SCCPI Southern California Cancer Pain Initiative
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Ms. Kimberly Topper
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Topper:

On behalf of the Southern California Cancer Pain Initiative (SCCPI), we are writing to you to express our grave concerns regarding recent consideration of decreasing quotas and availability of opioid analgesics.

As members on the Board of Directors of SCCPI, a 1400+ member professional organization whose mission is "to promote optimum pain relief for all cancer patients with pain," and as clinicians and researchers, we are acutely aware of the potential dangers posed by misuse and diversion of Schedule II Controlled Substances. However, we also recognize the significant benefit to quality of life and reduced suffering that opioid analgesics offer for patients who needlessly suffer, especially with terminal illnesses.

Indeed, there are many necessary precautions when prescribing and dispensing Schedule II controlled substances. Physicians, pharmacists, nurses, and patients share a responsibility to maintain integrity in prescribing, dispensing, and utilizing controlled substances. SCCPI promotes sound judgment and adherence to laws and regulations with regard to all medications. Yet, we also note that there are regulatory and educational barriers that preclude many patients from receiving adequate relief. For instance, in California, we face the restriction of triplicate prescription requirements despite the fact that there is a concurrent electronic monitoring system in place. Nevertheless, we believe a balance can be struck between the need for regulatory scrutiny and the right to pain relief. Reducing quotas of analgesic medications is not the answer.

Increasing medical education along with educating regulators, and engaging in a rational dialogue with all affected parties, are two ways preferable to responding to concerns of imposition of increased restrictions. There are several activities among professional organizations addressing barriers to pain management while highlighting professional and personal responsibility to prevent drug diversion. The Pain and Policy Studies Group (PPSG) of the University of Wisconsin advocates for a balanced approach to regulation,

drug availability, professional responsibility, and the use of opioids for pain management. Similarly, SCCPI continues to be a leader in California in advocating for the rights of citizens for pain relief and for educating healthcare professionals on proper use and delivery of medications for pain management. SCCPI also promotes a balanced approach. Hysteria either in favor of or in opposition to the use of opioids for pain relief will only create additional barriers to pain management, heighten physician reluctance to treat pain, and will leave more people to suffer needlessly.

A consensus statement developed by the American Pain Society and the American Academy of Pain Medicine addresses the proper "Use of Opioids for the Treatment of Chronic Pain." This report was a result of years of working among healthcare professionals, licensing and regulatory bodies. It assumes that current regulatory restrictions and laws are sufficient to prevent diversion and misuse of controlled substances and that prescribers have a responsibility to prevent diversion but also to treat pain aggressively. Moreover, the Federation of State Medical Boards developed "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" which states that diversion of controlled substances must be prevented. The Guidelines also assert that prescribers must be allowed to treat pain of suffering patients without fear of regulatory scrutiny. Likewise, citizens have a right to the relief of pain within the confines of the current laws and reasonable medical practice. Access to appropriately prescribed medications is among those rights.

Studies have shown that cancer-related pain could be well controlled in 80-90% of patients, yet fewer than 50% of patients nearing the end of life are relieved of pain. Research by the American Pain Society revealed that in chronic pain conditions, pain management is equally as grim whereby four out of every 10 patients with pain do not receive adequate relief and in fact rate their pain as moderate to severe, and "out of control." As policy makers and clinicians, we already face a public health crisis of unmanaged pain. To reduce quotas of Schedule II controlled substances would significantly interfere with pain control for patients and perpetuate suffering.

It is extremely unreasonable that a reduction in quotas of Schedule II controlled substances will reduce illicit use by known drug abusers. Most of the news stories about abuse involve reports of addiction and overdose by persons who crush the pills and then snort or inject the medication. In most of those cases, alcohol and other drugs are being consumed in addition to the pain medication. The fact that those individuals mix various substances, against the advice of medical professionals and without approval of appropriate authorities, represents a drug problem and a need for substance abuse treatment. **Those individuals <u>do not</u> represent the vast majority of persons who take prescription pain medication**.

National figures on drug abuse have indicated that there are more deaths from overdose by over the counter medications, such as Tylenol, than from Schedule II controlled substances. One study reported that in one year, there were approximately 8,000 deaths that resulted from Schedule II controlled substance abuse compared to 80,000 that were a

result of abuse of over the counter medications. Any loss of life from drug abuse is unwarranted and tragic. However, allowing people to live and die in pain when the appropriate means for relief are available- but not allowed- is a profound statement of how policy makers are allowing those who use illicit drugs to control rational balanced thinking, public policy, and the medical field's obligation to offer pain relief.

Yet, news reports indicate, and as the DEA Administrator recently testified, there are movements to reduce Schedule II availability while there seem to be no attempts to address other dangers and disparities associated with other "legal" substances. Moreover, state regulatory agencies have the responsibility to maintain integrity and scrutiny over the practices in their respective regions. Increased federal restrictions would demonstrate a lack of trust in state agencies to carry out their obligations and a failure to take a balanced, sound approach to the problem.

We urge you to give careful consideration and weigh ALL sides in this highly volatile situation. We, like you, are committed to prevent drug diversion. We are also wholeheartedly committed to maintaining our ethical and legal responsibility to provide legally prescribed pain medications to those who rightfully need and deserve them. We hope that together we can resolve this issue of hysteria and miscommunication so that we can serve the higher good of the citizens and uphold the laws and regulations with a balanced approach.

Sincerely,

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