

A proposal to allow medical marijuana for chronic pain offers hope for patients and cannabis startups, but narcotic painkillers remain less expensive and easier to prescribe BY CAROLINE LEWIS

udy Andino, a paralegal from Monroe, N.Y., spent nearly four years taking oxycodone, morphine and other heavy narcotics to overcome chronic pain and muscle spasms. "It was just disorienting mentally," said Andino, 28, who suffers from peripheral neuropathy, a painful condition affecting the body's nerves, and ankylosing spondylitis, a form of spinal arthritis. "There's no way I could be on all that stuff and work."

Since getting a medical marijuana card in March, she has stopped taking everything else in favor of a few puffs a day on a skinny black vaporizer pen filled with cannabis oil. Now, she says, she can get through the work day and go on outings with her children.

"It doesn't take away my pain completely, but it's given me the ability to deal with it and function," she said.

Andino is one of 12,764 patients who have enrolled in the state's medical marijuana program since the first dispensaries opened a year ago. Thousands more patients might soon gain access to cannabis, thanks to proposed rules that would expand the market from patients diagnosed with one of just 10 conditions, including cancer and neuropathy, to include people with any severe pain lasting at least three months.



HEALTH CARE | ADDICTION'S COST

Medical marijuana offers an alternative to opioid drugs for treating chronic pain and gives policy makers another tool to combat the state's growing addiction crisis, according to proponents. The new rules also could boost the state's struggling cannabis companies by adding customers.

But most doctors in New York are still reluctant to embrace cannabis as a medical treatment. Only 833 physicians, about 1% of the state's total, are certified to prescribe the drug. Critics cite a paucity of conclusive research on its efficacy, a lack of insurance coverage and the tension between state law and marijuana's federal status as an illegal drug. And they express a fear of repeating the medical community's past mistakes. "We saw what a mess happened with opioids," said Dr. Houman Danesh, director of the Integrative Pain Management Division at Mount Sinai Hospital. "We don't want to cause the same mess with marijuana."

No one disputes that the stakes are high. New York ranked 19th nationwide in heroin-related deaths and 34th for prescription opioid overdose deaths in 2014, but the problem has grown significantly faster here. In the past decade, New York's opioid-related deaths for both heroin and prescription painkillers have increased at a greater rate than in almost any other state.

"The main reason a lot of our team of professionals and physicians stepped into this realm was to fight the war on opioids," said Dr. Kyle Kingsley, chief executive of Vireo Health, which has licenses to produce and sell medical marijuana in New York and Minnesota. "The inclusion of chronic pain allows us to directly fight opioids in New York."

Addressing opioid overdoses

New York lawmakers allocated nearly \$200 million in prevention and treatment in last year's state budget, representing an 82% increase since 2011.

In addition, new state measures took effect at the beginning of January, limiting how many pills doctors can dole out on the first prescription and requiring insurers to cover addiction treatment.

Andino's physician, Dr. Junella Chin, is an osteopath who has certified about 250 cannabis patients at her clinics in Manhattan and White Plains since the drug became legal. Many have been able to ease up on their use of potentially addictive opioid painkillers or cut them out altogether, Chin said.

"They call me in a panic," she said.

"What they'll usually tell me is, 'I skipped a couple of days [of opioids]. Is that OK?"

Chin receives about 60% of her patients through referrals. Like other New York cannabis doctors who spoke to *Crain's*, Chin said many of those referrals come from physicians at major health systems who said they face institutional barriers to recommending the drug or are skittish about federal law.

Under New York's proposed rules, which are in a public comment period through Feb. 6, chronic-pain patients must experience failure with at least one other therapy or have unbearable side effects before they can get a cannabis prescription. Chin's patients, who tend to suffer from neuropathy or another debilitating condition, are likely to have tried several opioids by the time they get to her.

"They're on a lot of opiates, even morphine and fentanyl patches" she said.

Dr. Bernard Lee, associate chief medical officer for MJHS Hospice and Palliative Care, an early supporter of the state's cannabis program, has been treating patients with cannabis during the past year. He said he has seen it benefit many people with chronic pain, including some who were previously addicted to opioids.

Getting too stoned is the worst side effect Lee's patients have reported, he said. To address that problem, he often starts patients on a product with a low dosage of THC—which can be less effective but also can prevent patients from getting uncomfortably high. If a patient upgrades to something stronger, he recommends they buy a product high in CBD, an extract that serves to offset THC's psychoactive effects.

