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Commentary

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'The Answer Certainly Does Not Lie With Current Opioids': An Interview With Lynn Webster, MD

Part 3 of 3

In this issue, *Pain Medicine News* completes its three-part series with Lynn R. Webster, MD. In this Q&A, he addresses the third goal for his presidency of the American Academy of Pain Medicine: investigating new treatments that are more effective and safer than current options.

Pain Medicine News: **Why is this goal so important, and what new therapies do you see with potential to improve safety and effectiveness?**

Dr. Webster: The need for safer pain therapies is an imperative. Over the past year, we have seen how epidural steroids can cause dozens of deaths and permanent neurologic deficits due to meningitis. And the challenges of safely and effectively prescribing opioids continue to daunt the best efforts of pain specialists and primary care clinicians. Some patients do well on opioids, but opioids bring risks to individual patients and to society that must be addressed. Over-the-counter medications also can cause harm. The FDA has cited acetaminophen as the leading cause of acute liver failure in the United States, and deaths from gastrointestinal bleeding linked to nonsteroidal anti-inflammatory drugs (NSAIDs) rival deaths from opioids, according to some estimates. The cardiovascular effects of NSAIDs must also be considered. Less frequently but no less significantly, spinal injections and neuromodulator systems have caused paralysis and other severe complications. A patient seeking relief from unremitting, severe pain shouldn't have to pay such a terrible price, but the fact is all therapies have risks. Not treating the pain is also risky, as patients can fall into patterns of behavior and states of mind that effectively curtail their involvement in society. In some cases, the risk of untreated pain can make a patient desperate enough to take his or her own life.

Over the past two decades, truly innovative advances in pain therapies have been minimal. Providers have been forced to use symptom-modifying medications and interventions. Even the multidisciplinary treatment programs considered to be the gold standard approach to

treating moderate to severe chronic pain are, for the most part, palliative. Yet many of us in the pain field now believe pain is a disease that requires disease-modifying therapies. We need breakthrough therapies with a new focus on the mechanisms of pain, which are most complex. We need to find ways to heal injured nerves, reverse central sensitization and abolish inflammatory disorders, whether they are central or peripheral. These needs are only the beginning.

PMN: **Given the reality that opioids will continue to be a necessary part of the arsenal of pain therapies, what message do you see in recent actions from the FDA, which approved Purdue's Citizens' Petition, while rejecting Endo's? How will this affect the development of abuse-deterrent formulations going forward?**

Dr. Webster: Abuse-deterrent formulations are a small step toward safer therapies, but let's be clear: Opioids are fraught with problems, even if they have abuse-deterrent properties, so we need more than safer reformulations. This is not to say that this step is not important in making extended-release formulations safer.

As for the petitions, I do not have access to the data that led to the FDA decision allowing Purdue to claim the reformulated OxyContin has abuse-deterrent properties while refusing to block generic forms of the Endo product. My understanding is that the FDA saw differences between the safety advantages offered by one product versus the other. My hope is that eventually all opioids, both extended-release and immediate-release formulations, will have abuse-deterrent properties. But until there are replacements for opioids as strong analgesics and the will to offer patients these replacements at prices they can afford, we will continue to see problems with opioids.

PMN: **Some patients do achieve greater control of pain and improved function from opioids while never misusing their medications. How much should those people be asked to compromise in order to introduce less abusable formulations to market? For example, you mentioned price. Are the newer formulations going to cost patients more out of pocket?**

Dr. Webster: Of course, this is the big question. We have a serious public health problem with opioids, so there may need to be a public health solution where only opioids with abuse-deterrent properties are allowed on the market. Think of a comparison to the safety belts in a car that are now mandatory, regardless of the driving record of the driver. All purchasers of cars are paying for this safety measure, regardless of the amount they drive and their risk in driving. In the same vein, it may cost patients a bit more for abuse-deterrent formulations, but there may be overall less cost to the system if we see less diversion and nonmedical abuse of medications. Part of the solution would require insurers to rethink their coverage options for abuse-deterrent opioids and also for alternatives to opioids. The Centers for Disease Control and Prevention (CDC) reports that nonmedical use of prescription opioids costs health insurers about $73 billion every year, so there is obviously enormous will to do something about the problem [*MMWR* 2011;60;1487-1492]. We must make sure that the voices of patients who suffer every day with terrible pain are not lost as these changes occur. Those

patients who have done nothing wrong should not be made to suffer while solutions to the prescription drug crisis are found.

