

LUCIO S. VILLA-REAL, M.D.

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

Dear Ms. Topper:

Oftentimes, I wish I could have been a doctor practicing in the "horse and buggy" times when no Insurance companies or governmental meddling interfered with a doctor's judgment on how to best take care of his patients.

Nowadays, doctors are so harassed by and beset with too many institutions and entities influencing his judgments and decisions and jeopardizing the management of his patients to the extent of instilling the "fear of God" in him that he is compelled to alter his regimen, often against his better judgment, simply to obey, even blindly, what the insurance companies and governmental agencies tell him what to do, fearing that non-compliance will be detrimental to his ability to maintain his practice.

This is totally against the grain of the practice of good medicine and accepted standards of care. As an example, the prescribing of long-acting Opiates in patients with chronic moderately-severe to severe non-cancer pain as is seen in Fibromyalgia, "Failed-Back Syndrome," some failed post-laminectomies, and severe Degenerative Joint Diseases, to name a few, which fail to respond to the usual non-narcotic analgesics and Non-Steroidal Anti-inflammatory Drugs, is a practice now being looked at long and hard by Federal and State regulatory agencies to the degree that doctors are backing down from prescribing these much-needed Long-acting Opiates for fear of reprisals upon their licenses by these regulatory agencies, depriving patients of the benefits and pain-relief they well-deserve. The patients are the only ones who stand to suffer, if that is what you all desire, when doctors abstain from prescribing these Long-acting Opiates.

It is true that there have been instances of abuse, addiction and dependency. I have encountered a patient who was being given as much as 200 to 400 Percocets every month by a "Pain Management Specialist" with instructions to take them "i-ii q 4 h prn for pain," which I thought was excessive and inappropriate and prone to give that particular patient a drug-dependency. I switched that patient to a long-acting Opiate and is now taking less Opiates than before.

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If a doctor takes it upon himself to practice diligently, especially in documenting the patient's needs, to include a thorough history and physical examination to determine the cause of the patient's pain, keep records of plans and prescriptions conscientiously, and keeps a tight control on the Opiates for a patient who needs it, there should be no problem or harsh criticism of his actions, much less place his license to practice at risk.

One simply has to see chronic pain-sufferers and feel for them. The problem lies in the fact that when doctor ceases to practice actively seeing patients in their offices, they merely become a bunch of paper-pushing administrators imposing harsh regulations on the practice of medicine from their stuffed chairs somewhere downtown. Another problem arises when politicians and governmental agencies, who can barely do their governmental administrations properly, begin to feel they can manage and control a field as complicated and complex as Medicine, which most of them know very little or nothing about.

In my opinion, Long-acting opiates have their proper place in the safe and optimum practice of good medicine for chronic pain-sufferers when nothing else works!

Sincerely,

A handwritten signature in cursive script, appearing to read 'Lucio S. Villa-Real'.

Lucio S. Villa-Real, M. D.