

N.J. allergist envisions a vaccine for poison ivy

By Stacey Burling
INQUIRER STAFF WRITER

There are a lot of things Sean Hartmann likes about his job as a tree trimmer. It pays well, and the roadsides where he works are often beautiful, especially in the spring and fall.

But he definitely does not love poison ivy. It's everywhere. Hairy vines the size of his forearm climb the trees he must cut. Even if he can manage not to touch it, it winds up on the chain saw and in the wood chipper. Fragments fly all around him.

Until this year, the result was constantly blistered, oozing skin. On a 1-10 scale of misery, "it would be a 10-plus," said Hartmann, 25, who lives in Brick, N.J. The only solution was frequent visits to the doctor for steroid pills.

Then he heard that Robert Coifman, an allergist in Millville, was testing something interesting: a poison-ivy vaccine. Hartmann decided to try

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Poison ivy

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it in March. "I have nothing to lose," he thought.

After seven shots over three months, Hartmann said that although he still reacted to poison ivy, the rash was much milder now and it has gone away quickly. "It's to the point I don't even know I have it," he said.

Figuring out how to protect people like Hartmann, who face occupational exposure to poison ivy, has been something of an obsession for Coifman since 2008. Another tree trimmer, who was on steroids 10 months a year, inspired his quest.

Currently, there is no treatment to protect the 75 percent of us who get bad reactions to poison ivy, a common plant that is the bane of gardeners, landscapers, and Boy Scouts. There were vaccines available into the 1980s, Coifman said, but they lost their licenses when they couldn't meet new effectiveness standards from the Food and Drug Administration.

To get started, Coifman contacted Catherine Yang, a biochemistry professor at Rowan University who is interested in developing drugs, usually for diabetes and cancer.

"He called me, emailed me, many times," she said.

Then her son got a very bad case of poison ivy. She called Coifman.

Since then, she has been refining the process to extract urushiol — the compound that causes the itching and oozing — from poison ivy plants harvested very carefully from the farm of one of Coifman's employees. Coifman's first batch of vaccine was made with Everclear he bought at a liquor store, but the poison ivy extract is now mixed with ethanol. Though most allergy treatments are injected just under the skin, the poison-ivy vaccine goes into muscle. Like other allergy treatments, the dose starts small and gradually increases. Coifman measures progress with skin-sensitivity tests.

Insurance companies have been paying for the treatment. After trying various forms of the treatment on 18 patients, he said, he is now applying for approval of the project from an institutional review board at his local hospital, Inspira Medical Center Vineland. That step is required before a scientific journal will publish Coifman and Yang's work.

To someone accustomed to the deeply detailed research protocols and consent forms at the region's scientific centers, Coifman's work may seem unorthodox. He has tried different dosages and timing in an effort to make the treatment more convenient for patients who come to see him from out of state. He has given the shots to himself.

Despite the small number of



Sean Hartmann gets poison ivy doing his job. STACEY BURLING / STAFF

patients and the lack of FDA approval for the vaccine, the website of Allergy & Asthma of South Jersey, Coifman's practice, declares: "We also developed and offer the world's first allergy vaccine for poison ivy that WORKS." Patients are asked to sign an informed-consent form that states there is no FDA-approved vaccine. It also says Coifman's vaccines "have had no problems with safety."

Asked whether that might be jumping the gun, Coifman said: "To the best of our experience, it is the world's first safe and effective immunotherapy for poison ivy."