Chin's and Lee's anecdotal successes with cannabis echo recent studies showing fewer opioid prescriptions and overdose deaths in states that have legalized medical marijuana. States with legally protected dispensaries have seen a reduction of at least 16% in opioid overdose deaths and at least a 28% drop in admissions for treatment of opioid addiction, according to a 2015 working paper by the RAND Corporation. The longer the dispensaries were open, the greater the decline in opioid-related problems.

But to make a real dent in the opioid crisis, doctors and insurers need to stop relying on drugs as the first line of defense against pain, said Dr. Andrew Kolodny, who recently left his post as chief medical officer of the addiction-treatment nonprofit Phoenix House to become co-director of opioid policy research at Brandeis University's Heller School for Social Policy and Management.

There are plenty of safe approaches to treating pain that are underutilized besides cannabis, including such non-pharmaceutical options as acupuncture, physical therapy and mindfulness

meditation, Kolodny said. Guidelines for prescribing opioids that were released recently by the U.S. Centers for Disease Control and Prevention direct doctors to try non-pharmaceutical approaches first.

"I do think it makes more sense to try patients on cannabis than opioids," Kolodny said when pressed to compare the two. "And I do think if we stop putting chronic-pain patients on longterm opioids and instead prescribe cannabis, that potentially will have a helpful effect in the long term on our opioid crisis."

Most in New York's medical community are not yet ready to make that transition. For one thing, cannabis is still federally illegal, Danesh noted. Although the federal government has taken a hands-off approach to state cannabis legalization, the change of administration in Washington has introduced uncertainty about the drug's future status.

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Since the state proposed cannabis for chronic pain, Danesh has fielded a growing number of questions about the drug from curious patients, forcing him to do his homework, he said.

So far, cannabis hasn't been linked to any overdose deaths, and two decades of research reviewed by the National Academies of Sciences, Engineering and Medicine show it is effective in alleviating many types of chronic pain. But marijuana is not without its dangers. It has been connected to drugged-driving accidents and an increased risk of psychosis.

Like many doctors, Danesh said he is concerned that scientific studies have yet to address many questions about medical marijuana's potential risks and side effects. Largely because of a lack of federal support for cannabis research, anecdotes and observational studies on the drug's effectiveness often stand in for the randomized clinical trials that serve as the scientific standard.

Danesh said he tries to prescribe acupuncture and other non-pharmaceutical therapies before turning to drugs, but he's still willing to put a patient on opioids for up to six months. Opioids are also by far the easiest pain-management tool to get covered by insurance, he said. No state insurers cover the costs of medical marijuana.

High cost of cannabis

Danesh's concerns are shared by many in New York's medical community. In a December letter to the state Health Department, the Medical Society of the State of New York called the plan to approve cannabis for treating chronic pain premature.

"I think it's great that groups like MSSNY are looking out for physicians," Lee said. "I just would hate to be so cautious at the expense of patients."

Perhaps more than any other state, New York has strived to make cannabis more like other pharmaceuticals, with consistent dosages and safety measures. Companies are required to extract the active ingredients from the plant and mix them in precise ratios into pills and tinctures, which then must be tested by an independent lab and dispensed by in-house pharmacists.

For some people, especially older adults and parents of pediatric patients, such regulations provide peace of mind. The rules also allow doctors and patients to test out different formulations of the drug to see what works best for a particular condition.

But treating cannabis like a pharmaceutical also contributes to higher expenses for cannabis companies and prohibitive costs for many patients, who pay for the drug out of pocket.

Andino pays about \$350 per month for legal cannabis—significantly more than she would pay on the black market

Andino swallows the extra cost so she can take cannabis legally at work, but Chin and other cannabis doctors said many patients end up turning to the black market after getting certified, because it's less expensive.

"I don't get it every month, because I can't afford to do that," said Brittany Barger, another of Chin's patients, who uses cannabis to treat chronic pain and low appetite related to her cancer diagnosis. Barger was prescribed about \$500 worth of cannabis medication per month, but she often buys less and rations it. The high cost also has forced her to rely on opioids more than she'd like, she said.

"What I'm able to do depends on what bill I'm going to skip that month," she said.

Other states' experiences suggest that expanding medical marijuana to include the treatment of chronic pain would boost New York's cannabis industry. Consider Minnesota, which in August extended approval of cannabis for "intractable pain." By the end of December, enrollment in the program had increased 158%, with pain patients accounting for 57% of all active enrollees, according to the Minnesota Department of Health.

But it's unclear whether the addition of chronic pain, along with other recent reforms, will expand the legal cannabis market enough to make industry startups profitable and bring down prices.

