

ACTIQ Sales Training

March 12, 2003

Paula Castagno

Product Manager

PLAINTIFFS TRIAL
EXHIBIT

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PCS Sales Force

Mission Statement

Copyright 2001 by Randy Glasbergen. www.glasbergen.com



**“Our old mission statement was more eloquent,
and dignified, but not nearly as effective.”**

Overview

- History of ACTIQ
- 2003 Key Marketing Issues
- Product Performance
- 2003 Key Marketing Strategies
- 2003 Key Tactics
- Promotional Material Review

History of ACTIQ

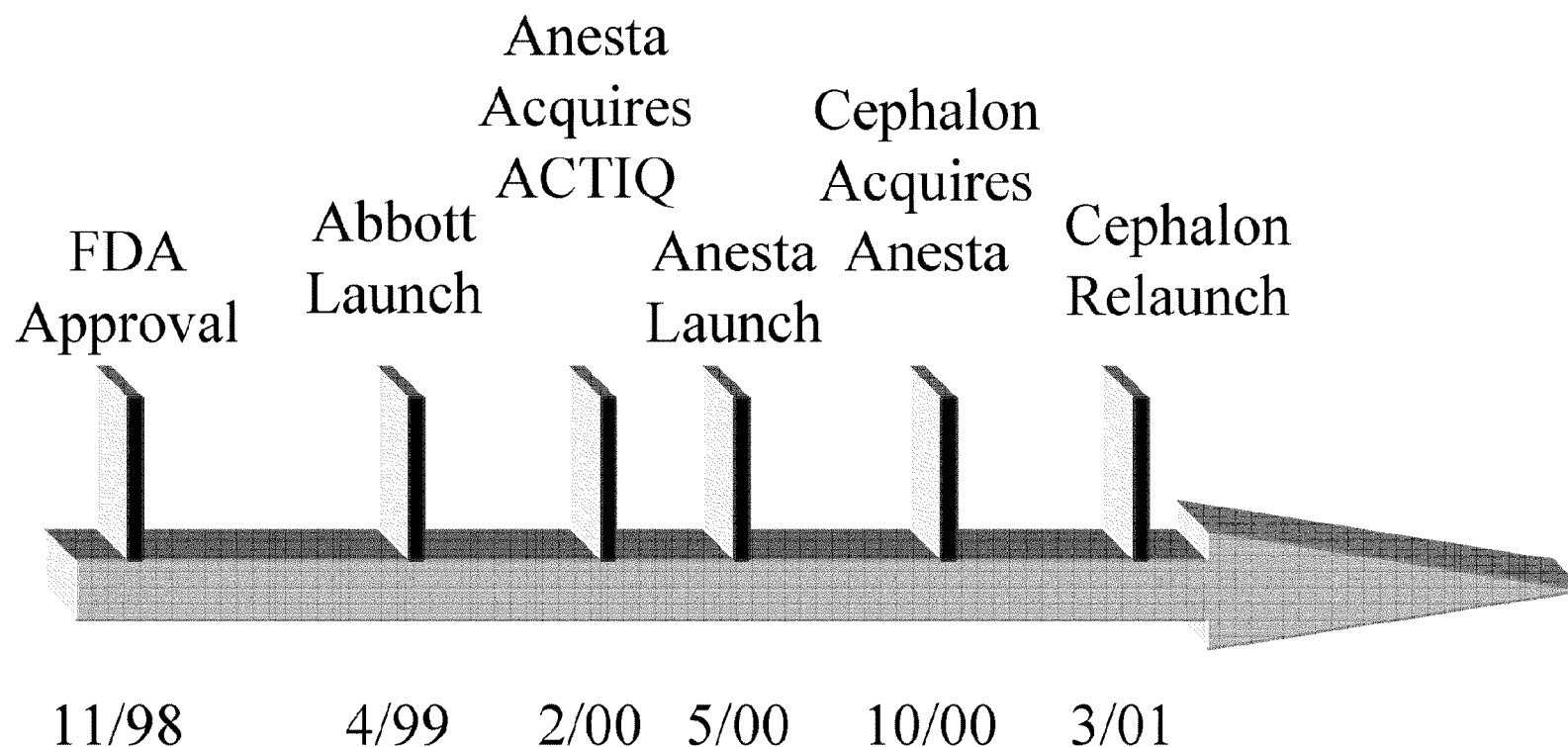
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Chronology of Ownership



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Historical

Sales Force, Sales & TRx

Year	Sales Force	Sales	TRx
1999	20 reps 2 AM 6 ML	3.5M	5,548
2000	48 reps 6 AM 10 ML	16.0M	26,259
2001	48 reps 6 AM 10 ML	55.0M	73,514
2002	60 reps 7 AM 10 ML	133.7M	186K

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2003 Key Marketing Issues

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Key Issues at Cephalon Relaunch

March 2001

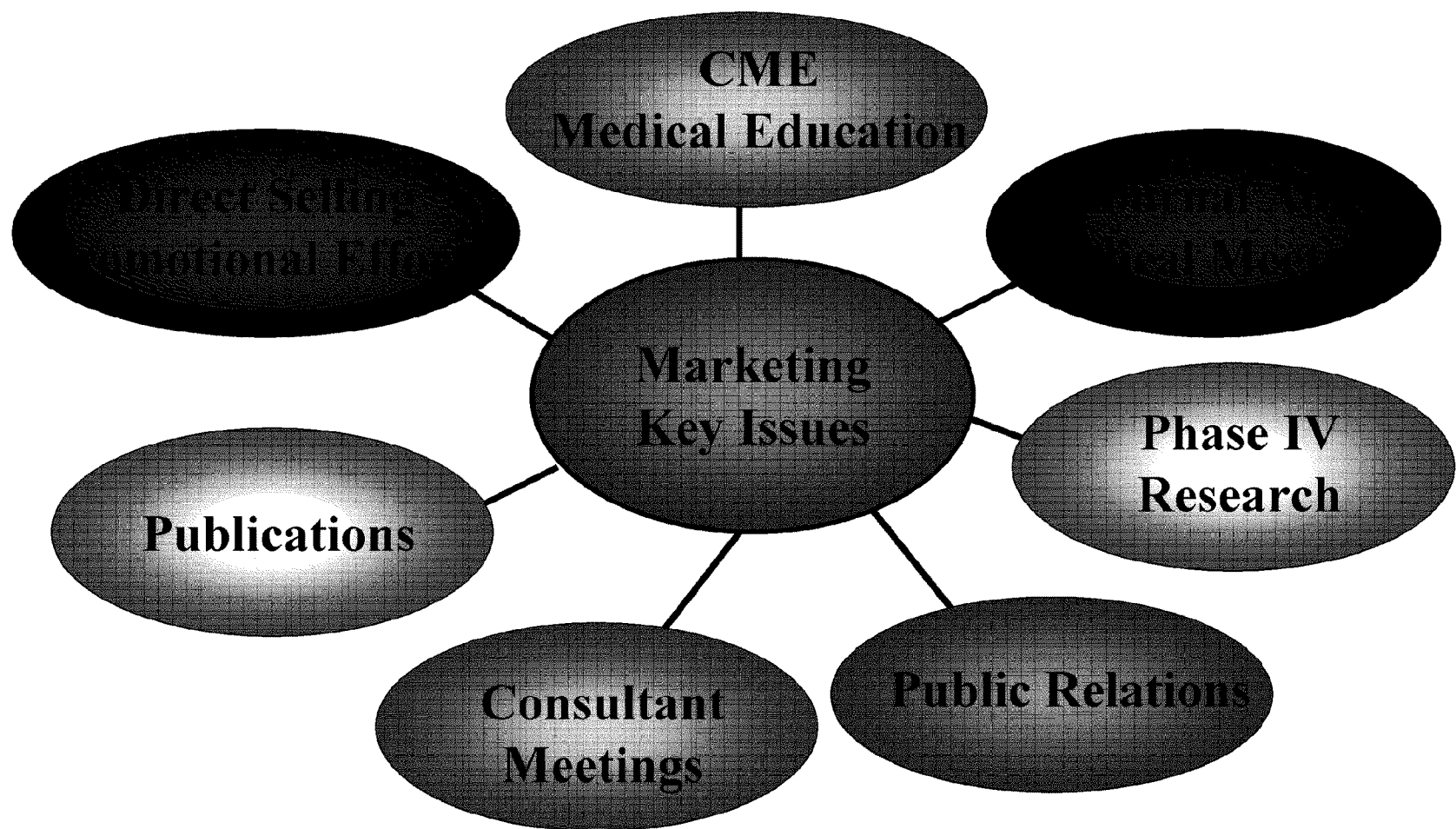
- Product Ownership Changes
 - Lack of continuity – company support??
 - Negative product perception
- Weak Concepts and Poor Product Positioning
 - Concepts focused on OT delivery system and clinical entity of BTCP
 - Did not position product based on differentiating benefits
- BTP Misunderstood
 - Newer concept – not well understood, assessed, treated by many in pain community

