

THE FOLLOWING EXCEPT IS FROM A TRANSCRIPT OF A TWO-DAY FDA MEETING CONVENED TO DISCUSS A SCHEDULE CHANGE FOR HYDROCODONE COMBINATION PRODUCTS. AT THE CONCLUSION OF THE MEETING, THE INVITED PANEL VOTED 19-10 IN FAVOR OF MOVING HYDROCODONE COMBINATION PRODUCTS FROM SCHEDULE III TO THE MORE RESTRICTIVE SCHEDULE II CATEGORY.

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

FDA White Oak Campus

Silver Spring, Maryland

Friday, January 25, 2013

DR. KOLODNY: Hello, my name is Andrew Kolodny. I'm President of PROP, and I'm chair of psychiatry at Maimonides Medical Center. PROP, Physicians for Responsible Opioid Prescribing. Its members include clinicians and researchers in the fields of addiction, pain, public health, emergency medicine, primary care, and other specialties. PROP considered for quite a while the question of whether or not we wanted to support up scheduling of hydrocodone combination products. And after thinking this through carefully, we decided to support this. And, in fact, we believe that this may be the single most

important intervention that can be taken on a federal level to bring the epidemic under control.

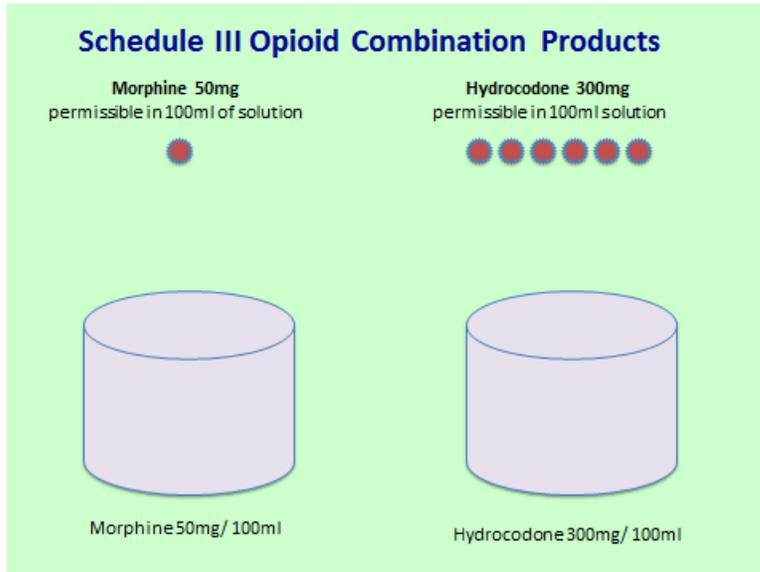
We've heard some very good questions yesterday and today from Dr. Lorenz, asking how will this schedule change help. And if we look at Schedule II drugs, that are already being widely abused, you can say, well, why is moving hydrocodone to Schedule II going to help this problem? And I'm hopeful that my presentation will help answer that question.

I think the reason that we're all here today is that a mistake was made 40 years ago when the Controlled Substances Act was written. The real mistake was a mistake about the potency of hydrocodone. And you can find evidence of that when you look at the ratios of opioid permitted in combination products. So the Controlled Substances Act allows actually a morphine combination product in Schedule III, but would only allow 50 milligrams of morphine in a 100 milliliter cough syrup, whereas it allows 300 milligrams of hydrocodone.

We know from the presentation yesterday by Dr. Walsh and from other research that the potency of hydrocodone and morphine is similar. In fact, the best evidence suggests that hydrocodone is more potent than morphine, yet, the Controlled Substances Act treats hydrocodone as if it's six times weaker.

To illustrate the point, this is the amount of morphine that would be permissible in a morphine Schedule III combination product. And in fact, it's such a small amount of morphine, that we don't have any morphine combination

products because there's not enough morphine in there to have a biological effect. This is the amount of hydrocodone permissible in a combination product.



The reason that this mistake was probably made is that when the Controlled Substances Act was passed, the only hydrocodone combination product on the market was Hycodan, an infrequently prescribed cough syrup.



Vicodin didn't enter the market until several years later. And you can see that when the manufacturer introduced Vicodin -- I don't know how well it shows up on the slide, but you can see that they took full advantage of this mistake in the Controlled Substances Act. They took full advantage of this loophole. If you look, it says in this advertisement, that you can telephone prescriptions in, that you have up to five refills in six months, that you don't need to write the prescription on your triplicate pad.



FREEDOM FROM PAIN!

**Extra strength pain relief
free of extra prescribing
restrictions.**

- Telephone prescribing in most states
- Up to five refills in 6 months
- No triplicate Rx required

Excellent patient acceptance.
In 12 years of clinical experience, nausea, sedation and constipation have rarely been reported.¹

COMPARATIVE PHARMACOLOGY OF TWO ANALGESICS				
	Hydrocodone	Hydrocodone	Hydrocodone	Hydrocodone
HYDROCODONE	0	0	0	0
HYDROCODONE	0.01	0.01	0.01	0.01

There have been reports of abuse and addiction. Some patients have had dependence and withdrawal symptoms. The most common side effect is constipation. Do not use if you are taking MAO inhibitors. See package insert for complete prescribing information. © 1997, Schering-Plough, Inc. All rights reserved. Vicodin is a registered trademark of Schering-Plough, Inc. All other trademarks are the property of their respective owners.

