

Oxy sales in China driven by misleading addiction claims

November 20 2019, by Erika Kinetz



Tony Chen, a former OxyContin sales representative who spoke on condition that he only be identified by his English name, for fear of retribution, said Mundipharma required sales staff to upload copies of patients' private medical records, obtained without consent, to a company group chat, in apparent violation of Chinese law, during an interview in China on Sept. 19, 2019. (AP Photo/Ng Han Guan)

Thousands of lawsuits across the United States have accused a drug company owned by the billionaire Sackler family of using false claims to push highly addictive opioids on an unsuspecting nation, fueling the deadliest drug epidemic in U.S. history.

Yet, even as its U.S. drugmaker collapses under the charges, another company owned by the family has used the same tactics to peddle its signature painkiller, OxyContin, in China, according to interviews with current and former employees and documents obtained by the Associated Press.

The documents and interviews indicate that representatives from the Sacklers' Chinese affiliate, Mundipharma, tell doctors that time-release painkillers like OxyContin are less addictive than other opioids—the same pitch that Purdue Pharma, the U.S. company owned by the family, admitted was false in court more than a decade ago.

Mundipharma has pushed ever larger doses of the drug, even as it became clear that higher doses present higher risks, and represented the drug as safe for [chronic pain](#), according to the interviews and documents.

These tactics mirror those employed by Purdue Pharma in the U.S., where more than 400,000 people have died of [opioid overdoses](#) and millions more became addicted. An avalanche of litigation over the company's marketing has driven Purdue Pharma into bankruptcy in the U.S.

In China, Mundipharma managers have required sales representatives to copy patients' private medical records without consent, in apparent violation of Chinese law, current and former employees told AP. Former reps also said they sometimes disguised themselves as medical staff, putting on white doctor's coats and lying about their identity to visit patients in the hospital. As in the U.S., marketing material in China

made claims about OxyContin's safety and effectiveness based on company-funded studies and outdated data that has been debunked.

The AP examined more than 3,300 pages of training and marketing materials used by Mundipharma staff, as well as internal company documents and videos. These files came from three independent sources and were verified by cross-checking. AP also spoke with one current and three former OxyContin sales representatives who worked at the company last year.

Mundipharma has promoted its blockbuster product, OxyContin, in questionable ways in other countries, including Italy and Australia. But the company has particularly high hopes for China—the world's most populous nation and second largest economy— where it has said it wants sales to surpass those in the U.S. by 2025.

Though Mundipharma and Purdue are separate legal entities, both are owned by the Sackler family. Today, Mundipharma is a bargaining chip in negotiations to settle sweeping U.S. litigation. The Sackler family agreed to cede ownership of Purdue, but wants to keep Mundipharma for now to sell OxyContin abroad. They have discussed eventually selling Mundipharma to fund the family's contribution to a nationwide settlement in the U.S.

Mundipharma said it was taking immediate action to investigate the allegations uncovered by AP. In a statement, the company did not respond to specific allegations but said it has rigorous policies in place "to ensure that our medicines are marketed responsibly and in accordance with China's strict regulatory framework governing analgesics."



Dr. Fan Bifa, director of the pain clinic at the China-Japan Friendship Hospital in Beijing, speaks at a medical conference in Beijing, China on May 23, 2019, where he points to a chart showing the results of a survey about specialized training for pain doctors. Fan says he had never looked for scientific evidence to prove that sustained release opioids are less likely to cause addiction. (AP Photo/Mark Schiefelbein)

In response to detailed questions, Purdue said Mundipharma is an independent entity, operating in a different country, under different laws and regulations. Representatives of the Sackler family did not respond to detailed requests for comment.

In the United States, Purdue stopped promoting OxyContin to doctors in 2018 and got rid of its entire opioid sales staff.

Meanwhile, Mundipharma is hiring in China.

