The Legal Aspects of the Latex Protein Allergy Epidemic

Gary O. Galiher JD and L. Richard DeRobertis JD

The epidemic of Type I allergies to latex proteins appears to be limited to healthcare workers and others who have used or been exposed to powdered latex gloves.[1] This phenomenon apparently began with the advent of universal precautions in the late 1980s and the consequent ten-fold increase in the demand for latex gloves.[2]

Lawsuits against the manufacturers of powdered latex gloves commenced in the 1990s. They are filed in both state courts and federal courts. Cases filed in Hawaii State Circuit Court have been designated "complex litigation" and assigned to the Hon. Gail C. Nakatani. Cases filed in federal courts have all been temporarily transferred by the Multi-District Litigation panel to Philadelphia and assigned to the Hon. Edmund Ludwig. One recent jury trial in Wisconsin resulted in a verdict of $1,000,000.[3] Documents produced by the manufacturers have been subjected to court protective orders which prohibit even alluding to their contents. Yet, published articles on this topic contend that the manufacturers shortened or eliminated the post-oven leaching time of their latex gloves and thus produced gloves with high extractable protein content.[4] Some members of the industry appear to concede that changes in the manufacturing process, such as the shift from alcohol coagulants to water and decreasing the use of zinc-bearing components may be one of the factors in the increase in Type I reactions to latex.[5] Leaching has long been described in the manufacture of "rubber gloves" as "probably reduc[ing] the risk of dermatitis to the wearer."[6]

Persons with Type I allergies have at least two parallel legal recourses: (1) filing worker's compensation claims for occupational disease (which provided limited benefits) and (2) filing product liability actions against latex glove manufacturers (which provide full compensation for losses). Occupational diseases, including disabling allergies, have long been compensable under state workers' compensation laws.[7] A causal connection between work and the disease is sufficient. Product liability is more complex. Under Hawaii law, a manufacturer is liable to end-users for personal injury and disease caused by its defective products. A product is defective if rendered dangerous by a flaw in the manufacturing process, or it is defectively designed, or if the manufacturer fails to warn of dangers in the expected uses of the product by the public.[8] A product is deemed defectively designed if (i) it is not as safe as an ordinary consumer or user would expect when used in a reasonably foreseeable manner; or (ii) the benefits of the product as designed are outweighed by the dangers imposed by the product.[9]

To the extent that latex glove manufacturers decreased the total leach time to below the industry standard and this resulted in a higher level of latex proteins in the finished product, this would establish liability under both the manufacturing defect (i.e., flaw in the manufacturing process) and the balancing test for defectively designed products. That is, a product designed to have more latex proteins in the finished product than is otherwise necessary produces no added benefit to the end-user compared to the protective benefits already present in a properly leached latex glove.

A parallel theory of liability of the latex glove manufacturers is their failure to warn. Under well-established Hawaii law, a manufacturer is negligent if it fails to warn of the reasonably foreseeable dangers in its products.[10] It is established in the published literature that the latex glove industry knew since the 1930's that certain individuals can become sensitized to the naturally occurring proteins in latex gloves.[11] Therefore, the manufacturers had both a duty to eliminate the dangerous levels of latex proteins from the finished product and to warn end-users of the risks inherent in high protein powdered latex gloves. Failure to warn liability can also be established if the warnings were inadequate or misleading.[12] Thus, latex glove manufacturers which promoted their products as "hypoallergenic" when in fact they had high levels of protein allergens could be found negligent and consequently liable for sensitizing healthcare workers who develop Type I systemic allergies. Numerous documents in the public domain indicate that the latex manufacturers, through the trade association, Health Industry Manufacturers Association, actively resisted discontinuing the claims of "hypoallergenic" for latex gloves. On June 24, 1996, the FDA proposed that the term "hypoallergenic" be eliminated because it is false and misleading in that it incorrectly implies that the product labelled as "hypoallergenic" may be used safely by latex sensitive persons.[13]

It is vital for anyone with a Type I allergy to understand that their claims against the manufacturers and for worker's compensation benefits are subject to statutes of limitations. That is, a claim for being exposed and sensitized to latex proteins through powdered gloves will be barred if a legal action is not promptly filed. The exact knowledge which triggers the running of the statute of limitations is a technical legal issue and depends upon the particular facts of each individual case. Indeed, the elements triggering the running of the statute of limitations have been the subject of numerous appellate court opinions.[14] No healthcare worker should assume his/her claim is already barred; nor should he/she assume that it is safe to delay seeking legal advice.

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Correspondence to:
Gary O. Galiher JD and
L. Richard DeRobertis JD
610 Ward Ave, #200
Honolulu, HI 96814-3308

Scientists report that half of all cases of dog and cat bites carry pasteurella which can cause septicemia, bursitis and even meningitis. (JAMA & NEJM)

A recent study says calcium supplements (1,200mg/d) reduce the growth of colon adenomas. Researchers theorize that calcium binds with compounds that irritate the colon lining. (Time 1/25/99)

Mayo Clinic reports that 639 women with moderate to high risk of developing breast cancer underwent prophylactic mastectomies form 1960 to 1993, thus reducing their risk of dying from breast cancer by 90% (a figure which is debatable). Researchers have identified two major genes BRAC 1 and BRAC 2 whose mutations increase breast and ovarian cancers. Tests for these genetic mutations cost $2,400 for the first test per family and $400 for subsequent tests... (Time 1/25/99)

Medical Tid Bits III...

FDA has approved a hand-held imaging device called T Scan 2000 which sends tiny jolts of electricity into mammogram detected breast tumors. Malignant cells apparently conduct electricity differently from normal cells. The scan may prevent 200,000 unnecessary biopsies per year.

Root Canal specialists say that when a tooth gets knocked out, put it in a glass of milk. Milk keeps the tooth alive by nourishing the root cells for at least an hour.

The Wall Street Journal reports 10 deaths and 11 cases of GI hemorrhage attributed to Celebrax. Monsanto says there is no proof that the drug caused the deaths. Since January, 2.5 million prescriptions have been written for the drug. (Time 5/3/99)

Eating an egg a day won't keep the doctor away, but probably won't hurt your heart either or cause a stroke per JAMA. Researchers from Harvard and Brigham and Woman's Hospital in Boston studied egg consumption by 120,000 nurses and other healthy professionals with normal cholesterol levels and found no link between eggs and heart disease or stroke (except in diabetics)

Dietary fat may be unhealthy for the heart, but will not cause breast cancer according to a study involving 90,000 women.

Viagra may not work for women according to preliminary data. Thirty post menopausal women took the drug and only 21% reported improved sexual function viz enhanced desire and easily achieved orgasms... (Time 3/22/99)

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