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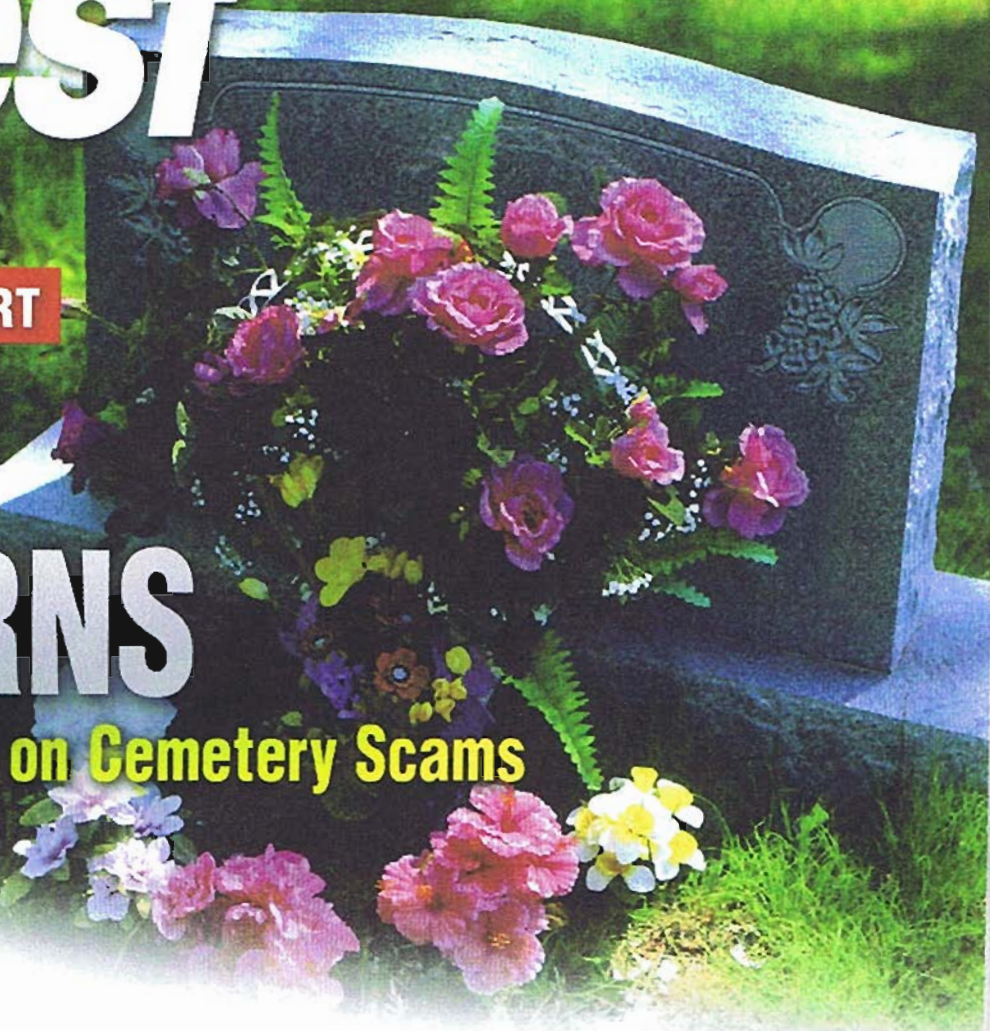
# Consumers Digest

APRIL 2010

**INVESTIGATIVE REPORT**

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## ALLERGY RELIEF

# Today's Most Effective Treatments

The most effective nasal allergy treatments that are on the market require a doctor's prescription, but be sure to ask for the newest drugs and drug combinations to get the best relief. Although researchers are pursuing other methods of treating airborne allergies, many of those are years away from providing help.

By Toni L. Goldfarb

"I am allergic to the planet Earth," says Kathy Klotz, who is a project manager for a software consulting firm.

