



Presentation to the Joint Meeting of the Anesthetic and
Life Support Drugs Advisory Committee and the Drug Safety and
Risk Management Advisory Committee
By Lennie Duensing, Executive Director of the
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My name is Lennie Duensing, and I am the Executive Director of the American Academy of Pain Management (the Academy), the largest professional pain management organization in the country. I am here, at the Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to speak on behalf of our Board of Directors, the 5,000 clinicians who are members of our organization (approximately 69% of whom are prescribers and pharmacists), the 76 million Americans who suffer with chronic pain, and the 10 million patients who are taking prescribed opioid analgesics to relieve it (1).

Although the Academy supports an interdisciplinary/integrative approach to pain management—one that encourages clinicians to employ several modalities into a treatment plan (including non-medication therapies)—we recognize that opioid analgesics remain the most effective medications for relieving pain, restoring function, and improving the quality of life for the millions of people who live with pain. These medications are an indispensable part of the prescriber's pain management armamentarium.

When I began working in the field of pain management, over a decade ago, it was already clear that chronic pain had reached epidemic proportions and was arguably the nation's number one public health problem. Little did we anticipate that another societal and public health crisis would emerge, and that is, of course, is the diversion, misuse, and abuse of these valuable medications. It is a staggering problem—one that pits good medical practice against effective law enforcement—and until it is solved, doctors will remain fearful of prescribing opioids and law enforcers will remain suspicious of doctors who prescribe them. But above all, the Academy recognizes that one of the most profound and tragic consequences of the increase in illicit use of opioids, is that the focus has shifted away from patients living with intense and debilitating pain—to those who use them to get high. So I ask you—who and what is driving our agenda? Is it the practice of medicine or the commission of crime?

Misunderstandings and fears about abuse and diversion, addiction, and regulatory scrutiny abound among prescribers. We, at the Academy, know this, not just from studies—we hear this directly and regularly from our members, and it is the number one topic requested in our annual educational needs assessment.

For this reason, I am here today to briefly discuss two issues that affect our members: The first is the need to have the widest variety of pain medication treatment options available to clinicians, which includes the availability of safe and effective abuse-deterrent opioids. Abuse-deterrent opioids may increase the likelihood that clinicians would prescribe these medications for legitimate pain patients. These medications also represent a technology that, in fact, has been long-awaited by: prescribing clinicians, pain patients, law enforcers, and by the FDA.

The second reason for my appearance here today is our concerns about Risk Evaluation and Mitigation Strategy (REMS). The American Academy of Pain Management acknowledges and applauds the FDA's efforts to ensure that opioid analgesics are available for chronic pain patients, and its concurrent efforts to confront the problem of non-medical use of these medications. But while the Academy recognizes the need for risk management, we are concerned that REMS plans that may include a multitude of requirements for prescribers, pharmacists, and patients, may prove to be so complex, so costly, and so time-consuming, that they, in and of themselves, will prove to be a significant barrier to optimal pain management. We have seen, for example, in states where there have been Prescription Monitoring Programs, practitioners were more likely to prescribe less Schedule II medications in favor of medications that had a lower risk, but were not nearly as effective (2). Such a strategy *may* reduce diversion and abuse of these medications, but an unintended and far more serious consequence of this may be that it fuels an already immoral, unnecessary, and unacceptable health crisis, and that is the undertreatment of chronic pain.

In addition, rather than the product-by-product approach the FDA is currently employing, we suggest a class-wide REMS plan, where the same standard tools would be used for all products with the same risk level.

And finally, we strongly recommend that the FDA bring together a panel of interested and affected stakeholders (such as prescribers, pharmacists, professional organizations, and patient advocacy organizations) to define desirable outcomes and how they will be measured, and to thoughtfully consider and address the most effective ways to meet the dual objectives of ensuring access to the full range of the necessary pain medications while reducing the risks associated with abuse and diversion. The Academy welcomes the opportunity to be involved.

Thank you for listening.

References

1) Parsells Kelly, J, Cook SF, [Kaufman DW](#), et al. "Prevalence and characteristics of opioid use in the US adult population." *Pain*. 2008 Sep 15;138(3):507-13

Note: Researchers from Boston University's Slone Epidemiology Center have found that in a given week, over 10 million Americans are taking opioids **for pain**, and more than 4 million are taking them regularly.

2) Twillman, Robert. ASPI website at: <http://aspi.wisc.edu/newsletter/0605.html>

About the American Academy of Pain Management

The American Academy of Pain Management (the Academy) is a non-profit organization that serves a broad range of clinicians who treat people with pain through education, information, and advocacy. Founded in 1988, the Academy has approximately 5,000 members and is the largest interdisciplinary pain organization in the United States. The Academy is also the only pain management organization in the nation dedicated to promoting an integrative model of pain care—one that brings together conventional treatment and "complementary and alternative" approaches.