EXCLUSIVE Report

PROMPT Challenges PROP's Petition

Jeffrey Fudin, BS, PharmD, FCCP
Adjunct Associate Professor
Pharmacy Practice
and Pain Management
Albany College of Pharmacy
and Health Sciences
Clinical Pharmacy Specialist
PainDr.com
Albany, New York

On August 2, 2012, I became aware of a citizen's petition that was initiated by Physicians for Responsible Opioid Prescribing (PROP),[1] a group that has been publically vocal about its stance to curtail acceptable prescribing of opioids for non-cancer pain beyond a specified timespan. The petition explicitly requests that the Food and Drug Administration (FDA) change current labeling for opioids (Table 1). My initial reaction was disbelief, as I couldn't imagine why cancer patients should have a monopoly on adequate pain treatment with opioids.

As someone involved in pain management, I quickly recognized discernible flaws in their request. Before even debating each point, several very important questions begged contemplation. That is, how does one differentiate the nociception of cancer pain from non-cancer pain? Are the central and peripheral nerves that cause these pains somehow different? Is cancer the golden goose diagnosis that should allow opioid use beyond 12 weeks, and if so, is it because we feel sorry for these patients? Does the petition consider that prostate cancer is a slow-growing malignancy compared to, let's say, pancreatic cancer, and an elderly patient is more likely to die from natural causes than prostate disease? Will patients with arachnoiditis or various other non-cancer pain disorders yearn for a malignancy or contemplate suicide because their non-malignant pain is inadequately treated?

If one can get past the absurdity of cancer versus non-cancer pain, the next issues are perhaps even more outlandish. PROP petitioners call for a maximum 100 mg daily oral morphine dose (or the equivalent). There is clear evidence that opioid response is variable depending on polymorphism and patient-specific physiological differences.[2-4] Also, there is no consensus among clinicians or professional organizations that consistently assigns a specific equivalent for morphine to other opioids. In fact, a recent review of online opioid calculators, all of which were programmed by "acceptable" opioid conversion tables, showed a calculated discrepancy ranging from -50% to +242%; this should perhaps be a major focus for physicians who seriously seek "responsible" opioid prescribing.[5]

Who decides when pain is severe, and when it is moderate? One patient's severe pain is another patient's moderate pain, both of which are well documented to be subjective.[6] On the 90th day post opioid initiation, are we required to abruptly stop the opioid? Does "90 days" really mean, let's say, 75 days, allowing the prescriber 15 days for opioid taper in an effort to avoid potential withdrawal symptoms?

After pondering some of these questions, I could not sit still to watch the chips fall as they may. My first engagement was reaching out to pain colleagues nationwide, involving those across multiple disciplines—not just physicians, as is the case with PROP. That effort was to ascertain whether or not my personal indignation was off the mark; I quickly learned that clinically based colleagues had similar resentment. In a way, therefore, we all owe PROP a debt of gratitude because they were the catalyst for the formation of Professionals for Rational Opioid Monitoring and Pharmacotherapy (PROMPT). According to our Web site, "PROMPT is a multidisciplinary group of clinicians, researchers, and academicians from various fields. Some include areas of addiction, anesthesiology, pain, pharmacy, primary care, psychiatry, psychology, and various board-certified specialties."[7] In fact, our four officers include doctors of medicine, psychology, and pharmacy. Like

PROP, PROMPT is seriously concerned about the safe use of chronic opioids. But, our strategic stance lacks the draconian approach taken by PROP, which, if accepted, would leave thousands of pain patients without therapy at the drop of a hat. PROMPT instead is "in favor of mitigating these risks with appropriate proactive and ongoing validated interventions intended for the benefit of patient care and public safety." Congruent with the FDA's recent initiation of risk evaluation mitigation strategies (REMS), PROMPT advocates for "clinician education, proactive risk stratification, and appropriate therapeutic monitoring."[7] (For more information on the FDA's REMS initiative, see page 45.)

Table 1. PROP's Proposed Labeling Changes

The petitioners suggested specific action should be taken by the Food and Drug Administration:

- Strike the term "moderate" from the indication for non-cancer pain
- Add a maximum daily dose, equivalent to 100 mg of morphine for non-cancer pain
- Add a maximum duration of 90 days for continuous (daily) use for non-cancer pain

PROP, Physicians for Responsible Opioid Prescribing
Based on reference 1.

