latex extracts are available for skin prick testing.

20. The significance of latex-specific IgG antibodies in diagnosing latex allergy is controversial.

21. Antibodies from different high-risk populations (e.g., patients with spina bifida and health care workers) may recognize different latex peptides.

22. The medical research community has agreed that the 14.6 kd rubber elongation factor is the single most important latex antigen.

23. There is no test that reliably and accurately predicts who will have anaphylaxis to latex.

24. Avoidance of latex is not necessary if preoperative medication is given to a latex-allergic patient undergoing surgery.

25. Powdered latex gloves can cause high aerosolized concentrations of latex allergens, which may cause reactions in latex-sensitive persons who never come into direct contact with the gloves.

Directions for questions 26-31: Select the lettered item that is most closely related to each numbered item.
a. Immediate, type I reaction
b. Delayed, type IV reaction

26. Mediated by IgE

27. Cell-mediated

28. Antigens are small latex proteins.

29. Antigens are manufacturing additives.

30. Diagnosis is made most commonly by patch test.

31. Diagnosis is made most commonly by skin prick test, RAST, or use test.

Answers to CME examination

Identification No. 898-106

June 1998 issue of the Journal of the American Academy of Dermatology

Questions 1-28, Ploysangam T, Breneman DL, Mutasim DF *J Am Acad Dermatol* 1998;38:877-95

1. d	8. a	15. a	22. d
2. a	9 a	16. a	23 a
3. b	10. b	17 c	24 a
4 d	11 c	18. b	25. a
5. d	12. d	19 d	26. a
6. d	13. d	20. c	27 c
7 c	14 c	21 c	28 b

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY San Diego STATE CA ZIP 92111

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE) Same

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Latex allergy at work with respiratory problems including asthma & anaphylaxis. I now have reactive airway disease & heart murmur. I am unable to work without reacting within 10 minutes of being within hospital. Am RN working recovery rm & OR.

VICTIM'S AGE 51 SEX F DATE OF INCIDENT 4/96

DESCRIBE PRODUCT INVOLVED Latex exam gloves

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☐ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME [redacted]

YOUR ADDRESS

CITY STATE ZIP

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Latex Balloons in hotels, restaurants sports arenas, grocery stores + florists shop cause my eyes to water + itch, and my throat to swell even after brief (2-3 minute) contact. MYLAR balloons are latex free + should be the only balloons used unless notice posted on the entrance.

VICTIM'S AGE 57 SEX F DATE OF INCIDENT CONSTANT - multiple dates

DESCRIBE PRODUCT INVOLVED latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME

YOUR ADDRESS [redacted]

CITY STATE ZIP

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Throat began swelling 1 hr after eating a Hamburger at Burger King in Minnesota (No. Mankato?) Also 2 Bar B Q restaurants in Kerrville + + Comfort, TX - If gloves are mandatory in restaurants, vinyl (NOT latex) gloves should be used or a latex sign posted.

VICTIM'S AGE 57 SEX F DATE OF INCIDENT May 98 + Feb 99

DESCRIBE PRODUCT INVOLVED Latex gloves by food workers

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

SOUTH EASTON MASS 02375
CITY STATE ZIP

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

* NATURAL RUBBER LATEX IS NOW A HAZARDOUS SUBSTANCE TO ME.

DESCRIBE THE INCIDENT OR HAZARD INCLUDING DESCRIPTION OF INJURIES I DEVELOPED AN ALLERGY TO NATURAL RUBBER LATEX AS A RESULT OF MY USE OF LATEX GLOVES WHILE WORKING AS A NURSE. I NOW HAVE A LIFE LONG TYPE I- ALLERGY WHICH CAN CAUSE ANAPHYLAXIS AND DEATH. I MUST AVOID ALL EXPOSURE TO NATURAL RUBBER LATEX IN ALL MY MEDICAL & DENTAL CARE AND IN MY PERSONAL LIFE.

VICTIM'S AGE 46 SEX F DATE OF INCIDENT FIRST DIAGNOSED 6/94

DESCRIBE PRODUCT INVOLVED LATEX GLOVES

PRODUCT BRAND NAME/MANUFACTURER ALL BRANDS AND MANUFACTURERS

IS PRODUCT INVOLVED STILL AVAILABLE? ☐YES ☐NO PRODUCT MODEL AND SERIAL NUMBER

WHERE WAS THE PRODUCT PURCHASED? * IT IS NOW IMPERATIVE THAT I BE AWARE OF THE NATURAL RUBBER LATEX CONTENT IN ALL PRODUCTS.