2003 Key Marketing Issues

Similar to 2002

- **Low awareness of BTP**
- **Low product awareness**
- **Restrictive labeling (education)**
- **Limited direct promotional reach (education)**
- **Limited KOL/advocates (education)**
- **Launch of new formulation (awareness & education)**
- **Potential new competitors (2005 ??)**

Strategically Addressing Key Issues



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Product Performance

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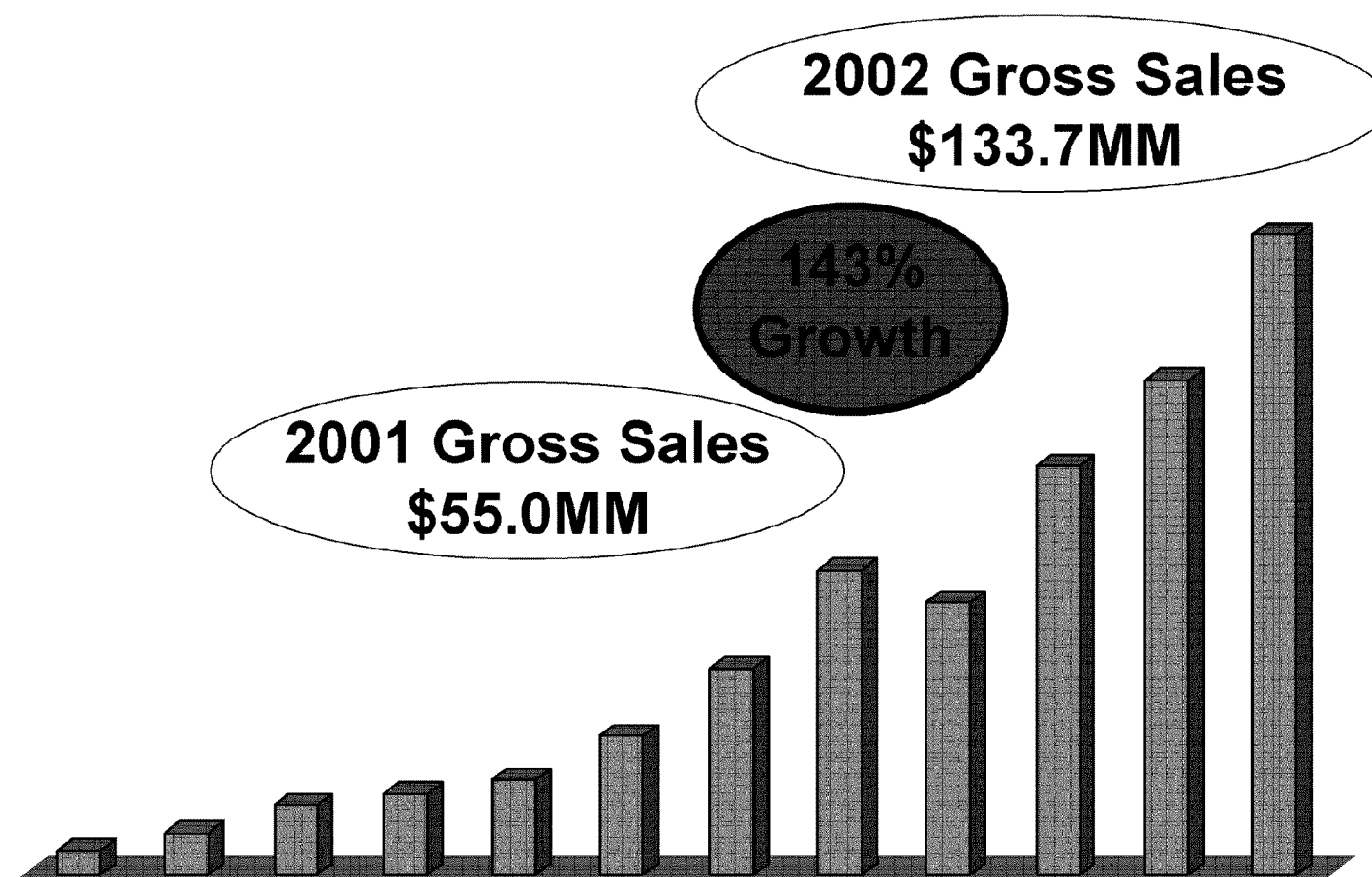
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ACTIQ Quarterly Gross Sales

