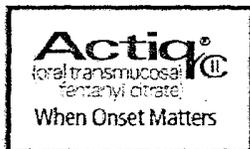
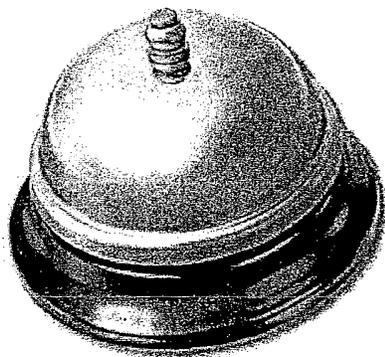


# 2003 Actiq<sup>®</sup> Marketing Plan



PLAINTIFFS TRIAL  
EXHIBIT  
**P-03608\_00001**

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## I. EXECUTIVE SUMMARY

### 2002 Performance Review

Cephalon experienced another extraordinarily successful year with ACTIQ in 2002. This achievement can be attributed primarily to focused and integrated marketing and sales efforts, which built upon the successful repositioning of ACTIQ in 2001. Key indicators of the growing demand for ACTIQ include:

- 2002 projected TRx of 176,847 (140% growth over 2001 and 33% greater than 2002 budget)
- 2002 projected sales of \$129.9 MM (138% growth over 2001 and 48% greater than 2002 budget)
- ACTIQ quarterly prescriber count has grown an average of 23% quarter-over-quarter since Q3 2000 to Q2 2002
  - 115% growth among anesthesiologists/pain specialists prescriber base (key targeted physician segment) from MAT June 2001 (665 prescribers) to MAT June 2002 (1431 prescribers)
- 60% increase in prescriber productivity among anesthesiologists/pain specialists from MAT June 2001 (25 TRx/prescriber) to MAT June 2002 (40 TRx/prescriber)
- 2.5% increase in TRx market share among pure short acting opioids (both branded and generic) from Q1 2000 (0.6% TRx market share) to Q2 2002 (3.1% TRx market share) and 0.8% increase in TRx market share from Q4 2001 (2.3% TRx market share) to Q2 2002 (3.1% TRx market share)
  - ACTIQ was the *only* branded pure short acting opioid to increase TRx market share over each of these time periods.

### 2003 Commercial Objectives

Based on the success of the current promotional platform, ACTIQ will continue to be positioned as fentanyl in a unique delivery system providing the most rapid onset of analgesia of any non-invasive opioid available. The commercial objectives for ACTIQ include the following:

- Achieve factory sales and TRx count targets
- Expand the ACTIQ prescriber base, especially among the most productive physician specialties
- Increase productivity among targeted physician specialties
- Improve prescriber retention
- Develop and execute an effective communication/publication plan, which will generate critical commercial information rapidly

| 2002 ACTIQ Gross Sales & TRx Budgets |              |             |          |
|--------------------------------------|--------------|-------------|----------|
|                                      | 2002 Actuals | 2003 Budget | % Growth |
| Gross Sales                          | \$133.8 MM   | \$218.8     | 64%      |
| TRx                                  | 185,467      | 279,880     | 51%      |

### **2003 Key Marketing Issues**

The key marketing issues facing ACTIQ in 2003 are as follows:

- Low awareness in the assessment and treatment of BTP
- Low product awareness
- Low awareness/lack of branding of Cephalon within the pain market
- Launch of the compressed powder formulation
- Limited advocacy among key opinion leaders as well inclusion of BTP/ACTIQ within pain treatment guidelines
- Limited clinical data and publications
- Potential new competition (branded competition anticipated in Q4 2004)
- Limited direct promotional reach

### **2003 Marketing Strategy**

The overall marketing strategy in 2003 will be to move physicians along the product adoption curve from awareness and trial to usage and adoption through appropriate and effective awareness and medical education programs. Specific marketing strategies have been developed for each key issue listed above.

### **2003 Tactical Summary**

ACTIQ marketing strategies will be executed through a variety of tactical initiatives that convey ACTIQ key messages and differentiate ACTIQ from its competitors based on its primary patient benefit: rapid onset of analgesia. Because the majority of ACTIQ prescribers remain in the trial stage of the product adoption curve, awareness programs focused on improving awareness of BTP and ACTIQ will be utilized among both patient populations and clinicians. In addition, due to ACTIQ's narrow and limited indication, medical education programs will continue to make up the most critical component of the ACTIQ tactical plan. CME programs and other peer-to-peer education initiatives will be critical to our success in 2003.

Two other critical factors that will influence our success in 2003 will be continued effective physician targeting and market segmentation, and timely publication/communication of commercially critical information regarding ACTIQ dosing/titration and potential therapeutic applications.

## II. SITUATION ANALYSIS

### A. 2002 REVIEW

#### *2002 Marketing Strategy Review*

The primary 2002 ACTIQ marketing strategy was to differentiate ACTIQ from its competitors by highlighting the primary product benefit, rapid onset of pain relief. Supporting strategies directly addressed each of the key marketing issues identified for 2002.

#### **2002 Promotional Strategy by Key Marketing Issue**

- Issue: Low product awareness among key targeted physician specialties  
Strategy: Strengthen the association of ACTIQ and its key benefit of rapid onset of analgesia through improved awareness and education
  
- Issue: Lack of knowledge in the assessment and treatment of breakthrough pain (BTP) among targeted physician specialties  
Strategy: Educate targeted physician specialties about the benefits of assessing and treating BTP with ACTIQ
  
- Issue: Limited clinical data and publications outside of the cancer patient population  
Strategy: Develop and begin execution of a phase IV research plan and publications plan with Medical Affairs
  
- Issue: Low product and disease state awareness among pain patients  
Strategy: Increase awareness of BTP among targeted pain patient populations and empower patients to discuss their pain openly with physicians
  
- Issue: Limited direct promotional reach  
Strategy: Direct the most effective promotional and educational efforts to the highest potential targeted physicians; maximize ROI of promotional and educational efforts

Overall, the marketing strategies implemented in 2002 have proven exceptionally effective, but not all of the strategies listed above have been executed. For example, specific strategies such as the initiation of a phase IV research and publications plan, have not developed as rapidly in 2002 as expected. Better execution on commercially meaningful publications and support for phase IV studies would be desired in 2003. Nonetheless, factory sales and total prescriptions are projected to greatly exceed initial 2002 targets.