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[redacted] (parents)

YOUR NAME

YOUR ADDRESS

Pittsburgh PA 15217

CITY STATE ZIP

[redacted]

YOUR TELEPHONE

NAME OF VICTIM IF DIFFERENT FROM ABOVE

same as above

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD INCLUDING DESCRIPTION OF INJURIES ANAPHYLAXIS, EDEMA, URTICARIA, HIVES

Adam experienced an anaphylactic reaction in a restaurant at the age of three. Latex gloves were utilized in the restaurant. The other above described symptoms/reactions were the result of his prescence in a room where balloons existed or had been blown up.. Latex gloves and balloons are the scariest items for his allergy. We would like to see all latex balloons come with a strict warning. Obviously we feel the same way about latex gloves. **BAN LATEX GLOVES & PRODUCTS IT KILLS!**

Adam's allergy has been confirmed by blood tests which are performed annually at the direction of his allergist.

VICTIM'S AGE 6 SEX M DATE OF INCIDENT Anaphylaxis on September 1996

DESCRIBE PRODUCT INVOLVED Latex gloves and balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒YES ☐NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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PLEASE PRINT OR TYPE FORM AND ATTACH ADDITIONAL SHEETS IF NEEDED

CPSC FORM 1753 (1/94) OMB CLEARANCE NO. 3041-0079

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YOUR [redacted]

YOUR ADDRESS [redacted]

CITY [redacted] STATE CT ZIP 06057

YOUR [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

Same

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Attended Springfield Mass. RV Show, Walked in balloons every where, clowns w/balloons After 30 minutes difficulty breathing, throat sticking, took inhalers & [redacted] put on respirator surgical mask; 30 more minutes later ± had to leave building, eyes burning, headache, difficulty breathing, continued attached

VICTIM'S AGE 34 SEX F DATE OF INCIDENT Approx Wknd Feb 20th, 1999

DESCRIBE PRODUCT INVOLVED Latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? X YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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[redacted]

Incident continued:

felt extremely tired (suddenly), took week + 1/2 to return to normal breathing and feeling - not being tired out.

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY New Hartford STATE CT ZIP 06057

YOUR PHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS Same.

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Washed Runner rugs with rubber backing - Took out of dryer 10:30pm - hands became extreme itchy, Nose runny, sneezing - overwhelming tiredness. Woke up at 2:30am - [redacted] chest, whole system [redacted] wire brush, crushing chest pain - took 14 days for systems to return to normc

VICTIM'S AGE 34 SEX F DATE OF INCIDENT 2/3/99

DESCRIBE PRODUCT INVOLVED Everyday - Runner Rug

PRODUCT BRAND NAME/MANUFACTURER - - bought at Walmart.

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY West Hartford STATE CT ZIP 06057

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)
Same.

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES: My husband got new work boots 2 pairs, had very noticable strong glue smell. My nose started becoming congested, raw feeling. Approx 2 hrs later granular sputum coming up, difficulty breathing. Very tired - went to bed - all I could smell was the glue - got up - took offensive boots out onto porch. Fri 8/6/99 am upon waking. Nose is swollen, inside very raw, 2 days later granular sputum still coming up.

VICTIM'S AGE 34 SEX F DATE OF INCIDENT 8/5/99 am

DESCRIBE PRODUCT INVOLVED Wear Guard Hi-top leather work boot - steel toes

PRODUCT BRAND NAME/MANUFACTURER Wear Guard

IS PRODUCT INVOLVED STILL AVAILABLE? X YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED? 8/99 [redacted]

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[redacted]

YOUR ADDRESS

St. Peters MO 63376
CITY STATE ZIP

[redacted]

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD INCLUDING DESCRIPTION OF INJURIES Use of latex elastic causes me to develop severe eczema. Since clothing is not labeled to indicate latex is used, I have no way of knowing if an article of clothing is safe for me. At present, I have had to make my own undergarments (or purchase custom made - very expensive). I have also had to give away many items I thought owned before learning of latex allergy or that I had thought were safe.