Phenomenal Success



Source: DDN

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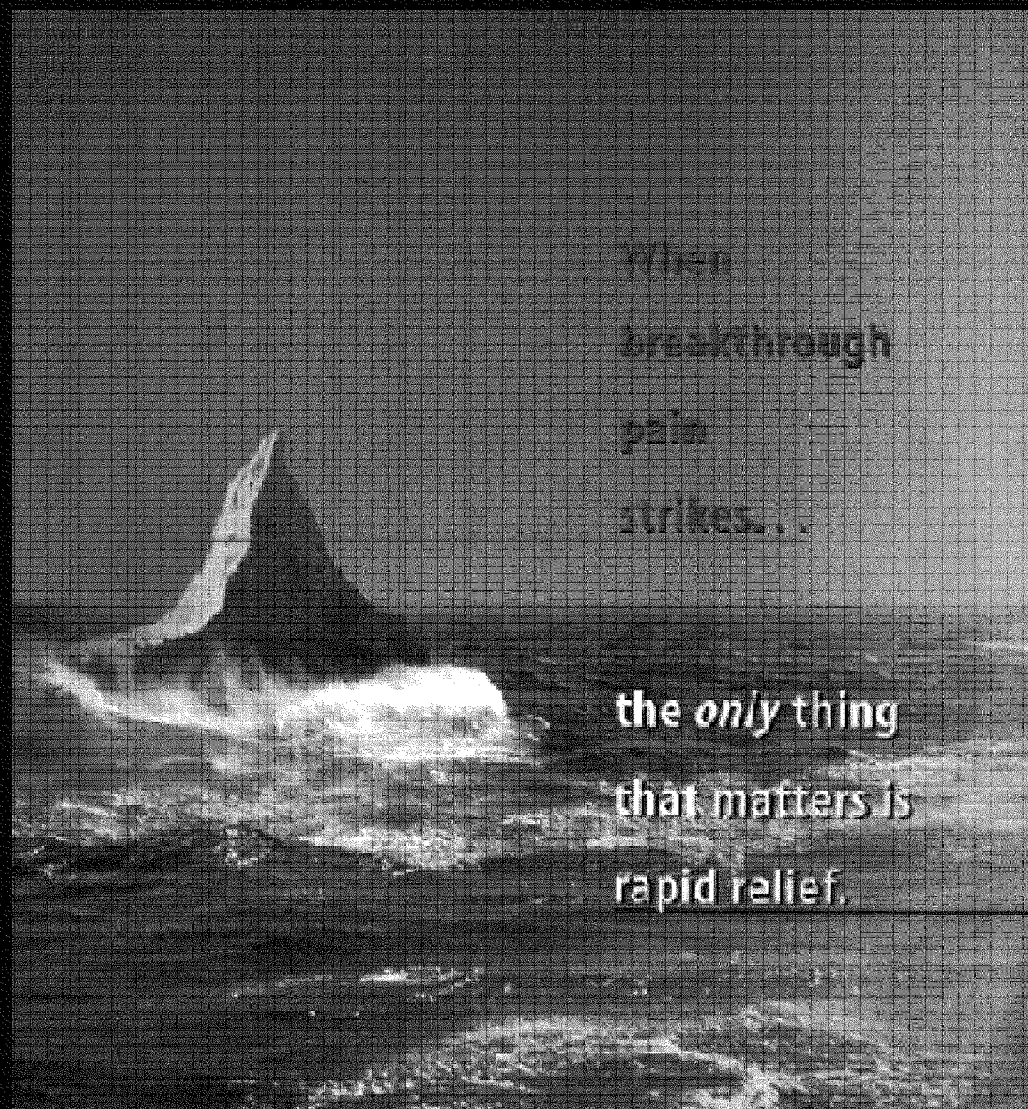
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Critical Success Factors

- **New concept focused on key product benefit (rapid onset)**



When
breakthrough
pain
strikes...

the *only* thing
that matters is
rapid relief.

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NOW AVAILABLE

A DELIVERY SYSTEM DESIGNED TO MAKE A DIFFERENCE

Breakthrough oral transmucosal delivery

Actiq® (oral transmucosal
fentanyl citrate)

Important Warnings



- > 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.
- > Because life-threatening hypoventilation 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.
- > Instruct patients/caregivers Actiq can be fatal to a child. Keep open units from children and discard properly.

See boxed warning and full prescribing information on following pages.

ACTIQ is a registered trademark of Anesteo Corp.



Abbott Laboratories Inc.
Hospital Products Division
Abbott Park, IL 60053-6154
1-800-ABBOTT3

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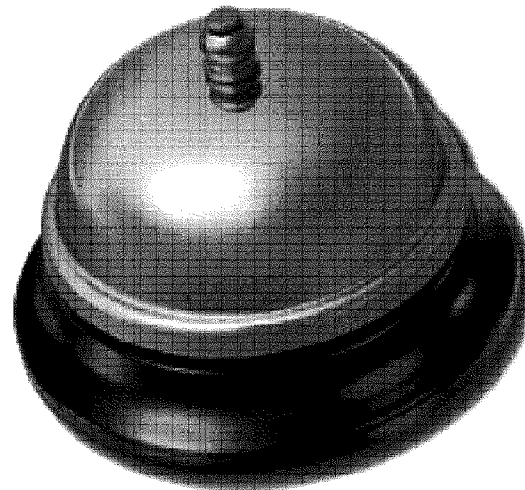
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Actiq® on call.



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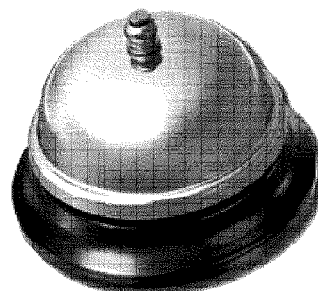
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2002



Actiq® on call.



With ACTIQ, pain relief may be observed in 15 minutes.¹

- Patients may begin experiencing pain relief while taking ACTIQ, but may not experience full relief for up to 45 minutes after finishing an ACTIQ unit.^{1,2}
- The median time to maximum plasma concentration (T_{max}) across four doses of ACTIQ varied from 20-40 minutes after a standardized consumption time of 15 minutes.¹
- ACTIQ produced significantly more pain relief ($P < 0.0001$) compared with placebo at 15, 30, 45, and 60 minutes following administration in opioid tolerant cancer patients.^{1,3}
- Longer or shorter consumption times than the recommended 15 minutes may produce less efficacy than reported in clinical trials.^{1,4}
- Patients should limit consumption to four or fewer units per day.¹

Important Warnings



- 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.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product *must not* be used in opioid nontolerant patients.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- The most common side effects observed were somnolence, nausea, vomiting, and dizziness.

