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**From:** Castagno, Paula  
**To:** Beckhardt, Stacey; Catherine Collier; Jacqueline Davis  
**Sent:** 3/23/2007 10:36:31 PM  
**Subject:** my ppt so far  
**Attachments:** HCPAB presentation 03 07.ppt

Slides 1-19 Michael's (now my) section

-Not sure how much data to review...let me know your thoughts (some data slides need updating – and prettying)

Slides 20-21 my 1st section

-review of FENTORA tools for feedback (need to make sure we have copies of everything there)

Slides 22-30 BTP part 1

-review current campaign, recent market research, play dvd of focus groups, end with revised messaging for discussion

Slide 31-39 BTP part 2

-reveal new concept and all planned BTP educational activities by audience and get feedback

Will we have internet access in the room?

Ignore the rest of the slides – its back up info.

Tx,

Paula Castagno

Assoc. Director, Pain Franchise

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PLAINTIFFS TRIAL  
EXHIBIT

**P-18545\_00001**

**Cephalon Pain Franchise**

**Health Care Professional  
Advisory Board**

**March 30 – April 1, 2007**

# **Review FENTORA Marketplace**

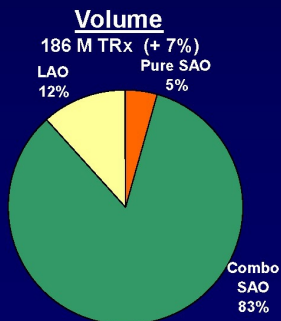
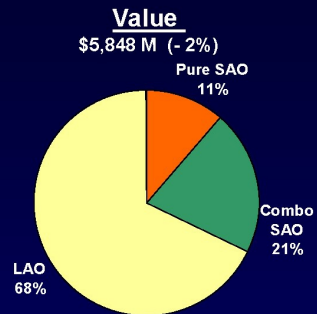
# Objectives

- Review current FENTORA marketplace
- Review 2007 Issues and CSFs
- Discuss potential opportunities and barriers for FENTORA & Assess marketplace needs





# Opioid Market Overview 2005



## Size & Growth

- Opioid market is large
- Value is relatively flat over '04 due to generic LAO entry
- Volume up 7%

## Share

- LAOs make up the largest share in value
- SAOs make up the largest share in volume

Source: IMS - NPA & NSP 2005



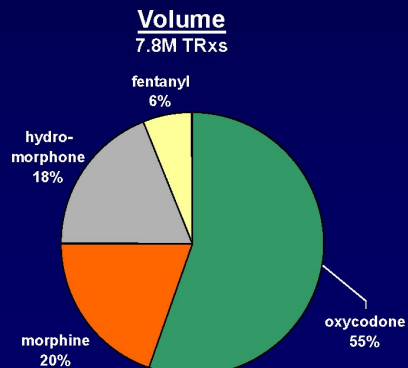
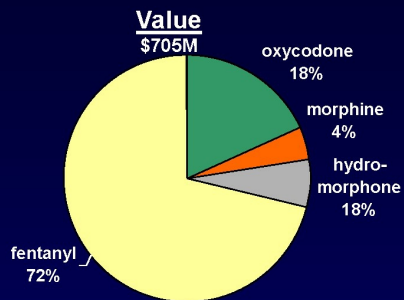
Big market – down slightly due to LAO generic entry

LAO make up biggest value (but slightly declining due to generic entry)

Actiq makes up the majority of pure SAO value (only branded pure SAO in 2005), but only captured a small part of volume

Combo SAOs make up biggest volume (mostly generic) – a large percentage used for acute pain

# Pure SAO Market 2005



Source: IMS, NPA Audit. Moving annual total, 2Q2005.

## Size & Growth

- Pure SAO market is moderate
- Value & Volume have strong growth (>20%)

## Share

- Actiq (fentanyl) made up largest share in terms of value
  - ▶ Only branded Pure SAO in 2005
- Oxycodone dominates in volume
  - ▶ Fentanyl is often perceived as more potent analgesic & held in reserve



Pure SAOs have strong growth in terms of both Value & Volume

Fentanyl made up the largest value in 2005 due to branded Actiq, all other compounds are generic

Oxycodone dominates the Pure SAO mkt in terms of volume

Fentanyl is often perceived as a more potent analgesic and held in reserve

Actiq makes up the majority of Pure SAO value (only branded in 2005), but only minimal volume

Oxycodone: 8 generics, OxyIR®, Oxyfast®, Roxicodone®, Oxydose®

Morphine: 9 generics, MSIR®, Roxanol™

Hydromorphone: 16 generics, Dilaudid®

Fentanyl: Actiq®

## BTP Treatment Patterns

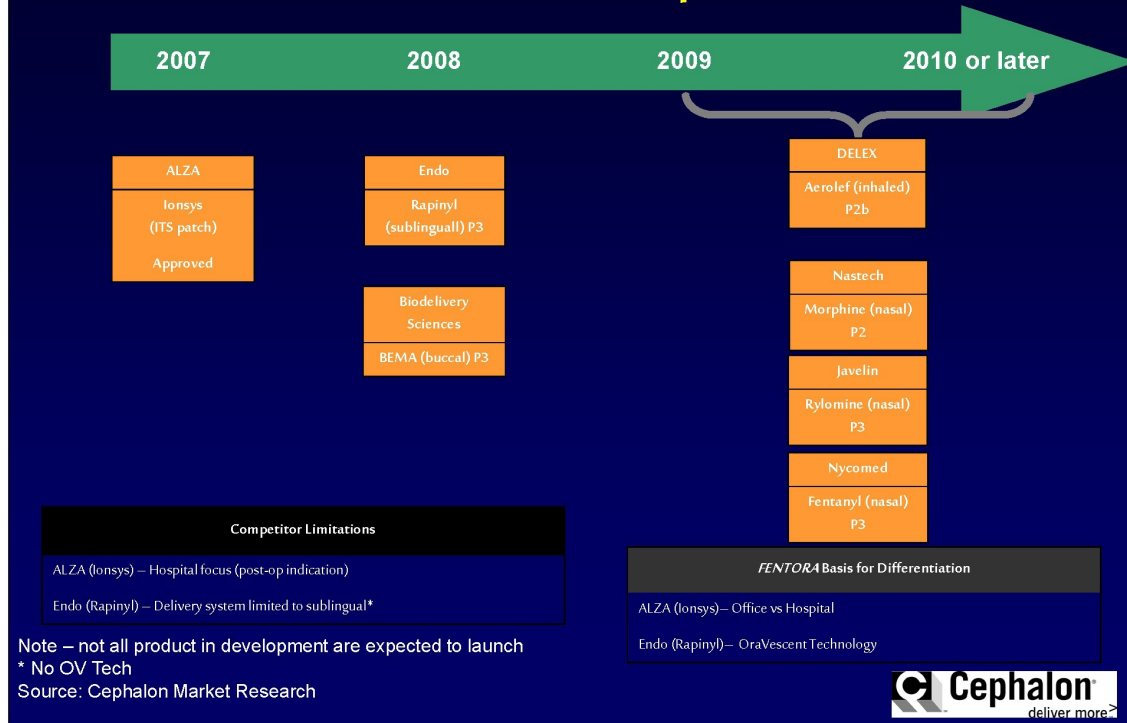
- The most common treatment choice is to increase the dose of LAOs regardless of # of episodes
- The next most common approach is to either increase the frequency or dose of the SAO
- Switching to an alternative SAO is typically the last course of action

Typical Course of Action	# of BTP Episodes	
	≤ 3	≥ 4
Increase dose of LAO	34%	64%
Increase frequency of LAO	7%	12%
Increase frequency of SAO	21%	10%
Switch the LAO	2%	7%
Increase dose of SAO	28%	4%
Switch the SAO	3%	2%

Source: GfK Market Measures – 05



## ROOs in Development



BDSI – Bema (fentanyl) is scheduled for early 3Q'08 launch - mucoadhesive disc designed to rapidly deliver the active ingredient across the buccal mucosa of the mouth

# Key Environmental Trends

## Key Factors

### Economic

- Unfavorable reimbursement environment
- Payers are increasing restrictions to drive usage to less costly drugs
- Payers don't understand BTP

### Social / Cultural

- Abuse and diversion are top-of-mind topics for physicians and other stakeholders
- Society (including many physicians) are critical of their patients' inability to cope with their pain
- Pain patients feel misunderstood by physicians, friends, and family and often become frustrated and depressed
- Patients are often looking for an easy short-term solution to their pain and are not focused on long-term wellness

### Political / Governmental

- Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids
- FDA is hypersensitive about safety issues in a post-Cox II and OxyContin world

### Legal

- DEA guidelines for writing opioids are unclear
- Ongoing issues between the DEA and various pain societies
- Perception that more physicians getting sued/licenses taken away

### Clinical / Technological

- Lack of significant practical advancements in pain medicine
- New drugs, routes of administration, and improved control of side effects
- New insights into the anatomy and physiology of pain perception
- Greater understanding of how to integrate pharmacotherapeutic, psychological, and behavioral pain management approaches
- New tracking technology for packaging to avoid diversion

## Current Dynamics



# Social: BTP Awareness

## Prescribers

- BTP is a relatively new disease state, only generally recognized by top tier opioid prescribers
  - ▶ First in print in 1990 (Portenoy survey)
  - ▶ Actiq first product indicated for BTP, launched 1998