*Objectives for 2002 included the following:*

- Achieve factory sales and total prescription (TRx) count targets
- Increase the number of ACTIQ prescribers, especially among the most productive physician specialties
- Increase the productivity among targeted physician specialties
- Evaluate and improve prescriber retention
- Establish a formal product communications plan and begin developing/renewing relationships with key opinion leaders and influencers

**B. SALES AND PRESCRIPTION UPDATE**

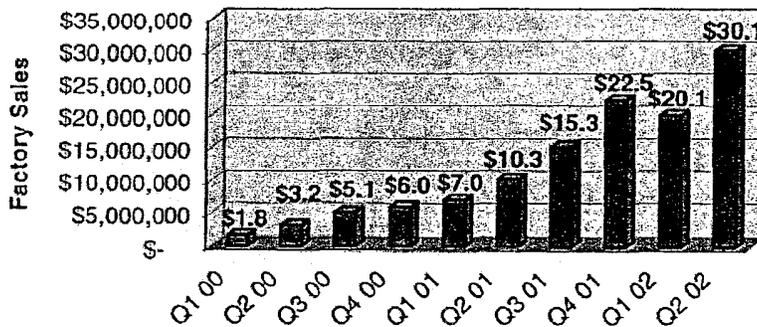
*Factory Sales Since Launch*

ACTIQ factory sales grew modestly through the first two years following launch in April 1999. The product suffered through two distinct, ineffective and under-supported launches (Abbott Laboratories April 1999; Anesta Corp. May 2000). Cephalon's re-launch of ACTIQ in March 2001 represented a critical upgrade in the quality of sales force and marketing personnel, as well as resources applied to both promotion and education. An immediate and direct correlation can be made with the Cephalon 2001 re-launch of ACTIQ and the sudden change in the factory sales growth trend observed.

*2002 ACTIQ Factory Sales*

The tremendous growth in factory sales observed in 2001 was sustained and accelerated in 2002 as we continued to build upon the successful re-launch and platform initiated in 2001. More focused promotional and educational efforts were employed in 2002 and directed toward pain specialists, resulting in a significant acceleration of growth.

**ACTIQ Factory Sales by Quarter  
(Q1 2000 - Q2 2002)**



Source: DDN

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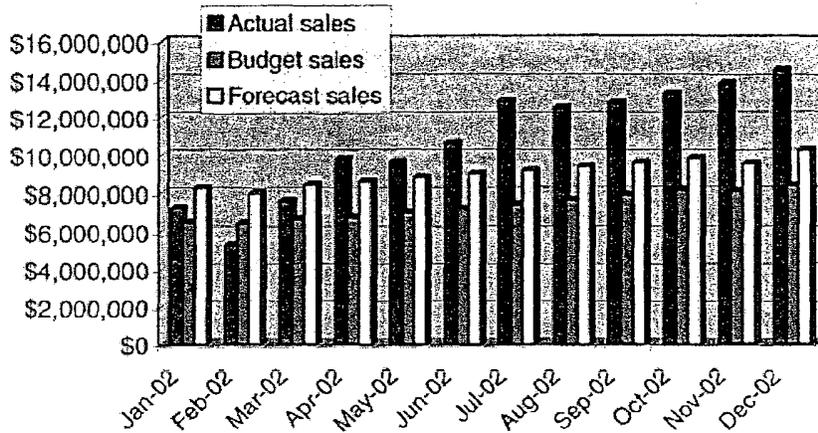
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Additionally, the discrete number of pain specialists prescribing ACTIQ more than doubled from Q2 2001 (481 pain specialist prescribers) to Q2 2002 (1048 pain specialist prescribers).

**2002 ACTIQ Factory Sales Versus Budget/Forecast**

ACTIQ factory sales are on target to reach \$129.8 MM in 2002 and exceed budget and forecast by 48% and 19%, respectively.

**2002 ACTIQ Factory Sales vs. Budget**



Source: IMS NPA

**Sales Distribution Channel Mix**

Year-to-date 2002 sales distribution amongst demand channels is seen below. Because ACTIQ is ideally utilized as an outpatient pain medication, it is no surprise that retail (95%) and mail order (1%) demand sales dollars combine to account for 96% of demand sales.

**Sales Distribution Channel Mix**

|                    | January - June 2002 | % of Sales |
|--------------------|---------------------|------------|
| Total Demand Sales | \$44,608,552        | 100%       |
| Retail             | \$42,425,635        | 95%        |
| Non-Retail         | \$1,686,498         | 4%         |
| Mail Order         | \$496,420           | 1%         |

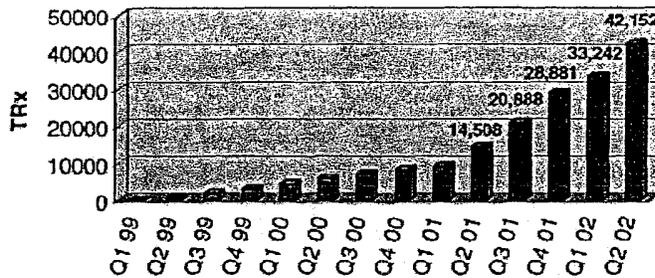
Source: IMS NPA

**Prescriptions Since Launch**

The total number of prescriptions (TRx) written since product launch in April 1999 exceeded 180,000 TRx through June 2002. Identical to factory sales, a direct and commensurate increase in prescriptions was observed with the Cephalon re-launch of

ACTIQ in 2001. The tremendous growth in prescriptions observed in 2001 was amplified in 2002 as we continued to build upon the successful re-launch and platform initiated in 2001. Again, more focused promotional and educational efforts directed toward pain specialists, the most productive prescribing segment, resulted in a significant acceleration in growth of prescriptions.

