

# Marketing Plan 2007

Confidential

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*fentanyl buccal tablet* ®

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PLAINTIFFS TRIAL  
EXHIBIT  
**P-24922\_00001**

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Focus: Product Situation, Strategy Tweaks, Tactics



# Executive Summary

Major Milestones	sNDA Target Submissions: Non-CA – 4Q07 3039 BTP CA Efficacy -2/23/07	PDUFA dates: 300 mcg – 3/3/07 Label modifications: 4/07 3039 BTP CA Efficacy: 8/07	Patent Expiration – 2019 (Method of Use – #6,200,604)																																																					
Market Overview	Source: IMS NPA & NSP	<table><tr><td></td><td colspan="3">Value</td><td colspan="3">Volume</td></tr><tr><td>Opioid</td><td>2005</td><td>2005</td><td>04-05</td><td>2005</td><td>2005</td><td>04-05</td></tr><tr><td>Category</td><td>(\$ - mil)</td><td>(%)</td><td>Δ</td><td>(TRx - mil)</td><td>(%)</td><td>Δ</td></tr><tr><td>Pure SAOs</td><td>\$663</td><td>11%</td><td>22%</td><td>8</td><td>4%</td><td>20%</td></tr><tr><td>Combi SAOs</td><td>\$1,221</td><td>21%</td><td>3%</td><td>156</td><td>84%</td><td>6%</td></tr><tr><td>LAOs</td><td>\$3,965</td><td>68%</td><td>-6%</td><td>22</td><td>12%</td><td>7%</td></tr><tr><td>Total Opioids</td><td>\$5,848</td><td>100%</td><td>-2%</td><td>186</td><td>100%</td><td>7%</td></tr></table>							Value			Volume			Opioid	2005	2005	04-05	2005	2005	04-05	Category	(\$ - mil)	(%)	Δ	(TRx - mil)	(%)	Δ	Pure SAOs	\$663	11%	22%	8	4%	20%	Combi SAOs	\$1,221	21%	3%	156	84%	6%	LAOs	\$3,965	68%	-6%	22	12%	7%	Total Opioids	\$5,848	100%	-2%	186	100%	7%
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<u>Growth Drivers</u>			<u>Growth Inhibitors</u>																																																					
<ul style="list-style-type: none"><li>• Aging baby boomers and growing US population will increase the size of the chronic pain patient population</li><li>• Increase in treatment of chronic pain with opioids</li><li>• Pain Specialists are more aggressive in treating chronic pain</li><li>• More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume</li><li>• Increasing understanding about the proper identification, diagnosis and treatment of BTP</li><li>• New competitive entries</li></ul>			<ul style="list-style-type: none"><li>• Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids</li><li>• Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids</li><li>• Chronic pain practice standards (especially for BTP) are still evolving</li><li>• Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by LAO manufacturers]]</li><li>• Perception by some physicians that SAOs are a preferred treatment option for BTP based on familiarity, ease-of-use, and cost</li></ul>																																																					

# Executive Summary

## Competitor Analysis

Company	2005 Pain Sales (US)	Primary Focus	Pain Products	Potential to Lead in Future
Purdue	\$1.4B	Pain Care	OxyContin (\$1.36B), MS Contin (\$32M), Palladone (\$20M)*, OxylR	Reputation suffers due to OxyContin issues and Palladone withdrawal
J&J	\$1.4B	Primary Care	Duragesic (\$687M), Ultracet (\$145M), Ultram (\$37M), Ultram ER*	Part of corporate strategy is to re-focus efforts in pain, developing new business unit
Endo	\$1.2B	Pain Care	Lidoderm (\$573M), Percocet (\$122M), Depodur, Opana, Opana ER, Additional generic opioids (\$370M)	Potential to lead in the future due to single focus in Pain Category
King/Ligand	\$179M	Oncology, Pain Care	Avinza (\$179M)	Strong presence in LAO market with a focus on TR (Remoxy)
Alpharma	\$140M	Pain Care	Kadian (\$140M)	Limited product portfolio

## Product Description

- Fentanyl incorporated into OraVescent® drug delivery platform
- Strengths: 100, 200, 400, 600, 800 mcg tablets
- Pack Size: 28 tabs (7 blisters with 4 tabs each)
- Indication: BTP in pts w/cancer
- Safety: Similar to other opioids
- RiskMAP: Secure Program

## Product Features

### Efficacy

- 10 minute onset & duration up to 120 minutes (last time point measured)

### Advantages over Actiq

- Greater absolute bioavailability (65% vs. 47%)
- Greater absorption through oral mucosa (48% vs. 22%)
- Simpler initial titration scheme
- More discreet, easier to administer, & sugar free

# Executive Summary

## Position Statement

*FENTORA* is the first and only fentanyl buccal tablet that utilizes an effervescence reaction to provide the most rapid onset of analgesia of any oral opioid resulting in improved patient functioning and activities of daily living\*

## Clinical Studies

NDA:		sNDA: expand indication to non-CA	
99-14	Efficacy: CA BTP	3040	Safety: all non-CA BTP (open label)
99-15	Safety: CA BTP (open label)	3041	Efficacy: neuropathic BTP
1026-29	PK: 4 main studies	3042	Efficacy: lower back BTP
		3054	Pain anxiety symptoms
		3052	Pivotal efficacy: non-CA
Labeling Supplement: Label Δ		Other PK Studies	
PK TBD	New doses: 300 mcg, high dose (mcg TBD)	1043	Buccal vs. sublingual
3039	BTP Efficacy CA	RP-1	Relative potency (IV morphine)
		RP-2	Relative potency (SAO)
H-2-H Studies			
3055	vs. OxyIR ST efficacy & safety		
3056	vs. OxyIR LT efficacy & safety		

\* This internal position statement is aspirational, and not intended to be used in promotional materials

# Executive Summary

## Key Issues

1. Reimbursement challenges
2. Need to expand prescribing audience
3. *FENTORA* is not well differentiated
4. Dosing & administration challenges
5. Risk for abuse & diversion
6. Limited KOL & society relationships
7. Limited BTP awareness/knowledge

## Critical Success Factors

- Maximize access
- Gain acceptance among Actiq users & beyond
- Physicians understand *FENTORA* is superior treatment option for BTP
- Clear & consistent messaging on dosing & administration
- Clear & consistent communication of *FENTORA* risks
- KOLs & professional societies support *FENTORA*
- Improve awareness & understanding of BTP

## Objectives

Total Revenue: \$139.5 M  
TRXs: 81,207

## Assumptions

- TRx Share @ month 12 = 28% of ROO (fentanyl) market
- *FENTORA* will grow from Actiq loyalist conversion & incremental market growth
- WAC/TRx = \$1,357 (2.5% annual price increase)

# Executive Summary

## Budget 2007

Category	Spend	Share of Total Spend
Market Research	\$1,750,000	6%
Consultants	\$400,000	1%
Journal Reprints	\$200,000	1%
Conventions	\$1,600,000	6%
Advertising/Promotional Materials	\$8,900,000	32%
Sample Coupons	\$6,000,000	21%
Public Relations	\$600,000	2%
Field Driven Speaker Programs (CSPs)	\$6,000,000	21%
Advisory Boards	\$2,500,000	9%
Corporate Contributions	\$50,000	0%
<b>TOTAL SPEND</b>	<b>\$28,000,000</b>	<b>100%</b>

## Tactical Timeline

BTP Education Campaign (fully evolved campaign execution Apr 07)

Vanilla campaign

Mocha campaign

Chocolate campaign



# Executive Summary

## Contribution Margin

Category	2007F (mil)
FENTORA Net Rev	\$139.5
Marketing Expense	28
Sales Expense	23
Contribution Margin	\$88.5

**Note:**

Contribution includes Marketing Budget expenditures and Sales Force personnel estimate only.  
Sales expense for 2007F factored on \$205K/person & includes 100% of 100 Reps, 12 DMs, & 2 RSDs  
(ONS, NAMS & MDMs not included)

Market Situation

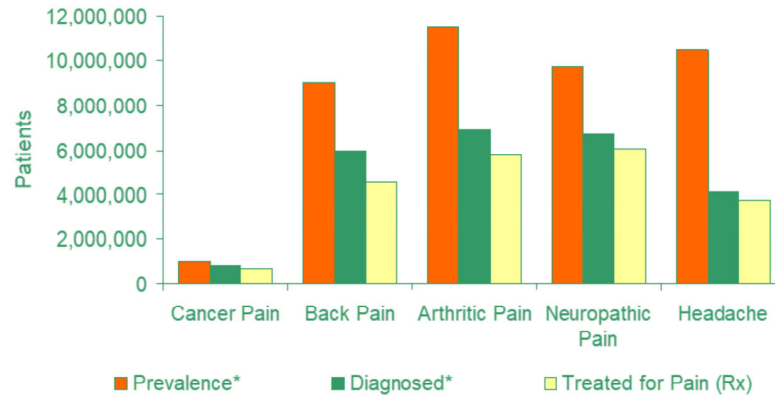
Disease Overview

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## Chronic Pain: Prevalence

- Chronic pain prevalence, diagnosed & treated by underlying conditions



Source: Analysis of secondary data reports by Cephalon Market Research Department

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Chronic pain is prevalent & when diagnosed is generally treated (areas where studying FENTORA is most prevalence)

The question remains, “Is it being treated effectively?”



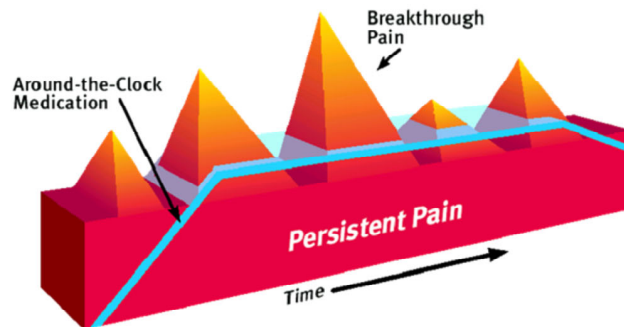
## Chronic Pain: Components

### Baseline or Persistent Pain

Pain that is continuous throughout the day ( $\geq 12$  hours/day) and is managed with around-the-clock medication.

### Breakthrough Pain

Transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain.



Portenoy RK, Hagen NA. *Pain*. 1990;41:273-281.  
Bennett D, et al. *Pharm Ther*. 2005;30:354-361.

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Chronic cancer pain is often thought of as having 2 components: *persistent pain*, or pain that is continuous throughout the day (ie, is experienced for at least 12 hours per day); and *breakthrough pain*, a transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain. Each component requires independent assessment and targeted treatment.

The graphic illustrates how breakthrough pain “breaks through” the level of analgesia provided by the around-the-clock medication used to control a patient’s persistent pain.

## BTP Prevalence & Characteristics

	Cancer BTP (N =63) <sup>1</sup>	Noncancer BTP (N=228) <sup>4</sup>
Prevalence	64% to 89% <sup>1,2</sup>	74%
Median Episodes/Day	4 to 7 <sup>1-3</sup>	2
Time to Peak Intensity	43% in 3 min	50% in 5 min
Median Duration	30 min	60 min
Incident Related	55%	92%
Pathophysiology	<ul style="list-style-type: none"> <li>• somatic (33%)</li> <li>• visceral (20%)</li> <li>• neuropathic (27%)</li> <li>• mixed (20%)</li> </ul>	<ul style="list-style-type: none"> <li>• somatic (38%)</li> <li>• visceral (4%)</li> <li>• neuropathic (18%)</li> <li>• mixed (40%)</li> </ul>

<sup>1</sup>Portenoy, Hagen. *Pain*. 1990;41:273-281

<sup>2</sup>Zeppetella. *J Pain Symptom Manage*. 2000;20:87-92

<sup>3</sup>Portenoy et al. *Pain*. 1999;81:129-134

<sup>4</sup>Portenoy, et al. *APS*. 2005

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(2) Fisher K, Stiles C, Hagen NA. Characterization of the early pharmacodynamic profile of oral methadone for cancer-related breakthrough pain: a pilot study. *J Pain Symptom Manage*. 2004;28(6):619-625.

(3) Robison JM, Wilkie DJ, Campbell B. Sublingual and oral morphine administration. Review and new findings. *Nurs Clin North Am*. 1995;30(4):725-743.

(4) Cleary JF. Pharmacokinetic and pharmacodynamic issues in the treatment of breakthrough pain. *Semin Oncol*. 1997;24(5 Suppl 16):S16-S19.

(5) Osborne R, Joel S, Trew D, Slevin M. Morphine and metabolite behavior after different routes of morphine administration: demonstration of the importance of the active metabolite morphine-6-glucuronide. *Clin Pharmacol Ther*. 1990;47(1):12-19.

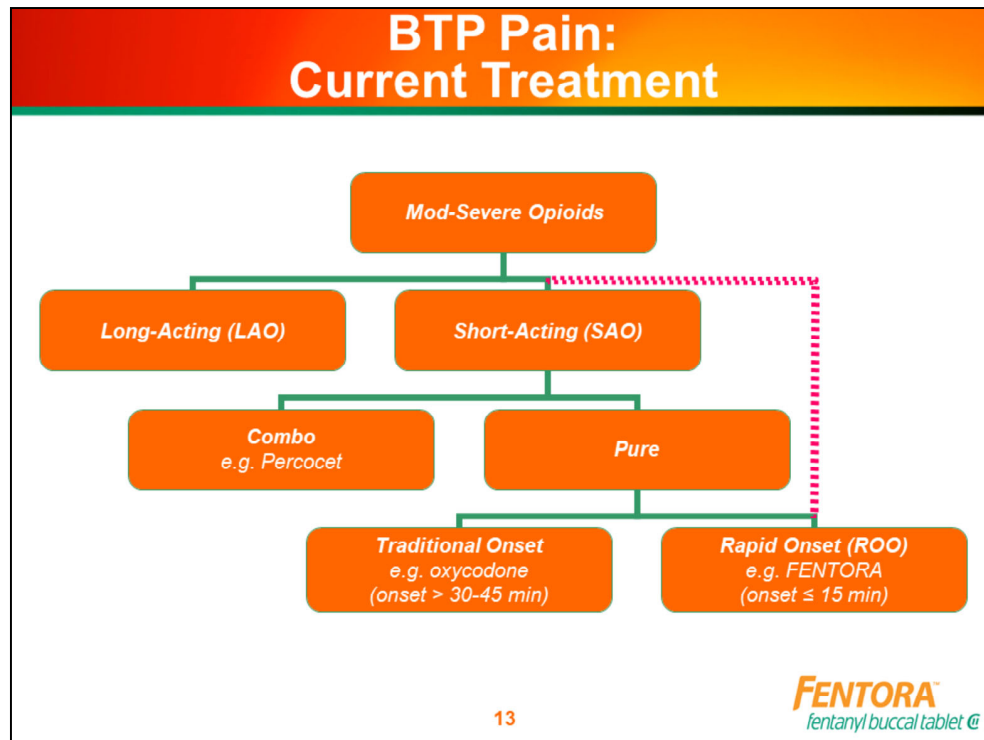
(6) Weinberg DS, Inturrisi CE, Reidenberg B, et al. Sublingual absorption of selected opioid analgesics. *Clin Pharmacol Ther*. 1988;44(3):335-342.

(7) Zeppetella G, Ribeiro MD. Pharmacotherapy of cancer-related episodic pain. *Expert Opin Pharmacother*. 2003;4(4):493-502.

(8) De Conno F, Ripamonti C, Saita L, MacEachern T, Hanson J, Bruera E. Role of rectal route in treating cancer pain: a randomized crossover clinical trial of oral versus rectal morphine administration in opioid-naïve cancer patients with pain. *J Clin Oncol*. 1995;13(4):1004-1008.

(9) Ripamonti C, Bruera E. Rectal, buccal, and sublingual narcotics for the management of cancer pain. *J Palliat Care*. 1991;7(1):30-35.

(10) Gardner-Nix J. Oral transmucosal fentanyl and sufentanil for incident pain. *J Pain Symptom Manage*. 2001;22(2):627-630.



What's it being treated with?

ATC – LAO or SAO, LAO + SAO

## BTP Treatment Patterns

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%

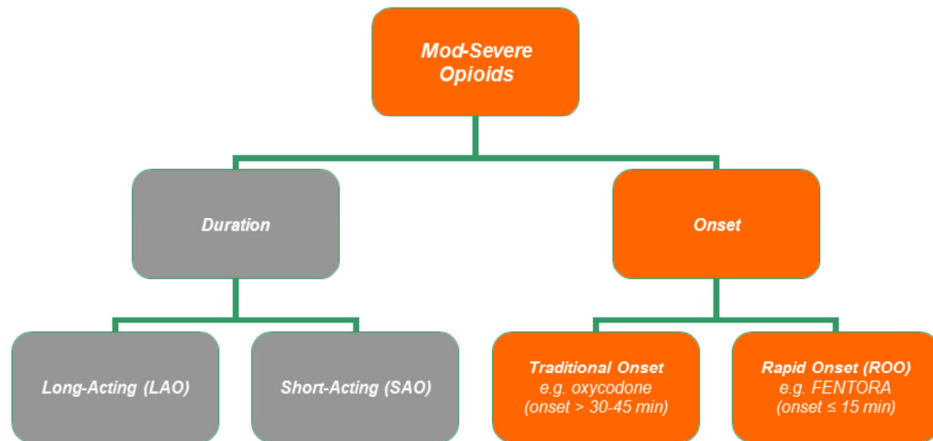
- The most common treatment choice is to increase the dose of LAOs regardless of # of episodes
- The next most common approach is to either increase the frequency or dose of the SAO
- Switching to an alternative SAO is typically the last course of action

Source: GfK Market Measures – 05

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## BTP Pain: Treatment Evolution



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What's it being treated with?

## Market Situation

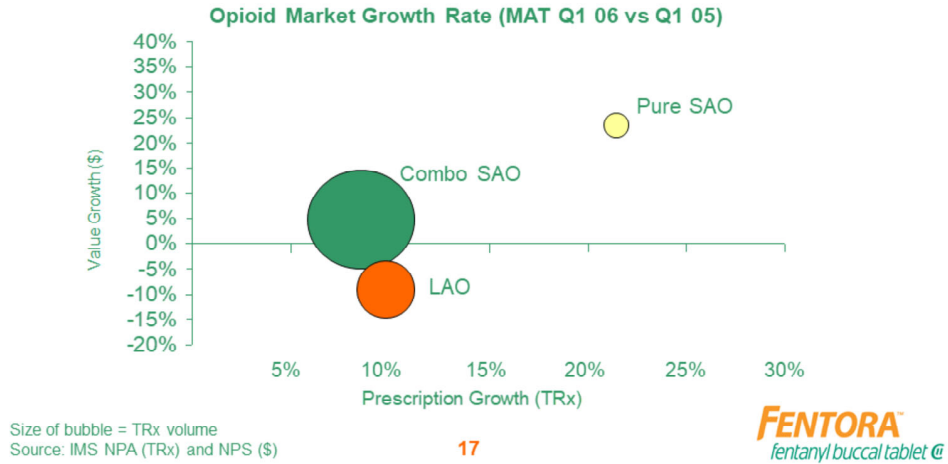
### Opioid Market

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# US Pain Market – TRx

- Total TRx market growing at 7%
  - Pure SAOs continue most robust growth in both value & volume
  - Combination SAOs (largest segment) continue modest growth in both value & volume
  - LAOs continue volume growth, but are declining in value due to generics

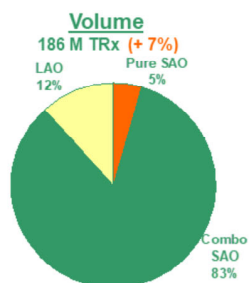
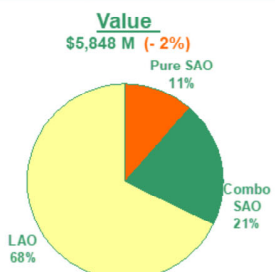


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First year LAO value declined

## Market Overview

### Opioid Market 2005



Source: IMS - NPA & NSP 2005

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#### 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 terms of value
- SAOs make up the largest share in terms of volume

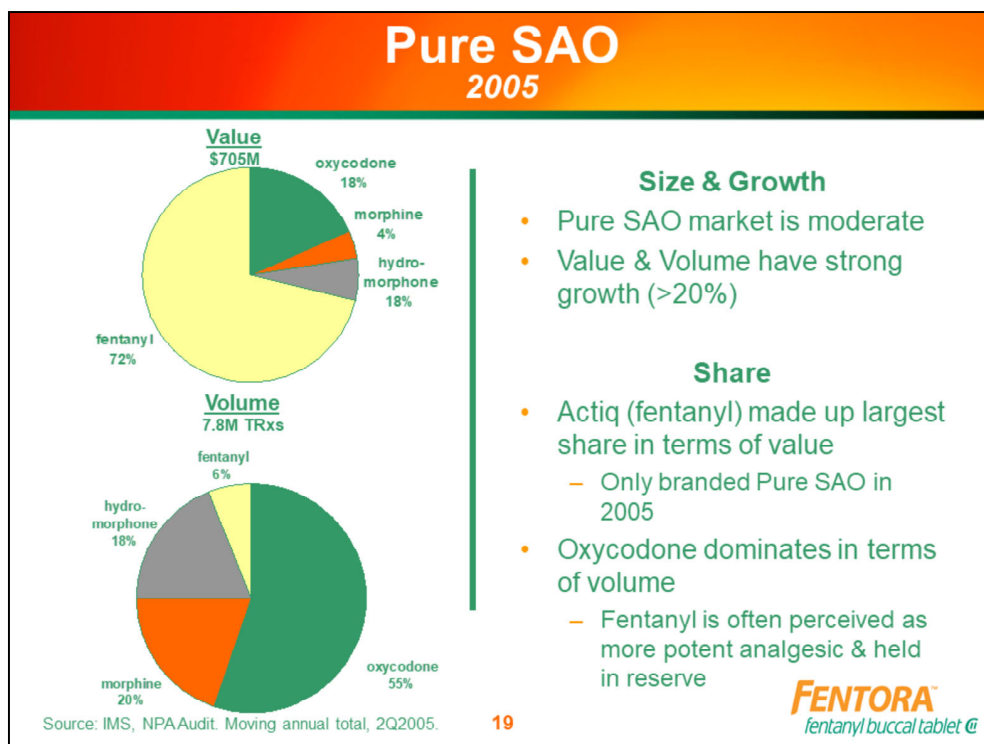
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Big market – down slightly due to LAO generic entry

- 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 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®

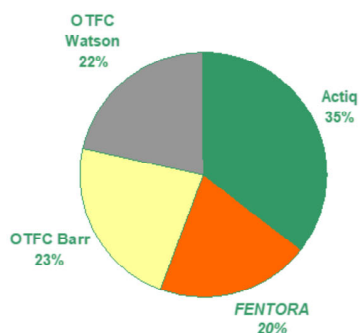
Morphine: 9 generics, MSIR®, Roxanol™

Hydromorphone: 16 generics, Dilaudid®

Fentanyl: Actiq®

## ROO Market December 2006

Volume (TRx)



