February 26, 2013

PATIENT ALLIANCE FOR NEUROENDOCRINEIMMUNE DISORDERS
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Food and Drug Administration
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Rockville, MD 20852

Re: Docket No. FDA-2012-N-1172, Impact of Approved Drug Labeling on Chronic Opioid Therapy

In reference to the July 25, 2013 petition letter to add more restrictions to prescribing opioids to those with non-cancer pain, we want to bring to your attention that this will put additional burdens and add more barriers that will prevent chronic pain patients from the treatments that reduce their suffering. The solution is in physician education of how to prevent and detect drug abuse and in improving adherence to current labeling guidelines.

While we understand the concern over opioid abuse, we want to echo the words of Dr. Phillip Pizzo, who chaired the committee that wrote the 2011 congressionally mandated Institute of Medicine (IOM) report titled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research."

"There's abuse on both sides," Pizzo told The New York Times. "There is abuse that occurs when individuals are drug-seeking and abuse that occurs in that people who need pain medications may not have access because physicians won't prescribe or the state has regulatory barriers." Already, under current FDA labeling requirements, the report says, "Regulatory, legal, educational, and cultural barriers inhibit the medically appropriate use of opioid analgesics."

Putting even more barriers between chronic pain patients who need the medication and use it responsibly because others abuse it is not the answer and will produce other problems: increase in suffering and possibly an increase in pain-related suicides. The IOM report states, "Given the burden of pain in human lives, dollars, and social consequences, relieving pain

should be a national priority." Notice, relieving pain should be the priority, not limiting access to pain treatments.

Pain treatment options today are limited and complex. Some patients try a variety of treatment protocols before they find the one that provides best outcome possible for them. As the IOM report says, "Because pain varies from patient to patient, healthcare providers should increasingly aim at tailoring pain care to each person's experience ..."

Cookie-cutter and arbitrary limitations do not take into consideration the individual needs of each patient and will increase the suffering of law-abiding and responsible patients who seek relief. For chronic pain, physicians most often already try other pain treatments first. However, allergies, low tolerance to other therapies, comorbid complications, other medications or adverse reactions leave just higher-dose opioids as the only treatment that works for some non-cancer chronic pain patient patients. The pain-control-educated physician who knows the patient's disease and treatment history is in the best position to determine whether and how long a patient should be on opioid pain medication and how much the dose should be.

Already, we have had reports of Drug Enforcement Administration agents calling doctors questioning why they are prescribing opioids instead of other treatments. A DEA agent is not trained in clinical care and should not be second-guessing the judgment of a physician when each patient's circumstances are unique. Similarly, we have had reports of pharmacists who refuse to fill opioid prescriptions. This climate of fear is already preventing the best practices that lead to optimal outcomes and limiting access to the pain medication some patients need. We are asking that the FDA not increase this problem.

The petitioners had three opioid labeling change requests: strike the term "moderate" from the indications from non-cancer pain, add a maximum daily dose equivalent to 100 milligrams of morphine for non-cancer pain, and add a maximum duration of 90-days for continuous (daily) use for non-cancer pain.

This discrimination against those with “non-cancer pain” is unjustified. Neuropathic pain can be just as debilitating, possibly more. This differentiation hints of bias, as though neuropathic pain, such as pain from fibromyalgia, myalgic encephalomyelitis / chronic fatigue syndrome, Gulf War illness, Lyme disease, multiple sclerosis or lupus, are not experiencing real pain and do not deserve aggressive interventions. This is very concerning because a 2010 study showed female Danish fibromyalgia patients are ten times more likely to commit suicide as healthy people, which is similar to that seen in other chronic pain patients. Thus, chronic pain is occasionally deadly, no matter whether it is caused by cancer or other conditions, and thus should be relieved with whatever medication and dosage is effective and tolerable.

Additionally, moderate pain is subjective to the patient, but is often limiting the patient’s function. If opioids are the most effective treatment for a patient’s moderate pain and is tolerated, then that is what the patient should receive. In the case of fibromyalgia, “Opioids can provide enough pain relief that the patient is willing to do the physical activities and exercises that will help their FMS,” said Arizona’s Dr. Jennifer Schneider, who is certified in Internal Medicine, Addiction Management and Pain Management. Whether a patient with moderate pain would benefit from opioid use is a decision best left to the pain-control-educated physician and the patient with the goal of increasing patient function and reducing suffering.

