

**File Provided Natively**



# Directors Meeting ACTIQ

December 2, 2004

# Agenda

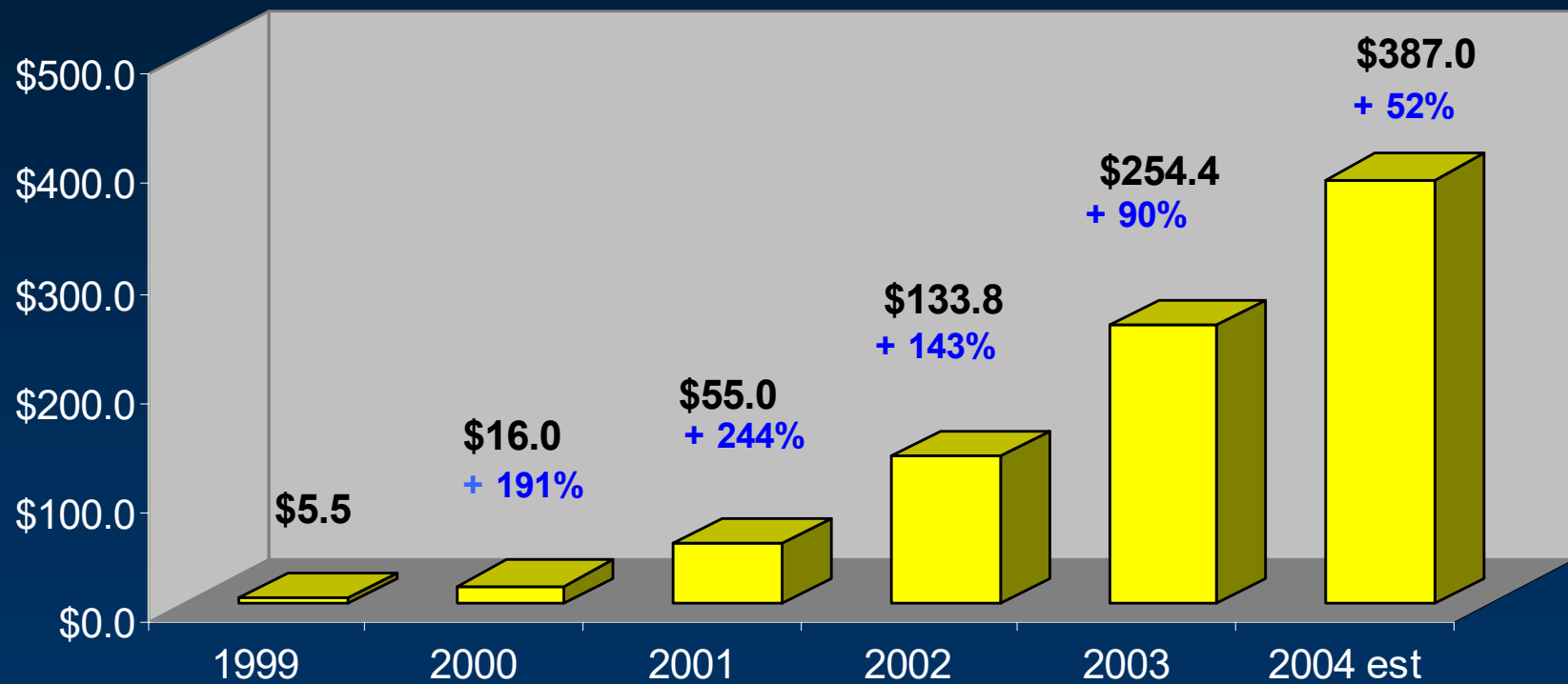
- 2004 ACTIQ Situation Analysis
  - Data trends
  - Current Challenges
  - Market Research Findings
- 2005 ACTIQ Marketing Plan
  - Key Issues and Strategies
  - Tactics

# ACTIQ 2004 Review

## Situation Analysis

- Primary ACTIQ 2004 marketing strategy
  - Raise awareness of BTCP and ACTIQ
  - Differentiate ACTIQ from its competitors by highlighting the primary product benefit: rapid onset of pain relief
- This strategy has not changed over the last several years and will again be the central focus in 2005

