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May 17, 2001

Ms. Kimberly Topper
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Topper:

RE: Anesthetic and Life Support Drugs Advisory Committee

I understand that a meeting will be held on June 14-15 2001 at the Holiday Inn in Gaithersburg, Maryland to discuss anesthetic and life support drugs and the use of opiate analgesics.

I have been a family physician for 25 years and have been on staff at the Catholic Medical Center in Manchester, New Hampshire for 22 years. During that time, I have served a population of patients through my practice as a primary care physician and, in addition, I have spent these 22 years managing patients with a variety of chemical dependencies and chronic pain syndromes. It is as an "expert" in these various fields that I am writing you to submit my comments to the Advisory Committee.

Patients who are chemically dependent, historically, have had a difficult time in achieving appropriate medical care and treatment. Like many chronic diseases, chemically dependent patients have periods of medical stability followed by periods of medical instability. In chemical dependence parlance these are areas of recovery followed by areas of relapse. However, when viewed in comparison to patients who have other chronic illnesses, e.g. diabetes, obesity, hypertension, people who are chemically dependent do better than those people who have "other acceptable" medical conditions.

Rarely do people who have chronic illnesses comply 100 percent to their medical regimen as a person who has chemical dependency must follow in order for them to be free of their psychological, social and physical symptoms. As a result of difficulties chemically dependent patients have, both in achieving treatment as well as finding physicians who will apply effective follow-up treatment, our society continues to create a stigma associated with chemical dependence that interferes with effective treatment. Despite the pitfalls in availability of trained physicians and providers of care, chemically dependent persons can clearly go on to have fulfilling lives that contribute to the nation's well-being. Examples of chemically dependent people who have contributed to the national health include former First Lady Betty Ford and the former governor of Texas and our current president of the United States, who has chosen not to continue alcohol use because of difficulties he experienced as a young man.

In the late 1980s, emerging from the background of chemical dependence, it became clear that a number of the patients that I was treating were chemically dependent, either on alcohol or opiate prescribed medications or narcotic street drugs or attempting to self-medicate for associated chronic pain syndromes. From that experience, I became known within the community of Southern New Hampshire as a physician willing to engage in the tough, but clear challenge, to manage patients who have had histories of chemical dependence along with histories of chronic pain syndromes and provide them with appropriate treatment.

This journey has been a difficult one for me, but mostly for my patients as they have gotten to the point of seeing themselves clear of psychosocial stigmata of the behaviors they engaged in, in order to achieve relief of their symptoms. With effective guidance and support and the use of appropriate psychotropic medication, most of these patients have been able to assume productive lives. Clearly, not all of my patients have been successful and some have continued to have problems associated with chemical dependence in the misuse of prescribed medication.

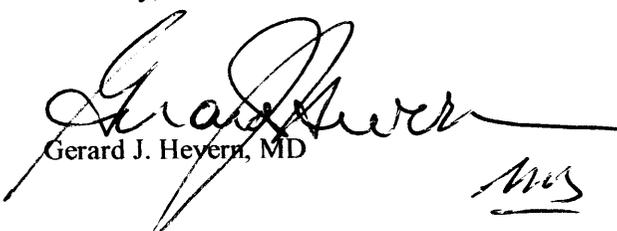
Therefore, it is my expert opinion that the general community of physicians has been poorly educated and poorly prepared for the management of both chemically dependent patients, as well as patients with both acute and chronic pain syndromes. Coincident with that is the psychosocial stigmata placed upon these patients by society, as well as government agencies, in preventing effective treatment protocols for chemically dependent patients, as well as patients who have chronic pain syndromes and clearly those patients who have both chemical dependence and chronic pain syndrome.

Rather than creating a situation in which current medications that are available for the management of chronic pain syndromes be identified as the "problem" underlying a recent surge of highly publicized difficulties with these medications, a more cautious and more reasonable approach would be to provide the foundation for effective education to physicians, reimbursement for their efforts and a reemergence of treatment facilities nationwide supported by both the government, as well as private insurance companies, for the effective treatment of both chemical dependence and chronic pain syndrome.

I suspect that in the next decade as the Genome project and the scientific ability to apply the knowledge obtained by understanding the genetic code emerges as the foundation for medical care in the United States, we will have effective tools in the identification and management of people genetically predisposed to both chemical dependence and chronic pain syndrome, as well as other physical and mental illnesses that we are only beginning to biochemically understand at this point.

Therefore, I request a measured response generated from the recent publicity concerning the unfortunate abuses and deaths that have occurred because of the misuse of chronic opiate medication. However, just as medicine faced the emergence 12 years ago of Prozac, a new class of antidepressants, with skepticism, Prozac and that class of medications has turned out to be the foundation for treatment of multiple mental illnesses.

Sincerely,


Gerard J. Heyern, MD

gjh/rlr