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

Dear Ms. Topper,

Pain treatment and the availability of appropriate drug therapy is essential to good medical practice. Physicians today cannot decline to treat pain and they cannot treat it inappropriately and expect to avoid accountability before civil courts or boards of registration. Restrictions of access to opioids to specialists would force other practitioners to subject their patients to substandard care and direct violations of JCAHO standards. Limitations of pain therapy to certain classes of illnesses would be nothing short of discrimination toward other individuals suffering pain from other causes. I will try to keep my present comments brief and focused but also I offer to meet with you or members of your staff to further discuss any of the points made or issues covered (by myself or others) at greater length at a subsequent time and place or by letter or phone.

Perhaps to begin, we should recognize that, in our country as a whole, the health care community has been slow to recognize the tragedy caused by the needless suffering of our parents, children, siblings and spouses. All of us are susceptible to both malignant (cancer) and non-malignant (non-cancer) conditions that cause pain. It is only humane and compassionate that where we do not have the ability to cure a condition, at least we can do our best to minimize the suffering. Recently, an animal at a zoo was euthanized to prevent it from suffering from liver cancer. How many of our children and seniors are, at this very moment, suffering from needless pain because

of fears and misconceptions? We do not allow assisted suicide, but we do not have to condone suffering and agony. We can and should do better. That is part of our challenge as responsible leaders in our community.

On January 1, 2001, the JCAHO put into effect the enforcement of six new mandatory standards that attempt to address that organization's concern that pain management, on a nationwide basis, had not been adequately understood, explained, assessed, treated, taught or evaluated. We need to recognize that it took several years to develop the standards, seek public comment and make providers aware of their responsibilities. Their efforts are being realized by better approaches to patients and their suffering. More individuals have access to pain relief now than ever before. We do not want to turn back the clock in response to a current serious dilemma with abuse and illegality. There are other things that we can do on many fronts to ensure the effective treatment of individuals in need and lessen abuse and diversion. If we are all willing to step back and work together, we can build on what JCAHO started and ensure that the principles they expounded are put into force without being oblivious of patient/community safety.

We must not lose sight of the realities that:

1. If someone took a car and ran down twenty people in a crowd, we would not ban the sale and use of all cars.

2. If individuals use syringes to shoot up heroin, we would not stop the dispensing of syringes to diabetics causing them to die from lack of treatment.

3. If individuals sniff glue, we do not ban stores from selling the product to modelers.

4. If someone drives in an inebriated state, that does not mean the solution is to stop the sale and distribution of all alcohol or cars.

5. If someone robs a bank, we do not close all banks down or force them to remove all their money.

The list goes on and on. Abuse is far more widespread than any of us would like to admit. We must be ever vigilant while we make sure that the innocent majority is not hurt by our well-meaning attempts to

control the harmful actions of an extremely small minority.

To understand pain management, we should realize that there are a limited group of drugs that are truly effective for pain. Salicylates (Aspirin) and acetaminophen (Tylenol) coupled with NSAIDS (such as Advil or ibuprofen) are fairly well known. Yet do we all remember the toxicity of Aspirin or Tylenol overdoses and do we all recognize the ceiling (or maximum) doses that can be used for these drugs without causing serious bodily harm? Newer Cox-2 inhibitor drugs (such as celecoxib or Celebrex) have fewer risks than the NSAIDS, but they too have ceiling doses. For patients with arthritis, effective use of a Cox-2 inhibitor such as Celebrex may prevent the need for use of a narcotic. However, all these drugs have limited effectiveness in more moderate to severe pain and drugs specific for pain need to be used (opioids). When we look at the pros and cons of opioid use, we can see that dependence (the inability to suddenly stop the drug without experiencing side effects) is common to all opioids as is tolerance (the tendency for the drugs to work less well as time advances). Neither concept is equivalent to true addiction, which is a dangerous and unwanted psychological dependence on the drugs's effects such that individuals do dangerous and often illegal things to get access to more drug. We need to understand that short acting opioids (such as short acting oxycodone/hydrocodone--Percocet/Vicodin) give higher blood levels than equivalent doses of long-acting forms of the drugs. Those higher blood levels can play with an individual's psychic state and lead to undesired "buzz" effects. They are also often combined with acetaminophen and thus limit the doses that can be used due to the potential toxicity of the acetaminophen component. There are only a few long-acting agents available. None of them work in all patients. If effective pain management is to be done, drug screens must be carried out to make sure patients are not abusing street drugs. Insurance companies need to understand that such laboratory work is part of good standard medical practice and cover the cost. If morphine is selected as the pain medication, then heroin users may be missed since the drug screen cannot distinguish readily the morphine of the prescribed drug from the morphine metabolite of the heroin. Methadone, which many patients wish to avoid since it is used for heroin detoxification, is sometimes harder to titrate. It is also not immune from misuse and resulting physical harm. Transdermal patches can be effective for some but for others do not provide sufficiently

consistent or rapid drug titration. Long acting oxycodone (OxyContin), taken properly, will provide readily titratable levels of pain control and not interfere with drug screen monitoring. Many patients in our communities are functional today only because of the efficacy of their pain control.

There are many things that we can do to help our community. But we must remember, the answer is not to worsen the suffering of our most vulnerable neighbors. Non-malignant pain can be as severe as malignant pain. I personally have patients who have told me in the past that they would have killed themselves long ago if they could not get relief from their pain. We do not wish to be so insensitive that we force people to drunkenness or suicide to relieve what we have the power to lessen just because of a few lawless individuals. We must recognize that substance abuse is more widespread than we wish to acknowledge. It does not have a quick or a simple fix. The challenges are great and the hurdles high but we can do things that will help.

It is perhaps because of the improvements made by providers and industry that we are seeing a desperation to robbery in some communities. Falsified prescriptions have been aggressively challenged by the efforts of pharmacists to verify appropriateness and by a pharmaceutical company's initiative to help develop prescription pads that are less able to be copied or falsified. Criminal activity should be dealt with on a law enforcement basis. Quicker methods of alerting law enforcement and increased scrutiny of pharmacies will help. I would be happy to expand with specifics later.

Vigorous adherence to Board of Pharmacy/DEA rules and regulations with respect to schedule II-V drugs as well as more careful identification of individuals picking up prescriptions will be beneficial. In addition, verification of all cash payment prescriptions in schedule II will lessen pharmacy shopping and acquisition of supplies for diversion. Phone verification of first ever prescriptions by a provider for schedule II drugs, would help to ensure less filling of illegitimate prescriptions.

Required CME programs in drug prescribing and appropriate office procedures for evaluation and treatment of pain patients will help to lessen questionable prescriptions from ever being issued, again lessening diversion supplies. Boards of Registration in Medicine have been aggressive in working tirelessly to

ensure the safe and competent practice of medicine within their jurisdictions. The assistance of those Boards in helping to meet the present problems should be sought and pharmaceutical companies in the field of pain management should be asked to step up to the plate and collaborate on further solutions. Industry should be asked to continue its long-established tradition of financially supporting efforts toward provider and patient education as well as helping to develop more innovative ways to meet the needs of patients while striving to ensure the safety of the community.

Mentoring for pharmacists or physicians by colleagues having flawed procedures (under the direction of their respective boards) will improve the quality of care provided and lessen unnecessary prescribing and therefore lessen diversion supplies.

Evaluation on a nationwide basis of the work done by Purdue Pharma in Maine in developing improved prescription blanks that were more difficult to copy should be done.

We hear and read about the horror stories. We also need to hear of the patients returned to work and productivity and kept off disability because their pain was effectively controlled.

Thank you.

Yours truly,



Walter H. Jacobs, M.D.