### 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 Dec 2006\*

- Generic OTFC
  - Captured 45% of volume
- FENTORA
  - Captured 20% of volume

Source: IMS, NGPS DEC 2006

\* Third month post generic OTFC and FENTORA launches

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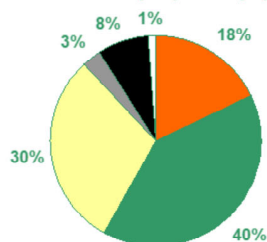
Fentanyl made up the largest value in 2005 due to branded Actiq, all other compounds are generic

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

# Customer Analysis\*

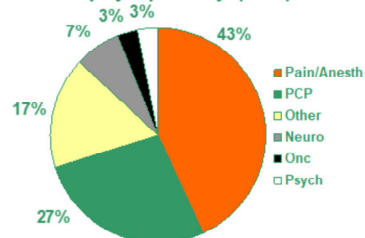
Pure SAO by Specialty (TRx)



## Pure SAO Sub-Class

- PCPs generate largest volume
- Pain/Anesth only account for 18% of volume

Actiq by Specialty (TRx)



## ROO Sub-Class (Actiq)

- Pain/Anesth generate largest volume
  - Typically early adopters of emerging therapies
- The other major contributors are PCPs & Other

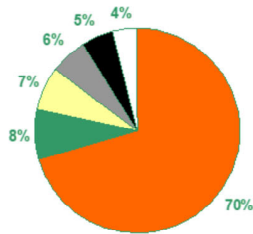
\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab  
 \*\*Source: IMS Prescribers - NPA TRx - Class of Trade - NSP Units

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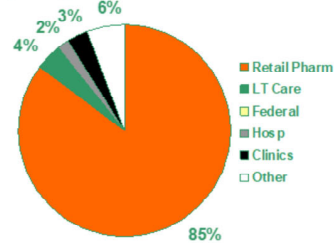
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## Trade Class

Pure SAO Distribution Channels



ROO (Actiq) Distribution Channels



- Vast majority of product moves through Retail Pharmacy
- Modest penetration of Pure SAO in non-retail segment
  - Non-Retail often provides spill-over effect
- Less penetration by ROO (Actiq) sub-class in non-retail segment
  - Non-retail segment is price sensitive

\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab  
 \*\*Source: IMS Prescribers - NPA TRx - Class of Trade - NSP Units

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Market Situation

Competitive Analysis

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# Major Chronic Pain Players

	2005 Pain Sales (US)	Primary Focus	Pain Products	Potential to Lead in Future
<b>Purdue</b>	\$1.4B	Pain Care	OxyContin (\$1.36B), MS Contin (\$32M), Palladone (\$20M)*, OxyIR	Reputation suffers due to OxyContin issues and Palladone withdrawal
<b>J&amp;J</b>	\$1.4B	Primary Care	Duragesic (\$687M), Ultracet (\$145M), Ultram (\$37M), Ultram ER*	Part of corporate strategy is to re-focus efforts in pain, developing new business unit
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<b>King/Ligand</b>	\$179M	Oncology, Pain Care	Avinza (\$179M)	Strong presence in LAO market with a focus on TR (Remoxy)
<b>Alpharma</b>	\$140M	Pain Care	Kadian (\$140M)	Limited product portfolio

\* Pulled from market due to alcohol risk  
Source: IMS 2006

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## Product Pipeline

Company	Phase I-II	Phase III	Reg. – Approval
J&J • Alza • OMP PriCara		Oros Hydromorphone Tapentadol	lonsys (Fentanyl Iontophoretic Transdermal System) – Approved May 2006
Endo	Lidoderm (chronic LBP) LidoPAIN (acute LBP) Chronogesic(Chronic moderate to severe pain) Ketoprofen patch Hydrocodone/paracetamol/dextromethorphan Oxycodone/dextromethorphan Oxycodone/paracetamol/dextromethorphan Sufentanil – DURECT Morphine/dextromethorphan	Rapinyl (BTP in cancer patients)	
Forest	Memantine Neramexane RGH-896	Milnacipran	
Purdue			Tramadol XR
BioDelivery Sciences		BEMA Fentanyl	

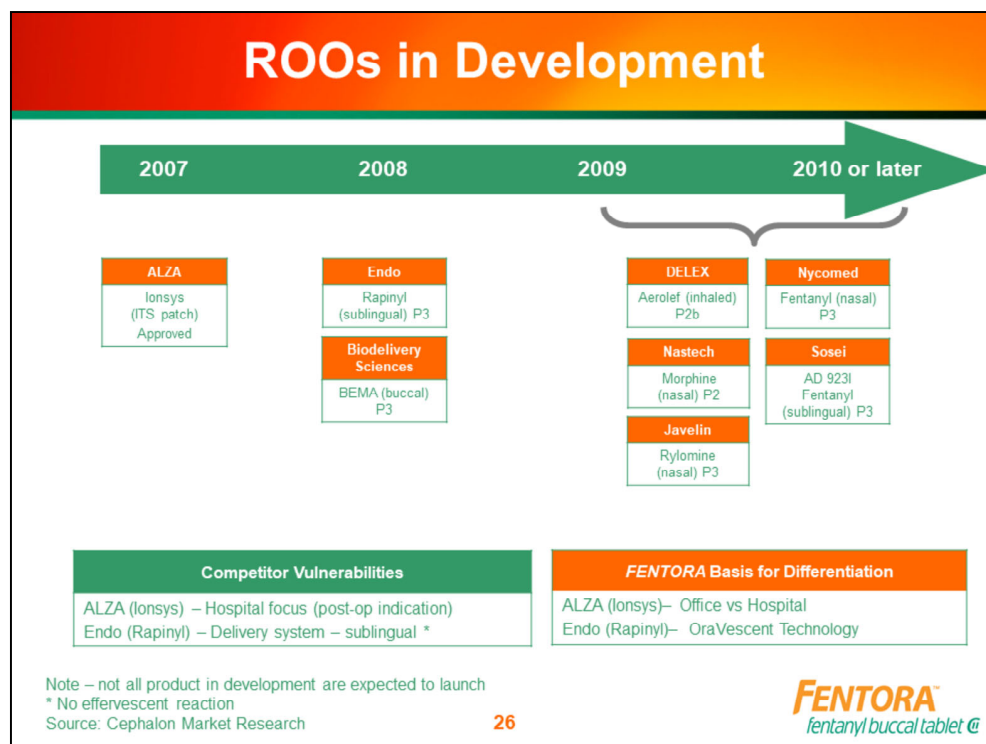
Source: Competitive Intelligence

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Endo is making significant efforts to be leader in chronic pain

Other competitors attempting to sustain market presence



BDSI – Bema (fentanyl) is scheduled for early 3Q'08 launch



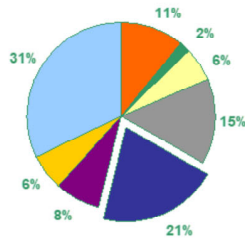
# Share of Voice

Rank	Pain	PCP
Depodur	1 <sup>st</sup>	8 <sup>th</sup>
Actiq	2 <sup>nd</sup>	5 <sup>th</sup>
Kadian	3 <sup>rd</sup>	4 <sup>th</sup>
Avinza	4 <sup>th</sup>	1 <sup>st</sup>
Duragesic	5 <sup>th</sup>	6 <sup>th</sup>
OxyContin	6 <sup>th</sup>	3 <sup>rd</sup>
Other	7 <sup>th</sup>	7 <sup>th</sup>
Combunox	8 <sup>th</sup>	2 <sup>nd</sup>

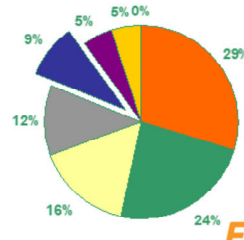
## Opioid Sales Calls (Q1 06)

- Actiq has a significant SOV in the Pain specialty (ranked 2nd vs. LA Depodur ) market segment
- The branded LAOs represent the greatest SOV in the PCP segment (approximately 63%) while Actiq SOV was limited to 9%

Pain Specialists



Primary Care



Source: IMS IPS Q1 06

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Market Situation

Market Environment

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# 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

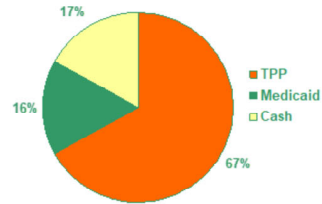
## Current Dynamics

29

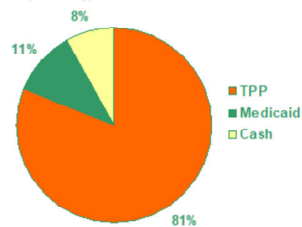
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## Economic

### Pure SAO (w/o Actiq) Reimbursement



### ROO (Actiq) Reimbursement



\*Source: NDC Claims - 2005

### Reimbursement

- Opioid market is highly genericized
- Vast majority of Pure SAOs & ROOs covered by TPP
- *FENTORA* more apt to have TPP reimbursement barriers due to its premium price
  - Tiered co-pays, co-insurance, PAs, step-edits, qty limits, dose limits
- Overall Pure SAO class has slightly greater share of Medicaid reimbursement compare to ROO sub-class

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Note: Medicare falls under TPP (to small to blow out)

## 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

- Do not recognize term “Breakthrough Pain”

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# BTP Communication

Topic	Physician*	Patient**
BTP Terminology	If BTP discussed, use "BTP" and "pain flares" interchangeably	Don't use "BTP", describe pain as "uncontrolled" or use descriptive terminology (e.g., flares, burning)
Quality of Life	Treatment success reported by patient in terms of function or activity	<ul style="list-style-type: none"> <li>Focus on holistic impact on life</li> <li>E.g. emotion, personality, social, &amp; function</li> </ul>
Fear	<ul style="list-style-type: none"> <li>Patient abuse, addiction, &amp; diversion of opioids</li> <li>Regulatory scrutiny</li> </ul>	<ul style="list-style-type: none"> <li>Addiction (loss of independence)</li> <li>Over medication (sedated / confused)</li> <li>Running out of opioids (rationing)</li> <li>Anxiety over severity and timing of next BTP episode (unpredictability)</li> <li>Physicians will stop prescribing opioids</li> </ul>
Communication of Pain	Distance themselves from chronic pain patients	Hold back communicating full impact of pain

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## Market Drivers – BTP Market

### Growth Drivers

- Aging baby boomers and growing US population will increase the size of the chronic pain patient population
- Increase in treatment of chronic pain with opioids
- Pain Specialists are more aggressive in treating chronic pain
- More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume
- Increasing understanding about the proper identification, diagnosis and treatment of BTP
- New competitive entries

### Growth Inhibitors

- Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids
- Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids
- Chronic pain practice standards (especially for BTP) are still evolving
- Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]
- Perception by some physicians that SAOs are a preferred treatment option for BTP based on familiarity, ease-of-use, and cost

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## Summary

- The chronic pain opioid market remains attractive because of its substantial size and growth
  - Pure SAOs – highest growth rate (TRx +21%, \$ +23%)
  - Combination SAOs – dominate volume (83% TRx market share)
  - LAOs – dominate market value (68% \$ market share)
- Generic expirations of blockbuster brands (ie, Duragesic) has resulted in a promotional void in the pain market
- Purdue to regain the patent on OxyContin; renewed promotion is expected
- Innovative drug delivery technology is the foundation of recent successful brands and drugs in the later stage of development



## Summary

- BTP remains a largely untapped market
  - Physicians rely heavily on LAOs when addressing patients' BTP
  - Physicians also utilize generic SAOs due to familiarity, ease of use and cost
  - Even among high-users of Actiq, SAOs remain the treatment standard for BTP
- For the treatment of BTP, a communication gap exists between physicians and patients
- Concerns over opioid misuse and reimbursement hurdles continue to be key barriers to utilization
- The pain specialist continues to be the key market segment for new brand adoption
- Several new formulations of ROOs are in development and should come to market over the next 1-5 years helping to solidify this emerging sub-class of opioids

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## Product Situation

### Profile & Position

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## FENTORA Description & Indication



### Description

*FENTORA*, which employs the OraVescent® drug delivery technology, is a potent opioid analgesic, intended for buccal administration. *FENTORA* is formulated as a flat-faced, round, beveled-edge tablet.

### Indication

*FENTORA* is indicated for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain

Prescribing Information

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*FENTORA* (fentanyl buccal tablet) is a potent opioid analgesic, intended for buccal administration. *FENTORA* employs the OraVescent® drug delivery technology and is designed to be placed and retained within the buccal cavity for a period sufficient to allow tablet dissolution and absorption of fentanyl across the oral mucosa.

*FENTORA* is formulated as a flat-faced, round, beveled-edge tablet that contains fentanyl citrate, sodium bicarbonate, sodium carbonate, citric acid, and other inactive ingredients.

# FENTORA

## Product Profile Comparison

Attributes		FENTORA	Actiq
Indication		Launch: BTP in patients w/ Ca 2008: BTP in non-Ca patients	BTCP
Efficacy	Onset	15 min (99-14) 10 min + "meaningful relief" (3039)	15 min
	Duration	60 min (99-14) 120 min (3039)	60 min
PK (FENTORA 400 mcg vs Actiq 800 mcg)	Absolute Bioavailability	65%	47%
	Transmucosal Absorption	48%	22%
	Cmax (mean ng/mL)	1.02	1.26
	Tmax (median, min)	46.8	90.8
Administration	Convenience	Discreet tablet	Lozenge on a stick
	Ease of Use	Passive administration	Active administration
	Dosage	Launch: 100, 200, 400, 600, 800 mcg sNDA: 300 mcg In development: higher dose	200, 400, 600, 800, 1200, 1600 mcg
	Titration	Multiple 100 & 200 mcg tablets	1 higher strength at a time

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## **FENTORA** Product Profile Comparison

Attributes		FENTORA	Actiq
Safety	AE Profile	Comparable to other opioids (except for application site abnormalities)	Comparable to other opioids (except for application site abnormalities)
	Abuse Potential	Comparable to other opioids	Comparable to other opioids
	Accidental Exposure	Comparable to other opioids	Lozenge on stick presents potential concerns: – Pediatric exposure – Partially used unit exposure
Formulation		Sugar-free	Sugar

## **FENTORA** Product Profile Comparison

Features/Benefits	<i>FENTORA</i>	Actiq	SAOs
Efficacy – Onset	+++	++	-
Efficacy – Duration	++	++	+
Convenience	++	+	++
Ease of Use	+	-	++
Ease of Titration	+	-	++
Side Effect Profile	+	-	++
Abuse Potential	-	-	-

Sources: TrialZ Study, Jan 2005 (Conjoint Study).  
MDS Study, Dec 2004

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Efficacy – Duration: matches BTP profile

SE – Fentora application site abnormalities, Actiq applic site + tooth decay, SAOs

## FENTORA Product Profile: Physician Reactions

### Physician Perception of FENTORA

Drivers	Barriers
<ul style="list-style-type: none"> <li>• Faster onset of pain relief</li> <li>• Overall efficacy</li> <li>• Convenient administration</li> <li>• Ease of use (vs IV administration)</li> <li>• Sugar-free</li> <li>• Unique delivery system</li> <li>• Utilizes less fentanyl</li> <li>• Discreet (ie, no handle vs Actiq)</li> </ul>	<ul style="list-style-type: none"> <li>• Anticipated high cost (reimb. hassle)</li> <li>• Potential for abuse</li> <li>• Potent opioid (held in reserve)</li> <li>• No handle administration*                             <ul style="list-style-type: none"> <li>— Actiq saves \$ with partial dosing</li> <li>— Perception Actiq can be removed if S/Es</li> </ul> </li> </ul>

- Overwhelmingly, the majority of physicians expressed an interest in this product and felt it had a place in their practice

\* Contrary to Actiq PI (physicians perception)  
Source: Summary of Market Research Q4 04 – Q1 06

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#### Market Research Barriers

#### Field Feedback/Objections:

- Taste
- Dosing & Titration (conversion chart)
- Application site abnormalities

## Position & RTB

### Position Statement

*FENTORA* is the first and only fentanyl buccal tablet which utilizes an effervescent reaction to provide the most ***rapid onset of analgesia*** of any oral opioid, resulting in improved patient functioning and activities of daily living.

### Reason to Believe

*FENTORA* employs the ***OraVescent® drug delivery technology***, which generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva<sup>1,2</sup>

- It is believed that transient pH changes accompanying this reaction may optimize dissolution (at a lower pH) and membrane permeation (at a higher pH)



## Messaging (*Vanilla at Launch*)

- Onset of pain relief within 15 min in some patients (1<sup>st</sup> time pt measured)
- Duration of pain relief up to 60 min (last time pt measured)
- OraVescent drug delivery technology may optimize delivery of fentanyl across the buccal mucosa
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%
- AEs comparable to other opioids, except for application site abnormalities (8%)
- Convenient, discreet, and sugar-free tablet

**Note:**

- only 9914 data available at launch

## Product Situation

### Actiq Performance

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## Actiq Gross Sales

- Actiq continues growth in Sales



Source: Internal shipment data

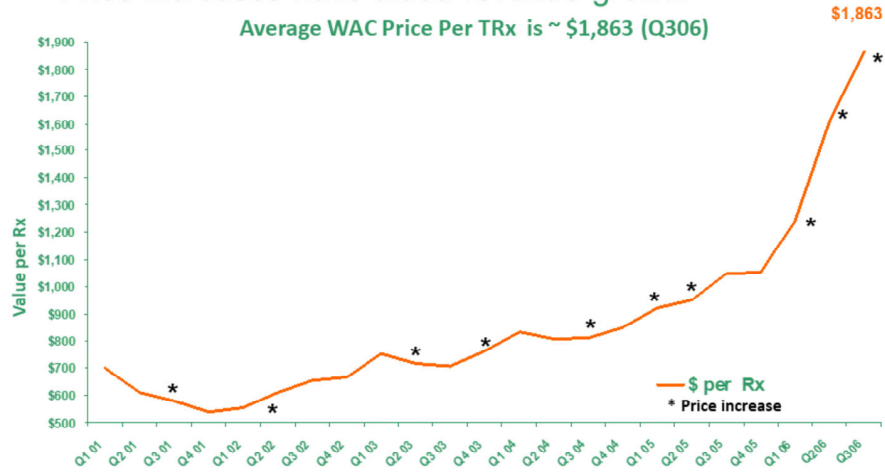
45

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# Actiq Pricing

- Price increases have aided revenue growth

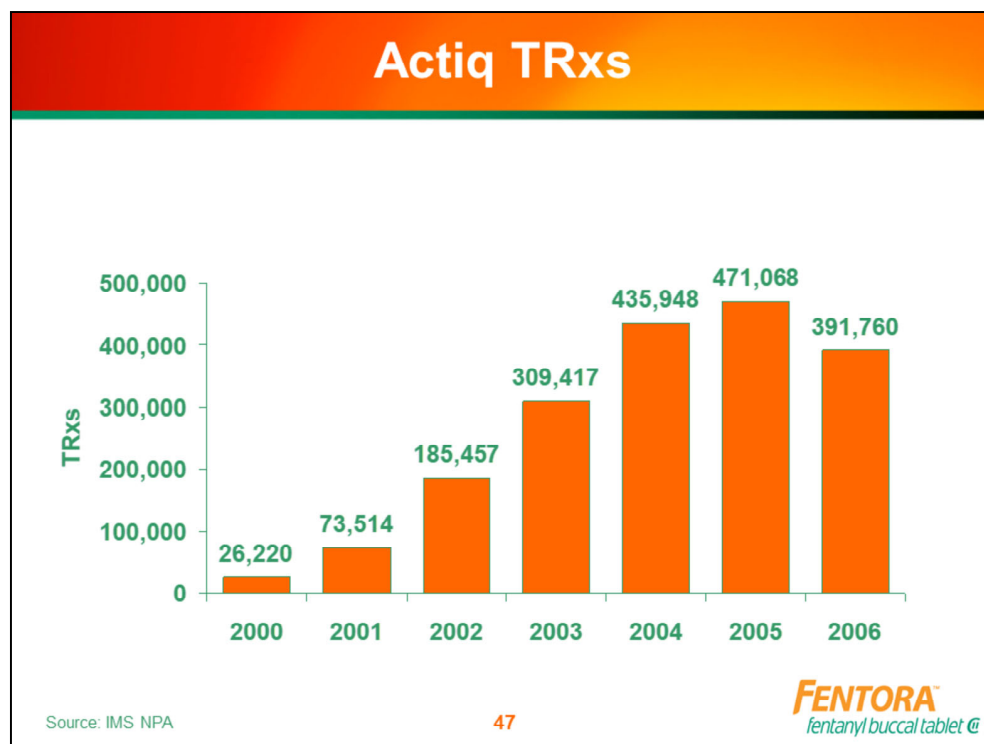
Average WAC Price Per TRx is ~ \$1,863 (Q306)



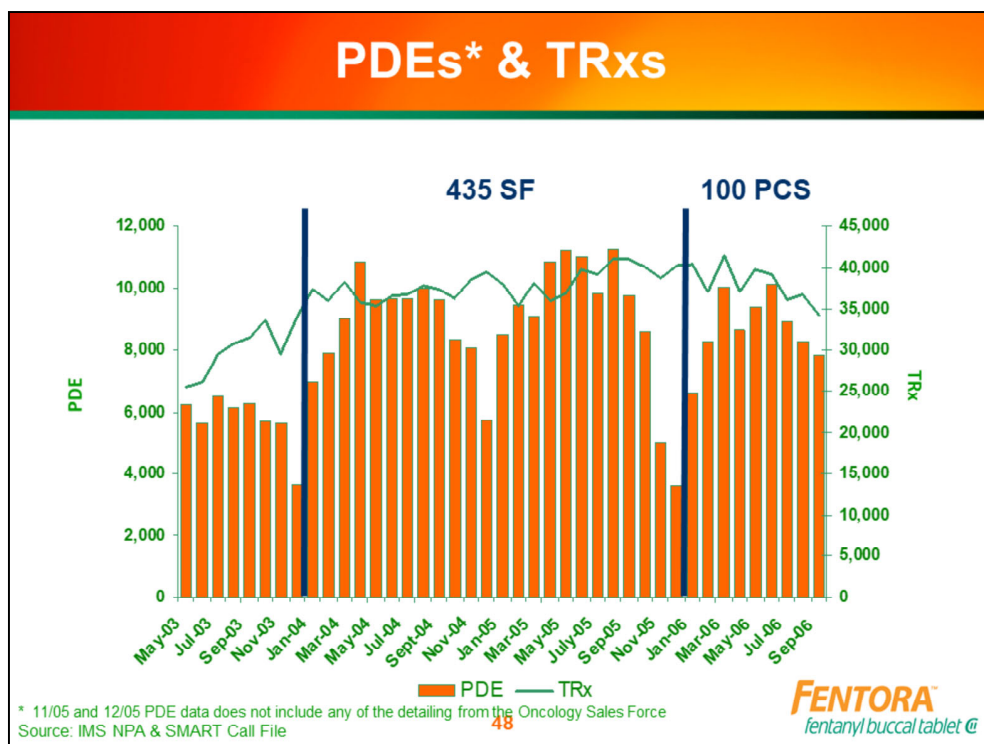
Source: IMS NPA Audit; Internal price as of Sep 2006

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Mention volume has leveled off



