



# CHRONICLE



## Gaining Access to Care

by Penney Cowan, Executive Director, ACPA

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**W**hen pain invades our lives the only thing on our minds is relief. We want the pain to end so that we can return to our normal daily activities. Naturally, we seek out medical care in the hope of receiving treatment to relieve our pain so we can be on our way. Unfortunately, things are not that simple these days.

Medical insurance plans now define how we go about interacting with health care providers. Each plan offers numerous ways to get access to care. The plan you choose determines what the process will be. Just about every procedure must be approved by insurance before you can proceed.

The cost of medical insurance has skyrocketed in the past two decades, leaving many people without any coverage at all. Today there are nearly 45 million people in the United States who do not have health care insurance. Their options for treatment are even more limited.

Some encounter other barriers. Evidence-based health care recommends an approach to each condition or presenting complaint that is based on a combination of current research, your doctor's experience, your personal reports of pain, and treatment outcomes. While this concept is excellent in theory, it doesn't always work out to everyone's benefit in actual practice. Some patients are denied first-line tests and treatments, including medications.

Those who depend on an opioid pain medication as one of their tools to reduce pain and suffering are faced with the complex process of signing contracts with the health care provider. If for any reason they "break" the contract, they can be denied care.



Simply finding a physician who understands and can effectively address pain is an on-going battle for many people with pain. The number of doctors who specialize in pain management seems to be shrinking while the demand for their services increases. Simply knowing your rights as a patient doesn't ensure that you will be able to find someone to treat you.

In this issue of *The Chronicle* we will explore the problem of access to care. Jennifer Bolen, JD, of the Legal Side of Pain, will discuss signing contracts with

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# Perseverance Led to Good Pain Management

by Sally Price

**D**allas Needham, 51, of Hemet, California, had double obstacles in finding good pain treatment. He lives in an out-of-the-way town in the southern California desert where there is no pain specialist and he's had to surmount barriers with his insurance providers.

Several years ago, he finally found help for his right-sided back and leg pain in the form of epidural injections. Relief was an hour's drive away at the Center for Pain Management at Loma Linda University Medical Center (60 miles east of Los Angeles). But then Dallas's insurance carrier changed.

He had to change doctors and never again found a doctor who would treat him with epidural injections. Six months ago, however, he found the Haider Spine Center in Riverside, California. The center has given him his life back, he said. And the distance he has to drive to get there—a 40-minute trip—is shorter too.

Dallas's journey with chronic pain, which began five years ago following foot surgery and hepatitis C, has been, at the least, very educational. "I have learned a lot from bad experiences," he said. In his prior treatment program, he was very subservient, he said, and "didn't know I could say no." On heavy medications, he was still trying to work at his shipping and receiving job and felt almost too drugged to function.

He also didn't realize how his emotions were affecting him. "I didn't realize the state of depression I was in. I was angry all the time. I wasn't a good candidate for this program," he recalled, admitting that part of the failure was his own responsibility.



He ended up having to give up his job, going from private to state insurance, and being threatened by homelessness. But his wife, Cyndie, who has multiple sclerosis, wouldn't let him give up. He was equally determined to find help.

Today he takes an antidepressant and is determined never to let himself sink into what he calls his "dark days." His advice to people with pain is: "Don't ever give up. Don't allow yourself to get into depression. It's one of the worst things you can do. It's so hard to get out."

It's important, Dallas said, to talk about what's bothering you. "Don't keep this stuff in. Talk about it. Find a support group." Dallas keeps his mind occupied

to stay positive, and walks for exercise. He walks with Cyndie on a path around their mobile home park, on a treadmill, and to his volunteer job in an emergency room.

This volunteer work has helped him to see past his frustration with doctors who wouldn't give him pain medication when he needed it. "There is rampant seeking of pain meds in the emergency room," he said. He actually apologized to one of his doctors, telling him, "I now understand why you feel the way you do."

But he also identifies with people with chronic pain who are frustrated when doctors don't believe in their pain. "I didn't feel believed until the last

*“Sometimes you’ve got to push yourself so far that every step hurts. But once I got [proper] pain management, it felt so good I knew I couldn’t ever go back to those dark days.”*

(and sixth) doctor,” he said. “Having someone believe in you makes all the difference in the world.”

Dallas said he was greatly relieved to find the pain treatment program at the spine center, which he completed six months ago. He fully committed himself to the program, going four times a week for eight weeks for medication, physical therapy, and a psychological session. He works with a medical team, returning once a month to see the doctor. It takes a whole day each time because of the long drive, but has been worth it.

The emphasis at the spine center has been to lose weight, stay active, and keep mentally fit, a formula Dallas said he has stuck with. Taking long-acting opioids and attending psychology sessions enhanced the combination of interventions and has brought good results. “I feel better mentally than I have in four to five years,” he said.

When Dallas learned that his psychologist uses ACPA materials in working with people with chronic pain, he tried to find an ACPA support group. The closest one was a 90-minute drive. So he started his own ACPA support group, called more than 30 locations to find an affordable meeting place, and recently held his first meeting. Persevering paid off, too, in finding pain treatment. Now, his health care flows along well, with his HMO providing a caseworker that he refers to as a “godsend.”

“She calls me every 10 days to ask how things are going,” Dallas said. “I could have had this all along. All you have to do is ask. But first you have to know the right questions.”

He is quick to advise people in pain to assume the next doctor knows nothing. Always go completely prepared with everything, including medical records and X-rays, he said.

And don’t be put off if your doctor wants you to sign a pain contract, he said. In his experience, contracts usually require that patients not go anywhere else for pain medications, not take medications other than what they’ve been prescribed, and go to only one pharmacy.

