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## Allergy Shots for Poison Ivy – Organic & Jersey Fresh

### Allergy Shots for Poison Ivy

Ragweed immunotherapy has been around for nearly 100 years, though it was not possible to define predictably safe and effective doses until scientists learned to measure the content of its major allergen in the mid 1960's. In the late 1960's and early '70's allergists at Johns Hopkins conducted a series of dose ranging studies, beginning with low doses known to be safe and working up until they identified a dose that was still safe (when given with appropriate precautions) but also predictably effective.

Poison ivy activates a different allergic mechanism. It has also been treated with empirically based immunotherapy. This was first done by various populations of American Indians who attempted to induce oral tolerance by eating leaves or extracts made from leaves. Unstandardized vaccines made from dried poison ivy leaves were marketed for immunotherapy in the 1970's and 1980's, for

*(Right) Ethanol  
extraction of urushiol*



administration as drops by mouth, in food or beverages, or by intramuscular injection in small volumes of 95% ethanol.

Patients found oral immunotherapy to be occasionally effective, and injection immunotherapy usually effective. A placebo-controlled trial of oral immunotherapy with the 1980's vaccine and an endpoint of improved clinical tolerance did not show a difference between patients receiving active allergen and patients receiving placebo. I know of no placebo-controlled studies of injection therapy for poison ivy using these materials. These vaccines were withdrawn from the market in the 1980's because of lack of standardization and the absence of objective proof of efficacy.

Since that time a quantitative assay has been developed for the major poison ivy allergen, urushiol, and a quantitative patch test has been developed to measure sensitivity. Innovators have developed what they believe to be improved poison ivy vaccines but to date none have been licensed for clinical development because

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# Poison Ivy, Cost of Allergy Shots

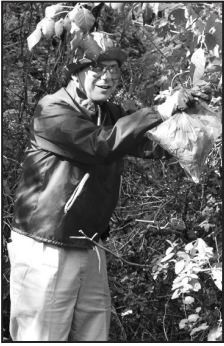
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the cost to meet FDA Good Manufacturing Practice standards is the same for an allergen that may or may not work as for a blockbuster drug like Lipitor. No manufacturer has been willing to make the necessary investment in the absence of evidence that poison immunotherapy can reduce sensitivity in individuals who are already sensitized. GMP manufacturing standards do not apply to an allergist who wants to prepare a small amount of a biological vaccine for use in his own practice, making it practical for us to validate and standardize immunotherapy for poison ivy in the same way that the Hopkins group did it for ragweed. The inventor of one of the new chemically-modified

poison ivy vaccines gave us a simple, high-yield extraction procedure in the hope that we can demonstrate efficacy and thereby interest potential buyers in his product.

Fresh poison ivy contains more urushiol than dried leaves, so a team of AASJ staff and friends harvested 900 grams of fresh poison ivy from an organic farm in Salem County before the

end of the 2008 growing season. We plan to concentrate and redissolve our extract across a wide enough range of concentrations to have a reasonable expectation of success in a dose-ranging immunotherapy study. At this time it is not clear whether we will be able to have quantitative urushiol assays performed locally as a college student chemistry research project or whether we will have to pay someone else to do them.



*Harvest*

We hope to be ready to test and treat patients with sufficiently severe symptoms to want immunotherapy beginning in January, 2009. Our protocol includes more quantitative testing than ragweed immunotherapy, for example, because immunotherapy for ragweed has already been validated and standardized. We know that poison ivy immunotherapy at our proposed starting doses is safe and will help some patients, but we don't yet know how much higher we'll have to go to safely and predictably help almost everybody. The only safe way to find out is to start low, document pre- to post-treatment changes in patch test reactivity, and offer re-treatment with higher doses to patients who fail to respond to lower dose treatment, increasing dose in steps which knowledge and experience predict to be safe.

This study does not have outside funding. As we expect every participant to benefit from the study intervention, normal office charges will apply for testing, office visits and immunotherapy. We have our own small education and research foundation (funded by assignment of honoraria I receive for sponsored lectures) and we may be able to use foundation funds to help patients with high co-pays for repeat skin test visits.

## Cost effectiveness of allergy shots for hay fever & allergic asthma

A group of German authors (*Annals of Allergy* 2008; 101:316) calculated the total economic burden of these diseases as a group (cost of care to third party + cost to patient + indirect cost including loss of work) to manage a representative distribution of these conditions in the German population with symptomatic

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# Cat Vignettes and More

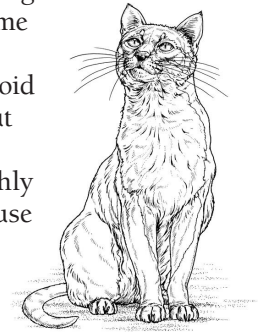
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treatment alone or with symptomatic treatment + standard subcutaneous allergen immunotherapy (IT). In calculating the total economic impact of adding immunotherapy to symptomatic care the investigators assumed a population average of only two years of immunotherapy because of patient discontinuation earlier than prescribed but they found that even this brief period of IT reduced the total economic burden of disease by 10% over 15 years and significantly improved quality of life. A U.S. analysis of the cost savings achieved by 5 years of IT for allergic rhinitis yielded greater savings (*Clin Allergy Immunol* 1004;18:151). By way of background, some of the depot allergen preparations available in Europe but not in the U.S. have produced durable protection following as little as three years of maintenance strength immunotherapy for such high potency allergens as grass, ragweed, dust mites with environmental controls, and cat in patients whose cat contacts are limited. The standard of care is 5 years for the non-depot formulations of these allergens available in the U.S., and longer periods of treatment are often necessary for weaker allergens (molds, trees, other weeds, dog) and for cat and dust mite in patients who continue to be exposed.

