

Senator Manchin's Efforts To Reschedule Hydrocodone

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America's Prescription Drug Abuse Epidemic



What is hydrocodone?

Hydrocodone is a narcotic painkiller used to treat moderate to moderately-severe pain. The controlled substance is nearly as addictive as morphine and it is increasingly abused for its opioid effects.

Drugs containing hydrocodone are currently the top-selling controlled substances in the U.S., with over 139 million prescriptions sold in 2010 alone. However, they are also some of the most commonly abused prescription drugs nationwide.

On January 25, 2013, an expert panel voted 19-10 to recommend that the U.S. Food and Drug Administration reclassify hydrocodone combination products from a Schedule III to Schedule II.

- Opioid abuse has jumped 287% in 11 years according to the report by the Center for Disease Control and Prevention.
- Prescription drug abuse has increased among all demographics.
- 9.3% of Americans, or 23.5 million Americans aged 12 and older, have used hydrocodone for non-medical purposes, according to a 2009 National Survey of Drug Use and Health.
- In 2010, a Monitoring the Future survey reported that 2.7%, 7.7% and 8.0% of 8th, 10th and 12th graders, respectively, used Vicodin non-medically.
- The National Survey on Drug Use and Health found the number of lifetime non-medical hydrocodone users has more than doubled. This number currently exceeds 24 million American users.
- Emergency room visits caused by hydrocodone use rose from 38,000 in 2004 to 115,000 in 2010.
- Police confiscations of hydrocodone-containing pills have increased from 13,659 in 2001 to 44,815 in 2010.
- In 2011, 131 million prescriptions for hydrocodone-containing products were filled for 47 million people. That is enough to give every man, woman and child in this country 24 pills.



For Immediate Release:

March 20, 2013

SENATORS MANCHIN AND KIRK JOIN REPRESENTATIVES BUCHANAN AND MARKEY IN BIPARTISAN INTRODUCTION OF “SAFE PRESCRIBING ACT”

Washington, D.C. – U.S. Senators Joe Manchin (D-W.Va.) and Mark Kirk (R-IL), along with Representatives Vern Buchanan (R-FL) and Edward Markey (D-MA) introduced bipartisan, bicameral legislation today to combat prescription drug abuse by tightening restrictions on some of the most powerful, addictive narcotics on the market. The “Safe Prescribing Act of 2013” will reclassify hydrocodone painkillers, such as Vicodin and Lortab, from a Schedule III to a Schedule II controlled substance. The reclassification will accurately reflect the drugs’ high potential for addiction and abuse.

“We have a responsibility to this great nation of ours – especially to our children – to win this war on prescription drug abuse. Drugs containing hydrocodone are some of the most abused substances in West Virginia and across the country,” Senator Manchin said. “This growing nationwide prescription drug abuse epidemic with drugs containing hydrocodone has already destroyed too many communities and devastated too many families. The heart-wrenching stories I hear from so many West Virginians underscore the serious need to immediately reschedule hydrocodone.”

“As responsible leaders, we cannot stand by and let prescription drug abuse become one of the fastest growing epidemics in our country,” Senator Kirk said. “Hydrocodone addictions account for more than 60 percent of all drug addictions, and the number continues to increase each year. This bill will give law enforcement greater tools to monitor distribution and decrease access to those who use these drugs for non-medical purposes. I am proud to join this bipartisan, bicameral group to help curtail the amount of drug-related deaths in this country.”

“Too many of our loved ones are dying every day from prescription drug overdoses and are abusing hydrocodone painkillers for non-medical purposes,” said Buchanan, noting that 131 million prescriptions for hydrocodone were written in 2010 alone. “This epidemic has reached such violent proportions that drug deaths now outnumber traffic fatalities in this country. I have personally met with the victims of this scourge throughout Florida and credit them with inspiring this legislation. I salute Congressman Markey and so many others for joining me in this fight.”

“Prescription drug abuse threatens families in Massachusetts and across the country with no regard for income, education, or political party. Congress needs to step up and take action to help fight the epidemic of prescription drug abuse sweeping the country,” said Congressman Markey.

