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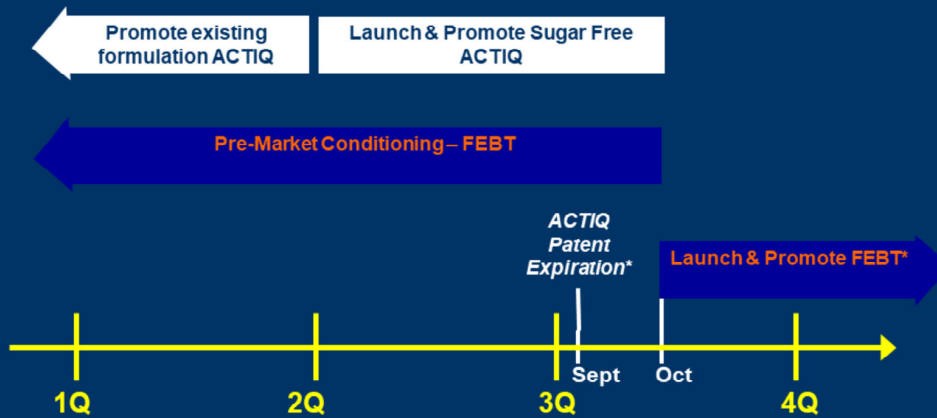
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ACTIQ®
2006 Marketing Plan

Outline

1. Major Assumptions
2. Situation Analysis
3. Product Overview (SWOT, positioning, messaging)
4. Key Marketing Issues & Strategies
5. Critical Success Factors
4. Objectives
5. Tactics

Pain Franchise Assumptions



Notes

- Sales Force related expenses will transition from ACTIQ to FEBT at launch
- Assumes no pediatric extension for ACTIQ

ACTIQ Major Assumptions

- Patent expiration September 2006; no pediatric exclusivity granted
- Launch date for SF is April 3, 2006
- Complete switch to new formulation April 3
- No trade name change for SF formulation
- Regulatory requires major changes to selling materials for SF; significant costs incurred for transition
- Cephalon does not launch its own generic OTFC
- Promotion of ACTIQ ceases with launch of FEBT

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Situation Analysis

- A. Market Dynamics
 - A. Pain Market Definitions
 - B. Treatment
 - C. Pain Market Size & Trends
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 - E. Competitors
 - F. Future Competitors
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 - E. Promotional Activities

Chronic Pain

- Definition
 - Chronic pain is defined as pain lasting beyond normal healing time (>3 months)
- Comprised of two components
 - Persistent and BTP – each requiring distinct assessment & treatment
- Pain is pain²
 - CA & non-CA patients – Pathophysiology the same regardless of etiology/underlying disease
- Burden of illness
 - About 50 million of the estimated 75 million Americans who live with “serious pain” suffer from chronic pain¹
 - Patients with chronic pain are 5X as likely as those without chronic pain to use health care services
 - Pain costs Americans an estimated \$100 billion each year – Patients, families, health care organizations, and society bear this financial burden¹

¹American Pain Society <http://www.ampainsoc.org/ce/npc/> ²Turk D. Clin J Pain 2002; 18(2):75-6

Breakthrough Pain (BTP)

- Definition
 - A transient exacerbation or flare of moderate-to-severe pain that occurs on a background of otherwise controlled pain¹⁻³
- Characteristics
 - Onset – May escalate to maximum severity in < 3 minutes¹
 - Duration – Median duration of 30-60 minutes¹
 - Frequency – Median number of 4 episodes/day¹
 - Types
 - Incident
 - Spontaneous
 - End-of-dose' failure^{1,4-6}

1 Portenoy & Hagen, Pain, 41 (1990), 273-281. 2 McQuay HJ, et al. *Cancer Surv.* 1994;2:17-24. 3 Mercadante S, et al. *Cancer.* 2002;94:832-839. 4 Zepetella G, et al. *J Pain Symptom Manage.* 2000;20:87-92. 5 Petzke F, et al. *J Pain Symptom Manage.* 1999;17:391-401. 6 Stromgren AS, et al. *J Pain Symptom Manage* 2004;27:104-113.

Breakthrough Pain (BTP)

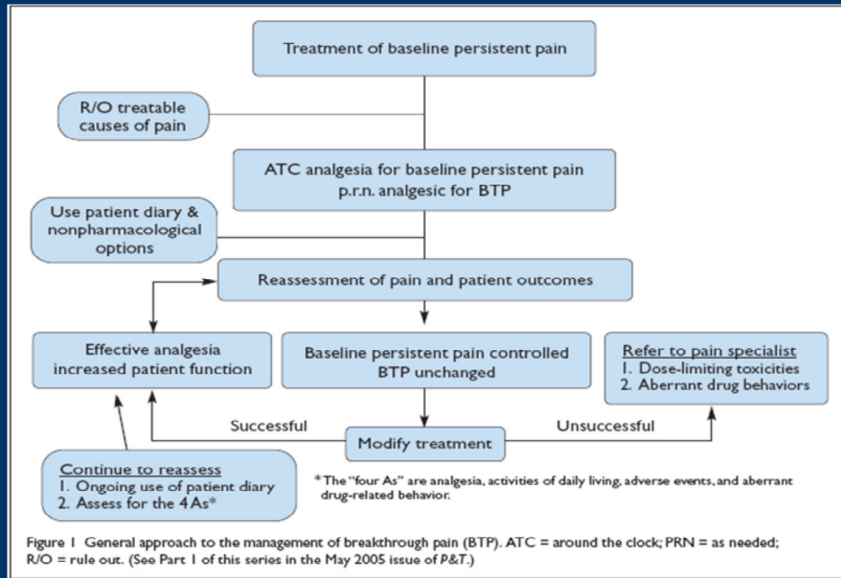
- Prevalent in both cancer and non-cancer chronic pain
 - Common mechanisms may underlie BTP in both cancer and non-cancer conditions⁸
 - Cancer – up to 86% of patients¹
 - Non-Cancer – up to 74% of patients⁷
- Burden of illness/consequences of BTP
 - Impacts ability to function & QoL¹⁰
 - Cancer patients with BTP are 5X as costly as those w/o BTP¹¹

1 Portenoy & Hagen, *Pain*, 41 (1990), 273-281. 7 Portenoy RK, et al. Poster Presented at: Annual Meeting of the American Pain Society (Poster #698); March 30-April 2, 2005; Boston, Mass.
8 Turk DC. *Clin J Pain*. 2002;18:75-76. 10 Portenoy RK, et al *Pain*. 1999;81:129-134. 11. Fortner BV, Okon, TA, Portenoy, RK, *J of pain*220; 3:38-44.

Situation Analysis

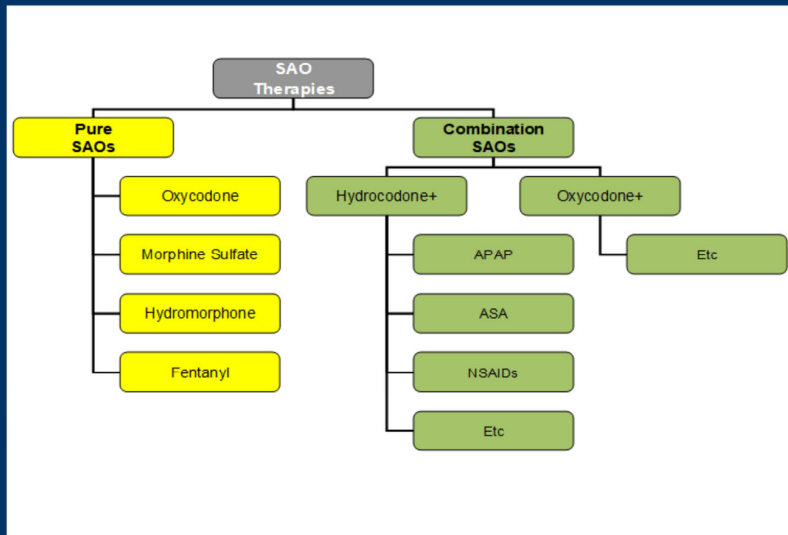
- A. Market Dynamics
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Treatment Algorithm



Source: P&T June 2005 Consensus Panel Recommendations for the Assessment and Management of Breakthrough Pain Part 2 Management

BTP Treatment Options



Situation Analysis

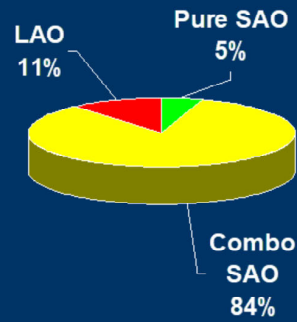
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Total Opioid Market

2004

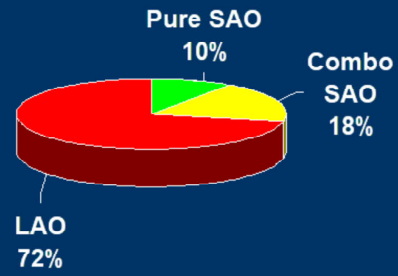
142.7 MM prescriptions

Opioid Market TRx Volume



\$5.9 billion

Opioid Market Value



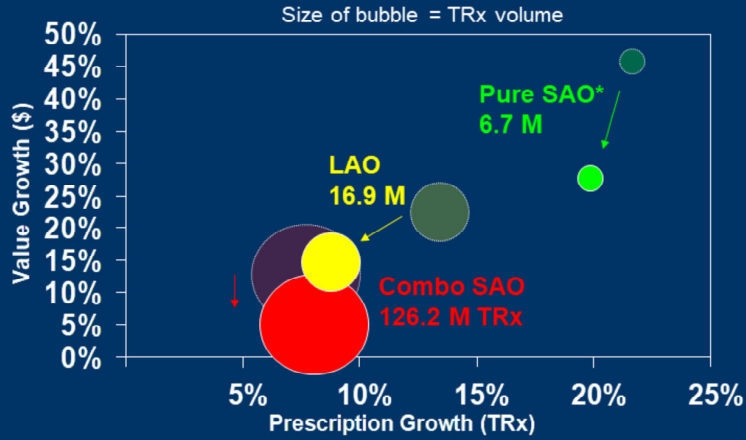
Source: IMS, NPAudit

Note: LAO = long-acting opioid, SAO = short-acting opioid

Total Opioid TRx market continues to grow (+7%)*

- Actiq TRx are growing at 38% rate (MAT 11/04 vs. 03) almost double the Pure SAO rate (+20% TRx)
- Despite this growth rate Actiq has a small base from which to grow