**ACTIQ Total Prescriptions by Quarter  
(Q2 1999 - Q2 2000)**

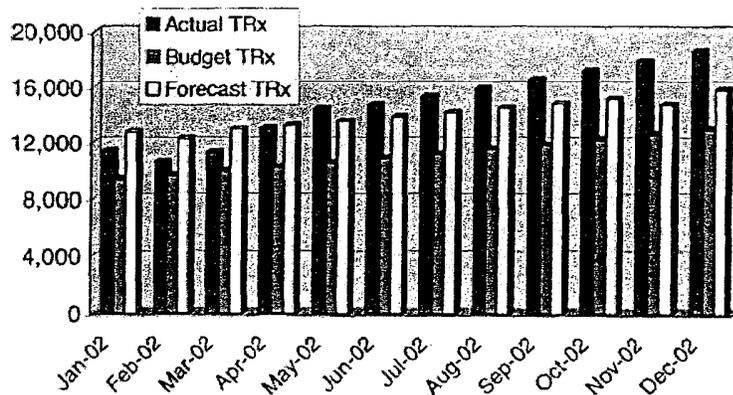


Source: IMS NPA

**2002 ACTIQ Total Prescriptions**

The total prescriptions written for ACTIQ through June 2002 totaled 75,394 and have exceeded the total of 73,514 TRx written for all of 2001. Year-end 2002 total prescriptions are projected to be 176,847, which will exceed the budget 132,695 and forecast 167,482 by 33% and 6%, respectively. The projected 2002 prescription total of 176,847 represents a 140% increase over 2001.

**2002 ACTIQ TRx vs. Budget**



Source: IMS NPA

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### ACTIQ Prescription Characteristics

The chart below illustrates the prescription characteristics for ACTIQ and provides a detailed comparison of data from MAT June 2001 versus MAT June 2002. The slight decline across all parameters evaluated below can primarily be attributed to the rapidly growing ACTIQ prescriber base. Most new prescribers fall within the trial phase of the product adoption curve and are therefore less productive initially. The objective will be to continue to gain new ACTIQ prescribers, while moving existing prescribers along the product adoption curve towards usage and adoption. As this occurs, the units consumed per day, average daily dose, cost per TRx and average length of therapy should no longer be in decline.

### ACTIQ Prescription Characteristics

|         | DACON (Units/day)  |             | Average Daily Dose (mcg/day) |              | Cost per TRx |              | Average Days Therapy |              |
|---------|--------------------|-------------|------------------------------|--------------|--------------|--------------|----------------------|--------------|
|         | MAT:Jun 01         | MAT:Jun 02  | MAT:Jun 01                   | MAT:Jun 02   | MAT:Jun 01   | MAT:Jun 02   | MAT:Jun 01           | MAT:Jun 02   |
|         | <b>ACTIQ TOTAL</b> | <b>5.20</b> | <b>4.39</b>                  | <b>5,034</b> | <b>3,767</b> | <b>\$610</b> | <b>\$575</b>         | <b>13.21</b> |
| 200mcg  | 3.70               | 3.31        | 116                          | 74           | \$106        | \$225        | 9.29                 | 11.18        |
| 400mcg  | 3.68               | 3.68        | 341                          | 398          | \$302        | \$345        | 10.22                | 11.96        |
| 600mcg  | 4.65               | 4.16        | 291                          | 354          | \$482        | \$489        | 11.40                | 12.29        |
| 800mcg  | 4.96               | 4.30        | 718                          | 772          | \$686        | \$633        | 12.88                | 12.99        |
| 1200mcg | 5.98               | 4.76        | 760                          | 553          | \$1,031      | \$1,004      | 12.22                | 14.21        |
| 1600mcg | 7.35               | 6.52        | 2,809                        | 1,616        | \$2,145      | \$1,669      | 16.98                | 13.95        |

Source: IMS NPA

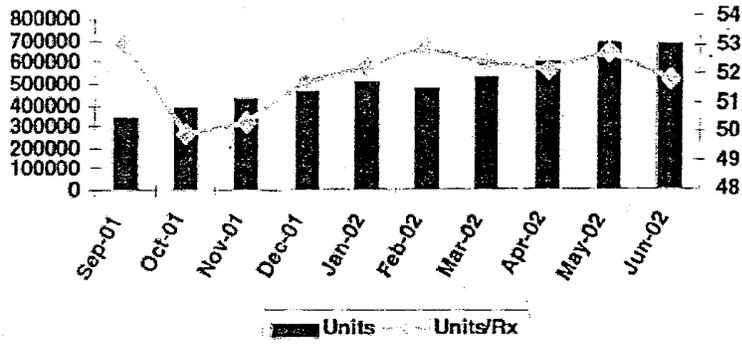
### Units Per Prescription

Units/prescription is a critical measure of our success with ACTIQ. Upon Cephalon's re-launch in 2001, prescribers generated a tremendous number of new patient starts (i.e. titration prescriptions written for a smaller number of units) and, therefore, total prescriptions outpaced total units for quite some time. Despite a declining units/Rx, this was an indicator of product usage and adoption among our targeted physicians and of our success.

Since January 2002, the units/Rx for ACTIQ has remained steady and above 52 units/Rx. This demonstrates three critical areas of success.

- First, it demonstrates that total units are growing commensurately with total prescriptions.
- Second, it demonstrates that maintenance prescriptions (which are typically written for a larger number of units) are most likely growing commensurately with titration prescriptions (which are typically written for a smaller number of units). It will be critical to maintain somewhat of a balance between total units and total prescriptions as ACTIQ continues along its current, tremendous growth trend.
- Third, it serves as an indicator that many physicians currently prescribing ACTIQ have moved toward the usage and adoption end of the product adoption curve.