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. www.actiq.com

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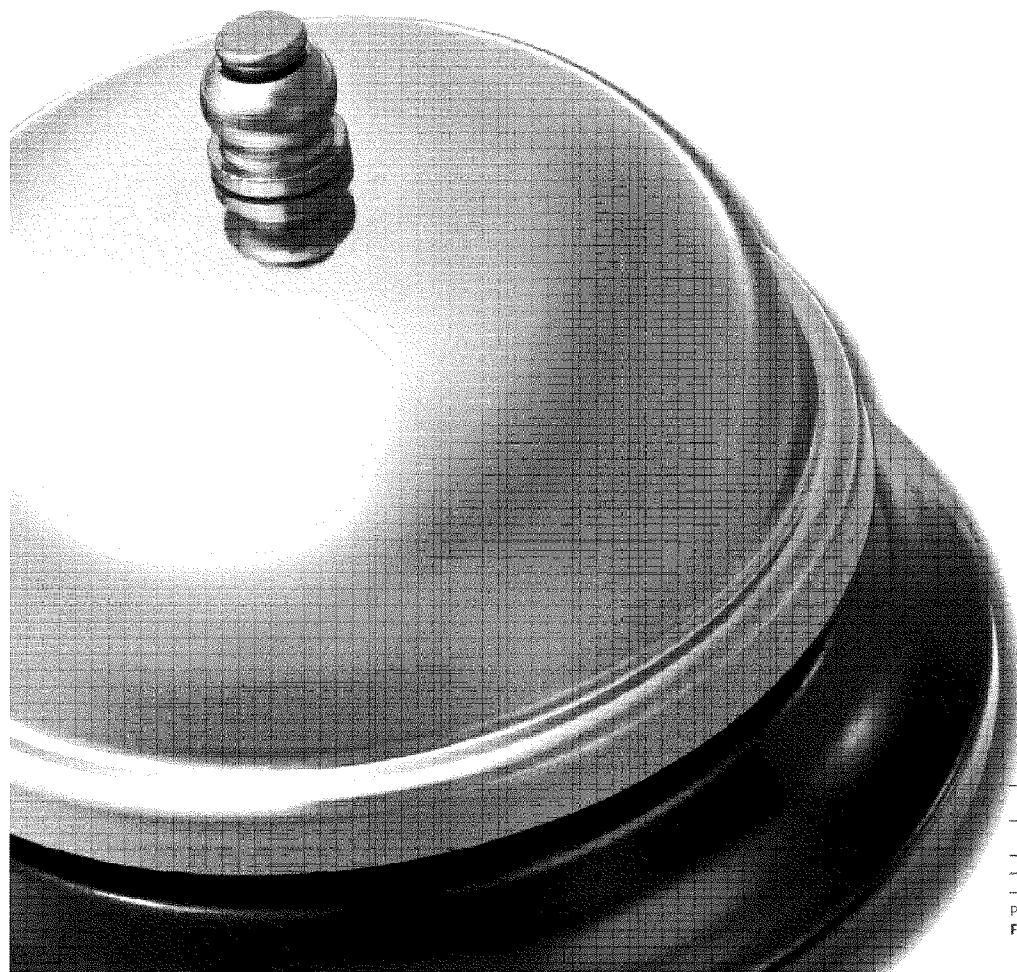
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2003

www.actiq.com

When onset matters...



Actiq® on call.



With ACTIQ, pain relief may be observed in 15 minutes.¹

Rapid transmucosal absorption

- The unique oral transmucosal system (OTS™) of ACTIQ allows for rapid oral mucosal absorption and slower GI absorption of fentanyl.¹
- Patients may begin experiencing pain relief while taking ACTIQ, but may not experience full relief for up to 45 minutes after finishing an ACTIQ unit.^{1,2}
- Analgesic effects of fentanyl are related to blood level, with delay into and out of the CNS (a process with a 3- to 5-minute half-life).¹
- Longer or shorter consumption times than the recommended 15 minutes may produce less efficacy than reported in clinical trials.^{1,2}

No pharmacologically active metabolites

- Safety and efficacy have been established in opioid tolerant patients receiving both long-acting oral and transdermal opioids.¹

Typical opioid side effects

- The most common side effects observed were somnolence, nausea, vomiting, and dizziness.¹

Portability, convenience, control

- The oral transmucosal delivery system and onset of action of ACTIQ provide patients with portability, convenience, and control.



⚠ Important Warnings

- 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.*
 - Because life-threatening hypoventilation 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 nontolerant patients.
 - Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
 - The most common side effects observed in ACTIQ clinical trials were somnolence, nausea, vomiting, and dizziness.
- 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.

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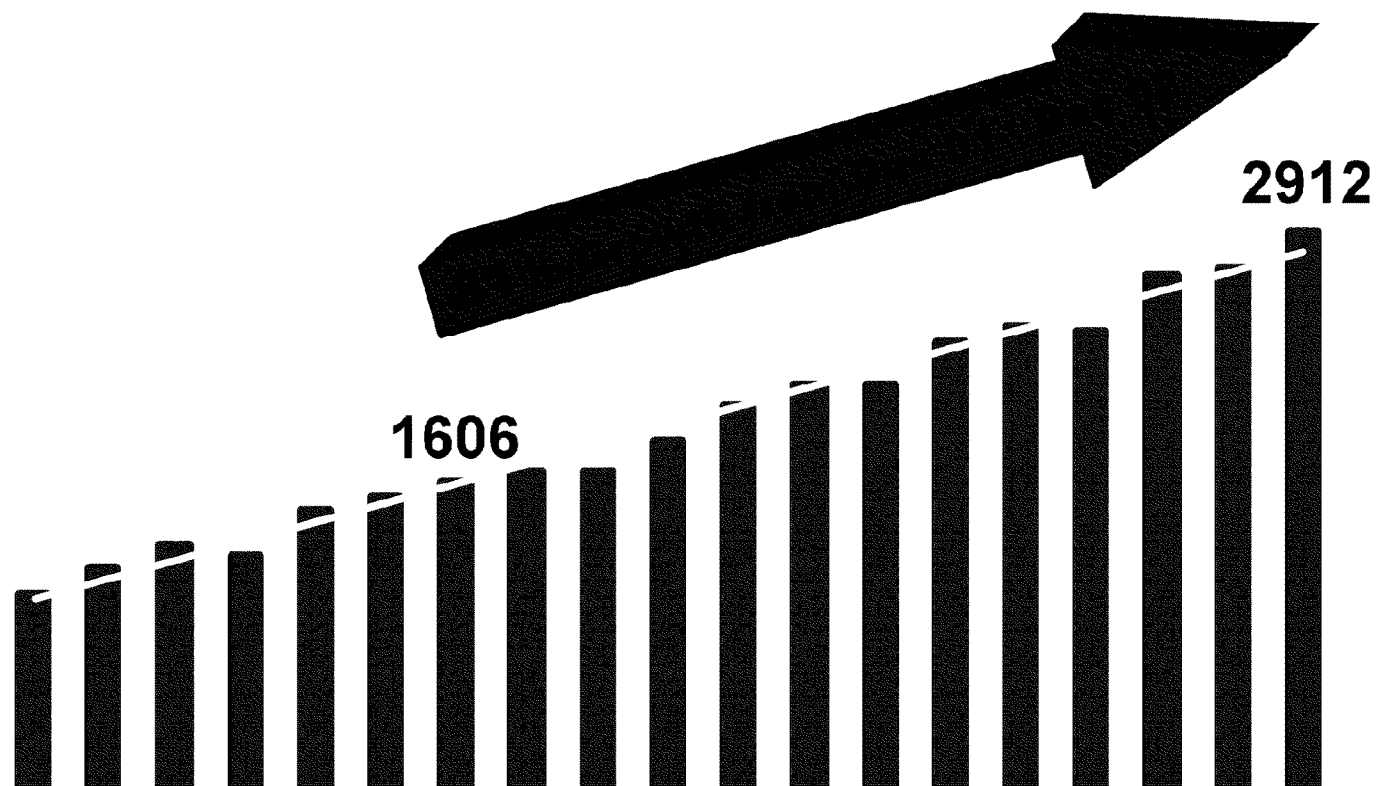
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Critical Success Factors

