

**Presentation by  
Ronna B. Hauser, Pharm.D.  
Vice President, Policy and Regulatory Affairs  
National Community Pharmacists Association**

**Independent Community Pharmacy Perspectives on the  
Proposed Class-Wide REMS for Opioids  
At the FDA Public Meeting on Risk Evaluation and Mitigation Strategies for  
Certain Opioid Drugs; May 27 & 28, 2009**

74 Fed. Reg. 17,967 (April 20, 2009) [Docket No. FDA-2009-N-0143]

Good afternoon and thank you for allowing me this opportunity to share the community pharmacy perspective regarding 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, pharmacy franchises, and chains.

I would like to provide the following general overview of the community pharmacy REMS perspective. Community pharmacists help to manage patient's often-complex medication regimens and positively impact health outcomes each and every day. It is important to note that in the provision of care process, pharmacists have standard workflow procedures that ensure prescription medications are safely delivered to their patients. To date, community pharmacy's experience with REMS have been challenging due to the lack of a common design or platform surrounding such programs as iPLEDGE and the Clozaril registry. Medication Guides have not provided the solution some had hoped. That is why NCPA is a strong advocate for the creation and use of a single, FDA-approved plain language document to replace existing written information distributed by pharmacies. NCPA has joined our pharmacy and patient care partners on a citizen's petition urging the FDA to issue guidance permitting pharmacies to distribute such document. In addition to the

need for a standard REMS platform, community pharmacy urges that REMS not become a standard of practice, as continuity of patient care may be severely compromised.

I will now respond to FDA's specific questions.

### **Certification of pharmacists**

Regarding certification and education of pharmacists that dispense certain opioid drugs, NCPA asserts that pharmacy certification requirements are unnecessary and proper education already occurs through a rigorous pharmacy school curriculum and required continuing pharmacy education. If FDA does require certification for pharmacists, then education should be allowed to be provided by pharmacy associations, who are experts in developing training and certification programs. In addition, any provider of continuing pharmacy education must be accredited by the Accreditation Council for Pharmacy Education (ACPE).

### **REMS patient education**

Patient education in relation to REMS should initially occur at the physician level, as this is the optimal time to educate a patient as to why a specific medication has been prescribed, expected risks and benefits, and the overall goals of therapy. The provision of a single, FDA-approved plain language document that I mentioned earlier could also be presented to the patient at point of prescribing. When the patient then visits their community pharmacy, the pharmacist provides valuable education through appropriate counseling on effective and safe use of the medication. Technology currently exists that allows for patient education in the pharmacy through a nationwide, systemized, platform.

### **Restrictive REMS systems**

It is worthy to note that community pharmacies are highly regulated in each state by Boards of Pharmacy and other administrative bodies in addition to being regulated by the DEA. It is therefore NCPA's position that any state- and DEA- licensed pharmacy should be eligible to

dispense opioid products. Not only do restricted distribution programs interfere with patient access to prescribed therapies, they may limit legitimate access to long acting opioid products and shift illegitimate use to other products. NCPA is also against implementation of any REMS that includes a patient registry component. The iPLEDGE program has been difficult to implement and maneuver in the community pharmacy environment due to an enormous amount of administrative burdens.

However, if FDA mandates a registry model, it should use existing, nationwide technologies that provide a seamless verification of the registrants through existing pharmacy software management systems. Interoperability between all participating systems is essential. Electronic prescribing, any registry, the pharmacy management system, technology used to document patient understanding at the point of dispensing and a system used to retroactively measure patient use should all be interoperable.

At the end of the day, have the intended iPLEDGE program goals been met? This is a very serious question the FDA must answer as it seeks to implement REMS for the opioid class of drugs. Community pharmacists are well versed in having to let patients know that for one reason or another, they are going to have to “wait a few days” for their prescription medication. This may be ok in the case of an acne product but it’s not ok when the patient is in severe pain in your pharmacy and you are unable to provide them a medication because their doctor hasn’t registered him or herself or the patient into a registry. Community pharmacists should not be put in the position to serve as prescription police.

### **Existing pharmacy systems**

NCPA cannot stress enough that any risk management system be created using a standard platform. As stated before, workflow standardization is an important component of filling prescriptions adequately and correctly. A standardized REMS process that can be integrated within existing pharmacy workflow is critical to the successful execution of the program. If the need for

prescriber verification does exist, we urge FDA and manufacturers to work with existing nationwide technologies that provide automation, scale, and efficiency in the transmission of electronic or hand-written prescriptions.

**In conclusion**

With the FDA looking to manufacturers to implement REMS for certain products, it is vital that community pharmacy have an active role in the creation of these programs.

Thank you for your time.