PRIMARY CARE NETWORK™

September/October 2005
Volume VII • Issue 5

PRIMARY ISSUES

Managing Pain in Primary Care Practices

FDA Ruling Creates Unintended Consequences

Roger K. Cady, MD

The withdrawal of COX-2 inhibitor valdecoxib from the market and the black box warnings on celecoxib and all other remaining prescription non-steroidal anti-inflammatory drugs (NSAIDs) have forced clinicians to rethink and reconstruct their strategies for pain management. They are also finding they need to allocate extra time to allay their patients' fears that, without these effective agents, their pain will get out of control.

To measure the dilemma that primary care clinicians encounter when trying to manage their patients' pain, Primary Care Network (PCN) conducted a nationwide faxed survey of more than 20,000 members. Of the replies, 1,035 were sufficiently complete to be entered into the database. Of those who reported degrees, 88% were MDs; 10% DOs; and 2% NP/PAs/other). The survey consisted of 10 questions concerning approaches and medications used for pain management.

Survey results revealed that pain management is a significant part of most primary care practices. Twenty-nine percent of the respondents stated they actively treat more than one-fourth of their patients for a pain condition. Thirty percent of respondents stated that they treat between 16% and 25% of their patients for pain. In addition, respondents reported that prior to the FDA ruling, NSAIDs and COX-2 inhibitors had been the medications prescribed most often for chronic pain management, followed by muscle relaxants and opioids.

Half of the respondents had previously been unaware of the cardiovascular risks associated with COX-2 inhibitors. Fully 87% reported they had no patients with suspected cardiovascular adverse events related to the use of COX-2 inhibitors; 90% reported that no patient taking non-selective NSAIDs had a suspect cardiovascular event.

After the recent FDA ruling, 78% of the respondents stated that their management plans for pain patients would have to change. As a result of the ruling, 25% of primary care providers reported they have decreased prescription of NSAIDs; 25% have increased use of muscle relaxants; and 32% have

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Our Mission: Primary Care Network, a not-for-profit private foundation, is a team of dedicated physicians and other professionals who create cutting edge medical education programs for physicians and other healthcare providers to help them in the treatment of their patients.

Nurse Case Management Benefits Patient Care

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increased prescription of opioids. Thirty-nine percent have suggested that more patients try over-the-counter medications (OTCs) for pain; 25% now recommend more topical products; and 31% have increased referrals to physical therapists.

Currently, fewer than half of respondents (480) use a formal screening aid for pain. However, three fourths of respondents (731) report they ask patients to rate their pain objectively. Similarly, 734 respondents said they use a 0-to-10 rating scale; a minority (146) also use the visual analog scale. Still others use a 4-point scale or measure pain by its impact on the person's ability to function.

Many patients taking COX-2 inhibitors had expressed concerns to their primary care providers when they learned of the FDA ruling. Fully 78% of respondents said some of their patients feared cardiovascular complications; 43% stated some patients feared inadequate pain control; 29% had patients who expressed suspicion of the FDA and the drug approval process in the United States; and 26% reported that some patients expressed negativity toward pharmaceutical companies. Only 12% of primary care providers noted their patients had no concerns about COX-2 inhibitors. Approximately two-thirds (67%) of primary care providers said they felt adequately prepared to assess the safety situation with the COX-2 inhibitors when patients asked about safety issues.

About equal numbers of patients and primary care providers initiated the discussion about switching from a COX-2 inhibitor to another pain medication. Forty-eight percent of the respondents indicated that their patients tended to bring it up first; 46% said they were generally the first to broach the subject with patients. Six percent said the question did not apply to them.

When asked to predict what would happen to pain management in their practices over the next few years, 53% expected it to remain the same; 41% expected to see it increase; and 6% thought it would decrease.

Most of the respondents requested one or more additional tools to help them effectively manage pain patients. Fully 58% said an educational program would help them learn more about the successful management of patients with pain; 51% wanted better availability of non-pharmacological treatment strategies; and 43% wanted a better understanding of such non-medication strategies. Some 34% wanted to be able to predict which patients would benefit from opioids and nearly half (46%) believed physicians should have discretionary power to prescribe COX-2 inhibitors to informed patients.