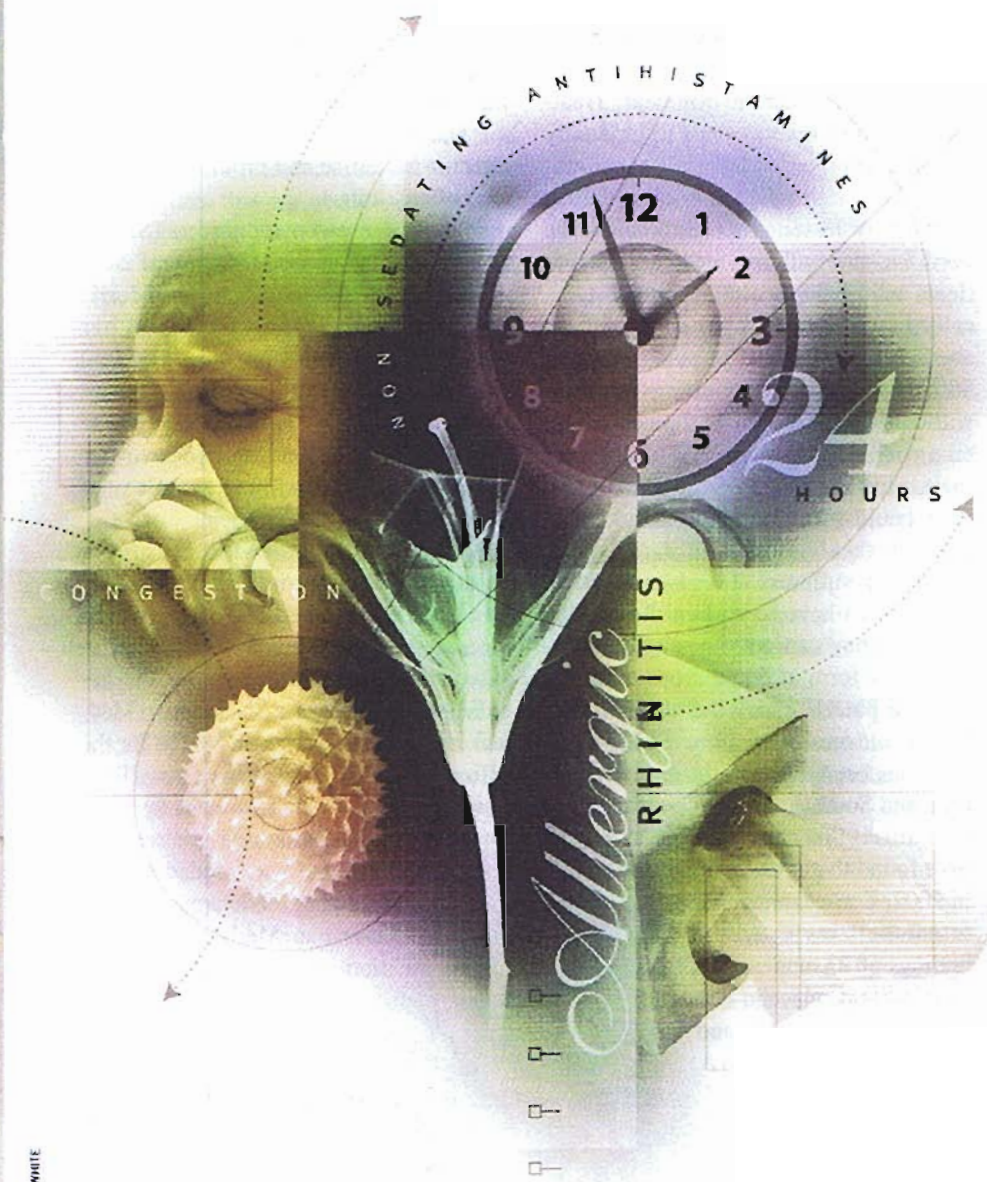
Klotz says she had mild allergies to grass, pollen and cats for most of her life but didn't take anything for them. "But when I moved from New York to Toronto, that all changed." She says that at least twice a year, she spent weeks when she could not breathe through her nose and would go days without sleep.

Klotz tried various over-the-counter medications and supplements, but she finally got her allergies under control after a doctor prescribed a combination of three different medications—Singulair (montelukast), Reactine (cetirizine) and Symbicort (budesonide/formoterol fumarate dihydrate). According to Klotz, the combination of medications changed her life.