### Total Units & Units/Rx Analysis

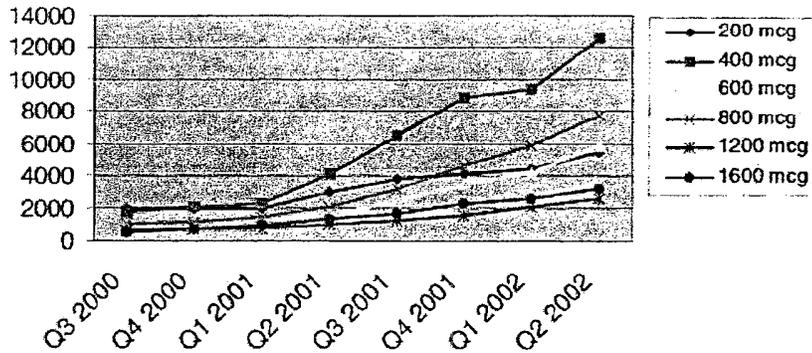


Source: IMS NPA

### Prescription Count by Strength

The 400mcg, 600mcg and 800mcg strength prescriptions have continued along the most rapid growth trend. This is primarily due to the sales, promotion and education efforts implemented around the titration process for ACTIQ in 2002. Publication efforts aimed at this specific issue, which have been delayed, would have greatly assisted this effort in 2002. Publications regarding simplified titration remain a valid opportunity for educating existing and potential prescribers.

### ACTIQ Quarterly TRx by Strength (Q3 2000 - Q2 2002)



Source: IMS NPA

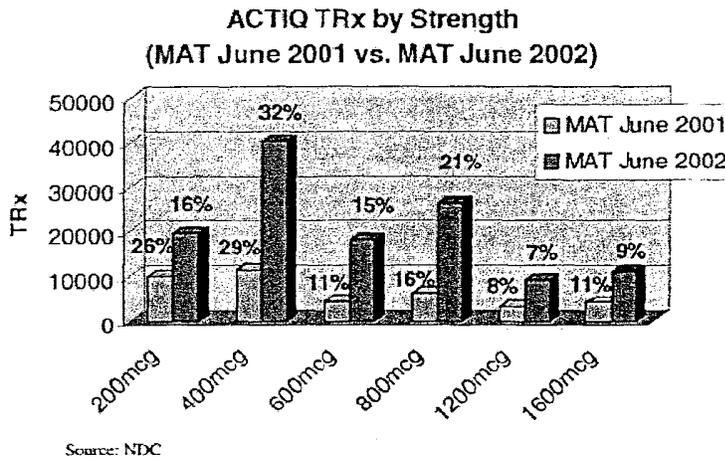
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**Prescriptions by Strength**

The 200mcg and 400mcg strength prescriptions accounted for 26% and 29% respectively and comprised the two largest percentages of prescriptions written among all strengths for the time period MAT June 2001. This can be primarily attributed to the former titration educational approaches as well as a reliance on a smaller number of high prescribers.

For the time period MAT June 2002, the 400mcg and 800mcg strength prescriptions accounted for 32% and 21% respectively and comprised the two largest percentages of prescriptions written across all strengths. Specifically, the 400mcg strength (32%) now accounts for double the prescriptions of the 200mcg strength (16%). The evolution from the previous mirroring time period can be primarily attributed to improved education regarding dosing and titration and a much broader prescribing base. This transition, from depending so heavily on the 200mcg strength to having the 200mcg strength comprise only 16% of all prescriptions written, was another critical step in the evolution of ACTIQ. Fewer prescriptions at the 200mcg strength during 2002 meant fewer patient failures/more patient successes, greater physician satisfaction and ultimately, greater and continued product use. Again, this transition is another significant indicator that many current ACTIQ prescribers have moved along the product adoption curve towards usage and adoption.



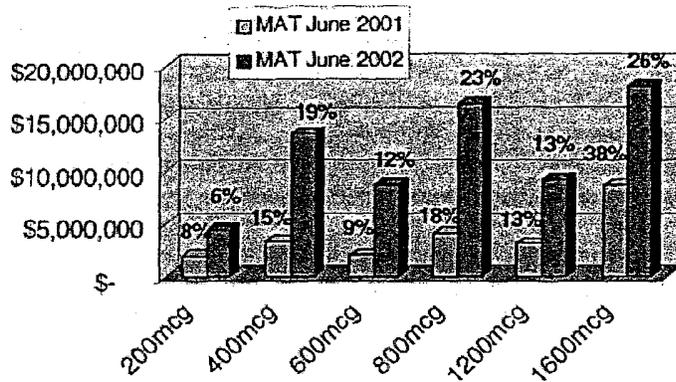
**Sales by Strength**

The 1600mcg (38% of demand sales), 800mcg (18%) and 400mcg (15%) are the product strengths that contributed most significantly to sales for the time period MAT June 2001.

For the time period MAT June 2002, the top three contributing strengths remained the same, with the dependency upon the 1600mcg strength greatly decreased. Decreased dependency on the 1600mcg strength indicates that business is being driven more evenly by all strengths. Among all strengths, the 400mcg, 600mcg and 800mcg strengths all

grew as a percentage of overall sales from the period MAT June 2001 to MAT June 2002, while the other three strengths decreased. This trend mirrors the educational initiatives implemented in 2002 regarding simplified titration and dosing.

**ACTIQ Factory Sales by Strength  
(MAT June 2001 vs. MAT June 2002)**



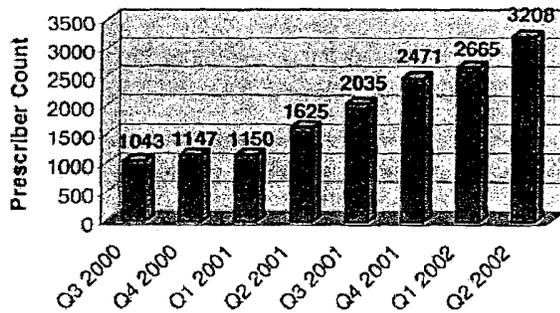
Source: IMS NPA

**C. PRESCRIBER BASE ANALYSIS**

*Total and Quarterly Prescriber Count*

For the time period MAT June 2002, the total number of ACTIQ prescribers was 5743. During the first and second quarters of 2002, there were 2665 and 3208 ACTIQ prescribers, respectively. The ACTIQ quarterly prescriber count has grown an average of 23% quarter-over-quarter since Q3 2000 to Q2 2002. This continued growth in the number of ACTIQ prescribers demonstrates the effectiveness of awareness programs and sales force efforts implemented and executed in 2002.

