

# Patients Irate With Insurers' 'Fail First' Policy

As Pain Advocacy Groups Fight Against the Policy, Proponents Argue It Cuts Costs

By DAN CHILDS, ABC News Medical Unit April 22, 2009

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Cynthia Toussaint, left, and Radene Cook both say that they have been threatened with the denial of effective medications due to health insurance companies' step therapy policies.

On March 16, 2000, Radene Cook, a reporter for radio station KFWB in Los Angeles, was hundreds of feet above the ground in a Cessna 172. During the flight, the single-engine plane was hit by a microburst -- a small, violent downdraft -- that sent it reeling toward the ground.

The damaged plane landed hard, and though Cook survived, she sustained a severe back injury. But Cook, now

42, said that the incident was only the beginning of her ongoing experience with chronic pain.

In what Cook describes as a four-year battle for pain relief, she said doctors with her workers compensation program relied on insurer guidelines to tailor her treatment. Rather than treatment with opioid drugs, she received rounds of steroid injections into her spine.

"There were 79 different needle punctures to my spine," Cook said, adding that each of the injections resulted in scarring. "The inside of my spine now looks like a Venus flytrap."

Cook was later diagnosed with a condition known as adhesive arachnoiditis, which she blames on the many injections she received. She eventually switched to a private health insurance plan and started seeing a new doctor in 2004. These steps, she said, allowed her to get the drug therapy she needed to control her pain.

"It took two years to titrate up to an appropriate opioid dose," she said. "Now I have a life back."

But she said that she believes the years of delay in getting this treatment were unnecessary. She blames a protocol commonly used by insurance companies, called step therapy, which is

designed to lower costs and ostensibly provide higher-quality care. The policies are also called "fail first" policies by some, since the drugs must fail to help the patient before the patient receives coverage for a different option.

Even today, Cook said that she is in danger of losing coverage for some of the drugs she relies upon. And she is not alone in her dissatisfaction with the step therapy protocol. Cynthia Toussaint, another California-based pain patient, said she has had similar experiences. Twenty-six years ago, Toussaint, a former ballerina, began experiencing severe and unrelenting pain. Only later did she learn that her condition had a name -- complex regional pain syndrome, or CRPS.

"Eighteen years ago, my insurance company switched me from Axid, which I was using to treat CRPS in my vocal cords, to a cheaper medication," she recalled. "As a result, I couldn't speak and even experienced pain when whispering. I was forced to 'fail' on two cheaper medications before getting the medication my physician originally prescribed."

Toussaint said that she had a similarly negative experience when her insurance company switched her off her brand name Klonopin -- a pain and anxiety drug -- to a cheaper alternative that left her in pain and experiencing hallucinations.

## **Pain Groups Speak Out Against Step Therapy**

"My doctor had to make an emergency request to get me back on my original medication," she said. Still, Toussaint said, her doctor engages in a battle with her insurance company every three months to ensure that the Klonopin she now takes will still be covered.

"If they succeed, I will probably be bedridden again."

Toussaint's fight against chronic pain led her to start the pain advocacy organization For Grace. On Tuesday, For Grace and Healthy African-American Families appeared at a hearing before the Assembly Health committee as lead sponsors for the California bill, AB 1144, written by California Assemblyman Curren Price and aimed at prohibiting step therapy practices by health insurance plans for chronic pain patients.

"This Bill would prohibit health plans and insurers from requiring a patient to use a different pain medication than the one prescribed by their physician," Price writes in an article in the March 26 issue of the California political newspaper Capitol Weekly. "AB 1144 will put an end

to patients in California being forced to endure weeks, months or even years of unnecessary pain and inappropriate treatments. The Bill would also prevent patients who have changed insurers from having to repeat the 'step therapy' process if they have already gone through it with their previous insurer."

## **What Is Step Therapy?**

The basic idea behind step therapy is to start with the most cost-effective and safest treatment, progressing to more costly or risky therapy only if the current treatment is not effective. In theory, proponents say, the strategy both minimizes risks to the patient and keeps overall costs under control.

Robert Zirkelbach, spokesman for America's Health Insurance Plans, said that when it comes to the bigger picture, step therapy is a key element in making the country's health care system more efficient by creating a standard system of care from state to state. He said that this saves costs, and it also ensures that patients get access to therapies that have been proved to be medically effective.

"We see individuals with the exact same illnesses get drastically different treatment depending on where they live," he said. "Right now there is no correlation between the money being spent and the health outcomes being advanced. Our goal is to help guide the patient."

