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August 5, 2003

Re: Risk Management Plans for Modified Release Opiate Analgesics

Dockets Management Branch, HFA-305
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

To The Anesthetic and Life Support Drugs Advisory Committee:

This letter is in response to your proposed Risk Management Plan for modified release opioid analgesics that will be discussed on September 9-10, 2003. I am puzzled by the need for a Risk Management Plan when controlled-release opiate analgesics are performing clinically as they were intended, are giving Americans in pain much needed relief and are not causing harm when used correctly. If the need for a Risk Management plan is motivated by concern for individuals and families that are being adversely affected by the illicit use of opiate analgesics, it is necessary to make you aware of a much larger picture. For every person that makes the personal and self destructive choice of gaining an illicit high, even at the risk of death, there are at least one thousand people who suffer pain that is extremely disruptive. Left untreated, this pain inevitably leads to a downward spiral of desperation. People suffering pain face the specter of depression, loss of normal daily activity, loss of employment and money, loss of self-worth, potential suicide, and the list goes on. In real numbers, far more individuals and families are affected by untreated pain than are affected by illicit drug use. Tragically, their silent suffering does not provide the sensational headlines that our nation has seen surrounding the illicit use of legal opiate analgesics.

It is essential to maintain perspective when dealing with the issue of illicit use of opiate analgesics. The net result of the hyperbole that has surrounded this issue is that people who have legitimate pain are being left to suffer because physicians are now afraid to offer adequate pain relief and citizens are fearful of being characterized as addicts. Is it right to ask countless thousands of people to suffer pain because of a few individuals who select self destruction through illicit drug use? Whose needs are being met?

Public policy must be created in a balanced manner, evaluating the needs of all stakeholders. In this instance, the needs of the Department of Justice and the Drug Enforcement Agency are at direct odds with the needs of the medical community and pain patients. The DOJ and DEA want to limit access to opiate analgesics with the hope of stemming the flow for illicit uses. Limiting access to legal and effective opiate analgesics, whether by limiting who can prescribe or by limiting who can dispense these medicines, will cause unnecessary suffering and will in fact not change the demand

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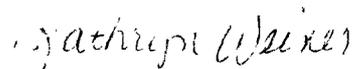
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created by those who seek an illicit high. Even President Bush has noted that the problem with substance abuse in America is not about the supply and availability, but rather the demand that some Americans have for these substances. History has repeatedly proven that prohibition is not an effective deterrent.

Drug diversion policy must be created to educate and change the drug seeking behavior at its source, the end user. The best solution for the abuse of legal opiate analgesia must be more education, not further restriction and more regulation. Furthermore, physicians must be trained how to evaluate pain complaints, how select appropriate treatment options and how to monitor safe opiate analgesic use. Sadly, few medical schools actually prepare their graduates for managing pain.

Thank you for your consideration of these comments. Your responsibility is awesome, because American look to you for insight, judgement and wisdom in providing them with safe and effective therapies. I ask you to remember the needs of the majority, not the minority, when establishing public policy regarding opiate analgesics.

Respectfully,

A handwritten signature in black ink that reads "Kathryn Weiner". The signature is written in a cursive style.

Kathryn A. Weiner, PhD
Executive Director