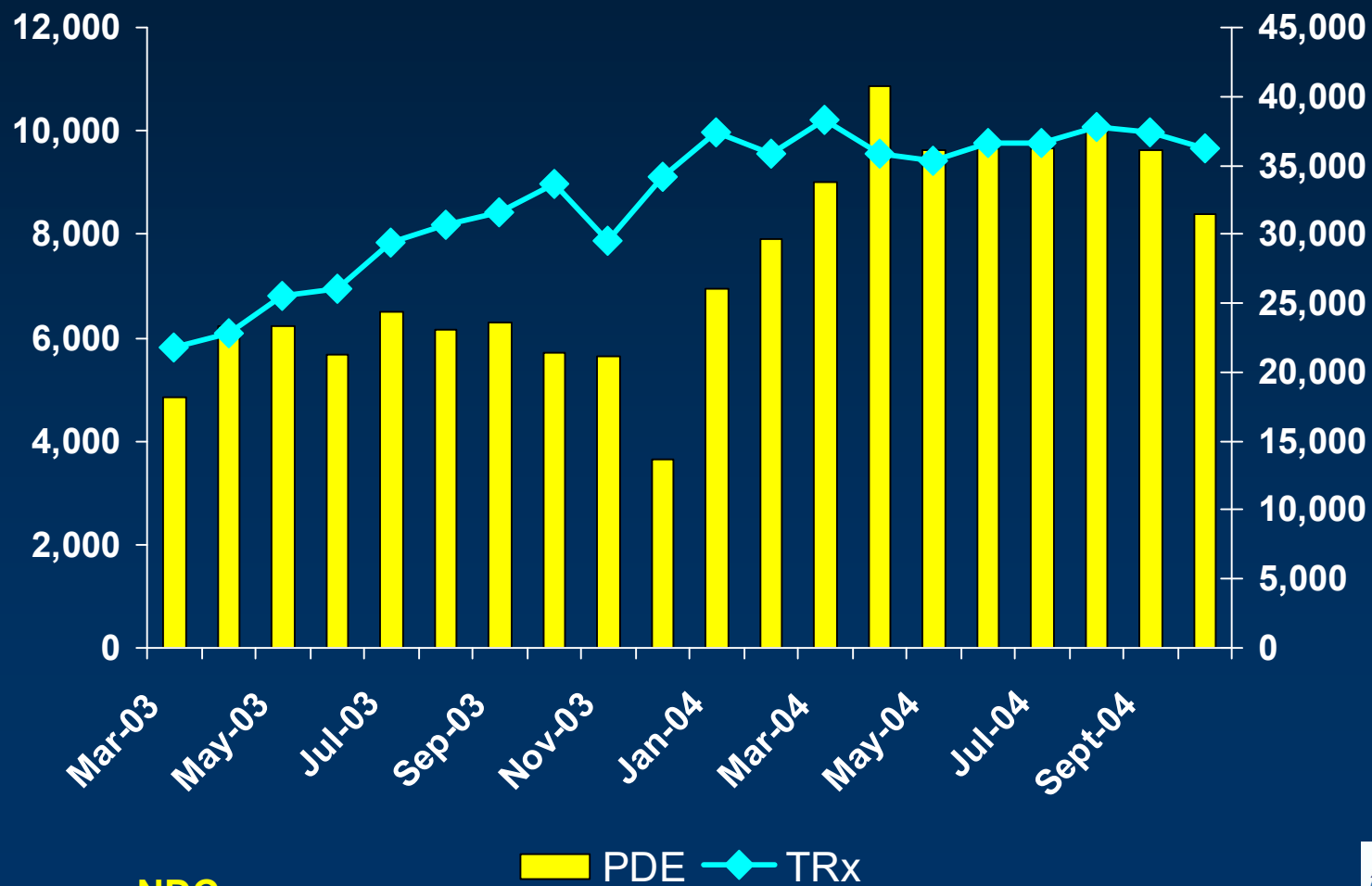
# ACTIQ Gross Shipments



Source: SPS

**Actiq®**  
(oral transmucosal  
fentanyl citrate)

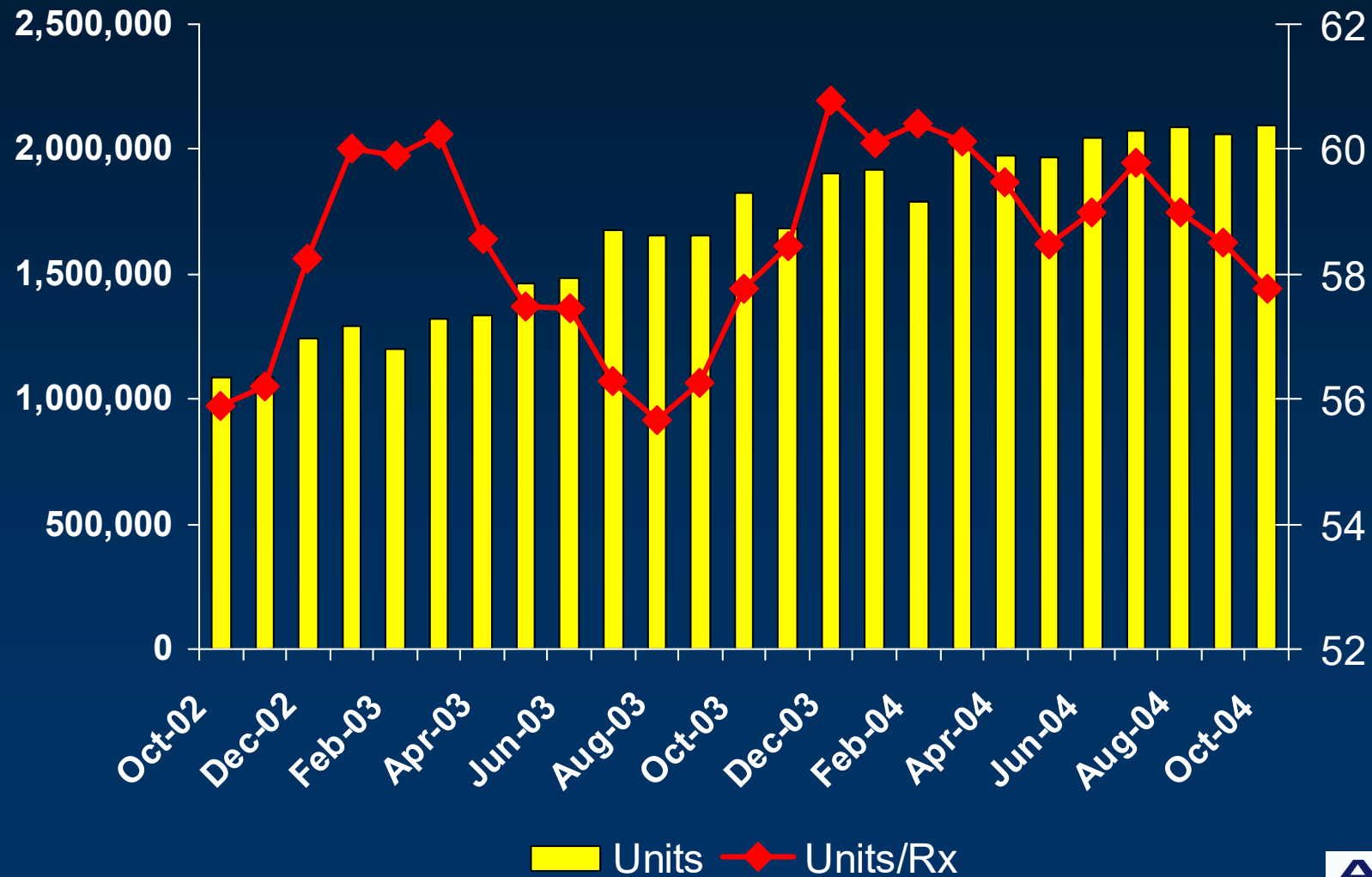
# Flat Monthly TRx Trend



Source: NDC

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

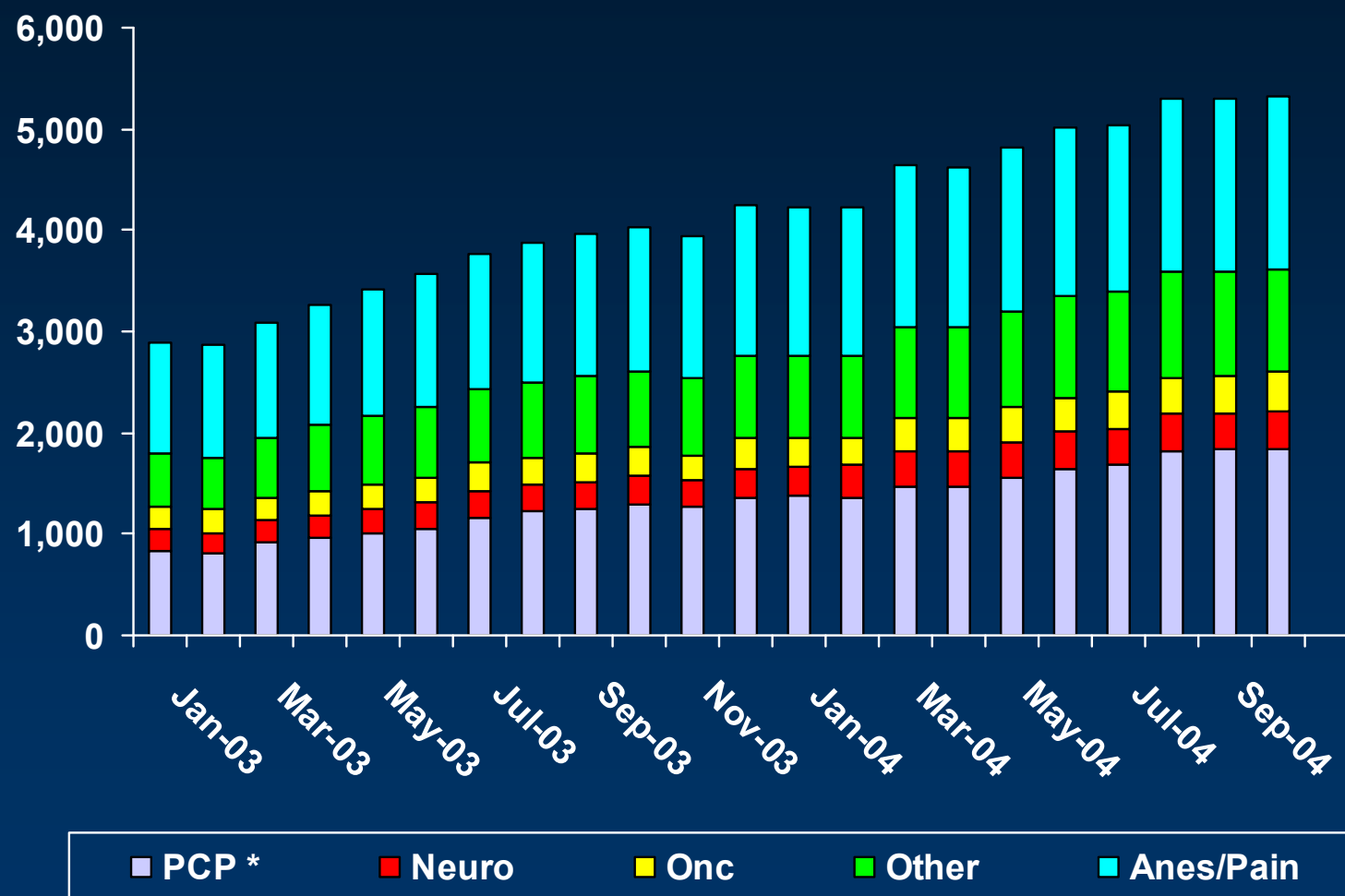
# Monthly Units & Units/Rx



Source: NDC

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# Monthly Prescriber Count by Specialty



Source: NDC

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)



# Actual Summary of Business

MAT Q2 2004

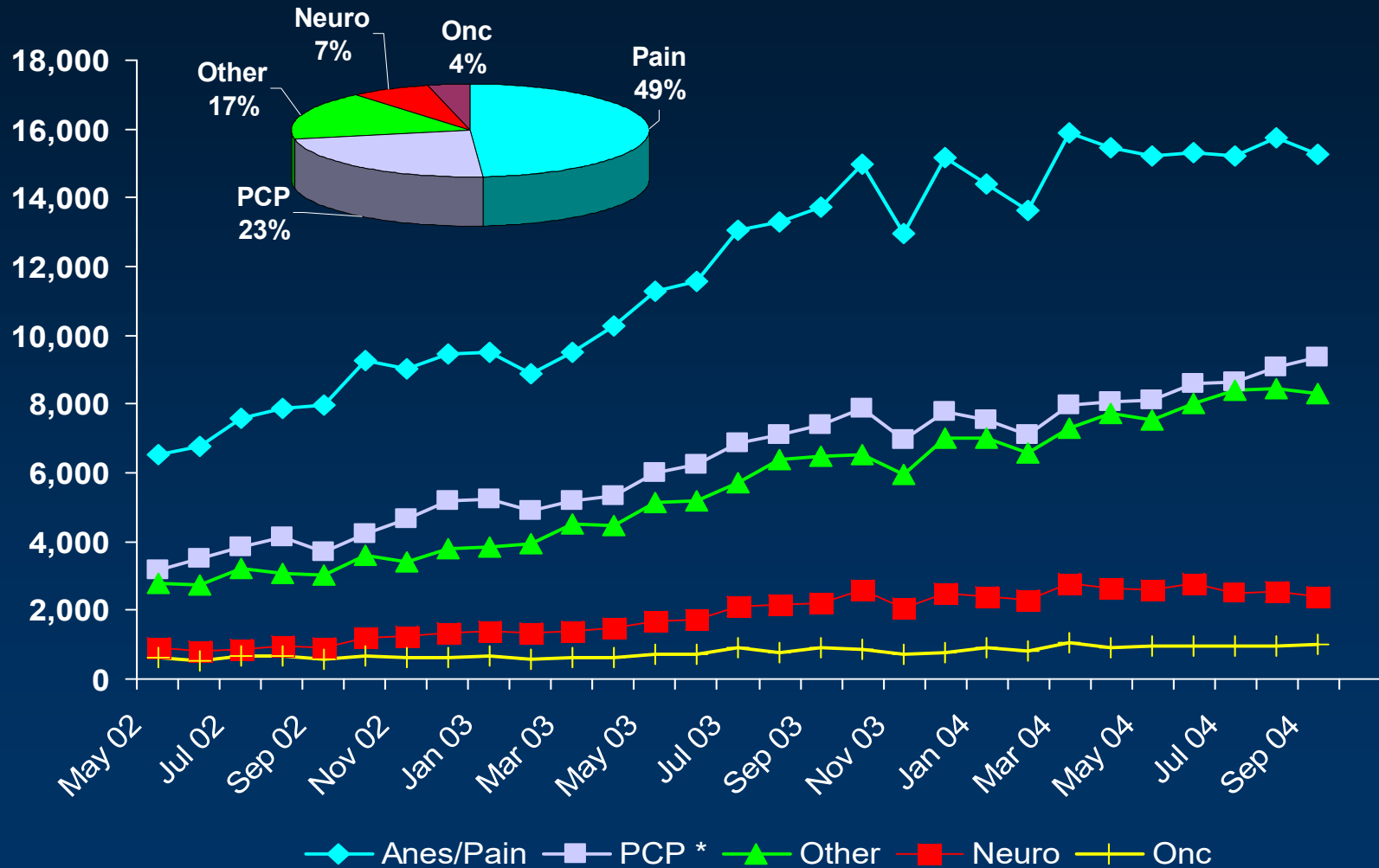
	<u>Rxers</u>	<u>TRx</u>	<u>Sales</u>
<b>Current</b> (beginning 7/02)	36% (47%)	85% (80%)	88% (83%)
<b>New</b> (beginning 7/03)	64% (53%)	15% (20%)	12% (17%)
<hr/>			
Anes/Pain	20% (11%)	51% (50%)	53% (51%)
PCP	38% (23%)	21% (19%)	17% (19%)

Source: IMS NPA

**Actiq®**  
(oral transmucosal  
fentanyl citrate)

# TRx Trend by Specialty

October TRx by Specialty



Source: NDC

**Actiq®**  
(oral transmucosal  
fentanyl citrate)

# Reimbursement Status

- ~90% of claims are being approved
- Majority of market (both commercial and medicaid) classify ACTIQ as a non-formulary reimbursed drug which has led to a higher co-pay status, prior authorizations (PA) and PDLs
  - Currently 16 states have incorporated a PA for ACTIQ
  - 2 States (CA and NY) account for ~30% of all Medicaid business nationally and CA has a PA in place
  - ACTIQ Prior Authorization criteria:
    - Approved within indication and requiring clinical data for uses outside of BTCP
    - One or two documented formulary agents used first
    - Quantity limits
- Many providers are limiting access to the opioid class in an attempt to reduce abuse and diversion

# Market Research Update

- “Egg” Research
- Segmentation research

# “Egg” Research

- Objective?
  - Talk to “good eggs” and “bad eggs” to identify barriers and drivers to ACTIQ usage
- Who?
  - Long-term writers who are writing more
  - Long-term writers who are writing less
  - Non-writer targets
  - New writers

# “Egg” Research

- Key Barriers to ACTIQ usage
  - reimbursement
  - concerns of abuse and addiction
- Key Drivers to ACTIQ usage
  - rapid onset of action
  - patient acceptance / satisfaction
  - low side effect profile

Attending Cephalon sponsored events is viewed as a valuable communication tool by users of the brand especially for the peer to peer communication.

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

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# “Egg” Research Quotes and Conclusions

“I like it a great deal, but insurance has limited us, they just deny it.”

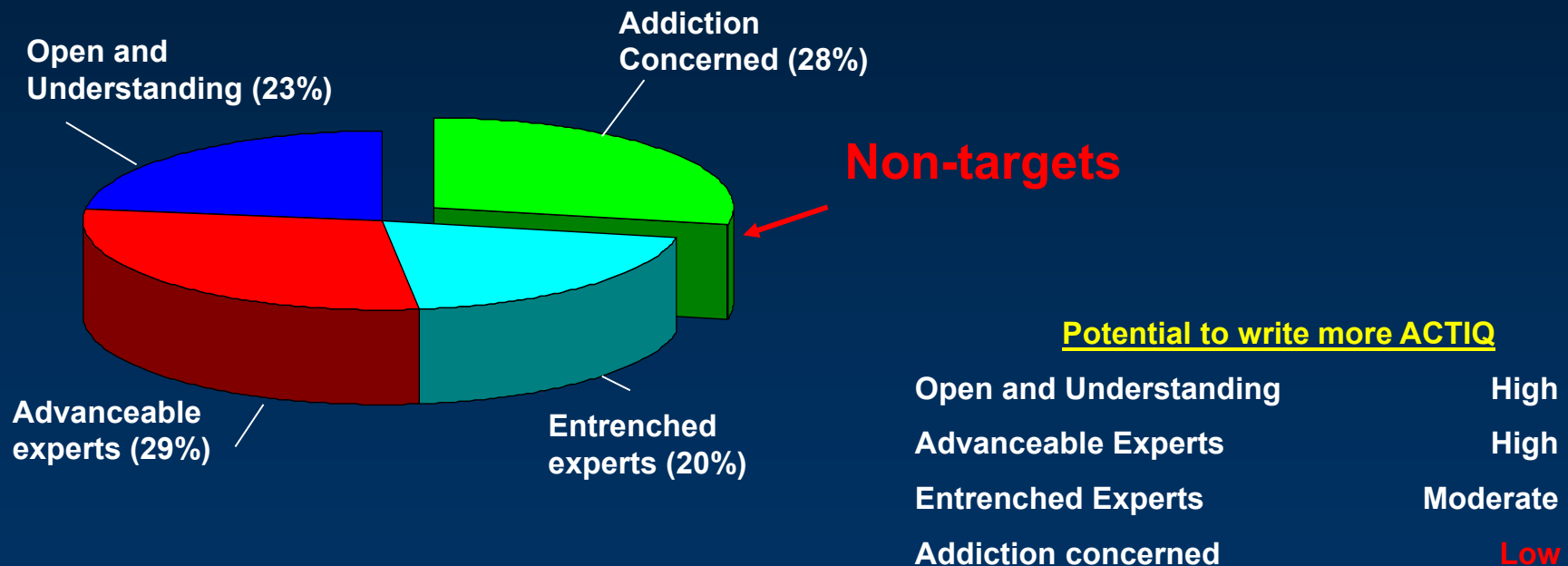
“It’s a great medication, its just too much of a burden to absorb the cost”

“All the insurance companies got the knee-jerk reaction to limit its usage”

- Key barriers across users and non-users are reimbursement and abuse/addiction.
- The most frequently mentioned barrier among those physicians prescribing less ACTIQ is cost/declining insurance coverage. They offered specific examples of insurance companies in their area that were severely restricting ACTIQ during the past year.

