

# ACTIQ MARKETING 2001

Andy Pyfer  
January 2001



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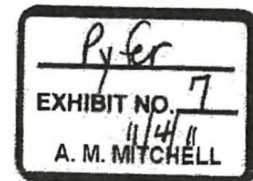
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PLAINTIFFS TRIAL  
EXHIBIT

**P-03647\_00001**

Exhibit 015

TEVA  
WITNESS: **PYFER**  
DATE: 2/20/19  
REPORTER: Amanda Miller Crr



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## History of Actiq

- FDA approval Nov 1998
- Actiq launched April 1999 (by Abbott Labs)
  - 20 salespeople, 6 MLs
  - 1999 sales 2+ MM
- Actiq promotional rights re-acquired from Abbott Feb 2000
- Actiq re-launched May 2000 (by Anesta)
  - 48 salespeople, 10 MLs
  - 2000 sales 15+ MM
- Cephalon acquires Anesta (& Actiq) Oct 2000
- Actiq to be re-launched Feb 2001
  - 48 salespeople, 10 MLs



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## Actiq Marketing Overview: Key Topics

- Opioid Market Review
- Actiq Sales Review/Analysis
- Key Issues and Recommendations



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# Opioid Market Review



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## WHO Ladder

- Three step analgesic ladder
  - Step One: mild to moderate pain
    - Non-opioids (Tylenol, Motrin, Celebrex)
  - Step Two: mild to moderate pain
    - Combination products (Percocet, Vicodin)
  - Step Three: moderate to severe pain
    - Pure opioids (MS Contin, Oxycontin, Duragesic, Actiq)
- Note: adjuvants used at each step (anticonvulsants, corticosteroids)



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## Prescription Opioid Market

- Short Acting Opioids
  - Short duration of action (2-6 hrs)
  - Opioid naïve
  - Acute pain
- Long Acting Opioids
  - Long duration of action (12-72 hrs)
  - Opioid tolerant
  - Chronic pain



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# Summary of Opioids

## SHORT-ACTING PURE OPIOIDS

Trade Name	Generic Name	Manufacturer
<i>Actiq</i>	Transmucosal Fentanyl	Cephalon
Roxanol MSIR	Morphine Sulfate	Roxane Purdue
Dilaudid	Hydromorphone HCL	Knoll
Oxy IR Oxyfast	Oxycodone	Purdue
Generic Morphine Generic Hydromorphone	Morphine Sulfate Hydromorphone HCL	Various Companies

## LONG-ACTING OPIOIDS

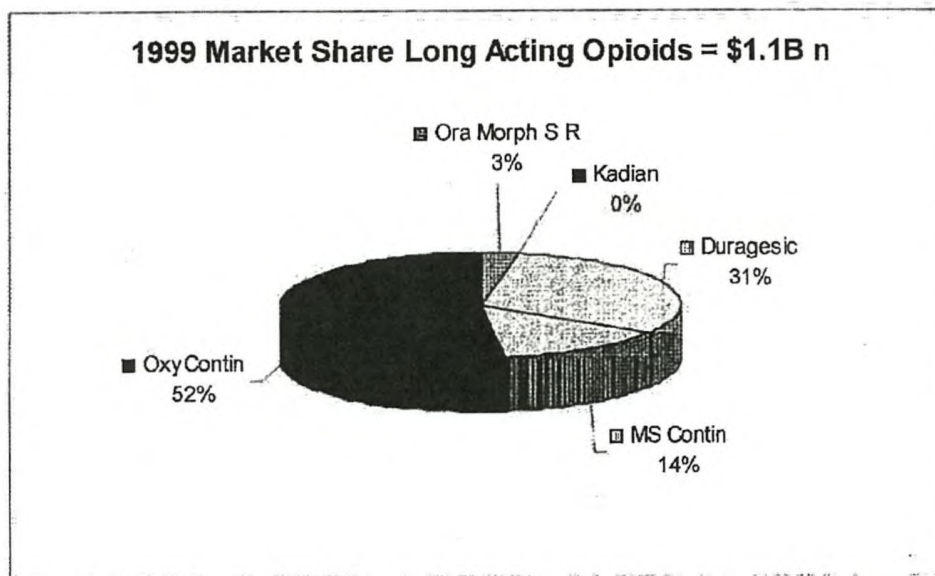
MS Contin Oramorph	Morphine Sulfate	Purdue Roxane
Kadian	Morphine Sulfate	Faulding
Oxycontin	Oxycodone	Purdue
Duragesic	Transdermal Fentanyl	Janssen



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## Market Share – Long Acting Opioids