## Cat allergy case vignettes

**Woman in mid 50's when first seen in 1994,** prior year hospitalization nearly one week per month with much of that in the ICU. Owned 17 cats but was unwilling to part with them as they were her “children” and it cost her nothing out of pocket to be in the hospital and very little for office care or meds. In the 15+ years since she came under my care she's been hospitalized only

twice for asthma accompanying acute flu syndromes, each time for a few days only. She now takes an inhaled asthma steroid daily, has a rescue inhaler but has not needed it for several years, and she receives monthly allergy shots for cat, dog, house dust and several pollens. She agreed not to get any more cats but at last count still had 7, of which 5 were “young.”



## Man in mid-40's when first seen ~10 years ago.

Newly developed asthma 4 months earlier but in ER twice in past 2 mos. Review of possible triggers revealed that he gave his young daughter a kitten 2 mos before developing asthma. He differed from Case #1 in having high deductible major medical health insurance so whenever he went to the ER it was for his \$500 and not that of his insurer. He got rid of his cat the same day I told him it was probably a trigger. Testing subsequently confirmed allergy to both cat and dust mites.

## An extremely fit and athletic looking woman

in her late 30's first came to see me ~12 years ago looking like a professional basketball player except for a small gun hanging from the side of her jogging shorts. She was a member of the narcotics swat team of an area police department, unable to go into a house on a drug bust unless another officer went in first and called out to tell her it was OK because there were no cats. She has now moved on to a desk job but was able to rejoin the swat team after about a year of shots for cat.

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**Woman with upholstery business unable to work on a couch from a house with a cat,** because cat allergen sticks to all cloth surfaces. Stopped shots after ~2 yrs as problem resolved, she was feeling washed out for ~2 days after each shot (an uncommon type of reaction that's not medically serious but can be very annoying. If she again becomes sensitive to the levels of cat allergen she encounters in her work she is prepared to resume shots but every 2 weeks instead of weekly, so that she only feels washed out 2 days out of every 14 instead of 2 out of every 7.

## Allergy Shot Safety

Allergy shots if properly prescribed and administered are safe, effective and cost-effective in comparison or in addition to other treatment options for IgE-mediated diseases of the respiratory tract (asthma and allergic rhinitis, rhinosinusitis & rhinoconjunctivitis) and for IgE-mediated insect sting allergy. They are not risk-free, however, killing an average of 2-3 patients per year in the US yielding a fatality risk for a patient receiving 2 shots per week 52 weeks per year ~ 8 times less than the risk of the average American being killed in a motor vehicle accident.

I like the comparison with the risks of driving, because just as safe driving techniques reduce the one risk, safe shot techniques reduce the other. *Most immunotherapy fatalities result from some combination of shots that should not have been given that day, failure of appropriate dose adjustments or administration of prophylactic meds, and failure of early recognition and appropriate treatment of the reaction.*

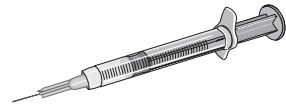
Several years ago we offered programs in allergy shot safety for physicians and physician

staff giving allergy shots, with CME credit for physicians. Attendance was poor enough to suggest that allergy shot safety just isn't a common concern.

We don't know how many primary care and other non-allergy practices give allergy shots. For those of you who do, we'd like to suggest that it may be worth an hour of CME time to learn warning signs for when not to give them, when to contact the prescribing allergist for changes in schedule or prophylactic meds, and to learn how to recognize and manage IgE-mediated allergy shot reactions.

If you would like a 60-90 minute safe allergy shot CME program we will be happy to give it for your hospital medical staff or department, your county or regional medical or osteopathic society, or your county or regional primary care or other non-allergy specialty society.

If interested, contact Kelli Moore by phone at 856.825.6960 or contact us by fax or e-mail at the addresses on our letterhead.



## Sub-lingual scopolamine

Some readers may remember our sub-lingual epinephrine project, which was sidetracked when the FDA demanded data in a different sequence than that for which we had applied for funding. That project remains on hold but what we learned about excipients in the course of that work has enabled us to formulate an inexpensive sublingual scopolamine for patients who would be candidates for trans-dermal scopolamine patches but are allergic to the adhesive. As with immunotherapy for poison ivy we'll want to start with low doses and increase cautiously based on observation of response, but the drug is available if you have patients who need it.