Also, he said, “Don’t let doctors make you feel guilty. Stand up. You do have rights.” Keep persisting to find good pain treatment, no matter how far you have to go or what you have to go through.

“Sometimes you’ve got to push yourself so far that every step hurts. But once I got [proper] pain management, it felt so good I knew I couldn’t ever go back to those dark days.”

**For more information on opioid treatment agreements, which are sometimes called pain contracts, see page 5.**

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## Access

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health care providers. We will review our participation in the the National Working Group on Evidence-Based Health Care (EBH) and what EBH means for your care. And we will hear first hand from ACPA members how they work through the challenge of gaining access to care.

Access to care is a growing problem. If your need goes beyond these issues we encourage you to write to ACPA with your questions and concerns. We will do our best to seek out answers and provide resources to help you find appropriate health care.



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# Achieving Better Evidence-Based Healthcare

**E**vidence-Based Health Care (EBH) is a concept that states that a patient's treatment should be based on a balance of scientific evidence, practitioner judgment, patient experience, and patient preferences.

Penney Cowan, executive director of the ACPA, represents the ACPA as a member of the National Working Group on Evidence-Based Health Care. The group works to protect patients and ensure balanced evidence-based health care policy through education, and to improve the quality of health care in the United States.

"As a concept, it is excellent, wonderful," Penney says. "Health care should be based on research. But in practice it doesn't always work out to everyone's benefit. We are working to change that."

The National Working Group was convened in January 2006 by Mental Health America and now has 33 health

care consumers, professionals, and advocates as members. They believe that health care should be based on solid science and be delivered by health care services that meet basic quality standards.

In a recently published brochure, the National Working Group states that "We must move to improve care with evidence-based medicine without viewing it solely as a way to cut costs. Improving quality care and making the best use of health care resources are not contradictory goals."

To learn more, go to [www.evidencebasedhealthcare.org](http://www.evidencebasedhealthcare.org) and download the Working Group Brochure, featured on the home page.

The National Working Group also reported that in April, Senator Max Baucus (D-MT), Chairman of the Senate Finance Committee, released legislative specifications to amend the "Medicare Prescription Drug Price Negotiation

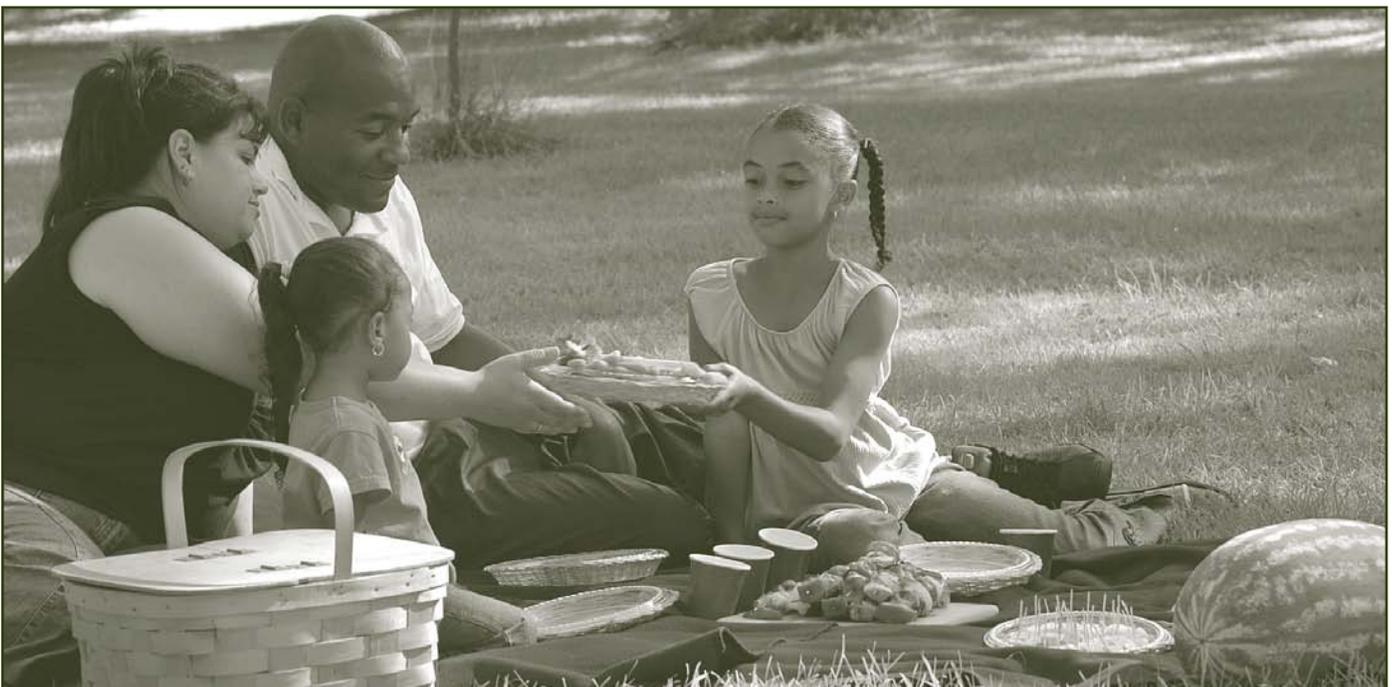
Act of 2007." It would strike the "non-interference" provision, which prohibits the Secretary of Health and Human Services (HSS) from interfering in negotiations between drug manufacturers, pharmacies, and prescription drug plan (PDP) sponsors.

Baucus mandates that the HSS develop clinical effectiveness studies of Part D drugs and acquire comparative effectiveness evidence to inform payer decisions about coverage of care.

