



NCPI Advisory Council Conference Call
February 17, 2009
4 –5 PM

Conference Call Summary Notes

I. Introductions

In attendance: Beverly Nicholson, Penney Cowan, Kathy Keller, Kathe Kelly, Lori Reisner, Ben Rich, Steven Rickards, Alecia Sanchez, Glenn Yokoyama, May Sung

Unable to attend: Judy Citko, Vicky Ferraresi, Judi Nurse, Mark Maginn, Janet Edrington, Vicky Ferraresi, Thurman Hunt, Donna Kalauokalani, Kathy Ellis, David Thorton

II. Review of Meeting Notes from January 20th conference call

No additions or corrections; accepted as written. Beverly recommends to email her if any specific errors are found.

III. Old Business

□ Stakeholder Pain Forum Follow-up

○ Transcription Review

Bev thanked everyone for their participation in the Pain Forum. Now our job is to keep up the momentum, bringing forward recommendations and deciding on actions. May reported that a transcriptionist was hired with grant funds. Transcribing was difficult because it was on a CD rather than a tape. It took her about 6 days to prepare an almost 60 page document. May is now reviewing for spelling and main content. May suggested that outcomes or recommendations be isolated and shared with this group. Kathy Keller, Ben Rich, May Sung, Beverly Nicholson and Alecia Sanchez have volunteered, and have invited anyone else who would like to participate in a call within the next week to go over the transcript to pare it down to manageable action items. Chris Miaskowski had previously volunteered to do a final review. The sooner that it can be done and distributed to other attendees, the better. May will finish initial corrections, then distribute to those interested in further evaluation. Penney asks if the final document will be distributed to all the participants? That was the goal. May plans to distribute as well as to post on website. Penney also suggested submitting final report to ACS-CAN. American Chronic Pain Association and SCCPI would like to link to it. Kathy asked if a press release would be a good idea. Penney suggested waiting until Stimulus and Budgeting issues have died down. Alecia suggests also that only recommendations and potential actions will be newsworthy.

○ Posting of Pain Forum Powerpoint Presentations

May reports that Ronna Kephart's PowerPoint cannot yet be posted because of a legal case still in progress. May had Chuck Hakkarinen, our volunteer Webmaster, compact the presentations to PDF format, but the files are still quite large. To date, Penney Cowan is the only presenter that has given permission to post her PPT on the NCPI website. Drs. Gilson and Fishman have been asked but they have not responded to date; staff will follow up again.

Kathe Kelly asks if the three-page summary report to ASC-CAN can be circulated to the SCCPI Board? Bev agreed that it would be fine to do so.

- **ASPI 2009 Conference Planning – San Francisco, October 23-25, 2009**
 - A Planning Committee is convened by Ronna Popkin to help plan the ASPI annual meeting and they have met by conference calls. Glenn was able to attend representing NCPI on the February 3rd call. Beverly Nicholson participated on the January 12th call. Glenn indicated that he and Ronna will talk about the evening event prior to the next conference call. He reports that there should be a lot of opportunities in San Francisco for this social / networking event. However, the limitation will be expenditures for transportation and attendance. The group discussed funding options for the event. Members noted that pharma companies are not permitted to sponsor social functions any longer, and only limited educational activities or exhibits to fund the educational portions of the conference. Planning Committee conference call is tomorrow, February 18 at 11am, so we can learn more information after it is held.

- **NCPI Advisory Council membership**
 - Recommitment Letters – Bev reports that she participates in C-DOC (California Dialog on Cancer) the coalition that oversees the California Comprehensive Cancer Plan. They have sent out letters to committee members asking for recommitment with guidelines for the promised activities. Bev suggests that we do this for NCPI's Advisory Council. Penney suggests that we make phone calls first to see if they really want to participate before sending a letter, that might get buried. May and Bev have already made some calls awhile ago to mostly those who had not been participating regularly. Respondents made verbal commitments but attendance on conference calls still has not improved.

Bev shared her ideas for content of the recommitment letter / guidelines that members should participate in at least __X# of conference calls per year or at least provide responses to NCPI conference emails. Kathe Kelly reports that SCCPI keeps track of volunteer hours. Participation in conference calls is a commitment and is counted as volunteer hours. Committee members are also asked to participate actively in their Gala by nominating people to receive awards and to sponsor a table for attendees. May notes there are currently 16 members on NCPI Advisory Council

with Ronna Popkin as a liaison, who is cc'd on notes. Bev says this would also be a way for people to reevaluate their ability to participate and their interest.