## Patients

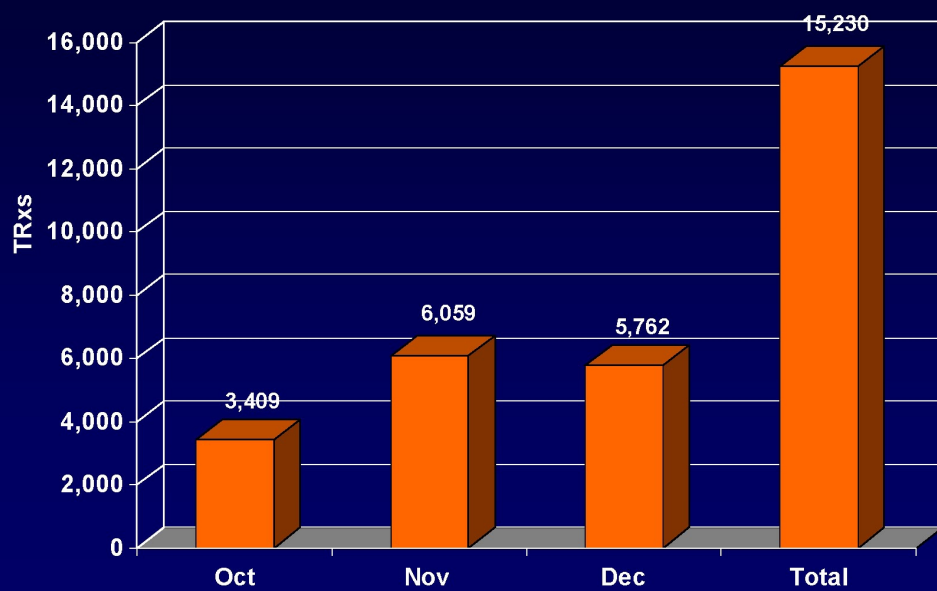
Communication Gap exists between Prescribers & Patients



