

## In quest for cure, money is short

**UA tries to protect people and pets from valley fever**

**By Tom Beal**

ARIZONA DAILY STAR

Development along the Interstate 10 corridor, from south of Tucson to north of Phoenix, has made it the nation's hot spot for valley fever, a disease infecting 90,000 Arizonans yearly.

Its toll: 5,000 serious illnesses, 30 deaths and \$86 million in direct hospital costs each year.

There is a promising drug to cure the disease and a vaccine in development to prevent it.

Both are hampered by the economics of the drug industry, which isn't willing to invest tens of millions of dollars with the potential payoff limited by the geography of the valley fever fungus, which thrives only in the semiarid Southwest.

Researchers at the University of Arizona, led by Dr. John Galgiani, hope to bridge that gap in interest by proving the drug and vaccine will work, finding efficient ways to produce them and taking them through early clinical trials.

But funding for vaccine research has "slowed to a trickle," Galgiani said. The state of California invested \$7 million. But Arizona? Zero.

Research into the treatment drug is being aided by an "orphan drug" grant from the Food and Drug Administration and by donations from Arizonans, including pet owners. Dogs contract valley fever in numbers similar to humans.

Medical researcher Dr. John Galgiani has spent his career helping "orphans" — finding ways to sponsor research into an orphan disease, finding money to bring an orphan drug that might treat it to market, and leading a drive to find a vaccine for valley fever.

The problem is that while valley fever is a big deal here in the developing deserts of Arizona, where we and our pets all have a 3 percent chance each year of inhaling the fungal spore that causes it, the disease's range is geographically limited by the semiarid conditions that produce it.

That means no pharmaceutical company wants to spend the tens of millions of dollars it would take to bring the drug or the vaccine to market. That's the classic definition of an orphan drug: not enough customers to make producing it worthwhile.

So in 1996, Galgiani, who has worked for 30 years to understand and combat valley fever, formed the Valley Fever Center for Excellence — co-sponsored by the University of Arizona and the Southern Arizona VA Health Care System (also known as the Veterans Affairs Medical Center).

He has now set up shop at the UA's Bio5 Research Institute and has enlisted an army of colleagues to help with basic research, clinical trials and pharmaceutical business plans in an effort to interest some deep-pocketed partners in bringing the drugs to market.

In the meantime, he's making do with Food and Drug Administration money specifically set aside for orphan drugs; a dwindling supply of money appropriated by the California Legislature for vaccine research; grants from institutions; and donations from Arizonans, particularly from pet owners who want a vaccine and easier treatment for their dogs and cats.

### IF YOU GO

**What:** Experts speak and answer questions on valley fever treatment and current research.

**Where:** University Medical Center, 1501 N. Campbell Ave.

**When:** 1 p.m. Nov 16.

**Admission:** \$7.

**More information:**  
[www.vfce.arizona.edu](http://www.vfce.arizona.edu)

### DID YOU KNOW

The UA's Bio5 Institute was founded in 2001 on the principle that collaboration among academic disciplines could help solve complex scientific problems, such as diseases. The institute brings together scientists from five fields — agriculture, medicine, pharmacy, basic science and engineering — and puts them in partnerships with industry leaders to discover new technologies and bring them to the market.

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## **What is valley fever?**

Valley fever is a potentially debilitating and sometimes fatal disease caused by a fungus, coccidioidomycosis, that is endemic to semiarid areas of the Southwest. It thrives 4 to 6 inches beneath the ground in alkaline soils that experience periods of wetting and drying.

The spores spread when the soil is disturbed and blown by wind. It is not transmitted person-to-person or by animals.

Most people can breathe in spores with little effect, but for an estimated 40 percent, it produces some level of flu or pneumonialike symptoms — fever, aches and difficulty breathing. In serious cases, it lingers for an average of six months. Valley fever sufferers miss, on average, a month of work, even with proper treatment.

In the most severe cases, it spreads from the lungs to the joints, the brain and the spinal cord, sometimes resulting in meningitis.

## **People die from it — about 30 per year in Arizona.**

"I have never been so weak — and like an absolutely lazy invalid — than I was with that valley fever," said Larry Farnum of Oro Valley.

Farnum, a retired Army colonel, is not the type to lie around, even at age 87.

He maintains the acre of land surrounding his home with daily labor and a trusty chain saw.

Last April, he started getting sick, but he thought he'd shake off whatever it was during his trip to Covington, Ky., for a reunion of Korean War Army veterans. He spent the time in bed in his hotel room, getting up only for the nightly dinners.

