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Hydrocodone: January 25, 2013

(I have no financial conflict of interest)

Is the rest of the world *wrong*, but the U.S. *right* about hydrocodone use?

According to the UN-associated International Narcotics Control Board's 2011 report, *Narcotic Drugs* (also source for data on the next 5 slides):

99 % of the Rx hydrocodone in the world is manufactured *and* used in the U.S.

The U.S. leads the world in the consumption of defined daily doses (DDD) of all Rx narcotics/ million people/day, with 47,800 such doses per day. A not very close second is our neighbor Canada, with 26,400 DDD/day (all DDD are per million people per day, thus population-adjusted).

The role of hydrocodone in total Rx narcotic use around the world

- Of the 47,800 DDD for all narcotics in the US, 26,500, 55% are for hydrocodone
- In Canada, only 258 DDD for hydrocodone out of 26,400 DDD for all narcotics, less than 1%
- In # 3 narcotics-consuming Germany, 34 hydro DDD out of 21,500 for all narcotics, < 0.2%
- Of the top 100 narcotic-consuming countries, only 1 (Canada) has more than 1% of the US DDD for hydrocodone. **Only 16 of the top 100 countries list any hydrocodone use. (None in 84)**

Some Equally Civilized Countries:
No Hydrocodone Use or < 1% of U.S. use
(use=DDD/ million population)

Germany

Switzerland

Denmark

Belgium

Austria

Australia

Spain

Italy

Norway

Netherlands

France

Sweden

Israel

Portugal

Finland

United Kingdom

Portugal

Luxembourg

Is the *unintended consequence* of moving hydrocodone compounds to schedule II, a large switch to oxy, based on evidence ?

- In the face of hydrocodone products either not being used at all or only very minimally in almost all other countries, it might be expected that oxycodone use would be flourishing there. Is it ?
- As with total DDD/ million for all narcotics and for hydrocodone, the U.S is also the world leader in oxycodone use, with 6600 DDD/ million people or 14 % of total U.S. DDD for narcotics

Aside from Canada, with barely more than 1/2 of the DDD for total narcotic use as the U.S. and less DDD oxycodone use (5640 vs U.S. 6600), no other country has a larger proportion of total narcotic use attributable to oxycodone than U.S.

All other countries, most with little or no hydrocodone use, still have much lower DDD oxycodone use than the U.S. The country with the largest percent of U.S. oxycodone DDD use, other than Canada, is Australia, with 40 % as much. All other countries, except Denmark (36% of U.S. use), have less than 21% of U.S. use.

What would be the *intended consequences* for hydrocodone products in Schedule II ?

- According to the 2011 *Narcotics Control Report*, the total DDD hydrocodone consumption for a year for the entire U.S. population is 2.8 billion doses, almost 8 doses per person.
- Some increase in prescriptions for oxycodone may result, but gauging from how most of the rest of the world uses little, if any, hydrocodone but also uses much less oxycodone than the U.S., the odds are great that the large reduction in hydrocodone use will outweigh any such risk.

“Opioid Epidemic in the United States” *

“the increased supply of opioids....contribute to the majority of fatalities...quadrupled sales of opioid analgesics between 1999 and 2010 are a perfect example of the therapeutic opioid explosion... increase from 96 mg morphine equivalents per person in the United States in 1997 to 710 mg per person in 2010....estimated to be the equivalent of 7.1 kg of opioid medication per 10,000 persons or enough to supply every adult American with 5 mg of hydrocodone every 6 hours for 45 days.”

More on the Opioid Epidemic*

“U.S. demand for hydrocodone, the most commonly prescribed opioid, is about 27.4 million grams annually compared to 3,237 grams for Britain, France, Germany, and Italy combined...

“Our greatest enemy is now inappropriate prescribing patterns, based on a lack of knowledge, perceived safety, and undertreatment of pain.”