MAT Nov. 04 vs MAT Nov. 03



Source: IMS NPA (TRx) and NPS (\$)

* Oxycodone, morphine, hydromorphone & fentanyl

Direct Competitors: Pure SAOs

All generic except ACTIQ

Pure SAOs	2004 TRXs	% of Total Market TRXs	TRX Δ 2003/2004	2004 Total Dollars	% of Total Market Dollars	Dollar Δ 2003/2004
Total	6,837,076		20%	\$584,205,089		31%
Oxycodone HCL	2,929,647	43%	40%	\$61,201,629	11%	91%
Morphine Sulf	1,640,588	24%	32%	\$26,141,437	5%	31%
Hydromorphone HCL	1,008,764	15%	30%	\$47,866,699	9%	50%
ACTIQ	436,059	6%	34%	\$364,032,160	67%	42%
Roxicodone	387,378	6%	-27%	\$36,951,256	7%	-15%
Dilaudid	176,953	3%	-10%	\$36,986,505	7%	-12%
All Other Pure SAOs	257,687	4%	N/A	\$11,025,403	2%	N/A

Source: IMS Health SPA and NPA

Situation Analysis

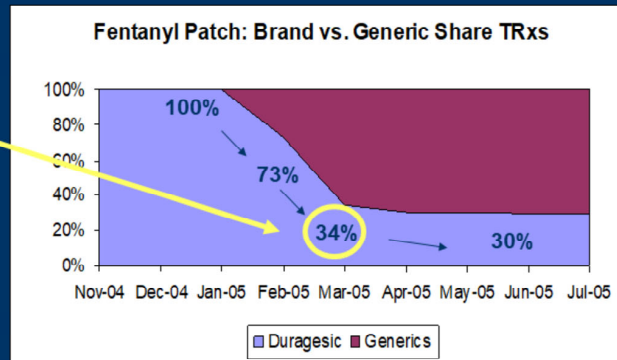
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Generic Erosion

Duragesic example

- Generally a branded product loses 30% in month one, 50-60% by six months, and 80-90% within a year

Duragesic lost 66% by month three

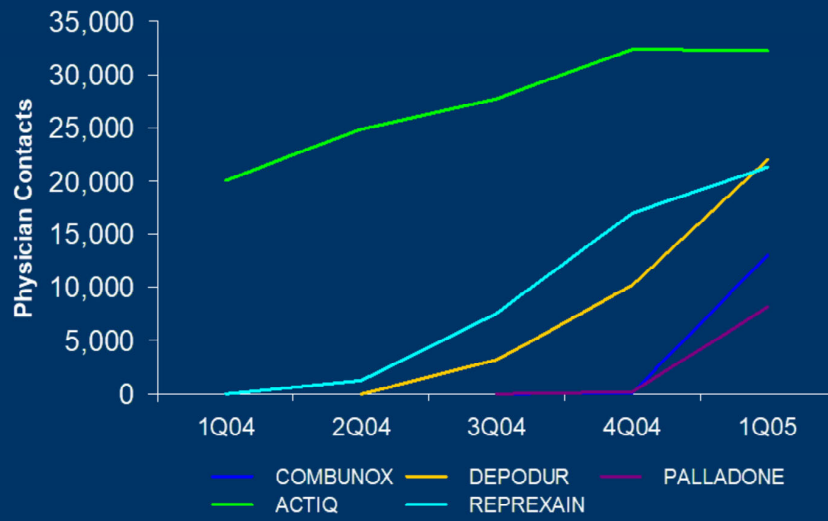


Source: IMS Health NPA

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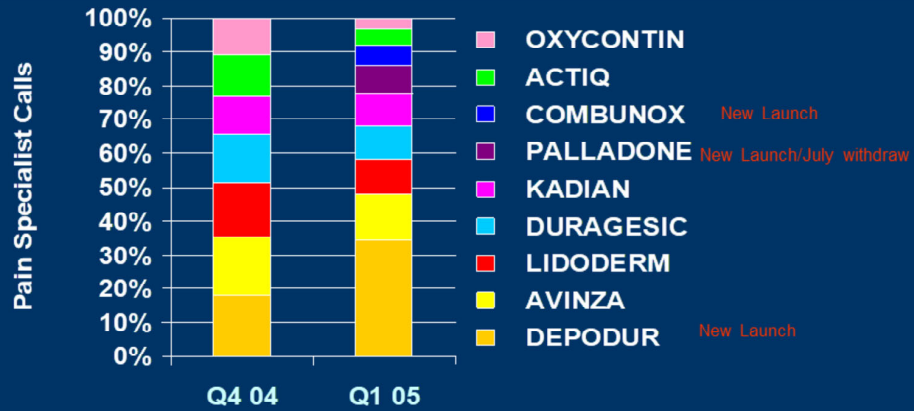
New Opioid entrants are increasing their level of promotion



Source: IMS ISP – All Specialties, Rolling quarters

ACTIQ opioid share of voice for Pain Specialist has decreased

•ACTIQ opioid SOV for pain specialists has decreased from 12% in 4Q04 to 5% in 1Q05

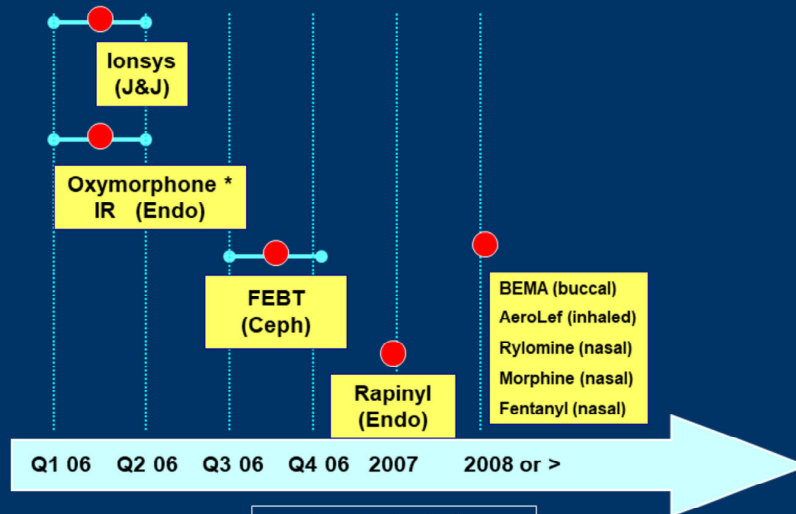


Source: IMS IPS - based on physician recall / perception

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Future Competitors Rapid Onset Opioids - Market Entrants



Source: Signia & Internal estimates

Estimated Launch

* Technically this drug is not in the ROO class (onset 15 min.) instead it's onset will most likely be 30 minutes but included because of potential claims of fast onset

Actiq patent expire based on SF launch and / or Pediatric exclusivity

Fentanyl Formulations in Development

Drug	Formulation	Phase	Indication/Comments
Rapinyl Endo	transmucosal fentanyl (sublingual)	Phase III	Acute pain, BTP/8-11 minutes for time to first detectable serum concentration
ETRANS Ionsys Alza (J & J)	iontophoretic transdermal fentanyl	Phase III	Postoperative pain
BEMA BioDelivery Sciences International, Inc	bioerodible transmucosal fentanyl	Phase II	BTP and chronic cancer pain
Titragesia ZARS (Cephalon)	transdermal fentanyl patch + CHADD patch	Phase III	BTP and chronic pain/ 5 minutes for CHADD to increase serum fentanyl concentrations (CHADD=Controlled Heat-Assisted Drug Delivery)
Fentanyl Taifun Lab International	inhaled fentanyl	Phase II	BTP/ 5 minutes
AeroLEF YM BioSciences	inhaled liposome-encapsulated fentanyl	Phase II	BTP/ 13 minutes

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Market Drivers

- Growth in number of chronic pain patients continues to drive prescriptions
- Market value continues to grow despite introduction of generics (2 largest brands went generic - Oxycontin® and Duragesic®)
- MCOs continue to limit access to opioids via PAs & step edits
- Pain specialists drive opioid prescriptions
 - Fear of abuse, addiction, & diversion persist
- Evolving chronic treatment guidelines regarding BTP

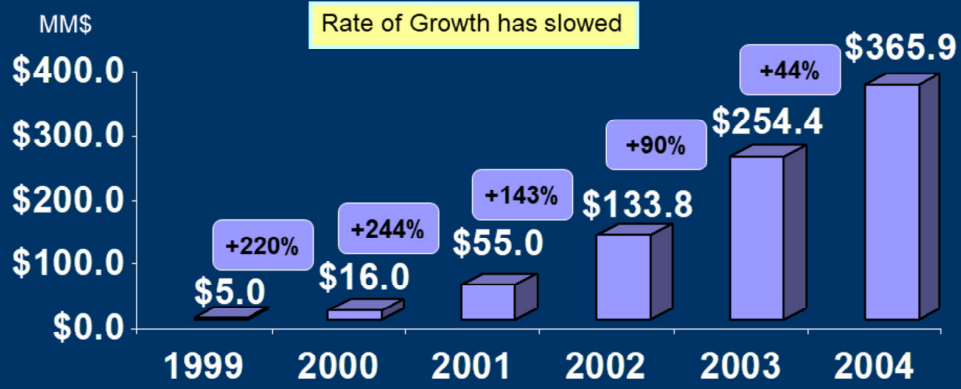
ACTIQ Performance

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ACTIQ Factory Sales

1999 - 2004



Monthly sales

ACTIQ Yearly TRx



Source: NDC

Monthly Shipments vs Budget

June YTD Shipments are 99% to budget



Source SPS

■ Budget Shipments ■ Shipments

* Budget shipments include gross sales in addition to product utilized for coupon and compassionate use programs