Information on the Medicare Prescription Drug can be found at: <http://www.medicare.gov/pdp-basic-information.asp>

The summary of Chairman's Mark Amendment to Medicare Fair Prescription Drug Price Act of 2007 can be found at: <http://www.senate.gov/~budget/democratic/chairmansmark/chairmansmark032002.pdf>. It is a 63-page document.

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# The Legal Side of Pain®

What rights do people have for pain relief and what should they know about Opioid Treatment Agreements and “one strike” policies?

by Jennifer Bolen, JD

As a person challenged by pain, I understand why people want to know their rights when it comes to pain treatment. I also think it is important for people to take responsibility for their pain management in a proactive manner. If you manage your pain, you should take steps to:

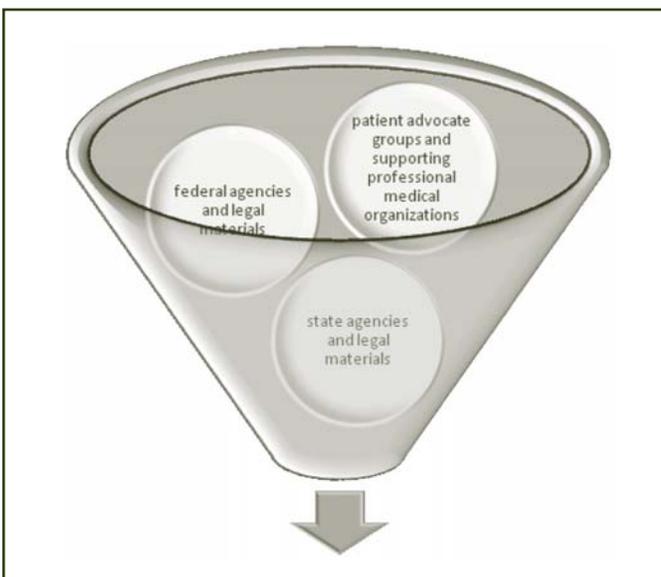
- \* Learn your rights and responsibilities
- \* Discuss them with your doctor
- \* Follow the plan you and your doctor agree on
- \* Bring problems to your doctor’s attention immediately

I suggest that each patient interested in his/her responsibilities and rights take the time to make a notebook containing:

- \* Federal materials on pain and a list of key resources
- \* State materials on pain and key resources
- \* Pain-related materials from professional medical organizations and patient advocate groups
- \* Physician contact information, a personal medication list, and key medical records

## Rights and Responsibilities

People have rights and responsibilities when it comes to pain management. These rights and responsibilities come from three main groups of resources: advocate groups and supporting professional medical organizations (Group One); federal agencies and legal entities (Group Two); and state agencies and legal entities (Group Three).



Sources for Patient Rights & Responsibilities Related to Pain Management

As you review the materials you collect in your notebook, it is important to consider which group is making the “rights and responsibilities” statements. Group One can make statements about patient rights and responsibilities, but cannot make laws. Groups Two and Three can make laws, but do not necessarily do so with the statements of Group One in mind. In this article, I will discuss statements made by Groups Two and Three, reviewing—from a legal perspective—a patient’s basic rights and responsibilities.

## Federal Government View of Patient Rights

By law, the federal government cannot tell doctors how to practice medicine. The federal government can, however, tell doctors what makes a prescription for a controlled substance valid or legal.

Federal law says that a prescription for a controlled substance is valid if it is issued for a legitimate medical purpose in the usual course of professional practice.<sup>1</sup> In September 2006, the U.S. Drug Enforcement Administration issued “*Final Policy Statement on Dispensing Controlled Substances for the Treatment of Pain.*”<sup>2</sup> This document gives doctors the responsibility to minimize the potential for abuse and diversion of controlled substances by monitoring or supervising patients according to the facts of each patient’s medical case.

What does this mean to you in terms of your rights and responsibilities?

It means the federal government wants to see proof from doctors who prescribe controlled substances that you:

- \* Have a real medical problem for which controlled substances are an appropriate treatment
- \* Have a valid physician-patient relationship
- \* Are acting responsibly with the medications you receive and following treatment recommendations, drug and non-drug.

More of the important statements issued by Group Two over the last seven years are available on my website, [www.legalsideofpain.com](http://www.legalsideofpain.com).

## How State Agencies View Patient Rights

State agencies include medical and pharmacy licensing boards, workers’ compensation programs, and state law enforcement groups. States are responsible for setting laws to protect their citizens. States have to follow federal law but can make state law stricter than federal law when it comes to controlled substances. CONTINUED ON PAGE 6...

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A drug that is not considered “scheduled” by the Federal government may be reviewed by a state. The state may decide there is a reason to schedule the drug within the boundaries of the state. So state lawmakers go to the state legislature and pass a law saying the drug is to be scheduled. This same rationale allows a state to pass an *Intractable Pain Treatment Act* or a *Patient Bill of Rights*, as California and a few other states have done.

Overall, statements made by Group Three tend to be more specific and contain a balance of rights and responsibilities related to pain management and controlled substances to treat pain. And, it is important to remember that many of the Group Three statements are specifically directed at doctors, and thus contain implied patient rights and responsibilities. It is rather easy to use Group Three materials to make arguments on behalf of patients.

## Sample Patient Bill of Rights

Key statements made in California’s “*Pain Patient’s Bill of Rights*”<sup>3</sup>, are explained below in terms of patient and physician rights.

### Statements

- ❖ Inadequate treatment of acute and chronic pain originating from cancer or non-cancer medical conditions is a significant health problem.
- ❖ For some patients, pain management is the single most important treatment a physician can provide.