Emergency room visits linked to hydrocodone abuse rose from 38,000 in 2004 to more than 115,000 in 2010. These drugs are now the most widely prescribed painkillers in the United States. The Drug Enforcement Administration has supported this change since 2004. In addition, an expert advisory panel to the Food and Drug Administration (FDA) recently voted 19-10 in favor of re-classifying hydrocodone painkillers as a Schedule II controlled substance. Senators Manchin and Kirk along with Representatives Buchanan and Markey have since urged FDA Commissioner Margaret Hamburg to adopt the board's recommendation immediately.

Under the new restrictions, a written prescription would be required in order to receive hydrocodone painkillers except in cases of emergency. Pharmacists would require patients to present an original prescription for refills, and traffickers would be subject to harsher fines and penalties.

Original co-sponsors to the “Safe Prescribing Act” in the U.S. Senate include: Senator Joe Manchin (D-W.Va.), Senator Mark Kirk (R-IL), Senator Dianne Feinstein (D-CA), Senator Kirsten Gillibrand (D-NY), Senator John D. Rockefeller (D-W.Va.) and Senator Chuck Schumer (D-NY).

Original co-sponsors to the “Safe Prescribing Act” in the U.S. House include: Chairman Hal Rogers, R-KY; Chairman Darrell Issa R-CA; Chairman Jeff Miller, R-FL; Chairman Bill Shuster, R-PA; Patrick Murphy, D-FL; Kathy Castor, D-FL; John Mica, R-FL; Corrine Brown, D-FL; Richard Nugent, R-FL; Alcee Hastings, D-FL; Mario Diaz-Balart, R-FL; Frederica Wilson, D-FL; Bill Posey, R-FL; Ted Deutch, D-FL; Ander Crenshaw, R-FL; Dennis Ross, R-FL; Steve Southerland, R-FL; Scott Tipton, R-CO; Lynn Westmoreland, R-GA; Bill Keating, D-MA; Joe Kennedy, D-MA; Stephen Lynch, D-MA; Dan Benishek, R-MI; Donna Edwards, D-MD; Steve Pearce, R-NM; Louise Slaughter, D-NY; Brian Higgins, D-NY; Pat Tiberi, R-OH; Steve Stivers, R-OH; Tom Marino, D-PA; Scott DesJarlais, R-TN; Stephen Fincher, R-TN; Diane Black, R-TN; Jim Cooper, D-TN; Dr. Phil Roe, R-TN; John Duncan, R-TN; Nick Rahall, D-WV; Shelly Moore Capito, R-WV.

The “Safe Prescribing Act” received widespread support from health care providers, addiction specialists, law enforcement, advocacy groups and victims across the nation:

Dr. Andrew Kolodny, President of Physicians for Responsible Opioid Prescribing, said, “This legislation will correct an error made over 40 years ago when the Controlled Substances Act (CSA) incorrectly classified hydrocodone combination products. There is clear and convincing medical evidence that hydrocodone has the same abuse liability as the Schedule II opioids.”

Janet Janes, co-founder and President of Mothers Against Prescription Drug Abuse, said, “It's heartbreaking to me how we as a country are still not recognizing the horrific epidemic of prescription drug abuse that is facing us. It is of utmost importance to educate the public to the dangers prescription drug abuse presents to their children and communities. It is equally important that we eliminate abusive access to all dangerous medications.”

Suncoast mothers Ruth Lyerly and Cindy Harney, who both tragically lost their sons to prescription drug abuse, said, “For over a decade, abuse and death from prescription drugs has escalated to what now is being called an ‘epidemic.’ We contacted Congressman Buchanan a year ago and thanks to his and Rep. Markey's ongoing efforts to have the FDA reschedule these highly addictive drugs, families might be spared the sorrow and pain of losing a child or loved one.”

To read the full bill, please [click here](#).

