OPIOID RISK MANAGEMENT
THE DEA PERSPECTIVE
Presented by:

Patricia M. Good
Chief
Liaison and Policy Section
Office of Diversion Control

Prepared for:
The Opioid Risk Management Conference
Tufts University School of Medicine

March 29, 2005
The Controlled Substances Act of 1970 mandates that:

• Controlled pharmaceutical drugs be available to the public having legitimate medical need

• A “Closed System” (Import, Manufacture, Distribution) be established to minimize the diversion and misuse of these products

• Practitioner authored prescriptions are integral to both stated goals
What is a Legitimate Prescription?

In order for a prescription to meet the requirements of the law it must:

• Be written by a licensed practitioner or physician

• The practitioner must be engaged in a recognized Doctor-Patient relationship

• The pharmaceutical drug must be for use in treating a legitimate medical condition

• As defined in 21 CFR §1306.04(a)
• Practitioners are prohibited from administering or dispensing narcotics to a drug dependent person for detoxification or maintenance without a separate registration as a Narcotic Treatment Program (NTP) [21 CFR §1306.07 (a)] or, in the case of specifically approved schedule III-V drugs, a waiver of registration as a NTP.

• Practitioners are NOT limited in their ability to prescribe, administer, or dispense narcotics to persons with intractable pain. [21 CFR §1306.07 (c)]
If a patient has a history of drug abuse or addiction, is it legal to prescribe long-term opioid therapy for pain?

There is no federal prohibition against such treatment. In general, pain patients fall into three groups –

1. Those whose pain is not complicated by a history of substance abuse (this accounts for the majority of patients)
2. Those who have a history of addiction but are in recovery (these patients require more consideration than the first group)
3. Those who are actively abusing substances (these patients pose the greatest challenge to the clinician)
• Dates back to the Harrison Narcotics Control Act of 1914

• Further defined by case law:
  *White vs. United States (8th Cir. 1968)*
  *Dunford vs. United State (4th Cir. 1954)*

• A License to practice medicine is not a license to “peddle pills”

• A doctor must perform an examination and make a determination that a particular drug will be beneficial to the patient

• Only this constitutes acting “within the course of professional practice”
• Medical viewpoint echoed in historical court decisions

• During the 1950s and 1960s, medical schools taught that narcotic substances should **ONLY** be used in the most dire circumstances

• This philosophy was largely due to the fear of addiction

• Medical community viewpoints have evolved over time
• Decision should involve the same criteria that governs any other drug choice

• Need to balance risk with benefits to fulfill the needs of the patient

• Opioids have the added consideration of patient dependence, addiction and diversion into the illicit market
Risks in the Medical Use of Opioid Analgesics

• Opioid Abuse –
  - DAWN reports an increase of 163% in the number of emergency department visits regarding narcotics between 1995 and 2002

• Opioids Diverted to Illicit Uses –
  - Thefts from manufacturers, transporters and retailers
  - Prescription fraud
  - “Doctor shoppers”

Clinicians should assess the risk of abuse, addiction, and diversion just as they would with any other adverse reaction to a drug therapy and manage their patients accordingly.
Adopt a universal precautions approach –

1. Assess the patient through a detailed history and physical examination
2. Establish a diagnosis for the pain problem
3. Consider multiple approaches to treatment
4. Consider opioid treatment for moderate to severe pain on a case-by-case basis
   - Are Opioids appropriate?
   - Are there other, better treatments?
   - Is the patient vulnerable to side effects?
   - Will the patient use the medication responsibly?
5. Recognize that opioid therapy is as much a “therapeutic trial” as any other treatment
Behaviors that are potential indicators of problems for patients on long-term opioid therapy –

- Complaints about need for more medication
- Drug hoarding
- Requesting specific pain medications (others “don’t work”)
- Openly acquiring similar medications from other providers
- Occasional unsanctioned dose escalation
- Non-adherence to other recommendations for pain therapy
Additional Potential Indicators

- Deterioration in functioning at work, in the family or socially
- Illegal activities such as:
  - selling medications
  - forging prescriptions
  - stealing medications from other patients
  - buying prescription drugs from non-medical sources
- Injection or snorting of medications
- Multiple episodes of “lost” or “stolen” prescriptions
- Resistance to changes in therapy
- Refusal to comply with random screening or referral to specialist
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians or pharmacies
The decision to prescribe an opioid based drug can be influenced by various factors:

- **Manufacturer promotions** – Pharmaceutical manufacturers spend vast amounts of their budgets to promote individual products.
- **Industry claims** – Whole classes of drugs are promoted by the industry.
- **Public opinion** – Direct to consumer advertising.
- **Patient preference** – Pressure applied by the patient for a specific treatment or drug.
Comparison of Total Promotional Dollars Spent

During the first 6 years of sales (adjusted for inflation)

OxyContin®

Duragesic®

MS Contin®

Source: IMS Health, Integrated Promotional Services Audit™, Extracted August 2002
Direct to Consumer Advertising through History

“At first, habit only binds us with silken threads; these threads finally change to links of strongest steel.”