- New members – Bev suggest specially inviting some who showed particular interest in joining NCPI, particularly those who attended the December Pain Forum, eg, Barbara Ward, Mark Holtzman, and Joan Jerzak were suggested. Kathy suggested we also invite Laura Sweet of the DOJ. There was general agreement. Bev will send each a letter inviting them to join the Advisory Council as there are no objections.
- NCPI General Membership – continue brainstorming on how to expand participation – what do we have to offer, what projects we will complete, etc.

IV. New Business

- APS Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain (Page 2) – NCPI actions?
Beverly notes that Ben was part of the committee who prepared these guidelines. What can NCPI do? Link on website? Ben thinks the wider the dissemination the better. These were the subject of discussion at the recent AAPM (pain medicine) meeting. He thinks it would be good to post this on our website. The journal (Journal of Pain) provides the ability to freely download a detailed outline from their website. NCPI can link or tell people how to get to the site. As best known, the complete guideline must be purchased. This was a two-year process with huge amount of background work being done by the OHSU to produce these guidelines.
- FDA Action on Opioids (Page 4) – any advocacy actions planned?
Attachment was forwarded to us by Kathe Kelly from a Mayday Fellow. Do we need to monitor this? Bev asks if the advocacy groups are being asked about their concerns. Penney reports there has been one meeting for the FDA to hear concerns from those who are affected. The group having lost family members are extremely vocal, often advocating extreme limitation on medication availability and usage. There is another meeting planned for March 3rd. FDA doesn't really know what to do about attacking this problem, how to implement REMS. Glenn opines that this is not really an FDA problem, but more of a consumer protection issue, Boards of Pharmacy. Lori reports the concerns are centered on misuse of specific agents such as OxyContin and methadone. It is a complex issue involving education of physicians, the public, electronic medical records and monitoring, etc. Kathe will keep us apprised of the issue and ongoing communications.
- American Pain Society Scientific Conference – San Diego, May 7-9, 2009 – NCPI or ACS representation? The ACPA will be there as an exhibitor and is planning to hold an advisory committee meeting. Beverly is planning to attend. Wonders if the NCPI or ACS should participate/exhibit? May reports there is no

ACS funding or plans to exhibit. Penney volunteers to share info on the state pain initiatives in her booth - a one page flier would work.

- The National Pain Care Policy Act reintroduced –NCPI signed on again as sponsor. Should be hearing something in the near future.

V. Standing Agenda Items

- SCCPI Liaison Report – Kathe Kelly reports they are planning to do outreach with the SCCPI report card to Medical Schools and the National Comprehensive Cancer Centers to make them more aware of SCCPI's work and resources. Will be holding a PRN course in September 2-4 and a social worker's course on elder care.
- Web Updates – previously discussed.
- Upcoming Conferences/Educational Opportunities – Bev reports her hospital will be sponsoring a nursing pain education course. Steven Rickards reports there is an upcoming I Can Cope teleconference for patients.

VI. Announcements – Open Agenda - no additional announcements.

Next Conference Call: March 17, 2009, 4-5 pm



RESEARCH
EDUCATION
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ADVOCACY

Attachment 1

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New Guidelines for Prescribing Opioid Pain Drugs Published
*American Pain Society and American Academy of Pain Medicine Recommendations
Help Physicians Treat Chronic Non-cancer Pain*

GLENVIEW, IL, Feb. 10, 2009 – A prestigious panel of pain-management experts representing the American Pain Society (APS) www.ampainsoc.org and the American Academy of Pain Medicine (AAPM) has published the first comprehensive clinical practice guideline to assist clinicians in prescribing potent opioid pain medications for patients with chronic non-cancer pain. The long-awaited guideline appears in the current issue of *The Journal of Pain*, www.jpain.org, the APS peer-reviewed publication.

“The expert panel concluded that opioid pain medications are safe and effective for carefully selected, well-monitored patients with chronic non-cancer pain,” said Gilbert J. Fanciullo, MD, a panel co-chair and director, Section of Pain Medicine, Dartmouth Hitchcock Medical Center. APS, AAPM and the Oregon Evidence-based Practice Center at Oregon Health and Science University collaborated for two years reviewing more than 8,000 published abstracts and nonpublished studies to assess clinical evidence from which their recommendations are based. The target audience is clinicians who care for adults with chronic non-cancer pain.