The heritage of VICODIN[®] over a billion doses prescribed.*

- VICODIN ES provides greater central and peripheral action than other hydrocodone acetaminophen combinations.
- Four to six hours of extra strength pain relief from a single dose.
- The 14th most frequently prescribed medication in America!²

vicodin ES
(hydrocodone bitartrate / 8 mg ibuprofen) white to light tan film-coated tablets

Tablet for tablet, the most potent analgesic you can phone in.

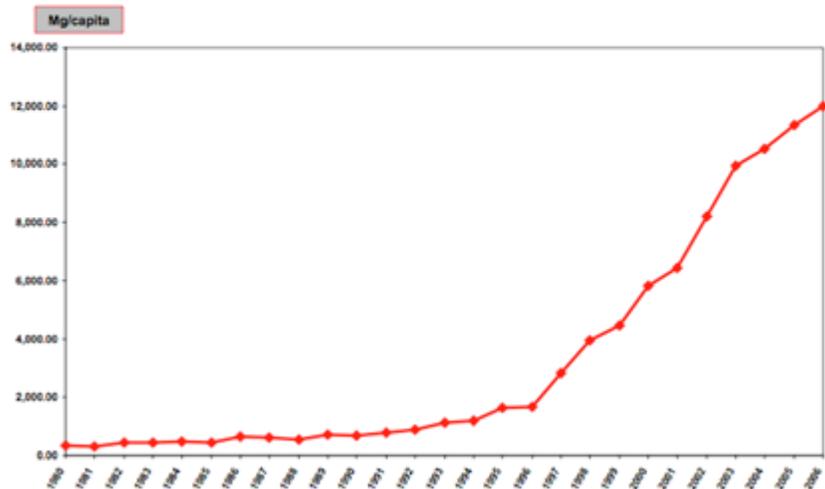
1. Hydrocodone Bitartrate 8 mg/ Ibuprofen 800 mg film-coated tablets and suspension. 2. Source: IMS Health, Inc. © 1997, Schering-Plough, Inc. All rights reserved.

What that meant in states across the country is that the physician can write the Vicodin prescription on their regular pad. In some states, they could write a Vicodin prescription on stationery, whereas all of the other controlled substances in Schedule II had to be written on their narcotic pad. And of course the manufacturer took full advantage to advertise the product as less addictive.

It took a while for this mistake in the Controlled Substances Act to begin to have an impact. And what we've been hearing from the CDC is that the increase in consumption of opioids is fueling an epidemic of overdose deaths and addiction.

Here on this slide, you see the increase in consumption of hydrocodone in New York State. And you can see that there had been a slight increase in the beginning of the 1980s, as the movement to de-stigmatize opioids was just getting going. And then you see it really takes off, and in 1996, when it received an infusion of support from industry to promote misinformation about opioids, that really fueled this increase.

New York Consumption of Hydrocodone 1980 - 2006



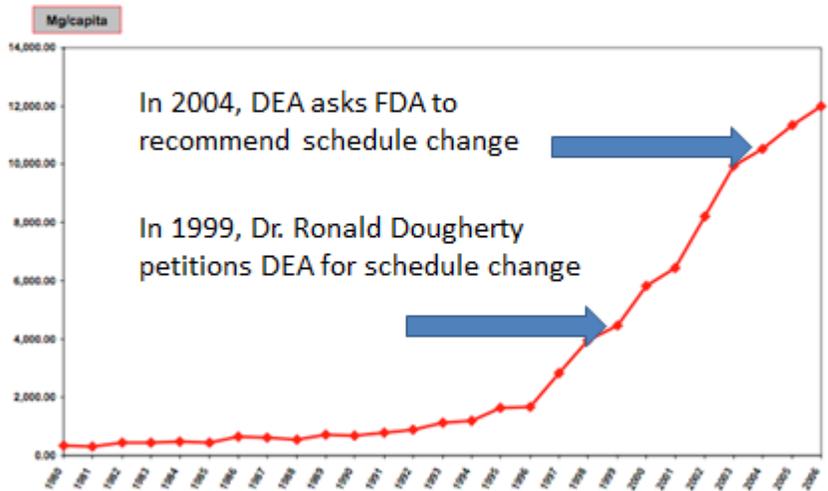
Sources: U.S. Dept. of Justice, Drug Enforcement Administration, Office of Diversion Control

Now it was in 1999 that Dr. Ronald Dougherty, an addiction doctor in upstate New York, began to see many patients, young adults, streaming into his

addiction treatment clinic, who were becoming addictive to opioids through use of Vicodin. And he took a look at the pharmacology, and he took a look at the Controlled Substances Act, and he said, there's a mistake here. He realized the same thing that we heard Dr. Ed Michna mention yesterday, something that pain specialists kind of keep as an inside joke, or as an inside secret, which is the fact that this is a mistake; that they know that the drug is in the wrong schedule.

He realized it was a mistake, so he petitioned the DEA to fix this mistake. Now, government moves slowly. It took the DEA about five years to respond to the petition. And when they did respond, through a very careful analysis, they decided that it did need to be changed, and they asked FDA to work with them because the Controlled Substances Act requires DEA and FDA to work together to make a change like this.

New York Consumption of Hydrocodone 1980 - 2006



Sources: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control

So DEA sent a memo to FDA, and they said, the Controlled Substances Act is wrong, that the potency of hydrocodone combination, or hydrocodone, is similar to morphine. They said we've got overwhelming data from animal studies, from human studies, that the effects are indistinguishable from morphine, that the abuse liability is similar to morphine, that in fact, hydrocodone combination products are among the most widely abused prescription drugs in the U.S., and that they could find absolutely no data that would support keeping it in the lower category.