# **FENTORA Updates**

## **FENTORA Monthly TRxs**

### **2006**

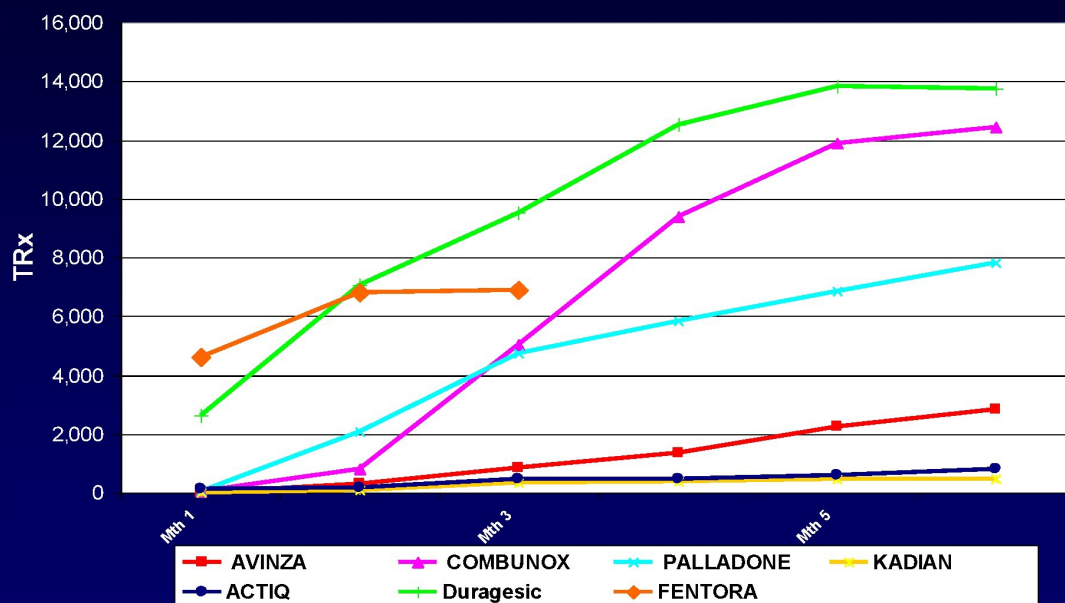


Source: IMS-NGPS



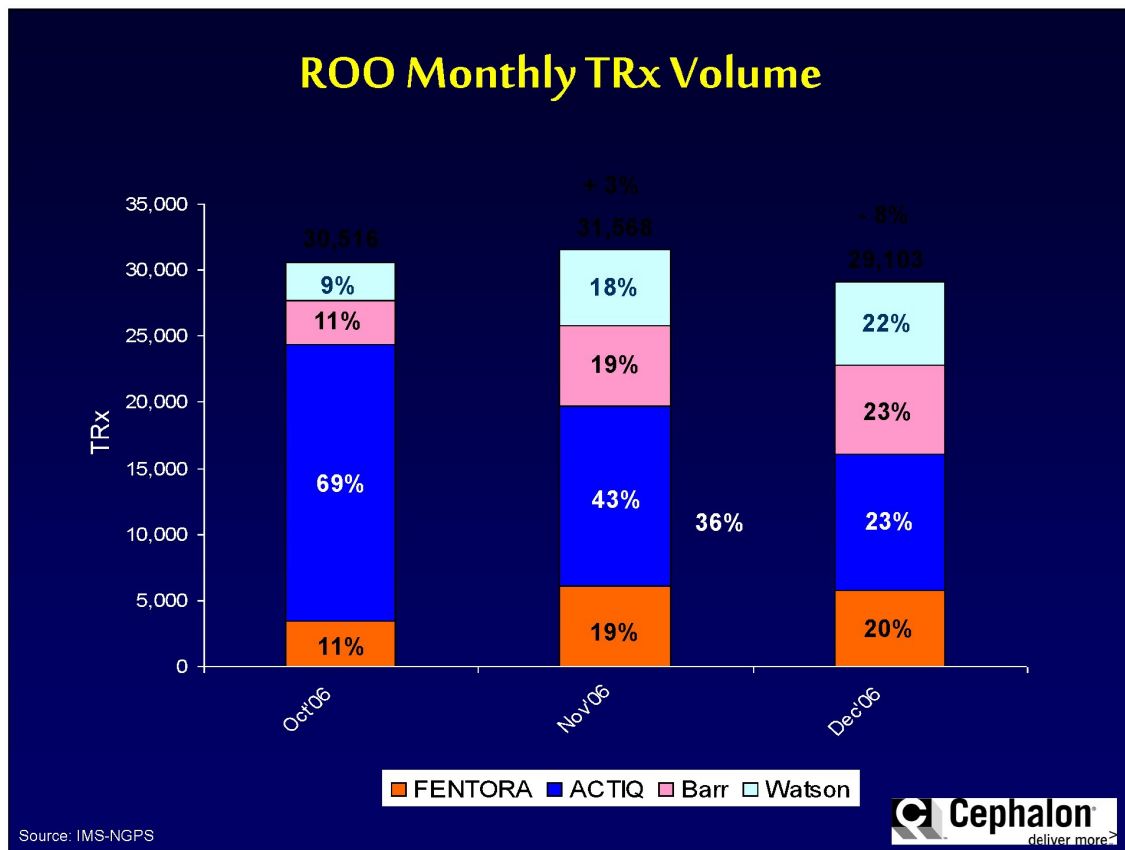


# Launch Curves: Opioid Analogs



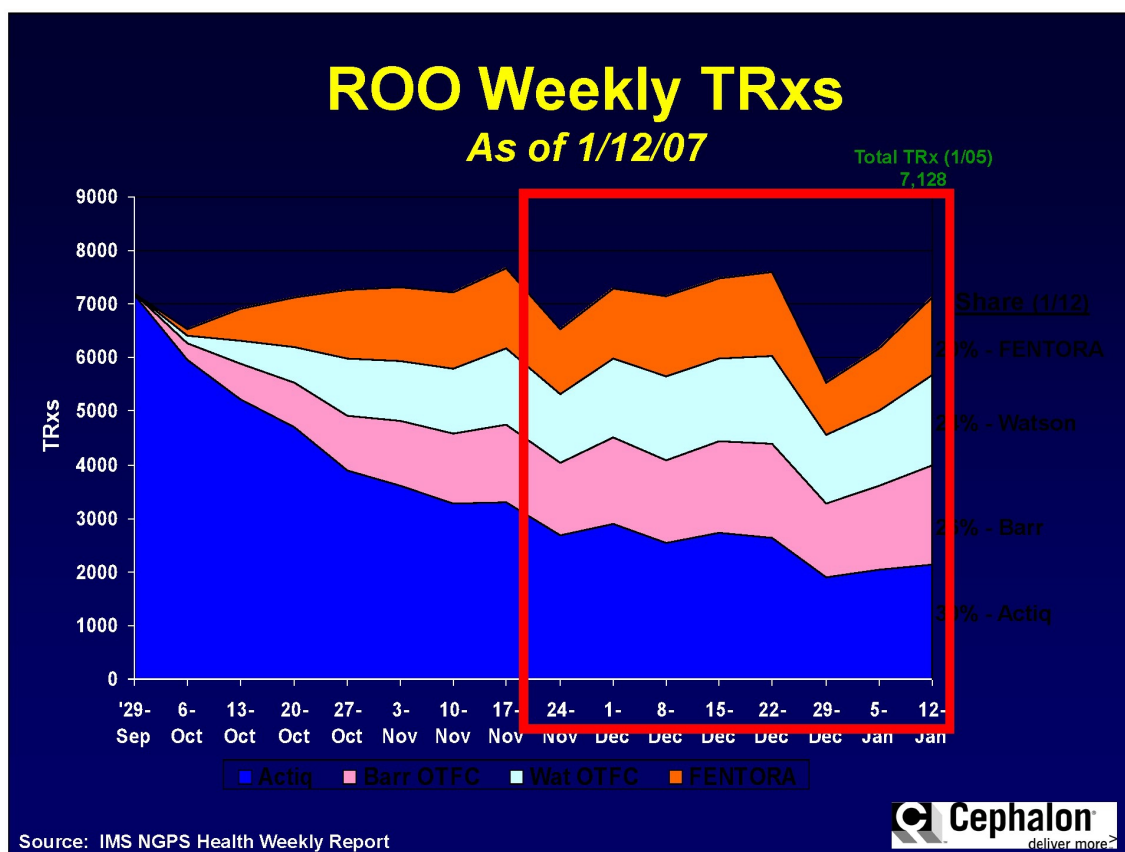
Source: IMS Health Monthly





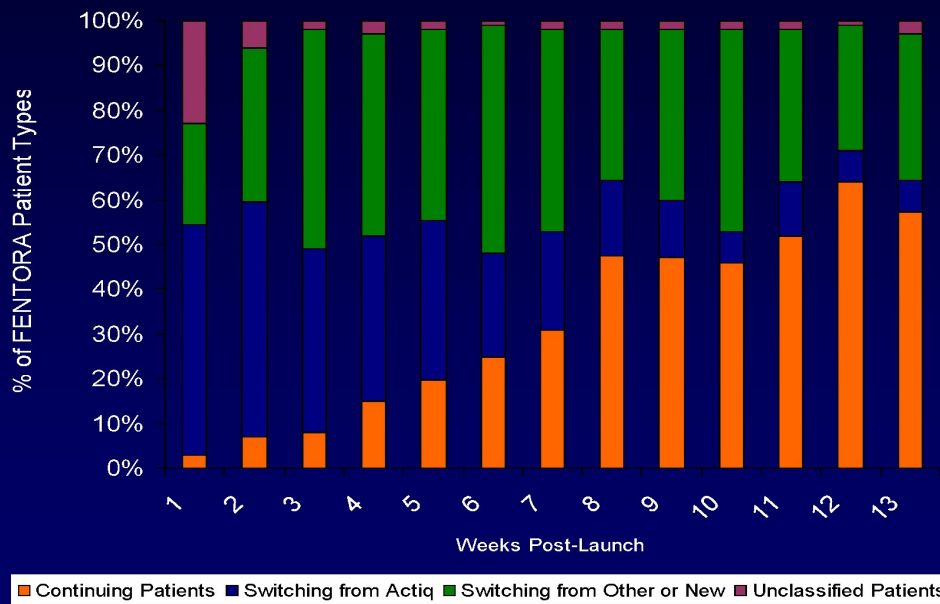
Prior to Oct 2006  
 Actiq was sole ROO  
 Consistent Value growth (more recently due to price increases)  
 Strong Volume growth up to 2004 (reached plateau)

As of Oct 2006  
 Generic OTFC introduced  
 Captured 21% of volume  
 FENTORA introduced  
 Captured 13% of volume  
 Fentanyl made up the largest value in 2005 due to branded Actiq, all other compounds are generic  
 But in terms of volume, oxycodone makes up the majority of the pure SAO mkt  
 Fentanyl is often perceived as a more potent analgesic and held in reserve



Importance of timing: FENTORA launch in concert w/ generic entry  
4th qrtr launch difficult - seasonality

## FENTORA Source of Business Share



Source: IMS NPA Market Dynamics

Data through December 29, 2006

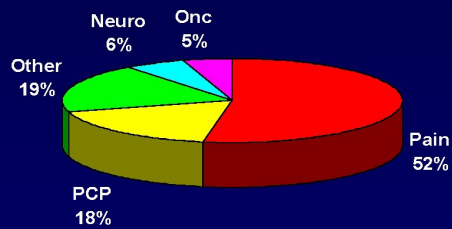


# TRx vs. Prescriber Count by Specialty

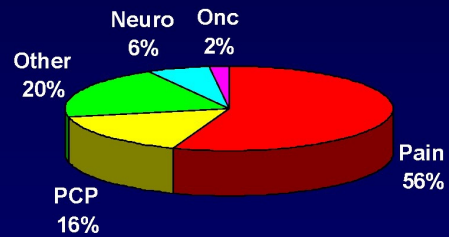
November 2006

Pain Specialists are early adopters & most productive

Prescriber Count by Specialty



TRx by Specialty



Source: IMS NPA and NDC

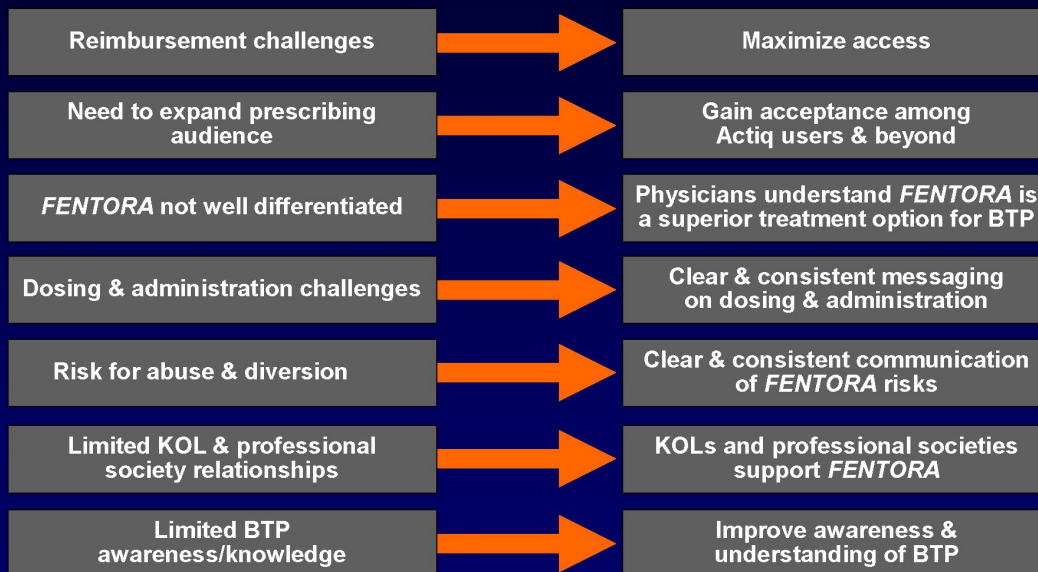


# **Review 2007 FENTORA Issues and CSFs**

# 2007 Issues & Critical Success Factors

## Issues

## CSFs



## **Questions & Feedback**



# **Patient Focused Marketing Tools**

# Feedback

- HCPs
  - ▶ Titration and dosing questions/issues?
  - ▶ Strengths – higher dose? 300mcg?
  - ▶ Issues with tablets boxed in 28s?
- Patients
  - ▶ Patient administration and titration sheet (need copies there for review)
  - ▶ Application site issues?
  - ▶ Taste issues?
  - ▶ Catalina Newsletters (need copies there)
  - ▶ Patient FAQs (need copies there)
  - ▶ Patient Starter Kit (need copies there)



# **Building Disease Awareness I**

## CSF: Improve BTP awareness and understanding of treatment options among physicians and patients

### Strategy

- Continue to establish BTP as a distinct clinical problem among appropriate physicians
- Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Support BTP educational initiatives

### Educational Activities

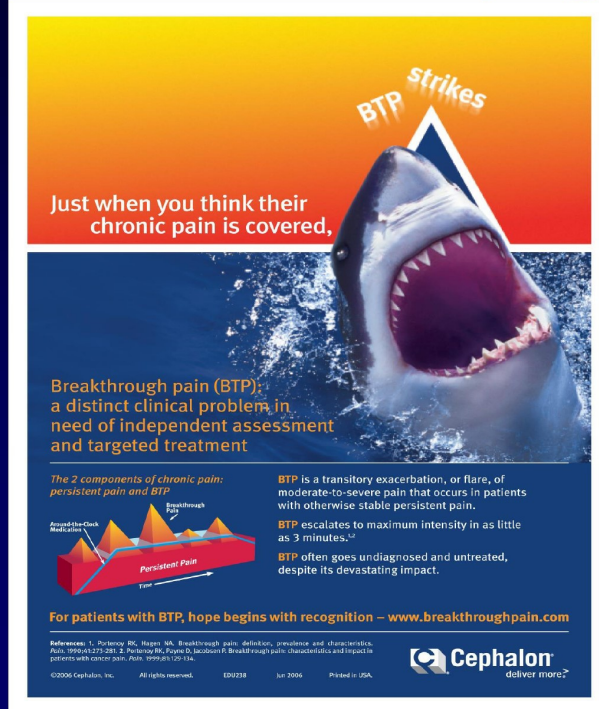
- BTP campaign
  - ▶ Journal ad & targeted media
  - ▶ DA Convention Booth
  - ▶ BTP website
  - ▶ Direct Mail
  - ▶ PR initiatives (outreach, etc)
- In-office patient material



# Breakthrough Pain Campaign



# Current BTP Campaign




**BTP strikes**

Just when you think their chronic pain is covered,

**Breakthrough pain (BTP): a distinct clinical problem in need of independent assessment and targeted treatment**

*The 2 components of chronic pain: persistent pain and BTP*



**BTP** is a transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients with otherwise stable persistent pain.

**BTP** escalates to maximum intensity in as little as 3 minutes.<sup>1,2</sup>

**BTP** often goes undiagnosed and untreated, despite its devastating impact.

For patients with BTP, hope begins with recognition – [www.breakthroughpain.com](http://www.breakthroughpain.com)

References: 1. Portenoy RC, Hagen MA. Breakthrough pain: definition, prevalence and characteristics. Pain. 1999;84:273-281. 2. Portenoy RC, Payne D, Jacobsen P. Breakthrough pain: characteristics and impact in patients with cancer pain. Pain. 1999;84:151-156.