She is one of the lucky ones. In 2006, an American College of Allergy, Asthma and Immunology (ACAAI)-endorsed telephone survey of more than 30,000 households nationwide found that 1 out of every 7 adults who were contacted had been diagnosed with airborne nasal allergies. But only 35 percent of allergy sufferers said they were very satisfied with their nasal spray treatments. About 50 percent complained that their allergy medications lost effectiveness during the day and didn't last up to 24 hours, and a majority of those patients kept switching medications to try to find better symptom relief.

A similar telephone survey in 2009 that was organized by a panel of noted pediatric allergy specialists found similar dissatisfaction with over-the-counter and prescription medications that were used to treat nasal allergies in children ages 4 through 17 years.

**NOTHING TO SNIFF AT.** Suffering from allergies is not merely a matter of dealing with sneezing, itching and a runny nose. In a 2008



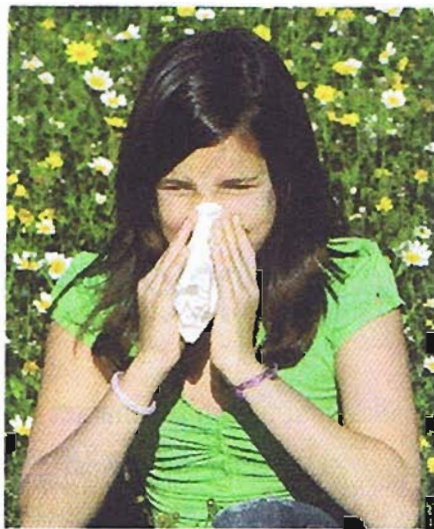
study. Dr. Hirsh D. Komarow, who is a staff clinician in National Institutes of Health's allergy division, and researchers at University of Maryland School of Medicine reported that peak pollen levels were associated with an increase in patients' memory problems, mood changes, anxiety and depression—all of which place patients at risk for suicide. (The group's preliminary findings suggest that springtime peaks in airborne allergens correlate with springtime peaks in suicide rates.)

"We don't understand the mechanism fully, but I think it's pretty clear that the allergic response to airborne allergens is not just limited to the nose and eyes and breathing," Komarow says. "It's also an effect on mental status, thinking, cognition and mood."

Ubiquitous TV commercials might show that swallowing a little pill or spraying some mist up your nose is all that it takes to conquer airborne allergies, but clearly there is a lot more at stake: *Allergic rhinitis*—hay fever and similar airborne allergies—was estimated in 2007 to affect about 60 million Americans, and that number is growing, according to American Academy of Allergy, Asthma and Immunology (AAAAI). The monetary costs also are growing: Department of Health and Human Services in August 2008 reported that the cost of treating allergic rhinitis in the United States was \$11.2 billion in 2005 (the latest year that data were available). More than half of that was spent on prescription medications.

If you're among those who suffer from allergic rhinitis, you'll find some relief from improved medications and new treatment combinations. Unfortunately, there isn't anything that is truly revolutionary on the horizon—that is, anything that Food and Drug Administration has approved for use in the United States. An immunotherapy that is used in Europe and by a few U.S. physicians that replaces allergy shots with under-the-tongue drops or tablets appears promising, but it's uncertain when that will be ready for FDA approval.

**'DROPPING THE SHOT.** Despite all of the allergy medications that are available, experts still recommend allergy shots for people who have symptoms



**SHOT SHOCK.** For those who have no insurance, allergy shots can cost \$100 per visit.

that pharmaceuticals cannot control. But this approach typically requires a lengthy series of doctor's visits in which tiny amounts of allergen are injected under the skin (*subcutaneous immunotherapy*) to help desensitize people to allergens in their environment. Treatment can take several years to gradually increase allergen doses until a maintenance dose is reached, and even then it might only lessen—not eliminate—the need for other allergy medications! Patients who have health insurance typically pay \$10 to \$25 per shot, with an average first-year out-of-pocket cost of \$800. But if you're an allergy sufferer without health insurance, the cost might take your breath away—\$20 to \$100 per visit, plus the price of the shot itself. That could mean as much as \$4,000 a year for weekly shots.

