Tightening the Lid on Pain Prescriptions

Stuart Isett for The New York Times

Dr. Jane C. Ballantyne with Christine Link, who has a degenerative joint disease and said many doctors refused to refill a prescription.

By BARRY MEIER
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SEATTLE — It was the type of conversation that Dr. Claire Trescott dreads: telling physicians that they are not cutting it.

But the large health care system here that Dr. Trescott helps manage has placed controls on how painkillers are prescribed, like making sure doctors do not prescribe too much. Doctors on staff have been told to abide by the guidelines or face the consequences.

So far, two doctors have decided to leave, and two more have remained but are being closely monitored.

"It is excruciating," said Dr. Trescott,

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Mary Crossman, a former nurse who has lupus, takes 80 percent less OxyContin each day than she did a year ago.

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High-strength painkillers known as opioids represent the most widely prescribed class of medications in the United States.

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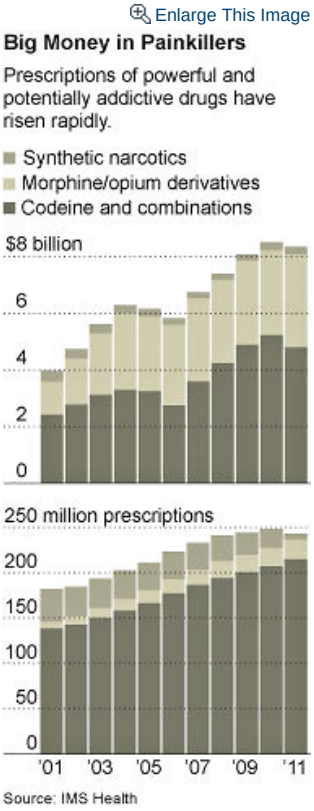

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who oversees primary care at Group Health. “These are often very good clinicians who just have this fatal flaw.”

High-strength painkillers known as opioids represent the most widely prescribed class of medications in the United States. And over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks, federal data shows.

“Doctors are prescribing like crazy,” said Dr. C. Richard Chapman, the director of the Pain Research Center at the University of Utah.

Medical professionals have long been on high alert about powerful painkillers like OxyContin because of their widespread abuse by teenagers and others for recreational purposes.

Now the alarm is extending from the street to an arena where the drugs had been considered legitimate and safe: doctors' offices where they are prescribed — and some say grossly overprescribed — for the treatment of long-term pain from back injuries, arthritis and other conditions.

Studies link narcotic painkillers to a variety of dangers, like sleep apnea, sharply reduced hormone production and, in the elderly, increased falls and hip fractures. The most extreme cases include fatal overdoses.

Data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous dosages. And while no one questions that the medicines help countless patients and that most doctors prescribe them responsibly, there is a growing resistance to their creeping overuse. Experts say that doctors often simply keep patients on the drugs for years and that patients can develop a powerful psychological dependence on them that mirrors addiction.

But changing old habits can be difficult — for doctors and patients alike.

The most aggressive effort is under way here in Washington, where lawmakers last year imposed new requirements on doctors to refer patients taking high dosages of opioids — which include hydrocodone, fentanyl, methadone and oxycodone, the active ingredient in OxyContin — for evaluation by a pain specialist if their underlying condition is not improving.

Even before the new provisions took effect, some doctors stopped treating pain patients, and more have followed suit. Christine Link, 50, said that several doctors had refused to refill the prescription for painkillers she had taken for years for a degenerative joint disease.

“I am suffering, and I know I am not the only one,” she said.

Washington State officials acknowledge some of the law's early deficiencies, including its sometimes indiscriminate application, and they are seeking to address them. But there is no retreat on the goal of moderating opioid use, and the movement extends well beyond Washington.

The federal Centers for Disease Control and Prevention has urged doctors to use opioids more judiciously, pointing to the easy availability of the drugs on the street and a mounting toll of overdose deaths; in 2008, the most recent year with available data, 14,800 people died in episodes involving prescription painkillers.

The Departments of Defense and Veterans Affairs are trying new programs to reduce use among active-duty troops and veterans. Various states are experimenting with restrictions, including Ohio, which is considering following the Washington model.

"We are trying to prepare our state for what we hope is the inevitable curbing of the use of opiates in chronic pain," said Orman Hall, the director of Ohio's Department of Alcohol and Drug Addiction Services.

The long-term use of opioids to treat chronic pain is relatively new. Until about 15 years ago, the drugs were largely reserved for postoperative, cancer or end-of-life care. But based on their success in those areas, pain experts argued the medications could be used to treat common kinds of long-term pain with little risk of addiction.