- **New concept focused on key product benefit (rapid onset)**
- **Targeting correct physician specialties**
- **Delivering ACTIQ's key messages**
 - **Rapid onset**
 - **Simplifying titration process / relative potency**
- **Utilization of Market Research to improve product messaging**
- **Consistent promotional branding**
 - **Concept, colors, visuals**
- **Appropriate and effective Med Ed programs**
 - **Rep-driven MEPs, consultant meetings, CME**
- **Improving product awareness**
 - **Journal ads, medical meetings, direct mailings, PR efforts**

ACTIQ Monthly Prescribers

Nearly Doubled



Source: NDC

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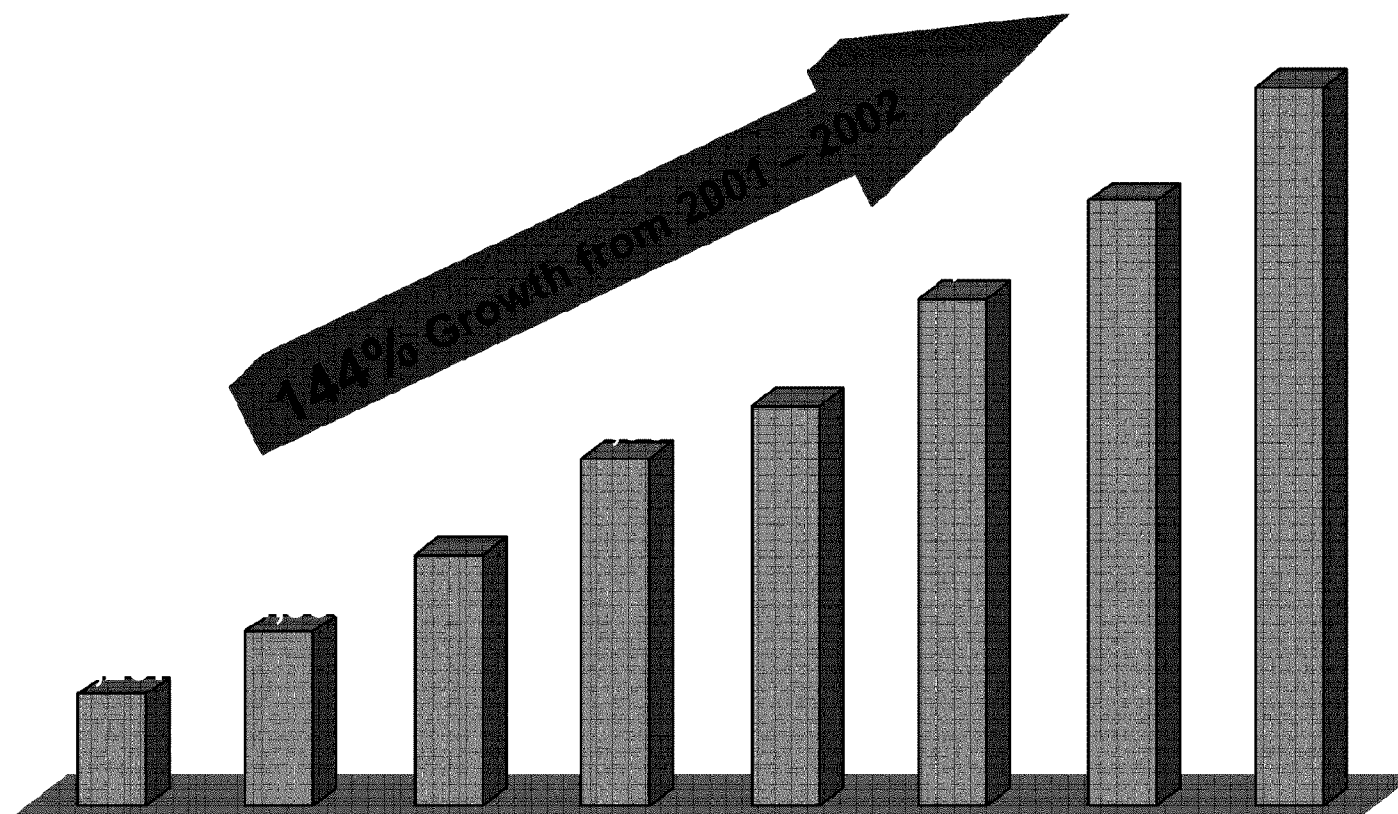
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ACTIQ Quarterly TRx

Consistent Growth



Source: IMS NPA

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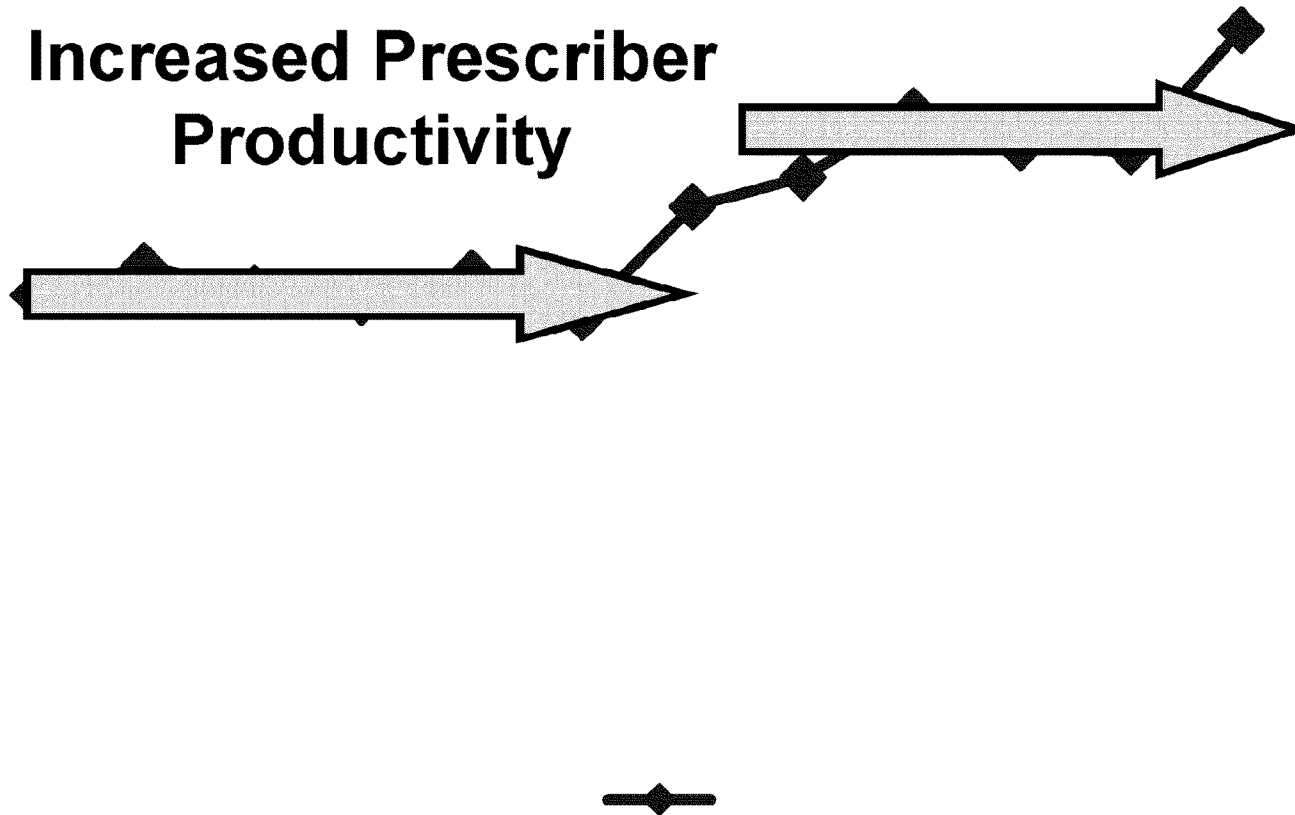
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Monthly Units & Units/Rx

