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Dr. Scott Gottlieb, MD
Commissioner
Food and Drug Administration
Silver Spring, MD

September 8, 2017

Dear Dr. Gottlieb:

The American Society for Pain Management Nursing® (ASPMN®) would like to inform you and your colleagues of our organization's commitment to the revisions you have planned for the Opioid REMS initiative.

The original opioid REMS, which was initiated in 2008, and included CME/CE education for all prescribers, but then was only designated for long acting or extended release (ER/LA) opioids. We, as an organization dedicated to the care of all patients who encounter pain at any point in their lives, were disappointed that only education for medications which were included in the long acting or extended release (ER/LA) category were included. ASPMN® membership includes nurses working in pain management in all clinical settings and with variations of clinical skill and expertise (RN, BSN, NP and DNP) felt there were more significant educational deficits for those who prescribe all opioids, which included short acting as well.

Following the recent FDA hearings and opportunity for public comment, we fully support the FDA and the manufacturers of all opioids in assisting with the educational endeavors. We are pleased with the revisions currently being discussed and are open to providing comment or support for the second generation of the opioid REMS as is soon to be required for prescriber education.

ASPMN® would welcome the opportunity to provide testimony, become engaged, and provide clinical knowledge at any point the FDA may find helpful.

Thank you for your ongoing efforts that encourage the provision of controlled substance use for those patients who may require them, while maintaining the level of safety and knowledge that should be utilized when offering them as therapies for appropriate patients and their care.

We wish you well in your future iterations of the REMS for opioids and offer our assistance whenever it can be of value to you and your colleagues.

Sincerely,

ASPMN® Board of Directors