VICTIM'S AGE 50 SEX F DATE OF INCIDENT

DESCRIBE PRODUCT INVOLVED bras, underwear, swimsuits, slacks

PRODUCT BRAND NAME/MANUFACTURER Hanes, Platex + others

IS PRODUCT INVOLVED STILL AVAILABLE? YES NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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EVENING TELEGRAM
SUPERIOR, WI
DAILY 12,661
SATURDAY
SEP 19 1992
BUBBELLES
243 ...edn TM

Area girl may have died from allergic reaction

By PEG LAMKIN
Telegram Correspondent

RICE LAKE – A 13-year-old rural Cameron girl may have died Wednesday from an allergic reaction to latex, after blowing up balloons in bath water, according to a St. Paul, Minn., doctor.

Denise Odenbrett, daughter of Gary Odenbrett, New Auburn, and Cathy Buckwalter, Cameron, was taken to a Rice Lake hospital Sunday morning after she was found unconscious and not breathing on a bathroom floor. She died at 12:50 p.m. Wednesday in Children's Hospital, St. Paul, where she had been transferred by helicopter.

Dr. Paul Kubic, pulmonologist at Children's Hospital, said the child is believed to have died of anaphylactic shock (an extreme allergic reaction), and an allergy to latex was "probably No. 1 of the diagnosis possibilities." Results of biochemical tests were not yet available.

Kubic said Denise and her family had a history of allergies, and she may have become sensitized to the substances during a recent hospital stay. She had been hospitalized with asthma and pneumonia within the past month, but had returned home and was said to be "feeling fine" in the day or so before her death, according to Kubic.

"It's something parents should take note of, especially if there is a strong family history of allergies," Kubic said. "Hidden allergens may be found anywhere in the environment, and latex allergies are well-known today."

He said many people become sensitized to latex during surgery, where they have contact with surgical gloves.

Buckwalter said her daughter had been playing with balloons in the bathtub, and while hospitalized earlier, had been blowing up surgical gloves.

Dr. Paul Kubic
Childrens Hosp St Paul, MN
612-220-6744

MINNESOTA DEPARTMENT OF HEALTH
Section of Vital Statistics

LOCAL FILE NUMBER ▸

CERTIFICATE OF DEATH

STATE FILE NUMBER

1. DECEDENT'S NAME (First)	(Middle)	(Last)	2. SEX	3. DATE OF DEATH (Month, day, year)	4. TIME OF DEATH
DENISE	RAE	ODENBREIT	Female	September 16, 1992	1300

5. SOCIAL SECURITY NUMBER	6a. AGE (Last Birthday) (Years)	6b. UNDER 1 YEAR (Months)	6b. UNDER 1 YEAR (Days)	6c. UNDER 1 DAY (Hours)	6c. UNDER 1 DAY (Minutes)	7. DATE OF BIRTH (Month, day, year)
394-84-9820	13					July 22, 1979

8. BIRTHPLACE (City and State or Foreign country)	9. WAS DECEDENT EVER IN U.S. ARMED FORCES? (Specify yes or no)	10a. PLACE OF DEATH (Check only one; give name of hospital or other location)
Rice Lake, Wisconsin	No	☐ HOSPITAL: ☐ Inpatient ☐ ER/Outpatient ☐ DOA ☐ OTHER: ☐ Other (Specify) ☐ Nursing home ☐ Residence

10b. FACILITY NAME (If not institution, give street and number)	10c. CITY OR TOWN OF DEATH	10d. COUNTY OF DEATH
United Hospital Childrens	St. Paul	Ramsey

11. MARITAL STATUS (Married, Never Married, Widowed, Divorced, Unknown)	12. SPOUSE (If wife, give maiden name)	13a. DECEDENT'S USUAL OCCUPATION (Give kind of work done during most of working life, even if retired)
Never Married		Student

13b. KIND OF BUSINESS/INDUSTRY	14a. STATE OF BIRTH	14b. COUNTY	14c. CITY OR TOWN OF BIRTH
Education	Wisconsin	Barron	Prairie Lake Township

15a. USUAL RESIDENCE (Street and number)	15b. INSIDE CITY LIMITS? (Specify yes or no)	15c. ZIP CODE	16. WAS DECEDENT OF HISPANIC ORIGIN? (Specify yes or no — if yes, specify Cuban, Mexican, Puerto Rican, etc.) ☐ Yes ☒ No
1908 10½ Avenue Cameron, WI	No	54822	

17. RACE (Give respective or other term)	18. DECEDENT'S EDUCATION (Specify only highest grade completed: Elementary/Secondary (0-12) or College (1-4 or 5+))	19. FATHER'S NAME (First, middle, last)
White	6	Garl Donald Odenbreit