The panel made 25 specific recommendations and achieved unanimous consensus on nearly all.

“The guidelines are based on the available evidence and also rely on an underlying assumption that chronic opioid therapy requires prescribers to have clinical skills and knowledge in both the principles of opioid treatment and the assessment and management of risks associated with opioid abuse, addiction and diversion,” said Fanciullo.

Opioid prescribing has increased significantly due to growing professional acceptance that the drugs can relieve chronic non-cancer pain, and the guideline acknowledges there are widespread concerns about increases in prescription opioid abuse, addiction and diversion.

“Decisions about chronic opioid therapy must weigh the benefits of these medications against the risks, which include side effects and adverse outcomes associated with abuse,” said Perry Fine, MD, panel co-chair and professor of anesthesiology, University of Utah Medical Center.

Opioids, such as morphine, oxycodone, oxymorphone and fentanyl are potent analgesics. They traditionally have been used to relieve pain following surgery, from cancer and at the end of life. Today opioids are used widely to relieve severe pain caused by chronic low-back injury, accident trauma, crippling arthritis, sickle cell, fibromyalgia, and other painful conditions.

Prior to initiating chronic opioid therapy, the guideline advises clinicians to determine if the pain can be treated with other medications. If opioids are appropriate, the clinician should conduct a thorough medical history and examination and assess potential risk for substance abuse, misuse or addiction. Fanciullo noted the strongest predictor of possible drug misuse is a personal or family history of alcohol and drug abuse. “For patients at higher risk for misuse of opioids, the guideline advises giving patients clear written rules, such as filling prescriptions at one pharmacy only, taking random drug tests, making regular physician visits, and locking their medications at

home,” he said.

Diligent Patient Monitoring Is Essential

A key recommendation urges clinicians to continuously assess patients on chronic opioid therapy by monitoring pain intensity, level of functioning and adherence to prescribed treatments.

Periodic drug screens should be ordered for patients at risk for aberrant drug behavior.

“Regular monitoring of chronic opioid therapy patients is warranted because the therapeutic benefits of these medications are not static and can be affected by changes in the underlying pain condition, coexisting disease, or in psychological or social circumstances,” said Fanciullo.

“For patients at low risk for adverse outcomes and on stable doses of opioids, monitoring at least once every three to six months is sufficient, but weekly monitoring is justifiable for those at high risk for abuse and other adverse events.”

Fine added that sometimes patient self reports are unreliable, so the guideline recommends that pill counts, urine drug screening, family member or caregiver interviews and prescription monitoring data be used to check for possible abuse. “Although strong evidence is lacking on the best methods for managing high-risk patients, potential risks can be minimized by more frequent and intense monitoring compared to lower risk patients,” he said.

Other recommendations in the APS/AAPM clinical practice guideline include:

Methadone: Use of methadone for pain management has increased dramatically but few trials have evaluated its benefits and harms for treatment of chronic non-cancer pain. Methadone, therefore, should be started at low doses and titrated slowly. Because of its long half-life and variable pharmacokinetics, the panel recommends methadone not be used to treat breakthrough pain or as an as-needed medication.

Abusers: Chronic opioid therapy must be discontinued in patients known to be diverting their medication or in those engaging in serious aberrant behaviors.

Breakthrough Pain: As-needed opioids can be prescribed based on initial and ongoing analysis of therapeutic benefit versus risk.

High Doses: Patients who need high doses of opioids (200 mg daily of morphine or equivalent) should be evaluated for adverse events on an ongoing basis. Clinicians should consider rotating pain medications when patients experience intolerable side effects or inadequate benefit despite appropriate dose increases.

Driving and Work Safety: Patients should be educated about the greater risk for impairment when starting chronic opioid therapy and counseled not to drive or engage in potentially dangerous work if impaired.

Pregnancy: Clinicians should counsel women about risks in pregnancy and encourage minimal or no use of chronic opioid therapy unless potential benefits outweigh risks.

The guideline on opioid therapy for chronic non-cancer pain is the sixth evidenced-based, pain management clinical practice guideline published by APS. Others have covered sickle-cell disease, arthritis, cancer, fibromyalgia, and low back pain.