### Patient & Physician Right

Patients suffering from severe chronic intractable pain should have access to proper pain treatment.

### Patient & Physician Rights with Conditions

- ❖ Patients suffering from severe chronic intractable pain may require referral to a specialist and may require a treatment team from different medical disciplines.
- ❖ Opiates can be an accepted treatment for patients in severe chronic intractable pain, if the patient has not obtained relief from any other means of treatment.

### Patient Rights

- ❖ A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities (treatments) to relieve his/her severe chronic intractable pain.

- ❖ A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for treatment of severe chronic as long as the prescribing is in conformance with the California Intractable Pain Treatment Act and other prescribing codes in the state.
- ❖ A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

### Physician Right

A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the California Intractable Pain Treatment Act.

### Physician Right with a Corresponding Responsibility to the Patient and Thus a Patient Right:

The physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

*“There is no doubt that a person has a right to quality pain management.”*

Some states have documents that focus on patient responsibilities related to the proper handling and safe use of controlled substances, which must be part of your understanding of your state’s position. Likewise, the whole matter of patient rights and responsibilities is a little more complicated than indicated by this article. However, there is no doubt that a person has a right to pain management and that both patients and physicians have responsibilities relating to the proper and safe use of controlled substances to treat pain.

### Opioid Treatment Agreements

Do physicians have to use treatment agreements or narcotic contracts in pain management? Is the “one strike and you’re out” policy regarding opioid treatment agreements justified and legal?

One of the key elements of many state prescribing rules or guidelines is the use of an “Agreement for Treatment,” which many doctors have chosen to rename “Narcotic Contract.” These documents set boundaries between you and your doctor, such as requiring one doctor for controlled substances, using only one pharmacy, having your medication counted on a regular basis, and appearing for urine drug testing.

Most states *do not* require doctors to use these documents with all patients. Rather, most states say they should be used with *high risk patients* (those who have a history of substance abuse or an active abuse problem). However, it is not illegal for a doctor to choose to use such agreements with all patients.

Some doctors make the decision to use a “Dear Patient” letter for most patients and reserve the agreement for the high risk patients. You should discuss this with your doctor and try to understand what is expected of you.

Further, a doctor who uses a treatment agreement does not necessarily think you abuse drugs. If a doctor is using the document properly, it is merely to set forth expectations and consequences for failing to meet them.

Finally, you should not just sign one of these documents automatically. Instead, take time to read what it says, and ask questions if you do not understand a particular term. This is your health care and you have a right to actively participate in all aspects of it. You can find out more about these agreements on my website.

### One Strike Policies

Problems can arise when you sign a Treatment Agreement and the unexpected happens—like car trouble, a delayed flight, or a sick child. These can stop you from following the agreement requirements like making an appointment on time, getting to the pharmacy within a two or three hour period to show your medication for counting, or to the doctor’s office to give a urine sample.

Your doctor has a right to expect you to communicate with his/her office if you face these challenges, and you have a right to explain what happened. After that, the water gets cloudy and it is hard to say for sure whether discharge or dismissal from the doctor’s practice is warranted because you could not comply with the demands of the Treatment Agreement.

To avoid communication problems, call your doctor immediately if you have a problem making an appointment, medication count, or urine drug test. Be truthful and follow up with a written note recounting your conversation and the problem you faced. The doctor has to make this part of the patient record.

## Be Responsible and Act Wisely

- ❖ Be active in your pain management.
- ❖ Be truthful with your doctor.
- ❖ You have as much of a right to document your medical chart your doctor does, so do your part and keep the record straight.
- ❖ Be polite to your doctor and his/her staff, even if they seem sharp or unkind to you.
- ❖ Be responsible for appointments and call ahead if you have to miss one that was scheduled or requested because of a Treatment Agreement.
- ❖ Be responsible with your medications.
- ❖ Participate in all other treatments that have been recommended and that you have consented to.
- ❖ Keep learning more about your rights and responsibilities.
- ❖ Do your part and you will help the many people who are trying to make pain management better.

Do not wait until your next appointment or even the next day to try to explain, and be sure to document what happened. Doctors need to remember that life does interfere with the ability to keep appointments—it happens to them occasionally as well. While I cannot promise that my recommendations will make it any easier for you to deal with your doctor, they might help you find some common ground.

Some pain psychologists are studying the issue of whether “one strike” policies are appropriate and you can expect more literature on this issue in the future.

Many state medical licensing boards have regulations, rules, guidelines, or policy statements that make it unethical for a physician to “abandon” a patient. Look for it on their website or have it mailed to you. Remember however, whether a one-strike-and-you’re-out policy constitutes abandonment depends wholly on the facts of the individual patient’s case.

<sup>1</sup> 21 Code of Federal Regulations Section 1306.04 (Purpose of Issue of a Prescription)

<sup>2</sup> FR Doc E6-14517 [Federal Register: September 6, 2006 (Volume 71, Number 172), page 52715-52723] Department of Justice, Drug Enforcement Administration, 21 CFR Part 1306, Dispensing Controlled Substances for the Treatment of Pain; Notice Issuance of Multiple Prescriptions for Schedule II Controlled Substances; Proposed Rule

<sup>3</sup> California Pain Patients Bill of Rights: California Senate Bill No 402, Passed the Senate September 5, 1997, Passed the Assembly September 2, 1997 (can be viewed at [http://www.paincare.org/pain\\_management/advocacy/ca\\_bill.html](http://www.paincare.org/pain_management/advocacy/ca_bill.html))

## Doing Less with More Love

*Supportive people helped me gain access to pain management skills*

by Patricia Nielsen, Blair, Nebraska

I recently ran across a quote from Mother Teresa that summarizes what living with pain has taught me: “It is not what we do but how much love we put into it.”