Allergy sufferers abroad—and a few here—don't have to endure the needle, though. They can get the same medication in the form of liquid drops or tablets that are placed under the tongue. This *sublingual immunotherapy* (SLIT) treatment has been available in several European and South American countries since the mid-1990s, and studies have found that it's working. In 2007, European medical researchers reviewed the findings of 23 randomized, double-blind, placebo-controlled clinical trials and concluded that SLIT is an effective and well-tolerated treatment

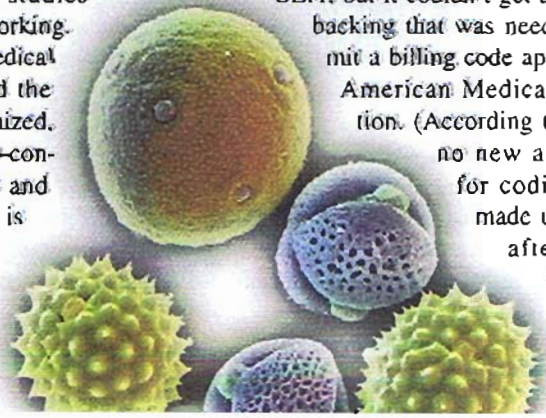
for the control of allergic rhinitis.

But don't expect to see SLIT in widespread use in the United States anytime soon. Because FDA hasn't approved its use, only a few doctors in the United States offer it.

Dr. Mary Morris, who is a Wisconsin allergist, is one of the few. She takes the FDA-approved allergen solutions (extracts) that are used for allergy injections and mixes the extracts to use as allergy drops. These are individualized for each patient's specific allergies—no one-size-fits-all versions. Morris defends her SLIT regimen as an off-label use. (If you read the label or package insert of any medicine, you'll see a list of uses that the drug was tested and approved to treat. However, doctors can—and commonly do—prescribe medications for uses that are not on the label.) In fact, as ACAAI's May 2009 report for U.S. physicians notes, off-label use of U.S.-approved allergen extracts for SLIT is not illegal because published studies substantiate the use. (However, it is illegal for pharmaceutical manufacturers to advertise and promote off-label uses of any drug.)

"There's research supporting [SLIT], and it is a logical extension of how these extracts are already used," Morris asserts. She and other doctors in her clinic have treated more than 100,000 patients via their allergy drops during the past 40 years, and she says there have been no serious reactions to her regimen—only occasional instances of itchy mouth and stomachache.

But you should know that because of its lack of FDA approval, no billing code has been established for SLIT, which means that Medicare and most health insurance companies do not cover the \$1- to \$3-per-day cost of a SLIT dose. (Medical insurance might cover the fee for the office visit.) In 2009, Blue Cross/Blue Shield in New England sought to cover SLIT, but it couldn't get the required backing that was needed to submit a billing code application to American Medical Association. (According to AAAAI, no new application for coding can be made until 1 year after a failed attempt.)



Although several other physicians with whom we spoke agree that SLIT shows promise, all objected to using it without FDA approval. That approval can't come until FDA has a specific treatment option to approve, and, so far, no pharmaceutical company has provided one. Clinical trials precede any drug that is being submitted to FDA, and a 2009 medical journal report by Dr. Thomas B. Casale, who is head of the allergy/immunology department at Creighton University, and other experts revealed numerous deficiencies in recent SLIT clinical trials, such as a lack of agreement on safe dosages. And Casale tells us that SLIT didn't prove to be effective in several U.S. studies that weren't published.

But don't give up hope. Companies that manufacture extracts for allergy shots are performing clinical tests to establish safe and effective SLIT dosing regimens. For example, a 2008 published study by Greer Laboratories, which is an extract company in North Carolina, identified safe SLIT doses of ragweed and timothy grass pollen extracts. That's the kind of data that are needed for eventual FDA approval, but none of the experts with whom we spoke could predict when that would be sought.

Whenever that happens, some allergists are lining up. A 2008 ACAAI survey of more than 800 allergists showed that although only 6 percent of respondents reported using SLIT, 60 percent said lack of FDA approval was the reason why they weren't using the treatment, and 66 percent said they would use SLIT if it were approved by FDA.

