**From:** Kiren A Patel </O=MAIL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KAPATEL > </O=MAIL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KAPATEL> on behalf of Kiren A Patel </O=MAIL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KAPATEL >
**Sent:** Thursday, February 11, 2010 6:31 PM
**To:** Toni M Picone
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Napoleon D Clark
**Subject:** Pain Assessment Tool
**Attachments:** image001.gif

Hi Toni,

The PRC team reviewed several Marketing Fentanyl promotional pieces which had questions on chronic and breakthrough pain that were not supported by any references and were very similar to the brand products promotional pieces. The PRC team provided changes to the promotional pieces to use a validated questionnaire for chronic pain and breakthrough pain. The Marketing agency SS&B was not able to find a validated questionnaire for chronic and breakthrough pain. The Medical dept was able to find a validated questionnaire for chronic pain but not for breakthrough pain.

If we don't have a validated questionnaire for both chronic and breakthrough pain, the Medical dept recommends using the American Pain Foundation pain tool as a second option. The tool is not a validated tool but it is published by a reputable foundation. The tool is the same one you sent to me, however at the PRC meeting SS&B was provided direction to support the promotional pieces with only validated pain tools.

Kiren

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**From:** Toni M Picone
**Sent:** Thursday, February 11, 2010 5:55 PM
**To:** Kiren A Patel
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Napoleon D Clark
**Subject:** RE: Pain Assessment Tool

Kiren,

**Attorney-Client**

Thanks,
Toni

Toni M. Picone
Marketing Manager, Generics
Watson Pharmaceuticals
360 Mt. Kemble Avenue



PLAINTIFF TRIAL EXHIBIT
P-28596_00001

Morristown, NJ 07960
P: 973-355-8214
F: 973-355-8584

**From:** Kiren A Patel
**Sent:** Thursday, February 11, 2010 5:38 PM
**To:** Napoleon D Clark
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Toni M Picone
**Subject:** RE: Pain Assessment Tool

Hi Napoleon,

**Attorney-Client**

Kiren

**From:** Napoleon D Clark
**Sent:** Thursday, February 11, 2010 4:58 PM
**To:** Kiren A Patel; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Toni M Picone
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn
**Subject:** RE: Pain Assessment Tool

Kiren, can you send us a copy or provide the direct link to the resource and tool for BTP. We understand that a final decision has not been made, but we would like to see what the tool is.

Thanks, NaP

**From:** Kiren A Patel
**Sent:** Thursday, February 11, 2010 11:00 AM
**To:** Napoleon D Clark; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Toni M Picone
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn
**Subject:** Pain Assessment Tool

**Attorney-Client**

Thanks,
Kiren

**From:** Napoleon D Clark
**Sent:** Wednesday, February 10, 2010 9:29 AM
**To:** Kiren A Patel; Marianne L Kenny; Ajay Paghdal; Denelle J Waynick; Toni M Picone
**Cc:** Gary D Kozloski; Jennifer G Lagasca; Diane F Miranda; Janie Gwinn
**Subject:** FW: RE:

All, unfortunately it appears that we have not been able to confirm a validated source for the Breakthrough Pain survey/questionnaire. In addition to the "Cephalon" source, we (and Kiren & Ajay) have researched various other sources with no luck. With the deadline approaching and understanding all of the work (website construction, etc.) that needs to be done, I ask what alternatives are available. I have two questions/comments that may be alternatives, but the team will have to comment:

- Janie, I am assuming that the Breakthrough Pain survey is an important requirement for this submission. If so can we submit survey questions for persistent and chronic pain now and resubmit breakthrough at a later point? I don't want to break up the survey, but given time limitations I am not sure what other alternatives are available from this standpoint
- **Attorney-Client**

Please comment at your earliest convenience.

NaP

**From:** Napoleon D Clark
**Sent:** Tuesday, February 09, 2010 3:13 PM
**To:** Kiren A Patel; Marianne L Kenny; Ajay Paghdal
**Cc:** Toni M Picone; Diane F Miranda; Janie Gwinn
**Subject:** FW: RE:

Kiren, Marianne: please see information below. We have a very tight deadline and unfortunately no one can seem to find a validated questionnaire for Breakthrough Pain.

Again, if we cannot find a validated survey, what else can we do?

NaP

**From:** Tom Bloodgood [mailto:tbloodgood@ssbads.com]
**Sent:** Tuesday, February 09, 2010 2:52 PM
**To:** Napoleon D Clark; Toni M Picone
**Subject:** FW: RE:

FYI this is the Emerging Solutions person.