20. MOTHER'S NAME (First, middle, maiden surname)	21a. INFORMANT'S NAME (Type/print)	21b. INFORMANT'S MAILING ADDRESS (Street and Number or Rural Route Number, City, State, Zip Code)
Catherine Mae Metz	Garl Donald Odenbreit	2348 4½ Avenue Chetek, Wisconsin 54728

22a. METHOD OF DISPOSITION: ☐ Burial ☐ Cremation ☒ Removal from state ☐ Donation ☐ Other (Specify)

23a. PLACE OF DISPOSITION (Name of cemetery, crematory, or other place)	23b. LOCATION - City or Township, State	23c. SIGNATURE OF PERSON ACTING AS FUNERAL DIRECTOR OR AUTHORITY
Pine Grove Cemetery	Cameron, Wisconsin	Lynette Kuhnert 2555

24a. LICENSE NUMBER (For Funeral Establishment)	24b. NAME AND ADDRESS OF FUNERAL ESTABLISHMENT	25a. CERTIFICATE-PHYSICIAN
0383	O.E. Larson-Osborne Mortuary 2301 Central Avenue NE, Minneapolis, MN 55418	I attended the deceased from _____ to _____ (Mo. day year) (Mo. day year) and last saw him/her on _____ (Mo. day year) ☒ Did not view the body after death.

25b. SIGNATURE, Degree/Title, Address of Certifier	25c. LICENSE NUMBER (If physician)	25d. DATE SIGNED (Month, day, year)
	0244921	10-7-92

26. NAME AND ADDRESS OF ☐ CERTIFIER ☒ MEDICAL EXAMINER OR CORONER	27. ACTUAL OR PRESUMED DATE OF DEATH
MICHAEL B. MCGEE, M.D. 155 HILL ST. ST. PAUL, MN 55102	OCT 13 1992

28. CAUSE OF DEATH

Part I. Enter the diseases, injuries, or complications that caused the death. Do not enter the mode of dying, such as cardiac or respiratory arrest, shock, or heart failure. List only one cause on each line.

☐ 28. Autopsy performed ☐ Check here

Approximate interval between onset and death

IMMEDIATE CAUSE (Final disease or condition resulting in death): a. ANOXIC ENCEPHALOPATHY

Sequentially list conditions, if any, leading to the immediate cause. Enter UNDERLYING CAUSE (disease or injury that initiated events resulting in death) LAST: due to or as a consequence of: b. RESPIRATORY ARREST

due to or as a consequence of: c. PROBABLE STATUS ASTHMATICUS

Part II. Other significant conditions contributing to death but not resulting in the underlying cause given in Part I

29a. WAS CASE REFERRED TO MEDICAL EXAMINER/CORONER?	29b. WAS AN AUTOPSY PERFORMED?	29c. WERE AUTOPSY FINDINGS AVAILABLE PRIOR TO COMPLETION OF CAUSE OF DEATH?
☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No

30. MANNER OF DEATH	30a. DATE OF INJURY (Month, day, year)	30b. TIME OF INJURY
☒ Natural ☐ Accident ☐ Suicide ☐ Homicide ☐ Pending investigation ☐ Could not be determined		

31a. INJURY AT WORK?	31b. DESCRIBE HOW INJURY occurred
☐ Yes ☐ No	

31c. PLACE OF INJURY - At home, farm, street, factory, office building, etc. (Specify)	31d. LOCATION - Street and number (City or township, State)

STATE OF MINNESOTA
RAMSEY COUNTY

I hereby certify that the above is a true and correct copy of the record on file with the Vital Statistics Registry of Saint Paul - Ramsey County Department of Public Health, City of Saint Paul, Minnesota.

(Signed) _____, this 3rd day of April 1998

Deputy Registrar Vital Statistics

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT	2. TELEPHONE NO. (Home) (Work)
Mary Ann Henderson	816-619-2933
3. STREET ADDRESS	**4. CITY / STATE / ZIP CODE**
205 E. Main, Apt. B P.O. Box 116	Drexel MO 64742

5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.)

My son NAVY Lt. Harold R. Henderson, died on August 29, 1997 due to complacation from Latex poisoning.