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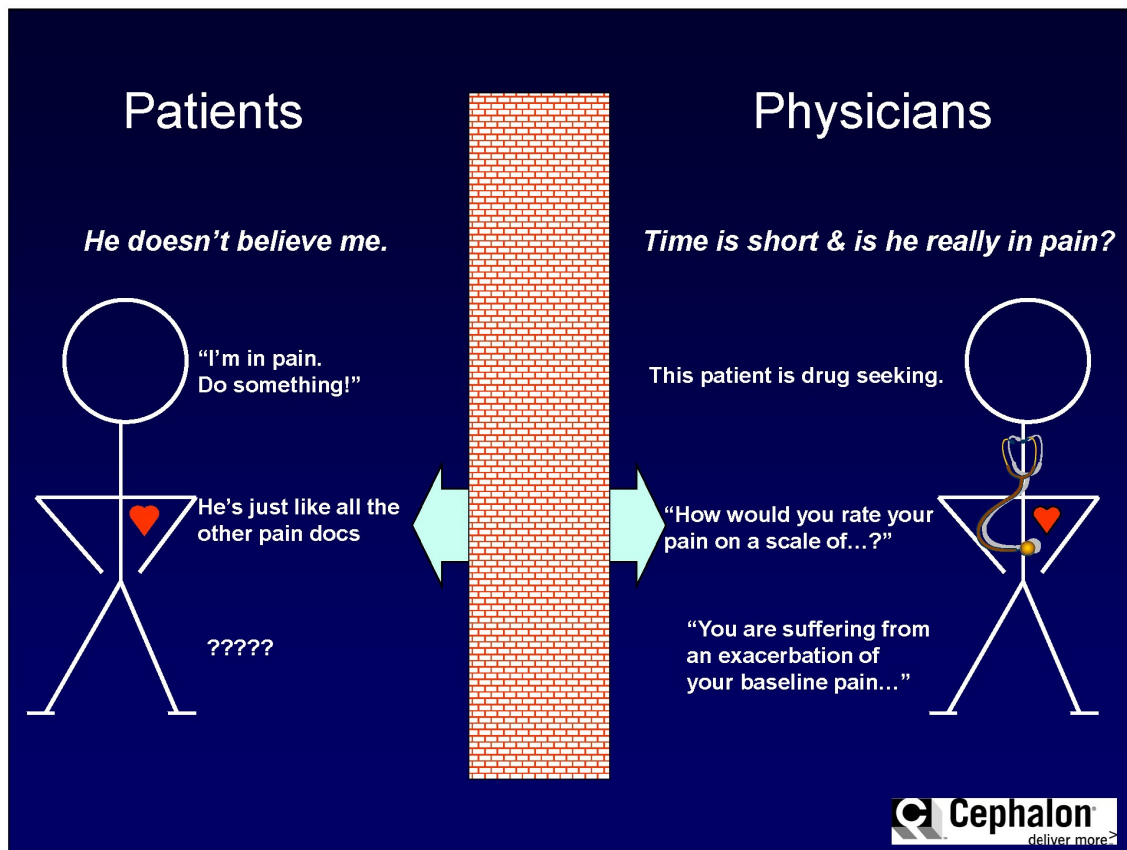
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You've all seen the shark – our current BTP campaign to raise awareness of this disease state. This is and has been a CSF for us and we are committed to expanding and evolving this campaign. It is currently geared toward HCPs and we are ready to broaden our audience – including patients. We sent our operatives out to conduct market research to understand how patients and physicians define, describe, think, & feel about BTP. Here is what we learned.

**Show BTP Market Research Video**





As you just heard, the research highlighted the wide communication gap between patients and physicians

- Patient inability to describe their pain effectively
- Time is short during the office visit
- They are not speaking the same language
- There is distrust on both sides

So we are rolling out a disease awareness campaign and tactical plan designed to raise awareness, educate and bridge that communication gap – to own that doctor visit and make it more productive.



## Discussion of BTP Market Research Video



# Messages to Bridge the Gap

Topic	Primary Message	Secondary Messages
<b>Definition</b>	Breakthrough pain (BTP) is a sudden flare of pain that “breaks through” the medicine taken for all-day pain.	<ul style="list-style-type: none"> <li>Chronic pain often has 2 parts: persistent pain and BTP</li> </ul>
<b>Characteristics</b>	BTP can be brought on by doing everyday activities.	<ul style="list-style-type: none"> <li>BTP can be triggered by activities as simple as getting out of bed, taking a walk, picking up a bag of groceries</li> <li>Some BTP episodes can be predicted, others come out of nowhere</li> <li>BTP episodes usually come on fast, peaking in as little as 3 minutes. Other episodes may escalate more slowly</li> <li>BTP can occur several times per day</li> </ul>
<b>Impact</b>	BTP is disruptive.	<ul style="list-style-type: none"> <li>Even when persistent pain is well controlled, BTP can prevent patients from doing everyday activities</li> <li>Patients with BTP often feel like nobody can understand or appreciate what they’re going through</li> <li>Patients with BTP may feel anxious and depressed</li> <li>Over time, BTP can harm relationships with friends and family. Patients feel like complainers</li> </ul>




# Messages to Bridge the Gap

Topic	Primary Message	Secondary Messages
<b>Legitimizing the Condition</b>	BTP needs to be understood as a separate condition.	<ul style="list-style-type: none"> <li>• Most pain patients on all-day pain medication experience BTP</li> <li>• BTP is not merely a symptom of chronic pain</li> </ul>
<b>Treatment</b>	By separating chronic pain into persistent pain and BTP, doctors can assess and treat <b>each problem individually and give better care.</b>	<ul style="list-style-type: none"> <li>• Since pain has peaks and valleys, it can be treated with 2 medicines: one for persistent pain and a second for the flares of BTP</li> <li>• The most appropriate treatment for BTP would begin to work quickly and last about as long as a BTP episode</li> </ul>
<b>Patient-Doctor Relationship</b>	Patients and doctors must work together to fight BTP.	<ul style="list-style-type: none"> <li>• BTP patients may have a hard time explaining what's been happening to them during a brief doctor visit</li> <li>• Patients must be able to provide details of their pain so doctors can better help</li> <li>• Patients can prepare for a doctor visit by using a pain Journal</li> </ul>




## **Building Disease Awareness II**

## Revised Concept



**If you're wondering if BTP is real, ask someone who has it.**

Breakthrough pain (BTP) is a serious condition whose proper assessment and treatment depend on good communication.



Breakthrough pain (BTP) is a sudden flare of pain that "breaks through" the medicine taken for all-day pain.

Arrows show the clock medication covers persistent pain.

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To learn more about BTP, visit [www.breakthroughpain.com](http://www.breakthroughpain.com)

Here is our BTP campaign – which will be used in journals, conventions, and online at BTP.com. The roll out of this campaign is May. It tested very well with physicians and patients and speaks to both the emotional aspect of BTP and the idea that it is a very real disease that needs independent assessment.

# BTP Activities

- HCP Education

- ▶ BTP.com Medical Professional Site

- Articles, tools, tips, on proper assessment of BTP and how to maximize patient/HCP communication
    - Alternative treatment discussions
    - Risks of using opioids
    - Video clips of Q&A, patient interviews, etc.
    - eNewsletter sign-up

- ▶ Epocrates alerts about BTP

- ▶ Educate via AAFP journal to educate on BTP



# BTP Activities

- HCP Education
  - ▶ BTP booth presence (new concept @ APS)
    - AAPM, ASPMN, ONS, APS, AAPM&R, ASA
    - AMCP & ASHP - managed care meetings
    - Staffed by Medical Science Liaisons
    - Booth materials include
      - BTP brochure & chronic pain assessment tool (need copies there to review)
      - Portenoy reprints
      - Making Pain Talk Painless (patient piece - need copies)
      - Shareyourpain.org postcard (patient piece – need copies)
      - Other ideas????



# BTP Activities

- HCP Education
  - ▶ Online assessment tool (internet access?)





# BTP Activities

- Patient Education
  - ▶ BTP.com patient site (internet access?)
    - Review planned site map for patients
  - ▶ Online assessment tool (internet access?)
  - ▶ Catalina newsletter on BTP (need copies)
  - ▶ SYP.org (internet access??)
  - ▶ Krames type brochures (need copies there)
  - ▶ Potential articles in Readers Digest, Womans World, Prevention



## Facilitate Patient & Physician Dialogue around BTP



Here is a look at one of our online initiatives to drive traffic to BTP.com. This is SYP.org and it will provide patients a forum to describe their pain using refrigerator magnets – it will get them used to using descriptive words for their BTP, and get patients talking about BTP. It also allows patients to share their “refrigerators” with others in an online pain community so they don’t feel so alone. And of course it links to BTP.com so they can learn more.

www.shareyourpain.org

blue diesel  
fuel your business™

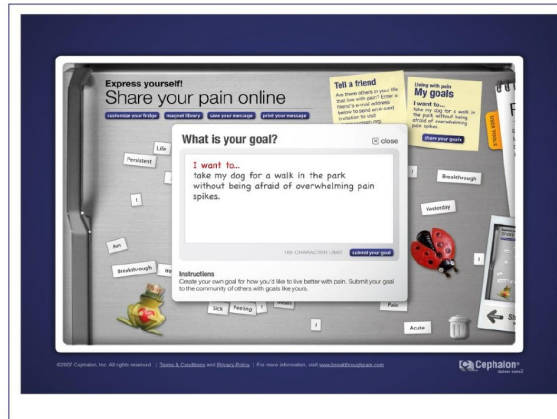
www.bluediesel.com

816.545.4575  
816.545.4575  
816.545.4575

380 31st WASHINGTON, IL • WASHINGTON, IL 62092

### Share your goal

This pop-up form presents the user with a single text field for sharing their goal with the community. The pop-up form is closed when the user submits their goal or by using the "close" button in the top right corner of the interface.