Increased Prescriber Productivity



Source: NDC

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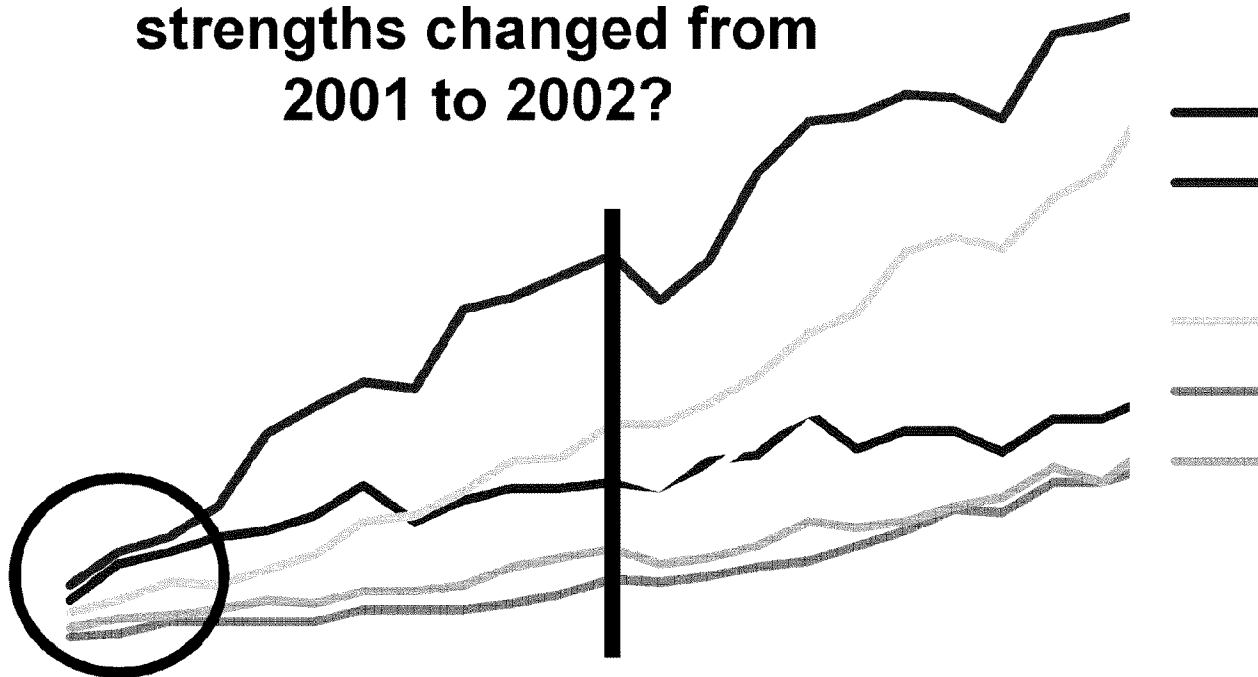
So...

- **Prescribers, TRx, units & sales are all growing strongly**
- **Where is the business coming from?**
Strengths?
Specialties?

Monthly TRx by Strength

Effective Dosing & Titration Messaging

**Has the distribution of
strengths changed from
2001 to 2002?**



Source: NDC

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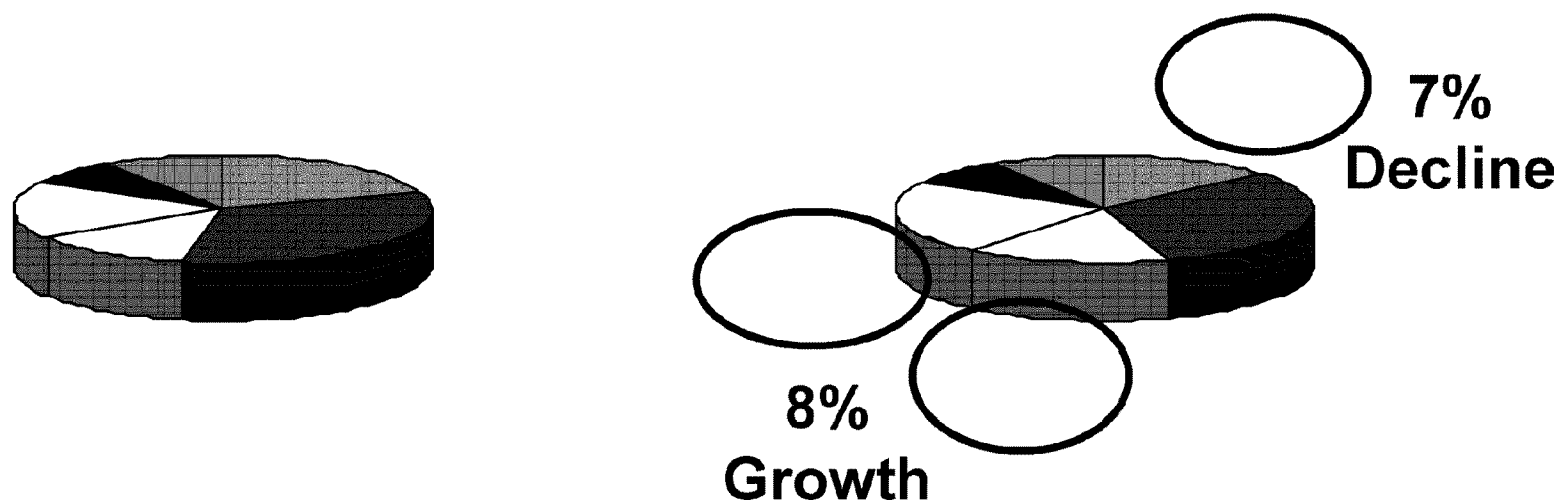
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Distribution of TRx by Strength