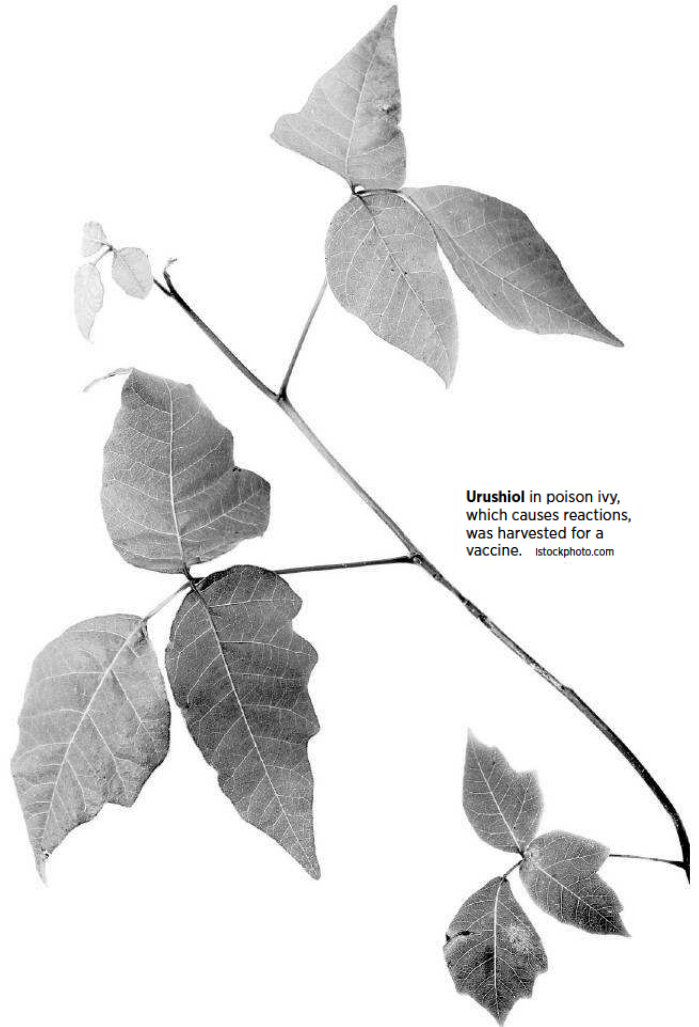
He said he had not needed FDA involvement or drug-trial approval because it has been acceptable to use plant-based treatments on a case-by-case basis in patients for whom there was no other treatment.

Documents provided by the FDA back that up — when the materials used are licensed. The poison-ivy vaccine is not.

But Coifman notes that because he isn't selling the vaccine or moving it across state lines, the FDA doesn't have jurisdiction. That will change when he settles on the final formulation and seeks to commercialize it.

An FDA spokeswoman refused to comment on Coifman's research or even the rules around developing a treatment that uses plant material. "We provide guidance to researchers who are conducting research," said Sarah Petticoard, "and it's up to the researchers to comply."

Coifman and Yang have a competitor who is taking a more orthodox approach. Mahmoud ElSohly, a pharmacist and chemist (and marijuana expert) at the University of Mississippi, has been studying poison ivy since the 1970s. The plant is unknown in his native Egypt. A colleague told him of the need for a vaccine. His product, which also is injected into muscle, combines synthetic urushiol and another ingredient that helps the urushiol bond with cell membranes. He says that is key to fostering



Urushiol in poison ivy, which causes reactions, was harvested for a vaccine. istockphoto.com

tolerance. His vaccine has been tested with success in guinea pigs. "I am now so happy to say we have a product that works," he said. He expects it will require only a dose or two to create immunity for at least a season.

Raymond Hage, the Bryn Mawr CEO of ElSohly's company, Hapten Sciences Inc., said he was filing for FDA approval to begin a clinical trial with human patients. It likely will be based in Tennessee. Hage estimates the vaccine could be available in two to three years. He expects a big market: 20 million to 50 million people a year get poison-ivy reactions.

The skin rash poison ivy causes is not what most of us think of as an allergic reaction, said Bobby Q. Lanier, a Fort Worth, Texas, allergist who is executive director of the American College of Allergy, Asthma, and Immunology.

Allergies are quick responses to substances like ragweed, cat

dander, or peanuts. The body releases histamines and other chemicals that usually cause just a runny nose, itchy eyes, and maybe some wheezing. Occasionally, allergies are life-threatening. They can be treated effectively with shots, but the treatment takes a long time.

The reaction to urushiol is mediated by a different part of the immune system and occurs much more slowly. People who get rashes when they touch certain metals — nickel is a common culprit — have the same kind of reaction. Lanier said no one had yet been able to create an effective treatment for that kind of reaction.

John Cohn, an allergist at Thomas Jefferson University, said the poison-ivy rash was known as "hypersensitivity" rather than allergy.

He said doctors didn't fully understand why some people reacted to what should be harmless substances, whether cats or poison ivy. He said he did not know whether increasing doses of poi-

son ivy were likely to induce tolerance.

"It's a different mechanism," he said, referring to regular allergies. "Tolerance is a really complex topic that we don't fully understand."

Coifman said results had varied in his small sample of 11 patients, with people who had suffered the most severe reactions to poison ivy having what appeared to be the best responses to the vaccine.

In practical terms, those who responded well — including tree-trimmer Sean Hartmann — were able to be around poison ivy without having their previous problems.

Side effects have included temporary lumps at the injection site.

Coifman and Yang are optimistic enough about the results that they have begun work on a vaccine for peanut allergy.

✉ sburling@phillynews.com
☎ 215-854-4944
📍 @StaceyABurling