These are indicators that show us that hydrocodone combination products are the number one most abused opioid in the United States. On these five very commonly used indicators, hydrocodone is number one: non-medical use, ED visits, poison control calls, surveys of key informants, college surveys.

Indicators where HCs are ranked #1

- Non-medical use (SAMHSA)
- ED visits for non-medical use (SAMHSA)
- Poison control calls (RADARS)
- Surveys of key informants (RADARS)
- College surveys (RADARS)

But in 2008, four years later, when the FDA finally responded to the DEA's memo, they said, yes, we know hydrocodone products are the most abused opioid, but, the rate of abuse is lower than Schedule II opioids. And even more surprising, shocking even, they put into their memo that pain patients may develop moderate or low physical dependence when they take Vicodin, but not addiction, which is certainly not true, but also not relevant, because the Controlled Substances Act says that if a drug that's abused can lead to addiction, it belongs in Schedule II, not a drug that's used medically.

2008 FDA Response

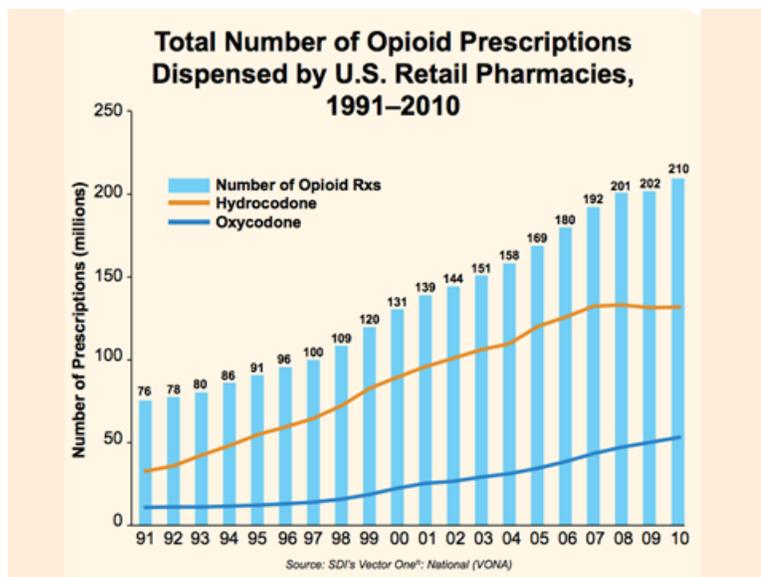
- **Yes, HCs are the most abused opioid analgesic BUT the rate of abuse is lower than Schedule II opioids.**
- **Pain patients “may develop moderate or low *physical dependence*, but not *addiction*”**
- **Concerned about “unintended consequences”**
- **FDA refuses to recommend up-scheduling**

Source: FDA 2008 "Basis for the Recommendation to Maintain Hydrocodone Combination Products in Schedule III"

The FDA put quite a bit into their memo, expressing concerns about unintended consequences of making this change. FDA felt that the arguments made by special interest groups about unintended consequences, and we just heard today from the chain pharmacy trade group. They felt that these arguments were compelling, and maybe some of these elements might be

compelling. But there's nothing in the Controlled Substances Act that says that unintended consequences should be factored. There are eight factors that we're supposed to use to determine where a drug goes. Nowhere does it mention unintended consequences.

FDA felt it had the authority to not necessarily enforce the Controlled Substances Act if they considered these arguments compelling. But the law really doesn't give them that wiggle room. FDA refused to recommend up-scheduling. So in 2008, FDA calculated the rate of abuse using numbers of prescriptions. And sure enough, when you look at the numbers of prescriptions, there are far more prescriptions for hydrocodone than oxycodone, a far bigger denominator, therefore a lower rate of abuse.



But counting prescriptions, which is really like counting pill bottles, and then making a comparison, doesn't work very well, because as we've heard

yesterday and today, an oxycodone prescription is far more likely to be prescribed for someone with chronic pain, is opioid tolerant, who is getting the medication every month. And it's a full pill bottle, for high doses, whereas a hydrocodone prescription is likely to be prescribed for acute pain.

Oxycodone Prescription



Hydrocodone Prescription



So DEA explained this to FDA, and FDA came back with a new analysis, which we heard, where they said, okay, we realize the best comparator is oxycodone combination products, Percocet. And they said we've got a new numerator, a new denominator using DAWN data. We're going to compare just Percocet to Vicodin, and that's how we'll determine rate of abuse. But the problem there, there's a very serious flaw, which is they used DAWN emergency room data, which is terrible for determining specific drug. You can't make that determination.

What I know as an addiction doctor is that when a patient tells me that they're using percs -- a perc isn't a Percocet, a perc is a 30-milligram oxycodone. But a patient who tells that to a doc in an emergency room or a nurse, and then it gets into a chart, a perc is probably a Percocet.

The best denominator was available all along and not used, which is consumption of opioids. This is ARCO's data. And what you see is that because oxycodone is prescribed in very high doses to opioid tolerant people over long periods of time, the consumption of oxycodone in the U.S. is far higher than hydrocodone.