Cephalon | Shareyourpain.org Campaign Web Site | Creative Comps 5

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# www.shareyourpain.org

**blue diesel**  
fuel your business™

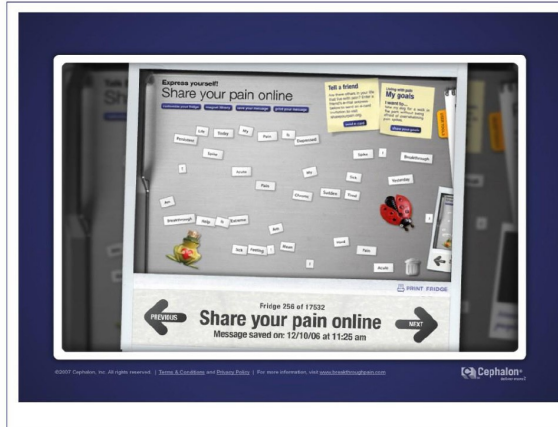
www.bluediesel.com

614.545.4225  
614.545.2155

100 10th Worthington Rd., Westerville, Ohio 43082

## Gallery

The gallery presents the user with the assortment of the constructed sentences that have been shared by the community of users. The interface presents the sentences in a gallery within a Polaroid-style interface, featuring prominent action buttons to cycle through the gallery. Additionally, the number of the viewed sentence and a tally of all shared fridge in the gallery are shown.



Cephalon | Shareyourpain.org Campaign Web Site | Creative Comps 8

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## FENTORA Strategic Update

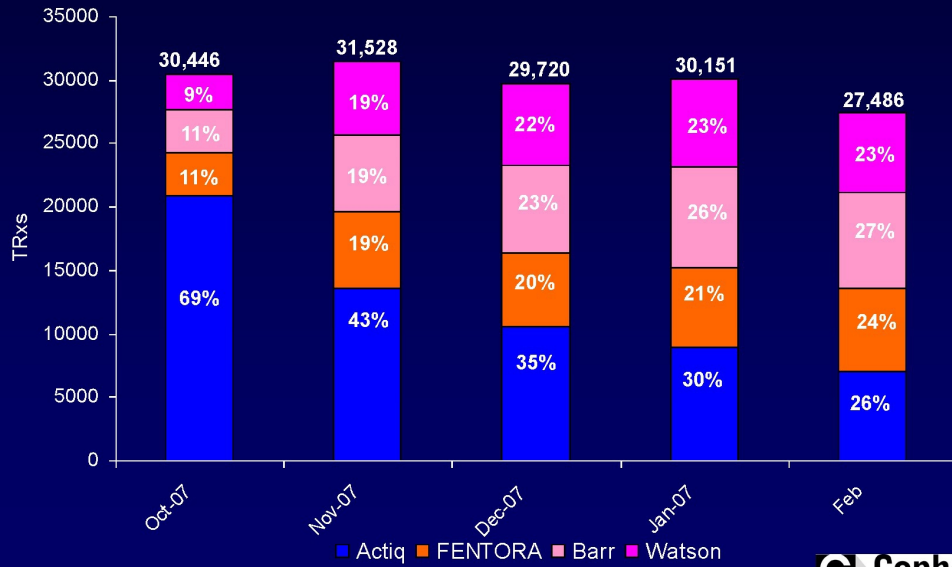
- Shipments
  - ▶ \$10.7M (February 2007)
- Prescriptions
  - ▶ Monthly TRx (Feb): 6,546
  - ▶ Market Share (Feb): 24% of ROO market
- Studies
  - ▶ Low Back BTP (3042): Pub *CMRO* 12/06
  - ▶ Neuro BTP (3041): Press Rel 1/8/07, AAN Poster 5/07, Pub *Clin Ther* 5/07
  - ▶ Efficacy Ca-BTP (3039 - onset): ASCO Abstract 6/07, Pub *J Supt Onc* 3Q07
  - ▶ Buccal/Sublingual PK (1043): Top line results 2/07
- Regulatory Activities
  - ▶ S-001 Modifications to PI, Med Guide, Carton, Blister: PDUFA 4/26/07
  - ▶ S-002 300 mcg tablet: Approved 3/2/07, commercialization tent 4Q07
  - ▶ S-003 3039 (onset data): submitted 3/2/07 (6 mth review)
  - ▶ S-004 sNDA Non-Ca: submitting 3Q07 (10 mth review)



# ROO Market

## TRxs & Shares

Market down in Feb due to short month, FENTORA TRxs & Market Share up

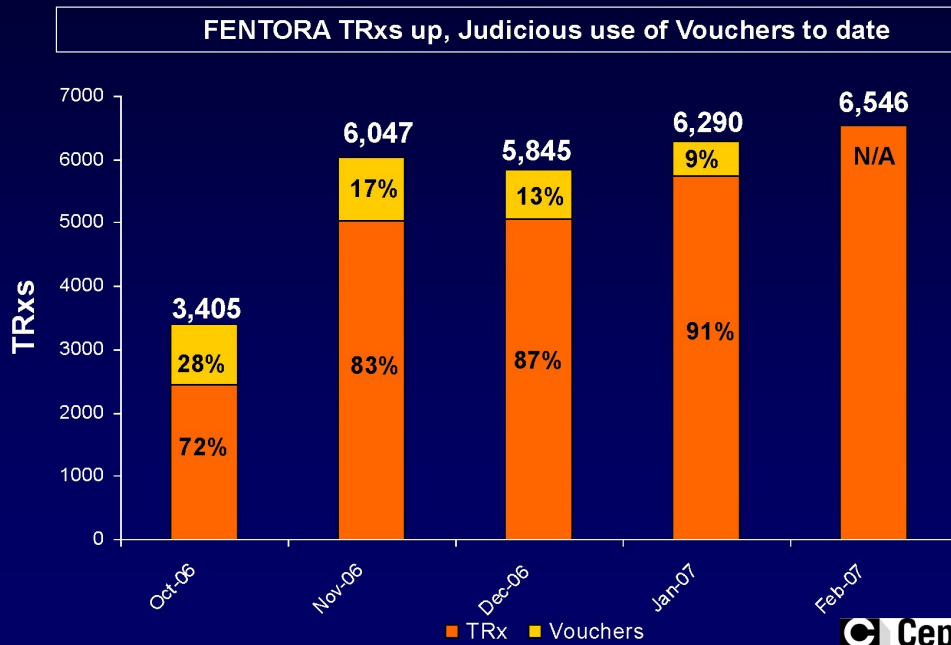


Source: IMS NPA (Updated for NGPS)