**ACTIQ Quarterly Prescriber Count  
(Q3 2000 - Q2 2002)**



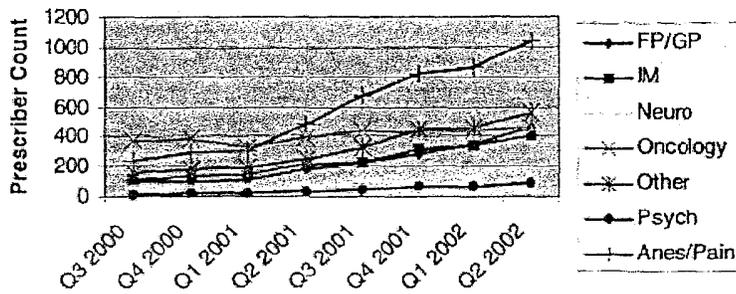
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Source: NDC

Examination of prescriber count by specialty over this same time period shows the most tremendous growth seen among pain specialists. Pain specialists have been the focus of key promotional and educational marketing and sales initiatives throughout 2002 and continue to comprise the largest and most productive segment of the ACTIQ prescribing base.

**ACTIQ Quarterly Prescriber Count by Specialty  
(Q3 2000 - Q2 2002)**



Source: NDC

**Prescription Analysis of Pain Specialists**

|                                    | MAT June 2001 |                 |                       | MAT June 2002 |                 |                       |
|------------------------------------|---------------|-----------------|-----------------------|---------------|-----------------|-----------------------|
|                                    | TRx Count     | Physician Count | Avg TRx per Physician | TRx Count     | Physician Count | Avg TRx per Physician |
| <b>Anes/Pain</b>                   | 16,625        | 665             | 25                    | 56,975        | 1431            | 40                    |
| <b>% Growth from MAT June 2001</b> |               |                 |                       | 243%          | 115%            | 60%                   |

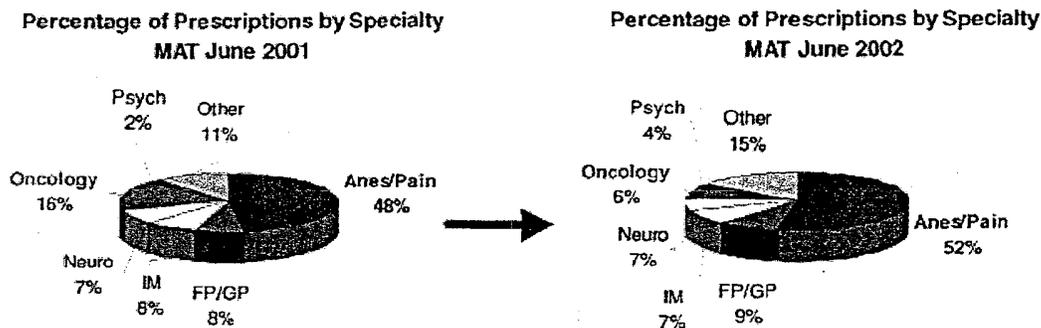
**Total Prescriptions by Physician Specialty**

Pain specialists wrote the majority of prescriptions (56,975 TRx) and increased their percentage of overall prescriptions 4% from MAT June 2001 (48%) to MAT June 2002 (52%), which represented the largest increase among all specialties. Conversely, the oncology segment of the prescribing base contributed only 6,535 total prescriptions, which represented only 4% of all prescriptions. Oncology was the only specialty that

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saw its percentage of overall prescriptions decline from MAT June 2001 to MAT 2002. Every other specialty either remained at its current level of productivity or increased. This can somewhat be attributed to the fact that Cephalon has primarily focused marketing and selling efforts on pain specialists (a prescriber base segment much more receptive to ACTIQ messaging), however, the true issue may be that oncologists are far less receptive to ACTIQ messaging and not primarily concerned with pain and symptom management.



**Prescription Count and Growth Among Pain Specialists**

Effective physician targeting continues to be critical to our success with ACTIQ. The focused targeting directive from 2001 has been maintained in 2002. Sales and marketing targets include pain specialists (anesthesiologists, physiatrists, neurologists, psychiatrists) and oncologists who are high opioid prescribers with the potential to treat breakthrough cancer pain.

Since the Cephalon re-launch, pain specialists have demonstrated themselves as the segment of the ACTIQ prescriber base most receptive to ACTIQ messaging and have most readily adopted the product as a part of their pain management armamentarium. The total number of prescriptions attributed to pain specialists has increased 243% from MAT June 2001 to MAT June 2002. Additionally, the average prescriptions per pain specialist has increased 40% over this same time period.

**Productivity by Physician Specialty**

An increase in total prescriptions was seen in all physician specialties from MAT June 2001 to MAT June 2002, with the largest increase seen among pain specialists. Pain specialists continue to be the strongest advocates and most productive segment of our prescribing base (40 TRx/prescriber). Despite the fact that the total prescriptions from the oncology base of prescribers increased from MAT June 2001 (5,739 TRx) to MAT

June 2002 (6,533 TRx) 13% (by far the smallest increase among all specialties), they remain as our least productive prescribing base segment, contributing only 6 TRx/prescriber over each of the time periods evaluated (no increase from MAT June 2001 to MAT June 2002).