PMN: **A recent movement has sought to limit the FDA-approved labeling for opioids for dosage, duration and indications related to chronic, noncancer pain. Is this likely to improve safety, or do you see problems?**

Dr. Webster: If the proposed changes were implemented, I suspect far fewer opioids would be prescribed; therefore, fewer would be diverted and, in time, we would see fewer people being treated for opioid abuse and addiction. However, the changes also would make it more difficult for people in pain to receive their medications, whereas people with addiction or the desire to abuse substances would likely shift their drug-seeking activities elsewhere—perhaps to illegal street opioids. This is already happening in some areas, including New England as reported in *The New York Times*. Many who have been abusing prescription opioids are moving to heroin.

PMN: **When you talk about safety with opioids, the conversation always turns to methadone. What needs to change in the delivery of methadone for the treatment of chronic pain?**

Dr. Webster: According to the CDC, one-third of unintentional opioid-related overdose deaths are associated with methadone, but methadone represents only about 2% of all opioids prescribed (http://www.cdc.gov/vitalsigns/MethadoneOverdoses). This demonstrates that methadone is more risky than any other opioid, and that there must be more caution with prescribing it and consuming it.

One thing that needs to change is the casual coprescribing of benzodiazepines with methadone and other opioids. The recent CDC report on women and overdose [*MMWR* 62;537-542] revealed a high involvement of benzodiazepines in many deaths. Second, too often payors will place methadone as a preferred opioid because it is inexpensive. Methadone should never be a first-line or preferred option for chronic pain. If payors wish to list methadone as a preferred drug, they should pay to educate physicians and other providers on how to safely prescribe it.

PMN: **What about pain-related research that does not involve opioids?**

Dr. Webster: According to the 2012 Institute of Medicine report, “Relieving Pain in America” (National Academies Press), the spending on pain-related research pales in comparison to the need. Despite the low investment, some very promising research is being done. Recent discoveries drawn from central nervous system imaging are very exciting. Research into the genetic and molecular levels promises a wealth of new understanding. Yet these studies are complex, and it is still too early for the development of therapies from such studies to have much impact on the worst types of pain.

PMN: **Is the goal to replace opioids altogether or to replace them with safer versions?**

Dr. Webster: I think the goal should be to find safer but also effective therapies that are not addictive and do not cause serious side effects like respiratory depression, but that are highly effective both for short-term and long-term pain. Most opioids are classified as μ-agonists. It may be possible for a μ-agonist to meet these criteria, but that dream has long eluded investigators. The answer certainly does not lie with current opioids. So eventually we need to replace the opioids we have today by discovering new μ-agonists that don't cause the same problems or non–μ-agonists that are as effective as opioids. What we also need—and right away—are new health care delivery models that incorporate the best evidence from multiple specialties, including psychosocial, biobehavioral, pharmacologic and nonpharmacologic treatments. This will involve cooperation at the research level and at the delivery-of-care level.

PMN: **What public and patient health message is the most important for everyone to hear, in your opinion?**

Dr. Webster: If I could use my platform as AAPM president to disseminate one message, it would be that government and private payors must not list methadone as a preferred analgesic. Methadone should be second- or third-line only, and all providers must demonstrate that they know how to use it before prescribing. Methadone has been part of my public message since at least 2004, and I have spoken and published extensively on this subject, trying to raise awareness of the need for caution. Maybe there should even be licensing to prescribe methadone for pain in the same way practitioners are licensed to provide medication-assisted addiction treatment. My hope is that AAPM will offer such a course by year's end, so that providers can earn continuing education credits and a certificate of training. The methadone issue is that important and AAPM can save lives with such a training program.

In addition to serving as AAPM president, Dr. Webster is medical director of CRI Lifetree Research, Salt Lake City, Utah.