PDEs with dedicated Field Force roughly mirrored that of combined Field Force

More focused details maintained TRx volume

Price increase impacted TRx volume in mid 2006





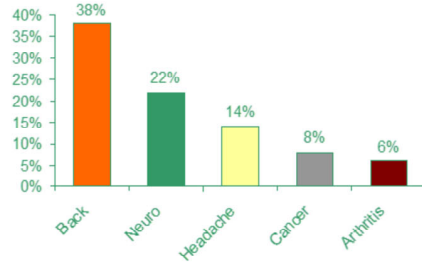


## Conditions Treated with Actiq

- Despite promotion in BTCP, Actiq use mirrors that of all opioids

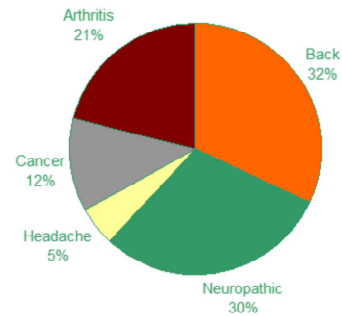
### Underlying Conditions Treated with Actiq

N=774 Patients



### Chronic Pain Patients Treated with Opioids

Estimate – 2.8 M Patients



Source: ACTIQ - Gfk V2 Chart Audit, 2006 \* Chronic pain – Cephalon market research 2nd reports

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Underlying conditions treated w/ Actiq mirror that of the opioid market

## Product Situation

### *FENTORA* Performance

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## Product Availability

- Initial supply chain limitations were resolved quickly
  - Initial stocking occurred faster in independent pharmacies
- Currently stocked in ~1,400 pharmacies
  - ~13% of the number of pharmacies stocking Actiq (11,000)
    - Pharmacies have limited “Secure” space (Actiq, OTFC, FENTORA, Duragesic, Oxycontin, etc.)
    - Rate-limiting step is increasing demand

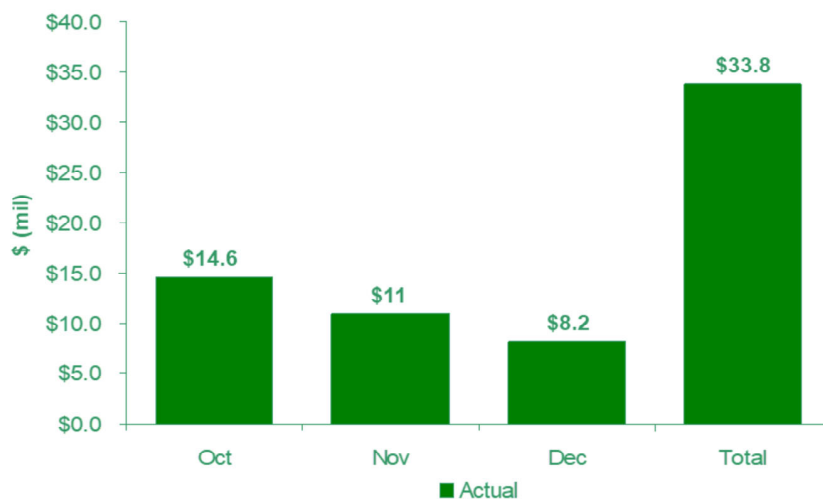
Source: October Pharmacy Stocking

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## **FENTORA Shipments**

*Actual*

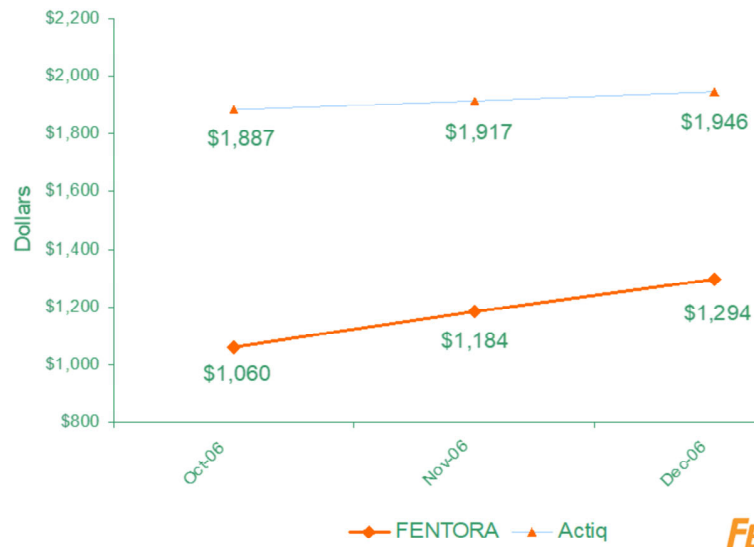


Source: SPS Shipments

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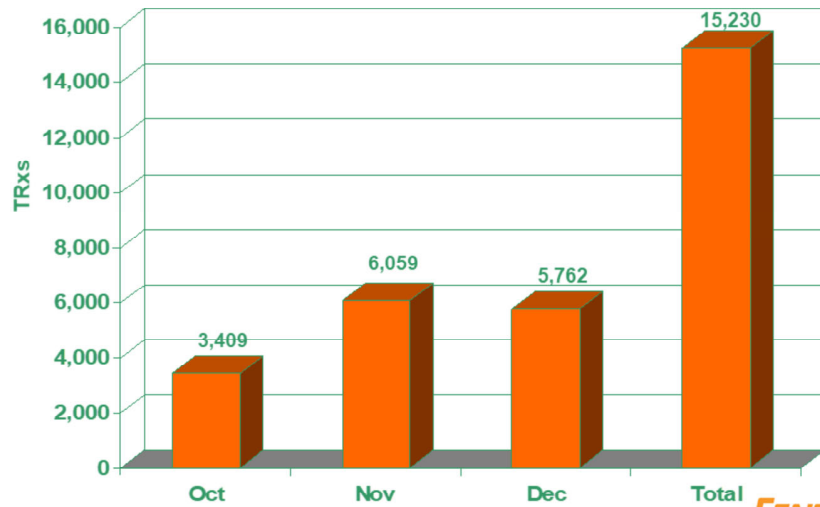
## FENTORA Monthly Average Cost per TRx



Source: IMS NPA (retail and mail order only); calculation is based upon NPA demand sales (units per strength\*WAC per unit strength) divided by NPA TRx

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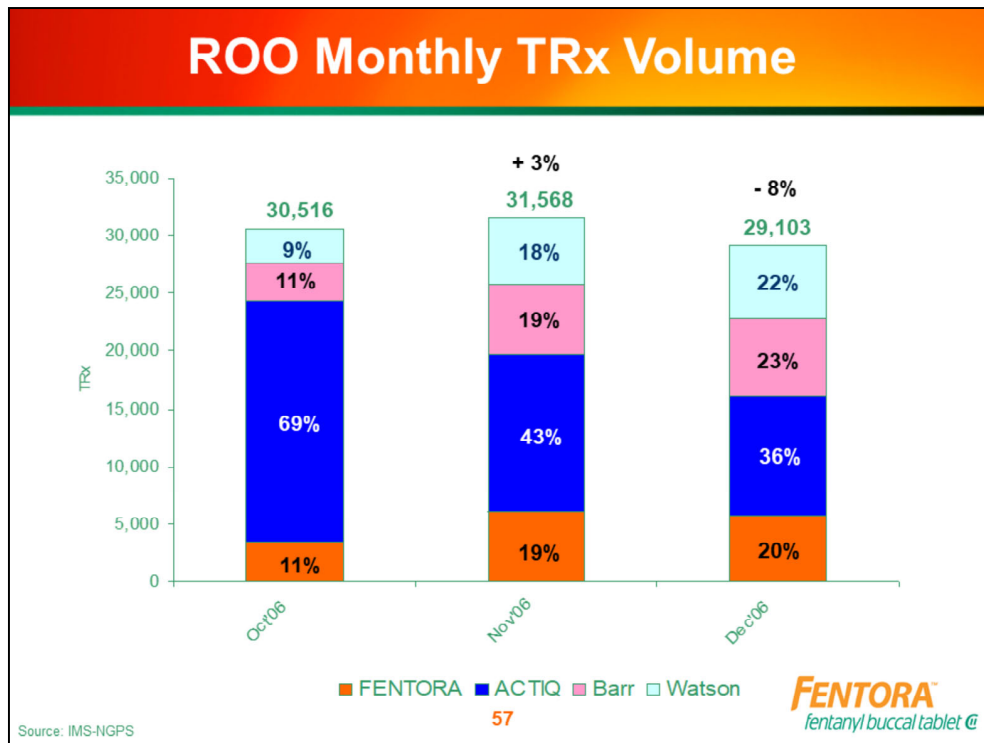
## FENTORA Monthly TRxs 2006



Source: IMS-NGPS

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## 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

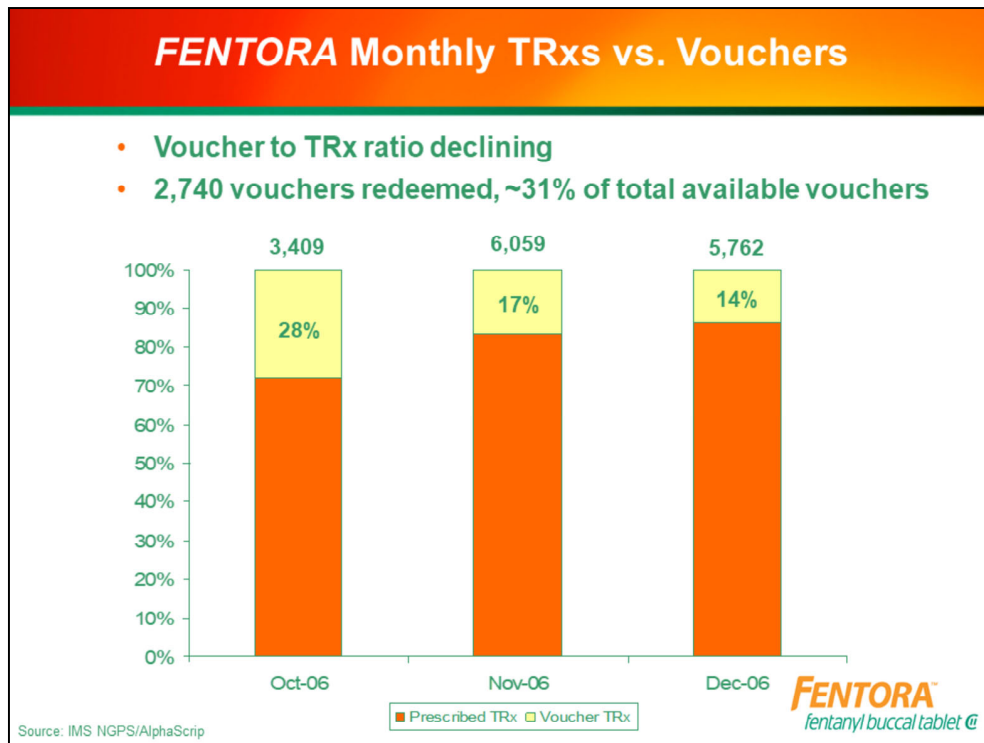
## –Captured 13% of volume

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





We had to make several assumptions.

All New York PCS and Oncology Reps. were removed from the data because they are not allowed to redeem Vouchers in that state.( 6 PCS and 3 Oncology)

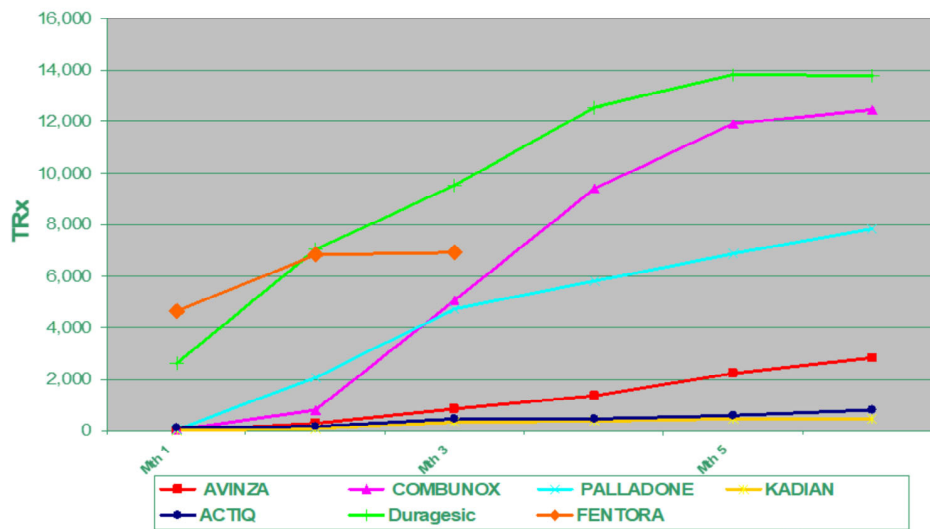
There are 75 Vouchers given to each PCS and Oncology Reps (PCS 75\*93=6975) (ONC 75\*25=1875) (Grand Total = **8850**)

We cannot determine how many vouchers the physicians received.

Q42006 had a total of **2740** Vouchers that were redeemed

**2740/8850 = 30.96%**

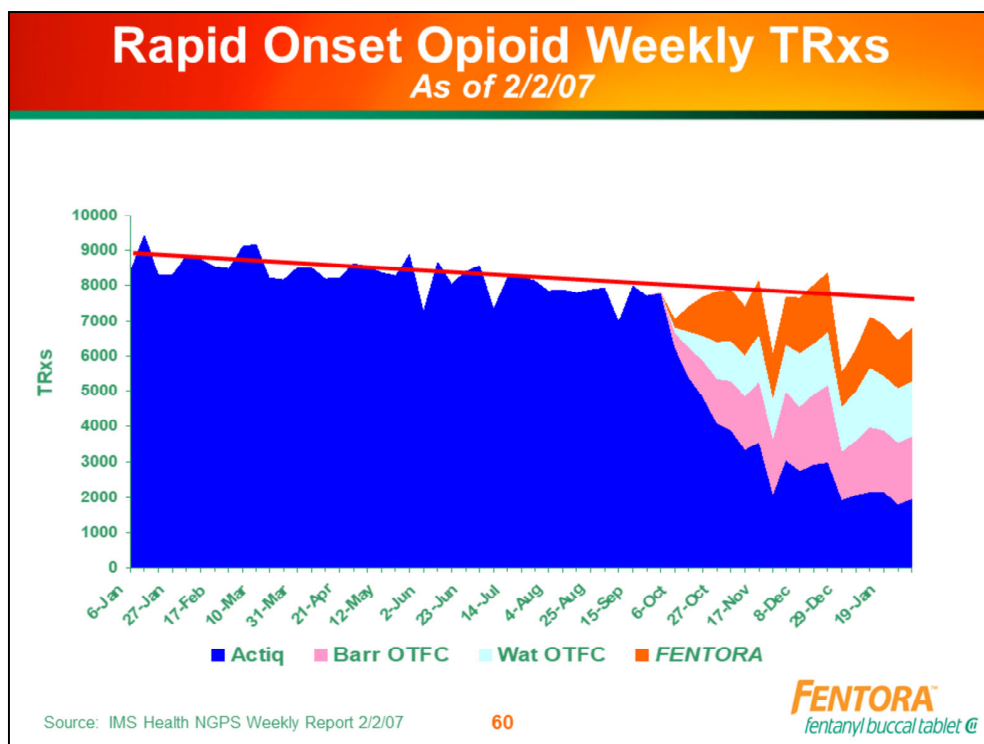
## Launch Curves: Opioid Analogs



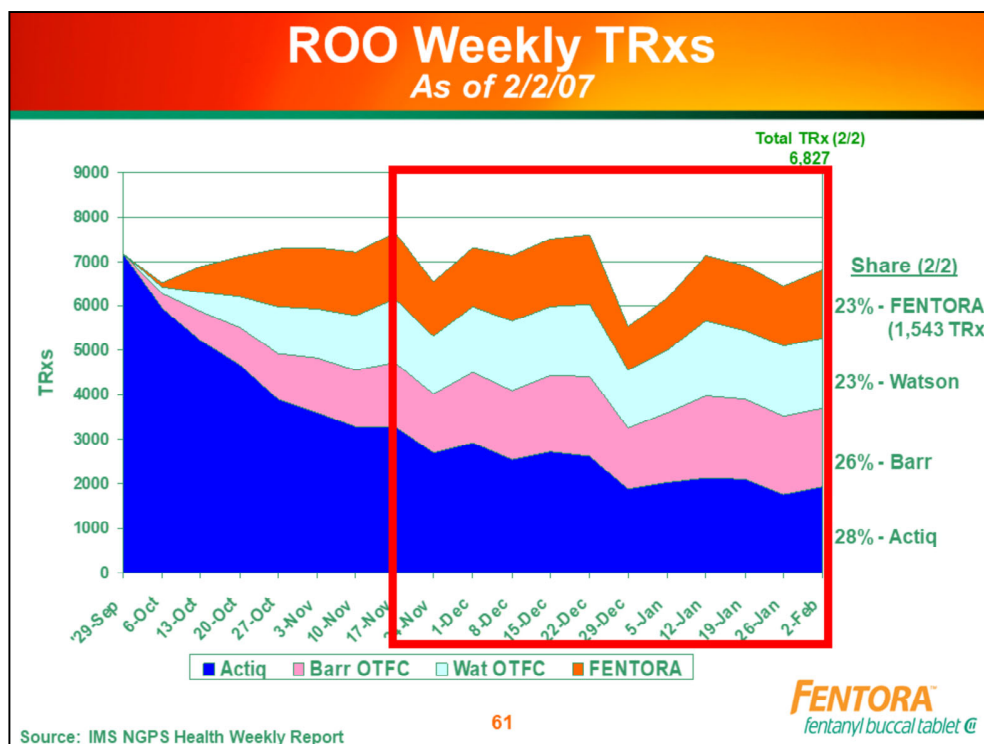
Source: IMS Health Monthly

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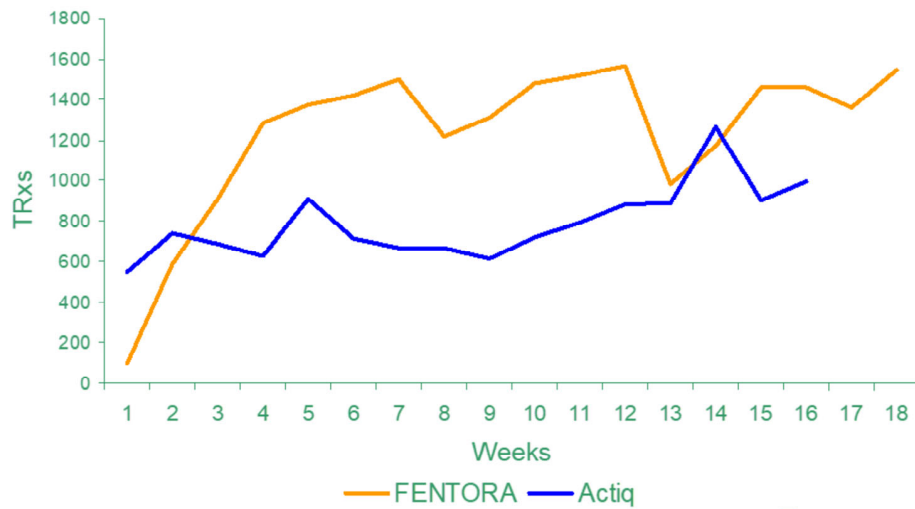


Actiq (only ROO prior to LOE) slightly declining in 2006 prior to LOE. Partially related to price increases



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

## FENTORA vs. Actiq\* Weekly TRxs

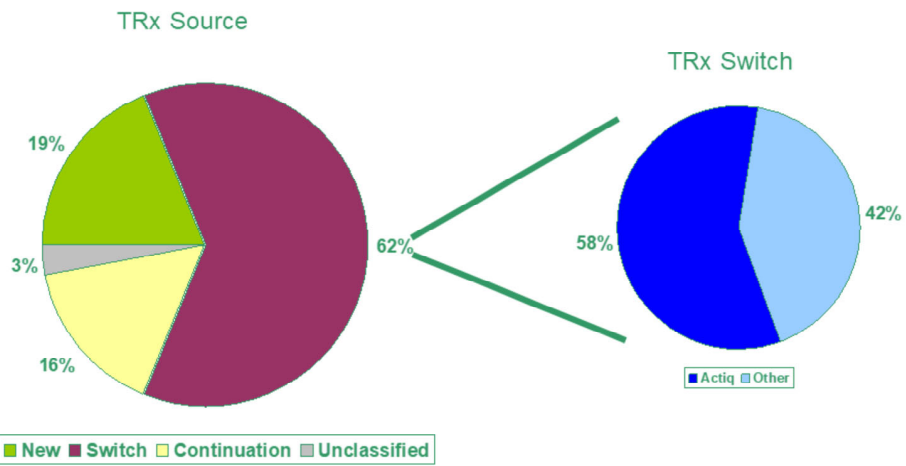


\*Actiq weeklies are from Cephalon re-launch (April 2001) 62

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# FENTORA TRx Origin

Sum of weeks 10/06 – 11/10

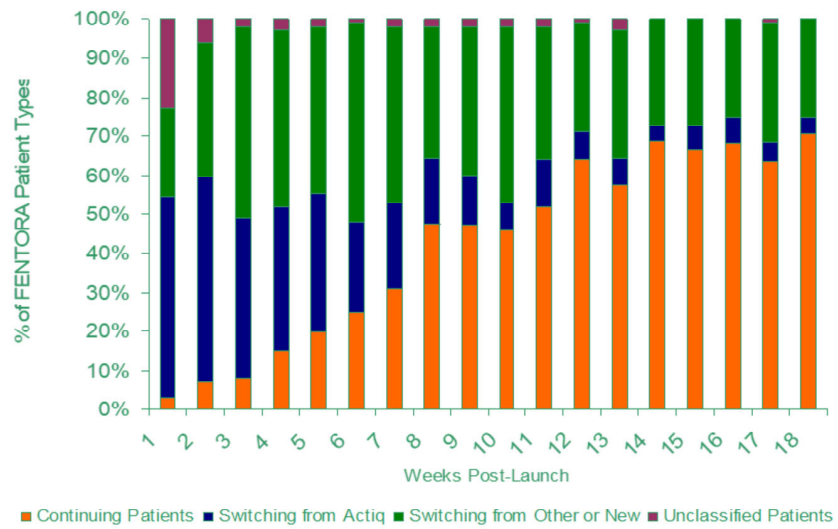


Source: IMS Weekly Longitudinal (Oct 6 – Nov 10)

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## FENTORA Source of Business Share



Source: IMS NPA Market Dynamics

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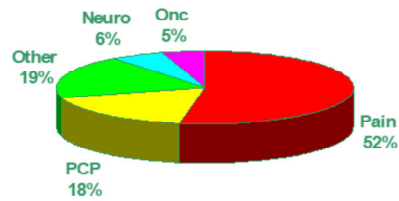
Data through February 2, 2007