# Segmentation Study Results

Primary market research has combined opioid prescribing behavior with psychographic identification techniques to develop preliminary segments to focus 2005 sales targeting



Source: Ziment Research, September 2004

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(oral transmucosal  
fentanyl citrate)



# Segmentation Study Results

High level summary of opioid market segments

	Advanceable Experts	Entrenched Experts	Addiction Concerned	Open & Understanding
Physician Characteristics	<ul style="list-style-type: none"> <li>• Moderately sympathetic to pain patients</li> <li>• More apt to feel personally responsible pain mgt</li> </ul>	<ul style="list-style-type: none"> <li>• Strongest opinions about how they treat pain</li> <li>• Feel their protocols are best</li> </ul>	<ul style="list-style-type: none"> <li>• More concerned with addiction than other segments which drives lower usage of opioids</li> </ul>	<ul style="list-style-type: none"> <li>• Very sympathetic to patients in pain, but less involved in the treatment of pain</li> </ul>
Physician Behaviors	<ul style="list-style-type: none"> <li>• High SAO writers</li> <li>• High ACTIQ writers</li> </ul>	<ul style="list-style-type: none"> <li>• High SAO writers</li> <li>• High ACTIQ writers</li> </ul>	<ul style="list-style-type: none"> <li>• Low SAO writers</li> <li>• Low ACTIQ writers</li> </ul>	<ul style="list-style-type: none"> <li>• Low SAO writers</li> <li>• Low ACTIQ writers</li> </ul>
Most appealing ACTIQ message	Efficacy / Fast Onset of Action	Efficacy / Fast Onset of Action	Dosing / Form / Mechanism of action	Ease of dosing convenience
ACTIQ potential	High	Moderate	Low	High

**Remember: Our targets are all higher decile, skilled opioid prescribers**

Source: Ziment Research, September 2004



# Data & Research Interpretations

- Flat TRx trend possibly due to:
  - Decreased TRx growth among CURRENT prescribers
    - Primarily among pain/anes (high Rxers)
  - Higher growth of NEW prescribers
    - Especially among PCPs & Other
  - Increased reimbursement issues/hassles
  - Less than optimal targeting & communication of key messages

# 2004 Internal Challenges

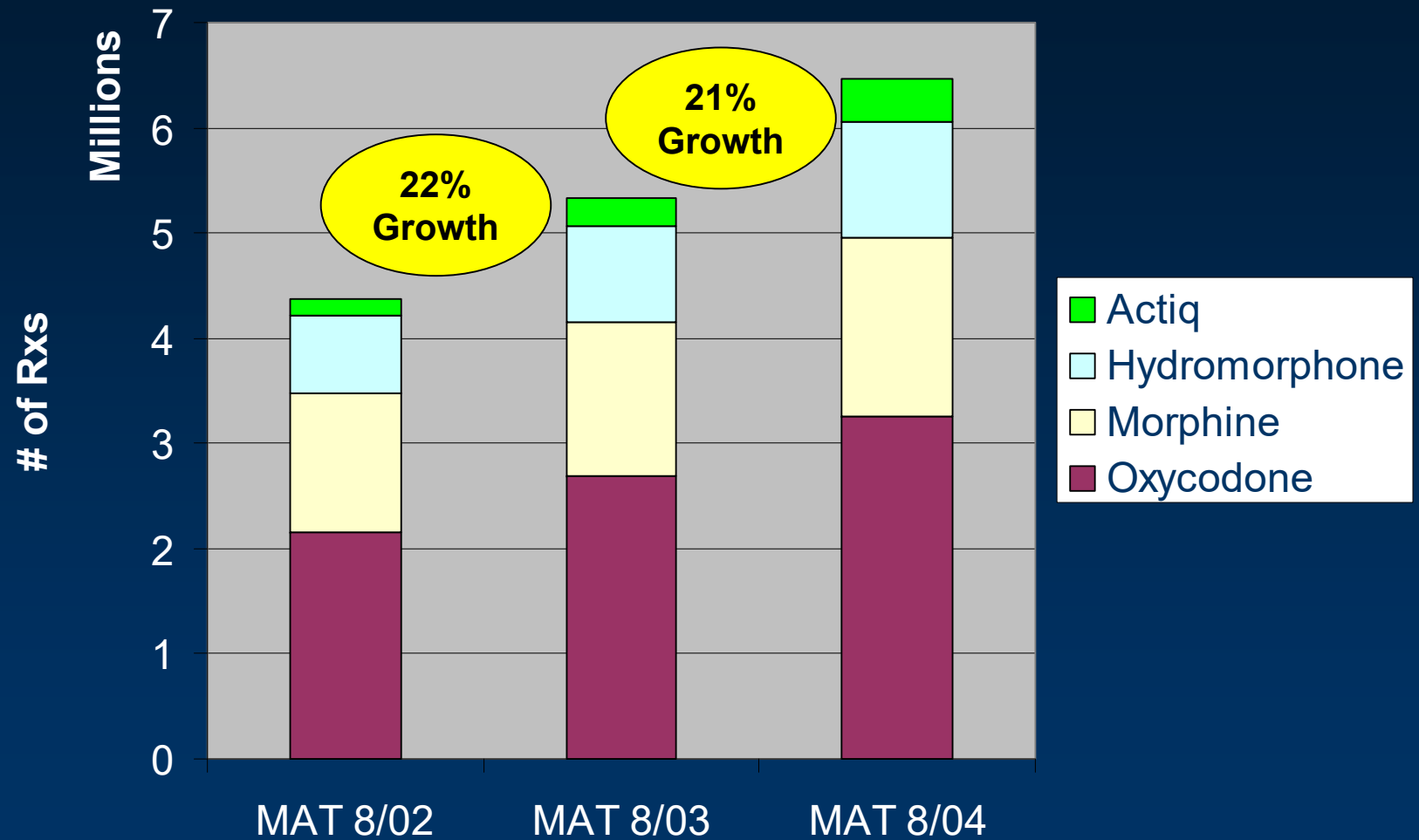
- Formulation change in Q3 2003
- Approximately 80% of current sales force new to ACTIQ/pain
- Competing demands on sales force time/effort
- Communication difficulties
- Market definition not uniform among departments
  - Generics not included in sales ops data

# 2004 External Challenges

- Increased media attention – Q2 2004
- Increased scrutiny from law enforcement and regulatory agencies
  - Meetings with states AG and FDA
- Difficult process for promotional materials development given FDA review & comment
  - Pulled ALL promo materials in August
- Growing “opiophobia”
  - Concerns of abuse/addiction/diversion
  - Concerns with increased prescriber scrutiny
- Increasing reimbursement barriers

# Market Dynamics & Competition

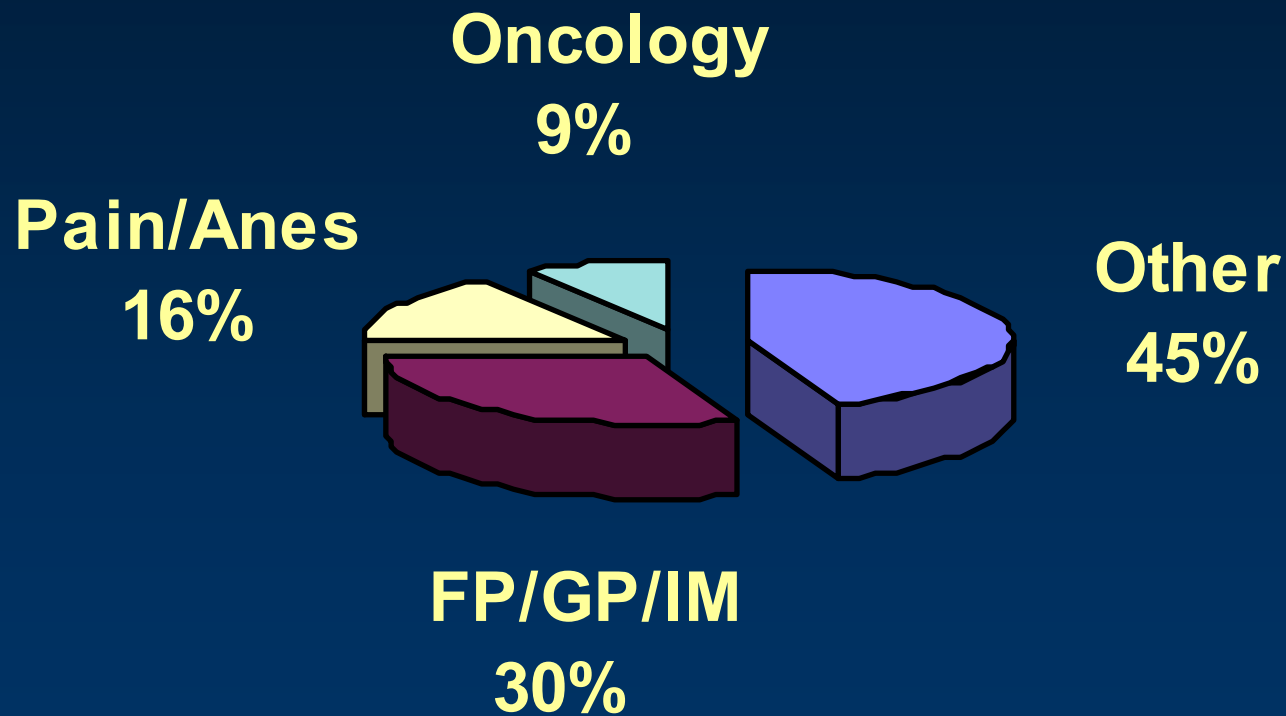
# Pure SAO TRx Market Growth



Source: IMS NPA

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(oral transmucosal  
fentanyl citrate)