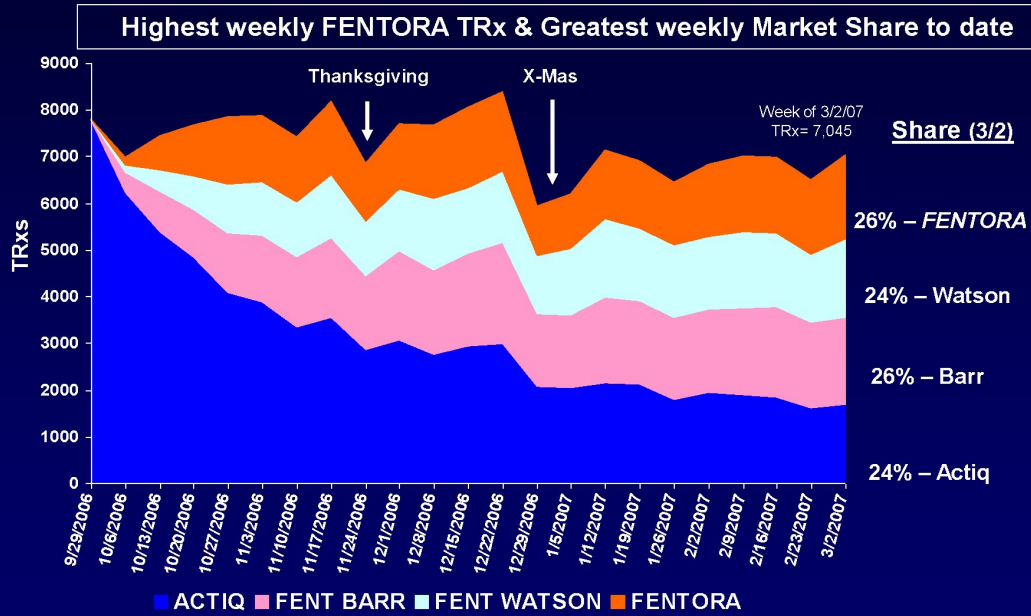




## FENTORA TRxs & Voucher %



## ROO Weekly TRxs As of 3/2/07



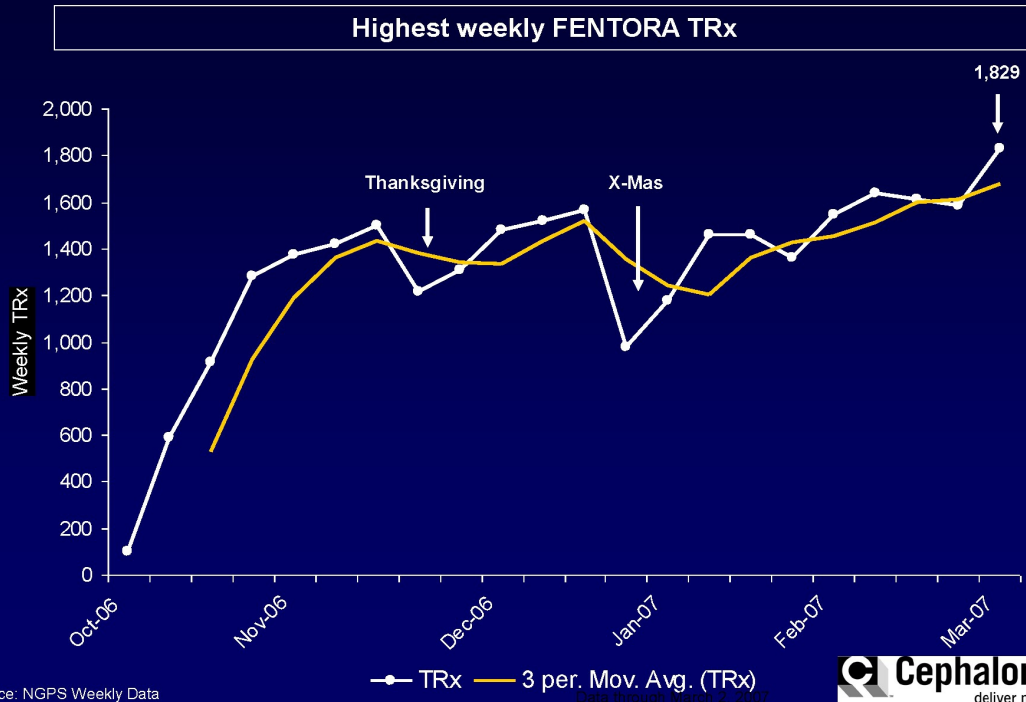
Source: IMS NPA/NGPS Weekly 3/2/2007



Importance of timing: FENTORA launch in concert w/ generic entry

## FENTORA Weekly TRx

As of 3/02/07

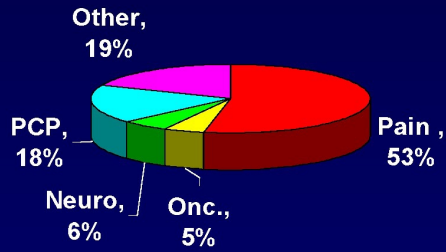


# TRx vs. Prescriber Count by Specialty

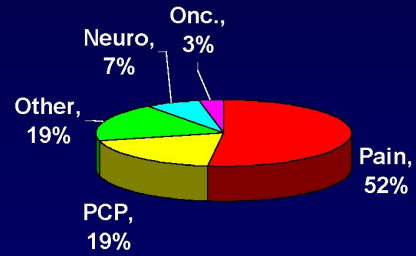
## December 2006

Pain Specialists are the early adopters and the most productive

Prescriber Count by Specialty



TRx by Specialty

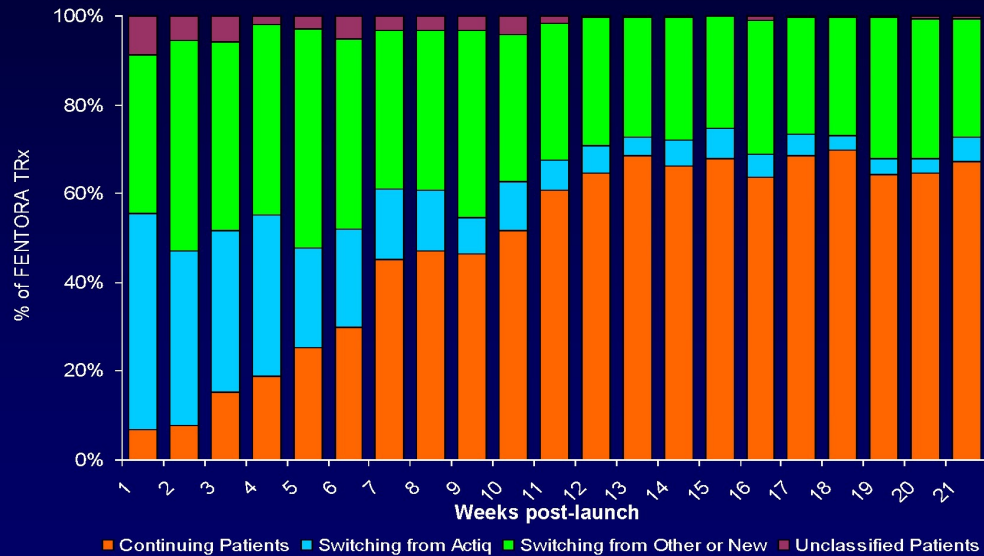


Source: IMS NPA and NDC



## FENTORA Source of Business Share

Captured Bolus of Actiq patients at launch, building customer base, new business primarily from Pure SAOs & new starts



Source: IMS NPA Market Dynamics

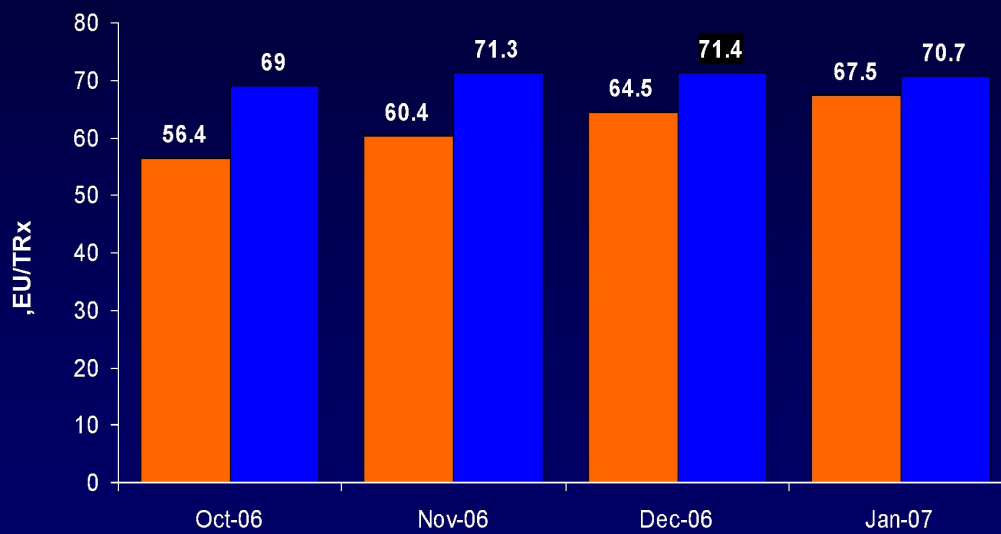
Data through March 2nd, 2007



## Extended Units / TRx

### Actiq vs. Fentora

Units / TRx slightly lower for FENTORA due to initial titration scripts



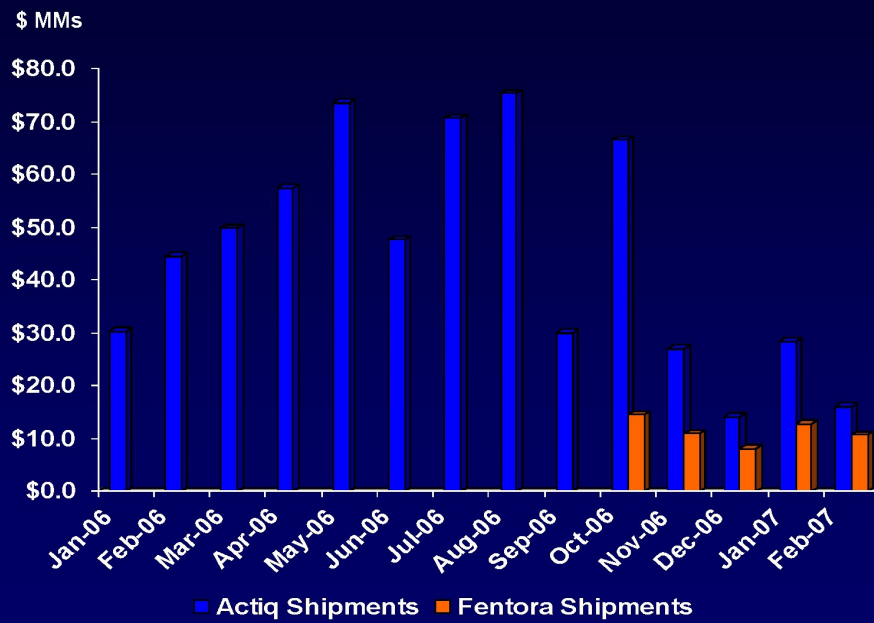
Source: IMS NPA (NGPS Methodology)

■ FENTORA ■ ACTIQ



# Monthly Shipments

## Actiq vs. Fentora



\* Shipments include gross sales in addition to product utilized for coupon & PAP  
Source: SPS