* From Pain Physician: Opioid Special Issue July 2012; 15:ES9-ES38

Opioid Deaths in Cuyahoga County

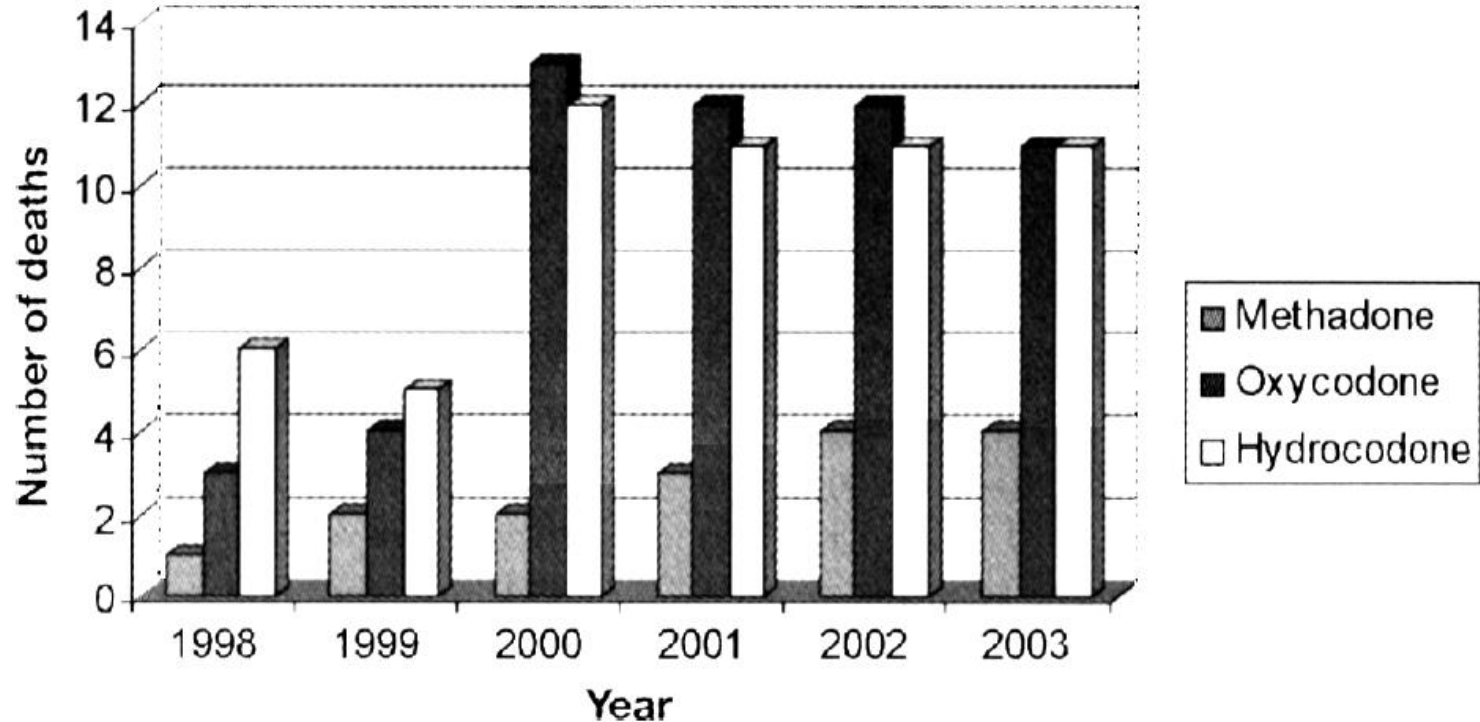


Figure 2. Total opioid lethal intoxications per year.

Oklahoma Data from 1994-2006

“Among all unintentional overdose deaths, the five individual substances most frequently contributing to deaths were methadone (31% of fatalities); hydrocodone (19%); alprazolam (15%); oxycodone (15%); and morphine (12%).

“Overall, oxycodone and hydrocodone were associated with 12.2 and 10.8 deaths/ equianalgesic dose sold, respectively, and both increased approximately threefold during the investigation period.”

Lack of Evidence for long-term (> 6 months) use of opioids to treat non-cancer pain

“It is concluded that, for long-term opioid therapy of 6 months or longer in managing chronic non-cancer pain, with improvement in function and reduction in pain...there is limited or lack of evidence for all other controlled substances, including the most commonly used drugs, oxycodone and hydrocodone.”

Is it too much of a burden to see patients with cancer pain or severe non-cancer pain at least once every 3 months ?

- If the answer is yes, it is likely that the patient is not receiving adequate medical care.
- If the answer is no, the multiple prescription provisions for Schedule II will greatly facilitate this process, allowing a visit once every three months, without any of the predictably more uncontrolled refills and other dangerously lax DEA regulations now in place for Schedule III drugs such as hydrocodone.

Code of Federal Regulations: Controlled Substance Act Schedule II

§ 1306.12 issuance of multiple prescriptions.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

“issued [by practitioner] for a legitimate medical purpose; practitioner provides written instructions on each prescription....indicating the earliest date on which a pharmacy may fill each prescription; practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.”

Why Benefits Outweigh Risks for Hydrocodone Being Rescheduled into Class II

- Decreased hydrocodone Rx's will greatly outstrip the smaller increase in oxycodone Rx's
- The U.S. will move toward, rather than contrast with, most of the world in less hydrocodone use
- Making it a more thoughtful process to prescribe this powerful narcotic will reduce inappropriate prescribing for moderate non-cancer pain
- We need to act more regularly based on the precautionary principle

