

August 17, 2001

Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857
By e-mail

Re: Anesthetic and Life Support Drugs Advisory Committee
September 13-14, 2001, hearing re medical use of analgesics

Dear Ms. Topper:

I am deeply concerned about the possible impact of the current publicity about and actions involving certain opioids and their actual and potential impact on the ability of legitimate patients to obtain often badly needed relief and wanted to contribute my thoughts for the upcoming committee hearing.

I am a, just retired, former deputy attorney general with the State of California. Over the past 25 years I have obtained disciplinary action against numerous physicians, pharmacies and others involved in drug diversion, including individuals whose conduct put millions of dollars (in street value) of controlled substances on the street. I have worked with various state and federal agencies on drug law enforcement and diversion control on major drug enforcement cases and projects and have been recognized for it. I put together the first statewide cooperative agreement in California among different state agencies and regional federal offices involved in investigation of drug diversion activities. I have taken the license of doctors who have been responsible for putting over \$10,000,000, in street value, of prescription controlled substances on the street in a single year. I have no sympathy for diversion of prescription controlled substances to illicit use or those who engage in or enable such conduct.

But I have also worked on writing and analyzing drug, pharmacy, controlled substance and pain management laws and policy over the years and recognize the fundamental need for balance in diversion control policy so that enforcement needs and efforts are balanced with respect for the professional judgment of the vast majority of practitioners who simply want to treat their patients properly and, more importantly, with respect for patient access to available, effective treatment. Before any new law or regulation or policy or practice, or any more restrictive law, etc. is passed or is put into effect, remember that the bigger problem with many drugs of abuse, including most, if not all, prescription narcotics, is not the abuse, but the inadequate use for proper medical purposes.

We must remember that the fundamental answer to drug abuse is to recognize the factors that

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contribute to it and to address them and to make sure that adequate treatment and other rehabilitation resources are available for those who are drug abusers. And we have to recognize that the factors that bar or inhibit adequate use include ignorance, unwarranted fear, and both actual and perceived regulatory restrictions.

It is clear that there is a problem with OxyContin™ abuse, using the latest drug getting the most attention as an example of the issue. But the problem is really nothing new. In the recent past it has been Talwin™ in the Midwest, especially in the 1970s and early 1980s, different narcotic cough syrups and codeine (often combined with one or more other depressants), and Dilaudid™, among others. In fact, before OxyContin™ was being referred to in press reports as the “new heroin”, Dilaudid™ was often known, in the addict community, as “drug store heroin”. Whether taken in its manufactured form or broken up and snorted or injected, the purity—the safety—of a prescription narcotic gains and ebbs in popularity, often in relation to the availability, price, and safety, purity and efficacy of street narcotics, particularly heroin. This is not new (abuse of opium and, over the last 150 years, derivatives developed and promoted for medical use, has a long, even ancient, history), and it is a function of the existence and needs of the addict community (and, of course, the foolish actions of recreational, often young, users), not a creation or fault of any particular prescription drug.

It would be a shame, maybe even a disaster for many patients who, since the release of OxyContin™, have finally obtained adequate relief not available even from the strongest medications previously available, if the abuse of some led to the restriction, directly or through publicity, policy, or practices, of availability for real patients. And, while I am not and do not claim to be a pharmacologist or clinician, it is clear from reports, studies, and the many practicing physicians with whom I have spoken and to whom I have lectured that the value of opioids, including OxyContin™, is not limited to acute pain states or to pain associated with terminal or end-stage illness or disease. Many patients in moderate to severe chronic pain benefit from, even must rely on, powerful prescription opioids for the relief necessary to enjoy life and to be able to function on a more normal basis.

Just as importantly, additional restrictions on availability—such as restrictions on the number of doses or excessively limited provisions for the length of time a single prescription may cover or even a restriction of the maximum strength of a particular drug—will not solve the problem of abuse and abusers. Such restrictions will interfere with the proper medical judgment of practitioners and the regimens of patients without unduly hampering abusers and the runners (those who pose as patients to obtain the drugs for street sales), transporters and traffickers who obtain and distribute legitimate drugs to the street market. Nor are production quota restrictions based on the fact of abuse rather than existing and expected legitimate need a proper solution. The only result of any significant quota restriction (or return to a much lower quota from a prior year) will, again, be harm to the legitimate patient.

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The problem is compounded by the hysteria with which the recent spate of OxyContin™ abuse has been covered, not to mention some of the responses from government and some of the particular onerous lawsuits that have been filed. It is unquestionable there have been at least a few deaths that have been caused due to OxyContin™ abuse—but that points out at least two major issues: the uses which led to death appear to be due to abuse and the number of reported deaths involving OxyContin fails to distinguish (1) whether the incident involved the trade drug or some other drug containing oxycodone and (2) whether oxycodone was simply reported in connection with a patient who died or was actually a factor in the death, much less a major factor or the actual cause. It is also probably true that drug companies heavily promote their brand drugs to those who might prescribe them, but, frankly, this is an issue that is endemic to our prescription drug distribution structure and which should be addressed by the FDA, the FTC and/or Congress generally in connection with the overall issue of prescription medication use and costs, not as to any one drug.

The pain patients whose stories I see on-line, in AOL's Pain Relief Center, are already reaping the fallout from recent highly negative publicity and actions. Practitioners are refusing to issue prescriptions because they do not want to deal with regulators or law enforcement, not because they now believe the patient does not need the drugs; pharmacies are refusing to stock certain drugs. It has only been 10 years or so since the efforts of pain practitioners, patients and an increasing number of aware and sensitive regulators (and others in government) began to result in sufficiently enlightened laws, policies and practices that prescribers and pharmacies have begun to feel comfortable with the significant—in terms of amounts and length of therapy—drug regimens many pain patients require. There are still states which do not have positive pain management laws or policies; actual practice—both by government and by health care practitioners—is still too inhibited, by ignorance and/or fear, if not by actual laws and policies, even in the most progressive states. And now an atmosphere has been created, and continues to be created, which threatens much of that progress.

Very little effort has been made in media reports or comments from government officials which I have read, with the notable exception of the balanced material made available by FDA, to temper the publicity about OxyContin™ with adequate, often any, recognition of legitimate use and need or of even the possibility the drug's role in recent deaths has been overstated. Much of the material I have read, including from some government officials or agencies, not only fails to recognize the importance of legitimate use, but even demonstrates a lack of understanding of such fundamental concepts as what constitutes drug abuse or an addict. Any attempt by this Committee, or by government generally, to propose restrictions on the availability of prescription narcotics in general, or specific drugs, or to condition their availability, is simply unwarranted in the absence of clear, substantial evidence not only of diversion and abuse and injury, but that such diversion, etc. is not only significant, but sufficiently significant when balanced against the much wider legitimate use of and need for such drugs that it justifies restrictions which can only

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harm many patients in pain.

I hope that this Committee, and the FDA, will keep the above in mind when addressing the issues pertaining to opioid use, abuse and availability, especially that the needs of the perhaps millions of patients who need pain medication be the first consideration in any recommendations.

Thank you for your kind attention,

Sincerely,

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