

---

---

**CONRAD H. DAUM, MD**

1912 Braeburn Drive Salem, Virginia 24153

Phone: (540) 989-6628 Fax: (540) 989-1834

---

---

8/13/01

Ms Kimberly Topper  
FDA  
Rockville MD

Dear Ms Topper

I am submitting a comment on  
the 9/13-9/14/01 meeting (see attached).  
I support the appropriate application  
of Virginia State Senate Joint Resolution  
#165 of 1998. (see attached)

Sincerely

Conrad Daum

Food and Drug Administration

**Name of Committee:** Anesthetic and Life Support Drugs Advisory Committee.

**Date and Time:** The meeting will be held on September 13 & 14, 2001, 8 a.m. to 5 p.m.

**Location:** University of Maryland, Shady Grove Campus, Multi Purpose Room, Building 9630, Gudelsky Drive, Rockville, MD 20850

**Agenda:** On both days the committee will discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. It will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics.

**Public Participation:** The entire meeting is open and the public is invited to attend without pre-registration. In addition, a portion of the meeting, the open-public hearing, is set aside so that the public may present relevant views to the committee. This portion of the meeting will be held from approximately 1 p.m. to 2 p.m. each day.

**IF YOU WISH TO SPEAK AT THE OPEN PUBLIC HEARING**

Please submit a statement of your position and how we might contact you before the meeting please e-mail the statement to [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov) or fax the statement to (301) 827-6801. **The statements must be received by August 17, 2001.** Please limit your presentation to 3 minutes. Any statements received after the deadline will be posted to the docket but will not be sent to the committee nor will you be scheduled time to speak. FDA **DOES NOT** pay for Open Public Hearing Speaker travel expenses.

**IF YOU WISH TO SEND A STATEMENT FOR THE RECORD**

All the letters already received will be posted under **docket number 01N-0256**. If you wish to send in a statement to be posted please go to:

<http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm> select "Submit electronic comments" and follow the prompts.

Letters/statements may be mailed to:

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

Due to the overwhelming interest in this meeting and time constraints - no statements will be read into the transcript by FDA staff. All statements received before the August 17<sup>th</sup> deadline will be available to the committee in advance.

**FINDING INFORMATION ABOUT THE MEETING ON THE WEB**

Because this **meeting is not aimed at a single specific drug** but to discuss the class of opiate analgesic drugs the background information will be posted shortly after it is sent out to the members. All the information that is available for this meeting will be posted on the FDA web site at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> (Click on the year 2001 and scroll down to Anesthetic and Life Support Drugs meetings.) This is the same web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about three weeks after the meeting.

**SUMMARY****SENATE JOINT RESOLUTION NO. 165**

*Conveying the Medical Society of Virginia's guidelines for the use of Opioids in the Management of Chronic, Non-Cancer Pain.*

Agreed to by the Senate, February 13, 1998

Agreed to by the House of Delegates, March 12, 1998

WHEREAS, the Joint Subcommittee to Study the Commonwealth's Current Laws and Policies Related to Chronic, Acute and Cancer Pain Management was established in 1994 and has been continued in the years since to conduct such activities as a symposium in 1995;

WHEREAS, the joint subcommittee found that, although there are national guidelines for acute and cancer pain management, no national guidelines have been developed for the management of chronic pain; and

WHEREAS, the joint subcommittee also found that physicians treating chronic pain patients frequently do not prescribe adequate dosages of drugs because of a lack of understanding of the proper treatment for chronic pain and because they fear regulatory or law-enforcement actions; and

WHEREAS, the proper treatment for chronic pain may include the use of alternative or complementary therapies as well as the prescribing of anti-inflammatories and opioids; and

WHEREAS, in 1997, the joint subcommittee arranged to cooperate with the Medical Society of Virginia in the development of chronic pain guidelines; and

WHEREAS, this effort has also been supported by the Board of Medicine, with the publishing of the guidelines as a stand alone Board newsletter; and

WHEREAS, these guidelines are Virginia's guidelines and are unique in the nation as a bell weather development accomplished through cooperation between a legislative group, the regulatory agency, and the professional association; and

WHEREAS, these guidelines, it is hoped, will improve treatment practices and increase the awareness of proper chronic pain management; and

WHEREAS, it is the joint subcommittee's wish that these guidelines will be officially recognized and transmitted to the citizens and physicians of the Commonwealth; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Joint Subcommittee to Study the Commonwealth's Current Laws and Policies Related to Chronic, Acute and Cancer Pain Management does hereby place into the public record and convey to the General Assembly of Virginia and the people and physicians of this Commonwealth, the following document:

**REPORT TO MEDICAL SOCIETY OF VIRGINIA  
AD HOC PAIN MANAGEMENT COMMITTEE**

**Preface**

Recently, there has been increasing interest on the part of physicians, regulatory agencies, legislators, the public, and patients for the proper diagnosis, timely workup, and state of the art treatment for acute, cancer, and non-cancer, chronic pain conditions. While there is widespread agreement among health care providers concerning the treatment of acute and cancer pain with opioids (also known as narcotics)-as exemplified by Federal Clinical Practice Guidelines published by the Agency for Health Care Policy and Research, U.S. Department of Health and Human Services-there has been a lack of consensus, misunderstanding and hesitation among health care providers (physicians, nurses, pharmacists), regulatory agencies, patients, and third party providers concerning the use of these same agents in the management of chronic, non-cancer pain.

Inadequate understanding about issues such as addiction, tolerance, physical dependence, and abuse has lead to unfounded stigma against proper opioid prescription. Fears of legal and regulatory sanctions or discipline from local, state, and federal authorities often result in inappropriate and inadequate treatment of chronic pain patients. Undertreatment or avoidance of appropriate opioid therapy increasingly has been reported by physicians, patients, and other health care team members.

The discipline of pain medicine has produced a new awareness about the necessity of proper diagnosis, history and physical examination, and treatment planning for the patient with chronic pain. Unfortunately, the paucity of specially trained physicians in the field of pain management often precludes patient access to specialized pain treatment facilities. The treatment for these patients will appropriately fall within the realm of the primary care or specialty physician. Until adequate guidelines are made for prescribers of opioids for patients with chronic non-cancer pain, episodes of undertreatment of this deserving population will continue.

As a result of the efforts and recommendations of the Governor's joint subcommittee studying pain, the House of Delegates of the

Medical Society of Virginia, at the 1996 annual meeting of its legislative body, recognized the lack of national consensus as well as the need for parameters concerning the proper use of opioids for patients with intractable pain of non-cancer origin within the Commonwealth of Virginia. The following guidelines are presented with the hope that they will attenuate fears about professional discipline, encourage adequate and proper treatment of chronic pain with all appropriate therapies, and educate about and protect patients as well as the general public from unsafe or inappropriate prescribing patterns or abuses.

The Society believes that physicians have an obligation to treat patients with intractable pain and to lessen suffering and that opioids may be appropriately and safely prescribed for many acute, cancer, and chronic pain conditions as long as acceptable protocols and standards are closely followed. The Society feels that physicians should be encouraged to prescribe, dispense, and administer opioids when there is demonstrated medical necessity and proper indication for these agents without fear of discipline, excessive scrutiny, or remunerative or restrictive legal penalties. These guidelines should not be interpreted as absolute standards of care in the treatment of chronic pain patients, nor are they absolute directives for clinical practice. Rather, they are guidelines by which, all physicians may more safely and comfortably evaluate and treat this very problematic and needy group of patients.

### **MEDICAL SOCIETY OF VIRGINIA'S GUIDELINES FOR THE USE OF OPIOIDS IN THE MANAGEMENT OF CHRONIC, NON-CANCER PAIN**

For the purposes of this document, the following terms shall mean:

"Acute pain" is the normal, predicted physiological response to an adverse (noxious) chemical, thermal, or mechanical stimulus. Acute pain is generally time limited and is historically responsive to opioid therapy, among other therapies.

"Addiction" is a disease process involving use of opioids wherein there is a loss of control, compulsive use, and continued use despite adverse social, physical, psychological, occupational or economic consequences.

"Chronic pain" is persistent or episodic pain of a duration or intensity that adversely affects the function or well-being of the patient, attributable to any nonmalignant etiology.

"Opioid withdrawal" is characterized by three or more of the following symptoms that develop within hours to several days after abrupt cessation of the substance; (a) dysphoric mood, (b) nausea and vomiting, (c) muscle aches and abdominal cramps, (d) lacrimation or rhinorrhea, (e) pupillar dilation, piloerection, or sweating, (f) diarrhea, (g) yawning, (h) fever, (i) insomnia.

"Physical dependence" is a physiologic state of adaptation to specific opioids characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is a predictable sequelae of regular, legitimate opioid or benzodiazepine use, and does not equate with addiction.

"Substance abuse" is the use of any substances for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

"Tolerance" is a state resulting from regular use of opioids in which an increased dose of the substance is needed to produce the desired effect. Tolerance may be a predictable sequelae of opiate use and does not imply addiction.

"Withdrawal syndrome" is a specific constellation of signs and symptoms due to the abrupt cessation of, or reduction in, a regularly administered dose of opioids.