Dr. Forest Tennant, head of the Veract Intractable Pain Clinic and editor of the trade magazine Practical Pain Management, is also Cook's doctor. He agreed that in theory, step therapy is not a bad strategy. And he added that doctors have traditionally employed a form of step therapy, in which they would gradually increase the dose of a given medication for a patient who was not responding until they were able to achieve the desired effect.

## **Doctors Employ Different 'Step Therapy'**

And even when it comes to designing a course of treatment, Tennant agreed that a cheaper approach is preferable, as long as it works for the patient.

"Given the cost of some of the medications I prescribe, I also want the patient to try the cheaper medication first."

But he said that the step therapy used by the health insurance industry is different in that it may actually place a preferred therapy out of reach of a patient. Particularly vulnerable may

be pain patients like Cook and Toussaint, who have experienced success with a given medication but are switched to a different drug by an insurer.

"What we have today is a situation where a patient is knocked around in the system, usually after they've already tried something that works for them but which they can't have," he said. "All of a sudden, the drug that they have been taking for quite some time is pulled away from them -- because it is more expensive, usually.

"Patients like Radene are losing medicines that work for them. A lot of this is unreasonable."

### **The Best -- or Just the Cheapest?**

According to data collected in 2006 by the health care analytics company Verispan, the drugs for which step therapy is most commonly used are anti-ulcer medications, with 58 percent of health insurance plans using step therapy for this class. The data also reveal that antidepressants are the fourth most common drugs subject to step therapy, with 45 percent of plans subjecting these to step therapy. Twenty-six percent of plans use step therapy for pain drugs, according to Verispan, and other drugs including heart medications and antipsychotics are also on the list.

Zirkelbach argued that in most cases, patients are allowed to switch drugs if the recommended option is not working for them, and if the drug that the patient is switching to is supported by medical evidence.

"If there is a good medical reason to switch to drug A versus drug B, health plans typically allow that to happen," he said.

But he noted that how long a patient is required to stay on a given medication before making a switch varies from case to case. Doctors who prescribe a drug that is unapproved by the insurance company risk receiving what Tennant calls a "tantrum letter" from insurance companies.

"The insurance companies hire auditing firms, and they demand to know why I prescribe [patients] certain drugs," he said.

The net effect, Tennant said, is a grave imposition on the doctor-patient relationship.

"I have to say [to patients], 'I can't tell you what you should take. I can only get you to get what your insurance can pay for, and I'll design a regimen,'" he said. "For the expensive medicine, the doctor no longer chooses what he wants."

And according to a Thomson Reuters study published in the February issue of The American Journal of Managed Care, step therapy may actually be more expensive for insurance companies, at least when it comes to patients receiving medication for high blood pressure.

## **Step Therapy May Not Be Cheaper**

In the study, which was sponsored by Pfizer, researchers looked at insurance claims for 11,851 people with employer-sponsored health coverage that incorporated a step therapy protocol for high blood pressure drugs. These patients' claims were compared with those of 30,882 patients on similar medication who did not participate in a step therapy program.

What the researchers found was that the group of patients treated for hypertension under the step therapy program had 3.1 percent lower drug costs. But these savings appear to have been wiped out by the apparent increase in hospital admissions and emergency room visits. Over two years, the step therapy patients incurred \$99 more in healthcare costs per quarter, on average, than the control group.

### **Hope for Step Therapy?**

If indeed California passes anti-step therapy legislation, it would not be the first to do so. New Jersey already prohibits such plans. And even the Centers for Medicare and Medicaid Services may be considering regulations to limit step therapy by health plans available to Medicare patients.

But Robert Taketomo, president and CEO of the Glendale, Calif.-based managed care contracting services organization Ventegra, warned that if such legislation passed in the state, patients may find that other parts of their coverage will be cut back to compensate.

"As long as healthcare is a benefit, and not a right, then measures such as step therapy are important means of preserving pharmacy benefits," he said. "If step therapy were to be prohibited through legislative means, there are other means through which a payor -- whether they be government, health insurer or employer -- could limit their cost exposure in pharmacy."

"These could include removal from formulary, increases in copayment, addition of deductibles (and increasing them), or 'carving out' pharmacy altogether and just cover medical expenses."

Tennant said he believes the true solution to the problem does not lie with new laws.

"There has to be some goodwill meeting of the minds for the people who practice medicine, those who need the help, and the people who are paying for it," he said. "Most of the [insurance companies] are trying to develop formularies comprehensive enough to get the job done without compromising patient care too much."

But Cook said that as long as her insurance adheres to a step therapy policy, she and other pain patients will worry about her medication one day becoming unaffordable.

"We all know that our lives could change at a moment's notice if the insurance companies say, 'Change,'" she said.