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Safe Prescribing Act of 2013

Sens. Joe Manchin (D-WV) and Mark Kirk (R-IL)

Reps. Vern Buchanan (R-FL) and Edward Markey (D-MA)

Endorsed by: National District Attorneys Association, Physicians for Responsible Opioid Prescribing, Association of Prosecuting Attorneys, Center for Lawful Access and Abuse Deterrence, Fraternal Order of Police, National Association of Drug Diversion Investigators, National Narcotic Officers' Associations' Coalition, National Troopers Coalition, American Society of Addiction Medicine, National Association of Drug & Alcohol Interventionists, Drug Free America Foundation, Inc., Educating Voices, Inc., National Coalition Against Prescription Drug Abuse, Save Our Society from Drugs, Mothers Against Prescription Drug Abuse, NOPE Task Force, Learn2Cope.

Prescription Drug Abuse Has Reached Epidemic Proportions in America

Prescription drug abuse in the United States has become an epidemic that is wreaking havoc on countless families and devastating communities. A recent CDC report shows that fatal drug overdoses have increased for the eleventh consecutive year – driven mainly by opioid abuse which has gone up 287% in the same time period. Annually, overdose fatalities outnumber the total number of traffic fatalities. Fueling this epidemic are products containing the powerful painkiller hydrocodone, such as Vicodin and Lortab. Emergency room visits involving hydrocodone rose from 38,000 in 2004 to more than 115,000 in 2010. These drugs are now the most widely prescribed painkillers in the country, with more than 131 million prescriptions for hydrocodone written in 2010 alone. That is more prescriptions than doctors wrote for the lipid lowering medicine simvastatin and the blood pressure medicine lisinopril, and enough to give 24 pills to every man, woman and child in the country.

Other opioid painkillers, such as OxyContin and Percocet, are made with the active ingredient oxycodone combined with other, less potent painkillers. The Drug Enforcement Administration (DEA) considers these products to have “a high potential for abuse with severe psychological or physical dependence” and thus classifies them as Schedule II controlled substances. Hydrocodone combination products, on the other hand, are currently classified as Schedule III drugs. Substances in this category are considered to have a lower potential for abuse. This perpetuates the misconception that hydrocodone combination products are less potent, less habit-forming, and therefore less dangerous than oxycodone combination products. In truth, they have proven to be just as dangerous when not used properly.

On January 25, 2013, an expert advisory panel voted 19-10 to recommend that the Food and Drug Administration (FDA) re-classify hydrocodone combination products to Schedule II. Many physicians, addiction specialists, law enforcement groups, and most importantly, those who have been directly impacted by this epidemic, have expressed support for this change. Others have expressed concern that re-classification could limit access to painkillers for patients with a legitimate medical need. However, detailed protections exist and must be maintained under Schedule II to ensure patient access.

Drugs are classified in the Controlled Substances Act according to their actual/potential for abuse and the risk they pose to the public health. The evidence demonstrates that hydrocodone-based painkillers are highly addictive and widely abused in the United States and thus deserve a Schedule II reclassification. The time has come to stop the abuse of these painkillers that bring untold misery to the children and families of our communities.

Solution

The Safe Prescribing Act of 2013 helps fight prescription drug abuse by regulating powerful hydrocodone painkillers in a way that appropriately reflects their high potential for addiction and abuse. Specifically, the bill:

- Re-classifies hydrocodone combination products as Schedule II controlled substances.
- Requires GAO to conduct an oversight study on how this change impacts legitimate use of pain medication, particularly for patients in rural areas and nursing homes.

FAQs

Why do hydrocodone combination painkillers need to be re-classified?

- The DEA classifies drugs based on their abuse potential and addictive nature. The high potential for addiction and abuse posed by hydrocodone combinations indicates that they are currently misclassified as Schedule III products. This misclassification sends the wrong message to patients and providers that these painkillers are less dangerous or less powerful than their Schedule II counterparts.

Could re-classifying hydrocodone combinations drugs harm access for patients with legitimate medical needs?

