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Ellicott City, MD 21042

July 2, 2001

Ms. Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857

Dear Ms. Topper:

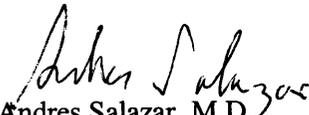
It is with much regret and trepidation that I observe how The Drug Enforcement Administration is planning to allot quotas to pharmaceutical companies to restrict the production of opioid analgesics. The cause of this action stems from data blaming opioids, especially long acting oxycodone, for a great number of deaths and an increase in the black market of these drugs.

There has been a great deal of attention generated by the media based on a few cases that resulted in negative outcomes. This snowball effect has drawn the DEA and government officials into wanting to enforce regulations that ultimately will hurt those who medically need these medications. Unfortunately, these measures do not address the fundamental problem of drug abuse and addiction. Removing a drug from the market or curtailing its production is not going to solve the social, physical and psychological problems related to addiction. On the contrary, the enforcement of restrictive laws for opioid production, prescription and dispensing will undermine not only the tireless efforts of our practicing physicians and medical societies to improve the quality of life of their patients, but also will cause undue suffering to their patients. This will take us back several years to a time when pain was ignored and our patients were completely neglected and mismanaged.

As a practicing physician I see the enforcement of these restrictions as nearsighted and unethical. We can not stop using or prescribing a good drug because a few individuals make improper use of it. Would it be fair to remove Tylenol from the market because some people around the world use this drug to commit suicide? Why not remove Aspirin from the market because of the multiple cases of fatal gastro-intestinal bleeding associated with it?

It seems to me that all this uproar regarding opioids is undoubtedly the result of the media trying to show our citizens the tip of the iceberg, pushing our DEA and government officials to make determinations that are not only unfair but unethical.

Sincerely,


Andres Salazar, M.D.