

May 27, 2009
Food and Drug Administration (FDA)
Opioid Analgesic and Risk Evaluation & Mitigation System (REMS) Public Meeting
Oncology Nursing Society Testimony
Delivered by Leslie Greenberg, RN, MSN, OCN, and Karen Kaiser, PhD, RN-BC, AOCN, CHPN

Below is a synopsis of the testimony delivered to the FDA on May 27th, 2009 at the Opioid Analgesic and Risk Evaluation & Mitigation System (REMS) Public Meeting. ONS will submit written comments to the FDA ahead of the June 30th, 2009 deadline.

- ◆ My name is Leslie Greenberg and I am an oncology nurse and the Health Policy Manager for the Oncology Nursing Society (ONS). On behalf of ONS, the largest professional oncology group in the United States, composed of more than 37,000 nurses and other health professionals, we thank you and the FDA for this opportunity to present our concerns and recommendations regarding the agency's efforts to develop and implement a Risk Evaluation and Mitigation System (REMS) for opioids.
- ◆ ONS exists to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer. To that end, the Society works to ensure that all people with cancer-related pain have access to the quality pain and symptom management care, services, and therapies they need and deserve.
- ◆ We represent the range of nurses involved in the delivery of cancer care and pain management, including registered nurses who administer pain medication, and advanced practice nurses, such as nurse practitioners, who prescribe and administer pain medication. In addition, our members provide patient support and education throughout the course of therapy, with a particular focus on ensuring that patients and their family understand how to engage in the safe and effective management of pain.
- ◆ ONS believes that all people with legitimate need must be assured access to the pain medication and therapies that they and their health care providers deem most appropriate. Undertreated pain is a significant public health problem, and policies and programs must ensure that people with legitimate need have unencumbered access to the relief they deserve.
- ◆ We recognize and appreciate that with the potential for abuse, our nation must maintain appropriate, yet reasonable, practices and regulations to ensure that these drugs do not fall into the wrong hands and are not abused.
- ◆ We commend the FDA for convening these public meetings and engaging in a dialogue with health professionals, manufacturers, and patient advocates to ensure that concerns are addressed.
- ◆ We share the FDA's goal of balancing access for legitimate patients, with the need to prevent and reduce misuse, abuse, addiction, and overdose deaths associated with opioid analgesics.

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- ◆ As an evidence-based, outcomes driven organization, ONS believes that a key focus of FDA's effort to create a REMS for opioids must begin with a clear understanding of where and how individuals are accessing opioids; this is essential to ensuring that the interventions FDA designs and implements are targeted to the right areas.
- ◆ I would now like to address a few of the questions posed by FDA in the request for public comment.

Are other REMS elements necessary to support the safe use of approved opioids?

Yes, ONS urges FDA to study the issue further and collect additional data, prior to launching a REMS nationwide. ONS believes we need to clearly identify the problem before we begin an intervention.

- ◆ In the 2007 National Survey on Drug Use and Health data, referenced by FDA, as the basis for the REMS, the survey found that of the individuals who reported that they took an analgesic for non-medical use (not prescribed for the person or taken only for the experience/feeling it caused):
 - 56.5% received the pain reliever from a friend or relative (for free);
 - 14.1% bought (8.9%) the drug from a friend or relative; and
 - 5.2% took/stole (5.2%) the drug from a friend or relative

The Survey did not specify/report what percent of the individuals who were the "source" for the pain medications had obtained them for legitimate purposes.

- ◆ Our representative at the May 4th stakeholder meeting asked whether or not FDA had additional information about the "sources" of the opioids and/or if the FDA had plans for additional study in this regard. We are concerned that no one from the agency who was present indicated there were plans for additional research.
- ◆ ONS believes that additional research should be conducted in advance of the design and implementation of an opioid focused REMS. We believe that additional follow-up questions should be asked of individuals reporting non-medical use of prescription analgesics to determine the particular diversionary paths, which in turn, would help identify the necessary points for public policy interventions.
- ◆ First, if the friends/relatives "source" had legitimate needs/uses for these analgesics, and were in turn, giving their prescription drugs to their friends or relatives, or were having their

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drugs stolen from them, then these patients with legitimate use likely need additional education regarding: (1) how to ensure the safe storage of their medications, and (2) the dangers of providing the drugs to others. However, if these friends/relatives were misusing or abusing the system to secure drugs for their friends and relatives, there are different policy solutions and interventions necessary to ensure that these prescription drugs only are provided to patients with legitimate needs.

How restrictive a system should be designed?

This is the key issue – we are not certain that a REMS will “solve” the problem. We maintain that REMS is unproven, and we are concerned that the burdens will outweigh any benefits. ONS recommends piloting any REMS first, before nationwide implementation. We also feel that state prescription drug monitoring systems should be reviewed/studied and evaluated for lessons learned and other factors that might be useful in the design of the REMS.

Metrics used to assess its success?

As Dr. Dal Pan stated at the May 4th meeting, FDA has never developed a program like this before, under this new authority. As such, ONS recommends piloting any REMS first, before nationwide implementation, in order to develop, define, and refine metrics to evaluate effectiveness and to identify challenges and allow for corrections and improvements to be made.

- ◆ We need to determine the areas/types of patients where diversion is occurring and then monitor those areas for change. For example, we need baseline data from surveys about the number of legitimate patients who are giving prescription pain drugs to friends and families and then do follow-up surveys after implementation of education and other REMS elements to determine if the percentage/numbers change over time.
- ◆ We also feel that the system should include other metrics to pick up problems with undertreated pain, barriers to access for legitimate need, prescribers fear of prescribing appropriate medication or of the burden any training may cause (also what if prescribers choose not to be trained) and other challenges that patients may face as an unintended consequence of the REMS.