**Productivity by Physician Specialty**

| Specialty    | MAT June 2001 |                    |              | MAT June 2002  |                    |              |
|--------------|---------------|--------------------|--------------|----------------|--------------------|--------------|
|              | TRx Count     | TRx per Prescriber | Units per Rx | TRx Count      | TRx per Prescriber | Units per Rx |
| Anes/Pain    | 16,625        | 25                 | 65           | 56,975         | 40                 | 54           |
| FP/GP        | 2,634         | 8                  | 73           | 9,604          | 12                 | 61           |
| IM           | 2,751         | 7                  | 49           | 7,856          | 9                  | 59           |
| Neuro        | 2,573         | 22                 | 61           | 7,136          | 28                 | 44           |
| Oncology     | 5,739         | 6                  | 33           | 6,533          | 6                  | 41           |
| Psych        | 727           | 13                 | 39           | 3,816          | 29                 | 34           |
| Other        | 3,912         | 8                  | 52           | 15,761         | 14                 | 50           |
| <b>TOTAL</b> | <b>34,961</b> | <b>12</b>          | <b>57</b>    | <b>107,681</b> | <b>19</b>          | <b>52</b>    |

Source: NDC

**D. USAGE BY DISEASE AREA**

*Limitation of Resources*

The current data source utilized at Cephalon for disease usage information is captured in the Physician Drug and Diagnosis Audit (PDDA) from Scott Levin. This audit does not include anesthesiologists, which represent the largest and most productive segment of the ACTIQ prescriber base. Scott Levin does include oncologists and neurologists in the PDDA audit, however, the data is very limited due to ACTIQ's limited prescription base. For example, there were 24,000 projected uses of ACTIQ in PDDA through June 2002. The validity of this data is questionable on two levels. First, the projected 24,000 uses fell among only five specific uses including: 5000 uses each in back pain, malignant neoplasm and lung cancer, and 4000 uses each in congenital spine anomalies and pelvic pain. Second, the projected number of 24,000 uses exceeds our best estimate of the current total number of ACTIQ patients (i.e. between 15,000 and 20,000 patients). Based on the preceding limitations of ACTIQ uses captured in PDDA, this data source does not adequately report a realistic representation of disease specific usage of ACTIQ.

*Tracking Studies*

In May and December of 2001, primary research was implemented to elucidate product awareness, perception and use by pain type among pain specialists and oncologists. Obviously, oncologists included in both tracking studies cited use of ACTIQ primarily in the treatment of BTCP. Additionally, participating pain specialists cited ACTIQ usage in the following disease states, illustrating a wide spectrum of application and opportunity.

Usage of ACTIQ Cited by Pain Specialists

| USE OF ACTIQ                             | (N) = | PAIN SPECIALISTS |        |  |
|--|-------|------------------|--------|--|
|  |       | BASELINE         | WAVE I |  |
|  |       | Total            | Total  | Of Those Rx'ing Mean # of Pts on Actiq |
|  |       | (25)             | (29)   |  |
|  |       | %                | %      |  |
| <u>% of MDs who have Rx'd Actiq for:</u> |       |                  |        |  |
| Lower back pain                          |       | 48               | 83     | 32                                     |
| Cancer pts.***                           |       | 40               | 62     | 22                                     |
| Adhesions                                |       | 24               | 55     | 11                                     |
| Reflex sympathetic dystrophy             |       | 36               | 52     | 15                                     |
| Fibromyalgia                             |       | 16               | 52     | 8                                      |
| Osteoarthritis                           |       | 20               | 48     | 7                                      |
| Post-trauma                              |       | 24               | 45     | 15                                     |
| Diabetic neuropathy                      |       | 16               | 45     | 10                                     |
| Arachnoiditis                            |       | 16               | 45     | 20                                     |
| Rheumatoid arthritis                     |       | 12               | 41     | 6                                      |
| Other type of headache****               |       | 24               | 38     | 12                                     |
| Migraine headache                        |       | N/A              | 34     | 12                                     |
| Systemic lupus                           |       | 8                | 14     | 3                                      |
| Other pt. types                          |       | 28               | 45     | 15                                     |

Source: December 2001 Baseline Tracking Study

Although different groups of physicians were included in each of the tracking studies, it is significant to note that for each of the 14 different disease states listed above, there was a tremendous increase in the percentage of pain specialists who stated that they used ACTIQ to treat these pain types from May 2001 to December 2001. The average increase in physician usage across the 14 specific disease states listed was 27%. In addition, migraine headache was not even mentioned as a therapeutic application in the May 2001 study, but was listed by 34% of pain specialists as being a pain type in which they have utilized ACTIQ in December 2001.

\*\*\*The proportion reported in Baseline wave reflects only those who responded "cancer patients" when questioned about use for "other" patient-types

\*\*\*\*Baseline wave only specified "headache"

ACTIQ usage by pain specialists in the aforementioned disease states may be due to several reasons, including:

- Familiarity with fentanyl (both IV and transdermal)
- Comfort with fentanyl in a unique delivery system (transdermal)
- Comfort with using many medications (especially adjuvants such as tricyclic antidepressants, anticonvulsants and corticosteroids) outside of their labeling in the management of chronic pain

#### *Clinical Needs to Expand Usage*

As noted in the *ACTIQ 2002 Marketing Plan*, anesthesiologists and other pain specialists who have similar prescribing habits, may not require substantial clinical evidence to implement ACTIQ in numerous disease states other than BTCP due to the reasons listed above, particularly their familiarity with fentanyl. Furthermore, these data may also suggest that small, exploratory studies and case series in pain disease states requiring rapid onset of analgesia will help to establish the clinical relevance of ACTIQ and foster significant additional usage in numerous pain-related syndromes. The disease states that represent the largest growth opportunities for ACTIQ include, but are not limited to osteoarthritis, rheumatoid arthritis, chronic back pain, migraine headaches, complex regional pain syndrome and postherpetic neuralgia. Medical affairs support describing the rationale for a rapid acting opioid would help to drive these uses. Unfortunately, only minimal progress has been made in the areas of phase IV research, case series and publications through October 2002.