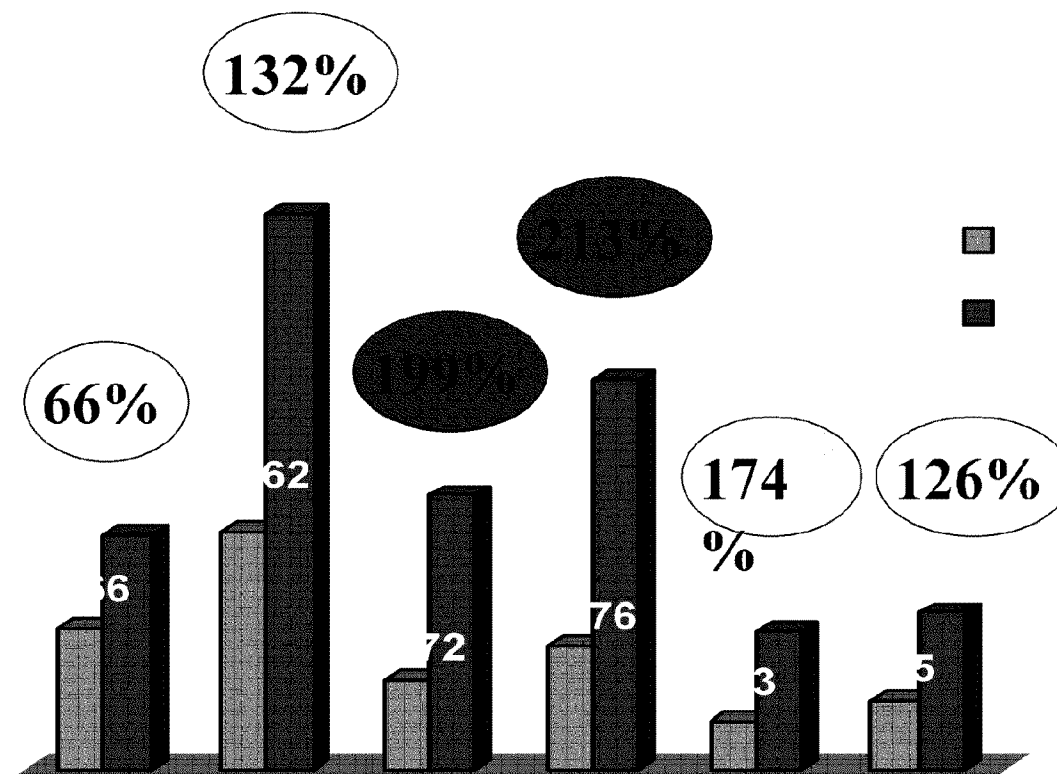
Solid Growth in Middle Strengths



63% ← 400, 600 & 800mcg → **70%**

Growth of TRx by Strength

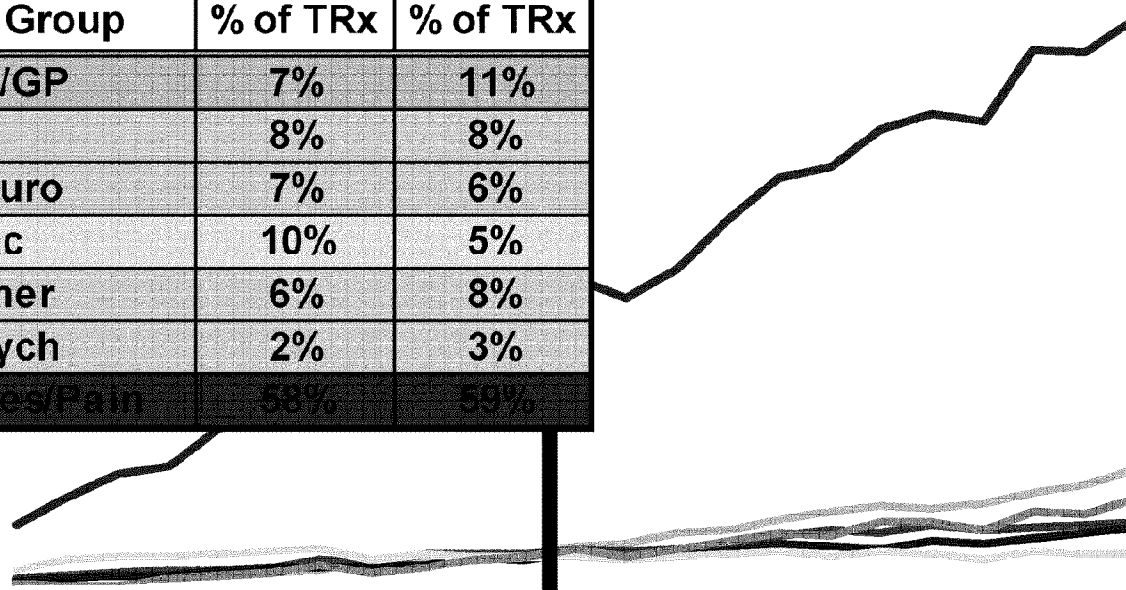
600 & 800mcg Growing at Fastest Rate



Monthly TRx by Specialty

Anes/Pain Still the Core

Specialty Group	2001 % of TRx	2002 % of TRx
FP/GP	7%	11%
IM	8%	8%
Neuro	7%	6%
Onc	10%	5%
Other	6%	8%
Psych	2%	3%
Anes/Pain	58%	59%



Source: NDC

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2003 Key Marketing Strategies

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2003 Marketing Strategies

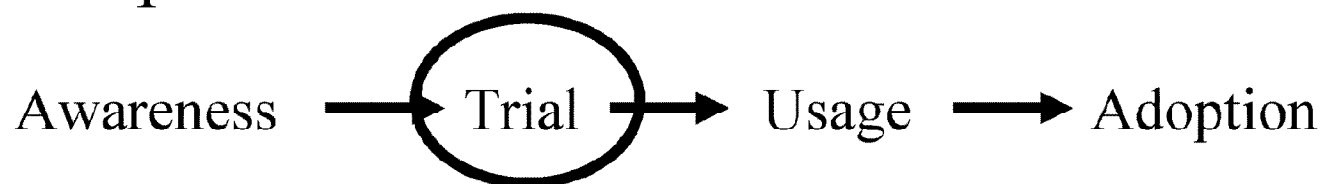
Similar to 2002

- **Improve awareness of BTP**
- **Improve awareness of ACTIQ**
- **Educate targeted physician segments about:**
 - **Potential application of ACTIQ**
 - **How to dose/titrate ACTIQ**
 - **Improved QoL**
- **Build/renew relationships with KOL/advocates (education)**
- **Proactively inform all audiences regarding transition to compressed powder formulation (awareness & education)**
- **Proactively position ACTIQ to defend against potential competitors (awareness & education)**
 - **Planning begins in 2003**

Overall Marketing Strategy

Awareness & Education

- Goal: Move prescribers along the product adoption curve



- How do we do this for ACTIQ?
 - Raise awareness of BTP & ACTIQ
 - Educate targeted physicians