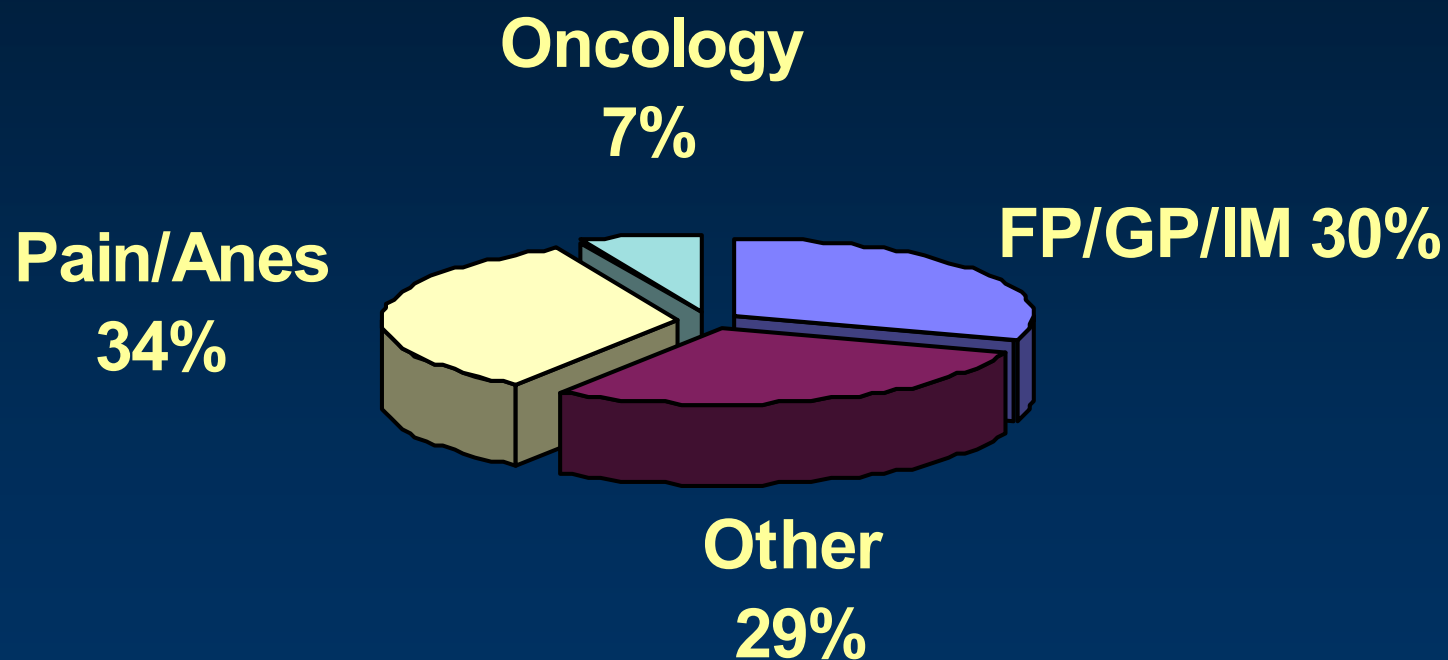
# Pure SAO TRx by Specialty



Source: IMS NPA

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)

# Pure SAO \$ Volume By Specialty



Source: IMS NPA

**Actiq<sup>®</sup>**  
(oral transmucosal  
fentanyl citrate)



## Key Issues

**Challenging sales  
process**



**Increasing  
reimbursement  
barriers**



**Opiophobia**



**Transition to SF  
formulation**



## Key Strategies

**Motivate & direct selling  
efforts**

**Develop tools &  
initiatives to overcome  
barriers**

**Launch *ESP***

**Utilize prior  
experience to  
ensure smooth  
transition**

## Other Issues

**Low awareness of BTCF  
& ACTIQ**



**Limited KOLs**



**Increased attention by  
media/regulatory/law  
enforcement with A,A,D**



**Limited clinical data and  
publications**



**Potential Branded  
Competitors in 2005/6**



## Strategies

**Educate targets about  
proper assessment & Tx**

**Establish ISCP and  
utilize IM2 dbase**

**Establish proactive  
responses to all groups  
concerned with A,A,D**

**Establish ISCP and  
support strategic  
decisions regarding IIS  
and publication efforts**

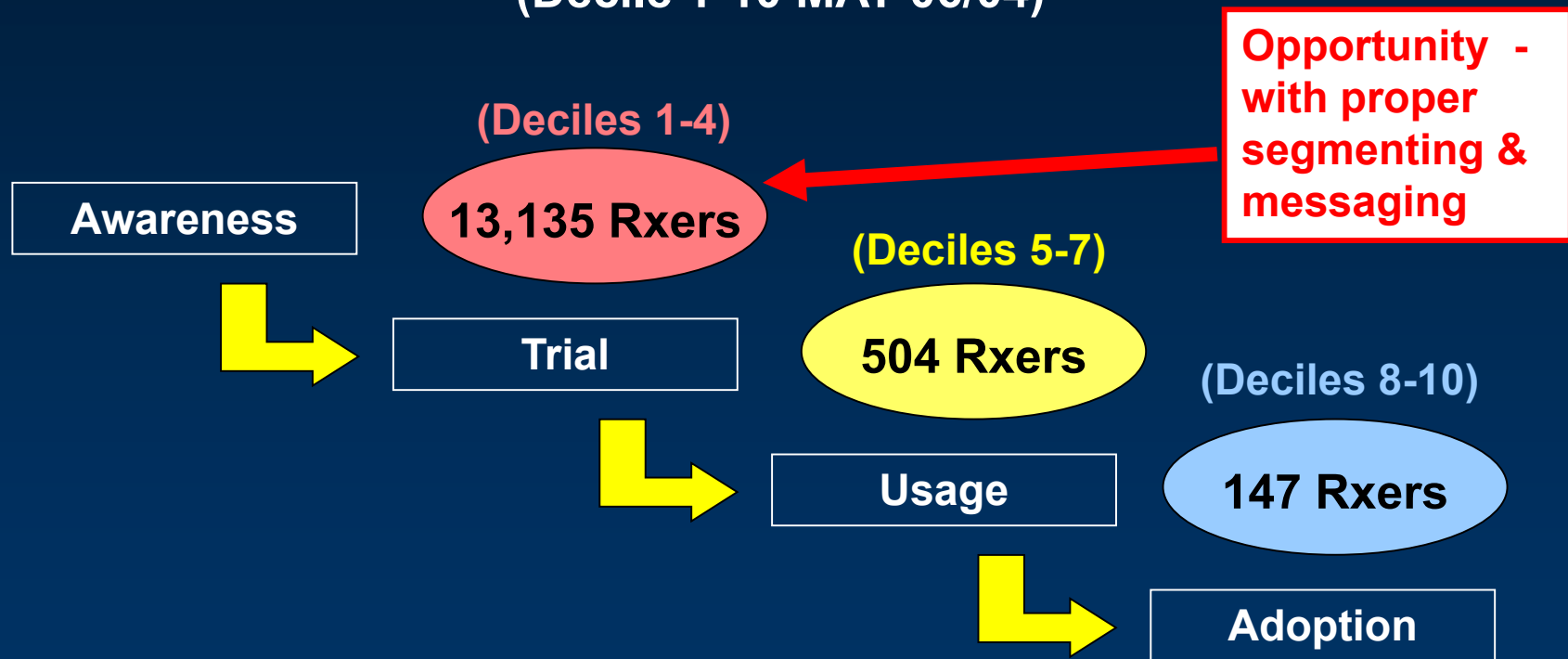
**Identify and proactively  
position ACTIQ to  
defend market share**

# 2005 Tactical Plan

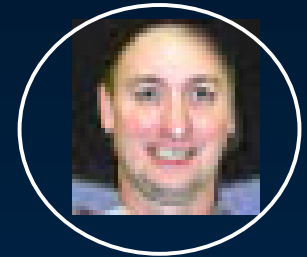
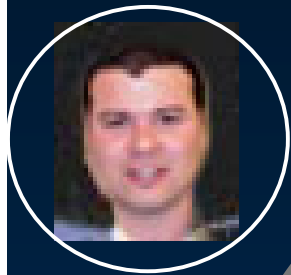
# Primary Marketing Objective

## *Product Adoption Curve*

13,786 Total ACTIQ Prescribers  
(Decile 1-10 MAT 06/04)



# Influencing Prescribers



**Actiq®**  
(oral transmucosal  
fentanyl citrate)

# 3 Pillars of 2005 Campaign

1. Targeting & Communication to Prescribers
  2. Reimbursement
  3. Abuse, Addiction and Diversion
- ACTIQ Sugar Free Launch Plan
  - Other Tactics

# 1. Targeting & Communication to Prescribers

# Targeting & Communication to Prescribers

Humanized Concept evolution – launched @ NSM



The advertisement features a central image of an ACTIQ unit (a small, round, metallic device) with a stethoscope around its neck. The unit is surrounded by a collage of black and white photographs showing various people in different settings: a woman in a hospital bed, a doctor, a group of people, a woman holding a cup, and others. The background is a light blue gradient.

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

**Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer. Because life-threatening hyperventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients.

*Actiq* is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

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

Please see boxed warning and brief summary of prescribing information on adjacent pages.  
For more information, please call Cephalon Professional Services at 1-800-896-5855.

**When onset matters... ACTIQ responds.**

The main benefit of ACTIQ is its time to onset of analgesia

- Within 15 minutes of starting medication, patients using ACTIQ rated their pain relief at 67% compared to 33% with their regular rescue medication (N=62). Full relief may not be experienced for up to 45 minutes after finishing an ACTIQ unit<sup>1</sup>
- 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- to 5-minute half-life<sup>2</sup>
- The unique oral transmucosal delivery system (OTSM<sup>TM</sup>) allows fentanyl to rapidly dissolve into the highly permeable and well-vascularized oral mucosa<sup>2</sup>
- Longer or shorter consumption times than the recommended 15 minutes may produce less efficacy than reported in clinical trials<sup>2</sup>

**Safety**

- Established in opioid tolerant patients receiving both long-acting oral and transdermal opioids<sup>2</sup>
- The most common side effects observed in ACTIQ clinical trials were somnolence, nausea, vomiting, and dizziness<sup>2</sup>
- Over 48 million units have been prescribed<sup>2</sup>

**Portability and convenience**

- Patients can use ACTIQ anywhere without water as soon as they begin to feel breakthrough cancer pain

**Relief at hand**

**Actiq<sup>®</sup>**  
(oral transmucosal fentanyl citrate)



# Targeting & Communication to Prescribers (cont'd)

- New sales aids
  - Update all existing sales aids with new concept (3/05)
  - Additional Sales Aids
    - Core sales aid
      - Improved and includes a pathophysiology of pain section
      - Will include an annotated sales aid for training purposes
    - Pharmacokinetic sales aid
      - PK of fentanyl
    - Patient Profiles
      - Case studies of various pain types in CA patients
    - BTP assessment tool & poster
    - New patient use video – DVD/VHS, Spanish & English

# Targeting & Communication to Prescribers (cont'd)

- Uniform Market Definitions
  - Definitions aligned between sales ops & marketing
  - Effective December 2004 (October 2004 data month), sales ops data for the opioid market will incorporate the generic opioids Hydrocodone, Hydromorphone, Oxycodone & Morphine Sulfate
  - As a result, the opioid Market will be restructured into the following three categories:
    - **Pure Short Acting Opioids:** Actiq, Dilaudid, Hydromorphone, Roxanol, MSIR, Short Acting Morphine, Oxy IR, Oxyfast, Roxicodone & Oxycodone HCL
    - **Combination Short Acting Opioids:** Hydrocodone & Oxycodone Combos (Percocet is now in this category with all combos)
    - **Long Acting Opioids:** Duragesic, Oxycontin, MS Contin, Oramorph, Kadian, Avinza, LA Oxycodone, Palladone & LA Morphine
  - We anticipate identifying a greater number of opioid skilled prescribers

# Targeting & Communication to Prescribers (cont'd)

- Segmentation research
  - 410 total physicians drawn from Cephalon list of D3-10 SAO writers
  - 4 attitudinal segments identified
    - Advanceable Experts, Open and Understanding, Entrenched Experts, Addiction Concerned
  - Next step – tie to prescribing level and label in call file
    - A and B targets plus an additional behavior tag (1-4)
    - Create training piece (“cheat sheet”) for reps defining behavior segments and appropriate message
    - Expected 70% accuracy (based on vendor experience)
  - Implementation of results – pilot with 4 areas/regions in Jan 2005 (may expand to include all regions)
  - Roll-out at NSM (based on pilot)