Quoted from a turn-of-the-century morphine addict.

Fast-rising Use of Opiates

At a time when medicine was relatively primitive, doctors and patients gratefully embraced the array of opiumlike morphine, potassium bichromate, opium, pungent (alcohol, opium, and camphor), and cocaine. There was a great enthusiasm for these drugs, which were easily obtainable and used casually. The widespread adoption of the hypodermic syringe made for easier, more potent delivery of morphine. The patent medicine industry catered to these dosing themselves with potions of products whose ingredients were secret, but sometimes included large amounts of alcohol and/or opiates.

Mrs. Winslow’s ads, American, 1888. Among the most notorious products of the patent medicine industry were the so-called baby soothers, like Mrs. Winslow’s. Ads for the product conveyed the image of peaceful scenes that were rare to ensure even baby children were properly doused. It makes a shocking contrast to the long lists of babies dead from the use of American Malaria Association (syringe).

Ludzaum. This was a popular remedy for fever, pain, and diarrhea first used in medieval Europe.
Unsubstantiated Claims

"For children teething. Greatly facilitates the process of Teething, by softening the gums, reducing all inflammation; will allay ALL PAIN and spasmodic action, and is SURE TO REGULATE THE BOWELS. Depend on it, Mothers, it will give rest to yourselves and RELIEF AND HEALTH TO YOUR INFANTS."

Note: Product contained tincture of opium and caused overdose deaths, addiction and constipation in direct opposition to the claims.
Influence of Direct to Consumer Advertising

Tom Toles by Tom Toles

I'd like a prescription for this drug.

It's very expensive and there are alternatives that work just as well.

I'd like to get a second opinion.

It will make you feel like frolicking in this flowery meadow.

Yes, I've confirmed my original request...

It's your money. It's not.

Office of Diversion Control

Opioid Risk Management: The DEA Perspective
Society’s Belief: “The Answer is in the Pill!”
Increased number of legitimate prescriptions for opioid based pharmaceuticals resulting from:

- The aging of the U.S. population
- The need to treat chronic pain

Necessitated an increase in the production of opioid based pharmaceuticals by industry resulting in:

- Increased opportunity for diversion into the illicit market
- Increased opportunity for abuse and/or misuse
Misconception and Perceptions
Production Quotas for Narcotics

Increase in Quota over 12 Year Period

- Fentanyl – 16 fold
- Oxycodone – 14 fold
- Hydrocodone – 4.6 fold
- Hydromorphone – 4.9 fold
- Morphine – 5.5 fold
In 2003, 6.3 million Americans used one or more prescription drugs for *nonmedical* purposes.*

**Sedatives**
- 0.3 million

**Stimulants**
- 1.2 million

**Anti-Anxiety Medication**
- 1.8 million

**Narcotic Pain Relievers**
- 4.7 million

Only category that showed an increase; all others decreased or remained the same.

*Number of persons age 12 and older reporting *nonmedical* use of prescription drugs during 2003.

Source: 2003 National Survey on Drug Use and Health (NSDUH)
(formerly the National Household Survey on Drug Abuse) published Sept 2004
Dept of HHS / Substance Abuse and Mental Health Services Administration (SAMHSA)
Legitimate medical practice is defined by the medical and scientific communities, *NOT* by the law enforcement community.

In 2001 DEA joined with several other groups (primarily medical and patient advocacy) to develop a consensus statement – “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.”

Led to the development of education materials that would cover the clinical and regulatory issues surrounding the prescribing of controlled drugs.

What Transpired

• The document was “withdrawn” due to misstatements of the law

• The document’s importance to the pain community compels DEA to correct the misstatements and republish the document under approved policy procedures

• During January of 2005 DEA published in the Federal Register an invitation to the medical community and public at large to comment on what issues DEA should address in its final policy document

• The comment period closed March 21, 2005
DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-261N]

Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice; solicitation of comments.

SUMMARY: On November 16, 2004, DEA published in the Federal Register an Interim Policy Statement on the dispensing of controlled substances for the treatment of pain. The Interim Policy Statement stated that DEA would address the subject in greater detail in a future Federal Register document, taking into consideration the views of the medical community. DEA is hereby seeking comments from physicians and other interested members of the public as to what areas of the law relating to the dispensing of controlled substances for the treatment of pain they would like DEA to address in the upcoming Federal Register document.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before March 21, 2005.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-261" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson- Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Daniel Dormont, Senior Attorney, Drug Enforcement Administration, Washington, DC 20537; telephone: (202) 307- 8010.