ACTIQ Demand Sales* vs. Shipments



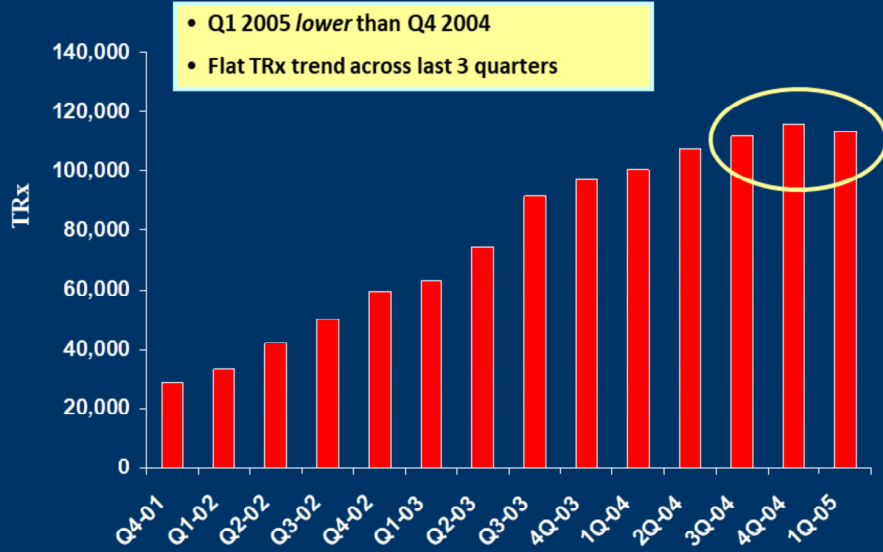
* Demand Sales = Retail + Estimated Non-Retail

■ Demand — Shipments **

** shipments include gross sales in addition to product utilized for coupon and compassionate use programs

Source: IMS NPA and RPP; historical prices calculated in; CORD/SPS

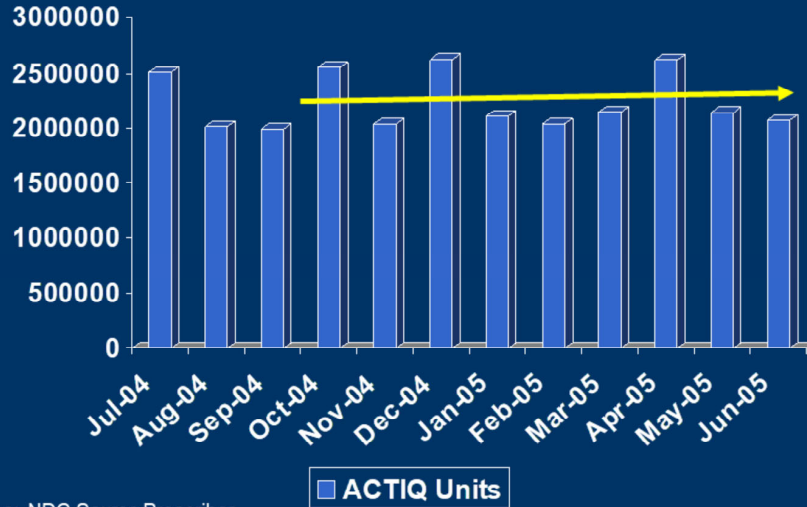
ACTIQ Quarterly TRx Trends



Source: IMS NPA

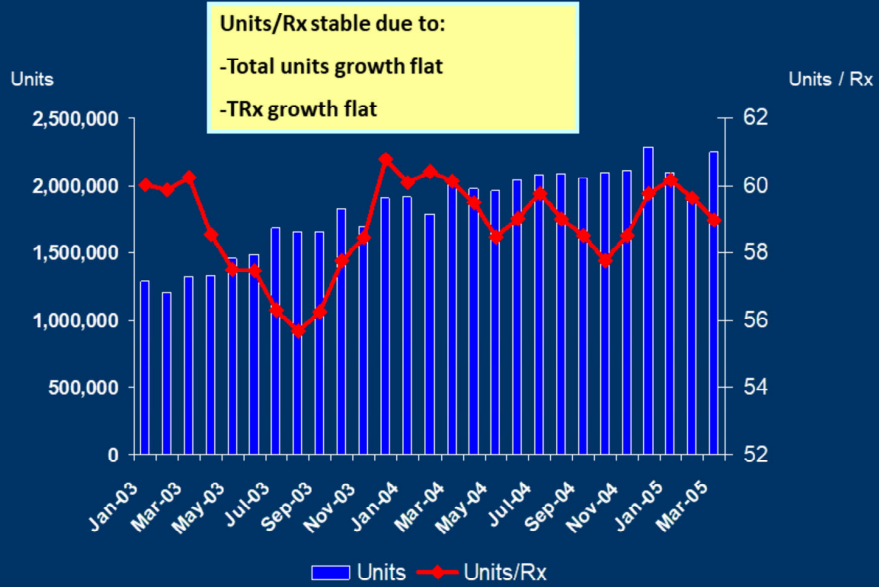
Total Units Analysis

Unit Growth has been flat



Source: NDC Source Prescriber

ACTIQ Monthly Units & Units/Rx



Source: NDC

ACTIQ Prescription Value

Rx Value Closely Correlates with Price Increase

- Rx value increasing primarily due to price increases, not increase in units/Rx
- Rx value may also be increasing due to more mature ACTIQ patient population on higher strengths (fewer new starts at lower strengths)



Source: IMS NPA Audit



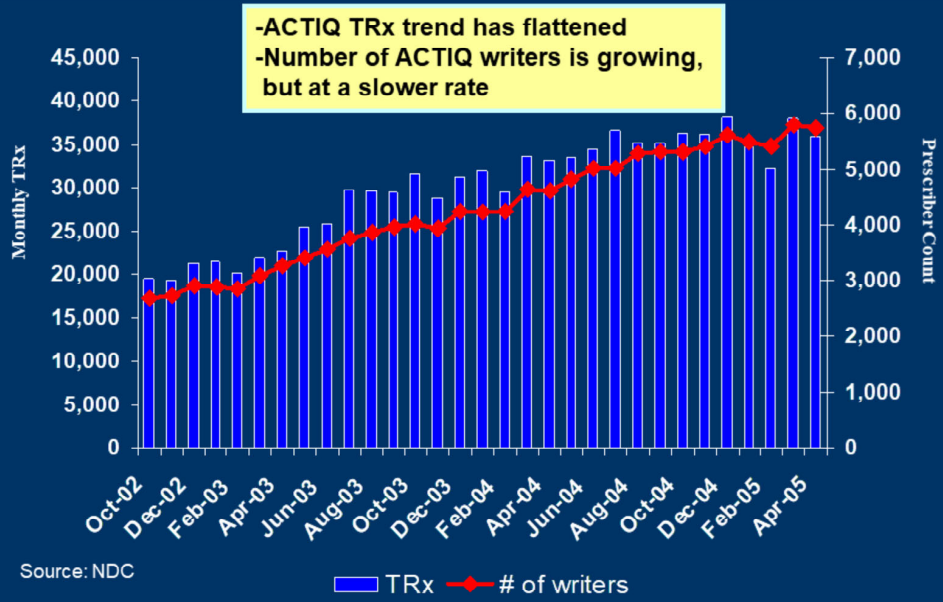
Summary

- Q: Do you have data showing sales are increasing but volume is flat...demonstrating all growth is price increase only??
- Factory sales rate of growth has slowed
- TRxs flat:
 - Total units
 - New starts
 - Units/Rx has remained stable
- Prescription values continue to increase primarily due to price increase

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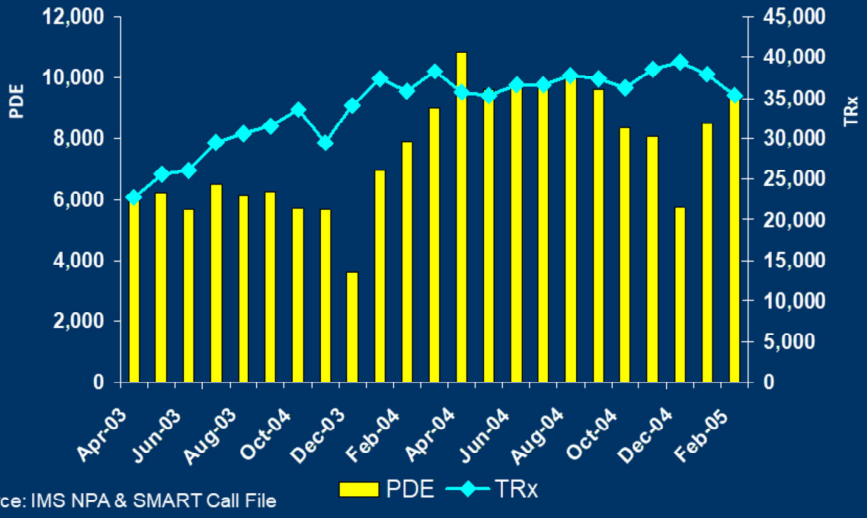
ACTIQ Monthly TRx & Prescriber Count