“This is a milestone collaboration in which two leading organizations representing pain management have developed the first comprehensive, evidence-based clinical practice guideline to assist clinicians in managing chronic opioid therapy,” said APS President Charles Inturrisi, PhD. “We are grateful to the American Academy of Pain Medicine for joining forces with APS in developing this long-awaited publication.”

New York Times: F.D.A. to Place New Limits On Prescriptions of Narcotics
Wall Street Journal: Pain Drugs to Get New Restrictions
USA Today: FDA dispenses opioid concern; Pills, patches 'extensively used'

New York Times

February 10, 2009

HEADLINE: F.D.A. to Place New Limits On Prescriptions of Narcotics

BYLINE: GARDINER HARRIS

DATELINE: WASHINGTON

Many doctors may lose their ability to prescribe 24 popular narcotics as part of a new effort to reduce the deaths and injuries that result from these medicines' inappropriate use, federal drug officials announced Monday.

A new control program will result in further restrictions on the prescribing, dispensing and distribution of extended-release opioids like OxyContin, fentanyl patches, methadone tablets and some morphine tablets.

These products are classified as Schedule II narcotics and already are restricted according to rules jointly administered by the Food and Drug Administration and the Drug Enforcement Agency. But the current restrictions have failed to "fully meet the goals we want to achieve," said Dr. John K. Jenkins, director of the F.D.A.'s new drug center.

"What we're talking about is putting in place a program to try to ensure that physicians prescribing these products are properly trained in their safe use, and that only those physicians are prescribing those products," Dr. Jenkins said in a news conference on Monday. "This is going to be a massive program."

Hundreds of patients die and thousands are injured every year in the United States because they were inappropriately prescribed drugs like OxyContin or Duragesic or they took the medicines when they should not have or in ways that made the drugs dangerous. The agency has issued increasingly urgent warnings about the risks, but the toll has only worsened in recent years.

The blame for this is shared among doctors who prescribe poorly, patients who pay little attention to instructions or get access to the medicines inappropriately, and companies that have marketed their products illegally.

The F.D.A. this year will hold meetings with manufacturers, patient and consumer advocates, and the public to ask for advice on how to carry out the new control program, officials announced. The first meeting will be on March 3, and no immediate changes in access to the drugs is planned.

The 24 medicines under review had 21 million prescriptions written for them in 2007, to 3.7 million patients, Dr. Jenkins said. They are extremely effective in reducing pain, which many medical studies suggest is widely undertreated in patients suffering serious illness. (A complete list of the drugs is at www.fda.gov/cder.)

But many doctors prescribe the drugs far too cavalierly, Dr. Jenkins said. The F.D.A. has received reports of patients' being prescribed such medicines to treat something as simple as a sprained ankle, he said. In such patients, the medicines can be dangerous.

Part of the problem is marketing. Several reports, for instance, have suggested that Purdue Pharma, the maker of OxyContin, helped fuel widespread abuse of the drug by aggressively promoting it to general practitioners not skilled in either pain treatment or in recognizing drug abuse.

The company has denied such a connection, but a holding company connected with Purdue and three top Purdue executives pleaded guilty last year to criminal charges that the company had misled doctors and patients by claiming for five years that OxyContin was less prone to abuse because it was a long-acting narcotic.

Doctors are also to blame. A common reason for disciplinary actions at state medical boards is the use of narcotics in patients who show clear signs of addiction or for whom the drugs are obviously inappropriate.

The F.D.A. generally avoids interfering with the practice of medicine because doctor behavior is governed by state medical boards. Instead, the agency usually tries to provide doctors with the best and most current information, and then allows them to decide how to use it.

Most of the drugs withdrawn over the last 20 years, however, were taken off the market because doctors continued to use the medicines in ways that the F.D.A. warned against.

For decades, the agency's armory in these battles held only a popgun and a cannon -- the popgun being the issuance of widely ignored warnings; the cannon being its ability to force a medicine's withdrawal. But a law passed in 2007 gave the agency a new, intermediate weapon -- Risk Evaluation and Mitigation Strategies. Known as REMS, these programs allow the agency to place strong restrictions on the distribution of certain drugs.

Wall Street Journal
FEBRUARY 10, 2009
HEADLINE: Pain Drugs to Get New Restrictions
BYLINE: JENNIFER CORBETT DOOREN

The Food and Drug Administration said Monday it will subject the makers of certain extended-release pain drugs to a new risk-management program designed to cut down on misuse and abuse of the products. New government figures show a rise in nonmedical use of prescription pain drugs among adults.