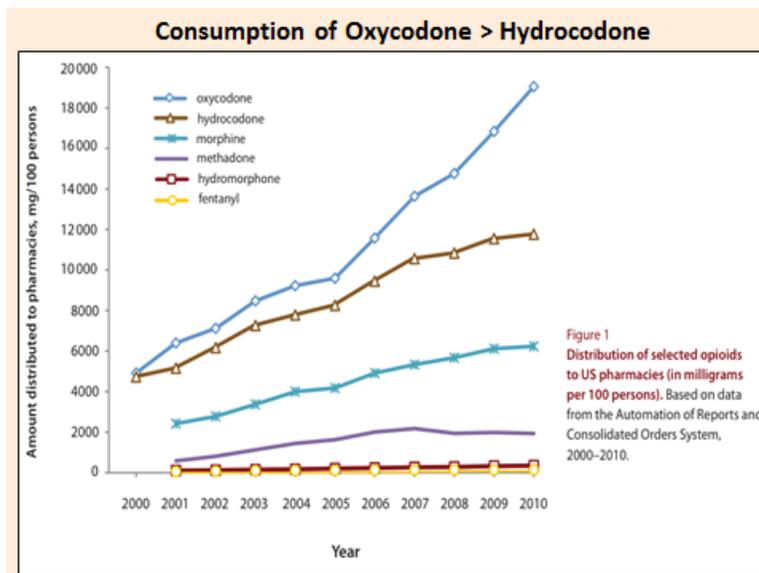


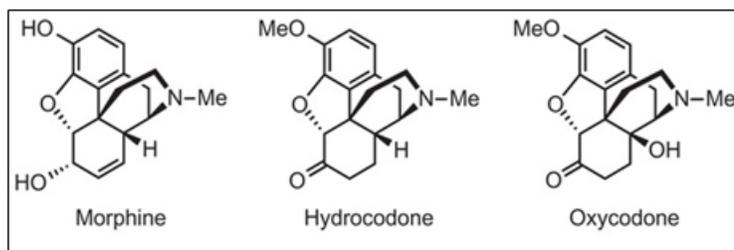
Figure 1
Distribution of selected opioids to US pharmacies (in milligrams per 100 persons). Based on data from the Automation of Reports and Consolidated Orders System, 2000-2010.

What this means is that the denominator is actually greater for oxycodone, that the rate of abuse for hydrocodone combination products is also larger. But all of this talk really about denominators and numerators is pointless, because you don't have to go much further than the molecule, or the research that Sharon

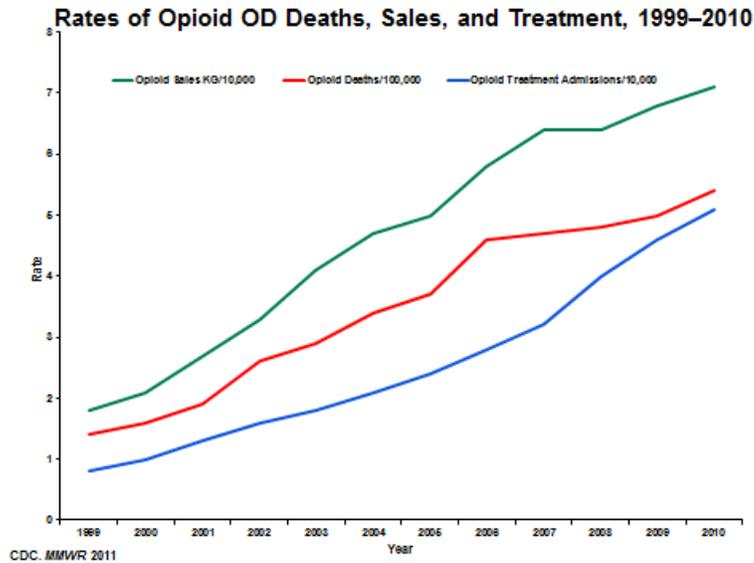
Walsh presented, or even the statement that is in the FDA's 2012 memo, which says that their review showed -- the review of the research -- that hydrocodone and hydrocodone combination products produce the same effects that other opioid agonists produce. And you've got morphine hydrocodone and oxycodone on the slide, but we could put up heroin there, as well, because what we're really talking about are heroin pills.

FDA Memo- October 12, 2012

"This review showed that [mono] hydrocodone [and HCs] produced similar effects to those of the typical mu-opioid agonists such as morphine, oxycodone or hydromorphone in a dose-related manner."



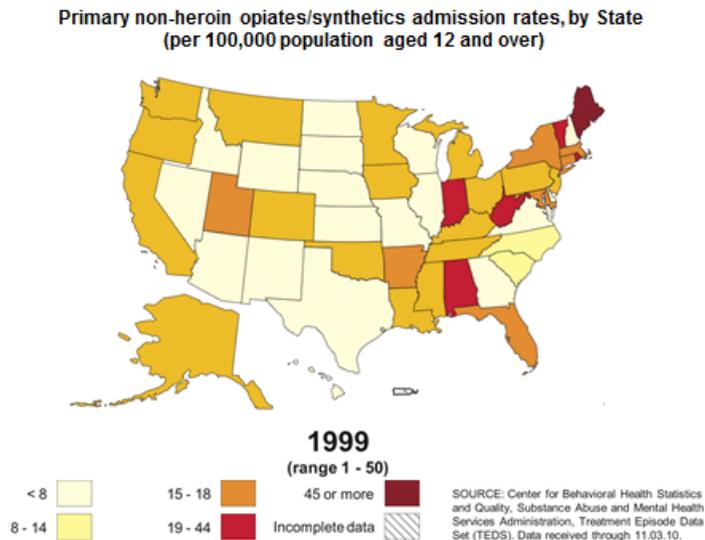
This is a CDC slide. The CDC has been showing this slide to make an important point. Now the top line represents sales for opioid analgesics consumption. That's the green line. The red line represents death, and the blue line represents people seeking treatment for opioid analgesic addiction. And the CDC is showing the slide to make the point that the increased consumption of opioids is fueling this epidemic.