PDEs & TRx

April 2003 – February 2005

- PDEs 47% higher in 2004 (vs. 2003)
- Due to increase in sales force from 79 to 435
- Higher PDEs in 2004 did not translate into increasing TRXs

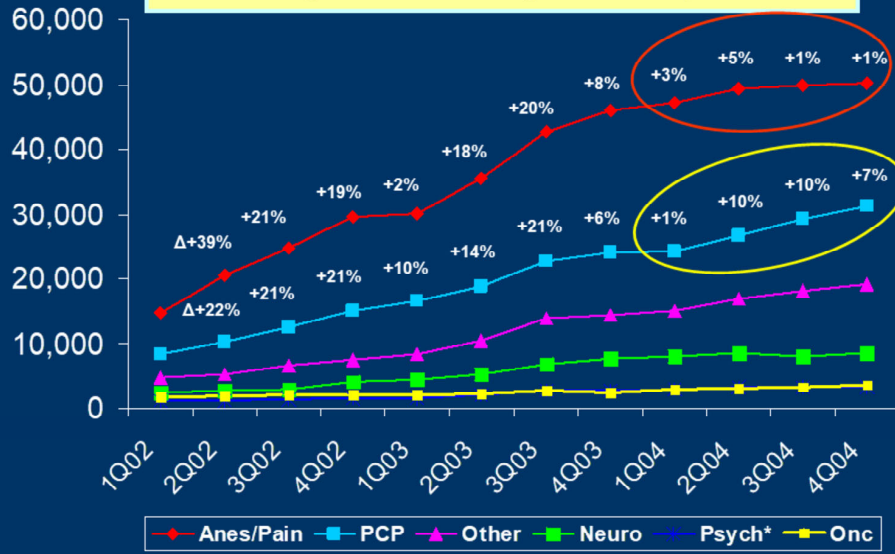


Source: IMS NPA & SMART Call File

■ PDE ◆ TRx

ACTIQ TRx Growth by Specialty Group

PCP growth continues to be greater than Pain/Anes

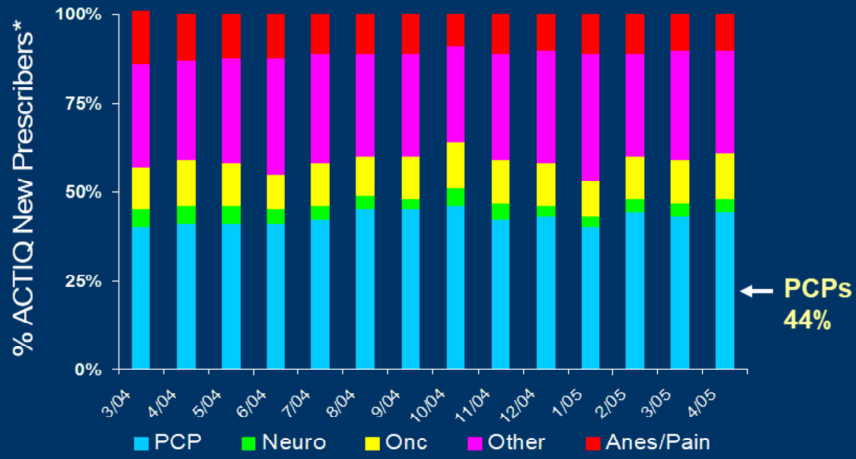


Source: IMS NPA

* Psychs are called on as safety targets

New Prescribers* of ACTIQ by Major Specialty Group

- PCPs continue to be the largest new user specialty
- Pain New Prescribers Remain Flat



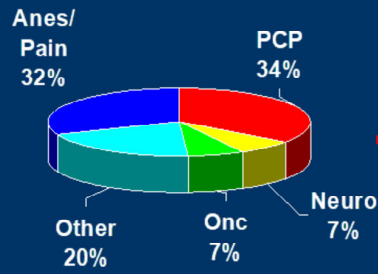
* New prescribers are defined as writing in current month but not in the last 12 months

Source: NDC

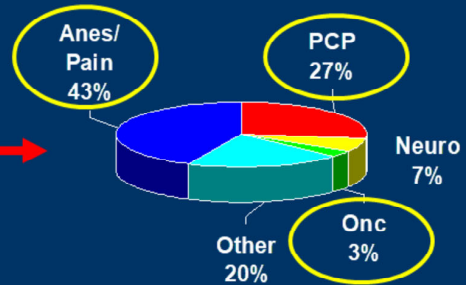
Productivity by Specialty

Regardless of increased activity in other specialties,
Pain specialty is still most productive

Prescribers by Specialty
May 2005

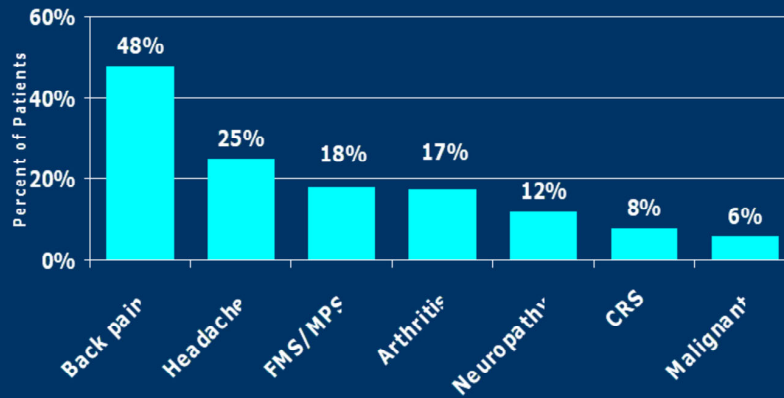


TRx by Specialty
May 2005



Underlying conditions treated with ACTIQ

Distribution of Conditions Treated with Actiq (Projected)



Source: IMS Chart Audit, 2004

ACTIQ Usage by Specialty

Condition	Anes/Pain	Neuro	PCP	Other	TOTAL
Malignant pain	13%	6%	4%	35%	10%
Back pain	49%	21%	81%	41%	55%
Headache	17%	97%	19%	14%	22%
FMS/MPS*	14%	11%	17%	18%	18%
Arthritis	12%	7%	21%	8%	13%
CRPS**	9%	2%	5%	5%	7%

* Fibromyalgia/Myofascial Pain ** Complex Regional Pain Syndrome

Source: IMS Patient Chart Audit, Oct 2003

Product Awareness Perception and Usage

Physician Perspectives

- Key Driver to ACTIQ usage
 - Efficacy – rapid onset of action (primary driver)
 - Secondary drivers
 - Patient acceptance / satisfaction
 - Low side effect profile
- Key Barriers to ACTIQ usage
 - Reimbursement
 - Abuse and addiction concerns
 - Nothing new

Source: Market Pulse Survey, Leo Gibney Associates, Sept. 2004

Physician: Perceptions of ACTIQ

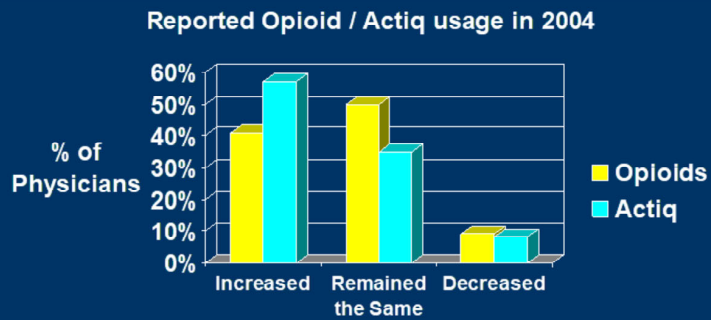
Strengths	Weaknesses
Rapid onset of analgesia (73%)	Cost (20%)
Efficacy (31%)	Sugar formulation (19%)
Ease of use (20%)	Formulary coverage (14%)
Convenience (8%)	Limited Cancer indication (10%)
Low Side effects (8%)	Longer duration of action needed (7%)
Low Abuse potential (7%)	Dislike new formulation (7%)

67% reported having experienced insurance coverage issues with ACTIQ

Source: IMS Chart Audit, 12/04 - Unaided Responses

ACTIQ users remain committed to the brand and opioids in general

- ACTIQ users reported a 41% increase in opioid prescribing
- ACTIQ users reported a 57% increase in ACTIQ prescribing
- Primary reason for increased opioid prescribing is larger patient volume



Source: IMS Chart Audit, 12/04

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Targeting

- Database changes
- Segmentation
- Call productivity

Target Identification Process Changed in 2005

- **Objective: Improve quantity of higher quality targets**
- Based on feedback from field
- Targeting identification process changed to accurately reflect marketplace, which is highly genericized

Higher Quality Targets

How did we accomplish this?

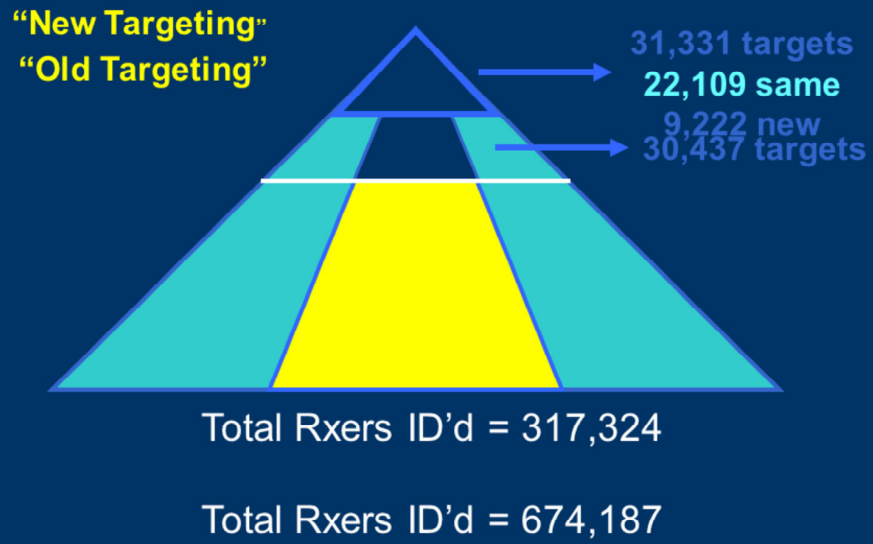
- Added in generic opioids hydrocodone, hydromorphone, oxycodone & morphine (Dec04)
- Addition of generics provides
 - More accurate reflection of prescriber behavior
 - Greater number of skilled opioid prescribers
 - Increase of overall quality of targets
- So – what does this look like?

