

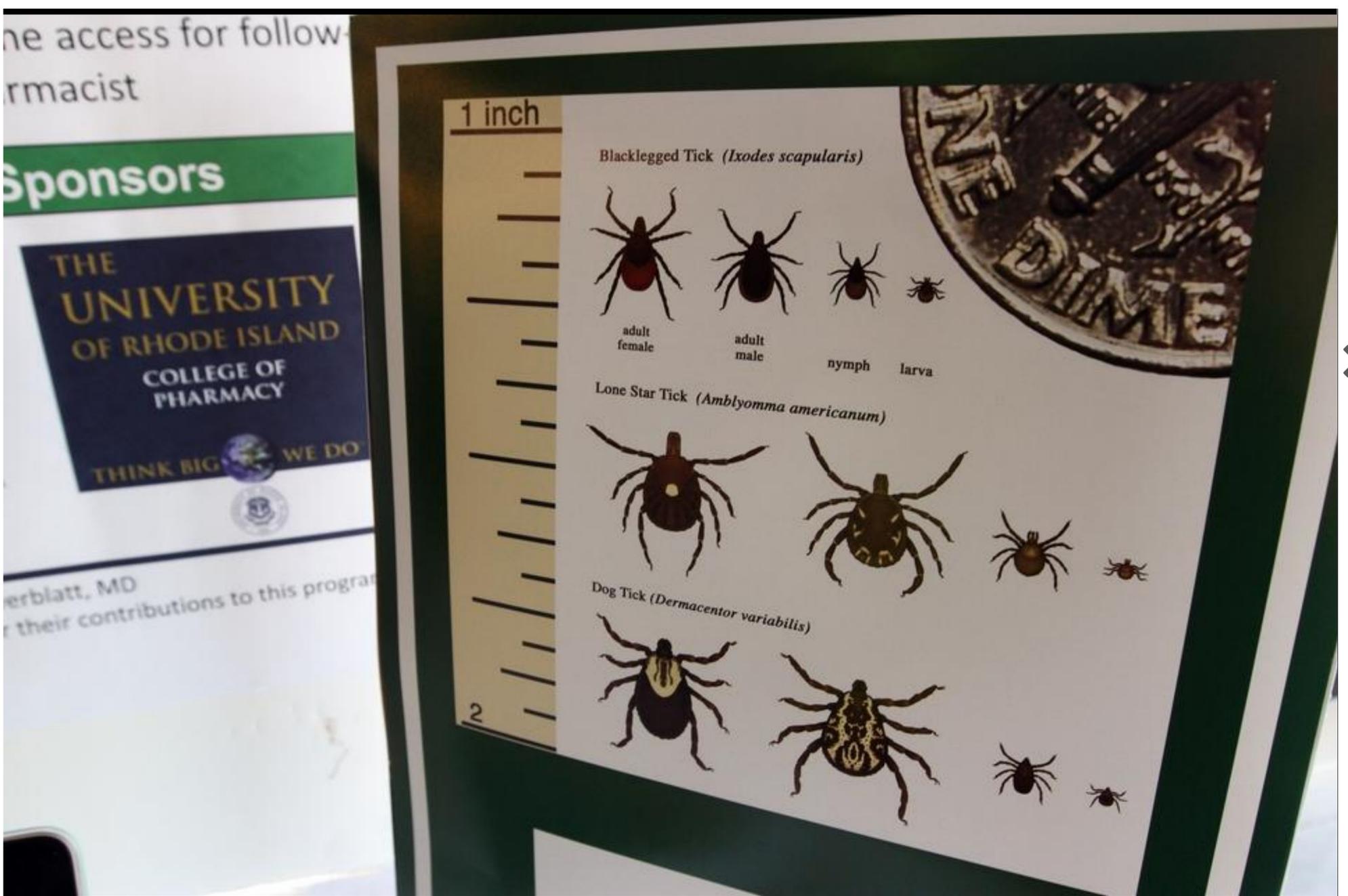
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Fighting Lyme disease: In R.I., a dose of antibiotic without a prescription



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A display showing various kinds of ticks at the Green Line Apothecary in Wakefield. [The Providence Journal / Bob Breidenbach]



By Lynn Arditi
Journal staff writer



Posted Jul 29, 2017 at 4:36 PM
Updated Jul 29, 2017 at 7:05 PM



Program allows S. Kingstown pharmacy to offer drug for tick bites meeting strict criteria: It must be a deer tick of a certain size found within 72 hours of the bite

SOUTH KINGSTOWN — A family-owned pharmacy in this seaside town recently began dispensing antibiotics to people without prescriptions to reduce the risk of developing Lyme disease.