# Targeting & Communication to Prescribers (cont'd)

- **MEP \$\$**
  - \$5 MM allocated for 2005 ACTIQ MEPs (less 20+% management fees)
    - vs. \$4.7 MM in 2004
  - About 6 MEPs per TSS (@ \$1400/MEP average)
  - About 10 MEPs per NAM and MDM
  - Teleconference ability still available
- **MEP Invitations/Topics**
  - “Assessment & Management of BTCP”
  - “ACTIQ Pharmacology” *Added Q4 2004*
  - “Pharmacologic Management of Cancer Pain” *Added Q4 2004*
- **Coupon allocation**
  - Coupons allocated to managers
  - 90,000 books for 2005 (500/manager/quarter)

# Targeting & Communication to Prescribers (cont'd)

- 2005 NSM
  - Teaser mailed to sales force before NSM
  - 90 minutes general session – all marketing updates
  - Sales training workshop – mock sales call utilizing segments and new detail aids
  - *Emerging Solutions in Pain* (ESP) rollout
  - Managers to provide info @ area breakouts on:
    - ACTIQ Sugar Free launch plan
    - New reimbursement services
    - Marketing will provide slides with notes to AMs & review at Feb 2005 managers meeting

## 2. Reimbursement

# Reimbursement Tactics

- Jan 2005 NAM Training
- Jan 2005 Managed Care Consultant Meeting
- MCO Dossier (completed in 2004)
  - MCO Dossier Slide Kit
- Supported TJU on BTP Guidelines through grant
  - To be published in March, *P&T*
- Reimbursement Hotline Expansion (Covance)
  - Sales aid, magnet & rolodex card, direct mail campaign
  - New LMNs developed by Professional Services
- WLF – Burton paper (?)
- Considering other outcomes/PE proposals
  - Will work closely with NAMs, Health Economics Dept (Ed Wang) & possibly expert consultants to establish plan

# 3. Abuse, Addiction, Diversion



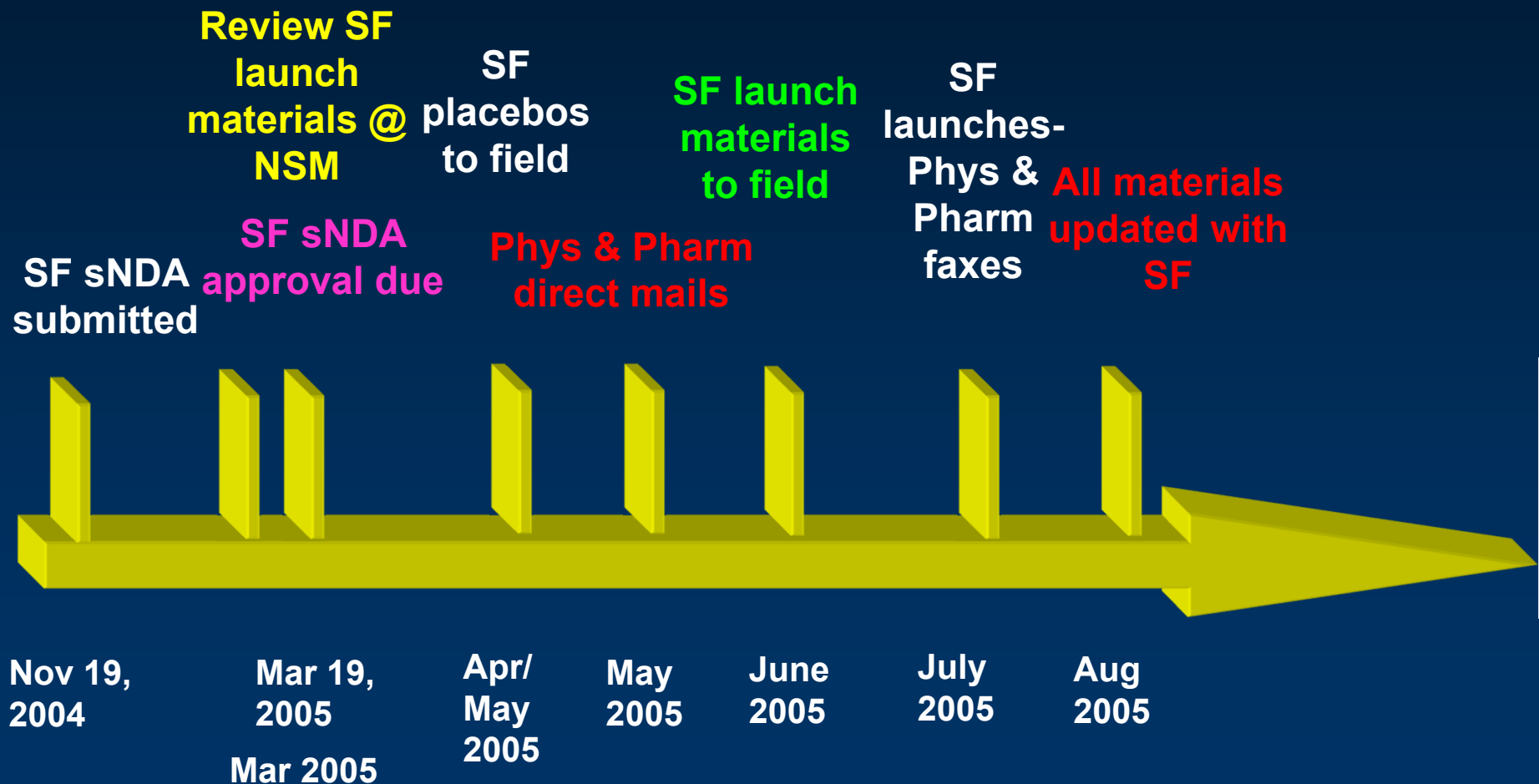
# 3. Abuse, Addiction & Diversion Tactics

- RMP sales aid
  - Flashcard to detail positives of RMP to increase comfort level of Rxing ACTIQ
- Local CME Dinner meetings
  - “Abuse, Addiction, & Diversion” topic
  - TT to cover details
- *Emerging Solutions in Pain* (ESP)
  - TT to cover details

# ACTIQ Sugar Free Launch

# Timeline of Sugar Free Plan

*Launch planned for July 1, 2005*



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fentanyl citrate)

# Other Tactics

# Other tactics

- Journal Ads
- Convention Presence (Pharmacy presence & possible PriMed symposia)
- Reprints
- E-detailing (marketing driven promotion)
  - Supplement direct selling
- PR
  - sales force communication
  - Safety update and FAQ (from sales training)
  - Training internal and external spokespersons
- Advisory panels
- Consultant meetings
- Speaker Training
  - Promo slide kit
- Medical education

# TT's Tactics

# Agenda

- Emerging Solutions in Pain (ESP) Initiative
  - Mission Statement & Objectives
  - Strategies
  - Tactics
- Medical Education Programs
  - Medicom CEP 252 Dinner Meetings
  - AAPM Symposia
  - APS Symposia
  - Websites
  - TJU BTP Guidelines
- Consultant Meeting Plan
- Speaker Training Plan and Update

# ESP Objectives

*We've taught physicians the benefits of opioids and how to prescribe them, but neglected to adequately teach them about the risks.*

**- Russell K. Portenoy**

- Broad-based
- Branded
- Awareness
- Education
- Improve Practice Management for Practitioners
- Minimize the risks of prescribing and dispensing opioids for physicians, pharmacists and patients
- Ensure that pain is identified and treated appropriately
- Enhance Cephalon image as a Leader in Pain Management



# ESP Mission Statement

- ***Emerging Solutions in Pain (ESP)*** is an ongoing initiative that is being developed by physicians for physicians, pharmacists and other healthcare professionals, to address some of the most critical issues in pain management today. These issues involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. Through the expertise of a cadre of leading pain and addiction medicine experts, the **ESP** program will provide clinicians with guidance in the implementation of good practice management techniques, emphasizing favorable interaction with regulatory and law enforcement agencies, as well as, effective assessment, monitoring and documentation strategies, which will contribute to the overall goal of optimizing outcomes for their pain patients. **ESP is a branded educational initiative supported by Cephalon, Inc and the Pain Franchise through an unrestricted educational grant.**

# Project Overview

- Ongoing Initiative
- Previously named *“Reduce the Risk”*
  - Originally focused on minimizing diversion and abuse
  - Tool Kit to help assess and manage risk
- *Emerging Solutions in Pain (ESP)*
  - Proposed as a broad-based “educational” initiative
  - Supported through an unrestricted educational grant by Cephalon & the Pain Franchise
  - Risk Minimization is an integral and core component of ESP

# Situational Analysis - External

**Market  
Overview**

**Target  
Audiences**

**Unmet  
Medical  
Needs**

**Environment**

**Identify and define Opportunities and Threats**

# Situational Analysis - External

## Market Overview

- Pain is a large, growing market
- Huge unmet medical needs
- H.R. 3244 passed in October 2000, declares 2001 – 2010 as the “Decade of Pain Control and Research”
- JCAHO requires initial and ongoing pain assessment for all patients – “Pain is the 5<sup>th</sup> Vital Sign”
- An imbalance exists between the need for pain control and the risks of abuse and diversion

# Situational Analysis - External

**Market  
Overview**

**Target  
Audiences**

- Anesthesiologists / Pain Specialists
- Oncologists
- Physical Medicine & Rehabilitation
- Primary Care Practitioners skilled in the use of opioids
- Neurologists
- Psychiatrists
- Addictionologists
- Pharmacists
- Regulators
- Patients

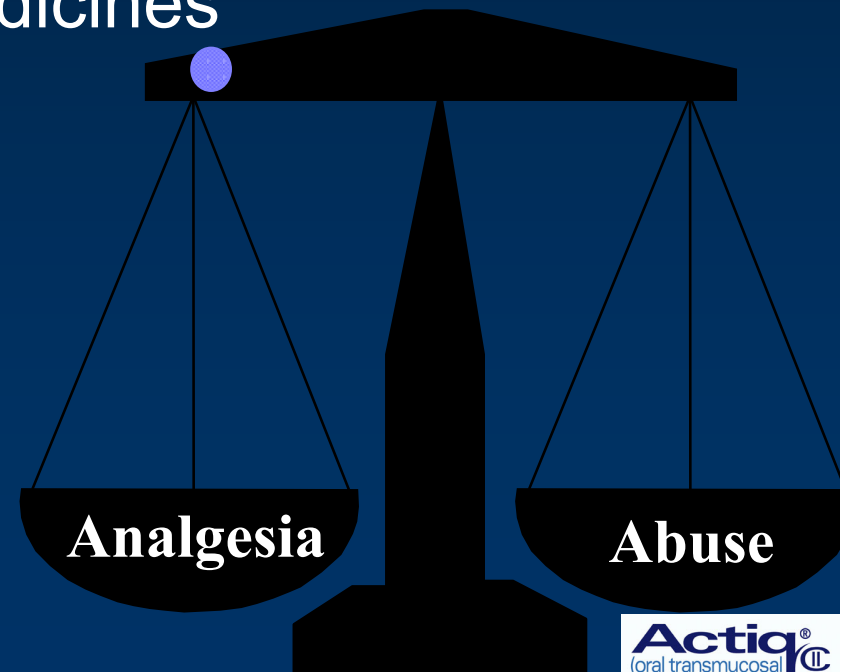
# Situational Analysis - External

Market  
Overview

Target  
Audiences

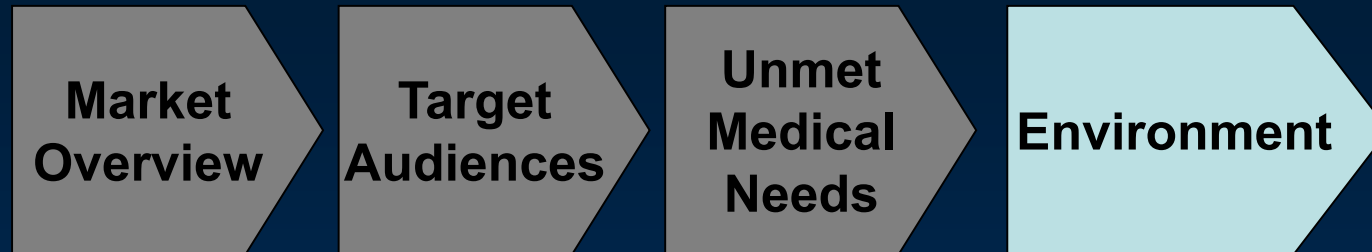
Unmet  
Medical  
Needs

- Chronic pain exists, despite long-standing availability of suitable medicines
- Need for Proper Balance



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# Situational Analysis - External



- Companies marketing pain products all have 'Branded' educational programs
  - Purdue Pharma: 'Partners Against Pain' (PAP)
  - Janssen: 'National Pain Education Council' (NPEC)
  - Endo: 'National Initiative on Pain Control' (NIPC) & PainEDU.org by Inflexxion, Inc.
  - Medtronic: support of 'Tamethepain.com' by WebMD



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## Welcome

Partners Against Pain is an alliance of patients, caregivers, and healthcare providers working together to alleviate unnecessary suffering by leading efforts to advance standards of pain care through education and advocacy.