Now, we've heard from many yesterday, from pain specialists, who are concerned that decreased prescribing of opioids will result in greater pain, that we'll be doing a worse job of treating pain if we were to prescribe opioids less frequently. If primary care docs prescribe Vicodin less frequently, there will be more untreated pain.

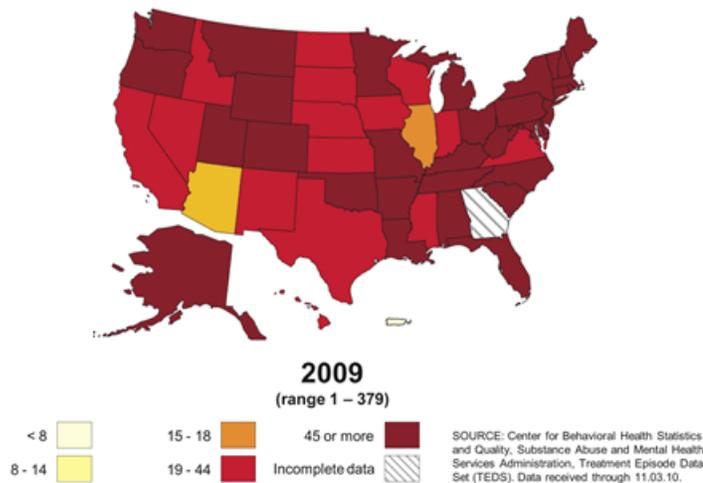
But the fact is that we have absolutely no evidence in the U.S., where we're consuming all of these opioids, that we do a better job than is done in France or Germany or England, that we do a better job at treating pain. But we have overwhelming evidence that as we've described opioids, as this consumption of opioids increased -- and it didn't increase because of new data that they were safe and effective. The increase was due to a brilliant marketing campaign. No evidence that we're now doing a better job of treating pain, or that reducing consumption would make untreated pain a bigger problem.

This is 1999. This was the year that Ronald Dougherty filed his petition with DEA. And you're looking at a map showing rates of addiction treatment for pain killers. The states with the highest rate are in states with red or maroon. I'd like you to see what's been happening with the increase in addiction.



Take a look what happens to the color of this map. This is 2001, 2003, 2005, 2007, 2009. Just about every single state in the country has had a dramatic increase in the prevalence of opioid addiction. And it's important to understand that when we talk about opioid addiction, that we're talking about a devastating illness that's fueling the increase in overdose deaths. But it's an illness that doesn't just affect the person who has it; it's an illness that affects their entire family. If it's a child who has the disease, it's affecting the parents. If it's a parent who has the disease, it's affecting the child. This is a disease that's devastating communities across the country.

Primary non-heroin opiates/synthetics admission rates, by State
(per 100,000 population aged 12 and over)



So how is changing the schedule going to help this epidemic? Why should we do this? Why should we be willing to have longer lines in pharmacies if that's what might happen? Why should we have the burden?

Well, I think to understand that you have to understand what's necessary to bring the epidemic under control. And the two things that are most important to bring the epidemic under control are the same as for any disease epidemic. You have to prevent new people from getting the disease, and you have to see that people who have the disease have access to effective treatment.

How to Control an Epidemic

1. Primary Prevention- prevent new cases of the disease.
2. Treatment- provide people who have the disease with effective treatment.

Now what doctors who treat opioid addiction recognize is that people are developing this disease pretty much in one of two ways. They develop it through non-medical use, and they develop it through medical use. And in both cases, the pills that a patient is using are coming from a doctor who meant well.

People who have the disease of addiction are going to pill mills. The people who are developing this disease are getting the pills, either they're finding them in a medicine chest and they're using them non-medically, and they're in that medicine chest because they were prescribed by a doctor who underestimated the risks, didn't recognize how addictive this is, because our Controlled Substances Act right now says it's less addictive. Or there are patients who are having them medically prescribed by doctors who also are under-estimating the risks, who think because they can write it on their regular pad, not on their narcotic pad, that it's less dangerous.

But even treatment. Very hard to treat somebody with opioid addiction if all they need to do is get a doctor's DEA number, call up a pharmacy, pretend to be the doctor, and get themselves a hydrocodone prescription with five refills on it.

So doctors who are on the front line of this epidemic who are treating opioid addiction are in support of this change. This is a letter that was written to Commissioner Hamburg in 2011 from the American Society of Addiction Medicine, urging her to fix this mistake in the Controlled Substances Act.



American Society of Addiction Medicine

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TREAT ADDICTION • SAVE LIVES

September 6, 2011

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Margaret Hamburg
Commissioner
Food and Drug Administration
U.S. Department of Health & Human Services
5630 Fishers Lane
Rockville, MD 20852

Dear Commissioner Hamburg,

On August 20, 2011, the Associated Press story, "Feds Resist Control for 2nd Most-Abused Pain Drug," noted that abuse of hydrocodone is a national crisis, accounting for tens of thousands of emergency room visits, law enforcement drug seizures, and overdose deaths. On behalf of the members of the American Society of Addiction Medicine (ASAM), I urge you to reclassify hydrocodone as a Schedule II narcotic drug.