**RUSH JOBS.** Although the slow-moving wheels of research are keeping SLIT from reaching nasal allergy sufferers, U.S. scientists are moving forward on another treatment that also is being used abroad—*rush immunotherapy* or *rapid allergy desensitization*. Unlike the standard regimen of administering allergen-extract shots at gradually increased dosages over many months, rush immunotherapy can shrink the timeframe to weeks or, in recent "ultra-rush" trials, 3 to 5 days—or, even a single day! Results are promising, but you should know that receiving multiple shots over several hours on the same day can spur

a systemic allergic reaction, or *anaphylaxis*, which is potentially fatal.

In a 2007 Indiana study of 893 people, rush immunotherapy patients first were given 3 days of pretreatment with corticosteroid and antihistamines that reduce the risk of anaphylaxis. The patients were injected with gradually increasing doses of allergens every 15 minutes during a 2-1/2-hour period. Only one person developed anaphylaxis and was hospitalized; 18 others had milder reactions that were controlled in the doctor's office.

The researchers calculated that rush immunotherapy eliminated about 6 months of standard allergy shot treatments, thus reducing the cost of allergy immunization by as much as 50 percent in the first year, or \$400 to \$2,000, depending on whether you have insurance. However, patients still had to continue with standard once-a-week allergy shots for 2 to 3 months to maintain their allergy protection level.

under the tongue | sublingual immunotherapy is undergoing U.S. testing.

No one with whom we talked could predict how soon the procedure might become widespread, but because it's an adjustment of an already-used therapy, it doesn't require FDA approval, says Dr. William L. Smits, who led that Indiana study. He says allergists from all over the United States are contacting him. "Many allergists are still reluctant to do [rush immunotherapy], because it's not accepted as the 'standard of care' yet," he says. "But I would not be surprised if someday it is."

**TWEAKING TREATMENTS.** Until these new treatments take hold, one of the main nasal allergy remedies in the United States will be good ol' antihistamines. If you've tried these pharmaceuticals without success, you might not have used them correctly or you might not have used the most effective formulations. For example, antihistamines work better as a preventative measure than when you already have allergy symptoms. (All of the experts with whom we spoke recommend at least a brief trial of prescription or nonprescrip-

tion over-the-counter antihistamines under medical supervision.)

Today's antihistamines rarely cause the drowsiness that was attributed to "first-generation" medications, but prescription antihistamine nasal sprays—which typically take effect more quickly than oral antihistamines—dry the nasal passages, which can cause minor nosebleeds and nasal irritation.

At least consumer complaints about bad-tasting drainage into the throat from antihistamine sprays didn't go unheeded. Two antihistamine nasal sprays that were approved in 2008—Astepro (azelastine), a stronger formulation of which was approved in 2009, and Patanase

(olopatadine)—contain artificial sweeteners to counteract the bad taste. The price might leave a bad taste in your mouth: These improved prescription medications are considerably more expensive than nonprescription antihistamine sprays—just above \$100 for a monthly supply of Astepro or Patanase.

Although antihistamines might provide adequate symptom relief for some allergy sufferers, *intranasal corticosteroids* that are administered in the form of nasal sprays remain the most effective preventive medications for allergic rhinitis, according to the latest AAAAI and ACAAI practice guidelines. In addition to preventing allergy symptoms, these drugs also relieve congestion by reducing inflammation in the nasal passages. Allergic rhinitis is an inflammatory condition, so treating the underlying inflammation is important, says Dr. Michael S. Blaiss, who is an allergist at The University of Tennessee Health Sciences Center in Memphis and past-president of ACAAI. The good news is that many intranasal corticosteroids are available as generic formulations. For

example, although Flonase costs about \$95 for a month's supply, you'll pay about \$75 for the generic—fluticasone propionate.

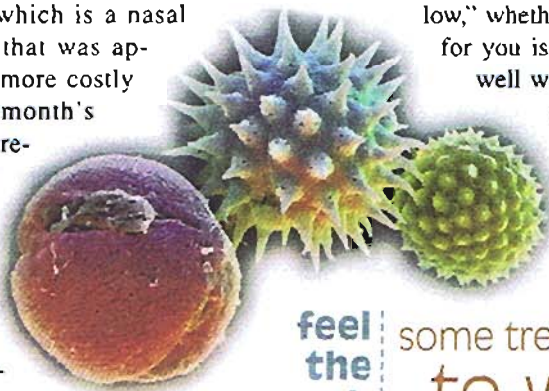
Another formulation, Veramyst (fluticasone furoate), which is a nasal spray formulation that was approved in 2007, is more costly (about \$100 for a month's supply), but it also relieves allergy-related red, itchy eyes.