Green Line Apothecary announced in late June that it is offering the single 200-mg prophylactic dose of doxycycline to adults within 72 hours of a deer tick bite if they meet the U.S. Centers for Disease Control and Prevention's [criteria](#) for infection risk.

Proponents of the program — reportedly the first of its kind in the country — say it serves an important public health need by expanding timely access to treatment that could prevent more people from developing the potentially debilitating disease. And they hope it will become a national model.

But experts caution that expanding access to antibiotics to prevent Lyme disease may do more harm than good. Most people who will get the preventative treatment, they say, would likely never have developed Lyme disease. For those who are infected, some doctors worry a prophylactic dose may not be enough to prevent the patient from getting sick. And misuse or overuse of antibiotics can contribute to another major public health problem: [antibiotic resistance](#).

The pharmacy program follows passage of legislation by the Rhode Island General Assembly in 2016 that [expands pharmacists' role](#) to include initiation of drug therapies under so-called collaborative practice agreements.

The state health department's approval of the Green Line program comes amid growing public concern over Lyme disease, which each year is diagnosed in [roughly 30,000 people](#) in the country, 95 percent of them in 14 states including Rhode Island, according to the U.S. Centers for Disease Control and Prevention.

In 2015, Rhode Island reported 904 diagnosed cases of Lyme disease, the [11th-highest rate](#) in the country, according to the CDC.

"As a state we are always looking at ways to be proactive in reducing the incidence of Lyme disease," said Dr. Nicole Alexander-Scott, the state health director who, on June 12, signed a two-year [collaborative practice agreement](#) with Green Line. The pharmacy program, she said, is "one of those approaches."

Washington County is Rhode Island's ground zero for Lyme disease, with [nearly twice the statewide rate](#), state health data show.

"Everybody knows someone who has been impacted by Lyme," said Anita N. Jacobson, a pharmacist and clinical associate professor at the University of Rhode Island College of Pharmacy.

Christina Procaccianti, a pharmacist and Green Line's owner, is one of those people. The vintage-style pharmacy and soda fountain opened in 2016 on Main Street in Wakefield.

Procaccianti, 34, contracted Lyme disease in 2011, while she was pregnant. After an eight-week course of antibiotics, she said, she made a full recovery and delivered a healthy baby girl. "I know how awful Lyme is," she said.

"If we can prevent it for anybody," she said, the effort will be a success.

The program kicked off June 22 with a poster display, informational fliers and offers of free "Lime Rickey's for Lyme Disease."

Peter Schunke was among the first to seek treatment. That morning, his wife, Elizabeth, had plucked a "pin-top size" tick from his back left shoulder. Schunke, 72, had contracted Lyme disease years ago, so he and his wife headed to the pharmacy.

They hadn't saved the tick. Procaccianti, the pharmacist and owner, showed Peter Schunke a chart with different types and sizes of ticks for identification. Then she asked him a series of questions. He signed consent forms, handed her his insurance card and walked out with two 100-mg doxycycline pills.

Later, Elizabeth and Peter Schunke said the tick looked like the smallest of the four pictured on a [poster](#) displayed at the pharmacy.

"I'm pretty sure it was not engorged," Peter said, "because it was so tiny."

The smallest on the poster — the tick larvae — would not meet the CDC guidelines for treatment.

If he had pointed to the tick larvae “we wouldn’t have given [doxycycline] to him,” Procaccianti, the pharmacist said. “He pointed to a tick that we positively identify as fitting the criteria. ... Every single checkpoint on his questionnaire is checked off.”

She added: “The problem with these deer ticks is that they’re so micro tiny that an engorged tick may not even look engorged.”

Lyme disease is caused by the bacterium *Borrelia burgdorferi* and is transmitted to humans through the bite of infected deer ticks, also known as blacklegged ticks.

Early signs and symptoms may include fever, headache, fatigue and, in some cases, a characteristic red rash, often shaped like a ring, called erythema migrans. But about [20 percent to 30 percent](#) of those infected with Lyme disease never develop the telltale rash. Later symptoms can include severe headaches, neck stiffness, arthritis, joint pain, facial palsy and problems with short-term memory, among others.