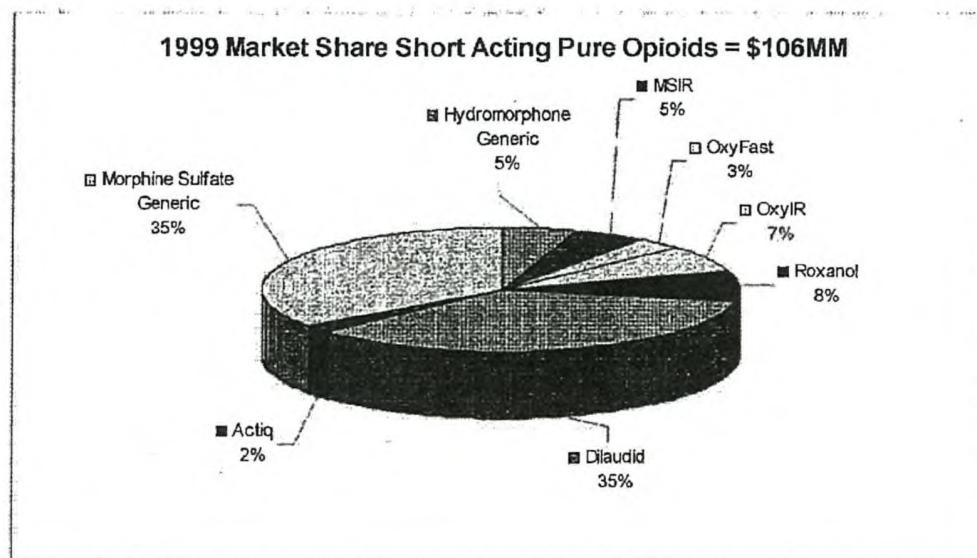


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## Market Share – Short Acting Opioids



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## Actiq Sales Review/Analysis

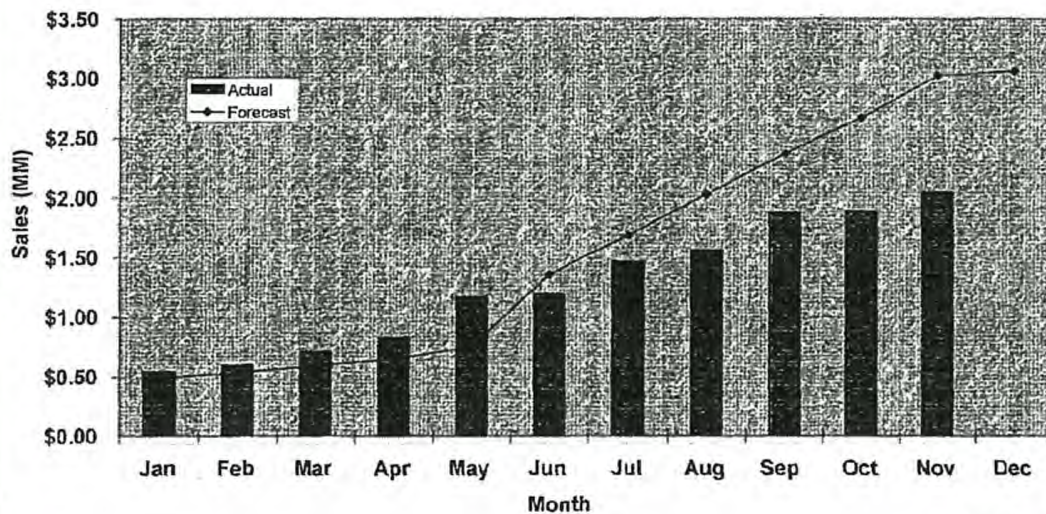


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# Actiq Sales Monthly Sales

Actiq Monthly Forecast & Actual Sales through Nov  
2000

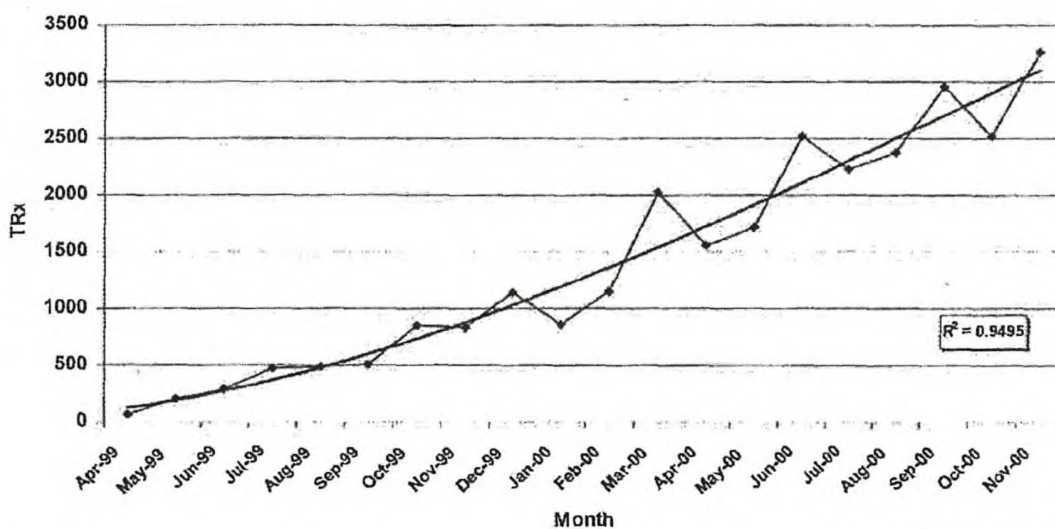


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# Actiq Prescriptions Monthly Scripts