Another class of allergy drugs that are marketed as providing relief—*leukotriene antagonists*—act by opening the airways and decreasing mucus production, which helps to relieve breathing difficulties. But only one of these medications—montelukast—is approved for the treatment of seasonal nasal allergies. And FDA has targeted montelukast for potentially dangerous side effects.

In March 2008, FDA warned that the use of montelukast and other leukotriene antagonists might be associated with behavioral changes and even suicide. Following a review of data from manufacturers, montelukast labeling was changed in 2009 at FDA's request to include a caution about possible neuropsychiatric problems.

But Merck, which manufactures montelukast under the trade name Singulair, reviewed at the request of FDA all suicide-related occurrences that were reported during clinical trials in more than 20,000 adults and children. Its study, which was published in October 2009, identified only one case of *suicidal ideation*, that is, the thought of suicide, and no suicides. Researchers at Maryland's medical school performed an independent review of these reports, and it concluded that data are insufficient to prove a link between montelukast and suicide. But *insufficient* isn't the same as

*nonexistent*, and FDA is continuing to evaluate montelukast risks. Although some experts such as Blaiss believe that the worries are exaggerated and the suicide risk is "unbelievably low," whether it's right for you is a question well worth asking your own doctor.



feel  
the  
rush

some treatments condense allergy shots  
to weeks or days.

**STILL SEARCHING.** Allergy researchers aren't pinning their hopes only on immunotherapy research and improving pharmaceuticals that are available. They're exploring numerous possibilities—including the use of carbon dioxide, directed lights and lasers.

Casale and his colleagues at Creighton, for instance, are testing the administration of carbon dioxide as a treatment for seasonal allergic rhinitis symptoms. The carbon dioxide is delivered by a special device that patients can carry with them for symptomatic relief. A 2008 study of 60 patients found that two 60-second streams of carbon dioxide flowing into each nostril significantly relieved symptoms within 10 minutes and that the relief lasted for 24 hours. Casale says it's too early to know whether this approach will merit eventual approval by FDA.

And British researchers literally are shining a different light on nasal therapy by using infrared light that is shined high up into the nose to help control allergic symptoms. In a 2009 study, 101 adult hay fever sufferers were given a 3-inch by 2-inch battery-operated power pack that had light-emitting diodes (LEDs) that transmit infrared light through two probes that are inserted into each nostril. Half of this group had inactive placebo light devices, and the other half had the real thing. After shining the light in their nostrils three times a day for 14 days, the group that had the active LEDs showed sig-

nificantly fewer symptoms when they were exposed to high amounts of grass pollen. Although researchers aren't sure exactly why infrared light reduces allergy symptoms, a device already is being marketed in Great Britain that is based on this treatment. We believe that it merits more study.

Meanwhile, Israeli researchers are investigating laser treatment to reduce nasal congestion and discharge in people who have allergic rhinitis. In a 2009 study, they gave one to three sessions of

nasal laser treatment to 48 patients. (A local anesthetic was administered to prevent pain from the laser.) A year later, examinations showed that 69 percent of patients had less nasal obstruction and 40 percent had less nasal discharge than they had before the treatment.

But all of these procedures—intriguing though they might be—focus only on the prevention and reduction of nasal allergy symptoms—not an actual cure. Dr. Peter Creticos of The Johns Hopkins University School of Medicine was the principal investigator in an international group of researchers that attempted to do just that by attaching ragweed allergen to DNA.

Although results that were reported in 2006 were promising—25 volunteers reported relief from ragweed symptoms 2 years after they were injected—Creticos tells us that the economic tough times have derailed further trials. He says most major pharmaceutical companies are "keenly interested" in pursuing variants to this vaccine approach, and that research, if it pans out, could have allergy sufferers breathing a lot easier. ♦

Toni L. Goldfarb is former editor and publisher of the consumer monthly *Medical Abstracts Newsletter*. She has been a medical journalist for more than 25 years.