## TRx vs. Prescriber Count by Specialty

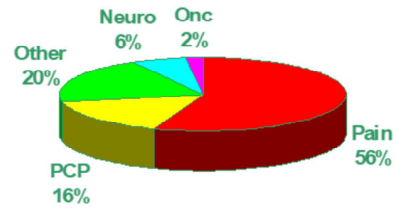
November 2006

Pain Specialists are early adopters & most productive

Prescriber Count by Specialty



TRx by Specialty

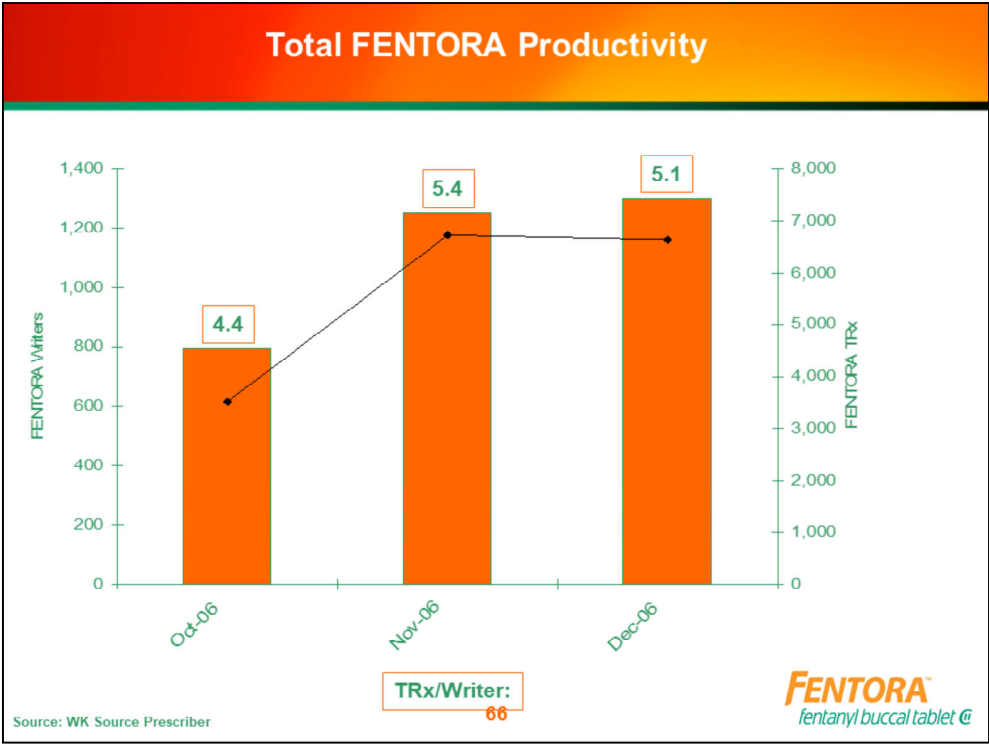


Source: IMS NPA and NDC, Nov '06

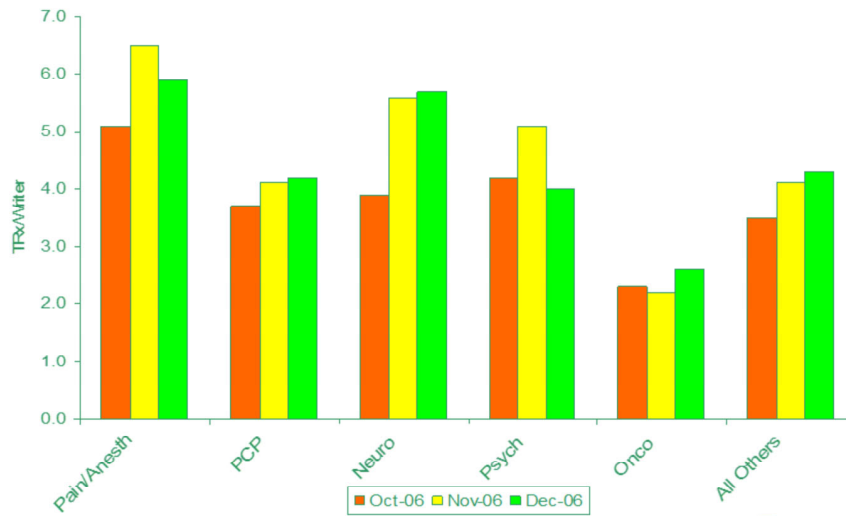
65

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## FENTORA Productivity By Specialty

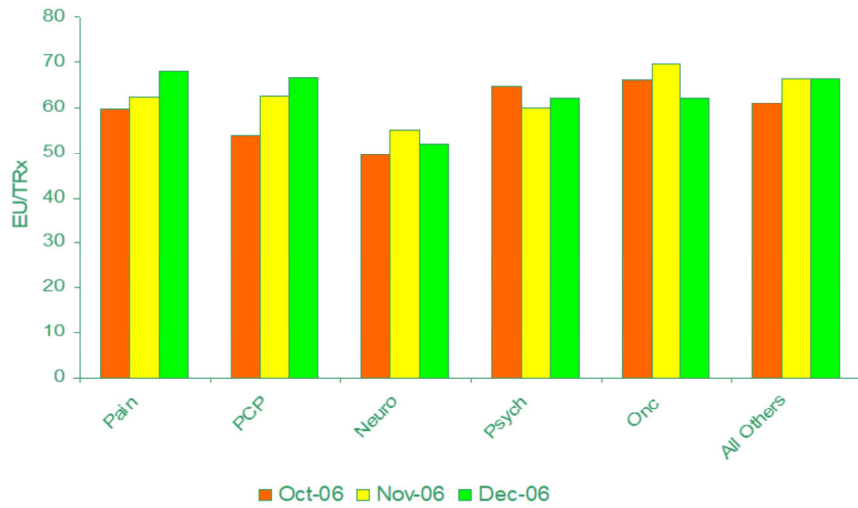


Source: WK Source Prescriber

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## Average EU/TRx by Specialty

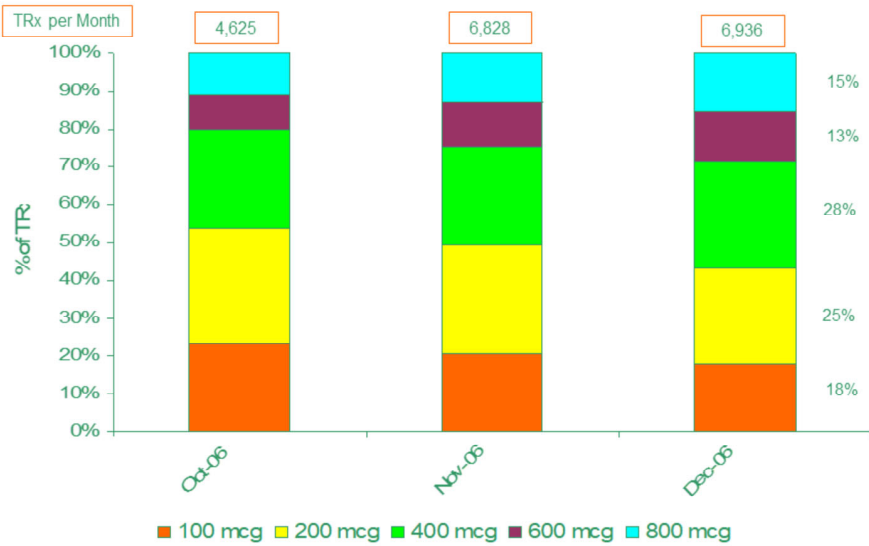


Source: IMS NPA

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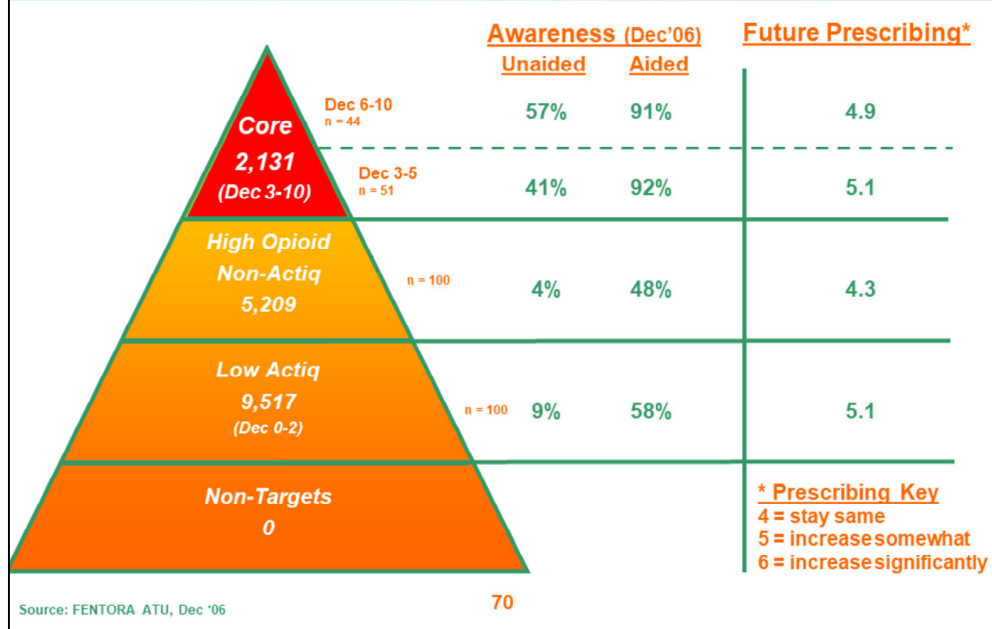
# FENTORA Monthly TRx by Strength

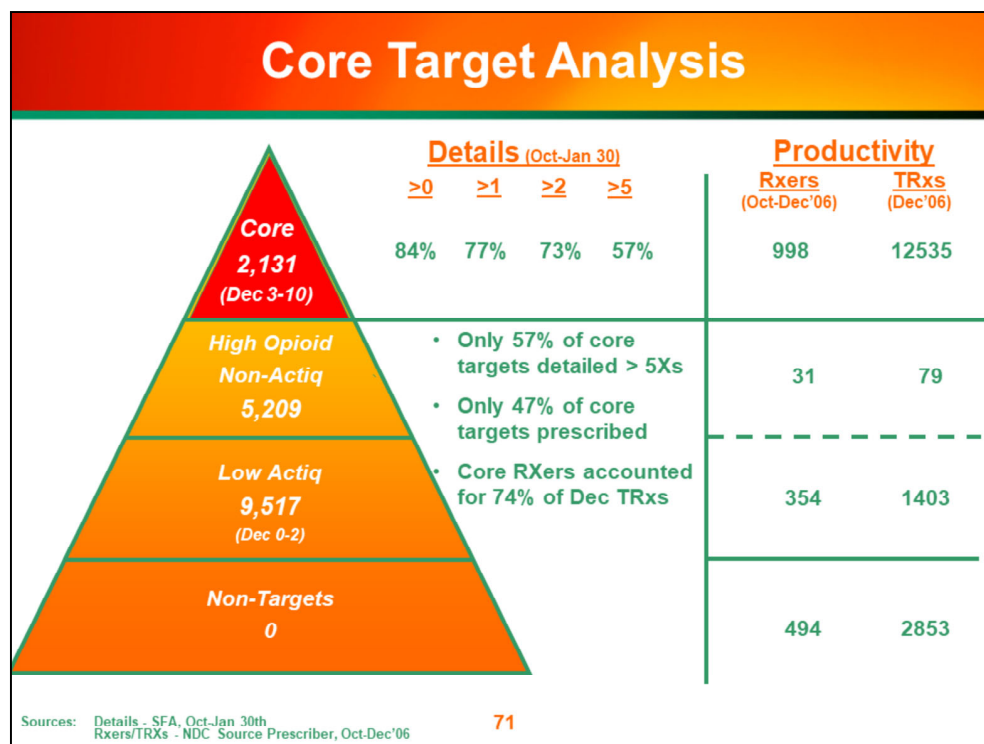


Source: IMS NPA

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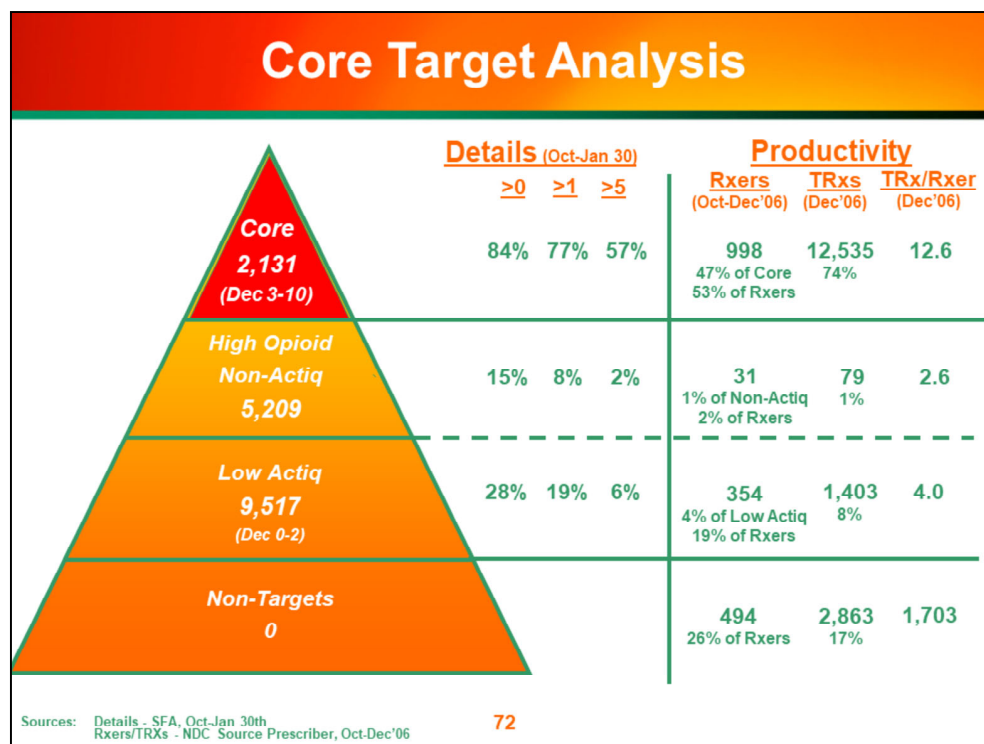
# Awareness & Prescribing Expectations





Still in launch phase, after 2 mths

Still our bread & butter



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Still in launch phase, after 2 mths

Still our bread & butter

## Field Activity 2006

- Cephalon Speaker Programs (CSP)
  - 284 Speakers Trained (148 E & 136 W)
  - Programs completed – 1,111
    - Reach: 7,895 attendees
  - Actiq average – ~ 400/qtr
- 2006 vouchers
  - 2,740 redeemed
  - ~31% of TRxs

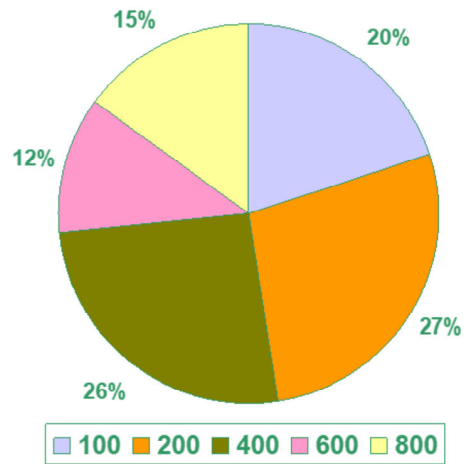
73

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## Vouchers by Strength 2006

Total vouchers redeemed: 2,740



Source: NDC 2006

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## SWOT & Key Issues

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# FENTORA SWOT Analysis

## Strengths

- Onset of analgesia 10 min
- Duration of analgesia 120 min
- Discreet and convenient dosing formulation
- Predictable bioavailability vs. Actiq
- Efficient drug delivery (65% absolute bioavailability)
- Easier dose titration scheme than Actiq
- Data on Actiq to *FENTORA* switch
- Clinical program to expand label
- Patent on *FENTORA* through 2019
- Published data in non-cancer BTP

## Weaknesses

- C-II abuse and diversion potential
- Cost vs. other SAOs (branded and generic alternative therapeutic options)
- Reimbursement restrictions
- Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study
- Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)
- Cephalon not a lead player in pain market
- Current sales force size limits ability to expand into new market segments, e.g., broader audience, hospitals, etc.

# FENTORA SWOT Analysis

## Opportunities

- KOL eagerness to evaluate and establish standards for treatment guidelines for BTP
- Increased focus on pain management from JCAHO (5<sup>th</sup> vital sign) and NIH (Decade of pain Control and Research)
- Though limited, there is some increasing awareness and understanding of BTP
- Concentrated Actiq prescriber base enables for focused targeting
- Limited number of promoted products within the market segment (SOV)
- Aging population
- Opportunity to develop outcomes data for BTP (burden of illness)

## Threats

- Limited understanding of BTP and its appropriate management outside a small community of pain specialists
- Fear of abuse and diversion with opioids
- Increasing government restrictions on C-II opioids
- Generic SAOs
- Generic OTFC
- Published data for Actiq vs. IV morphine documenting median time for pain relief 4.2 minutes
- Managed care and other third-party payers (including Medicare Part D and Medicaid) increasing their efforts to restrict high-cost drug use
- Competitive pricing pressure
- Treatment guidelines include competitive products, e.g. Actiq, SAOs
- Emerging ROO pain formulations (e.g., Rapinyl)

\*Pending study results 3039

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## Key Issues

- Third Party Payers manage costs by placing reimbursement limitations/restrictions on premium priced therapies
- Limited number of health care providers prescribe a ROO for BTP
- FENTORA is not clearly differentiated from other BTP and non-BTP treatment options
- Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain
- Anticipated dosing and administration challenges for both physicians and patients
- Risk for abuse, addiction, and diversion
- Limited KOL and professional society relationships impact peer-to-peer knowledge and uptake of FENTORA

## Marketing Strategy

### Mission & Strategic Vision

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# Mission

## Franchise Mission

Establish Cephalon as a major player in pain management

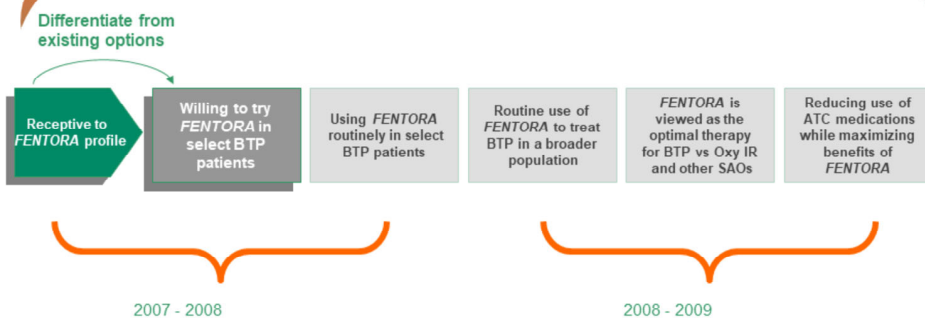
## FENTORA Mission

Establish FENTORA as the gold standard for BTP

# Three Year Strategy

What FENTORA Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed\*



Note – Strategy reflects clinical plan in development

\* This internal position statement is aspirational, and not intended to be used in promotional materials

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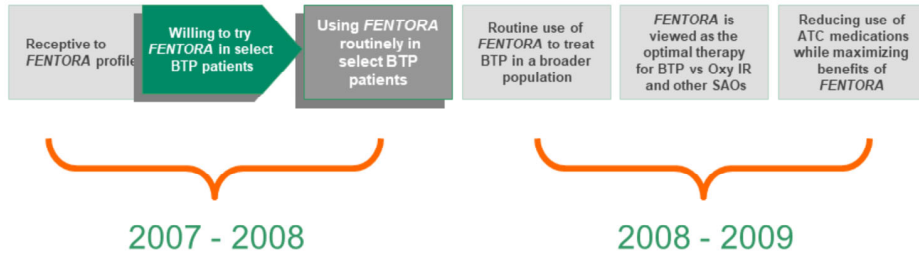


# Three Year Strategy

What FENTORA Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Reinforce and promote routine use



Note – Strategy reflects clinical plan in development

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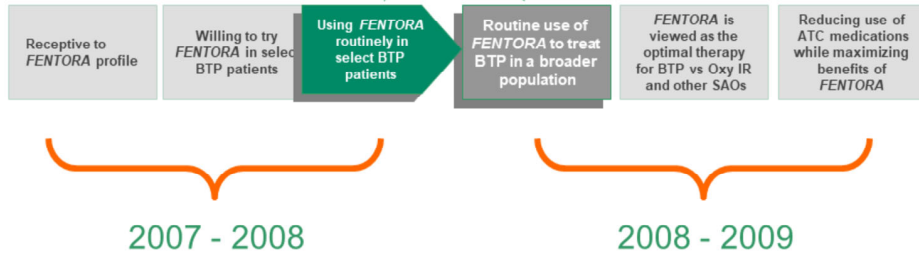
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# Three Year Strategy

What FENTORA Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Promote approved noncancer data



Note – Strategy reflects clinical plan in development

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# Three Year Strategy

What FENTORA Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Promote  
superiority data

Receptive to  
FENTORA profile

Willing to try  
FENTORA in select  
BTP patients

Using FENTORA  
routinely in select  
BTP patients

Routine use of  
FENTORA to treat  
BTP in a broader  
population

FENTORA is  
viewed as the  
optimal therapy  
for BTP vs Oxy IR  
and other SAOs

Reducing use of  
ATC medications  
while maximizing  
benefits of  
FENTORA

2007 - 2008

2008 - 2009

Note – Strategy reflects clinical plan in development

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# Three Year Strategy

What FENTORA Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Promote chronic pain management data