Though the Infectious Disease Society of America “does not generally recommend” antibiotics to prevent Lyme disease even after a deer tick bite, in highly endemic areas, such as Rhode Island, a 200-mg dose of doxycycline “may be offered to adult patients” who meet their criteria, the [CDC website states](#). (The CDC has separate criteria and dosages for children 8 years or older.)

“We don’t recommend it but we offer it,” said Dr. Timothy P. Flanigan, medical director of The Lifespan Lyme Disease Center at Newport Hospital.

The treatment’s effectiveness, he said, is based primarily on a single study. “It’s not wonderful evidence, but it is partial evidence,” he said. “Patients deserve to know the pros and cons and we let patients know that, and we let them make a decision.”

If someone gets bitten by a deer tick on a Friday afternoon or a weekend, Flanigan said, they may not be able to get an appointment to see their doctor within the critical 72-hour window. And the program could reduce costly emergency department visits.

“I think this is a good use of a pharmacy-based clinic,” Flanigan said.

The largest study of doxycycline as a prophylactic treatment to prevent Lyme disease was published in 2001 in [The New England Journal of Medicine](#). Led by Dr. Robert B. Nadelman, an infectious disease specialist, researchers found that among the subjects treated with doxycycline within 72 hours of a deer tick bite, only one developed the erythema migrans rash at the site of the deer tick bite compared with eight who received a placebo.

The Nadelman study concluded that a single 200-mg dose of doxycycline — twice the average daily [dose to prevent malaria](#) — given within 72 hours after a deer tick bite can prevent the development of Lyme disease.

The prophylactic doxycycline treatment, the study concluded, could reduce the risk of developing Lyme disease by 87 percent.

To be eligible for the treatment, however, the CDC requires the tick be positively identified as a deer tick and have been attached for 36 hours, “based on the degree of engorgement.”

If every person treated meets all of the CDC criteria, Jacobson said, statistically they would only need to treat 11 people in order to prevent one case of Lyme disease.

But that’s a big “if.” Can patients be expected to properly identify the offending insect from a tick-photo lineup? And how would they know if it had been attached for 36 hours?

Outside of a research study, the conditions to determine whether all of those seeking the prophylactic treatment qualify are “almost non-existent,” said Dr. Rade B. Vukmir, a spokesman for The American College of Emergency Physicians.

Ticks which can transmit Lyme disease are about the size of a poppy seed. They’re so small that “people almost never see the tick,” Vukmir said. “And the ticks they do see are typically not deer ticks.”

Vukmir practices medicine in Pennsylvania, which, in 2015, the CDC reports had the highest-rate of Lyme disease cases in the country.

Even in areas that are endemic for Lyme disease, he said, the likelihood of a tick bite transmitting the infection is so low — between 3 percent and 5 percent — that [about 50 people would need to be treated](#) with the prophylactic antibiotic to prevent one person from developing the disease. “You’re treating a lot of people without any benefit.” And overuse of antibiotics can contribute to antibiotic resistance. [At least 2 million people](#) in the U.S. each year become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die as a direct result of those infections, according to the CDC.

“If you’re that one person who benefited, you’d say absolutely that’s important to me,” Vukmir said. “[But] from the public health level there would really not be any way to justify that treatment.”

Laboratory tests have demonstrated that the antibiotics doxycycline and amoxicillin also “can induce a persistent form of the bacteria that are more tolerant to treatment,” [Dr. Ying Zhang](#), a professor at the Johns Hopkins Bloomberg School of Public Health.

It’s also not known whether a 200-mg dose of doxycycline is always enough to prevent Lyme disease, Zhang said. So someone may still become infected and get sick, he said, but the antibiotic could cause their blood to test negative for Lyme, making diagnosis more difficult.

Concerns about the pharmacy-based program recently prompted Rhode Island’s health director to take another look at the guidelines.

Last week, Alexander-Scott said she was considering modifying the collaborative practice agreement to require people seeking treatment at Green Line to bring in the tick or a photo of it to improve proper identification. Over the next two years, she said, state health officials will “collect and analyze data to see if this is a good way to address our challenges and diseases in our state.”