This is very comforting to me because I still have times when I feel guilty for not doing more. But overall, living with pain has indeed changed me.

Before my back injury, my life consisted of setting goals and stacking up accomplishments. Family and friends were secondary to my career and I judged the success of each day by the number of tasks that were crossed off my to-do list. Physically, I had a constant battle with my weight and I depended on a healthy body to work off the extra calories I consumed. Emotionally, my worth depended on my service to others. Spiritually, I depended only on myself.

In 1988, everything changed after two back injuries. I could not work outside



the home and needed help inside it. My eating behavior fluctuated between binging and starving. Since I could do little for others, my life had no purpose or meaning.

The ACPA was only eight years old at that time, but I found it immediately. I read the workbook like it was a Bible and couldn't believe that the director could help me over the phone. I opened myself to other forms of help as well by finding 12-step programs that addressed my eating and co-dependency and spent more time in prayer and meditation.

All along the way, supportive people offered their help. As they say, desperate times call for desperate measures. I reached out in humility as though my life depended on it, which it did. I in turn reached out to others by phone or mail. In my family, I tried to focus on listening more than talking.

My concept of “doing enough” has changed the most, although sometimes I still act as though I am Cinderella with my eye on midnight, trying to add task after task before my body says no.

I still occasionally make the mistake of pushing myself too hard and paying the price, but I am, on the whole, much more ready to do less with more love.

As Mother Teresa said, it is the amount of the love we put into each task that counts, not how many we do. I try to practice this at my part-time job and at home. I trust that, if this motto is good enough for Mother Teresa, it is good enough for me.

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## Sharing a Personal Perspective with Professionals

“Learn to live with it’ sounds like an impossible task to people with pain. But you can provide them with the skills they need to take an active role in the recovery process. This can help them to move from the mindset of a patient to that of a person.”

This was the message ACPA founder and executive director Penney Cowan brought to the British Pain Society (BPS) at its annual meeting in Glasgow, Scotland, April 24 to 27, 2007.

Penney was invited to address a plenary session and to conduct a workshop for the BPS, which is the largest multidisciplinary professional organization in the field of pain within the UK. Its membership comprises medical pain specialists, nurses, physiotherapists, scientists, psychologists, occupational therapists, and other healthcare professionals actively engaged in the diagnosis and treatment of pain and in pain research for the benefit of patients. The BPS is a chapter of the International Association for the Study of Pain.

Response among the 500 attendees at the plenary session was overwhelmingly positive. Many cited the clarity with which Penney communicated the experience of the individual, which they, as practitioners, often have no opportunity to hear. In addition, attendees found the ACPA materials to be powerful tools for helping people in the UK who, like so many here in the U.S., live with ongoing pain.

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# Successful Clinical Trials: A Team Effort Part II

by Alyse Cooper and Elisabeth Kurkimalis, Medical Affairs, Celgene Corporation; and Donald Manning, Medical Affairs, Celgene Corporation and Department of Anesthesiology and Pain Management, University of Virginia

In the March 2007 issue of *The Chronicle*, part one of “Successful Clinical Trials—A Team Effort” discussed the different phases of clinical trial research, focusing on the patient and some of the questions one should ask when deciding whether or not to participate in a clinical trial.

In this article, we will focus on some of the roles and interactions of the trial sponsor, trial site personnel, and person in the clinical trial process, presented in the order in which they occur in conducting a clinical trial. The roles of Institutional Review Boards (IRBs) and regulatory agencies (e.g. FDA) will not be specifically discussed in this article.

## Responsibilities of Trial Sponsors

A trial sponsor can be a pharmaceutical/biotechnology company, government agency, or an individual investigator involved in conducting clinical research. This article will focus on the responsibilities of pharmaceutical/biotechnology companies in conducting a clinical trial.

The primary responsibilities of the trial sponsor are to ensure that the rights, welfare, and safety of patients are protected and that they are not knowingly harmed.

Responsibilities include:

- ❖ Ensuring that an Investigational New Drug (IND) application for the investigational compound and indication (disease) to be studied has been filed with the FDA. The trial protocol and Investigator’s Brochure (IB) are included as part of this submission.
- ❖ Selecting qualified, well-trained investigators to conduct the trial. Investigators need to be knowledgeable, not only regarding the disease-state under study, but also with Good Clinical Practice (GCP) requirements. GCP, an international standard for conducting, recording, and reporting clinical trials, is geared toward protecting the rights of human patients involved in clinical trials, and ensuring the

reporting of high-quality clinical trial data (<http://www.fda.gov/oc/gcp/guidance.html#ich>).

- ❖ Making sure that the appropriate documentation has been received from site personnel prior to the start of the trial. Documentation includes investigator-signed FDA Form 1572 (see “Responsibilities of Trial Site Personnel—Investigator” for additional information), signed protocol, approved informed consent form, documentation that the protocol and consent form have been reviewed and approved by an Institutional Review Board (IRB), financial disclosure information, and a signed contract.
- ❖ Registration of the trial in the ClinicalTrials.gov database at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). This database provides patients and researchers with up-to-date information regarding industry- and research-sponsored clinical trials.
- ❖ Providing the trial drug, manufactured according to high-level quality standards.
- ❖ Incorporating a Data Monitoring Committee (DMC) into the trial design when appropriate. This committee, which monitors a trial’s efficacy and safety data, often has access to unblinded data (actual treatment a person is taking, e.g., active drug versus placebo in the case of a double-blind trial), which is unavailable to the sponsor until trial completion. They can recommend making changes to the conduct of the trial, including stopping one particular dosage of trial drug. They might terminate the trial early for safety concerns, for overwhelming treatment efficacy, or for a clear inability to show a treatment effect.
- ❖ Ongoing trial monitoring. Monitors confirm that appropriate participants are enrolled and have signed informed consent forms, that trial procedures are being performed according to the protocol, adverse events are being reported to the sponsor in a timely manner, trial drug is being stored in a safe area, data is appropriately recorded in the patients’ records and on the case report forms, and the site is performing the trial in accordance with GCP guidelines. In the event a site is performing poorly, the monitor (sponsor) is responsible for ensuring that the site is brought back into compliance. If unable to do so, the sponsor is responsible for stopping the site from continued trial participation.
- ❖ Reviewing the trial data in a timely manner. The sponsor must be sure that investigators are promptly provided with new information regarding significant new adverse events or risks associated with the trial drug, so that this new information can be relayed to patients and IRBs.
- ❖ Producing a final trial report and ensuring the prompt and accurate publication of trial results.