While chances of overdose increases when a patient is prescribed opioid doses higher than what is equivalent to 100 mg of morphine, we also don’t want those with intractable, severe pain to be suffering, possibly to the point of suicide, because they are not given the dose appropriate for their pain. Such a limitation will only increase the already widespread problem of undertreating pain. The pain-control-educated physician and patient know the dose that is appropriate for their situation to increasing function and lessening suffering.

Requiring a patient to see a physician each month for opioid prescriptions can be extremely burdensome. Some patients must travel great distances to find a pain-control-educated physician willing to prescribe the medicine that relieves the patient’s pain. This is especially true for those that the IOM report describes as currently having a geographic barrier by living in

rural communities. Putting up more obstacles to law-abiding, responsible patients and adding to their time and financial burdens because of the abuse of others is not solving a problem, but is increasing another problem. Some of these patients are homebound or are financially destitute, depending on others for transportation to physician visits. This change may even mean these patients can't get their medication because they are unable to make monthly doctor appointments, thus increasing the suffering and increasing chances of suicide.

Putting a 90-day limit on opioid prescriptions is of most concern when a patient's options for pain relief are limited. The FDA should make guidelines that reduce "physician shopping" or "pharmacy shopping" for pain medication. But, putting a 90-day limit on a law-abiding patient who needs opioids for pain relief will encourage these behaviors and turn the desperate patient to possibly violating the law in order to relieve their suffering. This is surely not the result the FDA wants. Thus, the length of dosage is best left in the hands of the pain-control-educated physician and patient with the goal of increasing patient function and reducing suffering. The IOM report says that "Optimal care of the patient should be the focus."

Both the proposed 90-day limit and dosage limit also increases the risk of "pseudoaddiction," which is when the undertreated patient displays behaviors falsely attributed to addiction. These behaviors are stopped when adequate pain treatment is provided. A circle of pseudoaddiction behavior and physician withholding medication can spiral to the point of patient taking drastic efforts to relieve their suffering.

The FDA is responsible for making sure a drug is safe and effective according to its labeled use. Studies that associate increase in overdoses do not attribute these to patients who followed the current labeling. Only when an opioid is misused or abused do we see a chance of overdose. Thus, the current labeling, when followed, is safe.

Additionally, the American Geriatrics Society wrote that opioids are safer than non-steroidal anti-inflammatory drugs. They "determined that clinicians caring for patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should consider opioid therapy if acetaminophen does not alleviate the pain," said the AGS in an April

2012 statement paper. “The AGS is deeply concerned that public policy may create barriers that will further limit older adults’ access to pain medicine and, ultimately, will lead to more frail elders living in pain as our population ages.”

Thus, denying the safer opioids to chronic pain patients may increase the high-dose use of other medications, such as non-steroidal anti-inflammatory drugs or steroids, which lead to organ damage and deaths. “Unlike NSAIDs, opioids do not cause GI bleeding, hypertension or organ toxicity,” said Dr. Schneider. From a safety standpoint, then, opioid use for pain relief should be just as accessible as NSAIDs and steroids.

Obviously, then, the primary reason for the suggested additional restrictions is fear of opioid drug abuse or addiction. Preventing drug abuse and addiction in chronic pain patients is best accomplished by physician education risk factors and abusive behaviors instead of adding more barriers to the law-abiding chronic pain patients and adding to their suffering and expenses.

What the FDA can do:

The best solution to the opposing goals (reducing opioid addiction and providing appropriate pain treatments) is physician education. The IOM report says that health profession education should “improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.” This would include how to prescribe the dosage to prevent the patient becoming tolerant. This also includes how to monitor patients on opioids to ensure abuse does not develop.

The IOM report said physicians can do the following to properly monitor patients on opioids:

- Analyze patients for psychosocial, family history and other factors that contribute to a risk of abuse.
- Monitor patient for aberrant behavior that may indicate abuse.
- Random urine drug screening and pill counts for patients a risk.

The IOM says that few primary care physicians prescribing opioids for chronic non-cancer pain appear to be using urine testing or other strategies to reduce risk of opioid abuse.

Until the nation has more pain specialists, the FDA can ensure access to adequate pain treatment and reduce abuse and overdose by requiring manufacturer education materials to physicians that include the above recommendations for monitoring patients prescribed opioids.

Educating physicians about how to responsibly prescribe opioids instead of imposing arbitrary limitations will accomplish the goal expressed in the April 2011 White House comprehensive action plan on prescription drug abuse that notes that "… any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use."

The proposed changes will not ensure access for legitimate use; instead they restrict it (dosage and period) even for legitimate pain relief in law-abiding sufferers. Thus, we ask that you reject the petitioner's request to change the labeling on opioids.

Sincerely,

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