Actiq Monthly NPA TRx



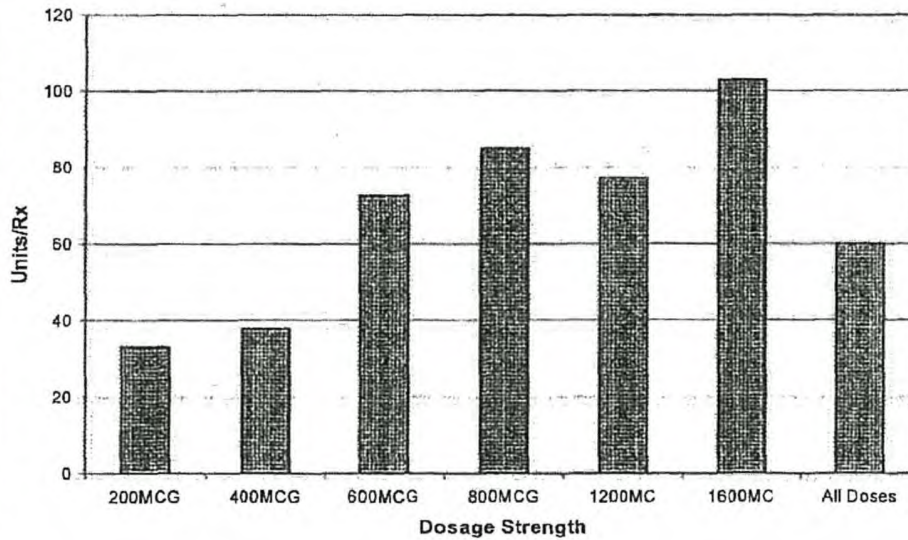
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# Actiq Prescriptions Prescription Size by Dosage Strength

Actiq Prescription Size by Strength - November



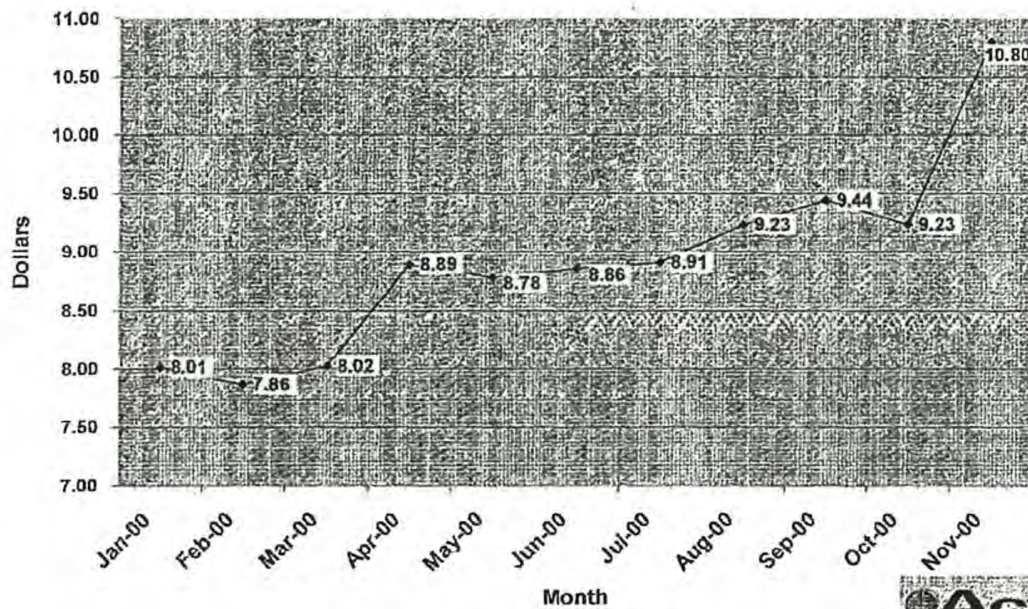
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# Actiq Sales Factory Average Net Selling Price

Actiq Factory Net Average Selling Price



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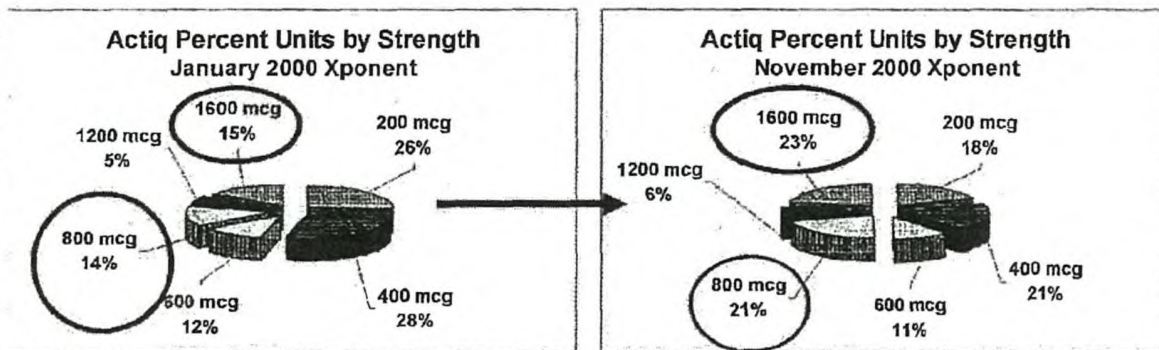
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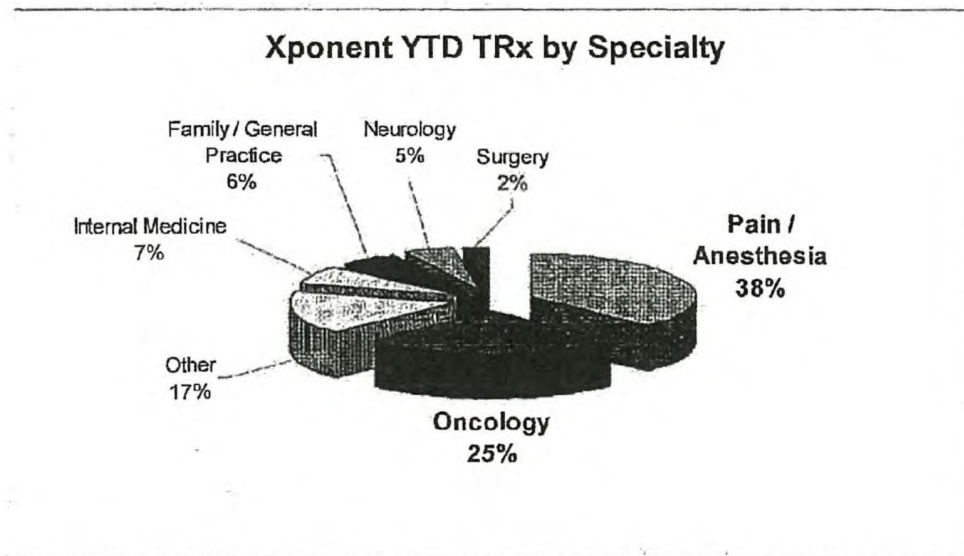
## Actiq Prescriber Analysis % Units by Specialty (snapshot)