6. DATE OF INCIDENT(S)	7. IF INJURY OR NEAR MISS, OBTAIN	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE
8/29/97	AGE ~~40~~ SEX ~~Male~~ AND DESCRIBE INJURY ~~latex poisoning~~	NAME ~~Lt. Harold R. Henderson~~ RELATIONSHIP ~~Son~~

9. DESCRIPTION OF PRODUCT	10. BRAND NAME
Use of latex rubber gloves	See attached sheet
11. MANUFACTURER/DISTRIBUTOR NAME, ADDRESS & PHONE	**12. MODEL, SERIAL NO.'S**
See attached sheet	
	13. DEALER'S NAME, ADDRESS & PHONE
	See attached sheet

14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED?	15. PRODUCT PURCHASED NEW ____ USED ____
YES X NO ____ IF YES, BEFORE OR AFTER THE INCIDENT? ~~Trying to make changes~~ Describe ~~DEAD!! From effects of latex poisoning~~	DATE PURCHASED ____ AGE ____
	16. DOES PRODUCT HAVE WARNING LABELS? IF SO, NOTE: NO NO NO NO

17. HAVE YOU CONTACTED THE MANUFACTURER?	18. IS THE PRODUCT STILL AVAILABLE?	19. MAY WE USE YOUR NAME WITH THIS REPORT?
YES ____ NO X IF NOT, DO YOU PLAN TO CONTACT THEM? YES X NO ____ OTHER ____	YES X NO ____ IF NOT, ITS DISPOSITION ____	YES X NO ____

FOR ADMINISTRATION USE

20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO.
		X983248
23. FOLLOW-UP ACTION		**24. PRODUCT CODE(S)**
25. DISTRIBUTION	**26. ENCORSER'S NAME & TITLE**	

CPSC FORM 175 (9/89)

T-23

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

See attached sheet.

I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

Mary Ann Henderson 3-21-98

Signature Date

☐ I request that you do not release my name.

☐ You may release my name to the manufacturer but I request that you not release it to the general public.

☒ You may release my name to the manufacturer and to the public.

X9832148

T-23

Consumer Product Incident Report

By filling out the form below and then submitting it, you can report any injury or death involving consumer products to us, or report an unsafe product to us. We may contact you by mail or by telephone (not via internet) for further details or to confirm the information you sent. Please provide as much information as possible. Your name, address, and telephone number are optional, but we can't contact you without that information. You can also report an incident or unsafe product by calling toll-free at 1-800-638-2772

When filling out the form, use the <TAB> key or your mouse to go to the next data area. Use the scroll bar to scroll down the form.

Your name: MARY Ann Henderson

Your address: 205 E. Main, P.O. Box 246

X983-2118

City: Drexel

ISSUE 23

State: Mo

MAR 0 2 1998

E-mail address:

Zip code: 64742

Your telephone: 816-619-2933

Name of victim (if different from above) LT. Harold R. Henderson, U.S. Navy

Victim address: 3162 Pageant Ave.

City: San Diego

State. CA

Zip code: 92129

Victim telephone: 1-619-538-3405

Describe the incident or hazard, including description of injuries

This was my son's address & phone No. at Time of his death, Aug. 29, 1997. Please read all enclosed information which will explain. I'm working very hard for Debi Adkins & Lisa C. Borel at LATEX ALLERGY Information Service, in behalf of My Son.

1 of 10

Thank You,
Mary Ann Henderson

Victim's Age. 40

Victim's sex
○ Female
✓ Male

Date of Incident: Aug 29, 1997

Describe product involved:
Read enclosed Material

Product Brand Name/Manufacturer:

Is product involved still available?
✓ Yes
○ No

Product model and serial number:

When was the product purchased?

Send to CPSC | Clear Form

This information is collected by authority of 15 U S C 2054 and will be entered into a database by a Consumer Product Safety Commission contractor The information may be shared with product manufacturers, distributors, or retailers However, no names or other personal information will be disclosed without explicit permission

OMB Control Number 3041-0029

January 7, 1998

To Whom it may Concern:

In regards to an Act to create 146.49 of the statutes: relating to prohibiting the use of Certain latex products by health Care providers and granting rule making Authority by the Wisconsin legislation.

Let me first introduce myself, I am Mary Ann Henderson, the mother of the late Lieutenant Harold R. (Hal) Henderson, RN, BSN, CEN, TNCC, NC, USN/Ret., Age 40 years of San Diego, California, who died Friday, August 29, 1997, at the Balboa Naval Hospital.

My son had been in very ill health for some time as the result by respiratory and Cardiac Complications associated with Latex allergy, he suffered a massive heart attack. Full life support was removed at 2:15pm. Pacific Time, August 29, 1997.