- The Safe Prescribing Act corrects the mistake made decades ago in classifying hydrocodone combination drugs as Schedule III controlled substances. It appropriately regulates these powerful painkillers to reflect their high potential for abuse while accommodating patients with legitimate medical needs.
- Nothing in federal law limits access to Schedule II controlled substances. Virtually all medicines containing controlled substances used for the treatment of acute and chronic pain are in Schedule II, including medicines containing morphine, oxycodone, hydromorphone, oxymorphone, fentanyl, methadone, meperidine and tapentadol.
- DEA has amended its regulations over time to make it easier for patients to obtain controlled substance medicines in Schedule II. For example:
 - A practitioner may provide individual patients with multiple prescriptions for the same Schedule II drug product to be filled sequentially. The combined effect of these multiple prescriptions is to allow the patient to receive, over time, up to a 90-day supply of that controlled substance.
 - Doctors are required to prepare a written prescription for Schedule II controlled substances. The patient is then required to deliver that prescription to the pharmacy. In cases of an emergency, however, a doctor may orally issue an order for a Schedule II controlled substance directly to the pharmacy.
- Additional accommodations have been made for patients in long-term care facilities (LTCF).
 - A practitioner (or his/her duly authorized agent) may fax to a pharmacy a prescription for a Schedule II controlled substance, which removes the burden of physically delivering a hard copy of the original prescription..
 - Pharmacies may install an automated dispensing system (ADS) at a long-term care facility, which physically places Schedule II controlled substances on site once a valid prescription is written.

- Pharmacies may also place “emergency kits” at LTCFs to provide for an immediate supply of controlled substances in emergency situations.

Will re-classifying these drugs alone be enough to combat abuse?

- The battle against prescription drug abuse is complex and multi-faceted. The Safe Prescribing Act is one part of what must be a broad effort including prescribers, patients, federal agencies, law enforcement, and addiction specialists.

February 14, 2013

Dear Commissioner Hamburg:

We are writing to respectfully urge your agency to act without delay to reschedule hydrocodone combination drugs from Schedule III to Schedule II, as recommended by the Food and Drug Administration's (FDA) own advisers. Hydrocodone combination drugs are some of the most commonly abused prescription drugs nationwide, and your own experts agreed it is time we take the necessary steps to address this deadly epidemic.

Last month, your agency held a Drug Safety and Risk Management (DSaRM) Advisory Committee meeting to publicly discuss the appropriateness of rescheduling hydrocodone combination drugs. The Advisory Committee responded with a resounding 19 to 10 vote in favor of rescheduling hydrocodone combination products. The message could not be more clear. Consequently, we respectfully request that the FDA hasten the rescheduling process and that you provide us with a written response detailing the FDA's next steps and your timeline for rescheduling hydrocodone combination drugs.

Since the hydrocodone combination rescheduling petition was originally filed with the Drug Enforcement Administration (DEA) in 1999, annual recorded toxic exposures to hydrocodone have more than doubled, according to the National Poison Data System. Further, the National Survey on Drug Use and Health has found that lifetime non-medical users of hydrocodone have also more than doubled in that time period – and currently exceed 24 million Americans. Hydrocodone combination products are currently the top selling controlled substance in the United States by far, with over 139 million prescriptions sold in 2010 alone.

The American people have waited too long for action from this agency. It has been 14 years since the initial petition requesting that the FDA and DEA evaluate the proper scheduling of hydrocodone combination drugs. In those 14 years, there has been a staggering number of hydrocodone related deaths and a drastic increase in non-medical users of these products. The DSaRM Advisory Committee's strong recommendation to the FDA to reschedule these drugs is extremely persuasive and we urge the FDA to take swift action.

Many DSaRM Advisory Committee members and various stakeholders expressed concerns regarding adequate access to pain medication for legitimate pain patients. We share these concerns, and urge you to maintain the specific protections for legitimate pain patients already in place for all Schedule II drugs, including 90-day supplies that must be filled incrementally and emergency refill options. We truly believe that these regulations protect patient access and foster a healthy and supportive patient-doctor relationship.