At the same time, pharmaceutical companies began to promote newer opioid formulations like OxyContin for chronic pain that could be used at greater strengths than traditional painkillers. Sales of painkillers reached about $8.5 billion last year, compared with $4.4 billion in 2001, according to the consulting firm IMS Health.

Along with Purdue Pharma, the maker of OxyContin, other producers include Johnson & Johnson and Endo Pharmaceuticals.

Dr. Russell K. Portenoy, who championed the drugs' broader use, said the new data about the potential high-dose risks was concerning. But he added that the medications were extremely valuable and that their benefits needed to be factored into policies like the one in Washington State.

"I don't think opioids need to be thought of any differently than any other therapies," said Dr. Portenoy, chairman of the pain medicine and palliative care department at Beth Israel Medical Center in New York. "It is just that right now, they have got our attention."

A pain expert here in Seattle, Dr. Jane C. Ballantyne, said she once agreed with Dr. Portenoy, but she now finds herself in the role of former believer turned crusading reformer.

"We started on this whole thing because we were on a mission to help people in pain," she said of the medical profession's embrace of opioids. "But the long-term outcomes for many of these patients are appalling, and it is ending up destroying their lives."

Alarms Sounded

The clues were buried in the dullest of places: thousands of workers' compensation claims.

In 2006, a state official here, Dr. Gary Franklin, called together 15 medical experts to discuss some troubling data found in the records.

Thirty-two injured workers who were prescribed opioids for pain had died of overdoses

involving the drugs. In addition, in just a few years, the strength of the average daily dose of the most powerful opioids prescribed to patients treated through the workers' compensation program had shot up by more than 50 percent. The number of patients taking the drugs in large quantities had grown to 10,000.

Doctors often increase opioid dosages because patients can adjust, or develop tolerance, to the drugs and need greater amounts to get the same effect. Pain specialists, including Dr. Portenoy of Beth Israel, had argued that it was safe to increase dosages so long as doctors made sure that patients were improving.

But the Washington data suggested that doctors were not monitoring patients; they were simply prescribing more and more. Such practices are common, said Dr. Trescott, the official at Group Health in Seattle, because treating pain patients, who are often also depressed or anxious, is time-consuming and difficult.

"Doctors end up chasing pain" instead of focusing on treating the underlying condition, she said.

That is what happened several years ago to a former nurse, Mary Crossman, after she was found to have lupus, an autoimmune disease that can cause severe joint and muscle pain. Her doctor put her on OxyContin and methadone and then raised the dosage every six months or so after she developed tolerance to the lower dosage.

Five years later, she was taking dosages so high that another doctor who examined her was shocked. "She said, 'I don't want you to die,' " Mrs. Crossman recalled.

In 2007, the Washington State panel approved a guideline that urged doctors to refer patients on large dosages for evaluation if they were not improving. Two professional groups representing pain specialists had already taken a similar step. But the Washington action had an important difference that soon proved contentious: it set a dosage level meant to prompt the referral.

As with most medical guidelines, doctors in Washington largely ignored the panel's suggestions, a later survey found — until last year, when the guidelines became law.

That bill moved so quickly through the State Legislature that its opponents were caught off guard. The maker of OxyContin, Purdue Pharma, tried and failed to stop it. Several national pain experts, including some with ties to the drug industry, also sought to block it, saying the new provisions would cause chaos by restricting patient access to care.

Even some supporters of the new law agreed that there was little evidence to support the dosage threshold, which was the amount of any opioid equivalent in strength to a daily dose of 120 milligrams of morphine. Nonetheless, they believed that drastic change was needed.

"I thought the new law was a necessary evil," said one Seattle-area physician, Dr. Charles Chabal.

A Cycle of Abuse

The state law has transformed the clinic at the University of Washington into a pain treatment center of last resort — and Dr. Ballantyne, the pain expert, into an appeals judge of sorts because she sees patients referred for evaluation under the law. On a recent day, she was seeing a stream of castoff patients, including Ms. Link, who sat hunched in a wheelchair, suffering from a degenerative joint disease.

"They all said that I can't treat you, you need to see a specialist," Ms. Link said of her other doctors.

Before the widespread use of opioids, the University of Washington's medical school was known for an approach to chronic pain that emphasized nondrug treatments like physical therapy and counseling. Some specialists like Dr. Ballantyne, who moved here a year ago, are now determined to revive that tradition.

"If doctors understood how hard it is to get patients off of these drugs, they would not prescribe them to begin with," she said.

Born and educated in England, Dr. Ballantyne was in charge of pain treatment for more than a decade at Massachusetts General Hospital in Boston before taking a post in 2008 at the University of Pennsylvania, in Philadelphia. She and her husband, who is also a doctor, bought an old house there to renovate, but when the University of Washington called, she jumped.