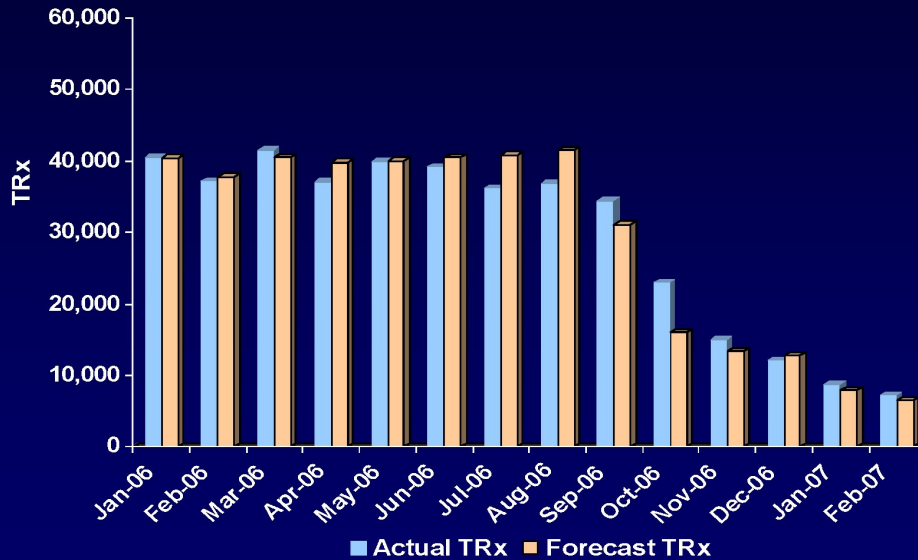


# **Actiq Performance**



## ACTIQ Monthly TRxs vs. Forecast

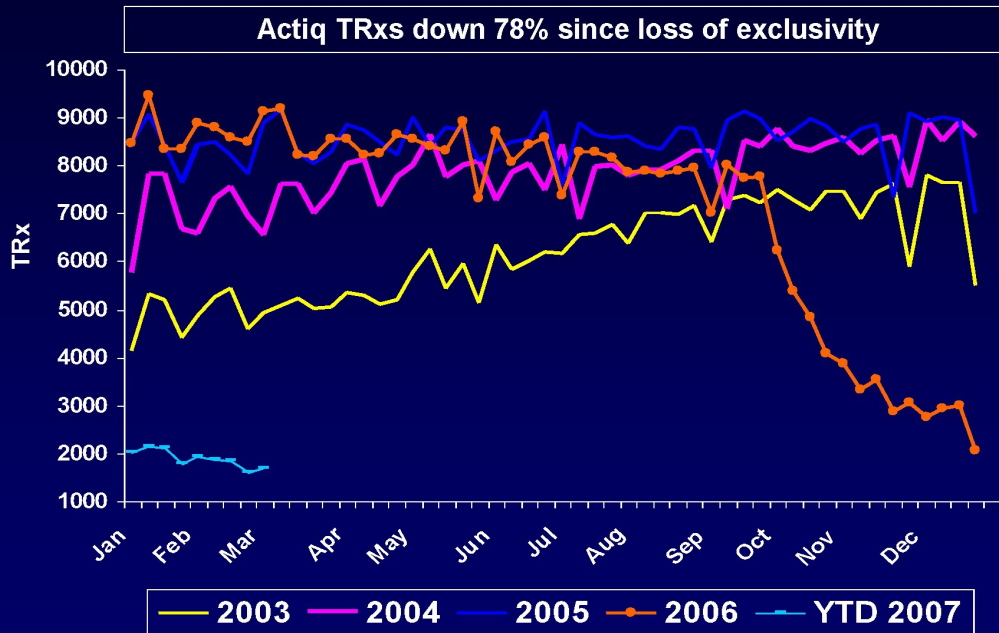
February 2007 Prescriptions are 109% to Forecast



Source: IMS NPA



# ACTIQ Weekly TRxs (2003, 2004, 2005, 2006, 2007 YTD)

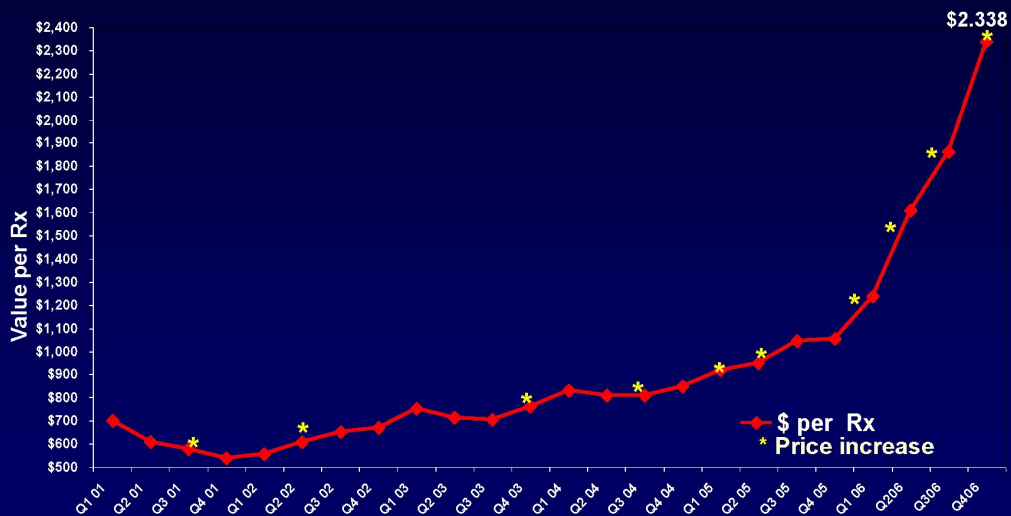


Source: NPA weekly data



# ACTIQ Dollar Value per TRx

Average WAC Price Per TRx is ~ \$2,338 (Q406)

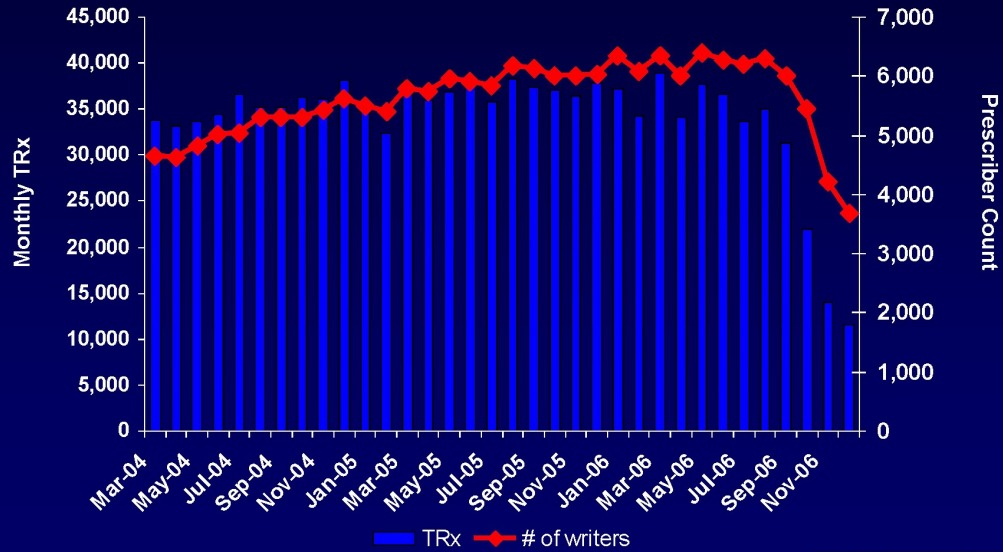


Source: IMS NPA Audit; Internal price as of December 21, 2006



# ACTIQ TRxs & Prescriber Count

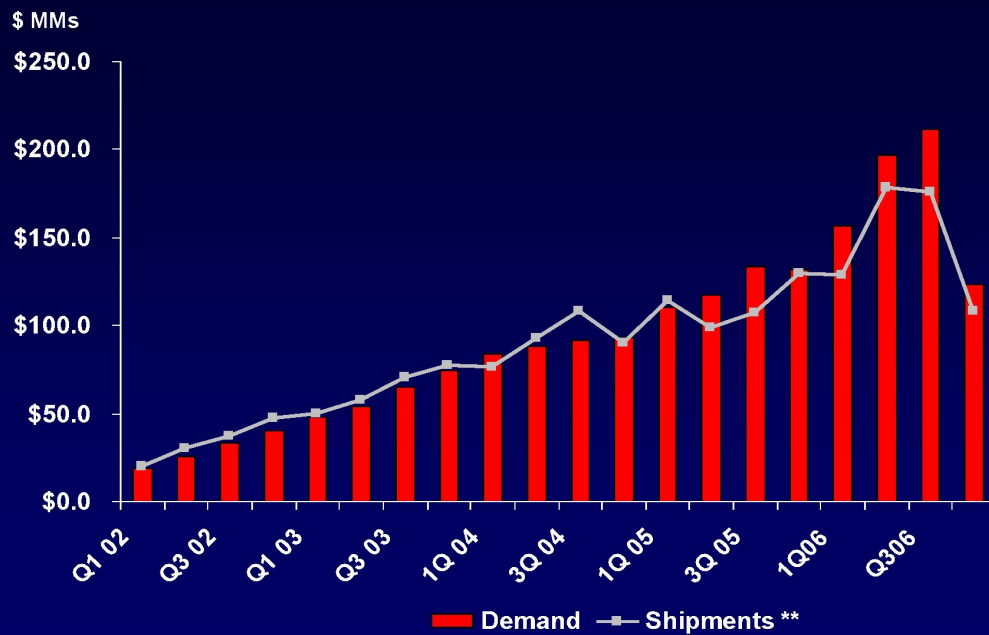
Number of TRxs & Prescriber Count declining in concert



Source: NDC



# ACTIQ Demand Sales\* vs. Shipments



\*\*\* Shipments include gross sales in addition to product utilized for coupon & PAP  
 Source: IMS NPA and NSP; historical prices calculated in; SPS

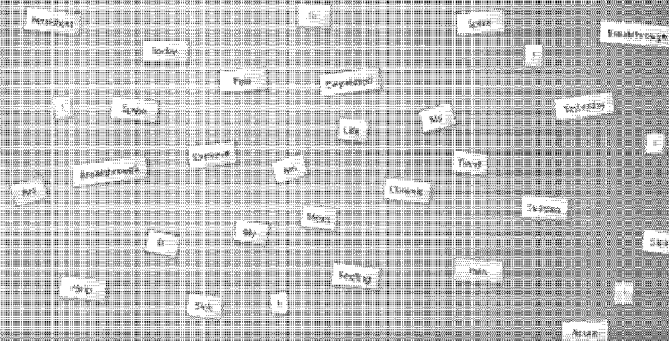


## Talk Breakthrough Pain ShareYourPain.org

Dolore facilisi blandit velit ut tation quis suscipit nostrud dolore dignissim facilisi feugiat illum. enim qui eu luptatum eum. Sciturs blandit ut lobortis illum. vulputate feugiat praesent consequat vel nibh at velit.