Opioid drugs formulated in extended-release versions of OxyContin, morphine and fentanyl patches are meant for round-the-clock pain management for patients with cancer and other chronic conditions.

Misuse and Abuse

FDA officials have said they've seen reports of inappropriate prescribing by doctors amid the increase in misuse and abuse, both intentional and unintentional, of the products since the drugs were first approved in the mid-1990s.

Active ingredients in the drugs are designed to treat pain for an extended time, such as 12 hours. Drug abusers can tamper with such products and get all the effects of a drug at once, creating a heroinlike high.

"We continue to see reports of an ankle sprain and [patients] are given a fentanyl patch," said John Jenkins, the director of the FDA's office of new drugs. He said a major part of the new program will be efforts to educate doctors about appropriate prescribing of the products. "This obviously is going to be the largest risk-management program we've undertaken," he said.

Although Mr. Jenkins and other agency officials wouldn't speculate about what the final risk-mitigation program would look like, it could have elements of a program designed to limit the use of the acne drug isotretinoin (commonly known by the brand name Accutane) by women of child-bearing age because the product causes birth defects. That program requires doctors, pharmacists and patients to register and meet certain requirements in order to get a new prescription each month.

The agency sent letters to 16 manufacturers of 24 products including Purdue Pharma LP, the maker of OxyContin, which is available in an extended-release form; a unit of Johnson & Johnson that makes a fentanyl patch; and King Pharmaceuticals Inc., the maker of an extended-release form of morphine. The letters told the drug makers of agency plans to require a risk-evaluation and -mitigation strategy, or REMS, "to ensure that the benefits of the drugs continue to outweigh the risks."

Getting Input

The FDA said it would meet with the drug manufacturers next month to talk

about developing a REMS and would then meet with other federal agencies, patient and consumer-advocacy groups and health-care professionals to get additional input in the coming months.

There will be no immediate changes for prescribers or users of extended-release pain pills. An estimated 21 million prescriptions for extended-release opioids were prescribed for 3.7 million patients in 2007, Mr. Jenkins said. Other pain pills that are immediate-release and more commonly prescribed for pain won't be affected.

The agency noted that previous efforts to cut down on abuse and misuse of extended-release products, such as putting additional warnings on products labels, haven't really worked.

"Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade," the agency said in a statement posted on its Web site. "The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access."

The FDA can mandate the elements of a risk-management plan as part of legislation that took effect last year. Mr. Jenkins said that authority should make the new effort to cut down on abuse and misuse more effective than previous plans.

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USA TODAY

February 10, 2009

HEADLINE: FDA dispenses opioid concern; Pills, patches 'extensively used'

BYLINE: Rita Rubin

The Food and Drug Administration announced Monday that it was stepping up efforts to reduce unsafe use of 24 narcotics products -- methadone pills, fentanyl patches and extended-release pills containing morphine, oxycodone and oxycodone, such as OxyContin.

"This is a very extensively used group of medications," said John Jenkins, director of the FDA's Office of New Drugs. In 2007, he said, U.S. pharmacies dispensed 21 million prescriptions for the 24 opioid products, used by 3.7 million Americans.

Despite label warnings and collaborations between the FDA and other federal agencies, misuse, abuse and accidental overdoses of the products have grown over the past decade, he said. The FDA is concerned about doctors prescribing the drugs inappropriately, to patients who don't have moderate to severe chronic pain, Jenkins said. For example, "we continue to see case reports where someone with a sprained ankle receives a fentanyl patch or extended-release opioid," which, when chewed instead of swallowed whole, releases a large dose.

In addition, non-medical use by adults is rising. Data released Monday by

the Substance Abuse & Mental Health Services Administration showed that non-medical use of prescription painkillers in Americans 18-25 rose from 4.1% in 2002 to 4.6% in 2007. Over that same period, non-medical use rose to 1.6% from 1.3% in Americans 26 and older.

The 16 companies that make the 24 products received FDA letters Friday saying their drugs must have a "Risk Evaluation and Mitigation Strategy," or REMS. A 2007 law authorized the agency to require REMS "to ensure that the benefits of the drugs continue to outweigh the risks," the FDA said. It will meet with the makers March 3 and with patient advocates and other stakeholders in late spring or early summer, Jenkins said.