Sales Ops. Placeholder

- Requested information regarding new vs. old targets
 - Called on vs. non-called on targets (old and new/productivity of each)
 - Productivity of old targets vs. new targets
 - Raw data on utilization of new target data

Higher Quality Targets

Addition of generic data

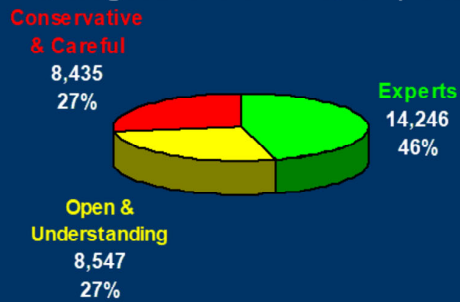


Segmentation Research Findings

3 Segments identified:

1. **Experts**
2. **Open & Understanding** (patient focused)
3. **Conservative & Careful** (concerns of A/A/D may limit usage)

ACTIQ Target Universe = 31,331 (Feb2005)



Segmentation: Sales Force Pilot

- Results of Segmentation pilot:
 - Was the physician accurately tagged?
 - About 50% of the time
 - Did the segmentation information help?
 - **“Yes, as a pre-call planning tool for new calls and to provide insights into a direction to take when it becomes clear which segment the physicians belongs to”**
 - **“Helped me prepare for call / opening statements”**
 - **“Would never have called on this physician based only on volume, but I will now add him to my list”**
 - **“Segmentation gave me the right mindset going into the call”**

During the sales force pilot the AMs & reps measured the accuracy of the tags and how helpful the information was. While the accuracy of the tags was lower than anticipated, the overall feedback was very positive. These segments do exist – even if the tags are difficult to get exactly correct every time, just knowing these segments and what approach to take on the call can help prepare better for the call.

NOTES: 6 AMs (except West & N. Central) chose 3 reps each to take part in the pilot

Segmentation: Roll-out

What's
planned
for next
year?
Will this
be a
part of
call
planning?
g?

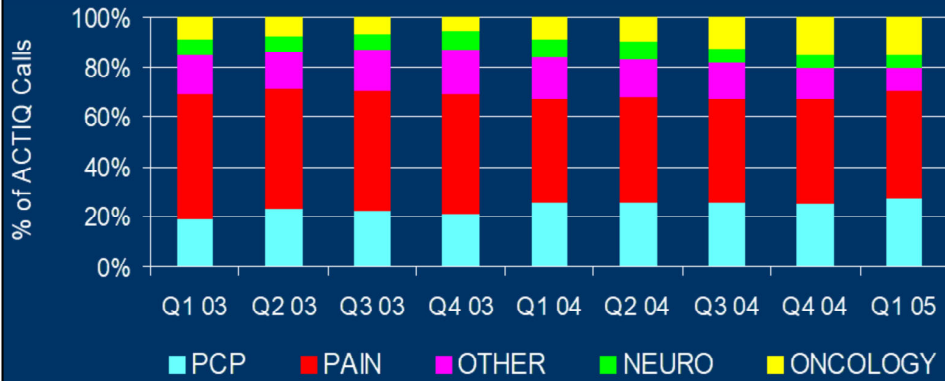
Roll-out:

- The physicians in SMART will NOT be tagged with the segments
- All managers will be provided with an excel spreadsheet from Sales Ops listing newly ID'd physicians: non-called on targets with segment info
- These physicians should be called on using the segmentation information to help plan the call
- The SMART system will have a pull down field where TSS can choose the segment based on their insights
 - The information will then be based on sales force insights
 - This will help build our database for future use

One the thing to remember is that onset of action message is always a priority to convey, no matter what the segment.

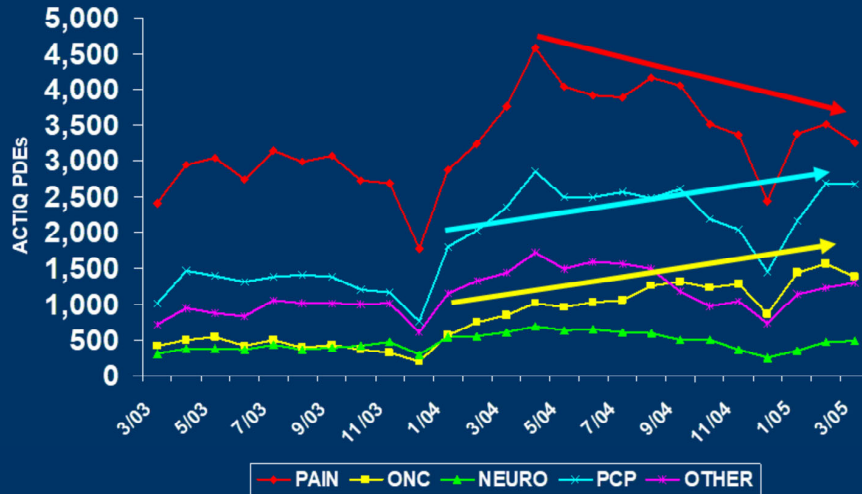
Percentage of ACTIQ PDEs by Specialty

•PCP and Onc Calls Increasing
•Pain Specialty Flat



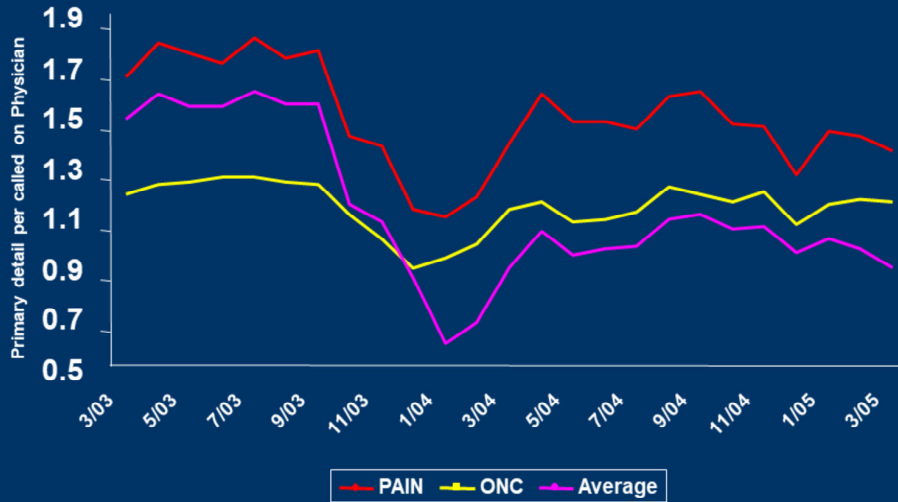
Total ACTIQ PDEs by Specialty

- Total Pain Specialists Calls Trending Down
- Total PCP and Oncology Calls Trending Up



Average Call Frequency by Specialty

- Most Productive Segment (Pain) – Frequency is declining
- Lesser productive segment (Onc) –Frequency is flat



Source: SMART database

Productivity Per Call Decreased Across All
Specialty Segments
(2003 vs. 2004)

Specialty Segment	TRx/PDE (2003)	TRx/PDE (2004)	
Pain	5.37	4.77	↓↓
Oncology	0.99	0.95	↓
Neurology	5.40	5.10	↓
PCP	4.96	3.39	↓↓
Other	4.83	4.76	↓
Average	4.31	3.79	↓

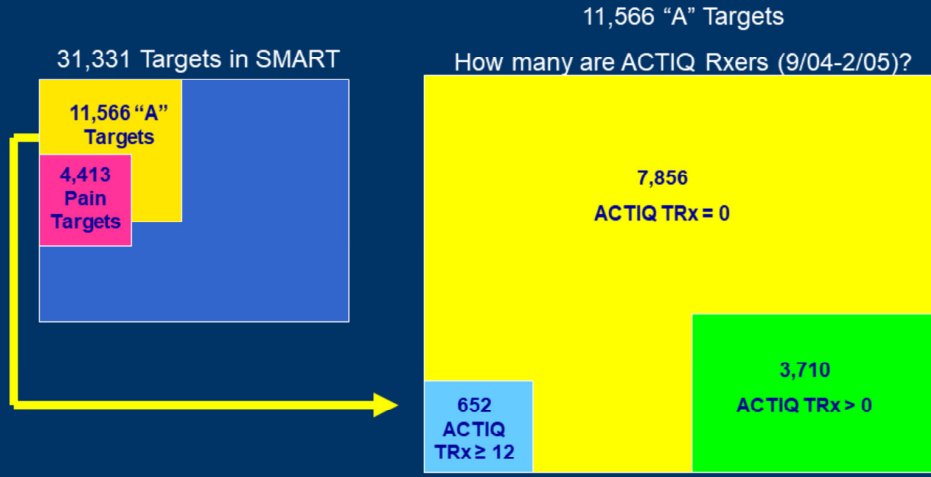
Source: SMART database, NDC

Biggest call increases have been with Onc. And PCPs which have resulted in the highest decrease of call productivity (**lowest productivity get lower**)