A CELESTIAL CHALLENGE

Mundipharma China was born in 1993 in a signing ceremony at the Great Hall of the People on Tiananmen Square. Just as in the U.S., the Sackler family's business interests in China coincided with their philanthropy.

The month after Mundipharma's creation, the Arthur M. Sackler Museum of Art and Archeology opened its doors at Peking University in Beijing. Outside the museum is a statue dedicated to Arthur Sackler and his wife by the China Medical Tribune, a journal he helped found that now claims a readership of more than a million Chinese doctors.

These seeds of philanthropy and political alliances would bear fruit for the Sacklers just as opioid prescriptions began to fall in the U.S.

China was a tantalizing market for the Sacklers. The country's per capita consumption of opioids was low and it had millions of new cancer cases every year.

But if convincing U.S. doctors in America that opioids are safe was a hard sell, in China, it would be even more difficult.

China fought two wars in the 19th century to beat back British ships dumping opium that fueled widespread addiction. Today, the cultural aversion to taking drugs—in Chinese, literally "sucking poison"—is so strong addicts can be forced into police-run treatment centers. The country does not appear to have an opioid crisis anything like in the U.S.



Boxes of OxyContin tablets sold in China sit on a table in southern China's Hunan province on Sept. 24, 2019. Representatives from the Sacklers' Chinese affiliate, Mundipharma, tell doctors that OxyContin is less addictive than other opioids—the same pitch that their U.S. company, Purdue Pharma, admitted was false in court more than a decade ago. (AP Photo/Mark Schiefelbein)

Two decades ago, as stories of OxyContin abuse began to circulate in the United States, foreign pharmaceutical companies helped spread a new gospel of [pain](#) treatment across China, recasting pain as the fifth vital sign—alongside blood pressure, heart rate, respiratory rate, and temperature—and pain treatment as a human right.

Dr. Yu Buwei, director of anesthesiology at Shanghai's prestigious Ruijin Hospital, was skeptical. Philosophical and soft-spoken, Yu was

deeply grounded in traditional Chinese medicine. During China's Cultural Revolution he used acupuncture as anesthesia on patients undergoing major surgery.

"It is necessary to treat pain," Yu said. "We agree with this. But raising it to a human right and the fifth vital sign, we think is controversial."

Many of his younger colleagues, however, appeared in thrall of these foreign ideas. They believed the best medical practices came from the United States. Few understood how deeply the Western consensus about pain had been shaped by the financial self-interest of pharmaceutical companies.

"In China, doctor's groups, especially the young doctors, show their respect to American doctors or the European doctors," Yu said. "What they say, that's truth. What you say, that's interfering."

