Statement for the Record

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"America's Addiction to Opioids: Heroin and Prescription Drug Abuse"
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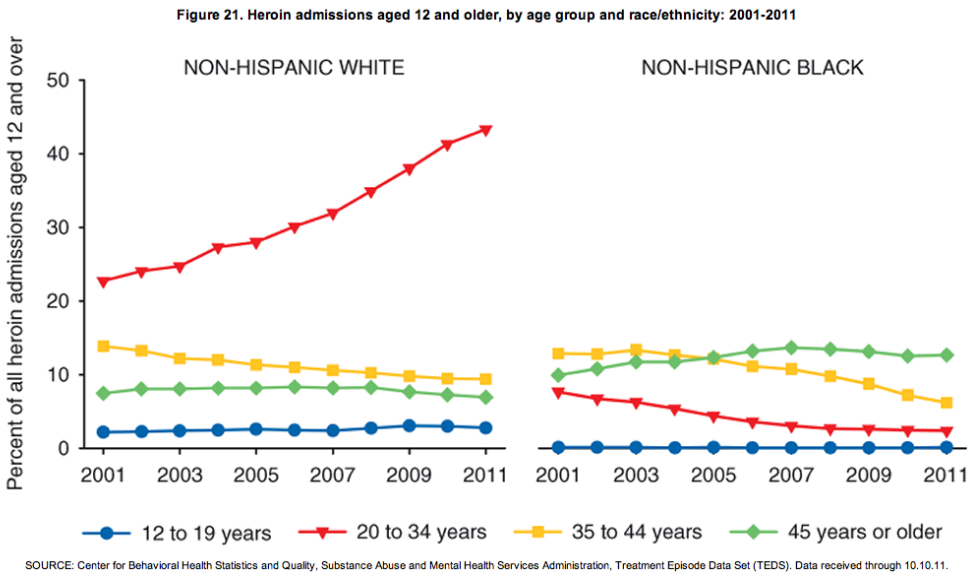
Chairman Feinstein, Co-Chairman Grassley, Senator Schumer and other distinguished members of the Caucus, thank you for the opportunity to discuss our nation's opioid addiction epidemic.

Understanding the rise in heroin use

The increasing use of heroin in suburban and rural counties across the country is easily explained. If you visit a Phoenix House program and speak with new heroin users they will tell you that they began using heroin after becoming addicted to opioid pain relievers (OPRs). They will also tell you that they switched to heroin because it was less expensive or easier to access. This phenomenon is not new. People have been switching from OPRs to heroin since the beginning of the opioid addiction epidemic. In fact, heroin use has been rising among whites between the ages of 20 and 34 since 2001:

Heroin admissions, by age group & race/ethnicity: 2001-2011



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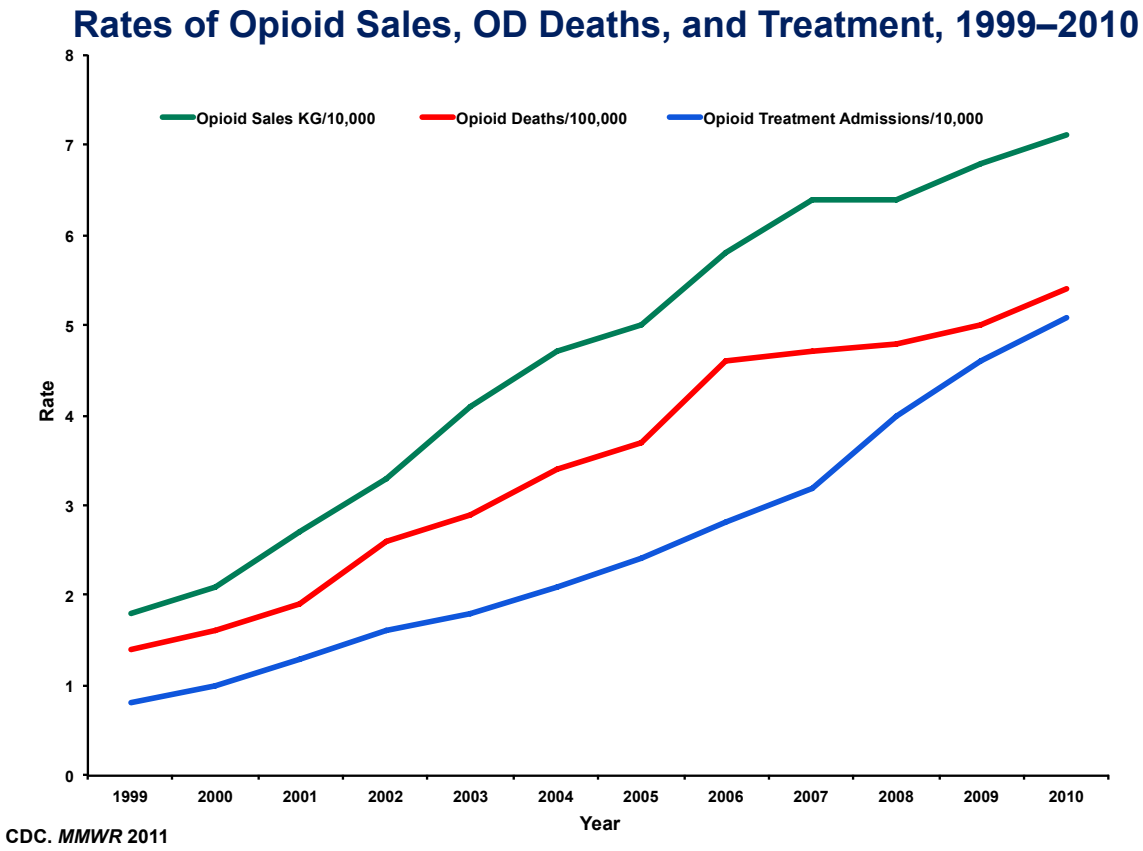
Like heroin, most OPRs are made from opium. Their molecular structure is nearly identical to that of heroin and the effects they produce in the brain are indistinguishable from heroin. What this means is that when we talk about OPRs, we are essentially talking about "heroin pills."

This does not mean we should never use them. It means we should use them cautiously. Opioids are important medicines for end-of-life care. They are also very helpful when prescribed on a short-term basis to treat severe acute pain. But when these highly addictive medications are taken around-the-clock, for weeks and months and years to treat common conditions, they may actually harm more patients than they help.

Opioid overprescribing caused this epidemic

The U.S. Centers for Disease Control (CDC) has been perfectly clear about the cause of this crisis. According to the CDC, the epidemic began in the late 1990s, when the medical community started to more aggressively prescribe OPRs. This is a CDC graph:



The rising green line represents OPR consumption in the United States. The rising red line represents OPR overdose deaths and the rising blue line represents OPR addiction treatment admissions. The CDC is demonstrating that our skyrocketing use of opioids has led to parallel increases in overdose deaths and addiction.

Please keep in mind that the red line represents more than 125,000 lives lost from OPR overdoses over the past decade. This is a public health crisis of catastrophic proportion. Millions of Americans have become addicted to opioids and thousands are dying each year from overdoses. Opioid-addicted individuals will struggle, and their families will struggle, with this devastating disease for the rest of their lives.

Every state in the country has counties that have been affected. The towns hit hardest have lost an entire generation. These are towns where grandparents raise grandchildren because young parents have died from an overdose or they are in jail or they are unfit to raise children because their addiction remains untreated. **According to the CDC, we are in the midst of the worst drug addiction epidemic in United States history.**

Doctors didn't start overprescribing opioids out of malicious intent. For most of us it was a desire to treat pain more compassionately that led to overprescribing. We were responding to an educational campaign (funded by opioid manufacturers) that minimized risks, especially the risk of addiction, and exaggerated benefits of using opioids long-term for common problems. We were led to believe that the appropriate way to treat any complaint of pain was with an opioid prescription. We were badly misinformed.

Concerns about the U.S. Food and Drug Administration's opioid policies

While the CDC is urging the medical community to reduce our prescribing of opioids, especially for patients with chronic non-cancer pain, the FDA continues to approve new, easily crushed, high dose opioids. Moreover, the FDA allows these drugs to be promoted for common problems like low back pain, where long-term use of opioids may be neither safe nor effective.