Thanks,
Tom
Tom Bloodgood
Partner
SS&B Advertising
227 Rt. 206, Bldg 2
Flanders, NJ 07836
Office: 973-252-0555

Cell: 908-581-5531
Fax: 973-252-6767

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**From:** Bronwyn Boyes [mailto:bboyes@medicaled.com]
**Sent:** Tuesday, February 09, 2010 2:50 PM
**To:** 'Tom Bloodgood'
**Subject:** RE: RE:

Hi Tom,

This questionnaire belongs to Cephalon so you will need to contact them directly.

Best wishes,

Bronwyn

---

**From:** Tom Bloodgood [mailto:tbloodgood@ssbads.com]
**Sent:** Tuesday, February 09, 2010 2:28 PM
**To:** 'Bronwyn Boyes'
**Subject:** RE:

Hi Bromwin,

Thank you for your quick attention this morning. I wanted to confirm that you received this e-mail and inquire as to if you were able to locate the original questionnaire and were you the actual source.

Thanks,
Tom
Tom Bloodgood
Partner
SS&B Advertising
227 Rt. 206, Bldg 2
Flanders, NJ 07836
Office: 973-252-0555
Cell: 908-581-5531
Fax: 973-252-6767

---

**From:** Tom Bloodgood [mailto:tbloodgood@ssbads.com]
**Sent:** Tuesday, February 09, 2010 11:32 AM
**To:** 'Bronwyn Boyes'
**Subject:** FW:

Hi Bromwin,

Below is the reference to Emerging solutions I mentioned. I'm also sending the assessment questions Cephalon lists on their site. Did you develop these? Here is the link that has the questions.
http://www.fentora.com/pdfs/pdf200_personal_pain_assessment.pdf

# FENTORA (fentanyl buccal tablet)

## BTP in Opioid-Tolerant Patients With Cancer



### Selecting appropriate patients for *FENTORA*

The following criteria can assist in selecting appropriate opioid tolerant patients with cancer for treatment with *FENTORA*:
**Establish** that the patient has breakthrough pain

- Do not prescribe *FENTORA* for acute pain, postoperative pain, or headache/migraine

**Ensure** that the patient is opioid tolerant

- Patients must be on ≥60 mg of oral morphine or an equianalgesic dose of another opioid daily for a week or longer
- Patients must continue using their ATC opioids for persistent pain as long as they are using *FENTORA*

**Execute** a plan for opioid therapy management that includes

- Continuation of ATC opioid medicine(s) during treatment with *FENTORA*
- Initial assessment for aberrant behavior
- Ongoing monitoring, communication, and documentation

Your *FENTORA* representative can help support your practice by providing you with validated assessment and screening tools. You can also access these screening tools at www.EmergingSolutionsinPain.com. This site is supported by an unrestricted educational grant from Cephalon, Inc.
**Click here** to learn more about SECURE, the Risk Minimization Action Plan for *FENTORA*.
*FENTORA* is indicated only for the management of breakthrough pain (BTP) in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. *FENTORA* should NOT be used in opioid non-tolerant patients.

PHYSICIANS AND OTHER HEALTHCARE PROVIDERS MUST BECOME FAMILIAR WITH THE IMPORTANT WARNINGS IN THIS LABEL.

**Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdose.**

***FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid daily for a week or longer.

***FENTORA* is not indicated for use in opioid non-tolerant patients including those with only as needed (PRN) prior exposure.**

***FENTORA* is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients.**

**When prescribing, do not convert patients on a mcg per mcg basis from Actiq® to *FENTORA*. Carefully consult the Initial Dosing Recommendations table. (See DOSAGE AND ADMINISTRATION, Table 7.)**

**When dispensing, do not substitute a *FENTORA* prescription for other fentanyl products. Substantial differences exist in the pharmacokinetic profile of *FENTORA* compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of *FENTORA* for any other fentanyl product may result in fatal overdose.**

Special care must be used when dosing *FENTORA*. If the breakthrough pain episode is not relieved after 30 minutes, patients may take ONLY one additional dose using the same strength and must wait at least 4 hours before taking another dose. **(See DOSAGE AND ADMINISTRATION.)**

***FENTORA* contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. *FENTORA* can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing *FENTORA* in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.**

**Patients and their caregivers must be instructed that *FENTORA* contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all tablets out of the reach of children. (See Information for Patients and Caregivers for disposal instructions.)**

***FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.**

The concomitant use of *FENTORA* with strong and moderate cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

SECURE: Risk Minimization Action Plan for *FENTORA*

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- **About Cephalon**
- **References**



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Thanks,
Tom
Tom Bloodgood
Partner
SS&B Advertising
227 Rt. 206, Bldg 2
Flanders, NJ 07836
Office: 973-252-0555
Cell: 908-581-5531
Fax: 973-252-6767