Summary of Call Activity

- Total PDEs increased after expansion
 - 2004 monthly average PDE = 8,798
 - 47% increase over 2003 (5,594)
- Average call frequency decreased 2003 vs. 2004 (continues to trend down in 2005)
 - Pain segment – historically most productive
 - PDEs trending down, call frequency down, productivity down
 - PCPs – though less productive than pain - are both the largest group on new users and have the fastest TRx growth
 - PDEs trending up
 - Oncology segment – historically least productive
 - PDEs trending up, call frequency stable, productivity down slightly
- Productivity per PDE down across all specialty segments 2004 vs. 2003
 - 2004 = 3.79 TRx/PDE
 - 2003 = 4.31 TRx/PDE

Big Opportunity Within "A" Targets



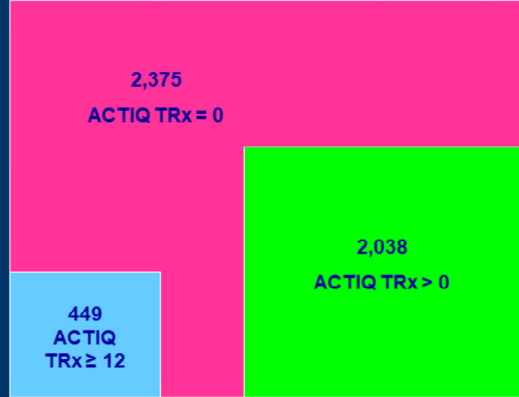
Big Opportunity Within Pain Segment

31,331 Targets in SMART



4,413 Pain Specialty Targets

How many are ACTIQ Rxers (9/04-2/05)?



- Add slide that clearly lays out targeting plan for 2006

Summary of Target Audience Analysis

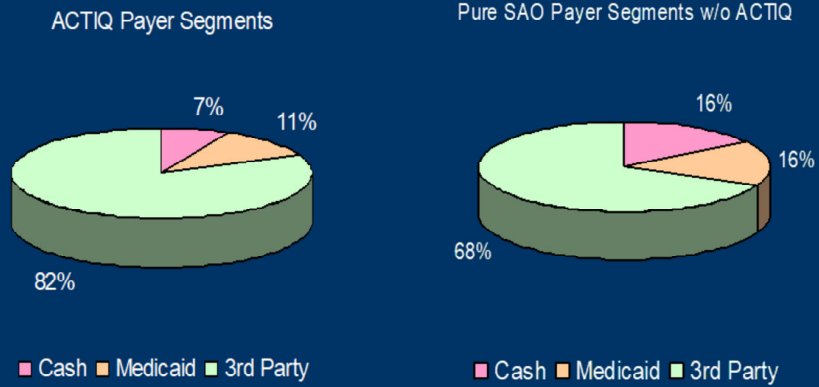
- Addition of generic data increased both quantity and quality of targets
 - 9,222 new targets added to SMART database
- Significant opportunity with 11,566 “A” Targets
 - 7,856 “A” Targets have not written an ACTIQ prescription in prior 12 months
- Significant opportunity within Pain Specialty
 - 2,375 Targeted Pain Specialists have not written an ACTIQ prescription in prior 12 months

Situation Analysis

- A. Market Dynamics
 - A. Pain Market Definitions
 - B. Treatment
 - C. Pain Market Size & Trends
 - D. Anticipated ACTIQ Generic Erosion
 - E. Competitors
 - F. Future Competitors
 - G. Market Drivers
- B. ACTIQ Performance
 - A. Sales/Rx
 - B. Prescriber Base Analysis
 - C. Target Audience Analysis
 - D. Reimbursement
 - E. Promotional Activities

ACTIQ vs. SAOs Payer Segments

Dec 2004



ACTIQ % of 3rd party payer segments is higher than pure SAO market

ACTIQ Formulary Restrictions

- Prior Authorization/Letters of Medical Necessity
- Quantity limits
- Use in labeled indication (BTP in cancer patients) only
- Step edits
- Dollar volume limit per month
- Third-Tier Co-pay

ACTIQ Claims: Reasons for Rejection

Prior Authorization Rate is Increasing

ACTIQ Claim Rejection Reason	1Q03	2Q03	3Q03	4Q03	1Q04	2Q04	3Q04	4Q04	1Q05
PRIOR AUTHORIZATION REQUIRED	25%	27%	28%	33%	35%	38%	40%	43%	42%
PLAN LIMITATIONS EXCEEDED	19%	17%	15%	15%	12%	13%	13%	13%	13%
PRODUCT/SERVICE NOT COVERED	11%	11%	9%	8%	7%	6%	9%	7%	5%
DUR REJECT ERROR (Step edit)	4%	3%	5%	6%	6%	6%	5%	5%	5%

NOTE: 94% of ACTIQ claims are eventually approved but we cannot quantify those Rx's that are never written due to these barriers

ACTIQ Prescribers Report Cost/Managed Care is a Major Issue

- Actiq users experience problems with managed care ¹
 - 19% stated not on formulary
 - 17% stated higher patient co-pay
 - 28% stated only covered for BTP
- Two-thirds of physicians report having experienced insurance coverage issues when prescribing Actiq ²
 - Impacts 50% of their patients (of those reporting issue)
 - Cost (20%) and lack of formulary coverage (14%) are major barriers

Source: 1. MDS 2004 Ziment 2. IMS Chart Study

High/Medium ACTIQ Users:

Increasing the depth of prescribing (primarily by alleviating some of the cost barriers) is the next step with this group.

Additionally, reps need to understand the major insurance carriers for their MDs and point MDs to the carriers with the best coverage (assisting them on pinpointing appropriate patients for ACTIQ).

Low/Non ACTIQ User Pain Specialists:

Detailing is central to this activating these MDs. Encouraging trial during details (and continued emphasis on couponing) will be essential moving forward.

They understand the 'Rapid Onset' benefits of ACTIQ, but it is just not enough –messaging needs to include the additional efficacy, dosing, titration benefits of ACTIQ.

Low/Non ACTIQ User Other Specialists:

Require less basic education as PCPs.

They too get the 'Rapid Onset' story, but it alone will not motivate them to Rx more. They need to also understand the additional efficacy, dosing, titration benefits of ACTIQ, as well as alleviating concerns about abuse potential.

Trial (again thru detailing/couponing) is central to growing this group.

Low/Non ACTIQ User PCPs:

Increasing ACTIQ awareness is necessary to engage these MDs. It will be pivotal to implement the ACTIQ segmentation to target these MDs to make detailing efficient.

Reimbursement Summary

- 3rd Parties and Medicaid are responsible for 93% of ACTIQ Sales (12/04)
- Plans continue to become more restrictive
- Physician feedback indicates reimbursement is becoming more difficult
- No way to measure impact of barriers (i.e., # of Rx's not written)
- Medicare Part D (*roll out Jan 2006*) beneficiaries are not expected to receive reimbursement for ACTIQ

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 - D. Reimbursement
 - E. **Promotional Activities**

Promotional Activities

- New “Montage” Advertising Concept
 - Maintains equity of “bell” concept that has been used successfully since 2001 (high recognition)
 - “Humanizes” the campaign by showing images of patients
 - Updated tag line
 - “When onset matters... ACTIQ responds”

Comparison of Advertising Campaigns

“Bell” Campaign

When onset matters...



Actiq on call.

With ACTIQ pain relief may be observed in 15 minutes.

Rapid transmembrane absorption

- Rapid transmembrane absorption of ACTIQ allows for rapid onset of analgesia.
- ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa.
- ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa.
- ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa.

No pharmacologically active metabolites

- ACTIQ does not have any pharmacologically active metabolites.
- ACTIQ does not have any pharmacologically active metabolites.
- ACTIQ does not have any pharmacologically active metabolites.

Typical opioid side effects

- ACTIQ does not have any typical opioid side effects.
- ACTIQ does not have any typical opioid side effects.
- ACTIQ does not have any typical opioid side effects.

Availability, convenience, cost

- ACTIQ is available in a convenient, easy-to-use, oral form.
- ACTIQ is available in a convenient, easy-to-use, oral form.
- ACTIQ is available in a convenient, easy-to-use, oral form.

Important Warnings

ACTIQ is a Schedule II controlled substance. It is a potent analgesic and may be abused. It may cause respiratory depression, especially when used in combination with other sedating or narcotic drugs. ACTIQ may cause drowsiness, dizziness, and impaired judgment. Do not drive or operate machinery while taking ACTIQ. ACTIQ may cause constipation. Do not take more than the recommended dose. ACTIQ may cause dry mouth, blurred vision, and changes in heart rate. ACTIQ may cause changes in blood pressure. ACTIQ may cause changes in breathing. ACTIQ may cause changes in heart rate. ACTIQ may cause changes in breathing. ACTIQ may cause changes in heart rate. ACTIQ may cause changes in breathing.



New “Montage” Campaign



When onset matters... ACTIQ responds.

The main benefit of ACTIQ is the time to onset of analgesia.

ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa. ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa. ACTIQ is a highly lipophilic drug that is rapidly absorbed through the oral mucosa.

