American Latex Allergy Association

Vial Stoppers--John's Hopkins Press Release from June 8th, 2001

Drug Bottles Containing Natural Rubber Stoppers May Place Latex Allergic Patients at Risk for Reactions: Hopkins Researchers Encourage FDA and Pharmaceutical Companies to End Natural Rubber Stopper Use

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Armed with evidence from a recent study of latex allergy skin reactions in patients, scientists at Johns Hopkins encourage the Food and Drug Administration (FDA) and drug makers to label all current vials as ?containing natural rubber? where appropriate and convert to using synthetic rubber for all medicine bottle stoppers.

If a drug is sold and stored in vials with a natural rubber stopper, no matter what precautions you take, latex allergens can contaminate that drug, says Robert Hamilton, Ph.D., professor of medicine at Johns Hopkins University. The FDA has asked for evidence that such allergens are present in pharmaceutical vials and that they can induce reactions in individuals already allergic to latex. Now we can provide it to them. Until the FDA requires all vials to be labeled as ?containing natural rubber? for easy identification and that the stoppers be latex free, some sensitized individuals will be at risk for a potentially serious or fatal allergic reaction.

Hamilton and his team make these recommendations based on a new study, reported in the June issue of the Journal of Allergy and Clinical Immunology, of 12 allergic and 11 non-allergic volunteers. All underwent puncture and intradermal skin testing with solutions from drug vials, two with natural rubber latex stoppers and three with synthetic stoppers. Two latex-allergic individuals had skin reactions even when the rubber stopper was not punctured and five had reactions when the stopper was punctured 40 times before testing. It is not unusual for drug vials to be frequently punctured by syringe needles, since vials contain multiple doses. Non-allergic individuals were not similarly affected.

The evidence from this study indicates that these stoppers pose a risk for reactions, says Hamilton. Even without a complete switch to synthetic stoppers, short-term solutions may help avoid allergic reactions and save lives. Doctors and pharmacists can ask, for example, whether their patients have latex allergy and identify drugs in vials containing synthetic but not natural rubber stoppers.

Pharmacists need to call the drug manufacturer, ask if a stopper is made of latex, and if necessary ask the company if they can provide the pharmaceutical in a vial with a synthetic stopper, says Hamilton. Although the FDA requires labeling of devices such as medical gloves as containing natural rubber latex, vial stoppers fall under the jurisdiction of the bureau of drugs and, therefore, do not have latex labeling requirements.

Latex allergy affects an estimated 1 percent to 6 percent of the general population, 8 percent to 16 percent of occupationally exposed individuals, such as health care workers, and as many as 50 percent of children with spina bifida. Symptoms range from mild local skin reactions, nasal congestion or hives, to anaphylaxis, the life-threatening allergic reaction that can constrict airways in the lungs, severely lower blood pressure and cause death.

Funding for the Hopkins study came from the Canadian Allergy, Asthma, and Immunology Foundation, National Institutes of Health, and Johns Hopkins University School of Medicine. For more information about asthma and allergy research at Johns Hopkins, visit **http://www.hopkinsmedicine.org/allergy** [2].

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