URI’s Jacobson, a past-president of the Rhode Island Pharmacists Association who led the effort to permit pharmacists to initiate drug treatments, said Green Line’s pharmacists are following the CDC protocol “to the letter.”

“If anything, I think we are improving antibiotic usage,” Jacobson said, “because the other way is you just call the doctor and say, ‘I got bitten by a tick.’ If it’s a Friday night and it’s an on-call doctor, what do they do?”

The doctor, she said, might just call in a prescription.

As of Friday, Green Line had treated 31 people and declined to treat another 27, most because the 72-hour window had already past, Procaccianti said. The pharmacy also last week began requiring that people bring in the tick or a photo of it to be eligible for treatment, she said.

“We don’t want to unnecessarily give anybody an antibiotic,” she said, “so we’re really being very careful making sure everybody meets the criteria.”

Dr. Fredric J. Silverblatt, an infectious disease specialist and head of South County Hospital’s Lyme clinic, is the prescribing physician for the Green Line program.

Silverblatt, who lives in a wooded area, said he has contracted Lyme disease “three, four times.” The last time, he developed encephalitis, a potentially life-threatening inflammation of the brain, and was hospitalized for several weeks. He now keeps a bottle of doxycycline in his medicine cabinet.

“If I pull a tick off,” he said, “I will take 200 milligrams.”

He said he offers the same prophylactic treatment to some of his patients.

Clinical studies published to date show “no evidence” that anyone treated prophylactically with doxycycline has developed Lyme disease six months to three years after treatment, Silverblatt said, and “that’s comforting.”

However, he said, overuse of antibiotics remains “a valid concern.”

“The chance that a person who has been bitten by a tick will actually get Lyme disease is between 3 percent and 5 percent,” he said. “So the question can be raised: Is this really worthwhile?”

That depends, he reasoned, if you’re one of the “unlucky 5 percent.”

Prevention tips:

- Wear long pants and tuck pant legs into socks
- Spray clothing, shoes and camping gear with the insecticide permethrin, which kills ticks on contact.
- Check your entire body thoroughly for ticks, especially the back of your knees, waistband, armpits or any other constricted places.
- Use sticky duct tape to remove tick larvae from you or your dog before they bite.
- If you find an attached tick, remove it immediately. Once attached, ticks do not wash off in the shower.

How to remove an attached tick:

- Using fine-tipped tweezers grasp the tick as close to the skin’s surface as possible.
- Pull upward with steady, even pressure. Don’t twist or jerk the tick; this can cause the mouth-parts to break off and remain in the skin.
- Clean bite area, hands and tweezers with rubbing alcohol, an iodine scrub, or soap and water.

- To save the tick for identification, place it in a sealed bag or wrap it in scotch tape.
- Take a photo of the tick and send it online to TickSpotters.
- Testing of individual ticks generally is not useful, the CDC states, because even if the test shows that the tick contained disease-causing organisms, that does not necessarily mean that you have been infected.
- If you develop symptoms, seek medical care immediately.