Just recently, Robert DuPont, the first Director of NIDA, wrote a letter to FDA, also asking for this change. And in his letter, he said, this is the single most important intervention the federal government can take to bring this epidemic under control.

Doctors who are underestimating the risk, who are not taking this drug seriously, are going to be more likely to over-prescribe it to their patients. Their patients are going to be at greater risk for addiction. We've heard quite a bit. The industry loves to present this issue as this dichotomy between the abusers and the bad actors and then the pain patients who are all helped; and don't do something about these abusers that are going to sacrifice the pain patients. But the fact is, there are many pain patients who are being seriously harmed because their doctors are underestimating the risks. And then, of course, the extra pills are winding up in the medicine chest where our children are finding them.

**Doctors who believe HC's are less addictive,
are more likely to overprescribe.**

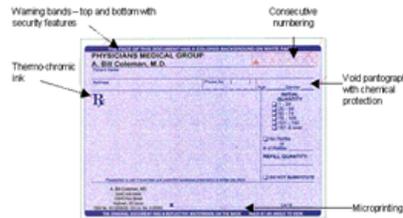


Young people are curious about experimenting with drugs. I suspect if everybody were to raise their hands here and be honest, if I asked, has anyone ever here experimented with a drug, I'm sure most hands would probably go up. But when I was younger, when I was that age, the drug that people were using, it was marijuana. And I think all of us should be pretty lucky that we were born at a time when our environment wasn't flooded with pain pills, because if we weren't, some of us might not be here today. We have a responsibility to protect this generation, and we're failing. We're losing a generation.



As I mentioned, in many states, you don't need to use a narcotic pad. And it also makes it very easy to forge these prescriptions.

**Security paper
Rx limited to
Schedule II drugs in
some states.**



**Some states have
allowed an Rx for
Schedule IIIs on
plain paper.**



We've heard about burden for pharmacists. And some of the concerns about unintended consequences are legitimate, some of them are frankly insulting, but your concern about unintended consequences should not be influencing your decision. You have the Controlled Substances Act, which makes it very clear how we're supposed to be classifying our drugs. It says that abuse, not medical use -- if abuse of the drug can lead to addiction, that drug belongs in Schedule II.

Concerns Raised About “Unintended Consequences”

- Burden for pharmacists, patients and doctors
- Decreased access to pain treatment
- Substitution effects

So pain patients who tell you they're using it medically and they don't get addicted, that's not the point. The point is if someone who abuses the drug can become addicted, it belongs in Schedule II.

Controlled Substance Act

Schedule II

1. High potential for abuse
2. Abuse may lead to severe psychological or physical dependence



Schedule III

1. Abuse potential lower than drugs in Schedule II
2. Abuse may lead to moderate or low physical dependence or high psychological dependence.



If you decide at the end of the day that you consider these unintended consequences compelling, and therefore you want to not fix this mistake that we've all gotten used to over 40 years, what you're telling the medical community is that you think this drug is less risky, because there's no way to communicate it. And I'd like you to think about the consequences of allowing our medical community to believe that hydrocodone combination products are less addictive. They're going to harm many patients and it's going to be very hard to bring -- (mic timed out) [the epidemic under control].

DR. J. WOODS: Thank you, Dr. Kolodny.

Questions? Dr. Kaboli?

DR. KABOLI: Just a quick question, just to make sure I understand this. From what we learned yesterday, and what you've gone through, it seems like hydrocodone -- these drugs fit the requirements or fit the rules for the eight categories for the Controlled Substance Act. Right? Is that your opinion?

DR. KOLODNY: That's my opinion, but I think that's also a fact. And I think it's been quite clear. I think we've heard that yesterday. I think the reason that there is an argument for not making this change is because of concerns about unintended consequences. But if the law were followed, it would be very clear that this drug belongs in Schedule II.

DR. KABOLI: Gotcha. So if we have unintended consequences -- we heard the words burden and inconvenience a lot. If that's the argument, shouldn't we actually be having the discussion of moving the drugs in Schedule II to Schedule III, to actually make it easier for all of these drugs? Because if we're putting an undue burden on people, if we move it to Schedule II, shouldn't we release the burden from Schedule II to Schedule III?

DR. KOLODNY: I think you're making a terrific point. In fact, you could take that even further, and say if you don't believe in scheduling drugs, if you think there's no point, why not make these over the counter? So I appreciate the point you're making.

DR. KABOLI: Okay. Thank you.

DR. J. WOODS: Dr. Lorenz?

DR. LORENZ: Sir, just a point of clarification, so that we're all on the same page. I understand one of the principles -- and I don't take it lightly in either direction -- to be that we have a responsibility to evaluate the public health impact of a scheduling choice. So I just wanted to ask whether pain is an example of a public health impact that's relevant to a scheduling choice.

I'll just give you an example. So from my own perspective, as a palliative care clinician, I consider the question of how scheduling might change the impact of pain management in a nursing home, where there are 3.2 million Americans, and up to 25 percent mortality in a year among frail elders, to be a relevant issue. So I just want to -- as a point of clarification -- make sure that that's something we should be thinking about, if that were to be impacted negatively. That's a public health consideration.

DR. KLEIN: Yes, I think that's a fair conclusion to reach. One of the factors is to look at the public health risk. And that's one of the factors in the scheduling documents.

DR. KOLODNY: I would just say, though, that your pointing out that one of the factors is -- one of the eight factors is public health. What you're really asking is a legal question, because the framers of the Controlled Substances Act intended public health to be the public health impact of the addiction related to use of these products.