It wasn't until May that he visited the emergency room at Northwest Medical Center, near Tucson. Like most valley fever sufferers, who wait on average 44 days before seeking treatment, he thought whatever he had would just go away.

Farnum was admitted for complications of pneumonia. He was tested for valley fever, something state health officials recommend for all community pneumonia patients, but which is done only 25 percent of the time, according to a survey of doctors. Galgiani suspects the figure is much lower.

Farnum was placed on anti-fungal medications and sent home after five days.

He didn't get better. So a week later, at 1 a.m., he drove himself to the Veterans Affairs Medical Center, on Tucson's South Side. He left his wife a note saying if he didn't return, she could find him there.

Another week in the hospital was followed by a long recuperation, but he is now fully recovered.

## **Treating valley fever**

There are treatments for valley fever: anti-fungal medicines that can speed recovery.

But there is no cure, though Galgiani and other researchers have identified a promising drug, nikkomycin Z, which was originally developed as an anti-fungal spray for shipping fruit.

The University of Arizona acquired the rights to the drug in 2005, and it is currently in first-phase safety trials being run by David Nix, an associate professor in the UA Pharmacy College, and Dr. Susan Hoover of the UA College of Medicine.

The clinical trials are being funded under the FDA's orphan-drug program, which gives grants for development of drugs that affect small populations.

Other colleagues are working to produce the drug more easily.

Part of the problem is that nikkomycin Z is linked to another compound known as nikkomycin X. Galgiani called on colleagues in an array of specialties to find the best way to separate the two.

He also funneled some money to chemistry professor Robin Polt to begin work on a synthetic version of the drug and series of structurally related compounds that might be even better or at least easier to reproduce.

The idea of it all, Galgiani said, is to prove the drug works and to overcome some of the stumbling blocks to producing it economically. Then, he said, he might find a partner for the company he formed, with a separate FDA small-business grant.

The UA isn't interested in becoming a pharmaceutical company, he said, but it also doesn't want to relinquish control of the process.

"We'd hate to see it licensed to sit on the shelf," Galgiani said.

He's new at the drug-development business, he said, but his colleagues in pharmacy have plenty of expertise.

"That's part of the reason I'm at Bio5. It is exactly the kind of research they do here; it has a translational aspect," Galgiani said.

### **Creating a vaccine**

Galgiani's Valley Fever Center for Excellence is simultaneously proceeding with work on a vaccine for which he and other researchers hold the patent.

Money for that drive has come in the past from the California Legislature and from a foundation that matched the lawmakers' \$7 million appropriation.

Here the goal is similar — to demonstrate the potential of the vaccine, and then entice a drug company to spend the money needed to bring it to market.

Scientists have always considered a vaccine for valley fever to be feasible, Galgiani said. The mere fact that so many people inhale it without becoming sick shows there is an immune reaction to tap into.

"We're continuing to do the vaccine work, but funding has become a trickle," he said.

Galgiani thinks public investment in a vaccine would be a wise economic decision. The state of Arizona has given no money to drug or vaccine research, he said, and Congress has made no direct appropriations.

The state Department of Health Services estimates that in Arizona alone, about \$86 million a year is spent on hospital treatment of valley fever patients. Add to that the cost of doctor visits and time lost at work, and you have a significant yearly loss to the economy that is much greater than the money it would take to bring the vaccine to market.

A vaccine would be the ultimate public health tool against valley fever, said Dr. Rebecca Sunenshine, deputy state epidemiologist. "That is exactly what we need, and they have vaccines that showed some promise," Sunenshine said.

Galgiani credits George Rutherford of the University of California at San Francisco for helping snare the previous research money from that state. Rutherford, a professor of epidemiology and preventive medicine, is part of a consortium of universities and a VA health center doing vaccine research.

It's not a slam-dunk, Rutherford said, but it is promising.

Researchers have "a road map for cocci," Rutherford said, and they've proved it in early animal testing.

"If you're a mouse, we have a vaccine," he said.

### **The animal connection**

Rutherford welcomes the interest shown in the vaccine by pet owners.

"I love the parallel-universe quality of it," he said. "You know, the first human vaccine for anthrax in the 1880s was originally developed for cattle."

Marta Saint-James, who lost two golden retrievers to valley fever after moving to Arizona in 1999 from Michigan, said she is continually amazed by how much easier it is to focus public attention on valley fever in pets than in humans.