Receptive to FENTORA profile

Willing to try FENTORA in select BTP patients

Using FENTORA routinely in select BTP patients

Routine use of FENTORA to treat BTP in a broader population

FENTORA viewed as the optimal therapy for BTP vs Oxy IR and other SAOs

Reducing use of ATC medications while maximizing benefits of FENTORA

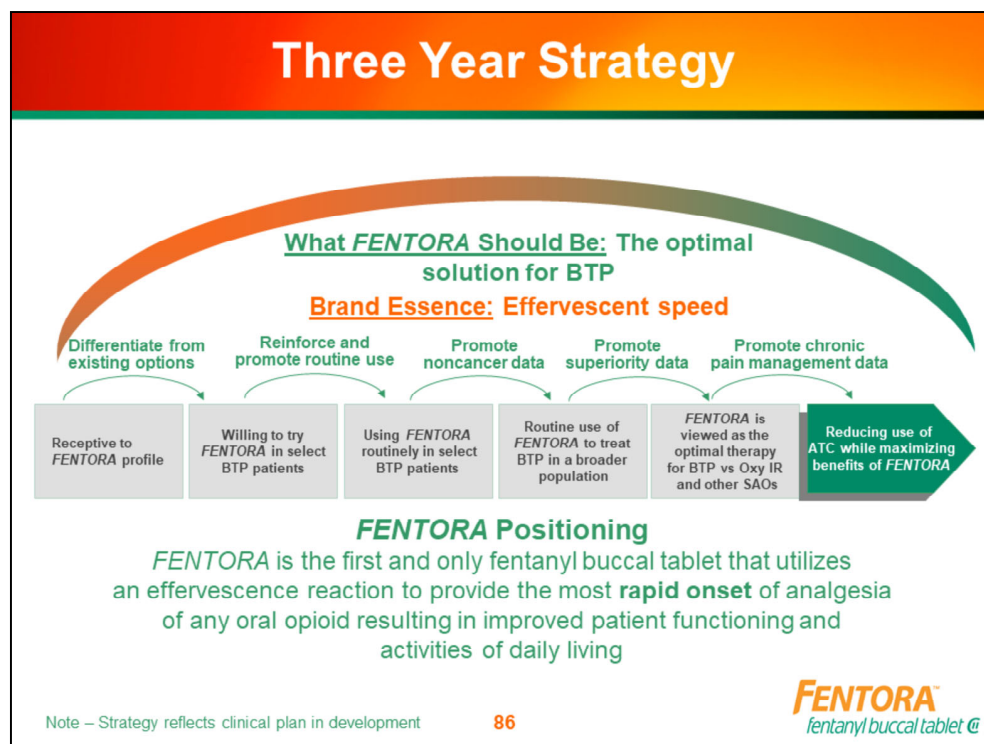
2007 - 2008

2008 - 2009

Note – Strategy reflects clinical plan in development

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Position doesn't change

# Marketing Strategy

## 2007 Objectives, CSFs, Strategies

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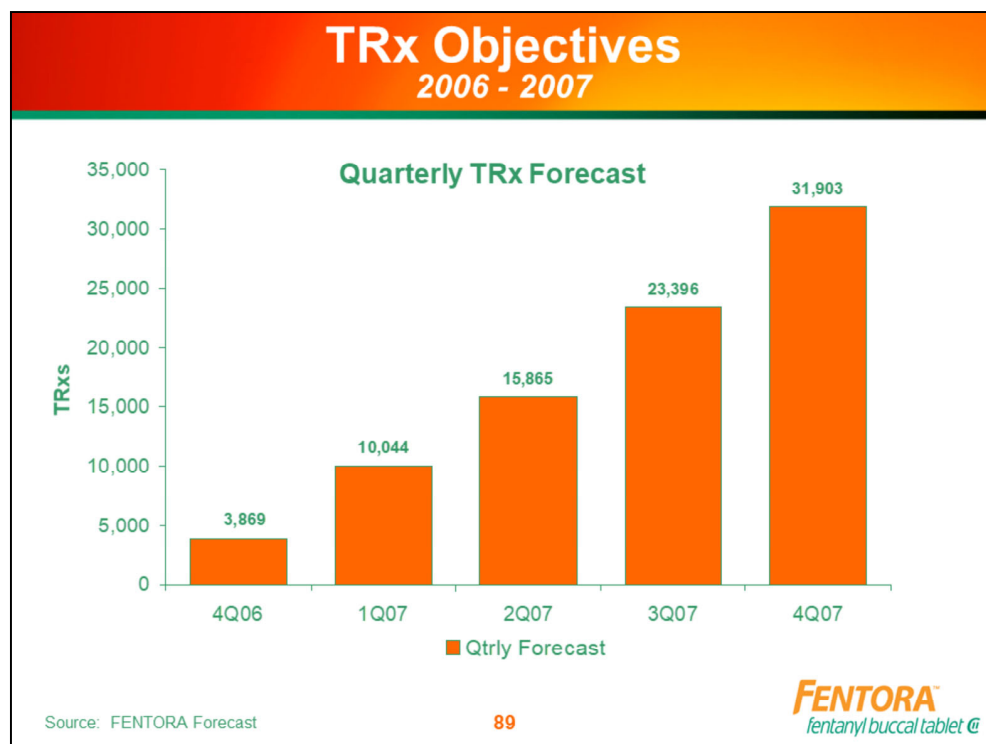
## Objectives 2007

**\$139.5M Total Revenue**  
**81,207 TRxs**

---

### Assumptions

- TRx Share @ month 12 = 28% of ROO (fentanyl) Market
- FENTORA will grow from Actiq loyalists conversion & incremental market growth
- WAC/TRx = \$1,357 (2.5% annual price increase)



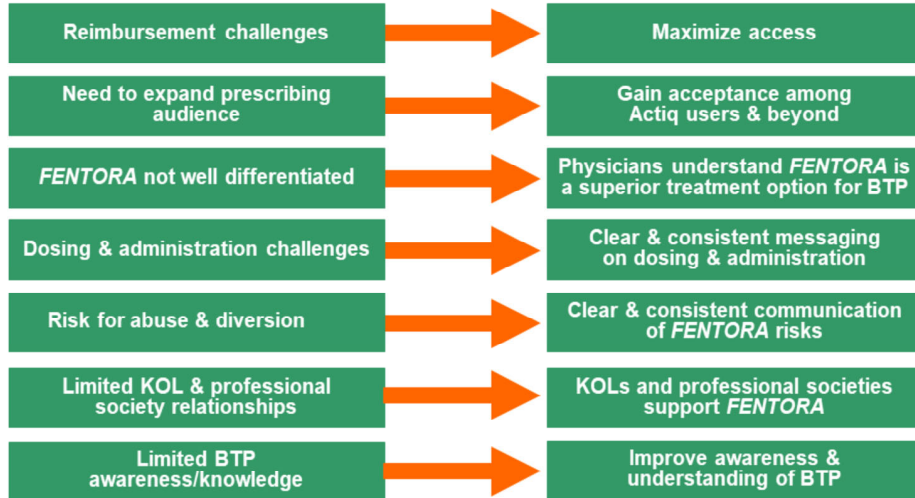
One data point



# Critical Success Factors

## Issues

## CSFs



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## Key Strategies – FENTORA

### Issue

Third Party Payers manage costs by placing reimbursement limitations/restrictions on premium priced therapies

### Critical Success Factor

Physicians & patients have access to reasonable/favorable reimbursement for FENTORA

### Strategies

Manage and mitigate managed care barriers (cost, generic step-edit):

- Selectively contract with MCOs
- Educate MCOs regarding:
  - FENTORA value to health system
  - BTP:
    - Optimal assessment and treatment of BTP
    - Establish the Burden of Illness of BTP
    - Further develop ROO sub-class as an optimal treatment for BTP
  - Minimize risk of Abuse, Addiction, and Diversion
- Provide physician/patient assistance access programs

## Key Strategies – FENTORA

### Issue

Limited number of health care providers prescribe a ROO for BTP

### Critical Success Factor

Expand FENTORA prescribing audience with Actiq users and beyond

### Strategies

- Maximize core prescriber to set the stage for expanded use
- Expand use with high opioid prescribers and low Actiq users
- Explore broader audience, non-retail segment opportunities, as well as other potential channels

## Key Strategies – FENTORA

### Issue

FENTORA is not clearly differentiated from other BTP and non-BTP treatment options

### Critical Success Factor

Physicians understand FENTORA is a superior treatment option for BTP

### Strategies

- Create high level of awareness among target segments
- Educate physicians on the potential limitations of prescribing LAOs and SAOs to treat BTP
- Leverage new clinical data when available and appropriate
- Further develop ROO sub-class as an optimal treatment for BTP

## Key Strategies – FENTORA

### Issue

Anticipated dosing and administration challenges for both physicians and patients

### Critical Success Factor

Physicians and patients understand the proper dosing and administration of FENTORA

### Strategies

Educate physicians and patients on

- How the delivery system is different from traditional oral administration
- Dosing, conversion and titration
- Package Handling & Administration

## Key Strategies – FENTORA

### Issue

Limited KOL and professional society relationships impact peer-to-peer knowledge and uptake of FENTORA

### Critical Success Factor

KOLs and societies support FENTORA as an effective treatment option for BTP

### Strategies

- Improve and expand KOL and society relationships
- Continue to consult KOLs to better inform Cephalon on the optimal design of FENTORA clinical studies, as well as the positioning of the brand

## Key Strategies – FENTORA

### Issue

Risk for abuse, addiction, and diversion

### Critical Success Factor

FENTORA risks are understood by health care professionals

### Strategies

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of FENTORA and allay fears of opioids
- Continue to implement risk minimization tools
- Maximize SECURE outreach program initiatives

## Key Strategies – FENTORA

### Issue

Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain

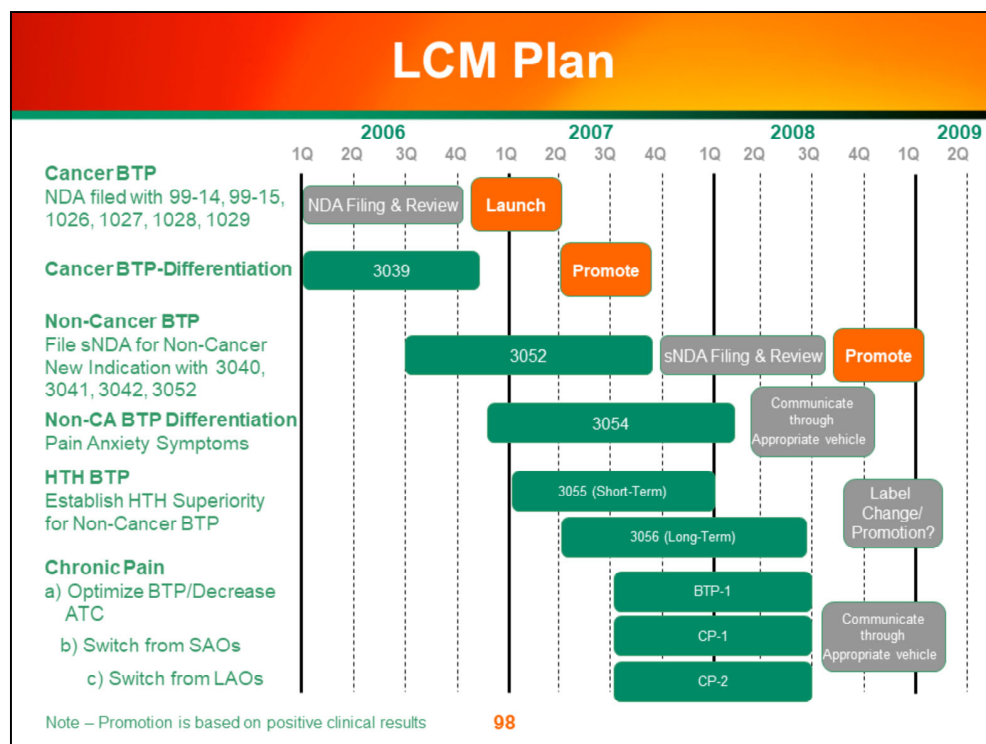
### Critical Success Factor

BTP awareness and understanding of treatment options among physicians and patients

### Strategies

- 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





## Clinical Plan Highlights

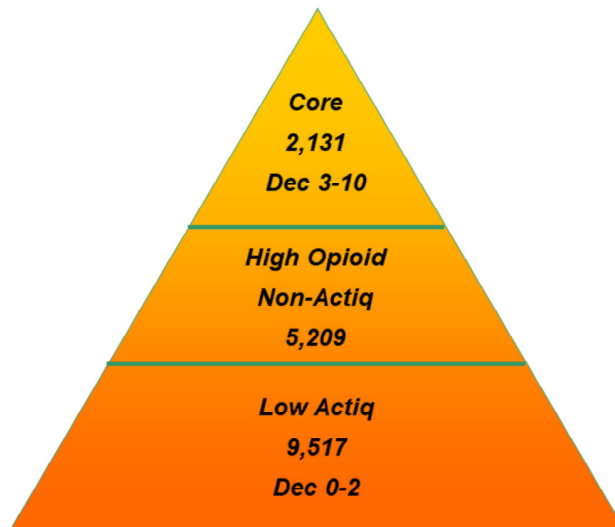
Study #	Study	Status
<b>PK Studies</b>		
TBD	PK/Efficacy Modeling	Phase 1 complete, awaiting 3039
1043	Buccal Sublingual	Start 1Q07, complete 1Q07
RP-1	Relative Potency (IV morphine)	Start 1Q07, complete 3Q/4Q07
TBD	PK Higher Dose	Start 2Q07?, complete 3Q07?
RP-2	Relative Potency (SAO)	Start 4Q07, complete 2Q08
<b>Cancer Studies</b>		
9915	OLLT Safety-Cancer BTP	LPLV Nov 06, DB lock Feb 07
3039	Efficacy-Cancer BTP (Onset)	Complete, data available
<b>Non-Cancer Studies</b>		
3040	OLLT Safety-Non-Cancer BTP	LPLV Jan 08, data Jan 08
3041	Efficacy-Neuropathic BTP	Complete, data available
3042	Efficacy-Back BTP	Complete, data available
3052	Non-Cancer Pivotal Efficacy	89 enrolled, LPLV May 07, DB lock Jul 07
3054	Pain Anxiety Symptoms	Study start Nov, complete 3Q07
3055	OxylR H2H ST Efficacy/Safety	Study start 2Q07, LPLV 4Q07
3056	OxylR H2H LT Efficacy/Safety	Study start 3Q07, LPLV 3Q08

## Targeting

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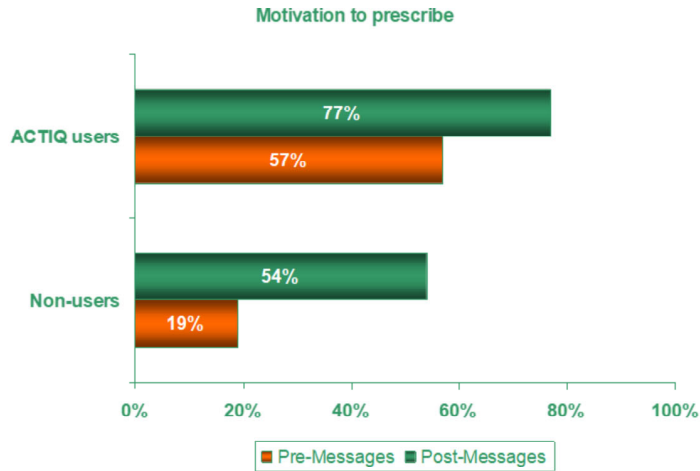
100

# Targeting



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## Rxers Reaction to Messages

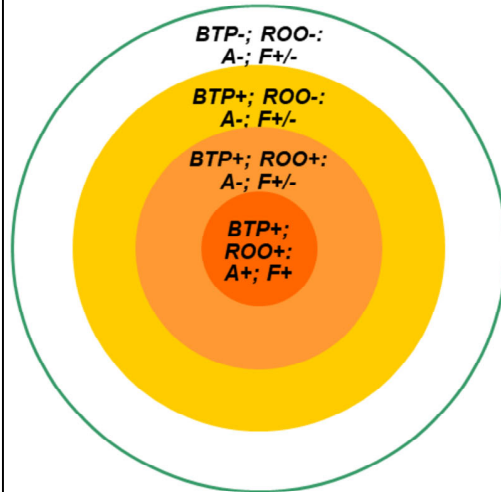


\* To what degree does this new information motivate you to prescribe FENTORA over other short-acting opioid (SAO) medications for breakthrough pain (1-7 scale)?

Source: Gfk V2 Q2 06 N = 77 (users) N = 52 (non-users)

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# Targeting

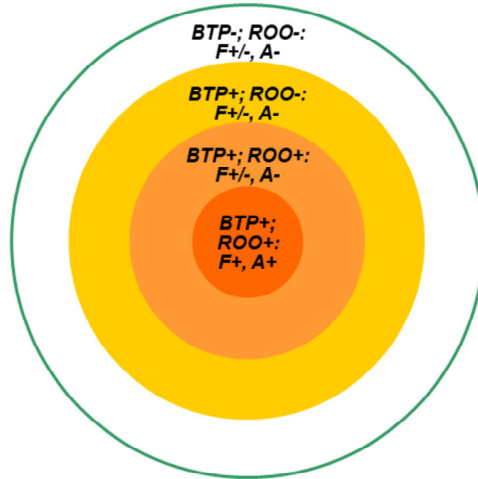


## Key

<u>Symbol</u>	<u>Meaning</u>
BTP+	believe in BTP
ROO+	believe in ROO
A+	like Actiq
F+	like <i>FENTORA</i>
BTP-	do not believe in BTP
ROO-	do not believe in ROO
A-	do not like Actiq
F+/-	may or may not like <i>FENTORA</i>

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# Targeting



## CSF

- Expand FENTORA prescribing audience with Actiq users and beyond

## Objective

- Maximize core prescriber to set the stage for expanded use
- Expand use with high opioid prescribers and low Actiq users

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## Tactical Plan

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# Tactical Plan

Overview  
Tactics by CSF

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# FENTORA

## Key Milestones

Campaigns: Vanilla

Mocha

Milestone	1Q	2Q	3Q	4Q
Publication 1029 (Multi-dose PK)	Jan/Feb			
AAPM – 3040, 3041 1st public presentation, 3042 abstracts	Feb 7-10			
NSM	Feb			
Final Data of 99-15 (OL Safety - CA)	Feb			
sNDA – Label update 3039 BTP CA Efficacy	Feb 23			
FDA Type B meeting – Non-cancer sNDA requirements	Feb/Mar			
PDUFA – 300 mcg sNDA	Mar 3			
3039 BTP CA efficacy – target pub date	Mar/Apr			
Efficacy 3039		✓		
Publication 1028 (Absolute bioavailability)		✓?	✓?	
PDUFA - label changes		Apr 26		
AAN - 3041 (NP – Secondary efficacy)		Apr 28-May 5		
APS - 3040, 3041, 3042 (LT Safety, NP, LB)		May 2-5		
PDUFA - Efficacy 3039 (Onset)			Late Aug	
Publication 99-11 + 99/18 (Dose proportionality)				✓?
Publication 3041 (NP)				✓?
sNDA Non-CA				✓?

## CSF #1: Physicians & patients have access to reasonable/favorable reimbursement for *FENTORA*

### STRATEGY

- Selectively contract with MCOs
- Educate MCOs regarding:
  - *FENTORA* value to health system
  - BTP:
    - Optimal assessment and treatment of BTP
    - Establish the Burden of Illness of BTP
    - Further develop ROO sub-class as an optimal treatment for BTP
  - Minimize risk of Abuse, Addiction, and Diversion
- Provide physician/patient assistance access programs

### TACTICS

- AMCP Dossier
- NAM Slide Kit
- Formulary Kit
- MCSPs (Mgd Care Scientific Presentations)
- Reprints
- BTP Collateral Material
  - Direct Mail, Journal Ads, targeted media
- ESP Tool Kit & Collateral
- AMCP Convention Presence
- Reimbursement Kit / Hotline
- In-Office Reimbursement Training
- Debit Card Pilot Program

## CSF #2: Expand *FENTORA* prescribing audience beyond Actiq users

### STRATEGY

- Maximize core prescribers to set the stage for expanded use (post label expansion)
- Expand use with high opioid prescribers and low Actiq users
- Explore non-retail segments opportunities, as well as other potential channels

### TACTICS

- NSM Workshops
- Field driven promotional programs
  - CSPs – \$6M
  - Vouchers – 100/qtr/rep 1st half, 50/qtr/rep 2nd half
  - Sales collateral materials (w/ 3039)
    - Actiq users material
    - Animation, case study series
  - Hospital CSPs – grand rounds
  - Case Studies
  - Reprints
- Marketing driven promotional programs
  - Direct mail, targeted media, journal ads
  - E-detail
  - Website
  - Convention presence

### CSF #3: Physicians understand *FENTORA* is a superior treatment option for BTP

#### STRATEGY

- Create high level of awareness among target segments
- Educate physicians on the potential limitations of prescribing LAOs and SAOs to treat BTP
- Leverage new clinical data when available and appropriate
- Further develop ROO sub-class as an optimal treatment for BTP

#### TACTICS

- Appropriate dissemination of clinical data
- Branded collateral material
- CSPs
- Case Studies Program
- *FENTORA* animation
- PR outreach to KOLs, societies, advocacy groups, & pain centers of excellence
- Government affairs outreach to USP

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## CSF #4: Physicians and patients understand the proper dosing and administration of *FENTORA*

### STRATEGY

- Educate physicians and patients on
  - How the delivery system is different from traditional oral administration
  - Dosing and titration
  - Package Handling & Administration

### TACTICS

- Administration poster
- Wallet card
- Administration script for Prof Services
- Pain diary
- Flip chart
- Patient starter kit
- Catalina newsletter
- E-detail
- Pod cast
- Blackberry download (in booth promotion)
- Case Studies

**CSF #5: *FENTORA* risks are understood by health care professionals**

**STRATEGY**

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of *FENTORA* and allay fears of opioids
- Continue to implement risk minimization tools
- Maximize SECURE outreach program initiatives

**TACTICS**

- Branded collateral materials
- Lunch & Learns
- AAD CSPs
- SECURE educational initiatives
- ESP Tool Kit & Slim Jim
- Media outreach training (issues mgt)

**CSF #6: KOLs and societies support *FENTORA* as an effective treatment option for BTP**

**STRATEGY**

- Improve and expand select KOL and society relationships

**TACTICS**

- Implement KOL Plan, e.g. roundtables, congress interaction, one-on-ones, HOVs
- Speaker Training / CSPs
- Media outreach training
- Society outreach initiatives, e.g. educational programs
- Implement Pain Centers of Excellence Program



## **CSF #7: BTP awareness and understanding of treatment options among physicians and patients**

### **STRATEGY**

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

### **Education**

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

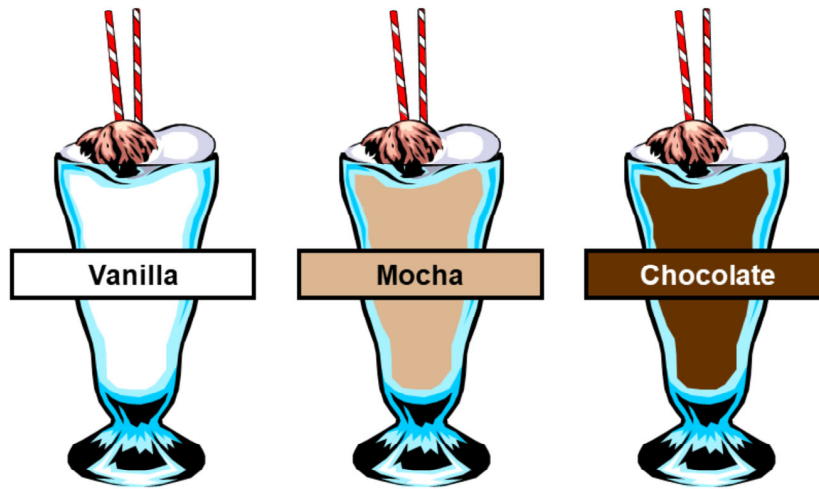
## Tactical Plan

### *FENTORA* Campaign Evolution

***FENTORA***<sup>™</sup>  
*fentanyl buccal tablet* Ⓢ

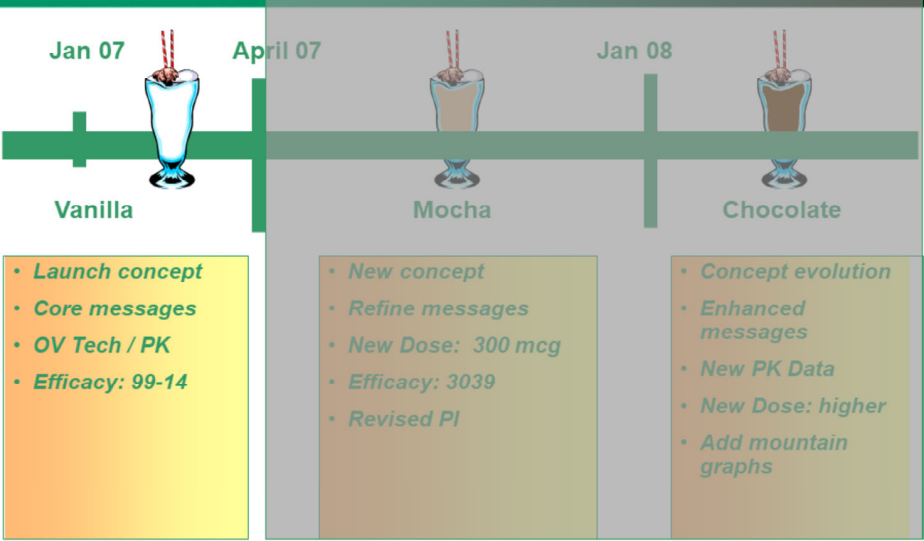
115

## Campaign



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# Campaign Evolution



## Current Campaign

**Now available**

**New FENTORA—relief for breakthrough pain in opioid tolerant patients with cancer**

- Onset of pain relief within 15 minutes in some patients\*
- Duration of pain relief up to 60 minutes (last time point measured)
- OraVescent® drug delivery technology may optimize delivery of fentanyl across the buccal mucosa
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%
- Convenient, discreet, sugar-free tablet