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## Actiq Prescriber Analysis Xponent - TRx YTD by Specialty

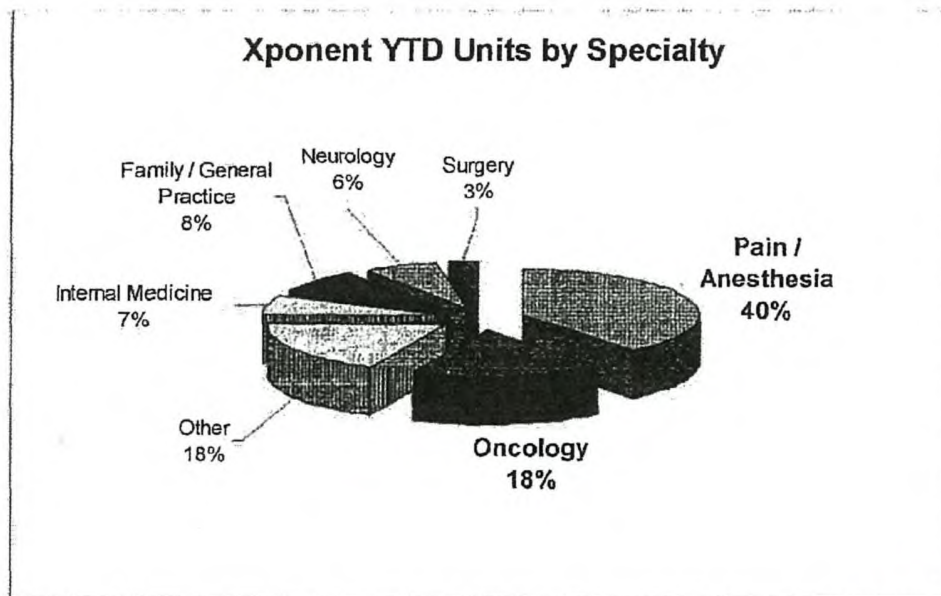


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## Actiq Prescriber Analysis Xponent – Total Units YTD by Specialty

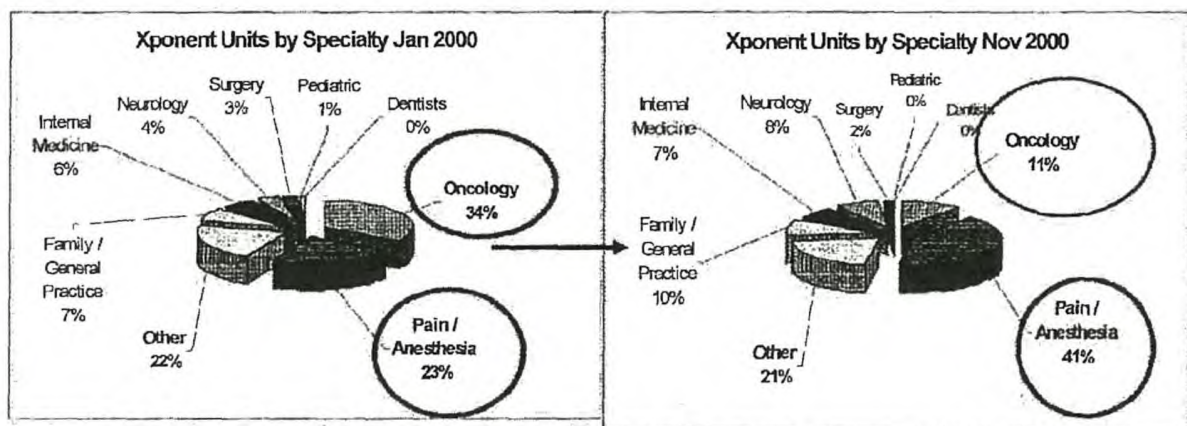


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## Actiq Prescriber Analysis