#### **Assessment, Documentation, and Treatment**

**A. History and Physical Examination.** The physician must conduct a complete history and physical exam of the patient prior to the initiation of opioids. At a minimum, the medical record must contain documentation of the following history from the chronic pain patient:

1. Current and past medical, surgical, and pain history including any past interventions and treatments for the particular pain condition being treated.
2. Psychiatric history and current treatment.
3. History of substance abuse and treatment.
4. Pertinent physical examination and appropriate diagnostic testing.
5. Documentation of current and prior medication management for the pain condition, including types of pain medications, frequency with which medications are/were taken, history of prescribers (if possible), reactions to medications, and reasons for failure of medications.
6. Social/work history.

**B. Assessment.** A justification for initiation and maintenance of opioid therapy must include at a minimum the following initial workup of the patient:

The working diagnosis (or diagnoses) and diagnostic techniques. The original differential diagnosis may be modified to one or more diagnoses.

Medical indications for the treatment of the patient with opioid therapy. These should include, for example, previously tried (but unsuccessful) modalities/medication regimens, diverse reactions to prior treatments, and other rationale for the approach to be utilized.

Updates on the patient's status including physical examination data must be periodically reviewed, revised, and entered in the patient's record.

**C. Treatment plan and objectives.** The physician must keep detailed records on all patients which at a minimum include:

1. A documented treatment plan.
2. Types of medication(s) prescribed, reason(s) for selection, dose, schedule administered, and quantity.
3. Measurable objectives such as:
  - a. social functioning and changes therein due to opioid therapy.
  - b. activities of daily living and changes therein due to opioid therapy.
  - c. adequacy of pain control using standard pain rating scale(s) or at least statements of the patient's satisfaction with the degree of pain control.

**D. Informed consent and written agreement for opioid treatment.** Written documentation of both physician and patient responsibilities must include:

1. Risks and complications associated with treatment using opioids.
2. Use of a single prescriber for all pain related medications.
3. Use of a single pharmacy, if possible.
4. Monitoring compliance of treatment:
  - a. urine/serum medication levels screening (including checks for non-prescribed medications/substances) when requested.
  - b. number and frequency of all prescription refills.
  - c. reason(s) for which opioid therapy may be discontinued (e.g., violation of written agreement item(s)).

**E. Periodic review.** Intermittent review and comparison of previous documentation with the current medical records are necessary to determine if continued opioid treatment is the best option for a patient. Each of the following must be documented at every office visit:

1. Efficacy of treatment.
  - a. subjective pain rating (e.g., 0-10 verbal assessment of pain).
  - b. functional changes.
    - i. improvement in ability to perform activities of daily living (ADL's).
    - ii. improvement in home, work, community, or social life.
2. Medication side effects.
3. Review of the diagnosis and treatment plan.
4. Assessment of compliance (e.g., counting pills, keeping record of number of medication refills, frequency of refills, and disposal of unused medications/prescriptions).
5. Unannounced urine/serum drug screens and indicated laboratory testing, when appropriate.

**F. Consultation.** Most chronic non-cancer patients, like their cancer pain counterparts can be adequately and safely managed by most physicians without regard for specialty. However, the treating physician must be cognizant of the availability of pain management specialists to whom the complex patient may be referred. The physician must be willing to refer the patient to a physician or a center with more expertise when indicated or when difficult issues arise. Consultations must be documented. The purpose of this referral should not necessarily be to prescribe the patient opioids. **G. Medical records.** Accurate medical records must be kept, including, but not limited to documentation of:

- a. all patient office visits and other consultations obtained.
- b. all prescriptions written including date, type(s) of medication, and number (quantity) prescribed.
- c. all therapeutic and diagnostic procedures performed.
- d. all laboratory results.
- e. all written patient instructions and written agreements.

#### **Summary and concluding remarks**

The treatment of patients with chronic, non-cancer pain should not be limited to pain specialists only. Because of complex social, regulatory, ethical, and legal issues surrounding the use of opioids in these patients, the physician who elects to help treat these patients may find it useful to utilize the guidelines and examples outlined in this document. While these guidelines do not define standard of care, it is the hope of the Medical Society of Virginia, working in close conjunction with the Virginia Board of Medicine, and the Commonwealth of Virginia's Joint Subcommittee to Study the Commonwealth's Current Laws and Policies Related to Chronic, Acute, and Cancer Pain Management, that physicians who do treat this very difficult and deserving patient population will find significant clinical benefits from this document and will be enlightened by the suggestions offered herein.

This document is the product of the Medical Society of Virginia's Ad Hoc Subcommittee on the Treatment of Chronic Non-Cancer Pain and is the result of many months of deliberation and study.



[Go to \(General Assembly Home\)](#)