A "PROMPT" Response to the PROP Opioid Petition

By Guest Author ***Jeffrey Fudin, BS, PharmD, DAAPM, FCCP***

After reading the petition dated July 25, 2012 to the FDA from *PROP* (Physicians for Responsible Opioid Prescribing) requesting opioid labeling changes [PDF here], Dr. Fudin posted his own thoughts in rebuttal on August 5, 2012 at his *PainDr.com* blog [PDF here]. Going further, he founded a new organization of healthcare professionals, called *PROMPT*, to help clarify issues regarding effective and safe opioid prescribing in patients with chronic noncancer pain. Following, is his update on these activities. *[Note: all links in this article open in a separate browser window, so you will not lose your place on this page.]*

My first reactions to the PROP Petition to the FDA were disbelief; a nagging requisite for swift response, but from a multidisciplinary group of healthcare providers. As a result, "PROMPT" (Professionals for *Rational* Opioid Monitoring & PharmacoTherapeutics) was born [info here]. Unlike PROP (Physicians for *Responsible* Opioid Prescribing [website here]), the intent was to include *a diversity of healthcare professionals* (after all, it takes a whole neighborhood of professionals to adequately address complex chronic pain) and not to assume that prescribers are otherwise *irresponsible* if they do not follow the PROP platform.

As of this post, we have partnered with many colleagues from every corner of the United States, in part to repudiate the Petition submitted by PROP. It all started with a blog post [here] that generated some heated debate among well-respected clinicians and other, nonclinical, professionals with extensive therapeutic pain management knowledge.

According to a press release by PROP [here], they admit the major goal of their Petition is not strictly to change opioid labeling; rather, the end game is to *preclude drug companies from marketing their opioid products* beyond a 100mg daily oral morphine equivalent dose (MED), for no more than 90-days, and with a restriction to only severe pain in noncancer conditions. This was in fact the message portrayed in a rebuttal statement by Andrew Kolodny, MD, president of PROP, in a recent *Pain-Topics UPDATE* [here].

PROP's inference, therefore, is that if pharmaceutical companies were limited to marketing their products for severe noncancer pain, and not to exceed 90-days or 100mg MED daily, the use of opioid therapy would somehow be safer. I say, show me the evidence!

Playing devil's advocate, what does this really mean?

1. PROP is implying that physician prescribers are so impressionable by marketing that they are otherwise incapable of selecting appropriate therapy based on patient needs rather than a protocol or regulatory mandate. Are physicians really that naïve? I doubt it!

2. Third party payers could refuse to cover payment for "off-label" opioid prescriptions

that do not follow the new labeling requested by the Petition.
Believe it or not, if one of the signatories on the PROP Petition (or any other prescriber) decided to wander outside of the 100mg MED dosage and/or 90-day limit, any community or hospital pharmacist could legitimately refuse to fill the prescription because it is outside the labeled dosing parameters.

You say, "no — it's perfectly legitimate to prescribe off-label." Think again. For example, oral ketorolac has a 5 day limit because of potential kidney dysfunction, and a competent pharmacist would not fill a prescription for oral ketorolac beyond 5 days.

PROP is saying opioids are killing people. Specifically, they are bootstrapping their argument to several statements, one of which is "Chronic opioid therapy at high doses is associated with increased risk of overdose death." A pharmacist would therefore certainly have justification *not to fill* a prescription falling outside the proposed "new" label changes. Worse yet, if he/she did fill the prescription and the patient overdosed —purposefully, unintentionally, and/or because of opioid combined with sedative-hypnotics (prescribed or unprescribed) — liability to the pharmacist would be escalated.

3. The liability to prescribing practitioners would similarly increase, legal cases would be less defensible, and legitimate care for patients truly requiring long-term opioid therapy would be more scant than it is now.

4. A daily dosing limit of 100mg morphine (or its equivalent) is somewhat arbitrary and adhering to that limit would require a range of doses depending on the opioids prescribed, because there is a large disparity in published dose equivalencies among the various opioids [discussed in a prior *UPDATE* here].