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# Successful Clinical Trials: A Team Effort Part II

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## Responsibilities of Trial Site Personnel

The primary responsibilities of trial site personnel are to ensure that the rights, welfare and safety of their participants are protected and to conduct the trial according to regulations and the protocol.

The investigator is responsible for conducting the trial according to the responsibilities specified in the FDA Form 1572. This form, which represents a contract with FDA, must be completed and signed by the investigator prior to the start of the trial. To falsify information on this form or disregard commitments is a criminal offense. The Investigator's commitments include: ensuring the IRB has approved the protocol and informed consent form; ensuring every patient has signed an informed consent form; conducting the trial in accordance with the protocol, FDA regulations, and under the conditions specified by the IRB; making changes in the trial only with the approval of the sponsor and IRB, except where immediate action is required to protect the welfare of the participant; having full knowledge of the trial compound and related scientific information (Investigator Brochure), reporting all adverse events in a timely manner; keeping accurate records, and personally conducting and/or supervising the investigation.

The Investigator must also delegate certain tasks to qualified members of the trial staff. Exceptions include specific tasks where a medical decision is involved (decisions regarding cause, assessment of adverse event causality [related to or not related to trial drug treatment] subject termination, drug dosing, evaluation of abnormal clinical data, etc.)

In addition, the Investigator is responsible for:

- \* Timely review of all clinical and laboratory data.
- \* Providing the sponsor with current, accurate information regarding his or her qualifications and disclosing any potential financial conflicts of interest.
- \* Ensuring the trial staff is trained on the protocol and in conducting clinical trials according to GCP Guidelines.
- \* Following HIPAA Guidelines.
- \* Making sure appropriate medical records are available for monitor and regulatory review. Meeting with trial monitor as required.
- \* Providing adequate medical care to participants for adverse events (including significant laboratory abnormalities) during and following completion of the trial.

- \* Ensuring trial records are retained according to FDA guidelines.
- \* Signing off on participant data recorded on case report forms.

The Trial Coordinator is responsible for coordinating the trial's day-to-day activities. Depending on the coordinator's qualifications (e.g., LPN, RN versus no medical training), the coordinator may also conduct some of the protocol-required assessments.

The Trial Coordinator's responsibilities include:

- \* Fully understanding and conducting the trial in accordance with the protocol.
- \* Completing all necessary paperwork for IRB and sponsor submissions. Providing ongoing updates of required information to IRB, FDA and trial sponsor.
- \* Coordinating trial-related activities (screening patients for inclusion, scheduling trial visits, lab work, ECGs, etc).
- \* Conducting the trial so as to ensure the safety of patients and the integrity of the data.
- \* Accurately reporting and tracking adverse events and reporting any serious adverse events to the sponsor.
- \* Developing and maintaining patient source documentation, regulatory files, screening logs, etc.
- \* Ensuring trial drug is properly stored.
- \* Developing and implementing a patient recruitment plan.
- \* Corresponding with trial sponsor when necessary.
- \* Accurate and timely completion of the case report forms.
- \* Ensuring patients are taking the trial drug according to protocol requirements.
- \* Performing protocol assessments (physical exam, electrocardiogram, drawing blood for laboratory tests, etc.) if qualified.
- \* Maintaining open lines of communication with the investigator. Ensuring all medical decisions are appropriately made.
- \* Ensuring all trial records are retained for the appropriate time-period required by regulations and documenting all related correspondence.

## Trial Participants are Most Important

The individual volunteering for the trial is perhaps the most important part of the clinical research process. In today's health-care environment, it is important that people take a more active role in making health-care decisions, including a decision to participate in a clinical drug trial. The decision

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# Pain Medicine in the News

## Exercise Could Help Curb Arthritis

Arthritis is a leading cause of pain and disability, affecting 21 percent of the U.S. population. A recent study from Australia—where 3.4 million people have arthritis—looked at the connection between physical activity and the incidence of stiff or painful joints in middle-aged and older women.

The results suggest that physical activity, about 75 minutes a week, was associated with decreased odds of developing stiff or painful joints over three years. These findings, recently published in the journal *Arthritis Research & Therapy*, indicate that older women not currently experiencing pain and stiffness should be counseled on ways to be physically active to reduce their risk of developing these conditions.

“If increasing physical activity participation by even small amounts could

delay the onset and development of symptoms of arthritis, there could be considerable cost savings to the health-care system and to older women themselves, not to mention reductions in pain and suffering,” the authors said.

—*Arthritis Research & Therapy* 2007, 9:R34; study by Kristiann C. Heesch, Yvette D. Miller, and Wendy J. Brown

## Researchers Debate Addictions to Pain Killers

More than 500 researchers, clinicians, and interested consumers attended Pain, Opioids, and Addiction: An Urgent Problem for Doctors and Patients, a conference in March sponsored by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH).