Many respondents wrote comments on the questionnaire such as, "I didn't even know Vioxx was being pulled off the market until a patient told me he had heard it on the news. Pharmaceutical companies should notify physicians before the media." "My patients are not ready to stop Vioxx without convincing data and proof." "I've heard conflicting opinions and I have not been apprised of risk-benefit ratio."

These remarks highlight the dilemma that the primary care clinician faces: What do I prescribe that is safe for my patient in pain? Many patients and clinicians alike now experience some distrust of drugs newly released to the market. Clinical trials do not seem to address the real-life issues that confront primary care providers in their offices.

Primary Care Network's survey results indicate that primary care providers are prescribing fewer NSAIDs and COX-2 inhibitors; suggesting that patients rely more on OTCs; and at the same time prescribing muscle relaxants and opioids more frequently. In terms of weighing the risks against the benefits, will these changes have unintended long-term consequences such as putting the pain patient at risk for car accidents, falls, and on-the-job mishaps?

Although muscle relaxants and opioids have long been traditional medications for the treatment of pain, they have not undergone the clinical trial scrutiny required of new drugs such as valdecoxib. Who is monitoring the long-term effects of muscle relaxants and opioids on the lives of pain patients and their families?

These patient-centered global issues lie buried beneath ivory-tower criticisms of both the FDA and Merck. After the smoke clears, the patient still asks, Doctor, what should I do for this pain? And the clinician has to offer the patient alternatives that help that person function at work, school, and within the community.

Patients, too, face a dilemma: How can I continue with my life while suffering from a pain disorder? Among the choices they may consider are, (1) to stop pain medication without medical supervision, (2) to fear taking any medication, (3) to use pain medicines while family and friends recount horror stories they have heard in the media, (4) to under-treat pain with OTCs, and (5) to use stronger medications which have problematic side effects that are as worrisome as pain, such as slurred speech and grogginess.

All of these options carry risks, and clinicians are in a quandary as they plan their next steps for patients in their professional practices. The regulators who precipitated this situation may not have understood the practical implications of their well-intended action. As one respondent wrote on the survey, "Administrators, stay out of pain management."

Missouri Pain Initiative Clinical Conference

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Pain topics include neuropathy, cancer, mood disturbances, quality of life, migraine, neuroanatomy, neurophysiology, and activism for policy change. For further information please contact Ann Corley, Missouri Pain Initiative, 888-222-0860, acorley@missouripain.org.

Wall Street Journal Smears Physician Educators

As he left the American Headache Society (AHS) meeting in early July, New York Neurologist, Lawrence Newman told his associate, "I've just been set up." And how.

Weeks later, an article appeared in the Wall Street Journal (WSJ) that implied that all physicians who make presentations sponsored by pharmaceutical companies–including Newman, an associate professor at Albert Einstein College of Medicine–are money-grubbing corporate shills.

[To read the July 15, 2005 article "New treatment: To sell their drugs, companies increasingly rely on doctors. For $750 and up, physicians tell peers about products; talks called educational," go to http://online.wsj.com/public/us and enter the first few words of the article title in the archive search box (cost $4.95) or call Shaine at 417-841-3615 for a faxed copy.]

At the AHS meeting, Dr. Newman had fielded a phone call from WSJ reporter, Scott Hensley. As course director for the American Headache Society's physician education program, Dr. Newman was accustomed to updating reporters on new trends in continuing medical education.

After a few minutes of pleasantries, the reporter confessed, "I snuck into a talk you gave the other day." Newman, who does not speak often, knew immediately which program it had been.

At a recent dinner in a noisy New York restaurant, he had been perplexed by an odd question from a physician in the audience. Turns out the questioner had passed off a reporter friend as an out-of-town doctor to get him admitted to the meeting, then asked a leading question for the reporter's benefit.

"Seems like you're just making this presentation to get more referrals," the doctor had accused. Dr. Newman laughed and told clinicians in the audience they needed to treat their own patients because he was much too busy. He pointed out that migraine is not hard to distinguish from sinus or tension headache, nor is it difficult to treat. Primary care providers should only refer a headache patient to a specialist if they can't make a diagnosis or can't figure out why the patient does not respond to treatment, he said. Migraine treatment is routine, Newman concluded, and should be "bread and butter for primary care doctors."

