

# Hope for peanut allergies? Pills, patches, drops and even nuts themselves are being studied

July 23 2018, by Yen Duong, The News & Observer (Raleigh, N.c.)

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Every year, Americans make 30,000 emergency room visits because of food allergies, according to the Food and Drug Administration.

Even touching a surface that previously held peanuts can trigger anaphylaxis, a life-threatening allergic reaction. When a [peanut](#)-allergic person starts feeling their throat close up, they stab themselves with an epinephrine, or adrenaline, device and then head to the ER for a few hours of monitoring.

What if there was another way?

Researchers, doctors and pharmaceutical companies are trying to make people less allergic to peanuts. A peanut pill and a patch could be widely available by the end of 2019.

And in the meantime, a small number of private-practice allergists have been offering oral immunotherapy, in which you gradually eat more peanut products under a doctor's supervision.

Right now, the majority of allergists only prescribe patients an epinephrine device and tell them to strictly avoid peanut protein, in hopes of warding off reactions such as hives, swelling, blood pressure loss and difficulty breathing. The FDA has not approved any treatments for peanut allergies, which affect 2 percent of children today.

This spring, Aimmune Therapeutics announced that it had wrapped up a 10-nation trial for its "peanut pill," AR101. Of the 69 trial sites, two were in North Carolina: the Food Allergy Institute at UNC-Chapel Hill and a private practice, Allergy and Asthma Partners in Charlotte.

"Our hope all the time is to make a cure, to make this go away permanently and never have to worry about it," said Dr. Edwin Kim, a researcher at the Food Allergy Institute and the father of a peanut-allergic child. "These kids don't want to think about it. They don't want to have to worry about it. They want to be normal."

## **UPDOSING AND MAINTENANCE**

For decades, people with "hay fever" or other environmental allergies have received allergy shots. Allergists inject you with increasing amounts of serum derived from whatever you're allergic to, building up your tolerance for the allergen. You start twice a week and stretch out the time between injections. After several years, you'll no longer need the shots.

"What we found out in the '80s and '90s was that doing something similar, like putting peanuts into an allergy shot, wasn't effective," Kim said. "That's where the idea of oral immunotherapy was born, since eating the food is how your body learns to tolerate it."

Oral immunotherapy, or OIT, works the same way the allergy shots do: slowly up your tolerance for the allergen, until you no longer have allergic reactions to it. You start with a very small amount of the food, check to make sure you don't have any reactions, and then gradually increase that amount in a process called updosing.

Dr. Wesley Burks at Duke University first demonstrated how to increase patients' tolerance to peanuts in 2009. His 29 patients then started with

mixing a few crumbs of peanut flour into applesauce or pudding, then updosed for months by eating a little more each day to build up tolerance for the allergen.

Once they passed a "food challenge" of eating about 16 peanuts at once, the patients entered maintenance, which meant they ate eight peanuts a day for years afterward. Every OIT study since then has followed a similar updose and maintenance pattern, with some including the food challenge.

## **THE PATH TO THE PEANUT PILL**

In 2011, a parent-run nonprofit brought together representatives from the National Institute of Health, the FDA, pharmaceutical companies and academic centers including Duke to figure out how to cure food allergies. Aimmune formed from that meeting.

"They asked: 'What will it take to get a treatment approved for food allergies?' " said Dr. Daniel Adelman, Aimmune's chief medical officer. "We needed a high quality, reproducible, reliable product, and there was no such thing at the time."

By 2013, the company created AR101, capsules of proprietary peanut flour that come with a standardized updose and maintenance schedule. As in the 2009 Duke study, patients mix the peanut product with food and eat it. Aimmune has tested AR101 on more than 1,000 patients.

By the end of this year, Aimmune will apply to the FDA for a license to sell AR101 in the U.S., Adelman said.

At the same time, another company hopes to offer a "peanut patch," called Viaskin, which patients will wear for increasing amounts of time to updose and then will wear all the time for maintenance.

Burks has moved to the Food Allergy Institute at UNC, where researchers are also working on peanut "drops" held under the tongue, Kim said. No pharmaceutical company has picked up the drops yet, so they will not be available for consumers for at least several more years.

If they pass, AR101 and Viaskin will be the first FDA-approved products to treat peanut allergies.

## **ELIAS' STORY**

When Elias Kroboth of Raleigh was a baby, he broke out in full-body hives when his brother ate a peanut butter sandwich across the table. So after Elias turned 2, he started OIT with a private allergist who had worked on the Duke studies. Over the past three years, he updosed from crumbs per day to his maintenance level, when he eats five to eight peanuts per day and then rests for two hours to watch for a reaction.

His mother, Kira Kroboth, said they worked closely with Elias' allergist. When Elias' immune system was fighting off colds from the rest of the family or travel, she texted the allergist to ask how much to lower his daily dose. It took her several tries to find an allergist who offered OIT instead of only preaching strict avoidance.