### Xponent – Units by Specialty (snapshot)

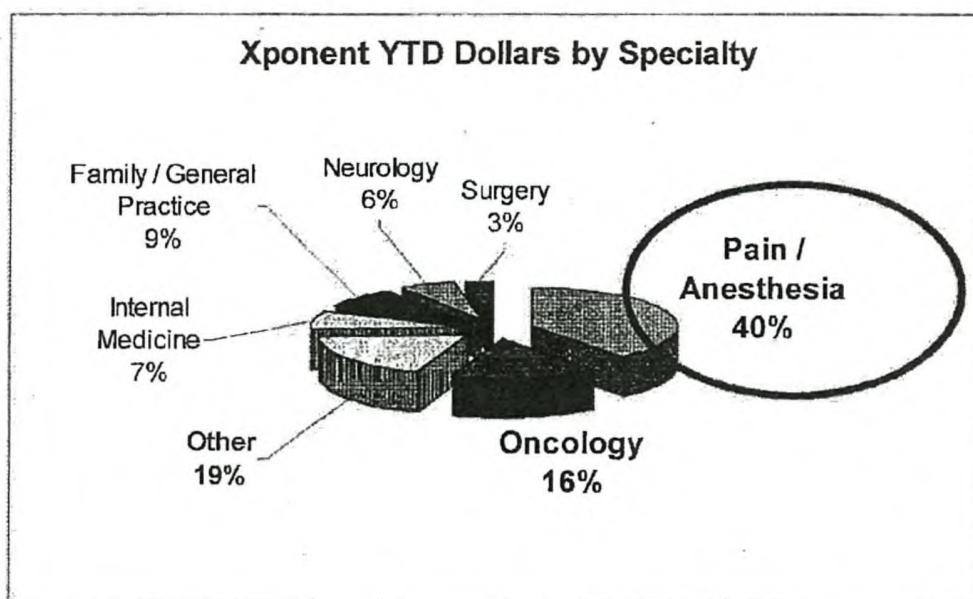


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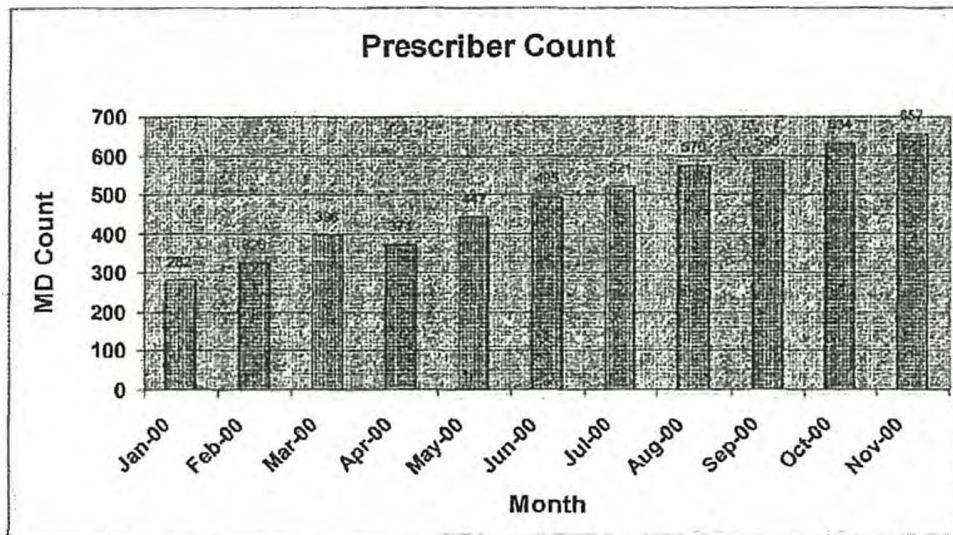
## Actiq Prescriber Analysis IMS – Total Sales YTD by Specialty



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## Actiq Prescriber Analysis Xponent – Monthly Prescribers