Now I ask your indulgence as I go back a few years, so that everyone understands my sons great love of the medical field. He was interested in the medical field about the fifth grade and he was able to attend Vocational Tec. School half days when he was a Junior in high school.

He was a member of Rotc in high school and towards the end of his Junior school year he told me he was going down to talk with the Navy Recruiter. Hal did this and signed a Contract to become a Navy Corpsman and join the Navy at the end of his senior year of high school in 1975, he could then persue his dream of becoming a Navy Trama Nurse. He achieved that dream from Navy Corpsman to Lieutenant Navy Nurse.

My Son was so very proud to serve his Country and was on the front lines in Desert Storm.

Hal loved working in the ER and FCU and because of this he

developed latex allergy from his occupational exposure to latex products. He began having life threatening reactions. At this time my son and I began having many long distance phone calls over the next couple of years. You see my son died because after years of medical apathy and their disbelief that an innocent balloon or a latex glove could cause a life-threatening reaction, because the very people treating him failed to give his Allergy and it's potential to be a pro-gressive Condition, proper attention the attacks became more frequent and his strong body slowly died.

My son would call me hardly able to breath or sounded just so weak to talk. He would tell me how the doctors at the very hospital he worked at would treat him in the ER with such disrupect, Contempt, And tell him that it was all in his head. He told me the Navy Head Brass were putting pressure on him to retire and give up his

Career in nursing and the Navy. He loved his service to the military. Each time he was rushed to the ER he said they treated him with such apathy that he said his self-esteem went to an all time low. He said they would even come in the ER or his room wearing powdered latex gloves. My son died in a hospital that still used products knowing full well that they caused serious, systemic life-threatening allergic reactions and death, and on these products were no warning labels.

Each phone call from my son in California to me here in Missouri, would tell me how he was going down hill, a mother can tell even over the phone.

When I went to San Diego, California the end of July 1996 to attend my sons beautiful wedding the beginning of August to his wonderful lady Christine, I saw how his 6' 7½" body had gone down hill. We had to all most hold him up for the

Ceremony, but Hal loved Christine so much, and he had told me that week before, "What ever it takes mom get me to the Alter on time". Even as ill as he was they shared together many happy memories in their one short year together.

My gut feeling when I flew home after the wedding that he was in very bad medical shape, and failing fast.

My Son remained optimistic after he was forced to give up his Career in nursing and his service to the military, that he could prevent others from becoming latex allergic, and to prevent others having to go through his great loss of career, health, self-esteem that he had suffered

After retiring Hal began Working tirelessly as a military liaison for ELASTIC Inc., He worked tirelessly with California Congressmen Randy "Duke" Cunningham (51st District) and Bob Filner (50th District) which resulted in a awareness of the seriousness and the

potential for progression of this Condition!

To my son, my new Angel with God, I have made a promise to continue to make others aware, inform and just keep talking. Perhaps my burying my 40 year old son before me, whose needless death should not have happen will keep me pushing for new awareness and will help me and ELASTIC Inc. and other State legislator to do his wishes saving lives and safe guarding the health of Countless people.

There is such a big hole in my heart, that will never be filled but by doing my sons Work it will help.

I am sending to my Missouri legislators of my home State your proposal and all added information on latex allergy, imploring them to join my band wagon against latex allergy & products made with latex

Thank You for allowing me to relate to everyone my feelings about this very life-threatening problem of latex allergy that is effecting so many people.

My son left behind myself, his wonderful wife Christine, Children Cara Jo, Brandon Paul, and Hal Jr, who turned 9 the day his father died and step-Children Nathaniel and Metthew.

He leaves many friends both in nursing and outside world.

To the Wisconsin Legislation, thanks for Caring.

Sincerely,

Mary Ann Henderson
205 E. Main, Apt. B
P.O. Box 246
DREXEL, Missouri
64742

Phone:
1-816-619-2933

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT	2. TELEPHONE NO. (Home) (Work)
Mary Ann Henderson	816-619-2933
3. STREET ADDRESS	**4. CITY / STATE / ZIP CODE**
205 E. Main, Apt. B P.O. Box 116	Drexel MO 64742

5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.)

My son Navy Lt. Harold R. Henderson, died on August 29, 1997 due to complacation from Latex poisoning.