2003 Core Tactics

What's it all about in 2003...
Awareness & MedEd

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2003 Core Tactics

Awareness Programs

- **Direct Mailings**
 - Promotional
 - MedEd
- **Journal Ads**
- **Convention Presence**
- **WebMD/Medscape**
- ***ACTIQ.com***
- ***Pain.com***
- ***EmergingSolutionsinPain.com***
- **PR Efforts**
 - Media Relations
 - Constituency Relations
 - Website Updates
 - Nurses Advisory Board
 - BTP Brochure
 - Patient Diary
 - Pain Assessment Tool

MedEd Programs

- **Promotional MEPs**
- **Consultant Meetings**
- **CME Symposia**
 - Regional/Local
 - Conventions
- **On-Line Advisory Panels**
- **MedEd Direct Mailings**
- **Teleconferences – CME**
- **WebMD/Medscape – CME**
- ***Pain.com* – CME Offerings**
- ***EmergingSolutionsinPain.com***
- **ESP CME Newsletter**
- **Beth Israel – CME BTCP Module**
- **Publication Efforts**
- **WLF Reprints**

Key Field-Related/Driven Tactics

1. Promotional MEPs
2. Regional/Local CME Symposia
 - CEP Lectures
3. Consultant Meetings
4. CME Teleconferences

1. Promotional MEPs

- **How much \$\$ will you manage?**
 - **Approx \$22 K/rep**
 - **Assuming average MEP cost of \$1670**
 - **14+ promotional MEPs/rep**
- **Rep-Driven MEP = Promotional MEP**
 - **Statement up front!**
 - **No MEP teleconferences in 2003**
 - **Automatic shipment of invitations (minimum 10)**

2. CME Symposia

- **Strategy**
 - **Provide balance to promotional MEPs**
 - Will run parallel to promotional MEPs
 - **Provide sales force with credible educational tool**
 - **Allow sales force (not marketing) to drive implementation & execution of programs**
 - Interactive web-based scheduling
 - Reps select where, when, topic, speaker, etc.
 - **Will have teleconference ability**

2. CME Symposia

- **Background Information**
 - **CEP Lecture Series Development Meeting (Nov 8-10)**
 - **40 attendees → “CME speaker bureau”**
 - **Goal of meeting: develop CME slide sets**
 - 1. Neuropathic Pain**
 - 2. Musculoskeletal Pain**
 - 3. Improving the Chronic Pain Management Paradigm**
 - **Characteristics and Management of BTP**
 - 4. Abuse, Tolerance, Pseudo Addiction, & Addiction**
 - 5. Migraine Headaches**
 - **Placement on-line at *EmergingSolutionsinPain.com***

CME Symposia

- **How much \$\$ will you manage?**
 - **Approximately \$23 K/rep**
 - **Assuming average cost/live program \$5500**
 - **4+ programs/rep (could be higher if teleconferences utilized)**
- **2 CEP Lecture Series Development Meetings planned for 2003**
 - **Expand CME speaker bureau**
 - **Develop new CME slide sets**

Promotional MEPs vs. CME Symposia

Summary of Differences

Promotional MEPs

- **Vendor: Cogenix**
- **Approx \$22K/rep**
- **Avg Cost \$1670/program**
- **No Teleconference**
- **Choose date, location, speaker and topic**
- **Automatic shipment of invitations to reps**
- **Statement up front!**
- **Promotional rules apply**

CME Symposia

- **Vendor: Medicom**
- **Approx \$23K/rep**
- **Avg Cost \$5500/program**
- **Teleconference**
- **Choose date, location, speaker and topic**
- **Automatic shipment of invitations to reps**
- **Invitations sent to docs**
- **CME rules apply**

3. Consultant Meetings

- **Critical success factors**
 - Faculty
 - Attendees
- **PCS Primary Responsibilities**
 - AMs coordinate invitation lists through rep & MLM interaction
 - AMs attend 1 NCM & 2 RCM
- **Things to Avoid:**
 - Pre-inviting physicians
 - Dates/locations may change
 - Meetings may become full before 2nd invitation wave
 - Inviting nurses (these are not nursing meetings)
 - Calling Christine/Palio

Consultant Meetings

- **Total allocation of \$3.6 MM allows for:**
 - **22 total consultant meetings**
 - **3 National Consultant Meetings**
 - **18 Regional Consultant Meetings**
 - **2 meetings/area**
 - **1 Convention Consultant Meeting at AAPM**
 - **Expansion & utilization of product advocates through greater speaking opportunities**

4. CME Teleconferences

- **Strategy**
 - Another Med Ed tool
- **Program**
 - **Topic: Advances in the Treatment of Musculoskeletal Pain**
 - Chronic back pain, arthritis, fibromyalgia, etc.
 - Considering migraine and/or CRPS series if successful with musculoskeletal pain
 - **12 dates (varying times)**
 - Starting May
 - **CME On-Demand (800# available to all)**
 - **2 Training teleconferences for reps**

4. CME Teleconferences

- **Advertising & Promotion**
 - **99% rep-driven recruitment with invitations**
 - **Invitations mailed to target MDs**
 - **Success of program depends heavily on rep recruitment**
 - **Provide feedback prior to initiating second series**
 - **What worked? Time of calls? Etc.**

Promotional Materials Update

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2002 Promotional Materials

- Core Sales Aid
- Patient FAQs
- Physician FAQs
- New “Pocket-Size” Dosing Guide
- Product Monograph
- Reimbursement Brochure
- ACTIQ Coupon Book (with dosing instructions)
- 5 ACTIQ-specific Reprints
- Patient Instructional Use Tear Sheet
- Non-branded BTP Wall Chart & Counter Card
- Pain Assessment Tear Sheet (non-branded)
- Medi-Message Pads
- New Magnet & Rolodex Card
- ACTIQ.com

2003 Promotional Materials

- Physician New Formulation Q & A Sales Aid
- Pharmacist New Formulation Q & A Sales Aid
- Pt. New Formulation Instructional Tear Pad
- 2 WLF Reprints
 - Coluzzi: MSIR vs. ACTIQ
 - Coluzzi: Sublingual Morphine: Efficacy Reviewed
- Non-Branded BTP Brochure

Giveaways

- Two ACTIQ pens
- ACTIQ 4”x6” post-its
- ACTIQ convention bags
- Medi-Message Pads (bigger size)
- ACTIQ wall clock

} Pending
Approval

Keys to Success

- **Appropriate and effective targeting**
 - **Still the biggest critical success factor**
- **Delivering the right messages regarding onset, titration & therapeutic application**
 - **Consistently and with the right frequency**
 - **Sales force is the most effective means of education**
- **Effective utilization of resources**
 - **MEP \$\$**
 - **CME programs**
 - **Promotional tools**
 - **Personnel – MLMs/NAMs/sales ops**
- **Consistent feedback to marketing**

Questions?

Actiq[®]
(oral transmucosal
fentanyl citrate)
II