Vireo Health's Kingsley said he is optimistic that the increase in patient volume in New York will be even greater than in Minnesota, because the program has caught on more quickly here.

Kingsley said he hopes getting more customers will allow him to reduce the price of cannabis in both states, but that hasn't been the case yet in Minnesota.

"The general rule of thumb is a company should be profitable before prices come down," said Kingsley, who hasn't broken even yet in either state.

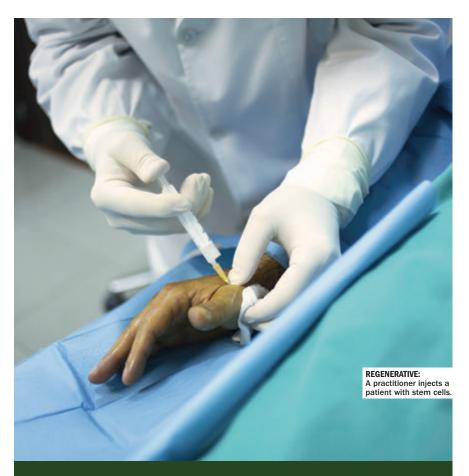
Hillary Peckham, chief operating officer of Etain, another New York cannabis company, said her business got off to a slow start but now has ramped up to more than 1,000 customers per month. Her customers spend anywhere from \$50 to more than \$1,000 on medication, she said. Still, she is cautious about how much the addition of more patients with chronic pain will boost business.

"It will help significantly, but not as much as everyone thinks. It's not a gold rush," Peckham said in a phone interview shortly after the Health Department made its announcement. "The reality is there hasn't been a significant increase in the number of doctors that have been registering."

As a provider, Lee said he understands the attitudes of colleagues who are cautious about recommending a drug with which they are unfamiliar, but he said he encourages them to become educated about it. "From what we've seen with the history of mankind and cannabis from anecdotal data out there," he said, "I'm comfortable with my risk as a certifying provider."

The state's addition of chronic pain to the list of conditions treatable with medical marijuana is unlikely to launch cannabis into the mainstream, said Nicholas Vita, chief executive of cannabis company Columbia Care. But he said he hopes the new rules will offer an opportunity for more coordinated research between the state, doctors and New York's five cannabis companies on the drug's effectiveness for pain and its impact on opioid use.

"This is a huge opportunity for us to engage in real research to validate the assumption that this is a suitable substitute," Vita said. "We believe that's the case based on what we've observed, but this will allow us to put the nail in the coffin in terms of any doubters."



A GUIDE TO ALTERNATIVE THERAPIES FOR PAIN CONTROL

S NEW YORK DOCTORS face pressure to cut down on their opioid prescriptions, some are looking to alternative therapies to treat pain, ranging from acupuncture and other ancient techniques to newer, costlier interventions such as stem-cell injections. But New York insurance plans differ widely in their coverage of pain therapies.

When it comes to acupuncture, for instance, some plans (including Medicare and New York's Medicaid plans) won't cover it at all, while others require patients to meet certain criteria to qualify for reimbursement.

The criteria for prescribing opioids? "Zero," said Dr. Houman Danesh of Mount Sinai Hospital.

The costs—and scientific evidence—for alternative pain therapies vary. Acupuncture typically costs about \$100 per session. Some of the interventions insurers have denied, including spinal-cord stimulators, cost thousands of dollars.

A spinal-cord stimulator costs more than a 30-day prescription of oxycodone, Danesh said, "but over the long term it's cheaper."

SOME OF THE OPIOID ALTERNATIVES PATIENTS ARE TRYING

ACUPUNCTURE A practice in which thin needles stimulate different points on the body

MINDFULNESS MEDITATION An awarenessraising technique that helps some patients decrease the intensity of chronic pain and address its psychological effects

NSAIDS (NONSTEROIDAL ANTI-INFLAMMATORY DRUGS) A group of pharmaceuticals that includes such familiar medications as aspirin and ibuprofen

PHYSICAL THERAPY The use of massage and exercise to improve motion and alleviate pain

REGENERATIVE MEDICINE Some pain clinics and hospitals offer nonsurgical procedures, such as injections of a patient's own stem cells or platelet-rich blood, to help heal injuries.

SPINAL CORD STIMULATOR A device that's surgically placed under the skin to send a mild electric current to the cord, blocking pain signals from reaching the brain

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) A device with electrodes that are placed on the skin to send low-voltage electrical impulses to painful areas

— C.L.