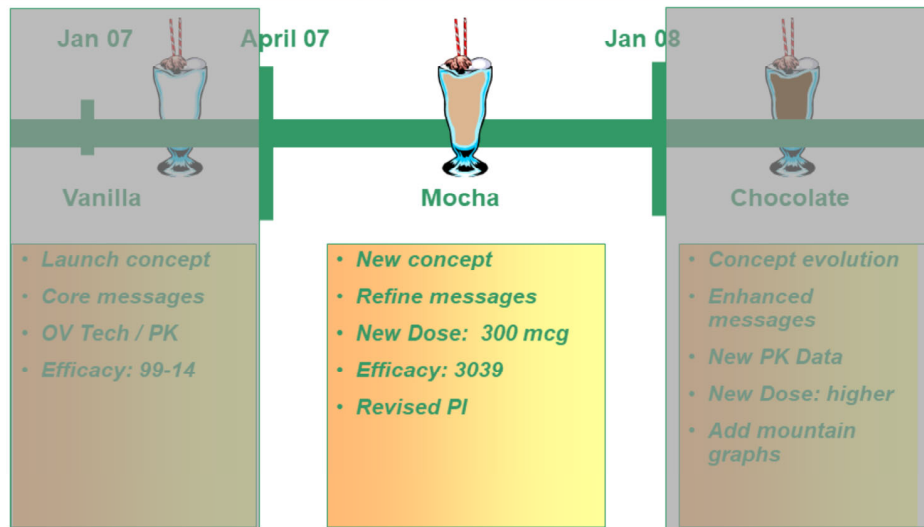
**New FENTORA**  
fentanyl buccal tablet @

**New FENTORA—relief for breakthrough pain in opioid tolerant patients with cancer**

- Onset of pain relief within 15 minutes in some patients\*
- Duration of pain relief up to 60 minutes (last time point measured)
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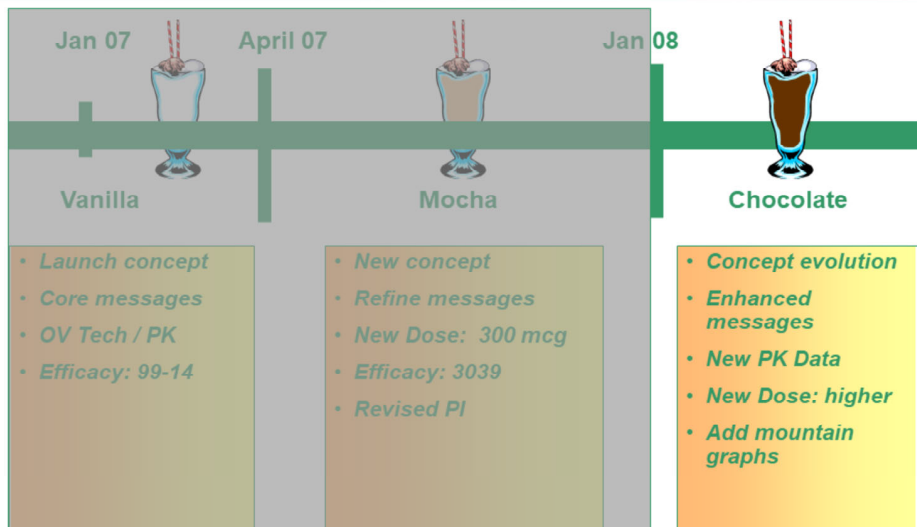
118

# Campaign Evolution

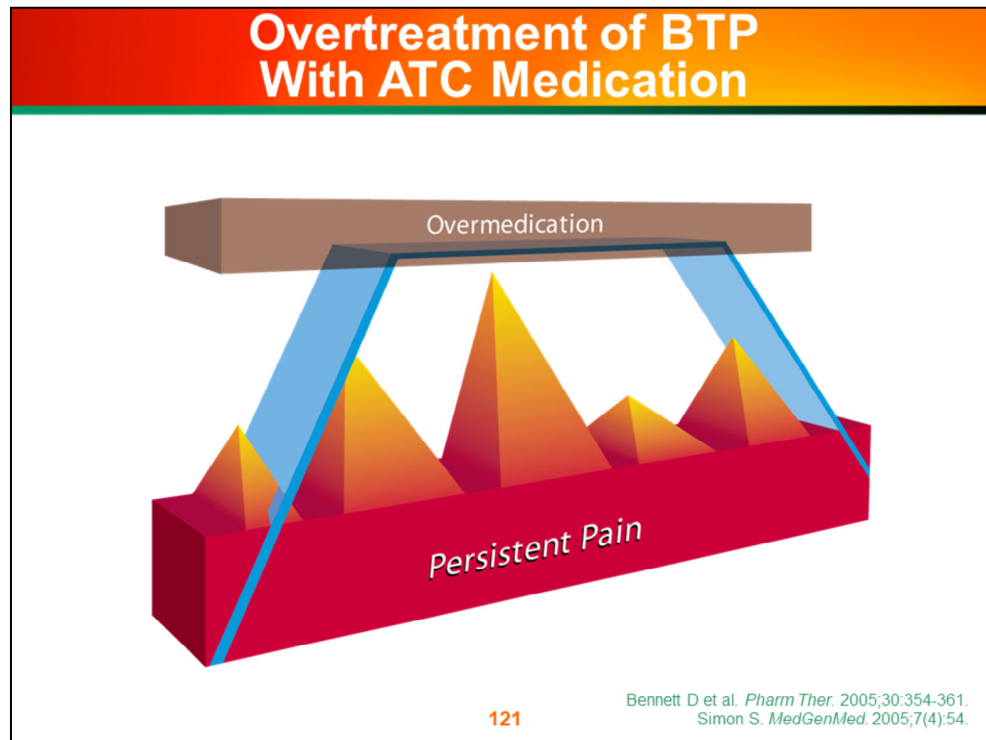


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# Campaign Evolution



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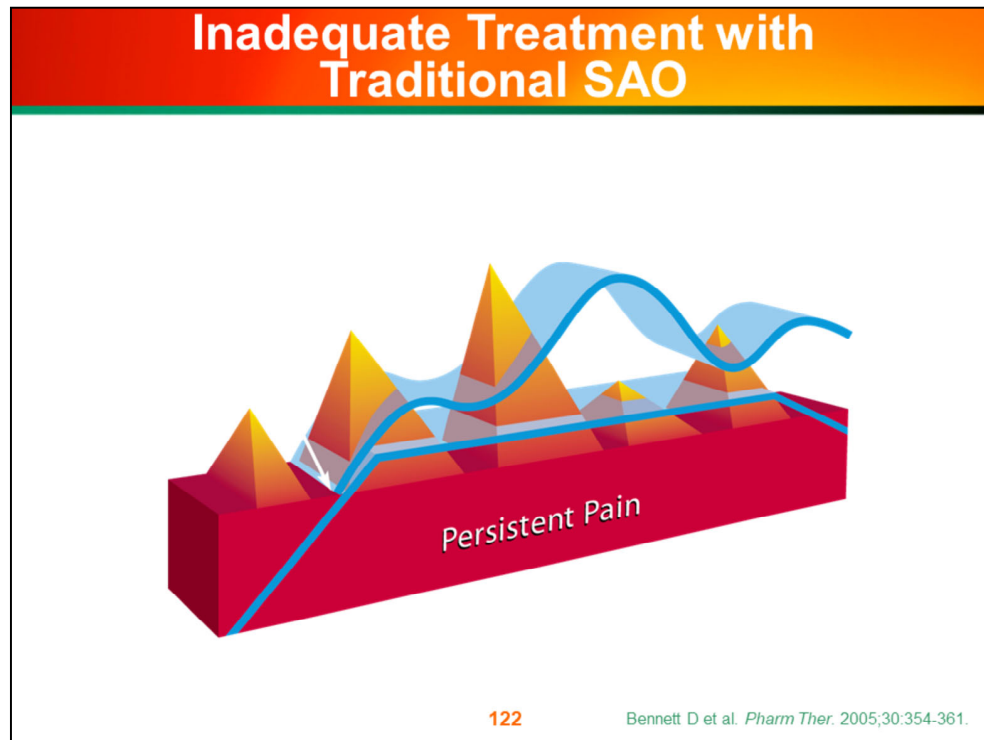


- A common approach to managing BTP is to increase the ATC medication to cover these episodes of BTP<sup>1,2</sup>
- However, if the ATC analgesic is raised high enough to cover the episodes of BTP, patients may become overmedicated and have increased likelihood of adverse effects<sup>2</sup>
- Patients typically report excessive sedation when overmedicated<sup>2</sup>
- By raising the ATC dosage excessively, the optimal balance between analgesia and adverse effects may be lost<sup>2</sup>

## References

1. Bennett D, Burton AW, Fishman S, et al. Consensus panel recommendations for the assessment and management of breakthrough pain. Part II—management. *Pharm Ther.* 2005;30:354-361. This article was supported by an educational grant from Cephalon, Inc. [p 356]
2. Simon S. Opioids and treatment of chronic pain: understanding pain patterns and the role for rapid-onset opioids. *MedGenMed.* 2005;7(4):54. Available at: [http://www.medscape.com/viewprogram/4756\\_pnt](http://www.medscape.com/viewprogram/4756_pnt). Accessed May 26, 2006. [p 2]

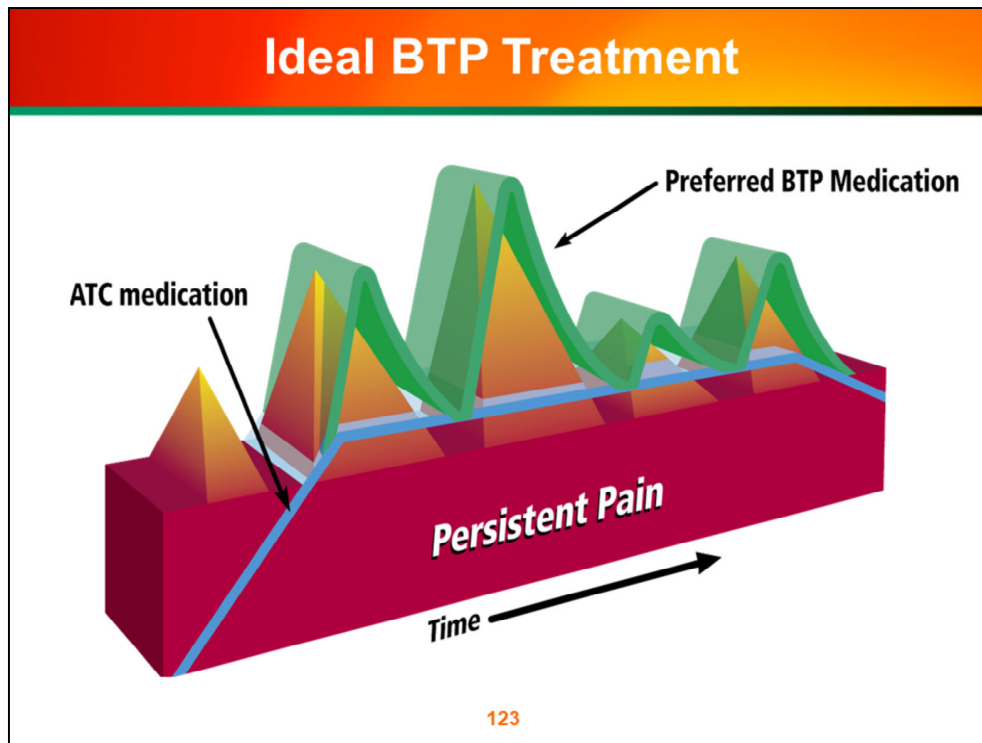




- To address the issue of overmedication, most dosing guidelines for cancer and noncancer pain recommend that whenever a longer-acting opioid is prescribed for chronic pain, a shorter-acting opioid should also be prescribed to treat episodes of BTP (ie, supplemental dose)<sup>1</sup>
- The goal for using a supplemental opioid dose to treat BTP is to provide rapid and effective pain relief without overmedicating the patient<sup>1,2</sup>
- The onset of effect with typical tablet and liquid-formulation hydrophilic opioids takes approximately 30–45 minutes; the onset of these medications may not match the rapid onset of a typical BTP episode<sup>1,2</sup>
- This results in a “pain gap,” which is the length of time between the occurrence of significant BTP and the time of meaningful pain relief<sup>1,2</sup>
- This time delay can be problematic for patients whose BTP reaches maximal intensity quickly<sup>1,2</sup>

### References

1. Bennett D, Burton AW, Fishman S, et al. Consensus panel recommendations for the assessment and management of breakthrough pain. Part II—management. *Pharm Ther.* 2005;30:354-361. This article was supported by an educational grant from Cephalon, Inc. [pp 356, 357]
2. Simon S. Opioids and treatment of chronic pain: understanding pain patterns and the role for rapid-onset opioids. *MedGenMed.* 2005;7(4):54. Available at: [http://www.medscape.com/viewprogram/4756\\_pnt](http://www.medscape.com/viewprogram/4756_pnt). Accessed May 26, 2006. [p 2]



The ideal pain medication would match the characteristics of BTP with rapid onset and a short duration. This would lead to fewer side effects for the patient because the phenomenon of overmedication would be unlikely to occur and it would not require the patient to “wait” for the medication.

## Tactical Plan

### BTP Campaign Evolution

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## Expanded BTP Disease Awareness Campaign

**Goal:** To continue to establish BTP as a distinct clinical problem & to facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP

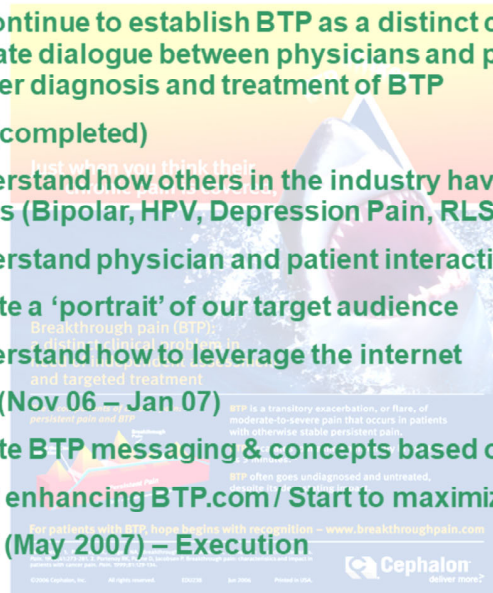
➤ **Phase I (completed)**

- Understand how others in the industry have built disease states (Bipolar, HPV, Depression Pain, RLS)
- Understand physician and patient interactions around BTP
- Create a 'portrait' of our target audience
- Understand how to leverage the internet and targeted treatment

➤ **Phase II (Nov 06 – Jan 07)**

- Create BTP messaging & concepts based on Ph I learnings
- Start enhancing BTP.com/ Start to maximize internet search

➤ **Phase III (May 2007) – Execution**



**Cephalon**  
deliver more.™

**FENTORA**  
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## 2007 Promotional Budget

Category	Spend	Share of Total Spend
Market Research	\$1,750,000	6%
Consultants	\$400,000	1%
Journal Reprints	\$200,000	1%
Conventions	\$1,600,000	6%
Advertising/Promotional Materials	\$8,900,000	32%
Sample Coupons	\$6,000,000	21%
Public Relations	\$600,000	2%
Field Driven Speaker Programs (CSPs)	\$6,000,000	21%
Advisory Boards	\$2,500,000	9%
Corporate Contributions	\$50,000	0%
<b>TOTAL SPEND</b>	<b>\$28,000,000</b>	<b>100%</b>

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## CSP Allocation

	Total	PCS	NAMS	OAS
CSP Budget Total	\$ 6,000,000			
CSP Budget (Minus Mgmt Fees)	\$ 4,500,000	\$ 4,000,000	\$ 300,000	\$ 200,000
Avg Cost per CSP	\$ 1,400	\$ 1,400	\$ 1,400	\$ 1,400
Total # of Programs per Year	3,214	2,857	214	143
# of Programs per Field Rep	45	29	11	5

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## FENTORA 2007 Tactical Plan

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# Tactics

The remainder of this deck describes the tactics planned to address the 2007 FENTORA CSFs and strategies. The tactics are organized within the following categories:

- FENTORA
- Dosing and Administration
- Managed Care
- Market Development
- Disease Awareness
- Conventions
- Advisory Boards
- Publications
- Promotional Education
- Public Relations
- Special Programs: SECURE (RiskMAP), Reimbursement Hotline, PAP

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# CSF and Strategy Coding

CSF	Strategy	CSF Number	Strategy letter
Majority of lives covered by Third Party Payers have access to reasonable/favorable reimbursement for FENTORA	• Selectively contract with MCOs	1	A
	• Educate MCOs regarding:	1	B
	• FENTORA value to health system	1	C
	• BTP: <ul style="list-style-type: none"> <li>– Optimal assessment and treatment of BTP</li> <li>– Establish the Burden of Illness of BTP</li> <li>– Further develop ROO sub-class as an optimal treatment for BTP</li> </ul>	1	D
	• Minimize risk of Abuse, Addiction, and Diversion	1	E
Expand FENTORA prescribing audience beyond ACTIQ users	• Further explore and maximize retail segment expansion opportunities	2	F
	• Explore non-retail segments opportunities, as well as other potential channels	2	G
	• Target segments and audiences with focused messages and programs/materials	2	H
Physicians understand FENTORA is a superior treatment option for BTP	• Create high level of awareness among target segments	3	I
	• Leverage new clinical data when available and appropriate		J
	• Further develop ROO sub-class as an optimal treatment for BTP		K
Measurable improvement of BTP awareness and understanding of treatment options among physicians and patients	• Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians	4	L
	• Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP	4	M
	• Support BTP educational initiatives	4	N

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## Coding (cont.)

CSF	Strategy	CSF Number	Strategy letter
Physicians and patients understand the proper dosing and administration of FENTORA	Educate physicians and patients on <ul style="list-style-type: none"> <li>How the delivery system is different from traditional oral administration</li> <li>Dosing and titration</li> <li>Administration</li> </ul>	5	O
	Educate HCPs on appropriate patient selection	6	P
	Educate patients about safe use of FENTORA and allay fears of opioids	6	Q
	Continue to implement risk minimization tools	6	R
FENTORA risks are understood by health care professionals	Maximize SECURE outreach program initiatives	6	S
	Partner with KOLs and key professional/advocacy societies to advance the field of pain management	7	T
	Elevate awareness of Cephalon dedication to advancing the science of pain therapy	7	U
	Expand Pain Franchise product offerings	7	V
Cephalon Pain Franchise is considered to be a leader in the pain market	Improve and expand select KOL and society relationships	8	W
	Continue to consult KOLs to better inform Cephalon on the optimal design of FENTORA clinical studies, as well as the positioning of the brand	8	X
Target KOLs and societies support FENTORA as an effective treatment option for BTP			

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
3039 Launch PCSF Selling Tools	Tactics updated to include 3039 data • Rev Enlarged PI • Core Sales Aid • File Card • Rev Regional TT Panels • Rev Local TT Panels • HCP FAQ • Product Monograph	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists	Field driven	Q2 - Q4	3	1
Launch Ads	4-page and 2-page launch ads updated to include 3039 data	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 - Q4	3	1
Online Advertising	• Banner advertising, primarily focused in rich media, will be aimed at driving site traffic; • Rich media advertising has the ability to deliver multimedia content including video, database registrations, and animated content in an expandable, near micro-site format	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3	1

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Targeted Media	PDR Pain Management Prescribing Guide PDR Addendum Direct Mail The Little Blue Book ePocrates - DocAlert Campaign Rep Triggered Mail MPR Prescribing Alert Physicians Weekly Triple I Prescription Pad Blitz Mailer Triple I Prescription Pads (or MediScripts) Medsite Catalina Newsletters NEJM Coverwrap Rx PROvisions Office Suite	Actiq and Non-Actiq Users Oncology Nurses Physical Medicine and Rehab Managed Care Executives	Non-field driven	Q2 - Q4	2 3 5	H I O
Launch Booth	Booth at major professional meeting to facilitate interaction with customers and provide information on FENTORA. Booth will be 40x40 and capable of breaking down into both 20x20 and 10x20	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 - Q4	3 4 5 6	I, J, K L, N O P, Q
Convention Media and Sponsorship Opportunities	Identify opportunities such as programs books, room drops, airport advertising, and association event sponsorships	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 7	I T

# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Convention Follow Up Letters	Letter thanking HCPs for visiting the booth to find out information about FENTORA. Letter will also include key selling messages	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q
Launch Mailers	Launch Letter and Direct Mail (4) updated to include 3039 data	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2	2 3 5	H I,J,K O
3-D Stereo or Animation	Video will communicate the key selling messages of FENTORA (ie, BTP, OV, Bio, PK, Efficacy, etc.) Video incorporated into the following: <ul style="list-style-type: none"> <li>- <b>Diamond Touch</b> - interactive game within launch booth</li> <li>- <b>Booth Handouts</b> - CD Rom and packaging</li> <li>- <b>Direct Mailer</b> - possibly included within one of the launch mail pieces</li> <li>- <b>Rep Deliverable</b></li> <li>- <b>Animation Clips</b> - incorporated onto the Website, patient video, booth panels</li> <li>- <b>Speaker Presentations</b></li> </ul>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 - Q4	2 3	H I,J,K