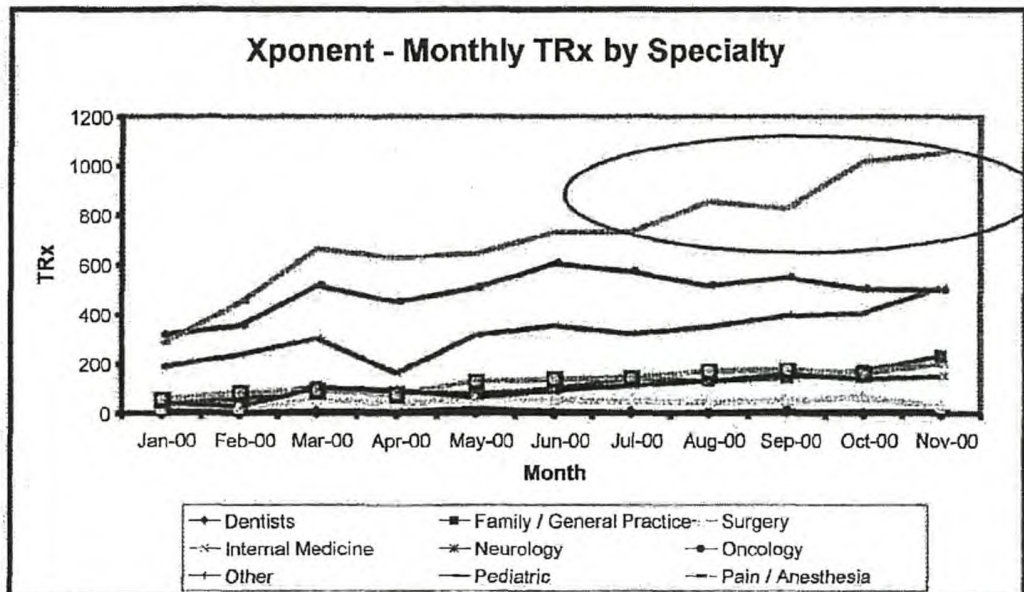


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# Actiq Prescriber Analysis

## Xponent – Monthly TRx by Specialty

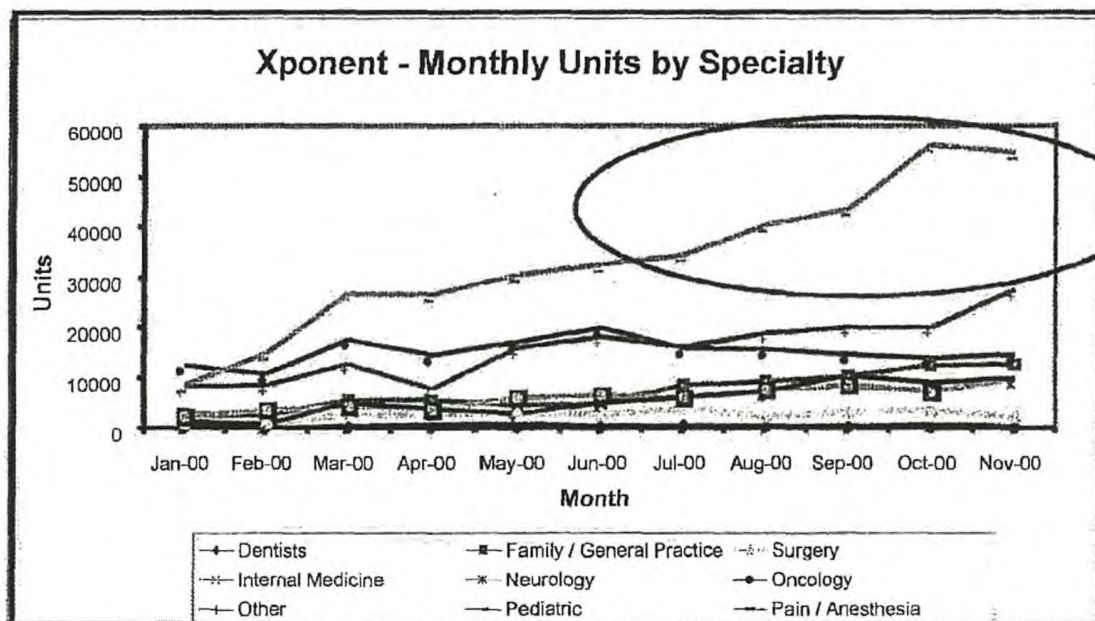


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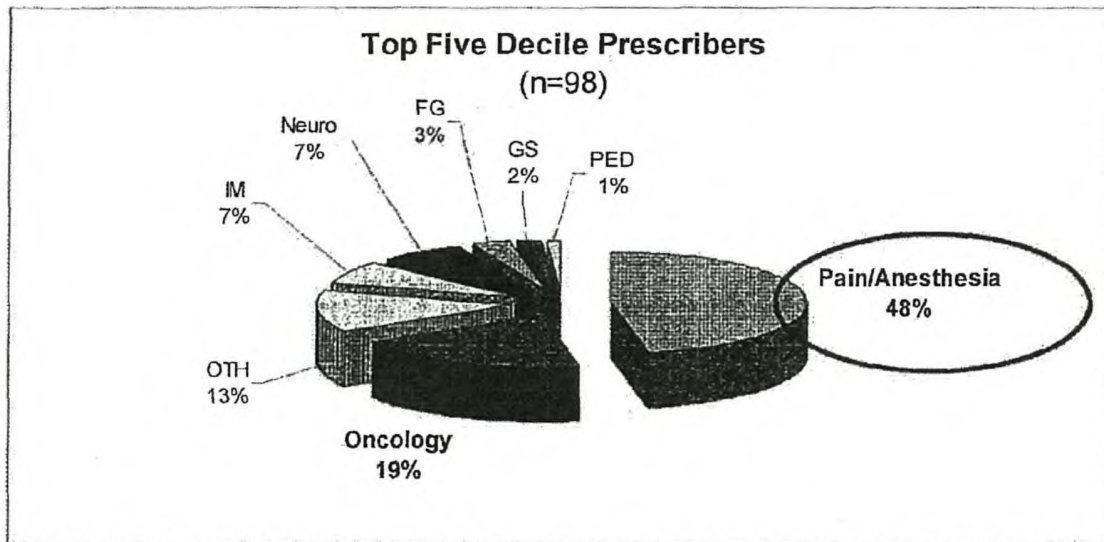
## Actiq Prescriber Analysis Xponent – Monthly Units by Specialty