I strongly believe that this public health catastrophe could have been avoided if the FDA had properly enforced the Federal Food, Drug and Cosmetic Act (FD&C Act) in 1996, when Purdue Pharma released OxyContin. The FD&C Act prohibits drug companies from promoting products for conditions where evidence of safety and efficacy is lacking. Instead of enforcing the FD&C Act, FDA allowed Purdue Pharma to promote OxyContin to family doctors for treatment of common aches and pains and to launch a campaign of misinformation about opioid risks and benefits.

By the early 2000s it was clear that OxyContin was causing addiction and overdoses in both medical and non-medical users. At that point the FDA could have started enforcing the FD&C Act by narrowing the indication on opioid labels to conditions where benefits of use are likely to outweigh risks. A narrower indication would have prevented marketing of long-term use for common problems. More narrow indications would not have interfered with clinical decisions because doctors are permitted to prescribe off-label. Instead, the FDA's analgesic division did the opposite. In private meetings, paid for by pharmaceutical companies, clinical trial rules were changed to make it easier for drug companies to get high-dose opioids approved. This has had the effect of pouring fuel on a fire.

In 2004, the Drug Enforcement Administration (DEA) asked FDA to help them correct a mistake in the Controlled Substances Act (CSA) that had misclassified hydrocodone-containing drugs like Vicodin in schedule III instead of schedule II. Schedule II

is the category for medications that are highly addictive. Had the FDA responded in a timely and appropriate manner to the DEA's urgent request, thousands of overdose deaths and tens of thousands of cases of opioid addiction might have been prevented. Instead, the FDA blocked the DEA's effort until 2013, when it was forced by legislation to convene a scientific review by outside experts. These experts voted overwhelmingly in favor of moving hydrocodone combination products into schedule II.

In 2009, when President Obama nominated Margaret Hamburg to be the commissioner of the FDA, public health advocates were cautiously optimistic. We were hoping she would change the FDA's course by putting the public's health ahead of the interests of opioid manufacturers. We have been sorely disappointed.

FDA recently announced its decision to approve a new, easily crushed, high-dose opioid over the objection of its own scientific advisors who voted 11-2 to keep the drug off the market. This has led to a firestorm of criticism from health officials, medical experts, attorneys general, governors, consumer advocacy organizations and members of Congress. Even Attorney General Eric Holder reported that he was "a little baffled" by the FDA decision.

In defending the approval, Commissioner Hamburg has echoed the opioid industry's talking points. On April 22, 2014 at the Rx Drug Abuse Summit in Atlanta, Commissioner Hamburg explained that FDA was "balancing" efforts to reduce prescription drug abuse with "the very real medical needs of the estimated 100 million Americans living with severe chronic pain".

For the past decade, as overdose deaths and addiction were increasing, the opioid industry has told policy makers that they must "balance" efforts to reduce harm to "drug abusers" against the needs of millions of "legitimate chronic pain patients" who are helped by OPRs. They would like us to believe that "legitimate pain patients" and so-called "drug abusers" are two completely distinct populations and that any limits on access to an increasing array of opioids will unfairly penalize pain patients. The FDA appears to have accepted this false dichotomy.

Opioid overprescribing is harming pain patients

In reality, harm caused by opioids has not been limited to non-medical users. An increasing body of medical literature suggests that for many chronic pain patients, opioids may be neither safe nor effective. Over time, patients often develop tolerance to the analgesic effects, leading them to require higher and higher doses. As the doses go up, quality of life and ability to function often declines. Opioids can even make pain worse, a phenomenon called hyperalgesia. Opioid addiction in pain patients on long-term opioids is common. Pain patients are dying from overdoses at alarming rates. The CDC recently announced that OPR overdoses had risen 414% in middle-aged women over the past decade.

Clearly, we are paying an enormous public health price for the overprescribing of opioids, yet there is no evidence that increased prescribing is helping us do a better job of treating chronic pain than in Western European countries were opioids are prescribed more cautiously. Because opioids are lousy drugs for chronic pain, to a large extent we may

be undertreating pain by giving patients opioids instead of safer and more effective treatments.