DESPERATELY SEEKING SALES

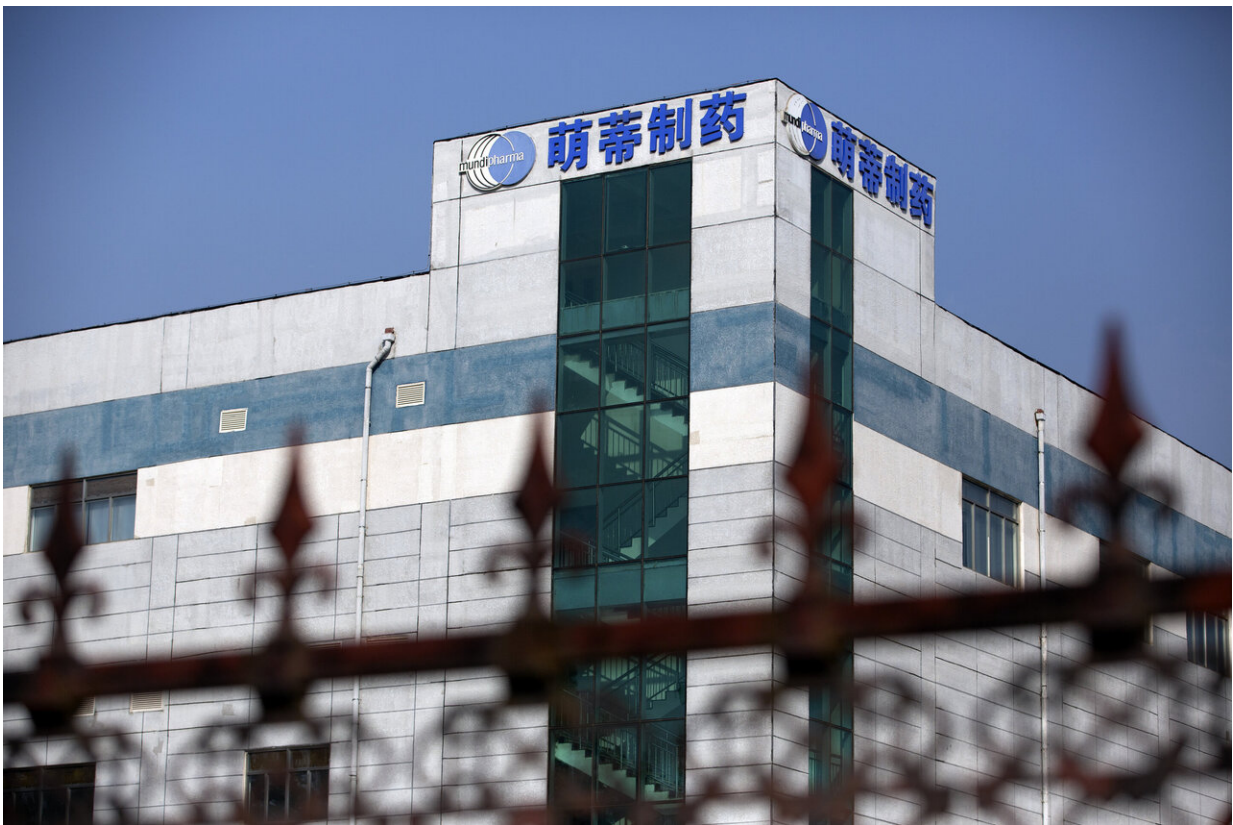
In 2007, Purdue and three executives pleaded guilty in U.S. court to misrepresenting OxyContin as less addictive than other opioid painkillers, and paid \$635 million in penalties, one of the largest settlements in pharmaceutical company history.

Sackler family members began to worry about a "dangerous concentration of risk" in their U.S. business, and trained their sights on the global market. Not long after, Mundipharma helped launch a campaign to improve cancer pain care in China called Good Pain Management, or GPM, according to interviews and company documents.

Today, the program is portrayed as a government public health initiative. But Zhang Li, director of internal medicine at Sun Yat-sen University Cancer Center in Guangzhou, said GPM "got the energetic support of

Mundipharma during the launch process."

According to Zhang, the GPM campaign was started in 2009 under his leadership, by a group within the Guangdong Provincial Anti-Cancer Association, a non-profit that accepts corporate funding. Pharmaceutical companies helped by covering the cost of training and educational materials, he said.



This Sept. 27, 2019 photo shows a Mundipharma facility in an industrial park on the outskirts of Beijing, China. As the Sackler's U.S. empire collapses, Mundipharma, which is also owned by the family, is using the same tactics to peddle opioids in China. (AP Photo/Mark Schiefelbein)

Two years later, the Chinese government launched the campaign nationwide. On February 22, 2011, Mundipharma won a contract to implement the program with an initial target of establishing model GPM wards in 150 key hospitals within three years.

It was a watershed moment for the company.

Mundipharma was responsible for helping train doctors and educate patients, as well as distributing pamphlets and placards to raise awareness about pain. "Mundipharma will eventually become your best supporter and partner in creating a demonstration ward," proclaimed a PowerPoint assembled in 2009.

The program was a three-way alliance among the then-Ministry of Health, the Chinese Society of Clinical Oncology and Mundipharma, according to Zhang and presentations used by Mundipharma sales staff.