### Get Started

Read our pain management facts  
and book a breakthrough



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**Cephalon**  
GOLDSCHMIDT



# Talk Breakthrough Pain Share Your Pain Online

customize your fridge magnet library save your message print your message

## Tell a Friend:

Are there others in your life that live with pain? Enter a friend's email address below to send an e-card invitation.

Email:

send e-card

## Living With Pain

### My Goals:

I want to...

take my dog for a walk at the park without being afraid of overwhelming pain spikes.

share your goals

Life Today My Pain Is Depressed  
Persistent Spike  
! Acute My Sick Breakthrough  
Pain Chronic Sudden Tired Yesterday  
Am  
Breakthrough Help Is Extreme Am  
Sick Feeling ! Mean  
Hard Pain  
Acute

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**Cephalon**  
Solving pain's problems

# Talk Breakthrough Pain Share Your Pain Online

customize your fridge

magnet library

save your message

print your message

## Tell a Friend:

Are there others in your life that live with pain? Enter a friend's email address below to send an e-card invitation.

## Living With Pain My Goals:

### I want to...

take my dog for a walk at the park without being afraid of overwhelming pain spikes.

share your goals

## Customize Your Fridge

close

### Fridge Color:

beige

white

stainless

black

yellow

green

### Instructions:

To update the color of your fridge, click a color box above.  
Once you are finished click the close button at the top right.

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Solve it here



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## Magnet Library

FUN MAGNETS

WORD MAGNETS

close

GOT AN IDEA? SUGGEST A WORD:

submit

Acute

Breakthrough

Chronic

Depressed

Extreme

Feeling

Am

Help

My

Pain

Sick

Spike

Sudden

Tired

### Instructions:

To add a magnet to your fridge, simply drag the magnet out of the library and onto the fridge. To delete a magnet, drag it to the trash can in the lower right.

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## What is Your Goal?

close

I want to...  
take my dog for a walk at the park  
without being afraid of overwhelming pain  
spikes.

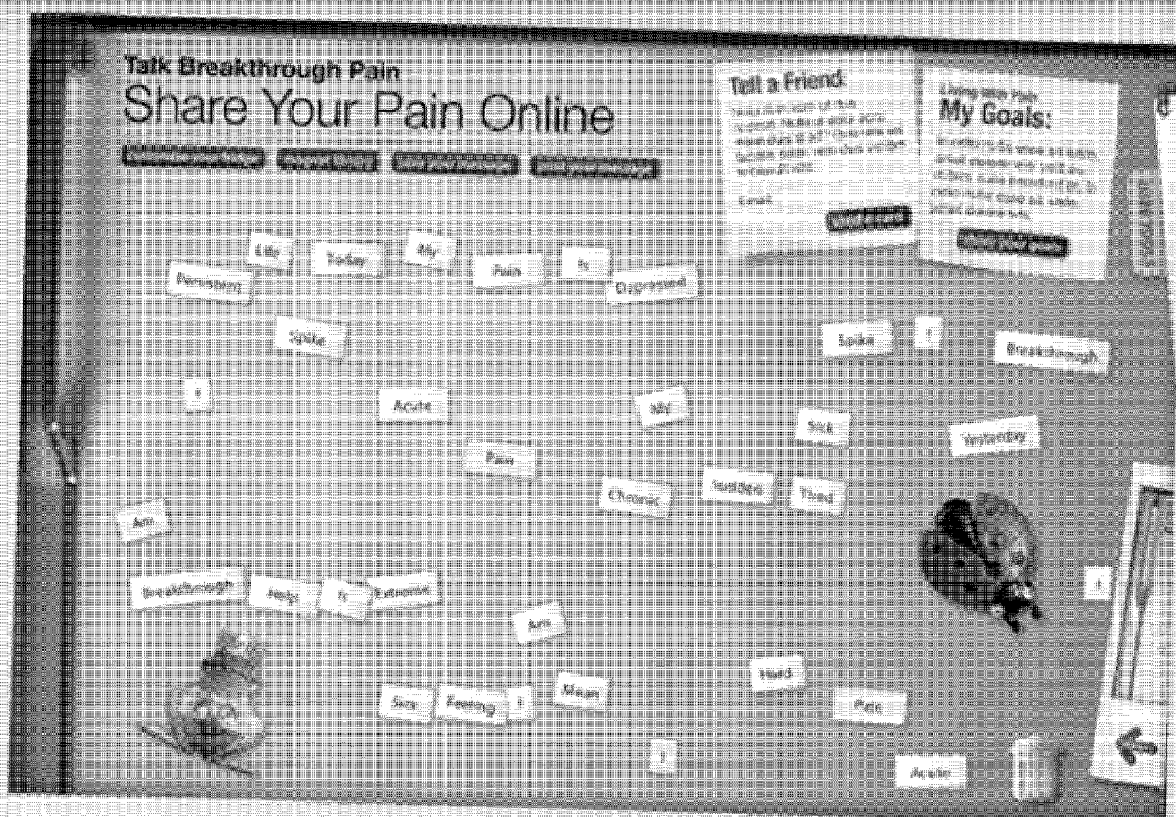
500 CHARACTER LIMIT

submit your goal

### Instructions:

Create your own goal for how you'd like to live better with pain. Submit your goal to the community of others with goals like yours.

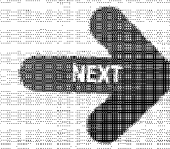




Fridge 256 of 17532

# Share Your Pain Online

Message saved on: 12/10/06 at 11:25 am



## Quick Definitions

✕ close

### **Acute pain:**

Pain that last for a short time, a few days to a few weeks. Acute pain may be caused by injury or surgery.

### **Chronic pain:**

Pain that lasts for more than 3 months. There are 2 kinds of chronic pain: breakthrough pain and persistent pain.

### **Persistent pain:**

This kind of pain lasts all day long. It does not spike like breakthrough pain. Your doctor might also call this pain "background pain" or "baseline pain."

### **Breakthrough pain:**

An intense flare or spike of pain that rises above your persistent pain. Breakthrough pain occurs only with controlled persistent pain. There are specific medicines to control breakthrough pain. [Learn more at breakthroughpain.com](http://www.breakthroughpain.com)

QUICK DEFINITIONS ABOUT THIS PROJECT PAIN RESOURCES



## About this Project



close

### Dolor Hendref

Enim odio in magna esse commodo dolore sit minim molestie, dignissim odio facilisi vel dolore lobortis ad. Molestie vulputate luptatum. Nonummy inure blandit lobortis, qui lobortis quis ipsum blandit exerci eum enim dignissim qui at. Nibh amet nonummy, odio te in consequat. Veniam dolor delenit commodo vulputate te nulla ex nulla, tation consequat tation aliquam suscipit eros in eros amet ut. Velit et, velit elit, eu eros facilisi adipiscing te justo duis te aliquip diam, facilisis minim commodo ut accumsan, nibh autem odio facilisis et feugait at nisi quis praesent ut exerci? Feugait veniam, aliquip luptatum velit aliquip ut blandit, esse nulla velit praesent dolor hendrerit nisi.

### Facilia Sum

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QUICK DEFINITIONS ABOUT THIS PROJECT PAIN RESOURCES

## Pain Resources

close

**BreakthroughPain.com**

[www.breakthroughpain.com](http://www.breakthroughpain.com)

**Pain.com**

[www.pain.com](http://www.pain.com)

**The American Chronic Pain Association**

[www.theacpa.org/](http://www.theacpa.org/)

**American Pain Association**

[www.painfoundation.org/](http://www.painfoundation.org/)

**American Cancer Society**

[www.cancer.org](http://www.cancer.org)

**American Pain Society**

[www.ampainsoc.org](http://www.ampainsoc.org)

**National Pain Foundation**

[www.nationalpainfoundation.org](http://www.nationalpainfoundation.org)

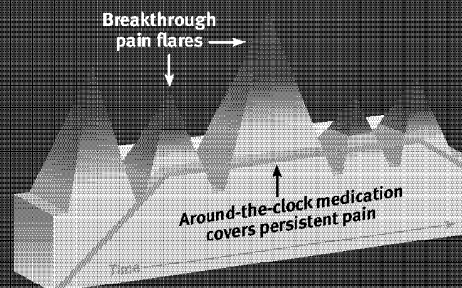
QUICK DEFINITIONS ABOUT THIS PROJECT PAIN RESOURCES





**If you're wondering if BTP is real,  
ask someone who has it.**

Breakthrough pain (BTP) is a serious condition whose proper assessment and treatment depend on good communication.



*BTP is a sudden flare of pain that "breaks through" the medicine taken for all-day pain.*

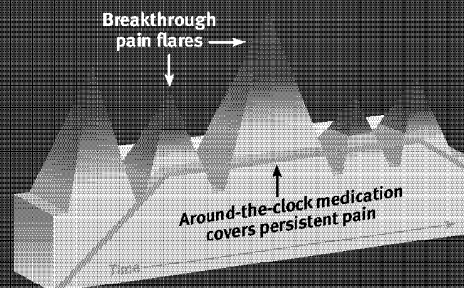


To learn more about BTP, visit [www.breakthroughpain.com](http://www.breakthroughpain.com)



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