We wouldn't be talking about putting these drugs in Schedule II if they didn't have a medical use. We all acknowledge that these are important medicines and we need access. That's why they're Schedule II and not Schedule I.

DR. J. WOODS: Dr. Crawford?

DR. CRAWFORD: Thank you, Dr. Kolodny. I was very impressed with the map that you showed, showing the growth in the rate of opioid abuse across the United States. So as a matter of policy recommendations, are there any lessons that could be learned and applied from the states with relatively lower rates, or is there anything else with policy recommendation that might or might not be in place regarding the states with the relatively highest rates?

DR. KOLODNY: When you look at that map I had for addiction across the United States -- can we pull up the 2009 map? If you look at that map, you'll see the map was pretty much all red. So every state has had a big increase in rates of addiction. But the CDC has done data where they look at differences in overdose deaths in different states, and what they've found is a strong correlation between consumption of opioids -- yes, 2009. What the CDC has found is that the states that have greater consumption of opioids have greater rates of overdose death. And there, the policy suggestion is that we need to reduce over-prescribing, and that the way to bring this epidemic under control is for doctors to prescribe more cautiously. And that's why we really need them

to understand the full risks of these drugs, and the incorrect classification is really fueling the misinformation about these drugs.

DR. J. WOODS: We have a question from Dr. Olbrisch.

DR. OLBRISCH: You mentioned that in other countries using far fewer of these drugs, they're not doing a worse job in managing pain. Can you say something about what they are doing?

DR. KOLODNY: I think that it's -- I don't know that we really have that information. I don't know of any evidence that in countries where they use opioids or prescribe them more cautiously, where physicians have a better understanding of the risks and benefits and prescribe less frequently, we have no evidence that pain is treated worse in those countries. But I don't know that there's any other evidence about what they're doing. I think -- is your question about how they're treating pain other than prescribing opioids?

I think, obviously, they're using non opioid treatments. They're using non-opioid analgesics. They're using physical therapy. They're recognizing that chronic pain can't be cured by putting people on long term opioids, that they don't work well, that we're harming more people than we're helping when we put them on long term opioids.

DR. J. WOODS: Dr. Morrato?

DR. MORRATO: I want to thank you for a very thoughtfully constructed presentation. I appreciate it. I believe you mentioned -- I think you were citing a

director from NIDA -- I can't quite remember, stating that up-scheduling would be the single most important intervention. And I was hoping you might provide a little bit more detail as to if there was some evidence that they were citing. And particularly, I'm interested is it making a distinction, because you said federal, between state level policies such as the prescription drug monitoring programs or was it related to over-prescribing which you just mentioned? I'm just trying to understand.

DR. KOLODNY: Right. Thank you very much for that question. So the reason that people in the field of addiction feel that this would have such a dramatic impact is that people who are treating opioid addiction recognize that the overwhelming majority of the time, a person comes in for opioid addiction treatment -- whether or not they're injecting heroin or snorting immediate release oxycodone -- what we hear over and over again is that their addiction began through exposure to hydrocodone; that this was the drug where it all started.

Some stick to hydrocodone. Others, if they transition to snorting, they're going to prefer something that they can snort more easily without Tylenol in it. But we see that this disease begins with exposure to the most easily available opiate. And that shouldn't -- I don't know of hard data on this, but it shouldn't surprise any of us.

We heard from the FDA that -- they presented in their report that high school students overwhelmingly are most likely to be using hydrocodone. And they actually said, well that's just because there's so much more hydrocodone prescribing, and we shouldn't really take that too much into consideration. But that's exactly the point. We have an environment flooded with hydrocodone, and that's why people are getting addicted.

So I think that's the primary reason. Federal, because there's most -- the regulation of medical practice is done on a state level. So, for example, we heard from optometrists that if this schedule change would be made, that they wouldn't be able to treat pain. There are many states in the country that don't allow optometrists to prescribe any controlled substances. New York, California, Florida have all decided that if someone has severe pain, they're better off going to an emergency room than an eyeglass store.

So a lot of this is handled on a state level, and it's for states to decide whether or not they want mid-levels to prescribe Schedule III. You know, if you have concerns, if you think optometrists in Alabama should be able to prescribe Vicodin, the idea that you would leave a drug in the wrong category and allow the entire medical community to think it's less addictive because you want the optometrist to be able to prescribe somewhere, it doesn't work that way. And the discussion of unintended consequences is very important, but it needs to be

held after the decision is made about changing the schedule, so that we have time to address these concerns.

DR. J. WOODS: Thank you. Mr. Yesenko?

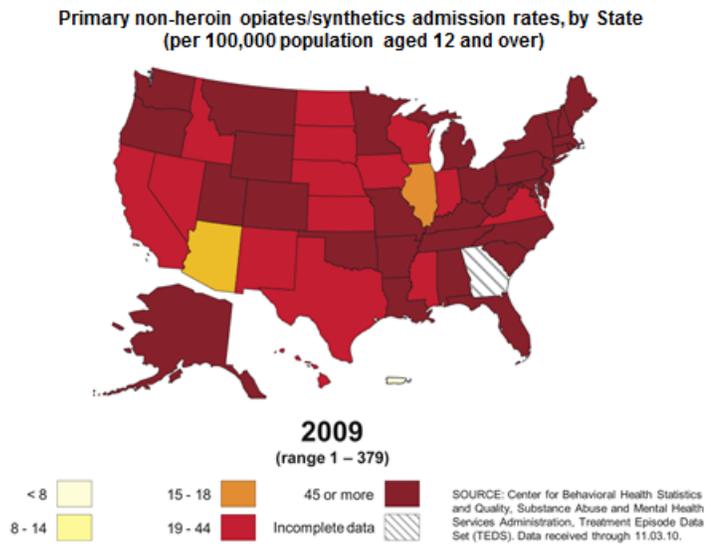
MR. YESENKO: Thanks, Dr. Kolodny, for your presentation. Very succinct. I appreciate the nod to treatment and the fact that this is an epidemic, not just a public health concern.