Bob Twillman, PhD, previously dissected and critiqued evidence presented in the PROP Petition very nicely in an *UPDATE* [here], as did the American Academy of Pain Medicine (AAPM), who graciously allowed us to publish at the *PainDr.com* blog their rebuttal letter submitted to the FDA [PDF here].

Coincidently, the Joint Commission just released a *Sentinel Event Alert* entitled "Safe Use of Opioids in Hospitals" [PDF here]. In that, they reference their database reporting on deaths or serious injuries from 2004-2011 in which "47% were wrong dose medication errors, 29% were related to improper monitoring of the patient, and 11% were related to other factors, including excessive dosing, medication interactions, and adverse drug reactions." The Alert states, "These reports underscore the need for the *judicious and safe prescribing and administration of opioids*, and the need for appropriate monitoring of patients…."

This illustrates that, even in a controlled hospital environment, patients can die from taking opioids that are improperly dosed, not properly monitored, and/or the result of drug interactions in the acute short-term pain setting — similarly to long-term opioid prescribing in outpatients. This is yet another reason that treatment limited to the arbitrary 90-days chosen by PROP is nonsensical.

It seems that the vital message here is to require intense and ongoing education among opioid prescribers for each and every opioid, whether long-acting or immediate release, and regardless of treatment length. This should include risk stratification, vigilant monitoring parameters, careful titration, and proper dosing.

PROP's supposition that less marketing will yield less diversion or fewer opioid-related overdoses and deaths is unproven and short-sighted. It may even encourage patients to

share medications or seek illegal substances should a new regulation otherwise prevent legitimate patients from receiving opioids prescribed by legitimate clinicians.

Turning back to PROMPT — Professionals for Rational Opioid Monitoring & PharmacoTherapeutics — where are we today?

> *We presently (as of August 20th) have 31 members from highly regarded clinical practices and varying fields of expertise, and the numbers continue to grow. The most current membership roster is publicly available [here]. On August 17, 2012, we posted our response letter to the FDA [PDF here], which basically supports and piggybacks on AAPM's well written Petition response (noted above).*
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> *The unique quality of our group is that it is multidisciplinary, which the physician membership of AAPM welcomes, as is evident in the closing paragraph of their response letter: "We welcome the opportunity to participate in a dialogue with FDA and other interested parties, including prescribers, pharmacists, behavior health practitioners, other healthcare professionals, the scientific community, government agencies, and patients, in reaching a positive outcome for those Americans who suffer unnecessarily with chronic pain."*

PROMPT is happy to live in the same neighborhood as AAPM and we will continue to build houses for *rational* caregivers that want to move in! Learn more about PROMPT [here], and there are related blog posts welcoming your opinions [here] and [here]. Let us hear from you.

About the Author: Jeffrey Fudin graduated from Albany College of Pharmacy & Health Sciences with his Bachelor of Science (BS) degree in 1981 and completed his Doctor of Pharmacy (PharmD) degree in 1998. He is a Diplomate of the American Academy of Pain Management (DAAPM), a Fellow of the American College of Clinical Pharmacy (FACCP), and a member of several other professional organizations. Since 1982, Dr. Fudin has worked at the Stratton Veterans Administration Medical Center in Albany, NY, where he practices as a Clinical Pharmacy Specialist and Director, PGY-2 Pharmacy Pain Residency Programs. He also is an Adjunct Associate Professor of Pharmacy Practice & Pain Management at the Albany College of Pharmacy & Health Sciences, and has been an Instructor of Pharmacology at SAGE Graduate School of Nursing for several years. He is a Clinical Pharmacy Consultant to Homedical Associates, a service dedicated to serving medically complex patients in their homes. Dr. Fudin is a section editor for the journal *Pain Medicine*, and was a member of the panel establishing guidelines on the "Use of Chronic Opioids for Chronic Non-Cancer Pain," a collaborative effort between the American Pain Society and the American Academy of Pain Medicine.

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