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Promotional MEPs

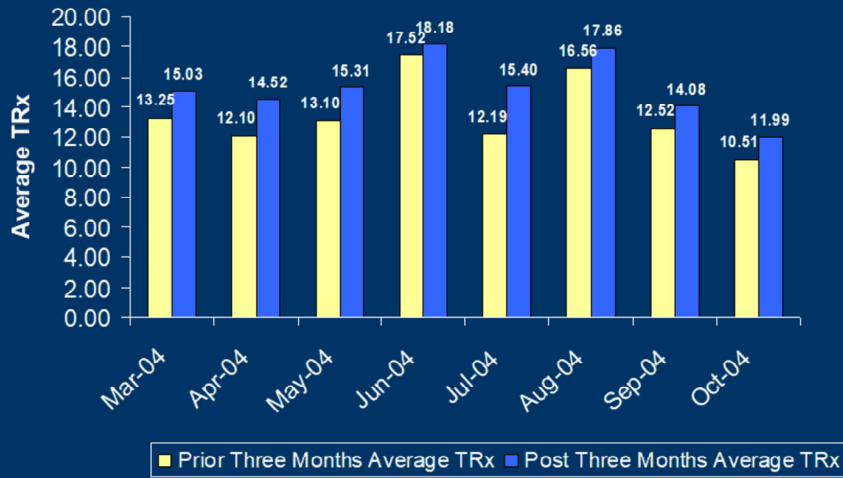
YTD July 2005

Peer-to-Peer Interaction is Major Driver of ACTIQ Business

- Over 1500 sales-driven MEPs executed (7/18/05)
- Over 4000 prescribers exposed to ACTIQ promotional message (7/18/05)

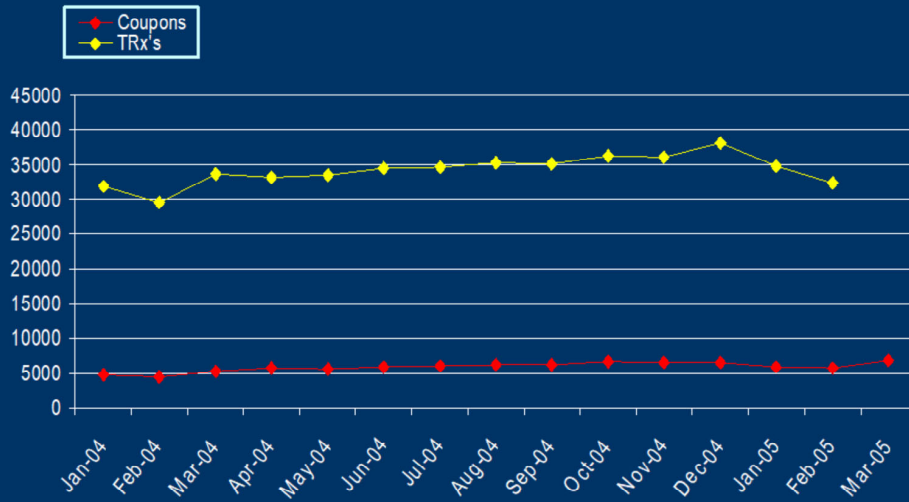
ACTIQ MEP ROI Analysis

Updated Data Requested



ACTIQ Coupon Usage vs. TRx Trends

Coupon Usage has remained constant vs. TRx Trend



Sales Force Update

- Plan as of August 2, 2005
 - Transition from single to multiple sales forces in October 2005
 - CNS/PCP (650 reps) – SPARLON, PROVIGIL → NUVIGIL
 - Pain (100 reps) – ACTIQ → FEBT
 - Oncology (28 reps) – TRISENOX & ACTIQ → FEBT
 - Addiction – (100 reps) – VIVITROL
 - It is assumed that both the Pain & Oncology sales forces will promote ACTIQ
 - Allows for focus and specialization leading to successful performance with ACTIQ growth
 - Allows for efficient/smooth shift to support FEBT launch in Q4 2006

Outline

1. Major Assumptions
2. Situation Analysis
3. Product Overview (SWOT, positioning, messaging)
4. Key Marketing Issues & Strategies
5. Critical Success Factors
4. Objectives
5. Tactics

SWOT

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none">• Rapid onset of analgesia• Solid clinical database within cancer pt population• OTS delivery and onset of action provides pts with:<ul style="list-style-type: none">○ Portability○ Convenience○ Control• Core product characteristics appropriate for Tx of BTCP• Only product w/ FDA approved BTP in cancer indication• Strong 5 year history of efficacy and safety data• Sugar free formulation in April 2006• Establishment of Pain Care sales force	<ul style="list-style-type: none">• Patent expiry September 2006• Narrow indication• Cannot make the claim "rapid onset" despite the clinical data• Challenging sales process• Limited promotional flexibility due to Subpart-H approval• Perceived cumbersome titration process• No equianalgesic dosing guidelines• High acquisition cost (limited pharmacoeconomic data available)• Perceived safety concerns• Formulation change projected for April 2006• Dental decay language in PI/PL

SWOT

OPPORTUNITIES	THREATS
<ul style="list-style-type: none">• KOL eagerness to evaluate and establish standards for BTP Tx• Increased focus on pain management from JCAHO (5th vital sign) and NIH (Decade of Pain Control and Research)• Opioid use being recommended and incorporated into a variety of treatment guidelines (APS, DEA consensus statement, etc.)• 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	<ul style="list-style-type: none">• Introduction of generic OTFC (September 2006)• Increased reimbursement issues• Medicare Part D• No validated treatment guidelines for BTCP• “Opiophobia” within pain market due to continued publicity around abuse, addiction, diversion (a/a/d)• Increased counter-detailing from competitors• Competitors continuing to be used to treat BTCP without label/indication for BTCP

Product Vision & Positioning

Vision:

ACTIQ is the ideal first-line option to treat BTP in opioid tolerant cancer patients.

Positioning:

ACTIQ is fentanyl in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available which makes it the ideal agent for BTP or rapid onset pain, such as BTP in cancer patients.

Key Messages

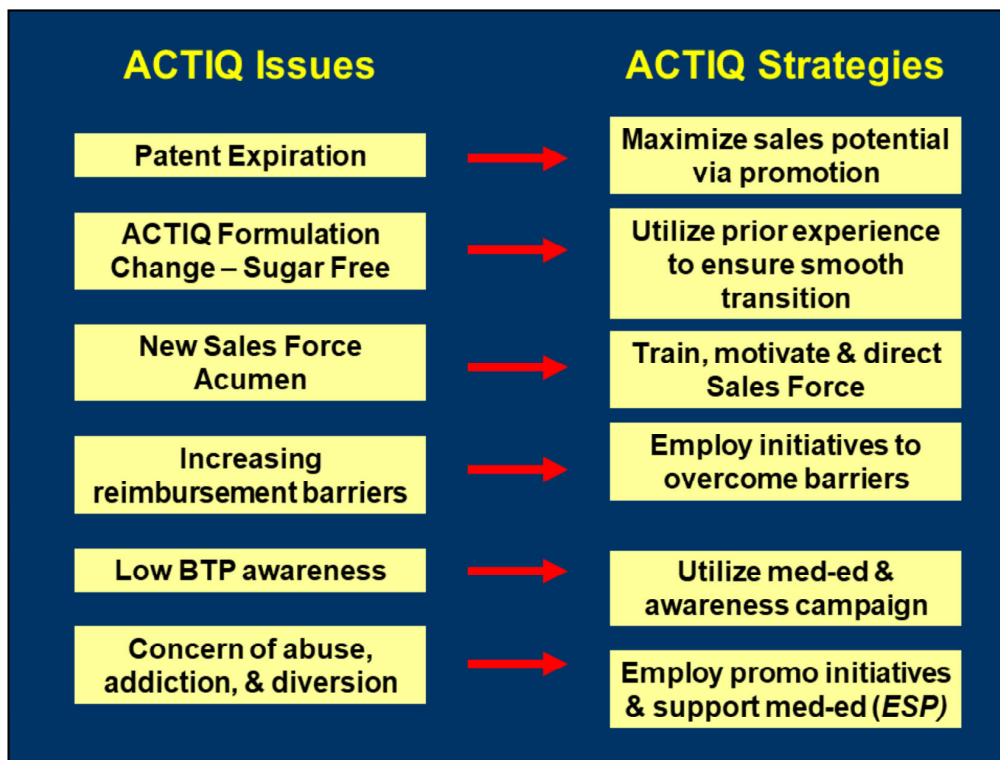
Efficacy	Within 15 minutes of starting medication, patients using ACTIQ rated their pain relief at 67% compared to 3% with their regular rescue medication
Safety	No pharmacologically active metabolites SF formulation: No dental decay
Side Effects	The most common side effects observed were somnolence, nausea, vomiting, and dizziness
Dosing & Titration	To achieve maximum relief, patients should finish the ACTIQ unit completely in 15 minutes
Convenience	Patients can use ACTIQ anywhere without water as soon as they begin to feel breakthrough cancer pain
Delivery System	The unique OT delivery system, allows fentanyl to rapidly dissolve into the highly permeable and well-vascularized oral mucosa
MOA of fentanyl	High lipophilicity of oral transmucosal fentanyl allows for rapid absorption across the oral mucosa into the blood and distribution into the CNS – a process with a 3-5 minute half-life

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Key Marketing Issues

1. ACTIQ patent will expire September 2006 (assuming no pediatric exclusivity granted to extension patent to February 2007)
2. ACTIQ sugar free formulation is expected to launch April 2006
3. A dedicated Pain Care Sales Force will be established December 2005 requiring that training, motivation, and direction be provided expeditiously to limit the promotion disruption
4. Managed care and other third party payers continue to increase ACTIQ reimbursement barriers; patent expiration will result in mandatory generic substitution
5. Limited awareness and understanding of appropriate assessment, diagnosis & treatment of BTP in cancer patients
6. Continued concern around risk of abuse, addiction and diversion of opioids



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ACTIQ CSFs

- **CSF #1:** ACTIQ TRx growth & market share is maximized prior to loss of exclusivity
- **CSF #2:** Effectively transition to new formulation
- **CSF #3:** New Sales Force is adequately prepared/trained, provided with effective tools and given clear direction on market segmentation/targeting and messaging
- **CSF #4:** ACTIQ prescribers are aware of reimbursement tools in place to assist physicians in overcoming managed care barriers
- **CSF #5:** Targeted physicians are aware of both proper assessment and treatment of BTP in cancer
- **CSF #6:** Minimize risk for abuse, addiction, & diversion of ACTIQ

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Sales and Prescription Volume Objectives 2006

Need the real numbers in
here....