In 2006, she helped Galgiani organize and promote Valley Fever Awareness Week in the Phoenix area. The Valley Fever Center for Excellence held a "whole week of wonderful symposiums," she said.

She held an educational event at a dog park in Gilbert, arranging for the appearance of some police dogs that survived the disease.

"The TV stations and the newspapers were so receptive to dogs with valley fever," she said. In contrast, "Dr. Galgiani didn't get good press."

Saint-James has formed a foundation in honor of Kramer, the second of her two golden retrievers to die after contracting valley fever. The money raised goes to veterinary research at Galgiani's center.

After her other golden retriever, Cody, died, she had Kramer tested regularly for valley fever. She also dressed him up and took him to hospitals and nursing homes as a therapy dog. She said it helped to cheer both of them up after Cody's death.

Kramer eventually tested positive, and he seemed to be responding to treatment when his health worsened and he had to be euthanized.

Saint-James donated Kramer's body for research at the Valley Fever Center for Excellence, and an autopsy discovered that his liver had been weakened, possibly by the drugs used to treat the disease, she said. It made her determined to find a better cure and to work toward a vaccine.

"It seems like people are responding more to dog stories, but I don't care where the support comes from," she said.

### **Valley fever timeline**

1980s — The first clinical trial of a valley fever vaccine produces a lot of sore arms.

1976 — Winds of up to 200 mph in California's Central Valley carry valley fever spores to the Bay Area. The first death is of a gorilla at the San Francisco Zoo.

1993 — The Jane Goodall Institute announces a move to Washington, D.C., and drops a plan for a chimpanzee retirement home in Tucson. Chimps' susceptibility to valley fever is one reason given.

1994 — Three deaths in the Los Angeles area, where valley fever rarely occurs, are blamed on fungus in dust dislodged by the Jan. 17 Northridge earthquake.

1995 — Jerome Beillard, co-founder of the People With AIDS Coalition of Tucson, dies of pneumonia partially attributed to valley fever.

1996 — Nick, the polar bear at the Reid Park Zoo, dies of complications from valley fever.

2001 — Loren Woods, center on the University of Arizona men's basketball team, misses the end of the season because of a valley fever infection that spread to his spinal column.

2003 — The Pima County Board of Health raises alarm about a spike in valley fever cases in Oro Valley and Green Valley.

2003 — Pro golfer Greg Kraft sues the PGA for failing to warn him about valley fever, which he says he contracted while playing in the Tucson Open in February 2002. He loses the case and an appeal.

2006 — Tucson HIV specialist Kevin Carmichael says valley fever is the biggest killer of his patients — 29 of 116 deaths over four years.

2006 — Responding to a record year of valley fever cases, Rep. Bill Thomas, R-Calif., proposes \$40 million for vaccine studies. The bill passes but is never funded.

2006 — The Food and Drug Administration grants "orphan drug" status to nikkomycin Z, a valley fever treatment being studied by researchers at the UA's Bio5 Institute under Dr. John Galgiani.

2007 — U.S. Rep. Raúl Grijalva, D-Ariz., proposes \$8 million in "earmarked" funding for valley fever research at the UA.

### **What health officials recommend**

If you live or travel in the valley fever zone and have a prolonged cough, fever, fatigue and shortness of breath, ask your doctor to test for valley fever.

### **Valley fever facts**

- The reported rate has nearly tripled in the past decade.
- Arizona had 5,535 cases in 2006; 4,832 in 2007; and 2,869 by the end of August 2008.
- Valley fever is the fourth-most-common infectious disease in Arizona, ranking behind chlamydia, hepatitis C and gonorrhea.

Valley fever patients, on average . . .

- Waited 44 days before seeking health care.
- Saw a doctor three times before being diagnosed.
- Had symptoms for six months.
- Missed one month of work.

- Took three months to resume normal daily activities.
- Had lived here 10 years before being diagnosed.

**Source:** Results from an unpublished Arizona Department of Health Services enhanced surveillance study, in which one in 10 patients treated for valley fever in Arizona in 2007 was surveyed.

#### Valley fever and medical care

When valley fever sufferers did seek treatment ...

- Half went to an emergency room.
- 1,700 were hospitalized.
- They ran up hospital charges of \$86 million, or about \$50,000 per patient.

Despite a state Department of Health Services recommendation to test all community pneumonia patients for valley fever, only 25 percent are tested.

**Sources:** The Valley Fever Center for Excellence; Arizona Department of Health Services; Dr. Rebecca Sunenshine, deputy state epidemiologist

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