PROMPT established an unofficial Internet presence on August 3, 2012. The first communiqué started with a blog post titled, "Label Changes for Opioids, FOR or AGAINST."[8] Three days later, I received a Twitter notification that PROP President Andrew Kolodny, MD, was "following" me. I sent him a direct Twitter message suggesting we speak and was encouraged when he initiated a phone call the very next day. We spoke and agreed on certain points, but it was clear our opinions were polar opposite on others. We did both agree that if the PROP proposal was accepted, some opioid access for otherwise legitimate non-cancer patients could be unjustly limited; the liability to prescribers for providing opioids off label for chronic non-cancer pain could increase; and third-party insurance payers would likely limit or refuse payment for chronic off-label opioids prescribed to valid non-cancer pain patients, perhaps the very patients who couldn't work to pay for such medications.

Two days later, PROMPT's new blog post featured a cartoon of Mickey Mouse and Dora the Explorer "duking it out" (which originally appeared in the November 5, 2010, edition of *The Wall Street Journal*) and summoned clinicians from all disciplines, and non-clinicians, to come forward and comment on PROP's petition. That blog post beckoned responses from many well-recognized pain clinicians and non-clinicians nationwide, including approximately 30 powerful well-written opinions, almost all of which were not favorable towards PROP's petition. This provoked yet another new blog post that promised a "PROMPT" response to the PROP petition. From that point forward, PROMPT became a viable group dedicated to challenging the PROP petition, but more importantly to seek ways we could advocate for safe opioid prescribing, and support that any changes moving forward be based on peer-reviewed validated evidence.

During this mayhem, the American Academy of Pain Medicine (AAPM) was busy writing their own response, which surfaced on August 15, 2012.[9] Since PROMPT's position was unmistakably aligned with AAPM's rebuttal, our most logical and expeditious response option was to support AAPM's letter. The new rate-limiting step was to gather all PROMPT member signatures and prepare a cover letter that all agreed to sign. That letter was completed, dated, and electronically submitted on August 17, 2012.[10] As of September 3, 2012, we have 35 clinical healthcare members and several patient and provider affiliate members.

On August 20, 2012, we invited chronic non-cancer pain patients who require opioid therapy to comment on a separate forum by telling their stories; there are about 48 earnest submissions (as of press time) and more on the way.[11] Four days following the launch of our patient blog, I reached out to PROP; my offer was to dissolve PROP and PROMPT, combine our groups, and collaborate in an effort to promote morality, professionalism, and superior patient care.[12] After tweets, live meetings amongst PROMPT members, e-mails, and telephone calls—all to no avail—we

remain at a standstill. It is doubtful the FDA will uphold PROP's request, considering the lack of any validated evidence in PROP's favor and its adversity to legitimate patients, but if the FDA did uphold PROP's request, the only people who would lose are pain suffers requiring opioid analgesics. ■

Author's Bio: *Jeffrey Fudin, BS, PharmD, FCCP, is Adjunct Associate Professor of Pharmacy Practice at Albany College of Pharmacy and Health Sciences, and Owner and Managing Editor of PainDr.com.*

Dr. Fudin is on speakers' bureaus for Janssen Pharmaceuticals, Inc., and Purdue Pharma. This commentary is the opinion of Dr. Fudin alone and does not reflect the opinions of his employers, employee affiliates, and/or pharmaceutical companies that he has consulted for currently or previously. He is a consultant to Practical Pain Management *in the development of an online opioid analgesic calculator.*

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The group also noted that over the past decade, there has been a four-fold increase in prescribing of opioid analgesics, which has been associated with a four-fold increase in opioid-related overdose deaths and a six-fold increase in individuals seeking treatment for addiction to opioid analgesics.[4]

In response to the PROP petition, a multidisciplinary group of clinicians involved in pain management formed Professionals for Rational Opioid Monitoring and Pharmacotherapy (PROMPT).[5] According to the group's Web site, the motivation for forming PROMPT was to address some of the concerns raised by PROP—the safe use of chronic opioids—"by mitigating these risks with appropriate proactive and ongoing validated interventions intended for the benefit of the patient care and public safety," notes Jeffrey Fudin, BS, PharmD, and one of the founders of PROMPT.

To further explore these two views of opioid safety, *Practical Pain Management* invited representatives from both camps—Dr. Fudin and Dr. Kolodny—to write commentaries, which began on page 12. In addition, *PPM* recently surveyed our editorial board members and asked for their opinions on the subject. A sampling of the board's responses can be found on page 17. ■

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