“Who is most at risk for addiction to pain killers?” and “How do you balance getting adequate pain relief with

the risk of addiction?” were discussed in the context of prescription painkiller abuse and the potential for addiction in patients with chronic pain conditions.

Narcotic pain relievers, such as Vicodin and Oxycontin, have many beneficial effects when used properly, particularly for those with chronic pain. Scientists discussed how a genetic variation alters how some people respond to stress and suggested that these people may be more vulnerable to addiction.

Under development are new types of pain relievers that do not create tolerance or dependence. Other tools, such as real-time functional magnetic resonance imaging, may soon help patients better manage their own pain. For more about the conference and a web cast from the meeting, go to [www.nida.nih.gov](http://www.nida.nih.gov).

## Clinical Trials CONTINUED FROM PAGE 10...

is an important one and should not be made lightly, for with it comes certain commitments and responsibilities. As a volunteer, you should:

- \* Fully understand the trial requirements before agreeing to participate and ask all relevant questions prior to signing the informed consent form.
- \* Provide accurate, complete medical information regarding current and past medical conditions, hospitalizations, medications, and other related information. This information is crucial in determining eligibility to participate in a trial. Enrollment of inappropriate participants could have an impact on patient safety as well as final trial results.
- \* Comply with all trial procedures, e.g., returning for visits when required, taking your trial medication as prescribed, not drinking alcohol or taking any unacceptable medications, etc.
- \* Be honest and provide accurate information to site personnel during the course of the trial. If you take an unacceptable medication, or miss a dose of the trial drug, you should tell the trial coordinator as soon as possible. They can determine if you are at any risk and also how your actions may impact the trial.

- \* Provide complete, accurate contact information not only for yourself, but also for next of kin in the event of an emergency.

As a participant, you should report all adverse events as soon as possible. Always ask questions if you are unsure about something. There is never any harm in asking a question; the harm may come in not asking. Also, never stop the trial drug without speaking with a member of the clinical staff. There could be serious safety implications in abruptly stopping a medication or not returning for a final trial visit.

The US drug approval process is a long, tedious, and costly undertaking. With development costs as high as \$1.7 billion (FDA White Paper; March 2004) and 10 years or more needed to get a drug approved, it is imperative that clinical research trials be high quality and done correctly the first time. Interactions among the trial sponsor, site personnel, and participants is key to producing timely reports. Each of these team members provides an important piece of the final product, but only through ongoing collaboration will the final goal of bringing new drugs to market be achieved.

# ACPA Update

## New ACPA Groups

Welcome to our new groups and facilitators.

**Catherine Cartwright**  
Vallejo, CA

**Ronnie Couture**  
Alpena, MI

**Donna Elberson  
and  
Jean Bascombe**  
“Never Feel Alone Again”  
Havertown, PA

**Theresa Hesse**  
Dallas, TX



### Tracking Pain Management Methods

The Pain Management Inventory (PMI) was developed by Gail Davis, RN, EdD, a professor at Texas Woman’s University and a member of the ACPA Professional Advisory Committee.

It is a helpful tool for people to use to assess their own pain management techniques, and communicate their results to their doctors. Dr. Davis is continuing to develop the PMI and to test its validity in relation to an outcomes expectations questionnaire and a pain experience questionnaire.

Being able to communicate which pain relief methods you use to ease or relieve your pain will help your doctors treat you. Some methods, as medicine, might be expected to provide pain relief promptly. Others, such as distraction and stress reduction, are appropriate for easing or handling the pain over time. When you believe that something is going to be helpful, then you will be more likely to use it.

To download the PMI, go to <http://myweb.twu.edu/~gdavis/index.html>. Complete it before you see your health care provider or doctor. The form has space to write in any other method you are using. At that web site you can also view pain management studies and other pain management instruments: the Chronic Pain Experience Instrument (CPEI) and the Pain Management Outcomes Expectation Instrument (PMOEI).

### Donate to the ACPA

The ACPA has been accepted as an approved charitable organization for the Fall 2007 Combined Federal Campaign (CFC) with agency code 10549. This code only applies to CFC—the world’s largest annual workplace giving campaign involving federal civilian, postal and military donors.

If you work for a CFC organization, please consider making a donation to the ACPA. And if others you know participate in a CFC program, please let them know that they can contribute to the American Chronic Pain Association and support people who live with pain.

### Dispose of Your Unused Meds Safely

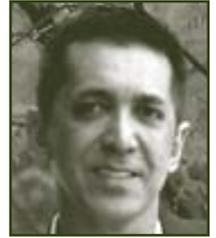
What’s in your medicine cabinet? Chances are that tucked in next to the spare toothbrush is a bottle of out-of-date prescription medicine. Drugs that are diverted (taken by someone other than the intended patient) or used inappropriately have the potential to do harm.

To reduce the diversion of prescription drugs while also protecting the environment, the White House Office of National Drug Control Policy (ONDCP), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) have jointly released new guidelines for the disposal of unused or out-of-date medications. They are very similar to those previously released by the American Pharmacists Association (APhA).

The guidelines suggest:

- \* Unused, unneeded, or expired prescription drugs should be taken out of their containers and the original prescription label destroyed. Mix the drugs with an undesirable substance, like used coffee grounds or kitty litter. Put them in an empty can or sealable bag, so that they will not be found by others or ingested by children or pets. Throw these containers in the trash.
- \* You should not flush medications down the toilet as they may remain in the waterways and harm wildlife.
- \* In some communities, there are pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal.