SUPPLEMENTARY INFORMATION: On November 16, 2004, DEA published in the Federal Register an Interim Policy Statement on the dispensing of controlled substances for the treatment of pain. 69 FR 67170. The Interim Policy Statement explained why an earlier document, which appeared on the DEA Office of Diversion Control Web site in August 2004, contained misstatements and was not approved as an official statement of the agency. The Interim Policy Statement corrected some of the misstatements in the August 2004 document and announced that DEA would address, in greater detail, the subject of dispensing controlled substances for the treatment of pain in a future Federal Register document, taking into consideration the views of the medical community. This upcoming document will stay within the scope of DEA’s authority by addressing the law the agency administers, the Controlled Substances Act (CSA), and the DEA regulations promulgated thereunder, as well as the pertinent court decisions. As indicated in the Interim Policy Statement, the document will contain a recitation of the relevant provisions of the CSA and DEA regulations relating to the dispensing of controlled substances for the treatment of pain. The purpose of this recitation will be to provide guidance and reassurance to the overwhelming majority of physicians who engage in legitimate pain treatment while deterring unlawful prescribing and dispensing of pharmaceutical controlled substances.

As was the case with the Interim Policy Statement, none of the principles addressed in the upcoming Federal Register document will be new. Rather, the document will reiterate legal concepts that have been incorporated in the federal laws and regulations for many years and are reflected in federal court decisions and DEA final administrative orders. DEA recognizes the desire of many physicians and members of the public to have these concepts reiterated in a single, comprehensive document. Toward that end, DEA is hereby seeking the input of physicians, pharmacists, and other interested members of the public. Any person who so desires should indicate, in writing, the areas of the law relating to controlled substances that they would like DEA to address in the upcoming document. DEA will consider all such comments submitted on or before March 21, 2005.

Dated: January 11, 2005.

Michele M. Leonhart,
Deputy Administrator.
• The solicitation will result in a formal DEA statement of policy (to be published in the *Federal Register*).

• This action will result in the convening of a broader base of interest groups to review, correct and expand the original publication.
DEA Policy

• The DEA focuses its limited manpower and resources on the most flagrant violations.

• State and local agencies also conduct investigations related to controlled substance diversion, fraud, or improper medical practice.

• The DEA investigates only a small number of practitioners.

• The DEA arrested 50 practitioners during FY2003 and 42 during FY 2004 whose activities were deemed to be knowingly and intentionally beyond the scope of medical practice (this represented less than ½ of 1% of practitioner registrants).

• Most frequently DEA responds to complaints, allegation of diversion, or some other impropriety.

• Joint investigations may occur when local police or state or federal agencies seek out the DEA for its expertise.
### DEA Actions Taken Against Doctors – FY 2004

**Total DEA actions taken against Doctors:**

- **621**
  - (0.06312% of registered doctors)

#### Breakdown of Actions:

- **Surrenders for Cause:** 477
- **Revocations of Registration:** 30
- **Civil Fines:** 14
- **Administrative Hearings / MOUs:** 43
- **Letters of Admonition:** 43
- **DEA Arrests:** 14

#### Total Number of Doctor Registrants:

<table>
<thead>
<tr>
<th>Description</th>
<th>Total Number</th>
<th>Percent of Doctor Registrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Doctor Registrants</td>
<td>983,860</td>
<td></td>
</tr>
<tr>
<td>Criminal / Complaint Investigations of Doctors Initiated in FY 2004</td>
<td>737</td>
<td>0.07490%</td>
</tr>
<tr>
<td>Total DEA Actions Taken Against Doctors in FY 2004</td>
<td>621</td>
<td>0.06312%</td>
</tr>
<tr>
<td>Doctors Arrested by DEA in FY 2004</td>
<td>14</td>
<td>0.00142%</td>
</tr>
</tbody>
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1. MD (Medical Doctor)
2. DDS / DMD (Dentist)
3. DO (Osteopath)
4. DPM (Podiatrist)
5. DVM / VMD (Veterinarian)
6. ND (Naturopath)

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2 In prior years, arrest numbers included arrests made by DEA (federal drug charges) as well as arrests made by state, local, and other federal agencies in which DEA participated. For FY 2004, arrest numbers reflect ONLY arrests made by DEA (federal drug charges). For purposes of comparison, a total of all Doctor arrests as described above would be 42.
Additional Educational Materials

- American Academy of Pain Management  
  www.aapainmanage.org/education/Education.php
- American Academy of Pain Medicine  
  www.painmed.org/cme
- American Academy of Physician Assistants  
  www.mecgeducation.com/jaapa/pain_management/default.asp
- American Geriatrics Society  
  www.americangeriatrics.org/education/manage_pers_pain.shtml
- American Medical Association  
  www.ama-assn.org/ama/pub/category/10171.html
- Beth Israel Department of Pain Medicine and Palliative Care  
  www.stoppain.org
- California Academy of Family Physicians  
  www.familydocs.org
- National Pain Education Council  
  www.npecweb.org