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## Actiq Decile Analysis Xponent – Physician Prescribers

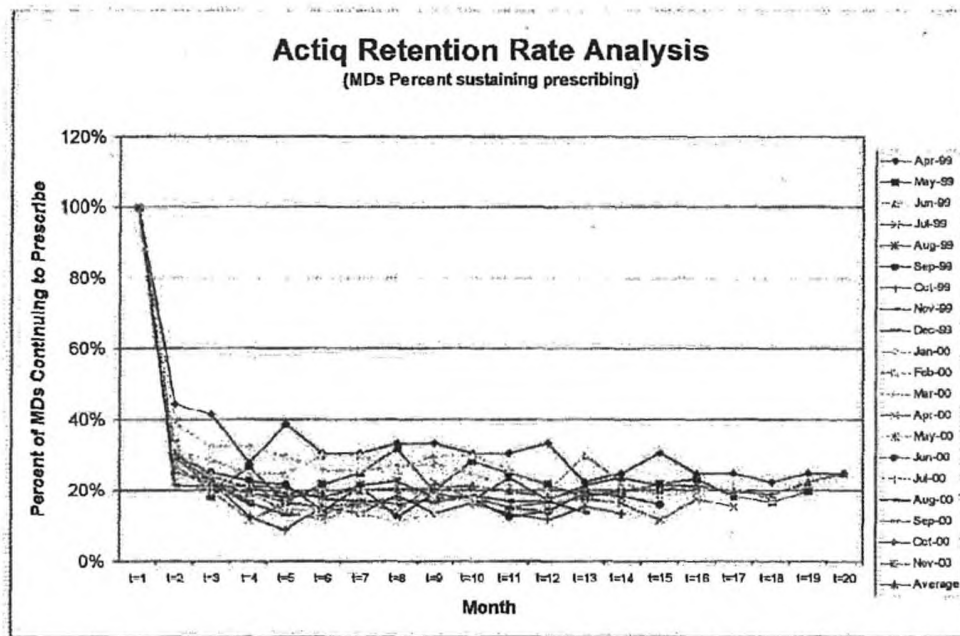


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# Actiq Prescriber Retention Rate Analysis



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## Prescriber Retention Research

- February 2000 – Market research study to examine prescriber retention
- Sample
  - 11 physicians who have discontinued writing Actiq
  - 13 physicians who have continued writing Actiq
  - 75% oncology/25% pain management



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## Prescriber Retention Research

### Results:

- Current and past providers are very satisfied with performance
  - Very few of those who've stopped writing are disillusioned
- Make or break issues
  - Relatively high cost
  - Reimbursement and availability hassles
- Lead product "like" – rapid onset
- Lead product "dislikes" – titration, cost
- Other limiting factors - lack of awareness/difficult to change prescribing habits



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## Prescriber Retention- Other Issues

- Titration process found to be cumbersome with key physician specialties
- Starting at recommended dose of 200 mcg often ineffective pain relief
- Need to encourage physicians to start higher and titrate faster to effective analgesic dose
  - Step through from 400 to 800 to 1600



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## Market Drivers

Market Driver	Jan 2000	Nov 2000	Trend
Script Size	38 units/script	49 units/script	↑
Average Selling Price	\$8.01/unit	\$10.80/unit	↑
Units/MD	125	182	↑

Average Retention Rate	21%
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## Key Issues and Recommendations



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## Key Regulatory and Clinical Issues

- Regulatory Issue with Actiq
  - The unique FDA scrutiny of Actiq
- Clinical Issue with Actiq
  - Limited / Lack of clinical data necessary to make critical claims



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## Issue: Unique FDA scrutiny of Actiq

- Subpart H approval
  - Definition: Allows for early approval of drugs
  - 30-day mandatory review of all promotional materials
  - Required Risk Management Program (RMP)
  - Inability to take advantage of WLF/FDAMA
- Actiq continues to be classified as a subpart H drug nearly 2 years after launch



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## Issue: Unique FDA scrutiny of Actiq

### Recommendation:

- Improve / expand our relationship with the FDA
- Gain a better understanding of the fair balance / safety issues
- Balance the playing field relative to the competition
- Goal: Loosen restrictions as they apply to Actiq promotion based on 2 years of successful, safe use with millions of units



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**Issue: Limited / Lack of clinical data  
necessary to make critical claims**

**In order of commercial priority:**

- Narrow indication (BTCP only vs. general BTP)
- Onset of action
- Relative potency - equianalgesic dosing
- Patient preference



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**Issue: Limited / Lack of clinical data  
necessary to make critical claims**

**Recommendations:**

- Obtain FDA input prior to executing new clinical trials to ensure acceptable trial design and valid endpoint selection
- Cephalon clinical and marketing should collaborate to determine desired endpoints
- Goal: Expand labeling to address key claim issues



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## Key Marketing Issues

- Lack of meaningful, focused positioning and message
- Prescriber retention
- Low awareness of Actiq due to limited promotional support
- Logistical barriers to product adoption that restrict access and prescribing
- Lack of understanding about the importance of treating BTCP and Actiq



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## **Issue: Lack of meaningful, focused positioning and message**