Conclusion

- ◆ Thank you again for this opportunity. We will be submitting written comments to the docket. Please know that ONS and our members stand ready to work with FDA to ensure balance between ensuring appropriate access and preventing misuse and abuse of opioids.

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Introduction

- ◆ My name is Dr. Karen Kaiser and I am pleased to be here as a representative of the Oncology Nursing Society. I am a PhD prepared, pain and palliative care oncology nurse and have been worked in pain management since the mid-1980s. I helped to develop the pain and palliative care service at the University of Maryland Medical Center and have previously chaired the Maryland Pain Initiative.
- ◆ When pain is severe, it interferes with activities and quality-of-life; diminishing physical, psychological, and interpersonal well-being. Under-managed pain often results in emotional and economic consequences, both of which have long-term costs to affected individuals and their families.
- ◆ Although considerable progress has been made to improve the adequate treatment of pain through efforts at educating health care professionals and the public, studies show that some patients with cancer receive inadequate or no treatment for pain.
- ◆ While surgery, radiation, and chemotherapy may be used to control the pain, by shrinking the tumor, drugs such as non-opioids, opioids, and adjuvant medications are the mainstay of pain treatment.
- ◆ The role of opiates in treating pain and suffering has been validated through clinical studies. It is, indeed, an unfortunate reality that this class of drugs, which has the potential to alleviate pain and suffering, also has the potential to be abused. Studies have shown, however, that very few people who are prescribed these drugs for legitimate use go on to abuse them.
- ◆ ONS believes it is essential that improved quality-of-life through expert pain control be available to all who have a legitimate medical need, and that such patients have access to the pain management therapies that their health professionals believe are most appropriate for them.
- ◆ As my colleague Leslie Greenberg noted, ONS feels that it is premature for the agency to implement a REMS for opioids nationwide. However, irrespective of whether the FDA proceeds with a pilot or a broader effort, there are a number of areas in which we wish to comment and make recommendations.
- ◆ Overall, we urge FDA to ensure that the development and implementation of REMS for opioids maintains the careful balance between ensuring access for legitimate patients and reducing and preventing misuse and abuse.

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- ◆ I now would like to address a number of the questions posed by FDA in the request for public comment.
- ◆ First, if a REMS were to be created, a single REMS program is preferred, instead of a patchwork of product specific, DEA schedule specific, dose specific, or formulation specific systems. It also should be the same program for all health professionals – prescribers, dispensers, etc. – as well as uniform for all indications/diseases/conditions.

Type of education and how certify education/training for prescribers? Type of education and how certify education/training for dispensers and those who administer?

- ◆ ONS strongly recommends that FDA consider educating prescribers, dispenser/health professionals by providing the following:
 - guidelines – developed in conjunction with a range of health professionals, including nurses – for practice that will assure access to opiates, based on sound clinical judgment and patient need, while increasing early recognition of problem behaviors;
 - information regarding how to identify non-legitimate patients, how to identify patients who have addiction problems, and how to effectively discuss with patients the importance of safe storage, safe disposal, and the responsibility that comes with opioid use – balancing the message of reassuring the legitimacy of opiates in treating pain, while giving guidelines regarding safe use and prevention of diversion and/or abuse;
 - specific patient education and support information and materials to disseminate to the patients for whom they prescribe opioids – standard information provided to patients that is culturally appropriate (health literacy);
 - a system to return dispensed opioids that are no longer needed and education of providers about this mechanism.

FDA needs to assure that any federal publications and REMS-associated information regarding opioids delineate clearly between substance abuse and legitimate pain management in acute pain, cancer pain, and chronic pain, as the evidence that addiction is very rare in patients who have pain should be acknowledged more widely.

We also encourage FDA to consider leveraging existing prescription monitoring programs to ensure that there are not duplicative or conflicting systems in place related to opioid prescribing.

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How to certify?

There needs to be easy, accessible one-time internet-based training for which continuing education credit is given to all health professionals who dispense, prescribe, and/or administer.

What education should be provided to patients and should the system ensure that such education is provided?

Ideally the prescriber/individual administering the drug should discuss with patients the importance of safe storage, safe disposal, and the responsibility that comes with opioid use. In addition, patients and their caregivers should be given specific written patient education and support information and materials (culturally and literacy level appropriate) that reinforces this “teaching.”

However, one challenge to delivering this education is that such a teaching requires, typically, between 15 and 30 minutes (depending on the learner/patient/family and the type of drug) of one-on-one time with the patient and, is not reimbursed; payment drives practice and with the existing pressures on health professionals, due to shortages of staff, limited time, and other challenges, few providers have the time and resources to provide such an educational session, short of being reimbursed specifically for it. ONS recommends reimbursing health professionals for their time doing education with patients and family members – coding and charting helps build documentation for the provision of the education (allow a higher level visit code).

Are other REMS elements necessary to support the safe use of approved opioids?

The issue of safe and appropriate disposal of opioids is one that must be addressed. ONS recommends that disposal and/or “take back” programs must be developed to help patients/family members with unused opioids dispose of them in a safe way that ensures the left-over drug does not fall into the wrong hands. A program, combined with patient education, should decrease the number of unused opioids remaining in people’s medicine cabinets at home, where they can be misused, diverted, or otherwise abused.

Conclusion

On behalf of my patients, their families, and my oncology nursing colleagues, thank you very much for this opportunity to provide testimony on this critical public health issue.