

**Presentation by
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Safety and Risk Management Advisory Committee
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Good morning and thank you for allowing me this opportunity to share the community pharmacy perspective regarding the FDA's proposal for a class-wide opioid REMS. I am Ronna Hauser, Vice President of Policy and Regulatory Affairs at the National Community Pharmacists Association (NCPA). NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies. First and foremost, NCPA applauds the FDA for making the process that led to this joint advisory committee meeting a transparent one.

Proposed Class Wide REMS

As patient care and safety are a top priority for community pharmacists, we continue to stress the importance of patient access to therapy while safeguarding against potential for abuse and misuse. We do not believe that REMS should interfere with the practice of medicine and pharmacy, and also have concerns regarding the potential proliferation of REMS programs. With that in mind, NCPA does support the FDA's proposed REMS, as it promotes patient safety without restricting distribution or requiring a physician or patient registry. We also agree that the burdensome logistics of registering the nearly 4 million patients currently using long-acting opioids would create a large number of prescribers and pharmacies who would potentially opt out of the program.

In addition, we applaud the FDA for their decision to not include immediate-release products as part of the REMS, as the burden to the system would be too great. The proposed approach represents the most feasible way to more easily implement a class wide REMS into practice settings, and at this time we feel that a more robust plan is not warranted.

Prescriber and Patient Education

NCPA supports the FDA's recognition of the prescribers' role to educate patients regarding medication use, storage, and disposal, and the use of a patient information sheet.

Though not required by FDA, we also want to encourage that the community pharmacists' role in patient education be considered, and strongly recommend that whatever components of REMS are provided to the patient via the prescriber be made known to the pharmacist as well. This continuity of care will attribute to the best outcomes and overall patient education.

We agree with the proposal that patient education should initially occur at the physician level. At the time of the office visit, the physician can examine patients to determine whether opioid therapy is appropriate and monitor for any signs of abuse. When the patient then visits their community pharmacy, the pharmacist provides valuable reinforcement of the physician's education through appropriate counseling.

Lastly, NCPA would like to reiterate our support for the creation and use of a single, FDA-approved document that would be distributed with these products to replace existing written information currently distributed by pharmacies, which will help to decrease the burden caused by the abundance of product specific Medication Guides. We appreciate the Agency's movement in this direction.

In conclusion

Once again, NCPA applauds the FDA for moving forward with a sensible REMS approach and would like to encourage the FDA continue to involve community pharmacists in the creation of these programs. Thank you for your time.