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Dr. Jeffrey Shuren
Associate Commissioner for Policy and Planning
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Shuren,

The Marti Nelson Cancer Foundation has serious concerns about the harm the FDA is likely to inadvertently cause cancer patients as a result of requiring implementation of Risk Evaluation and Mitigation Strategies for opioid drugs.

Unfortunately, there is a long history of inadequate cancer pain control because of under-use of appropriate pain control drugs by physicians. In some cases, this failure has been due to ignorance; but in too many cases, due to concern about government controls and procedures. Adding new REMS programs to this burden is unlikely to actually help people who are the victims of drug abuse, but it is very likely to harm patients who are the legitimate, intended "market" for these well-established, well-studied, and effective drugs.

The majority of the problem the FDA seeks to address through new REMS programs for opioids should not be the domain of the FDA, but rather of the Drug Enforcement Administration. There is substantial evidence that physician behavior and prescribing patterns are not the source of the opioid misuse and abuse problem. The problem is diversion of these drugs after they have been legitimately prescribed. The DEA investigates less than one-tenth of one percent of hundreds of thousands of physicians each year—because they have done nothing wrong. The outright theft of narcotics is the primary source of the problem of prescription drug abuse. From 2000 through 2003, nearly 28 million dosage units of all controlled substances were diverted from non-medical sources. This drug diversion is a criminal enterprise and should be addressed by authorities other than the FDA.

We are aware that the FDA receives reports of drug overdoses and drug misuse, and we agree that this is a sound basis for stepping up appropriate physician and patient education efforts. However, it is important to accept that education is not going to stop drug diversion and sale into a very profitable black market. For example, do you really believe that deliberate defeat of extended release mechanisms of long-acting opioids is a failure of education? Of course it is not, and no REMS program is going to stop such intentional misuse of these pharmaceuticals.

While it is tragic that so many individuals and families are irreparably harmed by drug abuse, the simple fact is that REMS programs will not stop the abuse of opioid drugs. An additional simple fact is that cancer patients do not need REMS programs to insure proper use of pain control medication.

If implementation of opioid REMS programs deprives cancer patients of much needed pain control, the FDA will not receive reports of the pain, suffering and agonizing deaths that directly result from unnecessarily limiting legitimate access to good, effective pain medicine. This is a serious problem that has not been adequately addressed in the public discussion focused on prevention of drug abuse.

Clearly, the federal "War on (Illegal) Drugs" has been a failure. What to do about that failure and its implications is beyond the scope of this letter. However, it would be a public health tragedy if the FDA were to react to this federal failure by depriving patients of opioid drugs for whom such drugs are an essential element of quality of life. No matter how good the intentions may be, implementation of REMS programs for these drugs, as they have been discussed so far, will have exactly that unwanted adverse effect.

Very truly yours,

Robert L. Erwin
President
Marti Nelson Cancer Foundation
www.CancerActionNow.org

cc: John K. Jenkins, M.D., Director, Office of New Drugs
Richard Pazdur, M.D., Director, Office of Oncology Drug Products
Theresa A. Toigo, Director, Office of Special Health Issues