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Patient starter kit	Patient Starter Kit (English and Spanish) includes the following: <ul style="list-style-type: none"> <li>– Holder</li> <li>– Patient Video</li> <li>– Placebo Pack</li> <li>– Patient FAQ</li> <li>– Pain Diary with Calendar</li> <li>– Caregiver Brochure</li> <li>– Voucher</li> </ul>	Patients	Field driven	Q2 - Q4	2 3 4 5	H I M O
Rev WebSite	Phase II of FENTORA site, focused on Physicians and Patients, will round out content truncated for the early release of the drug and the accompanying web site.  <u>New content includes:</u> Physicians: <ul style="list-style-type: none"> <li>– Pain Identification Tool; OraVescent Technology, Thought Leadership section (KOL videos, Reference links and PDF Resources)</li> </ul> Patients: <ul style="list-style-type: none"> <li>– Pain Identification Tool; Living with Pain section (Coping Strategies, Talking with Your Doctor, Addiction concerns, Treatment options)</li> </ul>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q2 - Q4	2 3 4 5 6 7	H I L,M,N O PQ T
eNewsletters	<ul style="list-style-type: none"> <li>– 2 Quarterly newsletters will target Physicians and Patients;</li> <li>– Content will be generated by Palio, Blue Diesel, and Cephalon</li> <li>– Delivering timely product, disease and treatment information,</li> </ul> <p><i>Long-term Goal:</i> Leverage sales channel and trade shows to help increase registrations and participation</p>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 - Q4	2 3 4 5 6 7	H I L,M,N O PQ T

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Search Engine Marketing Management	Provides a tracking site as well as search parameters to help stay on top of search engine changes and competitive landscape as it relates to search criteria	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 - Q4	3	I
Online Usability Study	Usability study to focus on the areas of the site to which identified target markets navigate and reach primary, secondary & tertiary content; – Can be facilitated through 1:1 interviews and computer activities; – Integration of eye-tracking usability for visual and quantitative results	Actiq and Non-Actiq Users Physicians & Assistants Nurses Pharmacists KOLs Managed Care Executives Patients	Non-field driven	Q2	3	1
Actiq Users Switch Selling Tools for PCSF	Tactics updated to include 3039 data – AUS Sales Aid – AUS Cling Posters	Actiq Users	Field driven	Q2 - Q4	2 3 5	H I, J O
Actiq Users Direct Mail and Email	Tactics updated to include 3039 data – AUS Direct Mail (7) – AUS Launch Letter – AUS Email	Actiq Users	Non-field driven	Q2	2 3 5	H I O

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Key Pain Meetings via Webcast	Utilize web channel to deliver key meetings via webcast and downloadable podcasts. Can be used for Key meetings across the pain franchise where & when appropriate to primary audiences of HCPs and Patients	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field and Non-field driven	Q1 - Q4	2 3 4 5 6	H I L,M,N O PQ
Hospital Program	The first goal of the program would be to establish awareness of FENTORA via Grand Rounds or possibly Tumor Boards. Second goal would be to get FENTORA on the hospital formulary by providing pricing, packaging, and other formulary-related information. Once awareness and formulary are established, the reps can provide in-servicing by utilizing the detail aid, clinical reprints, leave behinds, table tops, etc.	Physicians Residents Fellows Nurses Patients	Field driven	Q3	2 3 4 5	H I,J,K L O
300 mcg materials	Various tactics regarding the launch of the 300-mcg tablet will be developed and implemented. Most sales materials will also be updated to include the 300-mcg dose	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q3	2 3 5	H I O
Revised Med Guide	Med Guide updated with new language and 300-mcg dose	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q2 - Q4	3 5	I O

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# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Revised PI	PI updated with new language and 300-mcg dose	Patients	Field driven	Q2 - Q4	3 4 5	I M O
Quarterly Case Studies	On-demand audio case studies. Physicians dial in once each quarter to hear new case study highlighting FENTORA	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists	Non-field driven	Q1 - Q4	2 3 5	H I O
Reprint Folders	Folders will be produced highlighting the key findings of the studies and also include a copy of the article	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 - Q4	3	I
Pharmacy Article	Article will be written about rapid onset opioids (ROOs) to educate pharmacists on how ROOs can be used to treat BTP. Article will run in key pharmacy journal	Pharmacists	Non-field driven	Q4	2 4	H N
Product Monograph	Monograph will help educate healthcare professionals on the use of FENTORA in the treatment of BTP in cancer; includes 3039 data	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q2 - Q4	3 5	I O

# FENTORA Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Cephalon Pain University.com	In conjunction with top pain specialists, Cephalon to create a virtual pain university that would conduct clinical studies, generate position papers, fund fellowships, as well as provide current product information/materials and promotional activity updates. Could include Speakers' Corner - a password protected resource for speakers only, driven by eVites, provides online registration for training. Activities could be carried out to create awareness for this initiative as well	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists KOLs Managed Care Executives	Non-field driven	Q3 - Q4	2 3 4 5 6	H I LN O P,Q

## Dosing and Administration Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Administration Poster	Wall poster includes the "peel it, place it, feel it" information/illustrations. Placed within the physician office to help educate patients on FENTORA administration	Actiq and Non-Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	O
Administration Wallet Card	Small card could be placed inside patients wallet or even pocket. Includes the "peel it, place it, feel it" information/illustrations. Can also include information on "what not to do." Could possibly be included as part of the Patient Starter Kit	Patients	Field driven	Q2 - Q4	5	O
Administration Magnet	Small magnet could be placed within the patient's home. Includes the peel it, place it, feel it information/illustrations. Could possibly be included as part of the Patient Starter Kit	Patients	Field driven	Q2 - Q4	5	O

# Dosing and Administration Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Administration Script for Cephalon Professional Services/Medical Information	Cephalon Professional Services and/or Medical Information could have a script available to help answer physician and patients questions/concerns with regard to the administration of FENTORA	Actiq and Non-Actiq Users Physician Assistants Nurses Patients	Non-field driven	Q2 - Q4	5	0
Revised Pain Diary	Current Pain Diary would be revised to help patients with the titration phase. This can then be used as a tool to help physicians with redosing	Actiq and Non-Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	0
Flip Chart	Incorporating the copy/tabs from the Patient FAQ, Flip Book will be developed so that physicians, nurses, and PAs can educate patients on FENTORA, including the titration and administration information	Actiq and Non-Actiq Users Physician Assistants Nurses Patients	Field driven	Q2 - Q4	5	0

## Dosing and Administration Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Catalina Newsletter	Newsletters could be created to focus on patient titration and administration	Patients	Non-field driven	Q2 - Q4	5	O
eDetail	Administration animation can be incorporated into the eDetails	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists	Field driven	Q2 - Q4	5	O
Podcast	Titration and administration information/animation could be downloaded as Podcasts	Actiq and Non-Actiq Users Physician Assistants Nurses Patients	Non-field driven	Q2 - Q4	5	O
Blackberry Download	Titration and administration information/animation could be downloaded within the booth	Actiq and Non-Actiq Users Physician Assistants Nurses	Non-field driven	Q2 - Q4	5	O

# Managed Care Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Office Manager Advisory Boards	Advisory boards with office staff to gain feedback and insights on education, specific training, and appropriate tools to reduce PA resubmission and rejection rates	Office-based administrators	Non-field driven	Q2	1	A
AMCP Booth	Booth at spring and fall AMCP meetings. Disseminate product literature and educational materials.		Nam driven	Q2 Q4	1	A
Office Manager Training	<p><b>Regional Office Manager PA Training:</b> Workshop training program with office staff in top 25 markets to facilitate PA compliance and reduce resubmission and rejection rates</p> <p><b>Local Office Manager Luncheon Programs:</b> Luncheon programs to provide education, training, and appropriate tools to facilitate PA compliance and reduce resubmission and rejection rates.</p> <p><b>Office Manager Training DVD and/or Booklet:</b> 30-minute interactive presentation for office managers who review the PA process, methods on facilitating reimbursement, and typical completion of required managed care forms</p> <p><b>Office Manager Online Training:</b> Online training reviews the PA process, methods on facilitating reimbursement, and typical completion of required managed care forms</p>	Office-based Administrators	Field Driven	Q1 - Q4	1	A
Educational materials	Provide both CME and Non-CME educational materials to facilitate enhanced understanding of BTP and its appropriate assessment and treatment	MCO staff	Non-field and NAM driven	Q1 - Q4	1	A

# Managed Care Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
NAM Slide Kit	Provide NAMs with 3039 supplemental slides	P&T Committee Members	NAM driven	Q1	1	A
Formulary Kit	Updated to include all new data, new concepts and messages.	P&T Committee Members	NAM driven	Q1 - Q4	1	A
Key Reprints	Once studies are published, clinical reprint carriers will be produced and distributed to the NAMs	P&T Committee Members	NAM driven	Q1 - Q4	1	A

# Market Development Market Research

Research	Description	Target Audience	Implementation	Timing	CSF	Strategy
Rep Advisory Board	Brand Team, PCSF, and Agency can all meet at the National Sales Meeting to discuss what issues they are encountering, what's working/what's not, what materials they need, how the messages are working, etc.	Actiq and Non-Actiq Users	Field driven	Q1	2	F
Segmentation Study	Segmentation research with physicians to determine attitudinal, emotional, etc. reactions to FENTORA	Non-Actiq Users	Non-field driven	Q1	2	F
Path to Rx	Research to identify the dynamics and flow of the path to Rx. Target each area to identify points of entry: barriers, triggers, and leverage points	Actiq and Non-Actiq Users	Non-field driven	Q1	2	F
Message Refinement Research	Based on feedback from the rep ad board and path to Rx research, messages can be revised and tested with multiple segments	Actiq and Non-Actiq Users	Non-field driven	Q1	2	F

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# Market Development Market Research

Research	Description	Target Audience	Implementation	Timing	CSF	Strategy
Hospital Landscape Study	Determine points of use, attitudes, how FENTORA would fit within the hospital system, etc.	Non-field driven	Non-field driven	Q1	2	G
Consumer Identification and Connection	Includes the following Client and Agency development: – Brand Revolution Research – Target Delineation Research – Heart and Soul Research – Media Usage Analysis – Target Portraiture	Non-high prescribers, determined based on research results	Non-field driven	Q1	2	G
Brand Insight Synopsis	Includes a Brandscape Summary - Compilation of all the primary research that helps frame the forthcoming Positioning and Vision Development.	N/A	Non-field driven	Q1	2	G
Communication Strategy Development	Includes the following Client and Agency development: – Illumination Brief Development – Illumination Brief Client Review/Approval	N/A	Non-field driven	Q1	2	G

# Market Development Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Sales Training Materials	Based on findings from the path to Rx research and message refinement research, training tools for the PCSF will be developed. Tools will help educate them on the customer portrait matrix, ie, what multiple physician segments feel and what motivates them. Examples of materials might include specialty reference sheet and targeted messages by segment	Pain Care Sales Force	Non-field driven	Q2	2	F
Communication Platform and Tactical Plan Development	Includes Brand Arc Development - The Brand Arc bridges the gap between the current and desired mindsets, outlining realistic interim target mindsets necessary to reach the end goal. Also, new tactics will be incorporated into the master tactical plan	Determined based on research results	Non-field driven	Q2	2	G

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# Disease Awareness Education

Education	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Physician Materials	<p>Take findings from Futurescape and Brand Revolution Research to broaden reach to physicians. Once research is complete and targets have been identified, various types of materials can be implemented, such as the following:</p> <ul style="list-style-type: none"> <li>– Journal Ad</li> <li>– BTP Treatment Differentiator Flashcard</li> <li>– Differential Diagnosis: Identifying BTP Case Study</li> <li>– DM Wave 1: BTP Pamphlet and Holder</li> <li>– DM Wave 2: BTP Poster</li> <li>– DM Wave 3: BTP Assessment Sheet</li> <li>– Best Practices Meeting and Enduring Materials</li> <li>– Advertorial Series</li> <li>– Letters to the Editor Series</li> </ul> <p>Determine how all tactics translate to online activities</p>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q3 - Q4	4	L,M
Targeted Media	<p>ePocrates - DocAlert Campaign</p> <p>IMNG KOL Series</p> <p>The Patient Counselor</p> <p>WebMD Booklets</p> <p>Catalina Newsletters</p>	Actiq and Non-Actiq Users Oncology Nurses Physical Medicine and Rehab Managed Care Executives Patients	Non-field driven	Q3 - Q4	4	L,M

# Disease Awareness Education

Education	Description	Target Audience	Implementation	Timing	CSF	Strategy
Revised www.BTP.com	<p>Phase II of BreakthroughPain.com site, focused on Physicians and Patients, to expand the initial HCP-only focused site currently live. Site will be focus on 1 destination, with a specialized section for HCP content offerings.</p> <p><b>New content includes:</b></p> <p><b>Physicians:</b></p> <ul style="list-style-type: none"> <li>– Pain Identification Tool: Thought Leadership section (KOL videos, Reference links and PDF Resources); keyword-rich content development</li> </ul> <p><b>Patients:</b></p> <ul style="list-style-type: none"> <li>– Pain Identification Tool; Living with Pain section (Coping Strategies, Talking with Your Doctor, Addiction concerns, Treatment options); Education for Pain and Breakthrough Pain, Conditions affected by BTP, viewing/ordering The Path of Pain DVD; keyword-rich content development</li> </ul>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q3 - Q4	4	L,M
Online Usability Study	<p>Usability study to focus on the areas of the site to which identified target markets navigate and reach primary, secondary &amp; tertiary content;</p> <ul style="list-style-type: none"> <li>– Can be facilitated through 1:1 interviews and computer activities;</li> <li>– Integration of eye-tracking usability for visual and quantitative results</li> </ul>	Actiq and Non-Actiq Users Physicians & Assistants Nurses Pharmacists KOLs Managed Care Executives Patients	Non-field driven	Q2	4	N

# Disease Awareness Education

Education	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Content Feeding	<ul style="list-style-type: none"> <li>Focus on identifying those sites and potential partners willing to accept content generated through a PR development effort;</li> <li>Sites will be categorized by those requiring internal support for content inclusion, those accepting of automated syndication feeds, and those which can be updated by the PR team;</li> <li>Maintenance will continue through 2007 to continue to generate and feed content to the identified sites, along with any new entities deemed as worthy sources of pain information</li> </ul>	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1	4	L
Online Advertising	<ul style="list-style-type: none"> <li>Banner advertising, primarily focused in rich media, will be aimed at driving site traffic;</li> <li>Rich media advertising has the ability to deliver multimedia content including video, database registrations, and animated content in an expandable, near micro-site format</li> </ul>	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 - Q4	4	L
Online Viral Campaign	Implement an advertorial/sweepstakes/campaign or some other form of engaging, HCP-focused material that is compelling enough that users/viewers are included to forward on to colleagues; Material will help drive users back to the websites and create "buzz" about topic of BTP and FENTORA	Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives Patients	Non-field driven	Q1 - Q4	4	L,M

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# Disease Awareness Education

Education	Description	Target Audience	Implementation	Timing	CSF	Strategy
3rd Screen Downloadable Application	Includes information on BTP, as well as pain identification tool	Actiq and Non-Actiq Users Physician Assistants Nurses	Non-field driven	Q1 - Q4	4	L
Direct to Patient via Physician  Pain Care Centers of Excellence Program	<p>Pilot program with the top 25 PCCE to help educate healthcare professionals, patients, caregivers, and their families on BTP. Program components could include the following:</p> <p><b>Pain Day Patient Seminar/Community Outreach</b></p> <ul style="list-style-type: none"> <li>– Posters</li> <li>– Slides</li> <li>– Handout materials</li> <li>– Testimonials</li> </ul> <p><b>In Office Informational Center</b></p> <ul style="list-style-type: none"> <li>– Holder with pain related pamphlets</li> <li>– "How to Talk to Your doctor about Pain" brochure</li> </ul> <p><b>Reach a Patient Counseling Tools</b></p> <ul style="list-style-type: none"> <li>– Flipbooks</li> <li>– Path of Pain acetate tool</li> <li>– Take-home brochures</li> <li>– Acetate education tool</li> <li>– Patient Video</li> <li>– Video Take Away Brochure</li> </ul> <p>Tactics will be coordinated with PR efforts as well</p>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Patients	Non-field driven	Q3 - Q4	4	M

# Disease Awareness Education

Education	Description	Target Audience	Implementation	Timing	CSF	Strategy
Direct to Patient via Physician	Take findings from Futurescape and Brand Revolution Research to broaden reach to patients. Once research is complete and targets have been identified, various types of materials can be implemented, such as the following: <ul style="list-style-type: none"> <li>– KOL Advisory Board Slide Deck: Improved Dialogue between physicians and patients</li> <li>– Physician and Patient Speaker Program: Gain feedback from patients on improved Dialogue</li> </ul>	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Patients	Non-field driven	Q3 - Q4	4	M
Direct to Patient Journal Ad	Journal Ads in Publications (ie, Coping and Cure) Tactics will be coordinated with PR efforts as well	Patients	Non-field driven	Q3 - Q4	4	M

# Convention Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Convention Media and Sponsorship Opportunities	Identify opportunities such as programs books, room drops, airport advertising, and association event sponsorships	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 7	I T
FENTORA Booth	Booth at major professional meeting to facilitate interaction with customers and provide information on FENTORA. Booth will be 40x40 and capable of breaking down into both 20x20 and 10x20	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q
Convention Follow Up Letters	Letter thanking HCPs for visiting the booth to find out information about FENTORA. Letter will also include key selling messages	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 4 5 6	I,J,K L,N O P,Q



# Advisory Boards

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Consultant Meetings	Consultant Meetings: – 4 regional meetings – Including topics related to BTP, FENTORA – Segmented by behavior and geography – 50 MDs/meeting – 200 MDs total	Opioid prescribers KOLs	Non-field driven		8	X
Health Care Professionals Advisory Board	PR will coordinate 2-day meeting – in collaboration with the Marketing team – of the Health Care Professional Advisory Board; agenda to include topics such as BTP awareness campaign, product-related education activities, clinical developments, etc. Board will be consulted for expertise in patient communication.	Actiq and Non Actiq Users Physician Assistants Nurses	Non-field Driven	2Q - 4Q	6 7	Q T,U

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# Publication Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Journal Articles	Top priority manuscripts for key clinical data: 3042, 3041, 3039, 99-16, 1037	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	1 3 4	A I,J,K L
Journal Articles	Second wave manuscripts of clinical data: 99-11/99-18, 99-15, 1043, 3040, 3052, 1046, 3054, 3055, 3056	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	1 3 4	A I,J,K L
Other manuscripts	Additional manuscripts to support education efforts: •Statistical support paper •Expert Opinion in Investigational Drugs •ADIS Drugs Profile •FBT Drugs of Today Monograph •Patient/Physician Attitudes research •Case Histories	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	1 3 4	A I,J,K L
Abstracts	Abstracts of clinical data at congresses: 3040,3041,30,42	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	3 4	I,J,K L

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# Promotional Education Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Promotional CSPs	Field-Driven Medical Education Programs (CSPs)	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Hospitalists	Field driven	1Q - 4Q	3  5  6	I,J,K  O  P,Q
Promotional Programs Speaker Training	National Speaker Training with online follow-up	Actiq and Non-Actiq Users	Non-field driven	1Q	3  5  6	I,J,K  O  P,Q

# Non-Promotional Education Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Independent Medical Education-CME (see SciCom Medical Education Plan)	Examples of potential medical education initiatives: <ul style="list-style-type: none"> <li>– Live events: Satellite Symposium, Teleconferences, regional meetings</li> <li>– Print and Enduring Materials, i.e., Monographs, special reports</li> <li>– WEB based initiatives, i.e., Medscape, Pain.com</li> </ul>	Opioid Prescribers Physician Assistants Nurses Residents Hospital MDs Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	4	L,M,N
Emerging Solutions in Pain (see SciCom Medical Education Plan)	Examples of potential medical education initiatives: <ul style="list-style-type: none"> <li>–2006 Monograph collection</li> <li>–Monograph series with PPM</li> <li>–Expert Commentary</li> <li>–“In the know” abstract summaries</li> <li>–Ask the Expert</li> <li>–State Your Case</li> <li>–Pain and Addiction 101</li> <li>–Urine Drug Testing Tool</li> <li>–E-Journal Club</li> <li>–Live symposium (TBD)</li> <li>–Convention presence (booth)</li> <li>–Scholarship Fund</li> </ul>	Opioid Prescribers Physician Assistants Nurses Pharmacists Managed Care Executives	Non-field driven	Q1 - Q4	4	L,M,N

# Public Relations Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
BTP Awareness Campaign: Local Events	Roll out local campaign in three cities; selection based on presence of top 25 pain center, medical meeting, and/or other national/regional/local venue highlighting health issues. Elements may include:  Traveling exhibit/booth with computer kiosks linking to BTP site, self-assessment tools; appropriate giveaways Local panel discussions for patients with chronic pain led by pain expert, patient, etc.; Use of media and local celeb to promote activities, BTP as a health topic. Utilize existing website to raise awareness of events, and help develop appropriate content such as patient case studies, Ask-the-Expert section, articles by health care professionals (4) on BTP and help with repurposing videos into video vignettes for site. Develop patient BTP materials (to include brochure, fact sheet, identity materials, logo and stationary suite).	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q - 4Q	3	I,J,K
Third-Party Relationships: Organizations	Identify opportunities to maintain and extend relationships with third-party organizations; host event for patient advocates at the American Pain Society to highlight data presentations (Advocacy Group Clinical Update)	Patients with Chronic Pain Who Experience BTP Patient Advocate Groups	Non-field Driven	1Q - 4Q	6 7	Q T
Third-Party Relationships: Bylined articles and Educational Materials	Work with selected HCPAB members to develop content on BTP for newsletters and online outreach.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q - 4Q	3 6 7	I,J,K Q T

# Public Relations Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Media Relations: Abstract/Posters and Journal Articles	Work with investigator/author(s) and clinical to develop key messages. Coordinate media training when necessary; develop media materials, conduct media outreach.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q - 4Q	3 6 7	I, J, K Q T, U
Media Relations: Publicize sNDAs and Regulatory Milestones	Identify FENTORA investigators and patients, develop media materials including media alerts or press releases and fact sheets. Conduct outreach with key media outlets to publicize milestones.	Patients with Chronic Pain Who Experience BTP General Public FENTORA, Actiq and Non Actiq Users Physician Assistants Nurses Pharmacists	Non-field Driven	1Q - 4Q	3 6 7	I, J, K Q T
Issues Management: Media Monitoring	Incident-related media monitoring of FENTORA and OTFC-related stories including monitoring and coverage reports.	Internal	Non-field Driven	Q107- Q407		
Issues Management: Letters to the Editor	Draft media letters to the editors related to inaccurate coverage of FENTORA or BTP. Includes identification of appropriate KOL or internal spokesperson (if appropriate).	Patients with Chronic Pain Who Experience BTP Patient Advocates FENTORA, Actiq and Non Actiq Users	Non-field Driven	Q107- Q407		
Issues Management: Proactive Preparation	Prepare company spokespersons on intermittent basis and identify outside experts as needed. Help to develop or edit issues management materials containing key messages related to abuse, diversion, cost, and supply issues.	Internal	Non-field Driven	Q107- Q407		

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# RiskMAP Tactics

Tactic	Description	Target Audience	Implementation	Timing	CSF	Strategy
Lunch and Learn	PCSF can utilize a turn key kit that incorporates some of the RiskMAP tools as well as includes table top panels on the RiskMAP only	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Hospitalists	Field driven	Q1	6	R
RiskMAP Tools	Continue usage of all tactics within the RiskMAP plan (ie, patient FAQ, PharmAlert, RiskMAP flashcard, etc.)	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Patients	Field driven	Q1 - Q4	6	R
SECURE Program	Brand the SECURE program with logo, colors, etc. and roll out into the following: – RiskMAP flashcard – Web page – eNewsletter – Other sales and booth tactics where appropriate	Actiq and Non-Actiq Users Physician Assistants Nurses Pharmacists Patients	Field driven	Q2 - Q4	6	S