#### *ACTIQ Usage in Cancer*

Using information from the December 2001 tracking study, we assume at least 29% of our 2002 prescriber base is prescribing ACTIQ to treat BTCP (see table below).<sup>1</sup> Despite the fact that the percentage of physicians among our prescriber base utilizing ACTIQ to treat BTCP has decreased from last year (40% MAT June 2001 to 29% MAT June 2002), the true number of physicians utilizing ACTIQ to treat BTCP has significantly increased (1205 physicians MAT June 2001 to 1670 physicians MAT June 2002). The percentage decrease is primarily due to the fact that many new prescribers may see utility for ACTIQ in other therapeutic areas. Additionally, we do not include other specialties outside of pain specialists and oncologists in our tracking studies. Therefore, it is impossible to accurately determine or generalize what percentage of our prescriber base from other specialties is utilizing ACTIQ to treat BTCP. The true percentage of physicians prescribing ACTIQ to treat BTCP may potentially be much higher.

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<sup>1</sup> This number is derived using 100% of oncologists and 40% of all anesthesiologist/pain specialists of the 2001 ACTIQ prescriber base (40% of pain specialists cited usage in cancer).

**Minimum Percentage of Prescribers Using ACTIQ to Treat BTCP**

|              | Prescriber<br>Count<br>MAT June<br>2002 | % Of<br>Prescriber<br>Base | Multiple** | BTCP<br>Prescriber<br>Count | Minimum<br>% of BTCP<br>Prescribers |
|--------------|---|----------------------------|------------|-----------------------------|-------------------------------------|
| Anes/Pain    | 1431                                    | 25%                        | 4          | 572                         | 10%                                 |
| Oncology     | 1098                                    | 19%                        | 1.00       | 1098                        | 19%                                 |
| Neurology    | 252                                     | 4%                         | 0          | 0                           | 0                                   |
| IM           | 829                                     | 14%                        | 0          | 0                           | 0                                   |
| FP/GP        | 823                                     | 14%                        | 0          | 0                           | 0                                   |
| Psych        | 133                                     | 2%                         | 0          | 0                           | 0                                   |
| Other        | 1157                                    | 20%                        | 0          | 1670                        | 0                                   |
| <b>TOTAL</b> | <b>5723</b>                             | <b>100%</b>                |            | <b>1670</b>                 | <b>29%</b>                          |

\*Source: NDC Source Prescriber

\*\*The multiple = 4 for Anes/Pain Specialists (40% of APMs cite usage in cancer patients) Source: May Baseline Tracking Study

To further assess and clarify the existing therapeutic applications of ACTIQ, the ACTIQ marketing team will work with market research to implement a pseudo-PDDA type audit. This audit will be described in greater detail within the Market Research section.

**E. TARGET AUDIENCE ANALYSIS**

*Target Audience*

When identifying the target audience for ACTIQ, two critical factors must be considered.

- First, any physician prescribing opioids (regardless of specialty save pediatricians, dentists and surgeons) with the potential to treat BTCP should be considered a potential target for ACTIQ. Despite the limited indication and the very restrictive environment ACTIQ must be promoted within, the fact remains that it is an oral, short-acting opioid and most physicians who manage pain, be it malignant, chronic non-malignant or acute, will view ACTIQ as a potentially suitable medication despite the current indication and our conservative promotional efforts to date.
- Second, since launch, it has been established that successful promotion of ACTIQ is achieved through focused promotional and selling efforts dedicated and targeted to the highest potential prescribers. Success with ACTIQ to date has been achieved through the creation of a solid, core group of prescribers. Continued success will be achieved through the maintenance and expansion of this core group of prescribers. Therefore, it is critical for marketing and sales to identify the prescribers that have the greatest potential to fall within this core of physicians.

An analysis of prescriber level data was performed in 2001 with the intention of deriving two distinct, yet over-lapping, target audiences. These target audiences included both a larger universe of potential sales targets and a smaller target list considered to be

marketing designated sales targets. These targets remained static through July 2002, until such time enhanced NDC data was obtained, which enabled a newly focused and revised analysis of the prescriber level data.

The July 2002 analysis applied specific criteria to establish both the universe of potential targets and the marketing designated sales targets. The applied criteria and results of the analysis follow.

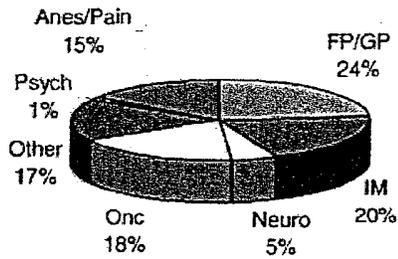
*Criteria for inclusion in the Universe of Potential Targets*

- ACTIQ prescribers January 2002 to June 2002 excluding general surgery, pediatricians, and dentists
- Duragesic prescribers greater than decile 2 excluding general surgery, pediatricians, and dentists
- Prescribers who were both a pure short acting opioid decile greater than decile 3 and long acting opioid decile greater than decile 3 excluding general surgery, pediatricians, and dentists



Source: NDC

**ACTIQ Potential Target Universe by Specialty  
31,314 Physicians**

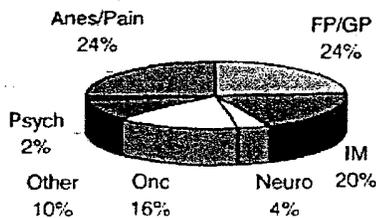


Source: NDC

**Criteria for inclusion in the Marketing Designated Sales Targets**

- ACTIQ prescribers January 2002 to June 2002 excluding general surgery, pediatricians, and dentists
- Duragesic prescribers greater than decile 6 excluding general surgery, pediatricians, and dentists
- Prescribers who were both a pure short acting opioid decile greater than decile 5 and long acting opioid decile greater than decile 6 excluding general surgery, pediatricians, and dentists

**ACTIQ Marketing Designated Sales Targets by Specialty  
8,464 Physicians**



Source: NDC

Several marketing initiatives in 2002 called for specific targeting of physicians among the 31,000+ physicians in the active universe, while other initiatives called for specific targeting among the 8,464 marketing designated sales targets. The criteria applied to

each specific marketing initiative varied based on the objective of the program (medical educational, direct mailing, etc.). Flexibility in targeting must be maintained in 2003 as the opportunities and targeted market segments for ACTIQ continue to evolve. Lastly, the size of the current sales force requires a focused targeting and sales effort.