- The advertising for Actiq has consistently featured the unit itself
  - Focused attention only on the delivery system without providing a clinically meaningful reason to prescribe.
  - Non-emotional approach
  - Lack of features & benefits of transmucosal delivery
  - Ineffectively explained the relative product “value” versus safety and price



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## **Issue: Lack of meaningful, focused positioning and message**

### **Recommendations:**

- Relaunch Actiq with revised branding and positioning that provides a meaningful, focused positioning and message
  - Current regulatory constraints limit our ability to drive home the key benefit (rapid onset of action)
- New campaign is currently being created



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## Issue: Prescriber Retention

- Almost 80% of prescribers discontinue writing Actiq (average retention 21%)
- Perceived cumbersome titration process
  - Often multi-step process
  - Significant physician and patient education required on how to consume, store and dispose Actiq
  - Product availability concerns
- Perceived high cost



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## Issue: Prescriber Retention

### Recommendations:

- Increase probability of positive therapy start for physicians
  - Refine / Expand Performance Script Program
  - Communicate one call physician support line (800-896-5855)
  - Develop a Relationship Marketing Program among targeted physicians to retain existing customer base
- Provide clear dosing directions via promotion
  - Develop materials to educate clinicians to provide:
    - appropriate control of BTCP and Actiq's role in this treatment algorithm
    - "Ease" of titration
  - Drive 400mcg strength as an optional starting dose
    - Implement peer-to-peer influence, speakers programs, and CME



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## Issue: Prescriber Retention

### Recommendations:

- Provide “value” position of Actiq
  - Develop / Utilize education materials for clinicians to provide:
    - Appropriate context for comparison to alternative therapies
    - “Cost” of poorly controlled BTCP
- Increase / Improve patient education and support materials



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## Issue: Low Awareness of Actiq

- Limited promotional support
  - 1999 Initial launch 20 salespeople; 2000 relaunch 48
  - Lack of presence at many major conventions
  - Lack of advertising in professional journals
  - Limited financial budgets to perform Speaker MEPs



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## **Issue: Low Awareness of Actiq due to limited promotional support**

### **Recommendations:**

- Improve / Increase direct promotional reach and frequency
  - Upgrade quality of sales force (in progress)
  - Refine target audience to increase efficiency and effectiveness of promotional activities
- Establish convention presence at medical meetings (in progress)



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## **Issue: Low Awareness of Actiq due to limited promotional support**

- Develop a comprehensive direct marketing program (direct mail, convention activity, journal ads, website upgrade) that reinforces and augments the sales force effort
- Enhance speaker advocates and expand speakers bureau
  - Develop extranet site that allows access to Actiq information and slide kits
- Increase MEP activity (in progress)



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## **Issue: Logistical barriers to product adoption that restrict access and prescribing**

- Retail pharmacists are reluctant to stock a higher cost product with infrequent utilization
  - minimal penetration of the top 2,000 opioid-dispensing pharmacies
- Lack of stocking contributes to physician adoption and limits prescriber retention (see previous issue)
- Insufficient and inconsistent reimbursement



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## **Issue: Logistical barriers to product adoption that restrict access and prescribing**

### **Recommendations:**

- Maintain appropriate wholesaler inventories
  - Distribution and Logistics Department
- Market research to identify problems / trends in retail pharmacies (in progress)
- Facilitate reimbursement
  - Expanded and branded reimbursement program
  - Customized contracting strategy
    - Evaluate special programs with hospice?



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## **Issue: Lack of understanding about the importance of treating BTCP and Actiq**

- BTCP concept first described in 1989
  - Yet to be established as a well-recognized, separate pain event requiring unique intervention beyond traditional oral opioids and combo products
- Pain management not primary concern of Oncologists
- Minimal pain management education performed in med school/residency
- Misperceptions about cost of Actiq
- Poor understanding of the relative potency of Actiq



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## **Issue: Lack of understanding about the importance of treating BTCP and Actiq**

### **Recommendations:**

- Educate clinicians about BTCP and Actiq
  - MEPs
  - CME programs
  - Promotional literature
  - Medical Affairs (medical literature/standard responses/support line) to assist in addressing relative potency and other objections
- Create advocacy among key thought leaders
  - MEPs, peer-to-peer education, ML activity
- Support concept of aggressive treatment of BTCP with key pain associations via PR efforts (PR plan to be developed)
  - New PR firm identified and has experience in the pain market



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## Current Tactical Projects

- Sales Aid
  - Revisions in progress (National Sales Meeting)
- Dosing Guide
  - Revisions in progress (National Sales Meeting)
- Booth Panel
  - In development
- Journal Ad
  - In development



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## Current Tactical Projects

- Direct Mail Campaign
  - Initial mailing: Announcement letter with coupons and demo unit
    - Targeted mailing late-February
- PCS Coupon Program
  - Reprinting (February)
  - New design targeted for May / June
- CME Programs



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## CME Programs

- Teletopics (May)
  - Dr. James Cleary – “New Pain Algorithm”
  - CD ROM
- Regional Symposia (topic to be identified)
- “Profiles in Pain Management”
  - Quarterly newsletter / CD ROM
  - Current hot topics / specific patient types / case studies
- CME Website
  - To provide access to all CME programs



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## Keys to Success

- Physician Targeting
- Simplifying Titration
- MEP (peer-to-peer)
- CME



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