6. DATE OF INCIDENT(S)	7. IF INJURY OR NEAR MISS, OBTAIN	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE
8/29/97	AGE 40 SEX Male AND DESCRIBE INJURY ~~latex poisoning~~	NAME ~~Lt. Harold R. Henderson~~ RELATIONSHIP ~~Son~~

9. DESCRIPTION OF PRODUCT	10. BRAND NAME
Use of Latex rubber gloves	See attached sheet
11. MANUFACTURER/DISTRIBUTOR NAME, ADDRESS & PHONE	**12. MODEL, SERIAL NO.'S**
See attached sheet	
	13. DEALER'S NAME, ADDRESS & PHONE
	See attached sheet

14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED?	15. PRODUCT PURCHASED NEW ____ USED ____
YES X NO ____ IF YES, BEFORE OR AFTER THE INCIDENT? ~~Trying to make changes~~ Describe ~~DEAD!! From effects of latex poisoning~~	DATE PURCHASED ____ AGE ____ 16. DOES PRODUCT HAVE WARNING LABELS? IF SO, NOTE: NO NO NO NO

17. HAVE YOU CONTACTED THE MANUFACTURER?	18. IS THE PRODUCT STILL AVAILABLE?	19. MAY WE USE YOUR NAME WITH THIS REPORT?
YES ____ NO X IF NOT, DO YOU PLAN TO CONTACT THEM? YES X NO ____ OTHER ____	YES X NO ____ IF NOT, ITS DISPOSITION ____	YES X NO ____

FOR ADMINISTRATION USE

20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO.
		X9832148
23. FOLLOW-UP ACTION		**24. PRODUCT CODE(S)**
25. DISTRIBUTION	**26. ENCLOSER'S NAME & TITLE**	

CPSC FORM 175 (5/89)

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

I want all manufactures of any latex products to made aware of the dangers to others. In my case the death of my son, Lt Harold Hal" R. Henderson USN. Ret. age 40.

I'm starting my next line of work in the name of my son to contact as many latex Manufactures that I can. and relate what their products can cause.

I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

Mary Ann Henderson March 16, 1998
Signature Date

☐ I request that you do not release my name.

☐ You may release my name to the manufacturer but I request that you not release it to the general public.

☑ You may release my name to the manufacturer and to the public.

I-23
X9932145

Ike, Skelton (Fourth Dist.)
2227 Rayburn House Office Building
Washington, D.C. 20515-2504

Richard A. Gephardt (Third Dist.)
1226 Longworth House office Building
Washington, D.C. 20515-2503

Karen McCarthy (Fifth Dist.)
1232 Longworth House office Building
Washington, D.C. 20515

Senators

Christopher S. (Kit) Bond
274 Russell Senate office Building
Washington, D.C. 20510-2503

John David Ashcroft
316 Hart Senate office Building
Washington, D.C. 20510-2502

Missouri State House

District 31st.
Harold L. Caskey
Room 320
State Capitol
Jefferson City, Mo. 65102

TON
Office Building
20515-2504
225-2876

Congress of the United States

House of Representatives

Washington, DC 20515-2504

514-B N W Seven Highway
Blue Springs, MO 64014-2732
(816) 228-4242

1616 Industrial Drive
Jefferson City, MO 65109-144
(573) 635-3499

219 North Adams Street
Lebanon, MO 65536-3000
(417) 532-7964

319 South Lamine
Federal Building
Sedalia, MO 65301-4393
(816) 826-2675

January 22, 1998

Mary Ann Henderson
E Main, #8
Box 246
el, MO 64742

r Ms. Henderson:

Thank you for writing to me with your concerns regarding latex allergies. I eciate hearing from you on this issue.

I regret that you have had such a devastating experience. I am pleased that you the time to share the tributes to your son as well as the information on latex gies. Although no legislation preventing the use of latex products by health care iders is before Congress at this time, rest assured that I will keep you and your son nd should related legislation come to the House floor in the days ahead.

Again, thank you for getting in touch with me. Please do not hesitate to contact n the future. With best regards, I remain

Very truly yours,

IKE SKELTON
Member of Congress

JOHN ASHCROFT
MISSOURI

United States Senate

WASHINGTON, DC 20510-2504

January 15, 1998

Ms. Mary Ann Henderson
P.O. Box 246
Drexel, Missouri 64742

Dear Mary:

Thank you for contacting my office and relating your concerns regarding latex allergies. Hearing your opinions on important issues facing the Congress and the country is necessary for me to make good decisions about the future of our nation.

I appreciate the opportunity to serve you in the U.S. Senate and to help change the way Washington does business. The ideas and opinions you have sent me will be a great help as this Congress formulates new policies for our country. Your information will help me understand how the issues facing America affect Missourians and all citizens. I will keep your views in mind as this issue comes before the Congress.