Mundipharma's initial contract with the oncology society gave it a seat on the GPM leadership team and barred the company from using the program to market its products, according to sections of the contract obtained by AP. In internal company documents, however, Mundipharma treated the program as part of its marketing strategy and used it to tout the superiority of its own products.

"We were definitely talking about OxyContin ninety percent of the time," said a former sales rep who spoke on condition of anonymity for fear of retribution.

The oncology society declined to answer questions. China's Ministry of Health, which was reorganized as the National Health Commission, said it hadn't designated a company to provide assistance for the program.

One GPM presentation that Mundipharma employees said was still being

used last year suggested OxyContin is the preferred option for cancer pain treatment under World Health Organization and other guidelines, before detailing why competing painkillers such as acetaminophen, fentanyl patches and immediate release morphine aren't recommended.

The WHO does not recommend OxyContin as superior to other drugs for cancer pain care.

In a statement to AP, the company said its role in GPM is only to assist with implementation. "The Program is independently initiated and managed with the goal of improving the medical community's understanding of cancer pain management treatments," the company said.



This Sept. 24, 2019 photo shows 40-milligram Oxycontin tablets sold in China in Hunan province. China fought two wars in the 19th century to beat back British ships dumping opium that fueled widespread addiction. Today, the cultural aversion to taking drugs, in Chinese, literally "sucking poison", is so strong addicts can be forced into police-run treatment centers. (AP Photo/Mark Schiefelbein)

Mundipharma told AP that all marketing materials undergo multi-level approval. But current and former employees acknowledged that they sometimes altered the officially-vetted presentations. The messages contained in all three sets of documents were consistent and contained information that Purdue Pharma has used in the United States.

In the years after GPM rolled out, from 2012 through 2018, sales of Mundipharma's oxycodone, the active ingredient in OxyContin, at nearly 700 of China's major hospitals rose five-fold, according to previously unreported data from the government-linked China National Pharmaceutical Industry Information Center.

During that same period, sales of morphine, widely considered an affordable "gold standard" for pain treatment, remained flat at those same hospitals. By early 2017, OxyContin had captured roughly 60 percent of the cancer pain market in China, up from just over 40 percent in 2014, company documents show.

Tony Chen, a former OxyContin sales rep who spoke on condition that he be identified by his English name, for fear of retribution, said he loved GPM because the government backing got him high-level access at hospitals and helped drive sales.

"We didn't need to bribe," he said. "That's why I liked it."

The pressure to perform was intense. Chen and other reps said quarterly sales targets rose by as much as 30 percent. If he surpassed them, he could more than double his take home pay. If he didn't, he could lose his job.

He said he was prepared to "get fired up" about driving growth. He wasn't prepared to break the law.

One current and three former sales reps who worked in different parts of China told the AP that managers required them to upload patients' medical records, obtained without consent, to a company chat group each day.

AP was shown snapshots of prescription records staff said were sent to managers. Handwritten on pink slips of paper, they included the patient's full name, age, phone number, ID number, diagnosis and prescription.

The more precise the information, the better Mundipharma could plan sales targets, as well as guide doctors to increase dosages and switch to OxyContin from rival drugs, former sales reps explained.



A former sales representative who spoke on condition of anonymity for fear of retribution speaks during an interview in eastern China on Sept. 18, 2019. He said he sometimes disguised himself as medical staff, putting on a white doctor's coat and lying about his identity to visit patients in the hospital. (AP Photo/Ng Han Guan)

Chen knew he had no legal right to copy personal information, and at first scribbled over patients' names before uploading the documents. He and his colleagues said they used to discreetly snap photos of patient records during the night shift, or during lunch breaks.

Ultimately, Chen said, he decided his effort to protect privacy was a waste of time because other people in his group were uploading full patient records. He told himself it was OK because the information

wouldn't circulate outside Mundipharma.

When it was time for hospital rounds, Chen sometimes slipped on a white doctor's coat and mingled with medical staff. If anyone asked who he was, he lied and told them he was a doctor or an intern. He said he sometimes asked patients directly if they felt sore, swollen or numb and how they were sleeping.