The bread-and-butter comment appeared like a smoking gun in the expose article about "physician-pitchmen." The article made

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Wall Street Journal Smears Physician Educators

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no mention of educational value, saying pharmaceutical companies use these pitchmen as an "effective tool for getting their message across to doctors."

Yet, in the telephone conversation at the AHS meeting, the reporter had acknowledged that Newman's dinner presentation had not been a commercial at all. "It wasn't what I expected," Newman remembers Hensley saying. "The only time you put up a slide about treatment, it contained all of the triptans, listing both the generic and brand names."

Although he complimented Newman on his impartiality, the reporter pushed for a concession that the industry has big problems. Newman acknowledged that some physicians do indeed make scores of bald-faced commercial presentations each year, from which they earn substantial income. When the reporter asked him to name names, Newman refused.

How could a reporter who complimented Newman on his impartiality end up writing such a negative article? His words were intermixed with those of a co-author, a reporter who had lined up evidence of abuses. Hensley may have felt uneasy, because he called Newman to warn "I'm writing about you in a positive light in a negative article."

In fact, the article was so negative that it overshadowed any positive portrayal of Newman. The article failed to mention many things: that most patients do not receive a correct diagnosis; that they suffer for years on a carousel of over-the-counter drug use that can lead to rebound headaches; that drug benefits are clearly established in multi-center trials. The reporter also did not mention that Newman most frequently speaks in hospital Grand Rounds or in CME programs.

Further, the article quoted a Harvard Medical School professor, author of a recent book critical of pharmaceutical companies. His self-serving comment, "An awful lot of the doctors in the audience are naïve about the fact that these are really sales talks," was patronizing and lacked credibility.

Most importantly, the article ignored the fact that physicians need the opportunity to have one-on-one discussions with experts in their field. Practicing medicine can be a lonely job, and some patients completely mystifying. Clinicians need to be able to hear comments from a thought leader whose papers they have read, and be able to ask specific questions about their problem patients.

The reporter had clearly gone in intending to write a smear, Newman said, and all physician educators ended up soiled by implication. "The only unethical part of the talk that night was not my presentation, but the two people who came to the talk under false pretenses." Still, he was philosophical about the whole experience.

"If I had known a reporter was going to be there, I'd have given the identical presentation," Dr. Newman said. "It was purely educational and would have been appropriate for medical students. It was just the luck of the draw and I got the bad hand."

Profile: Ellen Hirschman Miller, MD

"If a patient complains of being tired and fatigued, perhaps he or she is not sleeping well. Most patients with insomnia never discuss it with their health care provider. Sometimes they do not even know they have a sleep problem; although they are in bed all night, they are getting non-restorative sleep!"

- Ellen Hirschman Miller, MD

Ellen Miller, MD, is clinical assistant professor of medicine at the Albert Einstein College of Medicine, Bronx, NY, and vice president of academic affairs at Franklin Hospital Medical Center, Valley Stream, NY. In addition, she has a private practice in internal medicine, endocrinology, and reproductive endocrinology in Hewlett, NY.

Her areas of specialty present continual challenges. "I often see patients in my practice complaining of weakness and fatigue, who feel it might be due to Chronic Fatigue Syndrome or hypothyroidism," she said. "If their TSH is normal, I check their 25-(OH) Vitamin D level, and, in a surprisingly large number of individuals, I find the level to be low! These patients respond well to treatment with Vitamin D."

Dr. Miller received her medical degree from New Jersey Medical School and completed her post-graduate work at Beth Israel Medical Center and Columbia University, New York City. She serves on the Steering and Scientific Committee for the World Foundation for Medical Studies in Female Health. Other professional affiliations include the American Association of Clinical Endocrinologists, the American College of Physician Executives, and the American Society for Reproductive Medicine. Dr. Miller is also on the editorial board of the *International Journal of Fertility and Women's Medicine*.

She has conducted extensive research in the areas of endocrinology and women's health, and has authored dozens of articles that have been published in peer-reviewed medical journals, magazines, and on the Internet. Dr. Miller regularly presents CME programs and also speaks to both professional and lay audiences.

Despite her busy professional life she takes time to travel with her husband and two children. They particularly enjoy cruising the Mediterranean.