



FDA CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF ANESTHETIC, CRITICAL CARE, AND ADDICTION DRUG PRODUCTS
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MEMORANDUM

DATE: August 15, 2001

FROM: Cynthia G. McCormick, MD, Director *Cynthia McCormick MD*
Division of Anesthetic, Critical Care and Addiction Drug Products
Office of Drug Evaluation II, CDER, FDA

TO: Chair, Members and Invited Guests
Anesthetic and Life Support Advisory Committee (ALSAC)

RE: Overview of the September 13th and 14th ALSAC Meeting to Discuss
Opiate Therapies in the Treatment of Pain and Related Topics

This year begins the Decade of Pain. After a long struggle to raise pain management to a new level of importance among medical specialties and to begin to remove some of the stigmata associated with pain therapies, particularly the opioids, pain management will certainly gain greater visibility in the next ten years. Pain management guidelines are proliferating; many states have adopted legislation to insure that quality of life and pain relief are taken into full consideration in the terminally ill patient. There are many challenges ahead and we have a great opportunity to continue this effort in a studied and responsible way.

There are newer and more elegant opioid formulations and drug delivery systems on the market and in the development pipeline. These have the ability to provide opiates to the patient in more convenient, palatable and effective ways.

The awareness of the importance of good pain management has made its way into new populations, such as the pediatric treatment community, in spite of the difficulties in characterizing pain in the child and young infant, and in conducting adequate clinical studies to assess proper dosing. The FDA will invite discussion about the unmet needs in this age group, the kinds of delivery systems and agents that might be appropriate at various ages, the risks of having these medications in the homes where small children

may have access, and how these risks should be communicated and managed.

At the same time that we see the benefits of informed treatment and better product availability, we also see the dark side of opiate therapy emerging, with drug abuse, diversion and addiction on the rise, according to some available measurement tools. Some of these trends will be discussed during this meeting. NIDA has recently announced a new initiative for the study of Prescription Drug Abuse and we are all hopeful that we will see increased research into this problem. While prescription drug abuse has always been with us, as the higher dose formulations and elegant delivery systems make their way more fully into the population, this problem may increase. The FDA would like to hear an open and frank discussion of how the potential risks associated with these products could be managed in a way that will insure adequate patient care.

This meeting is about the patient suffering from pain who requires opiate therapy for adequate management. It is about the patient who is an addict who also experiences chronic pain. It is about the individual who may have a propensity for substance abuse who seeks opiate medication under false pretenses. It is about the youth who tries prescription drugs for the first time and dies from an overdose. It is about the infant or child suffering from a painful condition who may benefit from what once were "adult" medications.

Our hope for this meeting is that you, as the experts in pain management and addiction treatment, will provide the Agency your views on what is needed in the arena of drug development and risk management. It is our hope that you will bring the FDA up to date on your views regarding the unmet needs of the pain community and assist the FDA in thinking about ways in which we can carry out our mission responsibly with solid programs to develop good drugs while managing the risks associated with them, always keeping in balance the needs of the public.