Two other former OxyContin sales reps said they also disguised themselves in doctor's coats and sat in on patient meetings.

The key to this access was good relationships with doctors. Just as Purdue was accused of doing in the U.S., Mundipharma cultivated doctors with paid speaking gigs, dinners, event sponsorships and expense-paid trips to meetings, sometimes routing payments through third parties, sales reps said. Speakers, who sometimes delivered presentations created by or with Mundipharma sales staff, could earn 500 yuan (\$70) to several thousand yuan per speech, current and former employees said.

Two of Chen's former colleagues said they also used gift cards to encourage doctors to prescribe more. It was easy to fake receipts for company expense reports and get cash to fund under-the-table payments, they claimed.

Mundipharma told AP it promotes ethical behavior and compliance with Chinese law through internal monitoring as well as external audits. "We have detailed policies covering interactions with healthcare professionals, grants and donations, and sponsorships and incentives," the company said, adding that a compliance team monitors expense claims and meetings.

China has some of the strictest regulation in the world on the use of opioids. Opioid painkillers like OxyContin are not available at

pharmacies. They are stored under double-lock at hospitals and governed by so-called "red prescriptions," which only specially certified doctors can write.

But as pain treatment expanded in China, with the establishment of pain clinics beginning in 2007 and the rollout of GPM, more doctors became certified to prescribe opioids. Pain management ceased to be the purview of anesthesiologists like Ruijin Hospital's Dr. Yu. It became a matter for surgeons, pain clinicians and cancer doctors.

"Patients, or drug abusers, can get these kinds of drugs much more easily compared with 10 years ago," Yu said. "That's a problem."



Dr. Fan Bifa, director of the pain clinic at the China-Japan Friendship Hospital in Beijing, speaks at a medical conference in Beijing, China on May 23, 2019.

Fan told The Associated Press he has never taken money directly from Mundipharma. (AP Photo/Mark Schiefelbein)

Yu read about what was happening in the U.S. and worried for China. "There is already a quite enormous group of drug users in this society," he said.

Yu resisted the notion that opioid painkillers weren't addictive and could be safely used, at any dose, for all kinds of pain. He checked the scientific references on clinical presentations and often found them unconvincing. He barred sales reps from his department.

Yu said he tried to persuade colleagues that some of the new notions about pain were silly, even risky. "I remember I argued with them, muscle pain or joint pain is not a good indication for opioid drugs," he said. "But they said, it's a human right. You have to relieve the pain."

A FAMILIAR PLAYBOOK

When Chen started work at Mundipharma, he was taught that OxyContin was a good drug, and widely used in America.

The company gave him hundreds of pages of documents to study. Chen read that the risk of getting addicted to opioid painkillers was virtually non-existent and that OxyContin's slow-release formulation made it even safer. He didn't bother to check the references Mundipharma cited as proof. Neither did most doctors at China's notoriously overburdened hospitals. And the legal sanctions Purdue faced in the U.S. didn't apply in China, where some people had never heard of the company or its troubles.

"I considered this a problem in terms of humanistic care for patients," Chen said. "This is a really good product."

In the 2007 lawsuit filed by U.S. prosecutors, Purdue conceded that some of its employees had falsely claimed that long-acting opioids are less addictive because they have fewer "peak and trough" effects and cause less euphoria. Purdue entered into a legally binding agreement with the U.S. government to ensure that their staff never made such claims again.

"Purdue accepted responsibility for the misconduct in 2007 and has since then strived never to repeat it," the company said again in a legal filing in September.

Yet, three current and former employees of Purdue's international affiliate in China made the same claim to AP that OxyContin reduces the risk of addiction because it is released slowly into the bloodstream, causing fewer "peaks and troughs" than immediate-release drugs. This argument has no scientific basis, according to a 2016 U.S. Centers for Disease Control report.



Tony Chen, a former OxyContin sales representative who spoke on condition that he only be identified by his English name, for fear of retribution, speaks during an interview in China on Sept. 19, 2019. The pressure to perform was intense. Chen and other reps said quarterly sales targets rose by as much as 30 percent. If he surpassed them, he could more than double his take home pay. If he didn't, he could lose his job. (AP Photo/Ng Han Guan)

Sustained-release technology "further reduces the incidence of addiction," reads a Mundipharma PowerPoint slide staff said was still in use last year. It referenced a study in the scientific journal *Cancer* from 1989 funded by Purdue and co-authored by a Purdue employee, and a brief 2004 Chinese study.

Neither paper actually examined addiction risk.

Some influential doctors in China also continue to make Mundipharma's argument.

"The prolonged release formulation doesn't easily give rise to drug dependence," Dr. Fan Bifa, the director of the pain clinic at the China-Japan Friendship Hospital in Beijing, told the AP in May.

Dr. Fan has spoken at Mundipharma-funded conferences and appeared in a pain awareness video alongside Mundipharma China's general manager, other prominent doctors and celebrities. The China-Japan Friendship Hospital was among the first to obtain certification under the Good Pain Management program in Beijing.

Fan told AP he has never taken money directly from Mundipharma.

When AP told Fan about Purdue's 2007 guilty plea, he seemed shocked. He said he had never looked for scientific evidence to prove that sustained release opioids are less likely to cause addiction.

Other Mundipharma materials echoed a brief 1980 letter in the New England Journal of Medicine that has been repeatedly and incorrectly cited to suggest that opioids aren't as addictive as everyone had long thought. Even after the journal "for reasons of public health" took the unusual step of publishing a cautionary editor's note above the letter, it continued to be used in China.

"In the last 40 years, clinical studies at home and abroad have shown that the danger of opioid dependence occurring is less than 3/10,000," proclaimed a Sept. 2017 press release for a Mundipharma-backed cancer pain awareness campaign.

Three current and former OxyContin sales reps repeated similar statistics to AP.



This Sept. 24, 2019 photo shows 40-milligram OxyContin tablets sold in China in Hunan province. OxyContin's U.S. FDA-approved label warns that even if taken as prescribed, the opioid carries potentially lethal risks of addiction and abuse. (AP Photo/Mark Schiefelbein)

In a statement to AP, Mundipharma said that it "mandates warnings of addiction risk" in material used by [sales representatives](#), but did not provide further detail. The package insert for OxyContin in China warns that it has the potential for abuse but also says "concerns about abuse, addiction, and diversion should not prevent proper use for pain treatment."

The U.S. Centers for Disease Control says that as many as 1 in 4 people

prescribed opioids for long-term use struggles with addiction.

The Mundipharma sales reps told AP they had a pitch for doctors worried about addiction: If used properly, the risks of addiction to opioid painkillers are virtually non-existent. Patients who seem addicted may just need more drugs to control pain, staff PowerPoints explained.

"Based on my experience, that's like a joke," Dr. Yu said.

He said patients could slip into addiction within a few days. "They came to you and started talking repeatedly about pain and asked you to prescribe medicine," Yu said. "We call this drug-seeking behavior."

Mundipharma called it "pseudoaddiction."

It is a notion first popularized by Dr. J. David Haddox, who coined the term "pseudoaddiction" in a 1989 paper. Haddox went on to spend nearly two decades as an executive at Purdue Pharma.

OxyContin's FDA-approved label warns that even if taken as prescribed, OxyContin carries potentially lethal risks of addiction and abuse. Purdue now faces multiple U.S. lawsuits for spreading ideas about pseudoaddiction, as well as claiming the risk of opioid addiction is low and that doses can be increased without risk.

The idea that patients can safely take as much OxyContin as they want was great for Chen's bottom line. Mundipharma sometimes offered special bonuses for selling 40 mg OxyContin, the largest, most expensive dose sold in China, internal documents and interviews show.