Thanks again for your interest in latex allergies. If you have any further questions or concerns please feel free to contact me.

Sincerely,

John Ashcroft

John Ashcroft
United States Senate

JDA:sem

Obituaries

Lieutenant Harold R. "Hal" Henderson

Lieutenant Harold R. "Hal" Henderson,RN, BSN, CEN, TNCC, NC USN/RET, 40, of San Diego, California, died Friday, August 29, 1997, at the Balboa Naval Hospital. Lieutenant Henderson, who had been in ill health for some time as the result of respiratory and cardiac complications associated with latex allergy, suffered a massive heart attack. Full life support was removed at 2:15 p.m. Pacific Time.

Lieutenant Henderson, who had worked at Balboa Medical Center as an intensive care and emergency nurse, served in Desert Storm and was recently accepted into a master's program for nursing and community health at San Diego State University. Hal is survived by his mother Mary Ann Henderson and wife, Christine. The couple's first year anniversary was August 4, 1997. He leaves his children, Cara Jo, Brandon Paul and Harold R. Henderson Jr., as well as step-children: Nathaniel and Matthew Davis. Sadly, Lt. Hal Henderson died on Hal Jr.'s 9th birthday.

A good soldier, a wonderful man, a loving husband died on Friday, August 29, 1997 Lt. Hal Henderson, a 40 year old newly married, ER nurse, retired Naval Corp Officer had served with Desert Storm. Hal died because he had developed latex allergy from occupational exposure to latex products. Frequent exposure to latex containing products, especially powdered latex gloves, is causing more and more people to become allergic to latex and many to go on to develop disabling and potentially life-threatening chronic asthma. Hal died in a hospital that still used products known to cause serious, systemic, life-threatening allergic reactions and death, yet most of these items do not carry a warning or product content label.

Lt. Henderson died from respiratory and cardiac complications that can be part of latex allergy. Hal died because after years of medical apathy and disbelief that something as simple and seemingly innocent as a balloon or a latex glove could cause a life-threatening reaction, because some of those treating him failed to give this allergy and it's potential to be a progressive condition, proper attention, his once strong, military-honed body had had enough.

Lt. Henderson had been forced to give up his career in nursing, was unable to continue his service to the military, but remained optimistic that he could prevent others from becoming latex allergic. Hal worked tirelessly as a military liaison for ELASTIC Inc. His members of the California Congress, Randy "Duke" Cunningham (51st District) and Bob Filner (50th District) resulted in a new awareness of the seriousness and the potential for progression of this condition.

Hal's many successes will continue to receive attention, his spirit of public service is one to be admired and emulated. He wanted so much to prevent others from having to go through the same needless loss of career, health and self-steem, that he did. Hal, the members of ELASTIC, trust your wish; to prevent others from suffering from latex allergy, as you have, will be granted. It is our pledge to continue your work, to continue to increase awareness, inform and educate. Perhaps your tragic and needless death will open the eyes of those who doubt, may be this new-found awareness and a nudge from an angel or two, will allow your wish to be become reality.

Lieutenant Henderson, a soldier on earth, now a soldier of God. Hal Henderson, son to Mary Ann, loving husband to Christine, devoted father to Cara Jo, Brandon Paul and Hal Jr., step-father to Nathaniel and Matthew, steadfast friend to so many, ER and ICU nurse; saving lives and safeguarding the health of countless patients, now a guardian angel, watching from the heavens.

Hal, you are sorely missed, but your spirit and light will always be present in our hearts.

A Tribute to a Fallen Comrade

His was just a name to me,
for we never did formally meet.
Our goal in life was to teach the world
and this allergy we would beat.

But as time went on he became so ill
there wasn't too much hope.
His heart was weak, his lungs weren't strong
his body just couldn't cope.

A bright light went out--a candle dimmed
we lost a comrade and guide.
But as we work toward latex safe
He'll always be by our side.

A good friend we lost--
a husband, a father, a son.
He taught us well, this gentle man
Our battle will eventually be won.

Here's to you, Hal Henderson,
a nurse, a leader, a friend.
This makes us, the surviving ones,
work harder for an end.

Hal Henderson died August 29, 1997.
He was the Military advisor for
E.L.A.S.T.I.C.
He may be gone from our sights
but never our hearts and minds.
In Memory--Pat Lawson, CST