#### ***Target Market Penetration***

Currently, we have very low penetration of the 8,464 marketing designated sales targets. Only 3207 physicians (38%) of the 8,464 targets have prescribed ACTIQ in 2002. Of the 2,148 pain specialists among these 8,464 targets, 1102 (51%) have prescribed ACTIQ in 2002. This moderate penetration of key physician targets represents tremendous opportunity for continued growth.

#### ***Market Segmentation Needs***

Based on feedback from physicians at advisory panel meetings and consultant meetings held in 2002, it appears that there is a need to perform some analysis to further segment physicians treating chronic pain. Physicians cited use of ACTIQ in a multitude of pain types during these meetings and encouraged Cephalon to pursue research in these areas. These opinions came from physicians across a variety of specialties, however, it was obvious that certain physicians treat pain differently than others; there are different philosophies in treating certain types of pain. In order to better understand our market, it will be critical to perform an analysis of specific segments of the ACTIQ target universe to determine which physicians are potentially sensitive to particular ACTIQ messages. This will help us focus certain 2003 marketing specific tactics toward the correct market segment. The plans for implementing a market segmentation analysis will be described in the Market Research section.

#### ***Pain Care Specialist Call Activity***

Pain Care Specialists averaged 4.3 calls/day through June 2002, up from 4.1 calls/day in 2001. This represents almost 31,000 target physician interactions among 5,375 physicians through June 2002. This increase in call frequency is most likely due to the geographical size reduction of some of the PCS sales territories from the expansion from 48 to 60 PCS sales representatives. Further expansion of the PCS sales force will shrink sales territories even further, expand our direct promotional reach and, more than likely, increase our ability to not only reach designated targets, but reach them more frequently.

#### ***ACTIQ Prescriber Decile Analysis***

Analysis of the top five ACTIQ prescribing deciles MAT June 2001 versus MAT June 2002 highlights three key findings.

### ACTIQ Decile Analysis

| Actiq Decile Summary MAT Jun 2001 |                           |                    | Actiq Decile Summary MAT Jun 2002 |                           |                    |
|-----------------------------------|---------------------------|--------------------|-----------------------------------|---------------------------|--------------------|
| Specialty                         | MD Count in top 5 deciles | % of top 5 deciles | Specialty                         | MD Count in top 5 deciles | % of top 5 deciles |
| Anes/Pain                         | 59                        | 53%                | Anes/Pain                         | 117                       | 59%                |
| Neuro                             | 13                        | 12%                | Other                             | 31                        | 16%                |
| Onc                               | 12                        | 11%                | Neuro                             | 17                        | 9%                 |
| Other                             | 12                        | 11%                | FP/GP                             | 15                        | 8%                 |
| IM                                | 9                         | 8%                 | IM                                | 11                        | 6%                 |
| FP/GP                             | 5                         | 4%                 | Psych                             | 6                         | 3%                 |
| Psych                             | 2                         | 2%                 | Onc                               | 3                         | 2%                 |
| <b>TOTAL</b>                      | <b>112</b>                | <b>100%</b>        | <b>TOTAL</b>                      | <b>200</b>                | <b>100%</b>        |

Source: NDC

First, the number of physicians within the top five prescribing deciles has increased 79% from MAT June 2001 (112 prescribers) to MAT June 2002 (200 prescribers). Although 200 physicians is not a tremendously high number of prescribers, the fact that the number of physicians prescribing half of all ACTIQ prescriptions has nearly doubled is important because it greatly expands the number of physicians on whom we must rely. Also interesting, but not shown below, is the fact that the productivity levels required to be included among the top five deciles increased for all deciles except decile 10. Therefore, not only has the number of physicians among the top five prescribing deciles nearly doubled in the time period evaluated, but the productivity levels among these prescribers has also significantly increased.

The second key finding is the impact pain specialists have had and their dominance among the top ACTIQ prescribers. Pain specialist comprised 53% of the prescribers (59 of 112) among the top five deciles over the time period MAT June 2001 and increased to 59% (117 of 200) over the time period MAT June 2002. In fact, the number of pain specialist among the top five deciles during MAT June 2002 (117) was greater than the total physicians comprising all top five deciles during MAT June 2001 (112).

The third key finding is that every specialty represented except oncology increased in number of prescribers among the top five deciles from MAT June 2001 to MAT June 2002. The number of oncologists in the top five deciles decreased from 12 of 112 (6%) MAT June 2001 to two of 200 (1%) MAT June 2002. This is most likely a direct result of our pain specialty focused targeting approach and possibly related to oncologists' nature to be less aggressive in adopting new/innovative therapies in supportive care. It is important to note that although the number of oncologists among the top five prescribing deciles has decreased over this time period, the total number of oncologists prescribing ACTIQ has increased from MAT June 2001 (940 prescribing oncologists) to MAT June 2002 (1098 prescribing oncologists).

## F. PRODUCT AWARENESS AND PERCEPTION

### *Product Awareness*

Despite a marked increase from our initial baseline tracking study performed in May 2001, unaided product awareness of ACTIQ among pain specialists and oncologists remains low, as evidenced by the results of the December 2001 tracking study. Unaided awareness remains higher among oncologists and may be a result of former targeting directives and promotional efforts. Unaided awareness among pain specialists continues to improve but remains exceptionally low. Aided awareness levels decreased for both oncologists and pain specialists from May 2001 to December 2001, while overall awareness remained relatively static. Different groups of physicians were utilized in each round of research. Awareness of ACTIQ should be significantly higher in 2003 as the product continues to be repositioned based on the key patient benefit (rapid onset of analgesia), as promotional targeting evolves and as greater resources, including both sales/marketing personnel and financial resources, are placed behind the brand.

Specific results from the December 2001 tracking study include:

- Combined unaided awareness of ACTIQ was 38%<sup>2</sup> (vs. 18% in May 2001)
  - Unaided awareness among oncologists was 47% (vs. 22% in May 2001)
  - Unaided awareness among pain specialists was 29% (vs. 14% in May 2001)
- Combined aided awareness of ACTIQ was also 38%<sup>3</sup> (vs. 59% in May 2001)
  - