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The New Panic Over Prescription Painkillers

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"I don't *want* to be doped up all the time," says Mary Maston. "I want to be able to function. I have to be able to function for my kids. But the pain prevents me from doing so."

In 2008, Maston, 37, was diagnosed with Medullary Sponge Kidney, a congenital disorder that causes her to form large, painful kidney stones. She has since had three lithotripsy surgeries, all of which she says were unsuccessful, and has had to be hospitalized to drain the blood from her kidneys. She has also been diagnosed with stage two Chronic Kidney Disease.

For the first few years after her diagnosis, Maston lived in Tennessee. There, she says, "my doctor was pretty good about writing me a prescription for pain medication when I needed one." But in March 2011, Maston and her family moved to Florida to be closer to her husband's family, and her condition worsened. Florida doctors, she says, were much less willing to prescribe the level of medication she needed. In September, the daily pain from her condition forced her to quit her job. She says she's been to the emergency room seven times in the last eighth months, all due to overwhelming pain.

"I always wait until the last possible second, until the pain is so unbearable I am in tears and can't walk," Maston says. "I have a background in Human Resources, so I know [ER visits] drive up everyone's insurance costs. My husband literally carries me to the car to get me to the ER. This is no way to live."

Maston's many ailments are exacerbated by a purely man-made condition. Patients with high cholesterol levels are used to dealing only with their doctor, and not with law

enforcement officials, because Lipitor can't get you high. Pain patients, meanwhile, are in the drug war's crosshairs.

HuffPost readers: Do you live with chronic pain and face difficulty getting proper medical treatment? Email radley.balko@huffingtonpost.com and include a phone number if you're willing to be interviewed.

The most recent campaign against opioid painkillers began last year, when media outlets began reporting an apparent climb in overdose deaths in the state of Florida. As with the scare in the early 2000s (see part one of this series), politicians and law enforcement officials scrambled to action, promising new laws and policies to dry up the state's supply of oxycodone. By one estimate, more than twice as many oxycodone pills were prescribed in Florida as the next closest state. Governor Rick Scott signed laws imposing tighter regulations on physicians and pharmacies, testing requirements for patients, limits on overall supply of the drugs, and dedicating more money to law enforcement to fight the alleged epidemic.

Over the last year, the Centers for Disease Control (CDC) has put out several similar alarming reports using the same term, *epidemic*, claiming a three-fold increase in opioid painkiller overdose deaths across the country since 1999. The agency has compared overdose deaths to traffic fatalities (which have been falling steadily for several decades). The CDC believes the significant increase in opioid painkiller prescriptions over the last 10 years is to blame for these deaths, writing in one report, "The unprecedented rise in overdose deaths in the US parallels a 300% increase since 1999 in the sale of these strong painkillers."

But at the same time, studies also consistently show that chronic pain is tragically *under*treated in the U.S. (and around the world). Last June, an Institute of Medicine report called undertreated pain a "public health crisis" that affects 116 million Americans, and costs the economy around a half-trillion dollars per year in medical bills and lost productivity. The same month, three pain-related articles in the *Lancet* focusing on post-operative, cancer related, and non-cancer related pain, respectively, found mass undertreatment in all three areas. The journal ran an an accompanying editorial pointing to another study from Human Rights Watch showing that the problem is global, and more because of bad policy than because of a supply. In one recent study of 40 countries, 27 didn't consume enough opioid drugs to treat even 1 percent of patients with terminal cancer or HIV/AIDS. " Furthermore," the editorial added, "in 33 of 40 countries,

governments had imposed strict restrictions on prescribing morphine, beyond the requirements of UN drug conventions to prevent misuse."

So what's going on? How can we be facing an epidemic of overdose deaths wrought by too many prescriptions for painkillers and, at the same time, be facing a public health crisis of undertreated pain? There are a couple of explanations. The first involves taking a more skeptical look at the numbers the government is touting related to alleged abuse and overdose deaths. The other is to examine how both claims *can* be simultaneously accurate, and why.

The Government Makes Its Case for a Crisis

The CDC (along with the Drug Enforcement Administration (DEA) and National Institute on Drug Abuse (NIDA)) throws out a number of statistics in making the case for a crisis of painkiller abuse. The first and probably most alarming involves the overdose figures. According to the CDC, painkiller-related overdose deaths have swelled from 4,000 per year in 1999 to nearly 15,000 per year in 2008. The CDC also reports, "The misuse and abuse of prescription painkillers was responsible for more than 475,000 emergency department visits in 2009, a number that nearly doubled in just five years." Most government agencies also classify "abuse" of painkillers as any "non-medical" use, which means any use of a painkiller other than that for which it was prescribed.

But both these figures don't actually mean what they're commonly understood to mean. The emergency room data, for example, is taken from the Drug Abuse Warning Network (DAWN), which compiles the data from the information emergency room patients give to their doctors. Marijuana reform activists have long been critical of how the government manipulates these figures. The government counts any drug a patient mentions having taken, regardless of whether taking the drug is the reason why the patient is in the emergency room. It's *possible* that painkillers sent twice as many people to emergency rooms in 2009 as in 2004, but it's also possible that a good percentage of that increase is simply due to the fact that more people are taking painkillers, and that therefore any given person in an emergency room--for whatever reason--is more likely to mention having recently taken a painkiller. So you twist your ankle in a pick-up basketball game. A relative gives you a Percocet they have left over from an old dental surgery to help with the pain. The injury continues to swell, so you visit the emergency room. The government would likely count this as a painkiller-related emergency room incident.

There are similar questions about the overdose figures. In his 2006 Cato Institute paper "Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers," Ron Libby explains how determining overdose deaths is often a guessing game. Back in 2001, Libby notes, the DEA concluded that there were 464 "Oxycontin-related" deaths in 2000 and 2001 based on reports from 750 medical examiners across the country. But Libby points out that "Oxycontin-related" merely means that the drug was present in an

apparent overdose death. If the drug was found in the gastrointestinal tract, it was determined to be a Oxycontin-*verified* death. Mere mentions of the drug by family members, or its presence at the death scene, were also enough to count the death as verified. Libby notes that in 40 percent of the deaths in the DEA study, the deceased had also consumed anti-anxiety drugs like Valium, 30 percent had taken anti-depressants, and 15 percent had consumed cocaine.

Libby continues:

"Indeed,the March 2003 issue of the Journal of Analytical Toxicology found that of the 919 deaths related to oxycodone in 23 states over a three-year period, only 12 showed confirm evidence of the presence of oxycodone alone in the system of the deceased. About 70 percent of the deaths were due to 'multiple drug poisoning" of other oxycodone-containing drugs in combination with Valium-type tranquilizers, alcohol, cocaine, marijuana, and/or other narcotics and anti-depressants."

According to the headline-generating CDC report released last November, there were 36,450 overdose deaths overall in 2008. Of those, 74.5 percent specified one or more drugs that were involved in the death. Of those, 73.8 percent involved "one or more" prescription drugs. And of those, 73.8 percent (oddly enough) involved prescription opoids. That likely means that in a high percentage of overdoses attributed to opioids, other prescription drugs were present. In one studyof 295 overdose deaths in West Virginia, 80 percent had multiple "contributing" drugs in their system.

The drug that has shown the biggest jump in contributing to overdose deaths over the last 10 years is methadone, which is used not just for pain relief, but also as treatment for heroin addicts. Methadone stays in the body longer than commercial opioid painkillers, meaning that without careful attention, it's more likely to lead to an overdose. But it's possible that government policy more than careless doctors has driven any rise in methadone overdoses. Last December, the Seattle *Times* ran an investigative series on the use of methadone in the state. The paper found that state policies for patients who use government-subsidized health care strongly encouraged doctors to prescribe methadone over more expensive brand-name opioids. The result: Methadone made up only 10 percent of opioid prescriptions, but contributed to over half the state's overdose deaths. The drug was prescribed a third as often as OxyContin, but was three times more likely to contribute to an overdose death. If there has been a spike in overdose deaths, it may as much due to states trying to save money than to doctors who are too loose with the prescription pad.

There's also reason to suspect the raw overdose statistics in and of themselves. Dr. Steven Karch, who has written a widely used textbook on drug abuse and pathology, says because tolerance for opioids can vary so much from person to person, there's no

scientific way to definitively say that a death was caused by an opioid overdose. "There are plenty of people walking around with levels of opioids in their bodies that would be declared toxic if they were dead on a slab in a medical examiner's office," Karch says. "Toxicology is the least important part of making a diagnosis."
In other words, many of the deaths classified as overdoses in recent years may in fact have been caused by something else, but were called overdoses simply because the decedent had what appeared to be an abnormal amount of opioids in his system. Karch adds that opium levels can appear more concentrated after death, and can even vary depending on the part of the body from which the sample is taken. It's true that more people than ever are getting prescriptions for opioid painkillers. And as they take them, most people need to titrate up as they build up tolerance. That means a higher percentage of people who die today--of any cause--will have opioids in their systems at the time of death. That doesn't mean they died of an opioid overdose, or even a drug overdose. Many chronic pain patients suffer from a variety of other ailments; it's often those other ailments that cause the pain.

"I don't know where they got their numbers," Karch says of the CDC estimates. "There's no peer review of those figures. You follow the footnotes, and it looks like they're getting the information from medical examiners. But it doesn't say how the medical examiners are concluding that these were overdoses--if, say, they're just relying on toxicology results." Asked if that's usually how overdoses are diagnosed Karch says, "That fits my experience." That the government is using questionable overdose diagnoses in formulating public policy is bad enough, but it's particularly troubling when you consider that some physicians have been charged with manslaughter, even murder, because prosecutors used the same indicators to argue that the painkiller prescriptions caused a patient's overdose death.

The are other reasons to be cautious about the CDC's alarms. For example, look at Figure 2 of this report. Between 1999 and 2006 overdose deaths from cocaine increased at about the same rate as those from prescription opioids. Over that same period, the percentage of youth using cocainedropped dramatically. The percentage of adults who had used cocaine in the last month stayed about the same. And the number who admitted to using the drug in the last year increased slightly (from 1.7 percent to 2.1 percent, but enough to explain a doubling in overdose deaths), but the number reporting cocaine addiction was down. This suggests that the increases could be due more to changes in methodology, or more awareness and willingness to look and screen for overdose deaths. It could also mean that people who use illicit drugs like cocaine are more likely to use painkillers recreationally because they're more available. But the fact that cocaine-related overdoses have increased at the same rate as opioid-related cuts

against the theory that there's been a surge in legitimate pain patients overdosing and dying on painkillers.

Despite the scare stories about teenagers increasingly experimenting with prescription drugs to get high, according to the 2010 National Survey on Drug Use and Health,"non-medical use" of prescription painkillers in the last year among people aged 12 to 25 has actually dropped since 2002. The same report says overall painkiller "abuse or dependence" is up over the same period, but as explained in part one of this series, "abuse" doesn't necessarily mean using the drug to get high, and "dependence" isn't the same thing as addiction. But the government doesn't make that distinction.

Abuse and Under-Treatment

For all the flaws in the data behind the most recent prescription painkiller scare, there's no question that that many, many more people are taking them than ever before. It's also likely that plenty of opioid painkillers are making their way to addicts and drug dealers. There are likely more overdose deaths now than in years past, even if there may not be as many as the government claims. Even the most strident advocates for pain patients concede that there are an increasing number of unscrupulous doctors and "pill mills" writing scripts for patients they haven't adequately examined. So how can there be such an abundant supply of painkillers, yet still such a shortage of pain treatment?

The answer lies in some of the government's own data. From a recent CDC "Policy Impact Brief:"

Most prescription painkillers are prescribed by primary care and internal medicine doctors and dentists, not specialists. Roughly 20% of prescribers prescribe 80% of all prescription painkillers.

But the reason so few painkillers are prescribed by pain specialists is likely that after a decade of policies targeting doctors with costly investigations and criminal charges, there simply aren't many conscientious pain specialists left. In his paper for Cato, Ron Libby includes multiple warnings from palliative care specialists that this was exactly what was happening. In 2003, for example, David Brushwood, who is both an attorney and a professor at the University of Florida College of Pharmacy, told the *Decatur News* that physicians once had a cordial relationship with drug cops--that if a doctor suspected a patient was diverting, he would cooperate with the police to turn in the patient. But for the DEA, doctors became high-profile targets, and thanks to asset forfeiture, lucrative targets as well. Since the DEA campaign, Brushwood said, the cops "watch as a small problem becomes a much larger problem . . . [then] they bring the SWAT team in with bulletproof vests and M16s . . . with charges [of] murder and manslaughter."

After a series of high-profile prosecutions of doctors, one pain specialist told the *Wall Street Journal* in 2004, "I will never treat pain patients again." Another told *Time*, "I tend to underprescribe instead of using stronger drugs that could really help my patients. I can't afford to lose my ability to support my family. The *Village Voice* reported in 2003 that medical schools had begun advising students, "not to choose pain management as a career because the field is too fraught with legal dangers."

Federal prosecutors compared pain specialist William Hurwitz to the Taliban. Other prosecutors and DEA officials have over the years compared doctors to drug kingpins, and likened doctors' offices to crack houses. Some doctors were subjected to SWAT raids on their offices, and had all of their assets seized before trial, making it difficult for them to put on an adequate defense. Prosecutors have called press conferences in which they held up big bags of pills the doctor allegedly prescribed, eliminating all context, and effectively convicting those doctors in the press.

At the same time these high-profile investigations and prosecutions have been going on, the federal government has provided no safe zone for what is and isn't an acceptable way to treat pain with opioids. In fact, they've deliberately blurred the line between acceptable pain management and felonious criminal behavior. In August 2004, for example, the DEA posted a set of pain management guidelines on its website. The guidelines were the product of a three-year collaboration between the agency, several health care organizations, and specialists in the pain management community. They were intended to put at ease doctors and patients who worried that the agency's heavy-handedness was casting a chill over pain treatment. Three months later, the DEA removed the guidelines from its website. The DEA offered no explanation, but the likely reason is that William Hurwitz, the pain specialist the federal government was prosecuting in a high-profile trial at the time (see part one), was seeking to using the guidelines in his defense. The guidelines were replaced with an interim statement that emphasized enforcement.

The message was clear. There would be no safe harbor in which pain specialists could operate with worrying about an investigation. There would be no guidelines, and no set policy. What was and wasn't criminal would be decided on an ad hoc basis, worse yet, what was criminal versus what was acceptable medical practice would be determined not by other medical professionals, but by drug cops and federal prosecutors.

The DEA's move was so disconcerting that the National Associations of Attorneys General sent the agency a letter signed by 30 state attorneys general expressing alarm at the revocation of the guidelines, warning that the new policy would "have a chilling effect on physicians engaged in the legitimate practice of medicine."

But there was and still is a big demand for these drugs. And there's a big supply of them. That has opened a niche for less reputable, less conscientious doctors to open the pill mills and strip mall pain clinics that have sprung up, outfits that dispense hundreds of prescriptions per day. Even the legitimate, careful pain specialists who choose to risk their careers in order to continue to treat pain patients are likely to be overwhelmed with people needing treatment, again making them prime targets for investigation. The successful management of chronic pain requires careful treatment by attentive doctors. The DEA and federal prosecutors gone a long way to prevent that from happening. Instead, patients get rushed care from inattentive doctors, which is not only less effective, not only more likely to cause drugs to end up in the hands of dealers, it's also dangerous for patients.

Florida's New Law

Lawmakers and law enforcement officials have responded to a crisis created by bad policy with more potent versions of the same bad policy. Even if these new restrictions on how doctors can prescribe pain medication do reduce the amount of the drugs that make it to the streets, addicts and dealers will merely turn to other prescription drugs, or to street drugs. Pain patients don't have that option. (Pain patients could turn to street heroin, but that isn't exactly a desirable outcome.)

Since the new Florida legislation took effect, the pain patient Mary Maston says, "My doctors here very rarely prescribe any type of pain medicine for me, and on the few occasions they do it is for 15 pills. The last time I went to the ER, which was in January, the doctor wrote one for 20 pills, and said that is the maximum the state will allow. When they are gone, they are gone, and I am left to suffer until the pain gets so bad I am forced back to the ER."

Pain patients in Florida and across the country are often asked to regular drug tests, which they or their insurance are required to pay for, even if they have no history of drug abuse. The few good pain doctors left often err on the side of caution, understandably fearing a possible career ending investigation. Some require patients to sign a contract promising not to see any other doctors for treatment, even if that doctor concludes that they aren't really in pain. Patients must see their specialist each month to get their prescriptions refilled (assuming they can find one to treat them), and must pay for an office visit each time. There's only a short window to act between the time one prescription runs out and they're legally allowed to obtain a new one. Patients say they're made to feel like addicts. "I'm afraid they have labeled me as a 'drug seeker,'" Maston says.

According to Dr. Albert Ray, president of the Florida Academy of Pain Medicine, the recently enacted Florida law is already having unintended secondary effects, as the major players in pain care show extra caution in deference to the current political climate, which can again leave patients in the lurch. "Baptist Hospital in Miami, one of the best hospitals in town, has a spine care program, with excellent pain doctors directing it," Ray says. "They have decided, however, that they do not want chronic pain patients who need to be maintained on medications." (Ray emphasized that his opinions for this article are his own, and not necessarily those of any organization with which he is affiliated.)

Ray says medication distributors are also limiting the supplies of painkillers they send to pharmacies, and pharmacies have responded to the latest panic with their own new policies. "Some pharmacies, CVS in particular, are now deciding how much medication a patient is allowed to have, not the doctor," Ray says. "These pharmacies won't announce the criteria that they use, but they are sending doctors letters that they will no longer fill their prescriptions for controlled substances. This creates another hurdle for patients."

But it's hard to blame the pharmacies. Even as Ray and pain patients say they're presenting a new hurdle to pain treatment, last week the DEA shut down four Florida pharmacies that the agency says were filling prescriptions they should have recognized were suspicious or fraudulent. More disturbing, the agency also attempted to revoke the license of the drug wholesaler that supplied those pharmacies, a move that threatens to interrupt the supply of medication to 2,500 pharmacies across the south. Any patient who gets controlled medication from those pharmacies could be affected, not just pain patients. (A federal judge has stopped the suspension until a hearing next week.)
Law enforcement agencies have created a system where doctors, pharmacists, manufacturers, and wholesalers have been forcibly deputized to police one another. Given the severity of the penalty--loss of livelihood, even prison time--the overwhelmingly prevailing incentive is to err on the side of control, to halt distribution and report the slightest of suspicions. Some towns and counties in Florida have gone even further, passing yet more restrictions, many of which Ray says, "would bring legitimate pain care to a grinding halt on a day to day functional level."

Ray says pill mills and unscrupulous doctors are definitely a problem, but the reaction to them is not only excessive, it overshoots its intended target. "All legitimate doctors want to stop drug diversion and abuse and to close down the pill mills that are violating good medical practice principles for the sake of their greed," Ray says. "But these restrictions are costing the majority of legitimate patients and doctors much frustration, fear, time, energy, and discomfort."

But in that sense Florida's new law is really no different the laws that have come before it that have been aimed at controlling drugs with a legitimate medical purpose.
The *controlling abuse* side of the ledger takes priority, even when it means restricting access to the drug for the patients who need it.
"We need to view this through the lens that the patient comes first--what they need, and what the best ways are to get it to them," Ray says. "How to get the system to respond in that way remains a frustrating problem."

Mary Maston just wishes the war would be fought elsewhere. "Just because there are people out there that abuse prescription drugs," she says, "that doesn't mean everyone should be punished for it."

(This is the second part of a three-part series.)