



FORENSIC AND EDUCATIONAL CONSULTANTS  
*Alcohol, Drug Abuse and Pain Management*

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Kimberly Topper  
Food and Drug Administration, CDER,  
Advisors and Consultants Staff, HFD-21  
5600 Fishers Lane,  
Rockville, Maryland 20857

Dear Ms. Topper:

The abuse of chemical substances that causes mood alteration has been, is now and will always be attempted. Varying attempts to curb drug misuse, abuse and addiction has not been too successful but new methodologies and pharmaceuticals are being tested, i.e. the pending FDA approval of sublingual buprenorphine that can be prescribed for treating opioid addiction in Office Based Opioid Therapy (in the doctor's private office).

The percentage of toxicity, overdose and deaths from abuse of opioids, short or extended release formulas, is infinitesimal compared to non-controlled prescription legend drugs (PLD) and over-the-counter (OTC) products such as antibiotics, anticoagulants, non-steroidal anti-inflammatory drugs (NSAIDS), aspirin and acetaminophen. These episodes are not reported in the media because they are not reader seductive- no euphoria, no intoxication, no drunken drivers, no arrests and trials or license revocations with photos of your good old family Doc.

Last year there were over 17,000 deaths from prescription and OTC NSAIDS, 433,000 nicotine related deaths, thousands of deaths from illegally injecting legal and illegal drugs, tens of thousands of deaths from alcohol related auto accidents. Maybe the obvious solution is to prohibit the manufacture and distribution of NSAIDS, hypodermic syringes and needles and motor vehicles, or perhaps the better solution is to spend money on that good old standby- EDUCATION.

**Education** is the key for all people, patients and physicians. I have taught for thirty years in medical, osteopathic and dental schools and still teaching and forensic consulting as a pharmacist, psychopharmacologist, addictionologist and pain specialist.

But most health professional schools do not, in 2001, mandate as a part of the core curricula, organized, focused courses with an examination in applied opioid pharmacology, pain assessment and treatment, substance abuse (opioids, benzodiazepines, alcohol, stimulants, hallucinogens and steroids), the rules, regulations and laws and the medical record keeping inherent in the privileges that permit and govern the administering, dispensing and prescribing of controlled substances. This is an alarming deficiency in our medical education system.

There are a small number of professionals, like others in our society, that prey on the weak or sick for financial gains and even sexual exploitation in exchange for narcotics.

The six D's elucidate aberrant doctors:

- 1. the DATED Doc.** Still prescribing drugs of 30 years ago. No continuing medical ed.
- 2. the Duped Doc.** Believes every patient's pain story without proper examination.
- 3. the Disabled Doc.** Who is abusing drugs, partying and sharing drugs with the patient.
- 4. the Detached Doc.** Who does not belong to professional societies, does not go to seminars,
- 5. the Dishonest Doc.** Who is knowingly and willfully initiating or perpetuating addiction.
- 6. the Deviant Doc.** Who is sexually exploiting patients in exchange for narcotics.

**Docs 3 and 6 need treatment and license sanction until re-evaluated.**

**Doc 5 needs license revocation and criminal sanctions.**

**ALL need EDUCATION !!**

I teach a five and a half day course (44 hours) annually, "The Mini-Residency in the Proper Prescribing of Controlled Substances", to DEA and state registrants whose licenses have been sanctioned for injudicious prescribing of controlled substances. This course is utilized by 43 state professional licensing agencies/boards, the DEA for physicians looking to apply for reinstatement of their DEA permit and the College of Physicians and Surgeons of Ontario and Nova Scotia, Canada. On the first day of this program a pre-course test is administered and the results are disgraceful in that 75% of the attendees' score lower than 65 because of:

- 1.** Lack of pharmacological knowledge and applied pharmacology of controlled substances
- 2.** Lack of knowledge of the rules governing the prescribing these drugs
- 3.** Lack of knowledge of pain assessment and treatment protocol
- 4.** Lack or absent or inappropriate medical records and documentation justifying these drugs

At the termination of the weeklong conference a post-course test is applied. In the past 20 years of this course's history, 569 health professionals have attended and 565 passed the test.

**Most important, those 565 successful attendees have never been charged or sanctioned again, to date. NO RECIDIVISM. This is a 99.3% success rate!!**

Approximately 10-12 years ago I testified before the House Judiciary Committee, the Subcommittee on Crime and Drugs, chaired by William Hughes (NJ). I suggested that states'

licensing boards mandate and document continuing education for license renewal. Some have accomplished that ruling but all 50 states should be in conformity. Since relative **assurance of competency** accompanies the awarding of a diploma and degree, passing a national board exam for licensure to practice in a given state and passing an exam for a specialty practice, **why is there no exam for competency assurance in prescribing controlled substances which requires a special permit after all the other competency exams ?**

Is it not logical to confront this head-on rather having than state boards spend the time and money to investigate a doctor, have meetings with the respondent and his/her attorney, have an administrative trial with an administrative law judge ?

A short text with open book exam, taken at home or office, which has already been in design for years for presenting this proposal to six different interested state medical boards, could be mailed to each professional desiring a DEA permit,. This would be read and answered and mailed back, notarized, to a central agency, private or government. At the very least, each state would then be aware, for the very time, that their licensees have had some updated knowledge about controlled drugs. Since older controlled substances become obsolete or deleted from DEA Scheduled drugs and new ones are marketed and combinations of older and newer drugs become used and/or abused, updated “at home” exams can be implemented every 3 – 5 years.

I would hope that anecdotal news stories about the horrors of opioid analgesics and overdose and deaths that are more likely seen with combinations of controlled drugs and alcohol are factual accounts.

I would urge education of 4 th year medical students and practicing health care physicians.  
LET’S FOCUS ON EDUCATION TO REDUCE OR ELIMINATE PROSECUTION.

Respectfully submitted,



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