# Board Member Profile: Dr. John Encandela



*This is part of a series of articles intended to give readers more insight into the interests and contributions of ACPA board members.*

John Encandela, Ph.D., is director of the Graduate Medical Education Outcomes Project at New York Presbyterian Hospital, shared by Columbia and Cornell University medical schools.

In this position, he provides resources for training and evaluating residents in various competency areas. He also serves as a faculty member at Columbia University's Mailman School of Public Health and teaches program outcomes evaluation at Columbia University's Teachers College.

Dr. Encandela joined the board of the ACPA in 1996, several years after completing his doctoral dissertation on the chronic pain experiences of residents of continuing care retirement communities. This study focused not only on the pain experiences of individuals, but also on the response of organizations to the treatment and management of chronic pain within the confines of retirement communities.

"My involvement with issues of chronic pain is largely within the context of the ACPA. Of course, because my current career focus is in supporting the training of medical residents, how to treat and understand pain emerges as one of many training issues," Dr. Encandela said.

Dr. Encandela feels the strength of the ACPA is its connection with people with chronic pain. "The ACPA has very concrete and accessible educational materials and other resources for people with pain and for those who care about these individuals," he said.

"Our organization's strongpoint is being closely in touch with and supportive of people with pain. But at the same time, we should continue to make inroads with other professional organizations that could be supportive of ACPA's main mission," he added.

*"Our organization's strongpoint is being closely in touch with and supportive of people in pain."*

Employers, families, health care providers, and insurers all need to become more aware of the issues that affect people with pain, according to Dr. Encandela.

"My personal interest is in better educating health care providers, but I do believe that other constituents need to be educated, especially employers and insurers. I think families understand the issues of chronic pain (though a fair number may disbelieve or think that pain is only psychological). Still they do not always have intense understanding of ways that they can be most helpful in assisting family members with pain."

Dr. Encandela's technical background has largely focused on program evaluation and learner assessment. He was technical director and trainer in program monitoring and evaluation for the Centers for Disease Control and Prevention's Global AIDS Program from 2002-2005 and was Director of Evaluative Research for the Pennsylvania HIV Prevention Program while at the University of Pittsburgh.

He earned a B.A. degree at Geneva College, Beaver Falls, Pa., a M.A. degree at West Virginia University, and a Ph.D. degree in sociology from the University of Pennsylvania. He also conducted a National Institute of Mental Health post-doctoral fellowship at the University of Pittsburgh's Western Psychiatric Institute and Clinic.

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*We welcome essays, poetry, articles, and book reviews written by people with chronic pain or their families.*

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# Tributes

***In Loving Memory***  
**KRISTIE RAINES**

Given by  
 Christine Lamano  
 Fred and Linda Diamond  
 Allen and Patricia Hirschorn  
 Lucy Anderson  
 Steven S. Parker  
 Burnet Tucker

***In Loving Memory***  
**ROSCOE W. MITCHELL, JR.**  
 SURVIVED BY HIS WIFE KIRTSY MITCHELL

Given by  
 Lynn K. Anders  
 Memorial Piano Teachers  
 Houston, TX  
 Geneva Jamison

***In Memory of***  
**RICHARD SIKORA**

Given by  
 Catherine Pavur

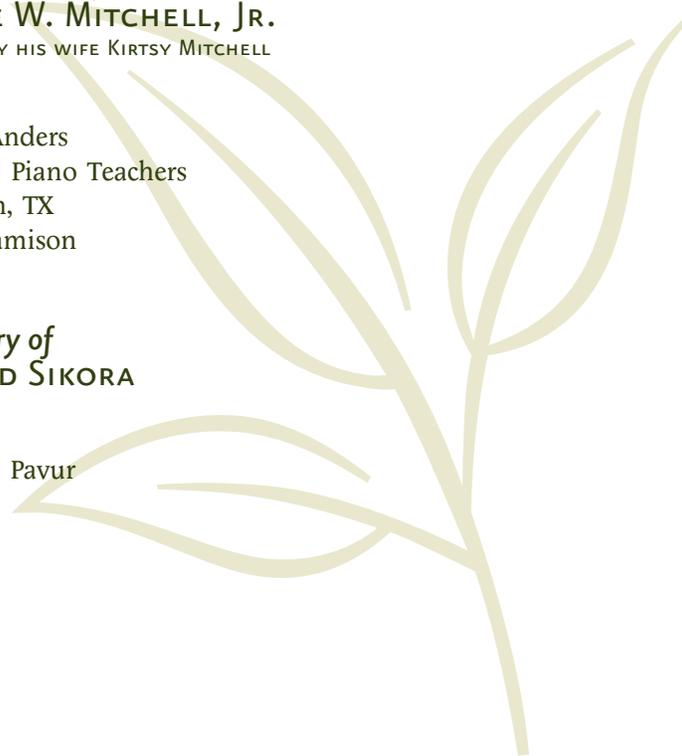
**LORETTA “PEGGY” VARGAS**

Loretta “Peggy” Vargas, a long-time volunteer and staff member at ACPA headquarters, passed away March 5, 2007 at age 67. She will be greatly missed at headquarters, where her daughter, Joni Armstrong, also works as administrative assistant.

Peggy was an amazing testimony of someone who worked hard for a cause she believed in. She loved keeping busy and the ACPA gave her purpose.



*Peggy Vargas and her daughter, Joni Armstrong*



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*The ACPA is a peer support organization: we help each other learn to live fully in spite of chronic pain. We also need to join together to make sure the ACPA continues to be there for us all with resources, materials, and that personal contact that can make such a difference.*

*Your membership, donations, and purchase of materials keep the ACPA alive and reaching out to even more people with pain. Thanks for helping us help others.*