Gross Shipments	Demand Sales	TRx
\$850MM	\$780MM	1,400K

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CSF #1: Maximize ACTIQ TRx growth & market share

STRATEGY	TACTICS
Apply majority of resources to field force activity	<ul style="list-style-type: none">•Ensure adequate training and motivation of the PCS force•Provide ample rep resources<ul style="list-style-type: none">–\$3.0 MM for MEPs (15 programs/rep)–50 coupon books/rep/quarter–Medically relevant giveaways–Placebos–BTP assessment tool/poster–The Little Blue Book & PDR Pain Mgt. Prescribing Guide•E-detail•Continue journal ads & convention presence

CSF #2: Effectively transition to new formulation

STRATEGY	TACTICS
Utilize past experience to ensure a smooth transition to sugar free ACTIQ	<u>Pre-Launch</u> <ul style="list-style-type: none">-Sugar-Free placebos to field-Direct mail to physicians and pharmacists-Creation and distribution of Sugar-Free launch materials-Representative Training <u>At-Launch</u> <ul style="list-style-type: none">-Physician and Pharmacist blast e-mail and fax campaign-Catalina newsletter to current ACTIQ patients (distributed at pharmacy)-Addition of "Sugar-Free" to promotional items and other collateral-Update ACTIQ Speakers

CSF #3: Adequately prepare, train, & motivate the new sales force

STRATEGY	TACTICS
Enhance initial training class (ITC), invigorate the sales reps at the national sales meeting (NSM), and provide clear guidance on targeting	<ul style="list-style-type: none">•ITC<ul style="list-style-type: none">–Brainstorm with Sales Training to enhance for pain experienced new hires•NSM<ul style="list-style-type: none">–Physician speakers at NSM on pain market & A/A/D with Q&A session–Interactive workshops on handling objections–Team-building events–Themed meeting with on-going initiatives for 2006•Targeting<ul style="list-style-type: none">–Directors to help us determine targets and frequency

CSF #4: Increase ACTIQ prescribers' awareness of reimbursement tools to assist w/managed care barriers

STRATEGY	TACTICS
Use targeted mechanisms to reach prescribers to raise awareness of Covance hotline	<ul style="list-style-type: none">•Continue to support and promote Covance Hotline (set appropriate expectations)•Provide ample reimbursement detail aids for reps•Direct mail initiative<ul style="list-style-type: none">–to mid-high level ACTIQ writers and writers who have dropped off in last 12 months–Includes Covance info, patient consent form, magnet, & checklist of items needed when calling the hotline

CSF #5: Increase targeted physicians' awareness of both proper assessment and treatment of BTP in cancer

STRATEGY	TACTICS
Use targeted mechanisms to raise awareness of the importance of assessing and treating BTP in cancer	<ul style="list-style-type: none">•MEPs•Support BTCP monograph & assessment tool for insertion in Pain Medicine News & Anesthesiology News•E-detail•Continue journal ads & convention presence•Catalina newsletter about BTP attached to Duragesic & Oxycontin TRxs•PR initiatives

CSF #6: Minimize risk for abuse, addiction, & diversion of ACTIQ

STRATEGY	TACTICS
Use targeted mechanisms to raise awareness of Cephalon's commitment to support physicians in safe opioid prescribing	<ul style="list-style-type: none">•Develop and distribute sales literature highlighting components of the ACTIQ RMP•Direct mail initiative providing awareness and education around ACTIQ's welcome kit•Continue support of ESP as needed•Create "Opioid Glossary" to facilitate discussion between physicians and patients•Continue to provide reps with quarterly safety update

Appendix

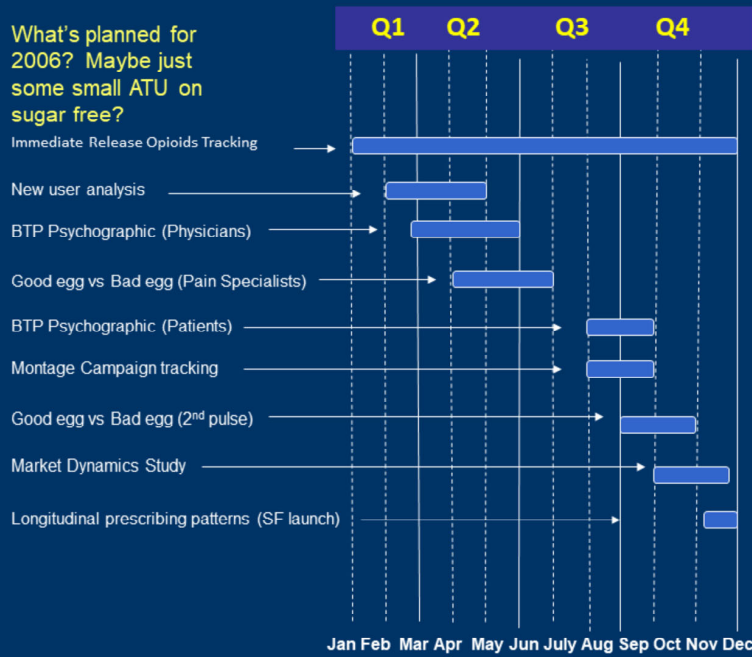
ACTIQ Chart Study

Assess Prescriber Characteristics

Conducted: Q4 2004

Market Research Plan 2005 - ACTIQ

What's planned for 2006? Maybe just some small ATU on sugar free?



ACTIQ Chart Study

Assess Prescriber Characteristics

- Objective
 - Primary – Assess characteristics of ACTIQ prescribing physicians
 - Secondary
 - Determine how ACTIQ is dosed and extent to which titration occurs
 - Update estimates of ACTIQ use by pain type
 - Determine demographic characteristics of ACTIQ patients
 - Continue to monitor the impact of formulation changes on physicians' perceptions of ACTIQ
 - Identify factors that may be increasing or decreasing physician prescribing of ACTIQ and opioid analgesics in general

Source: IMS Chart Audit, 12/04

Research & Anecdotal Feedback

- *“I have to write letters and go out of my way to convince insurers”*
- *“BCBS of Alabama put a moratorium on the use of Actiq and they cover probably 70% of patients. It’s a great medication, it’s just too much of a burden to absorb the cost”*
- *“I like it a great deal, but insurance has limited us, they just deny it. My feeling is that the volume was below the radar until the past year and that it reached some threshold and they imposed severe limitations*
- *“It’s very frustrating. I convince a physician to write ACTIQ for their patient and then the insurance company won’t pay for the prescription.” (should we keep this rep. comment?)*

ACTIQ Chart Study

- Who
 - A total of 88 high-ACTIQ decile physicians (deciles 3 - 10) participated in the study

	Sample Size	Total Population	
		Available Physician Count	Actiq TRX Range (6 Months)
Decile 3-5	60	1444	21-71
Decile 6-8	23	389	94-253
Decile 9-10	5	85	503-930
Total	88	1918	

Source: IMS Chart Audit, 12/04

Market Pulse Survey*

Identify Drivers & Barriers

Conducted: September 2004

*Previously named "Egg" Research

Market Pulse Survey

- Objective
 - Conducted research with opioid users (called on by Cephalon) to identify barriers and drivers to ACTIQ prescribing
- Who did we survey?
 - 47 physicians
 - Long-term ACTIQ writers who are writing more
 - Long-term ACTIQ writers who are writing less
 - ACTIQ non-writers (called-on targets)
 - New writers of ACTIQ

Source: Qualitative research N = 47, Leo Gibney Associates, Sept. 2004

Market Research Summary

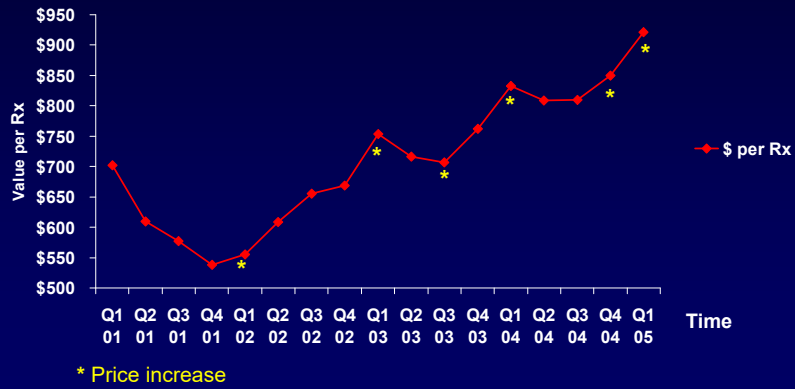
- Segmentation Information
 - Identified 3 broad groups of physicians: Experts, Open and Understanding, and Conservative and Careful
 - Very useful as a pre-call planning tool
 - Provides insight into what direction to take during a call
- Market Pulse Study
 - Key ACTIQ Driver: Efficacy
 - Key ACTIQ Barrier: Reimbursement
- Chart Study
 - Underlying conditions treated by ACTIQ has remained relatively stable over the last three years
 - Back pain most commonly treated condition
 - Rapid onset of analgesia and efficacy cited most commonly as ACTIQ strengths
 - Cost cited most commonly as ACTIQ weakness
 - ACTIQ users remain committed to ACTIQ and opioids in general

	Sample Size	Total Population Available Physician Count	Actiq TRX Range (6 Months)
Decile 3-5	60	1444	21-71
Decile 6-8	23	389	94-253
Decile 9-10	5	85	503-930
Total	88	1918	

File Provided Natively

Rx Value Closely Correlates with Price Increase

- Rx value increasing primarily due to price increases, not increase in units/Rx
- Rx value may also be increasing due to more mature ACTIQ patient population on higher strengths (fewer new starts at lower strengths)



Source: IMS NPA Audit



File Provided Natively