Again, we respectfully request that the agency reschedule hydrocodone combination drugs without delay. We truly believe that the evidence before you and the DSaRM Advisory Committee's overwhelming recommendation leads to a common sense decision for rescheduling and we look forward to your favorable decision and receiving your response.

May 9, 2013

Dear Commissioner Hamburg:

Thank you for your March 14, 2013 response letter regarding a citizen's petition to reschedule hydrocodone. While we appreciate your reply, we remain concerned about the already excessive length of time that this rescheduling process has taken. We are also disappointed that you did not provide the requested timeline for reaching a final decision regarding rescheduling hydrocodone combination drugs.

The Centers for Disease Control (CDC) have labeled the prescription drug problem ravaging our nation as an "epidemic." Recent CDC data underscores the role that opioid pain relievers, like hydrocodone combination products, play in unintentional overdose deaths. Its study demonstrated that drug overdose deaths increased for eleven straight years since 1999. Sixty percent of the drug overdose deaths (22,134) involved pharmaceutical drug products. Prescription drug products containing oxycodone, hydrocodone, methadone and others, represented three-quarters of those deaths (16,651).¹ A separate, independent analysis of autopsy reports from various coroners' offices between 2006 to 2011 conducted by the Los Angeles Times shed additional light on the role that hydrocodone plays in overdose deaths. Its analysis of 3,733 prescription drug-related fatalities in Southern California found that hydrocodone was involved in over a quarter of the deaths, more than any other prescription medication.²

This information underscores the scope and magnitude of the hydrocodone abuse epidemic and why we believe that it is imperative that the FDA complete its review and accept the recommendation of its Drug Safety and Risk Management Advisory Committee (DSaRM).

The Controlled Substances Act (CSA) requires that the:

"Evaluation and the recommendations of the Secretary [...] be made in writing and submitted to the Attorney General within a *reasonable time*." 21 U.S.C. §811(b) [emphasis added]

It has been 14 years since the initial petition requesting that the FDA and the Drug Enforcement Administration (DEA) evaluate the proper scheduling of hydrocodone combination drugs. Not only is 14 years more than enough time, but this rescheduling process has exceeded the "reasonable time" requirement of the CSA. Your own advisory board has already approved rescheduling by a 19 to 10 vote. The American people have waited too long for action from this agency. Your previous response failed to address our request for a timeline for finalizing your review and, accordingly, we are writing a second time to respectfully request a timeline of this 14-year petition.

Let us again emphasize that rescheduling hydrocodone combination products from Schedule III to Schedule II is an important step in addressing prescription drug abuse. We respectfully urge you to accept the recommendation made by the DSaRM Advisory Committee without delay, and we look forward to your response.

¹ Jones, C., Paulozzi, L., and Mack, K. "Pharmaceutical overdose deaths, United States, 2010". Journal of the American Medical Association (JAMA), 309(7), 657-659 (2013).

² Glover, S., Girion, L. (2013, March 20). Bill aims to tighten restrictions on painkiller hydrocodone. *Los Angeles Times*.

October 9, 2013, 2013

Dear Commissioner Hamburg:

I write regarding recent reports describing the improper relationship between the Food and Drug Administration (FDA) and the pharmaceutical industry. Specifically, private companies have paid thousands of dollars to participate in FDA advisory panel discussions concerning federal regulations for prescription painkillers. These allegations clearly demonstrate a conflict of interest by allowing pharmaceutical companies to have undue influence over the FDA's decision making process. I plan to call for a full congressional investigation into this issue to determine whether these relationships have impacted the FDA's rescheduling of hydrocodone combination drugs.

According to reports, two medical professors organized a panel in consultation with the FDA on how to test the safety and effectiveness of painkillers. According to e-mails between these two professors, pharmaceutical companies paid as much as \$25,000 each to have a seat at the table with FDA officials. When challenged by the companies on the cost, one of the professors responded that "20k is small change, and they can justify it easily if they want to be at the table." The professor continued to justify the high cost of admission to these closed-door meetings by pointing out that the pharmaceutical companies are "impact[ing] FDA thinking...for very little money."