Source: CDC; tickcounter.org

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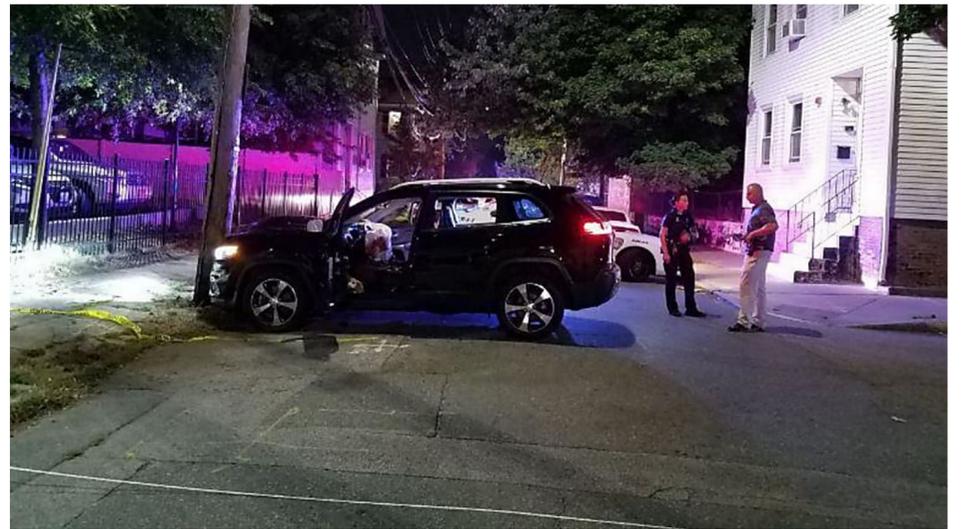
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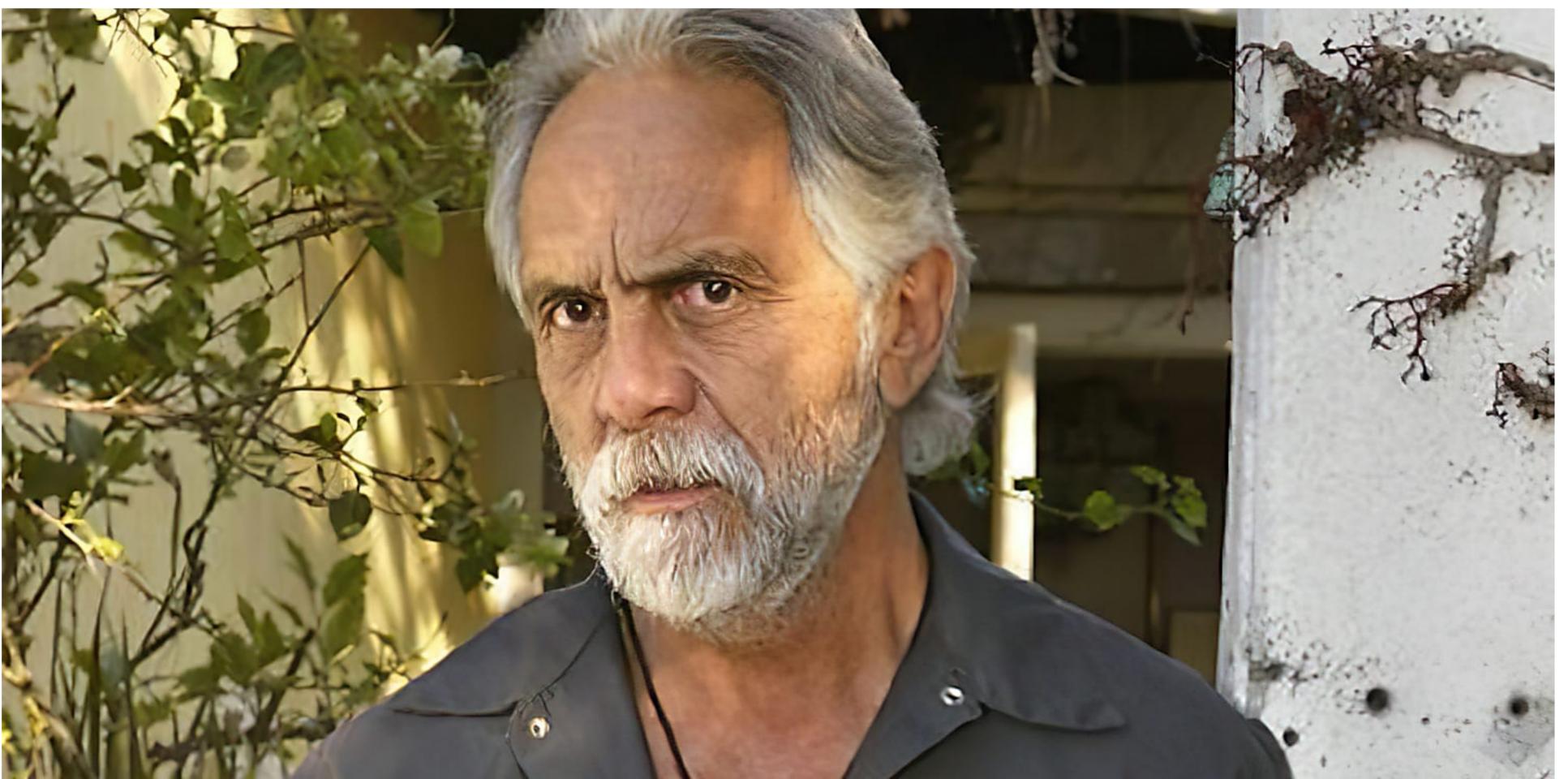
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