## Appendix

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

## Appendix A

### Publications Plan

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## FENTORA™ Publication Plan\*

-  Final data tables available
-  Abstract submission (1 primary, 2 secondary endpoints)
-  Congress presentation
-  Manuscript submission
-  Journal publication

\*To be approved and signed-off by core team December 15, 2006

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# FENTORA™ Publication Plan Overview (1)

Study	2006		2007				2008			
	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
1027 PK	M									
1028 PK		M								
3042 Low Back	○ A <sub>1</sub>	A <sub>1</sub> A <sub>2</sub> M M								
3041 NeP	○	A <sub>1</sub> A <sub>2</sub> M								
3040 Interim		○ A <sub>1</sub> A <sub>2</sub> A <sub>3</sub>								
3040/41/42 Pt Pref		○ A								
3041/42 Comb efficacy		○ A								
3041 vs 42 Efficacy		○ A								
3041/42 ATC corr		○ A								
3039 Ca Pain		○	A M							

## FENTORA™ Publication Plan Overview (2)

	2006		2007				2008			
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
3039/99-14 NeP		○	A	M						
3039/99-14 ATC corr		○	A							
3039/99-14 Dose convers		○	A							
3039/99-14 Comb efficacy		○	A							
Drugs of Today Review			M							
99-11/ 99-18 Dwell time			M							
99-15 Ca OL safety			○ A	M						
Ca PK Model			○	A M						
NonCa PK Model			○	A M						
99-16 Mucositis			A M							
Dosing review: all studies			○	A M						

## FENTORA™ Publication Plan Overview (3)

	2006		2007				2008			
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Ca/NonCa FBT comparison			●	A	M					
Safety review: All studies			●	A	M					
1043 Bucc vs subl				●	A M					
Mkt Res Physicians				M						
Mkt Res Nurses				M						
99-19 Jpn PK				M						
99-20 Jpn PK				M						
99-21 Jpn PK				M						
PK review: All studies					M					
BTP awareness review					M					

## FENTORA™ Publication Plan Overview (4)

	2006		2007				2008			
Study	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
BTP definition review					M					
Evolution of Tx review					M					
3054 Pain & Anxiety						A M				
BTP spectrum review						M				
BTP Tx review						M				
1046 Relative potency						A	M			
3040 Final data						A <sub>1</sub>	A <sub>2</sub> M <sub>1</sub>	M <sub>2</sub>		
3052 Pivotal NonCa						A <sub>1</sub> M <sub>1</sub>	A <sub>2</sub>	M <sub>2</sub>		
PK Model All pts							A	M		
3055 vs oxycodone								A	M	
3056 vs oxycodone										A

## **FENTORA™ 2007-2008 Congress Plan**

<b>Congress</b>	<b>Proposed Abstracts</b>
ONS April 2007	3039/99-14/ Lack of ATC/rescue dose correlation 3039/99-14 Dose conversion from ACTIQ to FENTORA 3039/99-14 Combined efficacy and safety
AAN April 2007	3041 Secondary efficacy measures
APS May 2007	3041/3042 Side by side efficacy 3041/3042 Combined efficacy 3040/3041/3042 Patient preference 3041/3042 Lack of ATC/rescue dose correlation 3040 Mood, functioning, and QOL 3040 Patient preference
ASCO June 2007	3039 Primary efficacy and safety 3039/99-14 Efficacy and safety in neuropathic pain patients 99-15 OL safety (late breaker) 99-16 Mucositis

## **FENTORA™ 2007-2008 Congress Plan**

<b>Congress</b>	<b>Proposed Abstracts</b>
NeuPSig June 2007	3041 Primary efficacy and safety
AAPMt September 2007	Cancer PK Model (or ASA) Noncancer PK Model (or ASA) 3041 Secondary efficacy measures (encore) 3041/3042 Side by side efficacy (encore) 3041/3042 Combined efficacy (encore) 3040/3041/3042 Patient preference (encore) 3041/3042 Lack of ATC/rescue dose correlation (encore)
AAPMR October 2007	3042 Secondary efficacy measures (rejected by AAPM) 3040 Interim safety and efficacy (rejected by AAPM) 3040 Mood, functioning, and QOL (encore) 3040 Patient preference (encore)
ASA October 2007	1043 Buccal vs. sublingual All studies – Dosing



## **FENTORA™ 2007-2008 Congress Plan**

Congress	Proposed Abstracts
Dworkin Neuropathic Pain Mtg November 2007	3041 CPRA analysis
AAPM/APS 2008	3040 16 month analysis 3052 Primary safety and efficacy
IASP 2008	PK Model all patients 1046 IV potency 3052 Secondary efficacy measures 3040 Final safety and efficacy 3054 Primary safety and efficacy Safety analysis all patients

## Appendix B

### Public Relations Plan

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## Cephalon Pain Franchise 2007 Public Relation Plan



Thursday, November 16, 2006


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## Key Audiences



**T**hird-party groups - patient support and advocacy



**K**OLs/Clinicians - professional societies, pain specialists, PCPs (high opioid prescribers), oncologists



**CHRONIC PAIN PATIENTS AND CAREGIVERS**

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## CSF: Improve BTP Awareness

### Strategy:

- Launch national *non*-branded DTP education campaign

### Tactics:

- National media launch
- Multiple city tour
- Traveling exhibit/booth
- Local events
- Breakthroughpain.com content

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## Tactic

- **Roll out activities targeting chronic pain patients through multiple city tour in:**

- Cities with identified top 25 pain center
- Cities where pain meeting will occur (e.g., APS in Washington, DC, ASPMN in Dallas)
- Other national, regional and local venues
- Venues such as:
  - AARP Life @ 50+
  - NBC Health Fairs
  - Regional patient group meetings such as Cure Patient Survivor Forums (4 per year)
  - September Pain Awareness events at local pain clinics
  - Support group meeting at NCI designated cancer centers
  - YMCAs and senior living facilities, NCOA chapters

- **Venues feature:**

- Traveling exhibit/booth
- Local events
- Publicity activities

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- Other Venues such as: AARP Life @ 50+ Event, NBC Health Fairs, regional patient group meetings such as Cure Patient Survivor Forums (4 per year), September Pain Awareness events at local pain clinics, support group meeting at NCI designated cancer centers, YMCAs and senior living facilities, NCOA chapters

## Tactic

- **Campaign components can be extensive\* or discreet**

- **Traveling exhibit/booth**

- Guest appearance by local celebrity\* and *FENTORA* patient
    - Scheduled presentation by HCP\*
    - Self-assessment questionnaire about chronic pain and BTP available at computer kiosk or hard copy
    - Staffed exhibit (staffing TBD)
    - Computer kiosk stations featuring BreakthroughPain.com
    - Giveaways such as on-site massages, premiums (i.e. stress balls), educational materials/brochures



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## Tactic

- **Local events**

- Panel discussion with Health Care Professional Advisory Board (HCPAB) member or local pain expert, BTP patient, local celebrity, patient support group representative
- Open to patients/families and local community (anticipated attendance 20-50)
- Feature booth (contingent on budget/space)



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## Tactic

- **Promote campaign in each city featuring celebrity/athlete, pain expert and *FENTORA* patient**
  - Conduct media outreach (TV & radio-news/talk shows, lifestyle & health reporters)
  - Coordinate mailings, flyers, print and radio ads
  - Partner with local third-party group
  - Publicize through third-party group newsletters, e-mail distribution lists
  - Revise *Do You Still Have Pain?* brochure; insert in local newspapers

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- Other Venues such as: AARP Life @ 50+ Event, NBC Health Fairs, regional patient group meetings such as Cure Patient Survivor Forums (4 per year), September Pain Awareness events at local pain clinics, support group meeting at NCI designated cancer centers, YMCAs and senior living facilities, NCOA chapters

## Tactic

- **Contribute to content for BreakthroughPain.com**
  - Online feature encouraging patients to share their BTP story
  - Promote via:
    - MAT feature article -- distributed to local newspapers and handouts to clinic/practice waiting rooms
    - Links from third-party pain group websites and banner ads
  - Include campaign information: city exhibit and event schedule, BTP patient case studies
  - Ask-the-Expert section
  - Utilize compelling stories for various national and grassroots outreach opportunities:
    - Media
    - Speaking events
    - Feature stories on third-party websites and in newsletters
    - Video vignettes posted on BreakthroughPain.com

***All activities could be source for patient database building***

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- Encourage patients to submit their story online about their journey through BTP in hopes that their stories may help others
- Patients fill in required contact information as provide their story
- Contact information is automatically entered into a database for follow up

## CSF: Improve BTP Awareness

### Strategy:

- Strengthen third-party and KOL relationships

### Tactics:

- Host third-party event at American Pain Society Annual Meeting
- Outreach to third-party and professional organizations
- Conduct Health Care Professional Advisory Board

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## Tactic

- **Host Third-Party Event at American Pain Society Annual Meeting**
  - **Advocacy Group Clinical Update**
    - Provide update on non-cancer trials data, response to *FENTORA* adoption; (Speaker TBD: Cephalon Clinical)
    - Educate about differences between rapid onset and short-acting treatments



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## Ad Board

- **Conduct Health Care Professional Advisory Board**

- Provide update on non-cancer data, response to *FENTORA* adoption
- Conduct media training for participants
- Build agenda collaboratively with Marketing
- Hold focus group for marketing topic TBD
- Host as 2-day meeting



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## Tactic

- **Outreach to Third-Party and Professional Organizations:**

- Support Media Telebriefing at AAPM meeting on “BTP Treatment Developments” (including *FENTORA*)
- Sponsor live web chat or teleconference about BTP with BTP patient and HCP
  - Potential partners: APF, CancerCare, PLWC
- Create feature/filler content on BTP for content for third-party websites and newsletters
  - Work with HCPAB to develop content (i.e., “BTP new treatment options”)
- Conduct a sweep of existing Internet content, especially third-party pain group websites, encourage updates to include *FENTORA* and BTP information

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## Tactic

- **Outreach to Third-Party and Professional Organizations:**

- Corporate contributions and grants
  - Maintain collaboration with and support for third-parties, including:
    - AACPI conference support
    - ACPA corporate contribution
    - APF corporate roundtable
    - CancerCare industry dinner
    - NCCS Tribute to ASCO President
    - NPF Triumph Dinner
    - OncoLink website development
  - Identify additional opportunities for interaction and other groups



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## CSF: Continue to differentiate *FENTORA*

### Strategy:

- Raise awareness of science and data of *FENTORA*

### Tactics:

- Data publicity and milestones
- HCP activities

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## Tactics

- **Publicize data:**

- Posters/abstracts presented at medical meetings



- Journal articles
- Emphasize unique features:
  - Rapid and efficient absorption
  - Faster onset
  - Convenience
  - QOL
  - Functionality
  - Preference
- Work with authors/investigators



- **Publicize sNDAs and Regulatory Milestones**

## Tactic

- **Work with HCPAB member to increase HCPs understanding of mechanism of action and unique features of *FENTORA***
  - Encourage development of *FENTORA* “Fast Facts” (by The University of Wisconsin) and EPERC (End of Life/Palliative Education Resource Center)
    - Proactively encourage similar adoption by other HCPAB members’ organizations/institutions
  - Work with HCPAB members on ad hoc basis to deliver consistent and uniform messages on BTP and *FENTORA*
  - Invite select HCPAB members to join Cephalon’s Speaker Bureau

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**CSF: Maintain clear and consistent communication  
about FENTORA risks**

**Strategy:**

- Anticipate and prepare messages around potential issues

**Tactics: Internal and external**

- Prepare company spokespersons
- Maintain issues management materials
- Monitor media environment

## Tactics

- Prepare company spokespersons on intermittent basis and identify outside experts and groups to enlist, as needed
- Maintain issues management materials containing key messages (i.e., abuse/misuse, diversion, cost, unintended exposure, supply issues)
- Monitor media environment
- Interact with media and submit letters-to-the editor, addressing/correcting serious inaccuracies



# **Appendix C**

## Medical Education Plan

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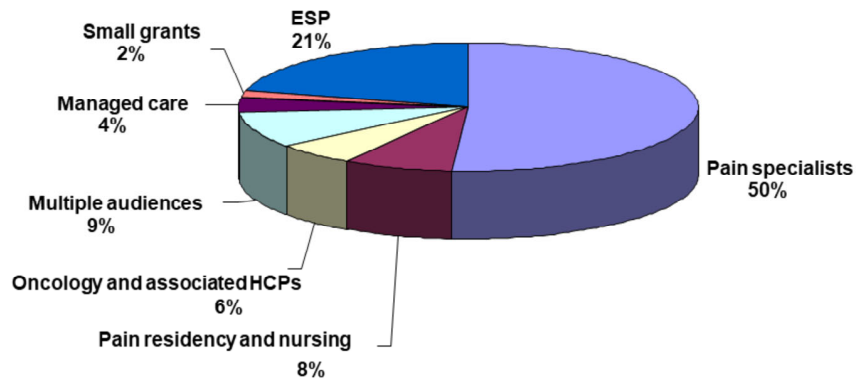
# **Pain Medical Education Tactical Plan 2007**

Bhaval Shah Bell PhD  
Senior Manager, Medical Education



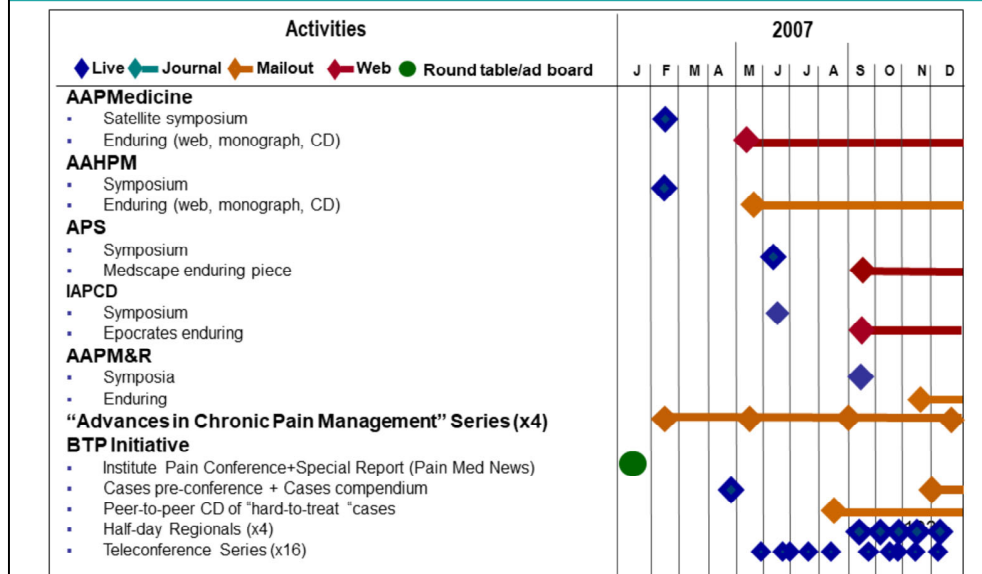
191

## Budget Spend by Audience



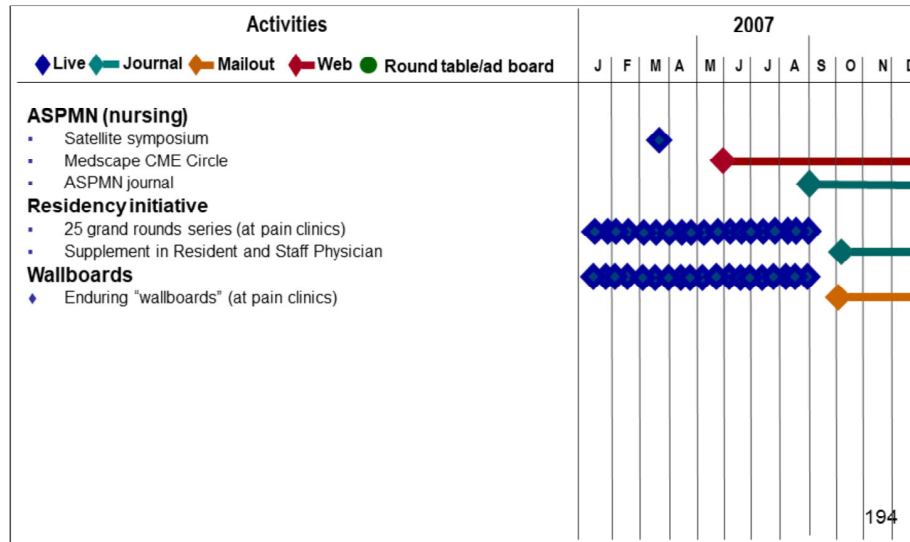
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# Pain Specialists

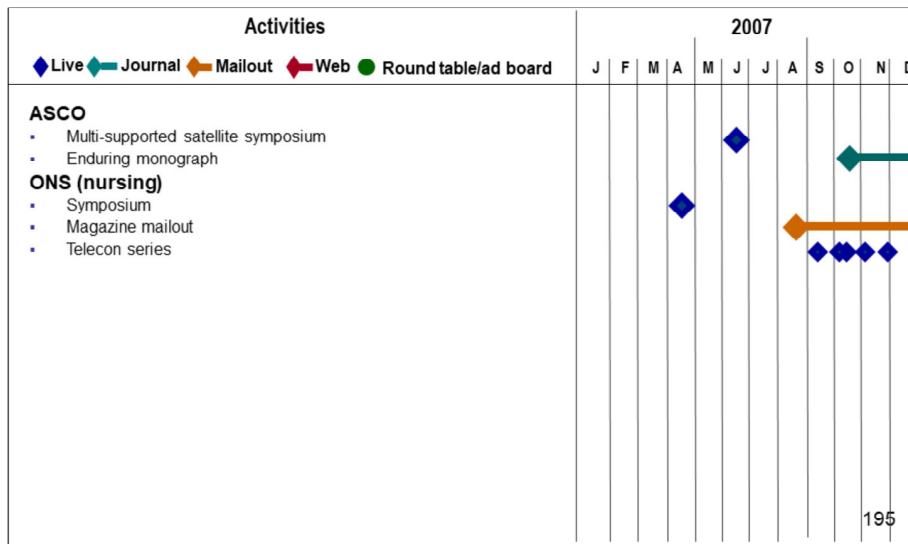




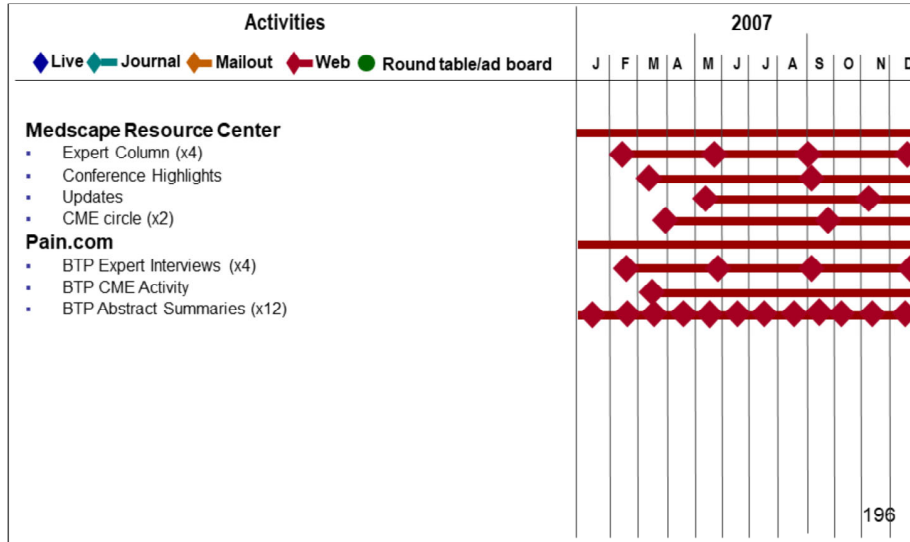
# Pain RNs, NPs, Residency



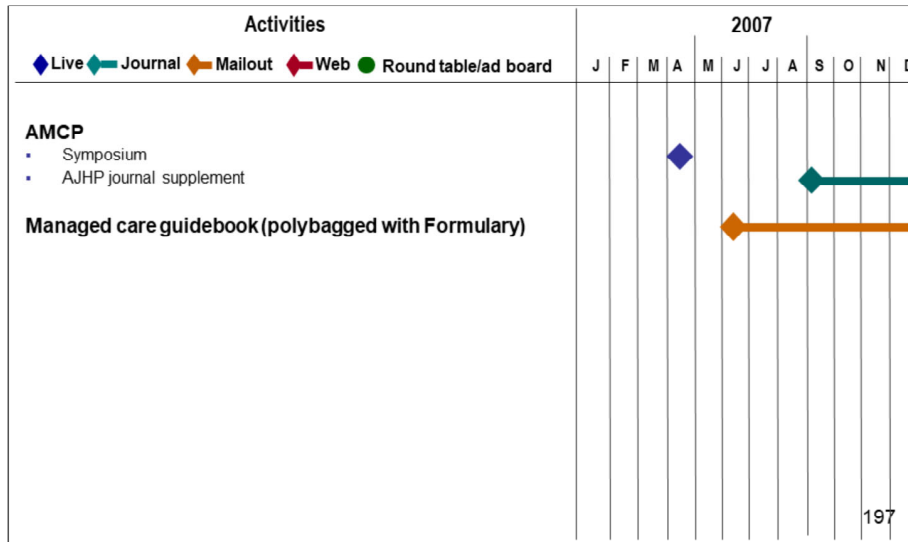
# Oncologists, Onc RNs, NPs



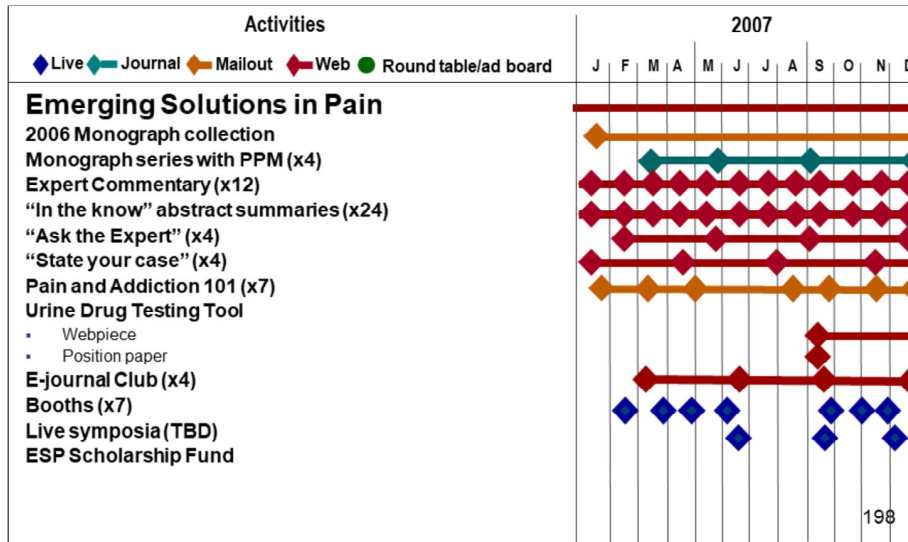
# Multiple Audiences



# Managed Care



# Emerging Solutions in Pain



**File Provided Natively**