"There was no other option besides 'here's an EpiPen, good luck,' " Kroboth said. "When we had that first appointment when he ate three tiny breadcrumbs of peanut, I felt OK, like we were doing something about this. Each updose was empowering."

A thriving parent network helps families find the rare allergists who offer OIT. The website OIT 101 ([www.oit101.org](http://www.oit101.org)) lists just over 100 private practice allergists nationwide, out of around 5,700 allergists certified by the American Board of Allergy and Immunology. The website emphasizes that patients should not attempt to do OIT

themselves and says that it only lists vetted allergists who offer OIT.

Of the 22 private-practice board-certified allergists in the Triangle and 21 in Charlotte, Kroboth said only three offer OIT. Eligible patients may enter the pill, patch or drop trials at UNC and in Charlotte, but Elias wasn't the right age when the trials began.

"I get frustrated because I feel like all the pharmaceutical powers are looking for a solution that ends up being profitable, like the patch or the pills," Kroboth said. "We already know what works. We just need to get allergists on board and get them familiar with the protocols and do what we know works."

Both the peanut pill and private practice OIT claim 80 percent to 85 percent success at desensitizing patients to peanut proteins and cross contamination. Both have strong supporters suspicious of the other regimen.

"If you go to the Whole Foods and get peanut flour, you don't know the protein content of that peanut flour," Adelman, the doctor with Aimmune Therapeutics, said. "You either are administering this as a drug where you know exactly what you're giving and you have confidence you're administering it in a controlled way, or you can kind of wing it and hope for the best."

"Frankly, as an allergist dealing with life-threatening allergies, I don't play dice with my patients' lives."

## **PEANUT GROWERS HOPEFUL**

About one in 13 children have at least one food allergy, according to the nonprofit organization Food Allergy Research & Education, and up to 15 million Americans total. Researchers, nonprofits and industry members

have been scrambling for solutions for decades.

Since 2001, the National Peanut Board has put over \$25.3 million toward peanut allergy research, including sending funding to Burks, the lead researcher of the 2009 Duke study. They also supported a 2015 study that showed that parents should offer peanut products to very young children at risk of peanut allergy, in hopes of preventing the allergy.

"For years, pediatricians had been telling parents to wait until the child is 2 years old before peanuts are introduced, and the (2015) study proved that is not the right way to go and that early introduction is going to be a deterrent to keep children from developing [peanut allergies](#)," said Bob Sutter of the North Carolina Peanut Growers Association.

In 2017, North Carolina produced almost 480 million pounds of peanuts. North and South Carolina are the 5th and 6th growers of peanuts in the nation.

Elias Kroboth, the peanut-allergic Raleigh child, doses with peanuts produced and specially processed in N.C., which avoid cross-contamination with tree nuts and other allergens.

"We're very excited by the possibility that children might be able to not have to avoid everything," Sutter said. "Hopefully this (pill) will limit the accidental exposure reactions."

Funding from the National Peanut Board and nonprofit organizations support academic research in labs and with small samples, then larger pharmaceutical companies step in for large-scale development and deployment.

If the FDA approves every product, parents will have several options if

they can find willing allergists: the pill, the patch, the drops under the tongue and private-practice OIT.

"The reason you have FDA approval of drugs is because they have oversight of manufacturing processes—there's a reason for regulation," said allergist Dr. Laurie McWilliams, who does not offer private practice OIT. "That keeps drugs at the level they should be. What if you get a different dose on a different day because that peanut doesn't have the same high amount of protein content?"

Kim, the allergist and parent from UNC, said the pill was the most effective but also the least convenient treatment. The patch is less effective, but has a short updose period and hassle-free application.

"In a perfect world it would be great to have multiple treatments," Kim said. "Every child varies. Maybe the child is higher risk, and even if there's a little more difficulty doing the treatment it's worth it for those. Maybe for other families it's all about convenience, and they need protection but they're pretty good at avoidance.

"I'd love for there to be options. That would give more power to the allergist and to the families as well."

The success of the peanut pill may spread the popularity of private practice OIT, McWilliams said.

"They might say the peanut product isn't different from what's in the grocery store, and they'll go grind it up," McWilliams said.

Beyond peanut, Aimmune is working on trials for egg and walnut allergies. The company behind the peanut patch also is developing patches for milk and egg allergies.

Wake County public schools do not have nut-free classrooms. Elias sits at the same lunch table each day for children with allergies, and teachers wipe him with soap and water before eating, as opposed to just water like [allergy](#)-free children. Using OIT to increase his tolerance for peanuts has helped the entire family, Kroboth said.

"There's no doubt in my mind if we had not done OIT it would have been a traumatic first year of school," Kroboth said. "We eat out, we fly, we've been on vacation, and these are all things we did not do in the beginning and we now do without fear. It's life changing."

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