What is your experience with e-prescribing and prescription monitoring programs of long term opiates?

DR. KOLODNY: I don't have much experience to report on e-prescribing on opioids, but on PDMPs, they're obviously an extremely important intervention. But you have to recognize what we can do with PDMPs. The main intervention that's been talked about is using them to identify doctor shoppers. People who are doctor shopping already have the disease of opioid addiction, so a PDMP effort to identify doctor shoppers does nothing to prevent new people from getting the disease of opioid addiction. If we really want to bring this epidemic under control, we have to stop creating new addicts, and PDMPs don't help us do that. They're great if you use them to link people with the disease of addiction to treatment. Unfortunately, that's not done enough.

DR. BAGIELLA: Going back to the 2009 map, what percent of those rates are Class II and what are Class III?

DR. KOLODNY: That a great question. So that data is collected -- if we can get that map up, again, that 2009 map. That data is collected by state-licensed addiction treatment programs that are required to ask people, when they come in for addiction treatment, what's your primary drug of abuse. And we're looking at people who are coming in for addiction treatment -- the whole range of treatment programs -- saying that their drug of abuse is an opioid analgesic.



Now the TEDS data set has attempted to try and find out which are the specific opioids. But kind of like the DAWN data, it's hard to tell, and it doesn't really mean that much, because people who are opioid addicted, they're going to use the opioid that they can get, once they have that disease. And if Vicodin happens to be the most easily available for them at a particular time, and they go into a treatment facility, they may say it was Vicodin. If they transition to

snorting, it's probably not Vicodin. But if you were to find out -- if we were to have the data, if you could survey the people coming in for treatment and ask them what opioid were they using when their disease of addiction developed, I think you would find overwhelmingly that their disease began through exposure to hydrocodone combination products.

DR. J. WOODS: Thank you, Dr. Kolodny.

Oh, I'm sorry. Ms. Landis? Excuse me.

MS. LANDIS: Thank you for your presentation. You had made a comment that drugs that cause abuse should be in a Schedule II, and the position of moving it to Schedule II basically is going to help that thought process, say, in primary care physicians, that there really is not a lot of risk with giving this to patients.

Are there other things that you would recommend other than moving it to a Schedule II to help the process? I know we've discussed a lot of things here today as far as education, systems in place, the monitoring programs. Is there anything else from your group that you would recommend other than just movement to a Schedule II to solve the situation of abuse?

DR. KOLODNY: Well, I think one of the most important things for bringing the epidemic under control is getting doctors to prescribe more cautiously. And for doctors to prescribe more cautiously, they need to have an accurate appreciation of the risks of the drug. And if we allow our hydrocodone

combination products to remain a Schedule III and let doctors prescribe it the way they've been prescribing, with multiple refills written on a non-narcotic pad, it's very difficult for us to communicate to the doctor that they have to take the drug seriously if they're putting it in the wrong category.

In addition to up-scheduling hydrocodone combination products, I think there's a general lack of appreciation of the risks of opioids altogether, but it's very clear that the medical community takes hydrocodone combination products less seriously. And that's because our federal government is telling them they should take it less seriously.

MS. LANDIS: Also, a follow-up question -- I don't think we've really talked much about it -- is the impact of insurance companies on the quantity the patients have to get. There are several companies that require that they get a 90-day, and a patient has the same co-pay, whether it's a 30-day or a 90-day. So obviously the patient's going to opt for just doing one co-payment versus three co-payments.

We're seeing physicians, now, saying, okay, the insurance requires this, so this is the direction we're going to. And I'm seeing -- if someone takes, say, eight tablets a day, whether it's an oxy or a hydro, that translates to prescription of 720 pills that are going out the door into a patient's home; or if they take six a day, that's 540; or four a day, that's 360. To me, that's an atrocity.

Do you have anything or any comments on this direction? And this has been I would say in the last year and a half to two years, that we're seeing this larger amount of medications going out without oversight.

DR. KOLODNY: I think you're raising an important issue, and I do think that there are insurance reimbursement policies on prescriptions that are important to consider. I think some folks may have been concerned that if this schedule change were made, a doctor might put more pills into the bottle so that it would be easier on the patient. And I think, actually, doctors, really, for the most part, are trying to do the right thing for their patients. And if they understand that the drug is highly addictive, and I think that's what we'd be communicating to them if we make this schedule change, I don't think they're going to just throw tons of meds at the patient because they're concerned about a co-pay. I think most doctors will do the right thing.

MS. LANDIS: And just for what I see every day. Regardless of whether it's Schedule II or Schedule III, it's all about the co-pay to the patient. So I see just as large quantities go out, whether it's Schedule II or Schedule III. And, again, it's because of the insurance companies saying either you have to have 90 days or we're not going to pay, or it's going to be a bigger burden to the patient. So I appreciate your comments.

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