### Pain & Cancer *A Fact Sheet from the Intercultural Cancer Council*

The Intercultural Cancer Council (ICC) has created a series of Cancer Fact Sheets focusing on medically underserved populations, such as racial and ethnic minorities, who experience disproportionately greater suffering and compromised health from cancer compared to the U.S. population as a whole.

[Read More...](#)



In the Face of Pain  
Pain Management Advocacy Toolkit

**REUTERS**  
HEALTH INFORMATION

[Arthritis News](#)  
[Backache News](#)

[Neurology News](#)  
[Pain News](#)

## Accessibility

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## Pain Management Kit

**Partners Against Pain®**  
Pain Management Kit

Tools for Healthcare  
Professionals

- Pain Assessment Forms  
& Scales

- Consent & Treatment  
Forms

- Pain Diaries
- Clinical Follow-up
- Drug Abuse Screening  
Tools

- Reference Papers and  
Definitions

[More](#)

## CME

**AMA Releases Online  
Pain Management CME  
Program**

- Pain Management: The  
Online Series

[More](#)





NATIONAL PAIN EDUCATION COUNCIL



About NPEC

Meet the Faculty

Pain Assessment and Documentation Tool **NEW**

Faces of Pain

Pathophysiology of Pain Video **NEW**

Gait Analysis Video **NEW**

Low Back Pain Assessment Video **NEW**

CME Online **NEW**

CasesToGo™ **NEW**

NPEC Slide Library

NPEC JournalToGo

Pain References & Links

Pain Glossary

Clinical Toolbox

For the Pharmacist

#### CURRENT FEATURES

##### CLINICAL TOOLBOX



Find everything from pain assessment forms to prescribing information for various pain medications



##### JOURNAL TO GO



A database of regularly updated references in the field of pain management



##### QUESTION POLL



Please take a moment to fill out our online survey



#### LEADING THOUGHTS ON PAIN

"It was as if a tangle of tiny nerves were being cut dexterously, one by one.... The pain was a pyramid made of a diamond; it was an intense light; it was an intense light; it was the hottest fire, the coldest chill, the highest peak, the fastest force, the furthest reach, the newest time."

- Jean Stafford (1953)

#### EMAIL A COLLEAGUE

#### NPEC PRESS KIT

Download the latest NPEC Press Kit. Click [Here](#) (1.8megs PDF).

## PAIN MANAGEMENT RESOURCES FOR YOUR DAILY PRACTICE

Learn about three resources that could enhance your approach to care. From cognitive therapy with the chronic pain patient to the elderly struggling with persistent pain, these resources are a great way to improve your knowledge of pain assessment and treatment. [GO](#)

### CLINICAL ROUNDTABLE

LEARN HOW PAIN MANAGEMENT EXPERTS HANDLE CRITICAL PAIN ISSUES WITH THEIR PATIENTS.

### IN THE SPOTLIGHT

READ OUR MONTHLY INTERVIEWS WITH LEADERS IN THE PAIN MANAGEMENT FIELD.

### BOOK REVIEW

CHECK-OUT EXPERT REVIEWS ON PAIN MANAGEMENT BOOKS FOR PATIENTS.

### NIPC



NIPC™ has developed educational resources ranging from physician tools, downloadable slides, and web-based / live CME activities for clinicians.

[Click for more](#)

### SOAPP



Concerned about prescribing opioids? Find out more about the Screener and Opioid Assessment for Patients with Pain.

[Click for more](#)

### PAINEDU COURSE



#### Online Interactive Course

This interactive, pain management course is designed for:

- ✓ Physicians
- ✓ Nurses
- ✓ Pharmacists
- ✓ Psychologists

Earn **NO COST** continuing education credits right now! [GO](#)

#### ACCREDITING AGENCIES



### CLINICIAN MANUAL



#### The PainEDU.org Manual: A Clinical Companion

Enhance patient care with this no-cost comprehensive pain management resource.

- ✓ Based on latest pain management research
- ✓ Includes medication information
- ✓ Details treatment options
- ✓ Can be used as a staff training tool

[Click here to order or download, it's FREE!](#)



## Join Medtronic's Effort to Tame the Pain<sup>SM</sup>

**Welcome to Tame the Pain<sup>SM</sup>!** If you're interested in learning how to step away from pain, you have come to the right place. Our goal is to provide an easy way for people to receive helpful information about chronic pain treatment options. Tame the Pain<sup>SM</sup> is brought to you by Medtronic, a global leader in medical technology.

**There is no cost for joining this program.** If you choose to join, you will receive:

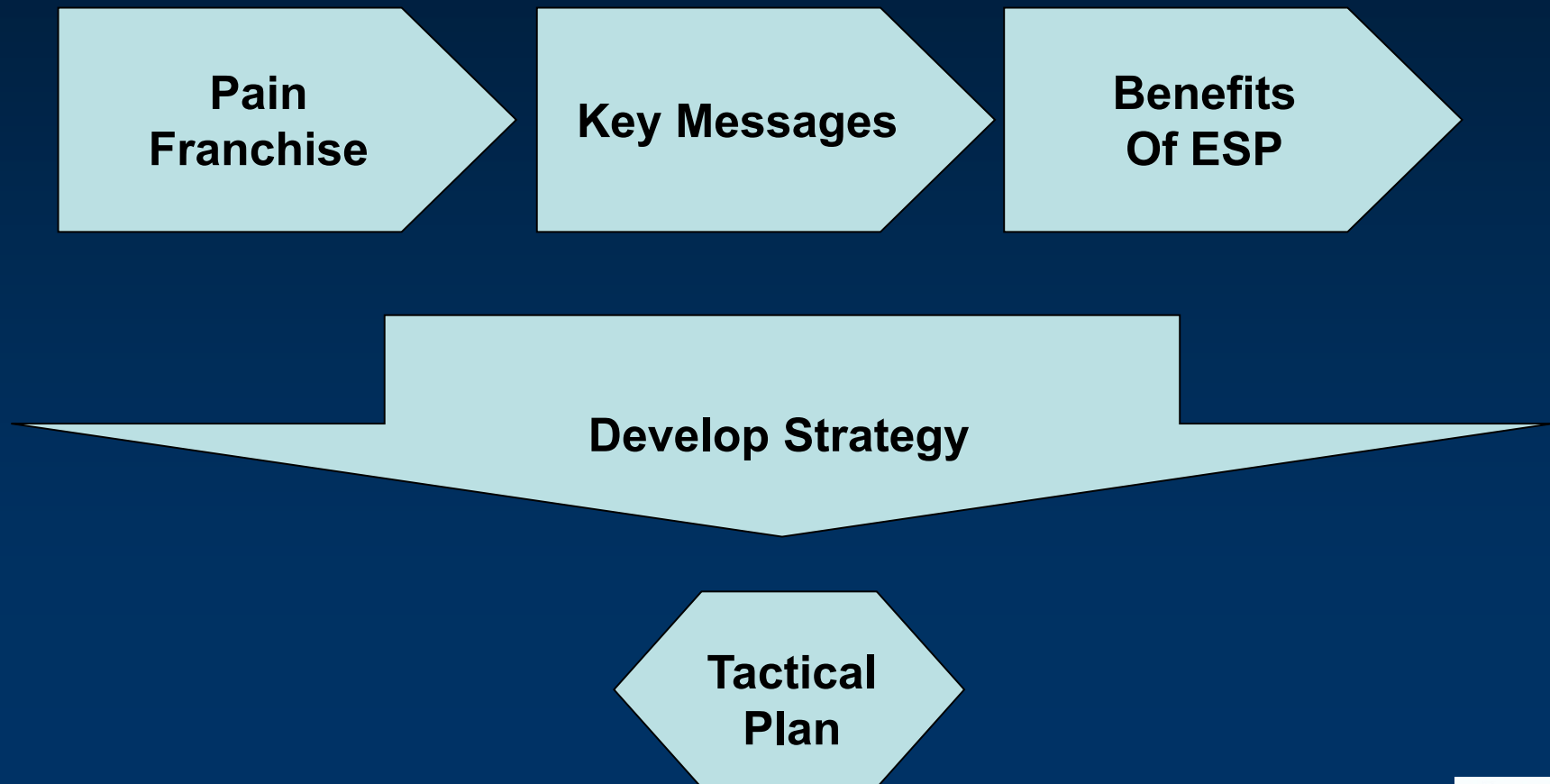
- A welcome package containing useful information, a video describing chronic pain treatment options, and a journal to record your day-to-day experience with pain so you can recall important information when visiting your doctor.
- Access to a website that connects you to treatment information, stories of people with chronic pain who have found relief, and contact information for pain management specialists who, collectively, have already helped thousands.
- Valuable information from leading pain management specialists who offer an array of treatments.
- Opportunities to hear from people who have won their battle with chronic pain.

If Tame the Pain<sup>SM</sup> sounds like it's for you, simply click on the box below and provide the information requested. [Click here to view our privacy statement.](#)

- ☐ **Yes**, I wish to receive information from Tame the Pain<sup>SM</sup> including a Welcome Package, access to a website containing pain management information, messages from leading pain management specialists and stories about people who have found relief from chronic pain.



# Situational Analysis - Internal



# Situational Analysis - Internal

## Pain Franchise

- Low awareness of chronic pain and breakthrough pain
- Low awareness of treatment strategies
- Limited evidence-based medicine
- Physician fear of prescribing opioids ('Opiophobia')
- Low presence of Cephalon in the pain community

# Situational Analysis - Internal

**Pain  
Franchise**

**Key  
Messages**

- Promote proper balance of pain control and abuse/diversion minimization
  - Reduce the risk to the patient - improve patient care
  - Reduce the risk to public health through minimization of diversion
  - Reduce the risk to the physician - protect the practices of those clinicians actively involved in pain management
- Facilitate practice management of pain

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(oral transmucosal  
fentanyl citrate)

# Situational Analysis - Internal

**Pain  
Franchise**

**Key  
Messages**

**Benefits  
Of ESP**

- Help differentiate Cephalon from other pain company initiatives
- Demonstrate partnership with the pain community
- Enhance relationships with KOLs
- Improve pain patient's QoL and reduce burden-of-illness
- Enhance Cephalon RMP activities; aid in minimizing corporate risk
- Improve corporate image
- Additional resource to complement sales force efforts

# Strategic and Tactical Recommendations



# Strategic Recommendations

- Enhance clinicians ability to treat chronic pain appropriately
- Improve relationships between pain practitioners and pharmacists/nurses
- Improve pain practitioners ability to stratify (based on risk) and manage pain patients optimally
  - Appropriate assessment and monitoring of pain patients based on risk
  - Referral of patients to a specialist
- Increase awareness of chronic and breakthrough pain
- **Ensure proper balance of pain control and abuse/diversion minimization**
  - How to address regulatory scrutiny
  - Which tools to use to detect addiction, abuse and diversion

# Tactical Recommendations

- Development of ESP Toolkit in CD-ROM format
  - Foundation of the key strategy
- Relaunch of new ESP website
- Development of “Meet the ESP Experts” booth
- ESP Slim Jims with mini disc
- ESP “Universal Precautions” Sales Aid
- Published white paper from ESP faculty meeting in NYC
- Case studies and direct mail monograph
- Downloadable power point slide sets from website
- Multimedia CD-ROM
- Medical Education Forums
- Media/Public Relations

# Tactical Recommendations

Strategy: Ensure proper balance of pain control and abuse/diversion minimization

- Develop and distribute ESP toolkit (*Launch at AAPM*)
  - Module One: Risk Assessment
  - Module Two: Patient Monitoring and Chart Documentation
  - Module Three: Practice Management

# ESP Summary

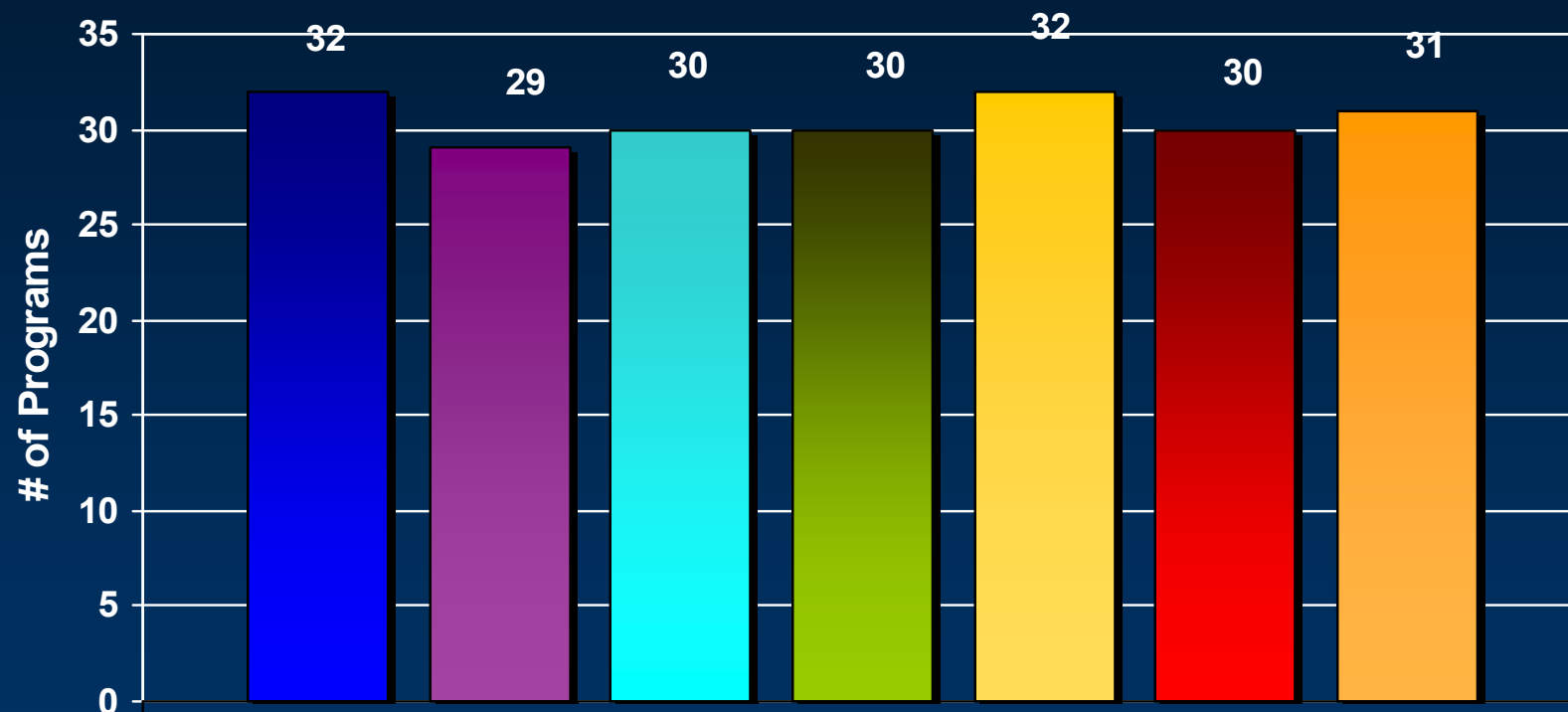
- Launching initiative at AAPM in February and at NSM
  - Toolkit and “Meet the Experts” booth
- Sales Force Involvement:
  - Disseminate ESP slim jim with mini disc to acquire toolkit
  - Potential recruitment efforts for RESPECT meetings
  - Potential development of “Universal Precautions” sales aid to help clinicians “protect their practices”

# Medical Education Programs

# Medicom 2004 CEP Dinner Meetings Series

# Clinical Experts in Pain Dinner Series

Regional Analysis (March – December 2004)



Programs Completed  
214 Completed Programs

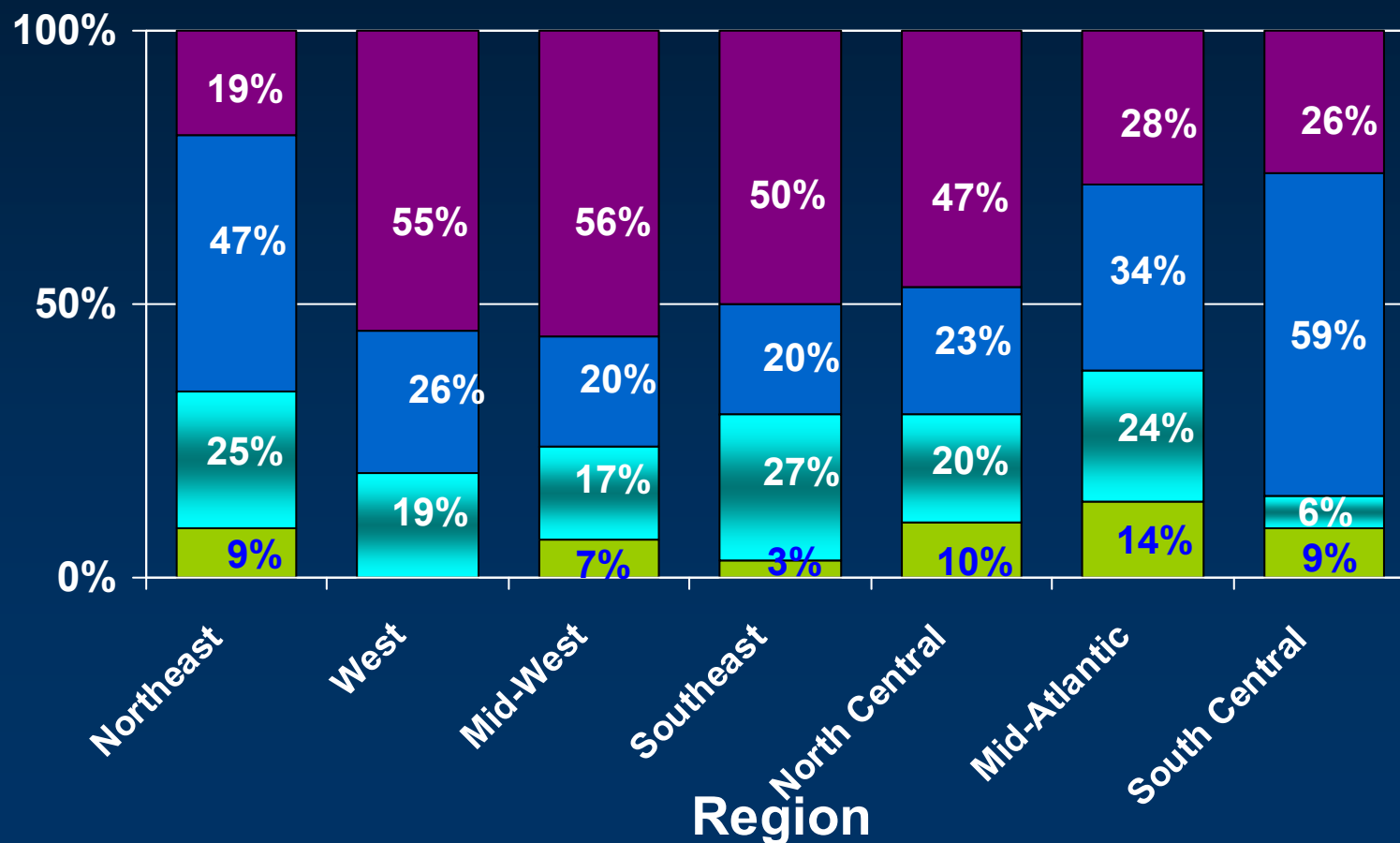
■ Northeast ■ Mid-Atlantic ■ Southeast ■ Mid-West ■ South Central ■ North Central ■ West

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# Clinical Experts in Pain Dinner Series

Regional Analysis by Program (March – December 2004)

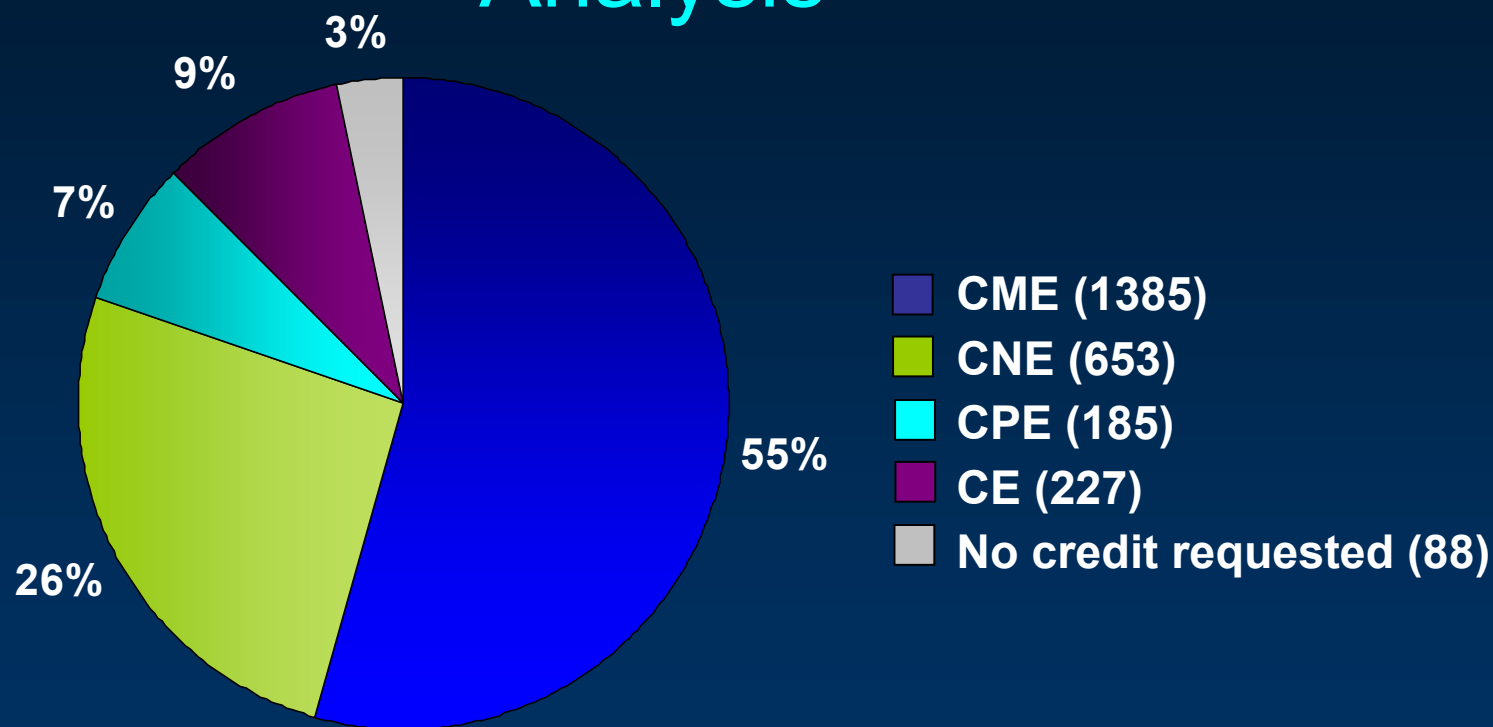
■ Musculoskeletal ■ Breakthrough ■ Chronic ■ Substance Abuse



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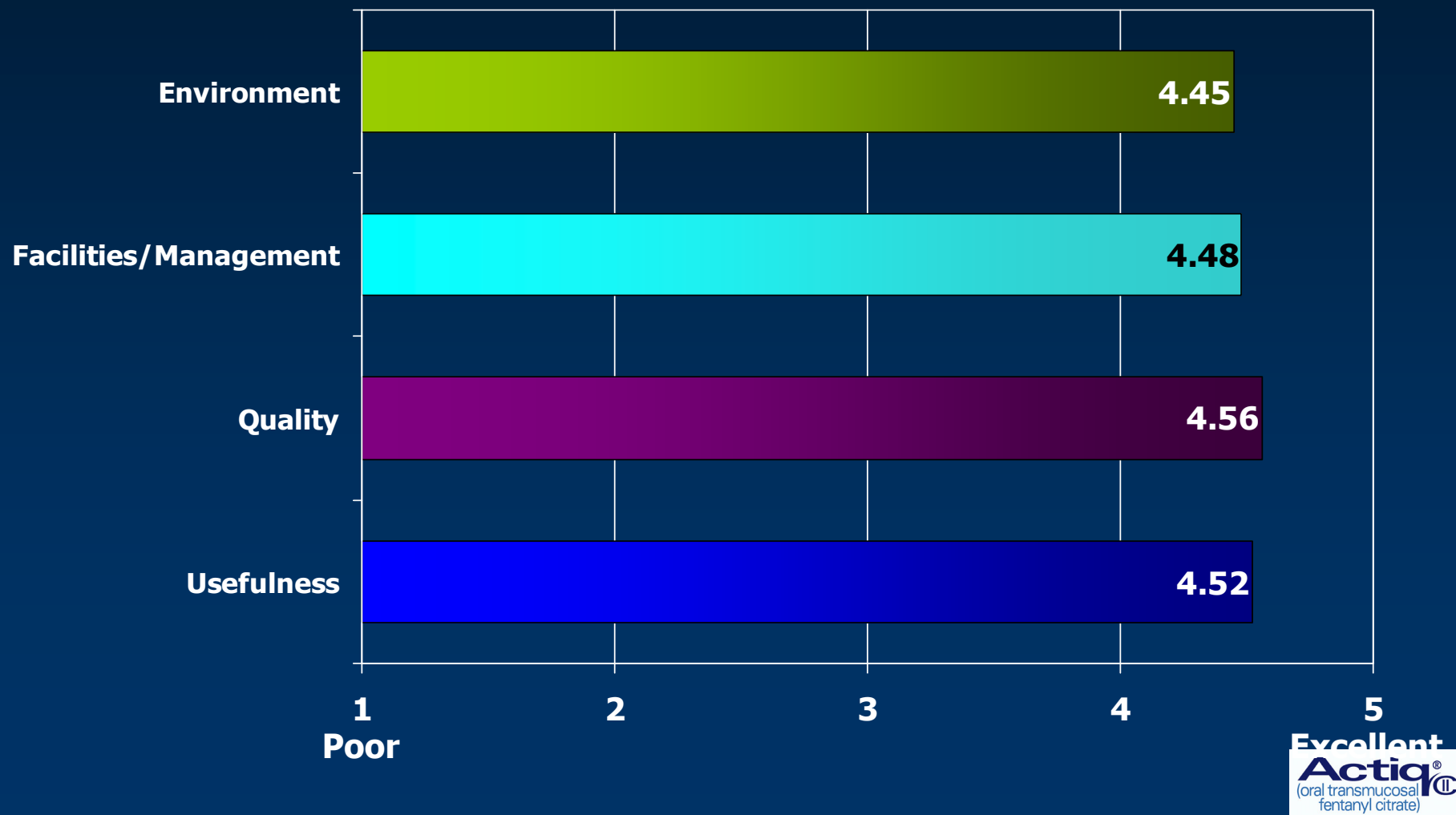


# Who Have We Reached? Clinical Experts in Pain Attendee Analysis



- Total Participant Evaluations Returned – 2538
- Average Evaluations Returned Per Program – 13

# Clinical Experts in Pain Evaluation Analysis



# Clinical Experts in Pain Outcome Analysis

This educational activity has contributed to my professional effectiveness & improved my ability to:

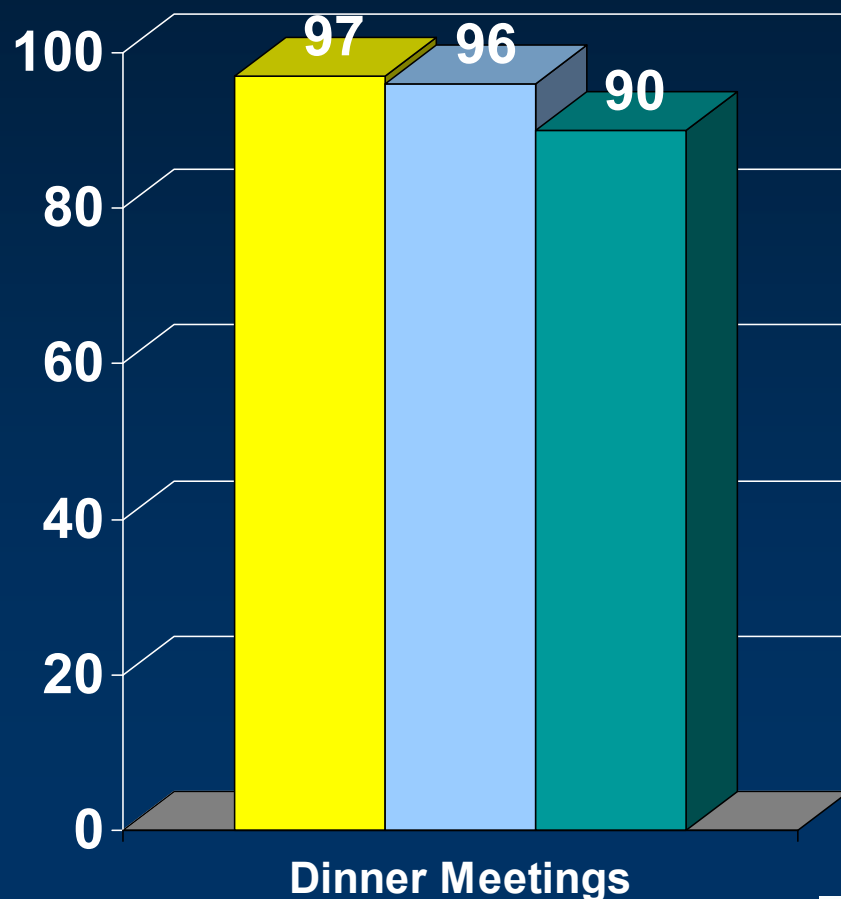


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# The Three Keys to Successful CME Programs

■ Course Objectives ■ Fair Balance ■ Usefulness

- Overall content meets the learning objectives and is clinically relevant
- Useful for their practice and fair balanced
- Participants feel it is a good use of their time and enhances their knowledge base



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# What Have We Learned in 2004?

- Participant feedback and expert opinion: unmet educational need in pain management
- Varying degrees of expertise in assessment, diagnosis and treatment of pain
- Fear of continued legal and regulatory scrutiny
- Moving forward
  - Foster positive partnerships in pain management
  - Develop strategies to elevate the importance, value and positive perception of accurate and effective pain treatment

# 2005 Key Objectives

- To establish Cephalon as a recognized industry leader in pain management education and resources
- To continue to build upon 2004 key objectives and focus on areas of greatest educational need and ROE
  - Abuse and addiction
  - Collaborative practice
  - Programs designed to increase awareness of appropriate use of opioids in both malignant and nonmalignant disease states
  - Guide clinicians practice and attitudes concerning recognition and treatment of pain

# 2005 Plan

- 252 Dinner Meetings to be completed in 2005
  - 36 Programs per region
  - Topics available:
    - Chronic Pain
    - Substance Abuse
  - Teleconference with **RDs** and Medicom on 12/15/04 to coordinate program execution according to CME guidelines
  - **RDs** will assign specific # of programs per area
  - **Reps** will be able to provide the following:
    - Suggested date, venue and speaker
    - Coordination of invitation process to target audiences requesting education

# Additional Activities



# AAPM Activities

- AAPM (2/23-27 in Palm Springs, CA)
  - Symposia
    - BTP Pro/Contra Live Debate & Monograph distribution
    - A Blueprint for Successful Opioid Pain Management: Providing Care While Preventing Misuse and Diversion
  - ESP Initiative Launch
    - Toolkit and Meet the Experts Booth
  - The following two IIS abstracts were submitted to AAPM 2005 by investigators
    - Prevalence and Characteristics of Breakthrough Pain in Non-cancer Patients with Chronic Neuropathic Pain
    - Prevalence and Characteristics of Breakthrough Pain in Non-cancer Patients with Chronic Back Pain

# APS Activities

- APS (3/30 – 4/2 in Boston, MA)
  - Symposia
    - The Building Blocks of Breakthrough Pain Treatment: **Assess, Believe, Communicate, Diagnose, and Effectively Treat**
  - ESP Initiative
    - Toolkit and Meet the Experts Booth
  - The following three IIS abstracts were submitted to APS 2005 by investigators
    - Prevalence and Characteristics of Breakthrough Pain in Patients with Chronic Non-cancer Pain
    - Degree of Pain Intolerance and Adverse Outcomes in Chronic Non-cancer Pain Patients
    - Oral Transmucosal Fentanyl Citrate: Efficacy in Neuropathic Pain Patients

# Supported Activities

- Supported websites
  - Medscape: [www.medscape.com/resource/rxmgmtpain](http://www.medscape.com/resource/rxmgmtpain)
  - Dannemiller Foundation: [www.Pain.com](http://www.Pain.com)
  - ESP: [www.emergingsolutionsinpain.com](http://www.emergingsolutionsinpain.com)
- Anticipated published literature
  - BTP Guidelines by Thomas Jefferson University
    - March Issue, *Pharmacy & Therapeutics*

# Consultant Meeting Plan

# Consultant Plan Objectives

- Primary Objectives:
  - Gain insight from consultant feedback
  - Provided recommendations on commercial and clinical plans for ACTIQ and OVF
  - Obtain advice on marketing strategy for both ACTIQ and OVF
- Secondary Objectives:
  - Share information
  - Provide a forum to improve the quality of care for patients

# Consultant Plan Process

## “Snap Shot View”

- Identify ~1000 Potential RCs
- Recruit/Contract 210 RCs

- Conduct OAPs Pre Live meeting

Regional Consultant Mtgs

- Conduct Post OAPs
- Coordinate Compliance Documents for file

# SYNERGISM!

# Consultant Plan Process

- Identification & Selection:
  - Marketing, SciComm and Sales Ops will generate regional list based on specific criteria
  - **Sales Force** reviews list and prioritizes
  - Selva Group performs OIG checks on all potential consultants
- Invitation Process:
  - **Reps** will disseminate invitations in waves
  - Participating consultants agree to a 12 month contract which includes 2 online advisory panels and 1 Live meeting
- **Goal: equal representation from all regions**

# Speaker Training Plan



# Speaker Training

- Marketing will conduct 2 National level meetings\*
  - First meeting: April (East)
  - Second meeting: June (West)
- \*Speakers must attend one of these meetings to become National Level Speakers, which qualifies them for highest permitted honoraria per MEP/year*
- MDMs will conduct regional training per RD direction

# Discussion