But Chen said cramming people full of pills "would lay heavy on my conscience."



A woman holds a plastic bag of OxyContin tablets sold in China in southern China's Hunan province on Sept. 24, 2019. Representatives from the Sacklers' Chinese affiliate, Mundipharma, tell doctors that OxyContin is less addictive than other opioids—the same pitch that their U.S. company, Purdue Pharma, admitted was false in court more than a decade ago. (AP Photo/Mark Schiefelbein)

Chen flipped through a PowerPoint presentation on high-dose opioids he said he got from his boss at Mundipharma and pointed to an example of a patient taking 1500 mg twice a day.

"It's terrifying," he said.

A year after the CDC said that taking more than 33mg of OxyContin a day at least doubles the risk of overdose, Mundipharma came out with a marketing plan pushing its 40mg pill.

Mundipharma said its training covers "appropriate dosage levels for cancer patients" and provides information "in accordance with current best practice."

As Chen looked back over his training documents, he found presentations touting opioid painkillers as a safe and effective treatment for chronic pain, citing outdated studies with authors linked to Mundipharma and other companies.

The co-author on a 2006 study of visceral pain went on to serve as a paid consultant for Mundipharma. One of the authors on another study, from 2003, cited as evidence that OxyContin is "ideal" for neuropathic pain, was a Mundipharma Canada employee. Mundipharma sourced OxyContin's effectiveness for osteoarthritis pain to the American Academy of Pain Medicine, a professional society that attorneys general allege, in multiple lawsuits, is a paid front group for corporate interests.

In the U.S., Purdue also set out to change the culture of pain by first focusing on cancer. But from the beginning, Purdue was after the far larger non-cancer pain market, according to budget documents released by the Florida Attorney General's office and published by Kaiser Health News.

The CDC says there are risks of "serious harms" from taking opioids long-term for chronic pain, but evidence for the potential benefits is lacking.

In a statement to AP, Mundipharma said that OxyContin "is used in practice only for the treatment of cancer pain in China."

But under Chinese regulations, OxyContin can be used to treat moderate to severe pain, whether it's caused by cancer or not. Government guidelines published in 2002 specify that strong opioids like OxyContin can be used after other methods have failed for non-cancer patients who are over 40 years of age and suffer from a handful of painful conditions.



A man rides a bicycle past the entrance gate of a Mundipharma facility in an industrial park on the outskirts of Beijing, China on Sept. 27, 2019. As the Sackler's U.S. empire collapses, Mundipharma, which is also owned by the family, is using the same tactics to sell opioids in China. (AP Photo/Mark Schiefelbein)

But the guidelines are not rigorously followed. AP spoke with three

doctors who said they prescribed OxyContin for a range of chronic pain conditions, though all said the numbers of non-cancer pain patients on OxyContin in China are small.

China's National Health Commission, the National Medical Products Administration, the State Administration for Market Regulation and the National Development and Reform Commission all declined to comment on detailed questions from the AP.

AN UNCERTIAN LEGACY

If the U.S. has entered an endgame in its battle with prescription painkillers, China is somewhere near the beginning. While some people believe China's painful history with opium and strict regulations will protect it against a U.S.-style outbreak, others fear for the future.

"Why am I afraid of a drug epidemic?" Dr. Yu said. "If our doctors can't stand temptation and want to make tens or hundreds of thousands of yuan a month, it is easy to be manipulated by other people."

Sitting in a large, Spartan office at Ruijin's campus in suburban Shanghai, Yu had an air of resignation. His beliefs about how to shepherd people through suffering had fallen out of fashion in China. But Yu seemed at peace with his lost prestige.

In the end, he said, "it relies on the doctor's conscience."

More information: Online: A selection of Mundipharma China documents, U.S. court filings and regulatory guidelines
[www.documentcloud.org/search/p ... arma-china-documents](http://www.documentcloud.org/search/p...arma-china-documents)

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