The FDA is responsible for protecting and promoting public health through the regulation and supervision of various products, including painkillers. This task requires the FDA to evaluate scientific data and put the public first. These recent reports raise serious doubts about the FDA's ability to make objective and scientifically based decisions regarding the proper treatment of prescription painkillers. Even worse, when challenged by another federal agency, the National Institutes of Health, on the stigma of this "pay to play process," the FDA balked and continued with the arrangement.

The painkiller industry is a booming business, with profits growing to \$9 billion in the United States. As the painkiller market grows, so does the "epidemic" of addiction and abuse. Recent data from the Centers for Disease Control (CDC) demonstrates the role that opioid pain relievers play in overdose deaths. The CDC study showed that drug overdose deaths increased for eleven straight years since 1999. Sixty percent of the drug overdose deaths (22,134) involved pharmaceutical drug products, and prescription drug products containing oxycodone, hydrocodone, methadone and others represented three-quarters of those deaths (16,651). This is a problem that the FDA must address.

As we have discussed on many occasions, I have been urging the FDA to reschedule hydrocodone combination drugs from Schedule III to Schedule II. In spite of these conversations, I continue to be frustrated with the amount of time the FDA has taken to properly schedule these drugs. It has been 4 years since the second petition requesting that the FDA and the Drug Enforcement Administration (DEA) evaluate the proper scheduling of hydrocodone combination drugs. Even more concerning, it has been over 8 months since I testified at the Drug Safety and Risk Management Advisory Committee (DSaRM) where the FDA's own advisory panel, consisting of leading scientists and researchers in the field, overwhelmingly voted to recommend rescheduling hydrocodone combination drugs.

These press reports raise troubling questions about the FDA's delay in issuing a recommendation regarding this petition. I truly hope that the FDA is not allowing their relationship with the pharmaceutical industry to influence their duty to protect the American public.

Mr. Douglas Throckmorton, a deputy director of the agency, said that because the panel was not initiated by the FDA, the rules prohibiting “pay to play” did not apply. I find that claim questionable and truly hope that the FDA will rethink their extremely misguided policy on this matter. If the FDA is seriously alleging that its conduct is proper and that payments by the pharmaceutical industry to participate in closed-door advisory panels is not impacting its decisions, then the FDA should have no problem disclosing the following information to my office in a prompt manner:

- The location, date and time of all meetings, discussion panels and conferences attended by FDA personnel where private companies, individuals and/or interest groups were able to attend if payments over \$1,000 were made to the FDA or the organizing entity. Examples of these meetings, discussion panels and conferences were described in the Washington Post article “Pharmaceutical Firms Paid to Attend Meetings of Panel that Advises FDA,” Peter Whoriskey, Oct. 6, 2013;
- The location, date and time of all meetings, discussion panels and conferences organized by Professors Robert Dworkin and/or Dennis Turk that involved the FDA;
- A list of all companies that paid to attend the meetings, discussion panels and conferences described in the first bullet and the amounts that they paid;
- The topics of discussion at these meetings, discussion panels and conferences described in the first bullet;
- All recommendations arising from these meetings, discussion panels and conferences;
- All e-mails written by Professors Robert Dworkin, Dennis Turk, and Mr. Douglas Throckmorton or anyone else at the FDA regarding these meetings, discussion panels and conferences described in the first bullet;
- The total cost of each of these meetings, discussion panels and conferences described in the first bullet broken down by category of disbursements (e.g., food costs, venue costs, etc.);
- Any funds related to these meetings, discussion panels and conferences described in the first bullet that directly went to the FDA or any individuals at the FDA;
- All individuals who attended these meetings, discussion panels and conferences described in the first bullet;
- A list of all former FDA employees who left the FDA for employment at any company that paid funds to attend these meetings, discussion panels and conferences described in the first bullet.

I respectfully request responses to these requests in a prompt and timely manner. I look forward to your answers.