Ending the epidemic

The strategy for bringing the opioid addiction epidemic to an end comes from the public health approach to disease epidemics. Here, the disease is opioid addiction- but the approach is similar to that of any disease epidemic. There are two things that must be accomplished: we must (1) prevent people from developing the disease in the first place and (2) see that people who already have the disease are able to access effective treatment.

If we hope to prevent new cases of opioid addiction, doctors, dentists, nurse practitioners and physician assistants must begin prescribing more cautiously- so that we don't directly addict our patients and so that we don't indirectly cause addiction in non-medical users by stocking medicine chests with a hazard. To promote more cautious prescribing, clinicians must have an accurate appreciation of opioid risks and benefits. If dentists understood how similar OPRs are to heroin they probably wouldn't give teenagers 30 tablets of Vicodin after removing wisdom teeth. If primary care doctors understood that risks may outweigh benefits when opioids are prescribed long-term for low back pain, headaches and fibromyalgia, they might offer safer and more effective options. For this to happen, prescribers must have access to education and training programs that are free of the misinformation that has driven overprescribing.

The epidemic has left millions of Americans with the disease of opioid addiction. These individuals will struggle for the rest of their lives and many will die from the disease. But with treatment, sustained remission and recovery is possible. I have been treating this disease for more than ten years. I have seen many patients go on to lead fully productive lives.

Buprenorphine is a medication that controls opioid cravings and allows opioid addicted individuals to function normally. Unlike methadone, which is also an effective treatment, buprenorphine can be prescribed from medical settings that offer more privacy, dignity, and convenience than a daily visit to a clinic. Patients may also feel more alert on buprenorphine than they do on methadone. Despite buprenorphine's advantages, methadone maintenance continues to be an important treatment option, especially for patients that require a stronger medication and more frequent clinic visits.

Unfortunately, in communities hit hardest by the epidemic, buprenorphine treatment capacity does not come close to meeting demand. This is due in large part to strict caps on the number of patients a physician may treat and because nurse practitioners are not eligible to prescribe.

Buprenorphine and methadone are literally a lifesaver for many patients but they are not the answer for everyone with opioid addiction. Similar to the way in which some people can control their type II diabetes with weight loss instead of insulin, some opioid addicted individuals can learn to manage their disease without medication. People who engage in the 12-step recovery model, long-term residential treatment followed by

aftercare and other evidence-based modalities can have good outcomes with and without medication.

Ending the epidemic will require both prevention and treatment. If we only curtail overprescribing without also expanding access to opioid addiction treatment, the outlook is grim. Overdose deaths will remain at historically high levels. Heroin will continue flooding into our neighborhoods. And our families and communities will continue to suffer the tragic consequences.

Recommendations

There is no single or simple solution to this complex problem. Bringing the epidemic to an end will require action from state and county governments, health insurers, health care providers, community-based organizations and individuals. Urgent and coordinated action is also required from Congress and from our federal agencies.

Chairman Feinstein, Co-Chairman Grassley, Senator Schumer and other distinguished members of the Caucus, I respectfully request that the Senate consider taking the following actions:

(1) Allocate more funding for evidence-based addiction treatment, especially in communities hit hardest by the epidemic.

(2) Amend the Drug Addiction Treatment Act of 2000 by eliminating barriers to buprenorphine treatment- remove patient caps and allow nurse practitioners to become eligible to prescribe.

(3) Provide funding for improvements in state prescription drug monitoring programs (PDMPs) that will allow interstate data sharing. And incentivize states to make prescriber use of PDMPs mandatory.

(4) Ask the Senate Health, Education, Labor, and Pensions (HELP) Committee to investigate FDA's opioid policies and the multiple failures of the Division of Anesthesia, Analgesia, and Addiction Products in the Center for Drug Evaluation and Research.

(5) Pass legislation imposing a moratorium on the approval of new opioid analgesics except for formulations that are clearly safer than existing products.

(6) Pass legislation to remove from the market all easily crushed high dosage unit opioid analgesics.

(7) Improve legal protection for individuals responding to an overdose and for use of naloxone by passing a federal Good Samaritan law.

(8) Impress upon President Obama the need for all Department of Health and Human Services agencies and the Department of Justice agencies to begin working together in a coordinated fashion to address this public health crisis.