Dr. Ballantyne, 63, once embraced the wider use of opioids. Her transition to skepticism began about a decade ago, when she noticed that hospitalized patients taking high dosages screamed when they were examined — as if the drugs had increased their sensitivity to pain.

She decided to research long-term data about the drugs and published a medical journal article in 2003 with her findings. It concluded that high doses might not be safe or effective.

Other experts accused her of undercutting years of effort to erase stigmas about the drugs. "They'd say, 'How could you do something like this after all we have worked for? ' " Dr. Ballantyne recalled.

Since then, other researchers have published papers about the drugs' medical dangers. Studies have shown, for example, that the drugs greatly suppress the production of sexual hormones.

"It is not just our sex lives that go away; it is our ability to get things done," said Dr. Chapman, of the University of Utah.

Dr. Portenoy, the expert in New York, agreed that doctors needed to be aware of such risks. But he said that the dosage threshold used by Washington officials was arbitrary and that the state had failed to put a system in place to evaluate the law's impact on patients.

"You would always want to look at outcomes to see what you did either harmed or helped," said Dr. Portenoy, who consults with opioid producers.

A patient advocacy group, the American Pain Foundation, which receives much of its financing from drug makers, has continued to oppose the law, calling it "inhumane." And even some supporters believe it needs reworking.

Dr. Ballantyne said she also feared that the problems encountered by patients seeking treatment could cause an adverse reaction to the law. But she said she hoped that the quandary for patients like Ms. Link, who was given a new painkiller prescription, were "teething pains" that would be remedied.

She has little patience, however, for those who believe that the opioid problem can be solved simply by screening out those patients who might abuse the drugs.

"I think that after 20 years of a failed experiment that there are not many people supporting this except for the die-hards and the pharmaceutical industry," she said.

A Lost Generation

About a year ago, Mary Crossman, the former nurse with lupus, was at a neighborhood cookout with her husband when she noticed something odd: she was more relaxed, talkative and sociable than she had been in a long while.

Not long before, her doctor had suggested reducing her use of the painkillers OxyContin and methadone. The doctor, who worked at Group Health, said they would reduce the drugs slowly but warned Mrs. Crossman that she would initially feel more pain and increased anxiety.

Mrs. Crossman, who is 58, was scared but agreed to try. When her lupus flared up, she took more drugs, but over all, her daily dosages steadily came down. Today, she no longer takes methadone, and the amount of OxyContin she takes each day is 80 percent lower than it was a year ago.

Looking back, she said the high dosages helped mask her pain. But the pain relief came at a price; she now feels more mentally alert.

“There are days when I still hurt a lot, but over all I’m doing O.K.,” she said.

Big health care systems like Group Health, which treats 420,000 patients at 25 clinics throughout Washington, can oversee how doctors prescribe drugs and provide patients with alternative treatments. Over the last four years, Group Health has cut the percentage of patients on high opioid dosages in half, the system says, and reduced the average daily dose among patients who regularly take opioids by one-third.

The system is now examining how those changes have affected patients. Studies elsewhere suggest the benefits of lower opioid use may be significant for many patients. For example, Danish researchers have published a study indicating that chronic pain patients getting nondrug treatments recover at a rate four times as high as those on opioids.

“These drugs don’t seem to be even doing what they are supposed,” said Dr. Per Sjogren, a pain expert in Copenhagen who led the study.

The obstacles to lower opioid use remain formidable, however; both insurers and public agencies must be willing to pay for other treatments, which can be costly.

“You can’t just take things away,” said Dr. Roger Chou, an associate professor at Oregon Health and Science University in Portland. “You have to give patients alternatives.”

There is also political and professional resistance to adapting requirements like those at Group Health to taxpayer-financed programs like Medicaid.

The Food and Drug Administration indicated in 2008 that it might require that doctors receive several hours of mandatory training in the use of opioids as a condition of prescribing them. But in 2010, the agency backed away from that stance in the face of opposition from some medical and patient advocacy groups. In addition, although the Obama administration announced plans last year to introduce legislation containing such a mandate, it has yet to do so.

Few programs are in place to deal with patients now on high opioid dosages who are not benefiting from them.

If the patients were taken off the medications, many would experience severe withdrawal or have to take addiction treatment drugs for years. Even avid believers in the new direction, like Dr. Ballantyne, suggest that it might be necessary to keep those patients on the opioids and to focus instead on preventing new pain patients from getting caught in the cycle.

“I think we are dealing with a lost generation of patients,” she said.

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