

---

**From:** Beckhardt, Stacey </O=CEPHALON/OU=US01 ADMINISTRATIVE GROUP/CN=RECIPIENTS  
/CN=SBECKHAR>  
**To:** Larijani, Susan  
**CC:** 'Lisa Weiss'  
**Sent:** 1/20/2005 7:02:01 PM  
**Subject:** ACPA 2005 Medications and Chronic Pain Supplement.doc  
**Attachments:** ACPA 2005 Medications and Chronic Pain Supplement.doc

Susan --

I revised the letter as we discussed. When you get back next week, check it out and make sure I captured all of your thoughts. We really need to get this out as we believe they are reviewing the document now. Great catch on Gabitril and Provigil -- I didn't even think to look for them. Talk to you Monday.

Best, Stacey

PLAINTIFFS TRIAL  
EXHIBIT  
**P-19214\_00001**

January 24, 2005

Nicole Kelly  
American Chronic Pain Association  
[nicolekelly@verizon.net](mailto:nicolekelly@verizon.net)

Dear Ms. Kelly:

We appreciate the opportunity to submit the following suggestions to the American Chronic Pain Association for consideration as you revise the Medication and Chronic Pain Supplement for 2005.

There are several sections where we see an opportunity to revise the content to help patients have a better understanding of their pain and be better able to explain it to their healthcare provider:

Chronic Pain Classification (page 11)

- Expand the description of chronic pain to define persistent and breakthrough pain as its two main components. We would propose the following language:
  - Persistent pain lasts 12 or more hours every day for more than three months. It is usually treated with medicine that you take at specific times every day so that you get pain relief throughout the day. Moderate-to-severe persistent pain may be treated with opioids.
  - Breakthrough pain consists of unpredictable pain flares that "break through" the medicine taken around-the-clock to treat persistent pain. These breakthrough pain flares typically peak in as little as three minutes and may last up to 30 minutes. Breakthrough pain may be caused by changes in an underlying disease, including treatment, or involuntary or voluntary physical actions - such as coughing or getting up from a chair. Breakthrough pain may also occur at the end of the persistent pain medicine dose. Treatment for moderate-to-severe breakthrough pain is a strong, short-acting pain medicine, such as an opioid, that works quickly and lasts about as long as a breakthrough pain episode.

Opioid Analgesics (page 14)

- Add information to the section on opioid analgesics about long- and short-acting opioids to help clarify types of opioids and when they are used, such as the following details:

- Opioids are typically used around-the-clock in people with moderate-to-severe chronic pain.
- Some opioids are used around-the-clock, while others are used as needed for breakthrough pain. Often, opioids are prescribed in combination where the around-the-clock medicine is used to treat the persistent pain, while a short-acting opioid is used to treat breakthrough pain.

Anticonvulsants or Antiepileptic Drugs (page 29)

- Modify discussion of tiagabine (GABITRIL) on page 30 as follows:

Preliminary data from clinical studies suggest that tiagabine (GABITRIL) may be useful for nerve injury or neuropathic pain. However, safety and effectiveness of GABITRIL have not been established for any indication other than as adjunctive therapy for partial seizures in adults and children 12 years and older. In epilepsy, the most common side effects include nausea, dizziness, drowsiness, weakness, abdominal pain, nervousness, tremor, and difficulty with concentration.

Post-marketing reports have shown that GABITRIL use has been associated with new onset seizures and status epilepticus in patients without epilepsy.

Activating Medications (Central Nervous System Stimulants) (page 39)

PROVIGIL:

- Expand approved use of modafinil (PROVIGIL) to include excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder.

References on the Internet (page 45)

- We also suggest that ACPA consider adding the following websites, since all contain useful information on chronic pain:

American Pain Foundation:  
[www.painfoundation.org](http://www.painfoundation.org)

American Alliance for Cancer Pain Initiatives:  
[www.aacpi.org](http://www.aacpi.org)

American Pain Society:  
[www.ampainsoc.org](http://www.ampainsoc.org)

[BreastCancer.org](http://BreastCancer.org)

Nicole Kelly – American Chronic Pain Association  
January 24, 2005  
Page 3 of 3

*CancerCare*:  
[www.cancercare.org](http://www.cancercare.org)

National Pain Foundation:  
[www.painconnection.org](http://www.painconnection.org)

OncoLink (pain management section):  
<http://www.oncolink.upenn.edu/coping/section.cfm?c=5&s=26>

Pain.com

Thank you for your consideration. Please do not hesitate to contact me at 610-738-6304 should you or your medical advisors have additional questions.

Sincerely,

Susan Larijani, RN  
Senior Manager, Professional Services / Medical Information  
Medical Affairs

cc: Stacey Beckhardt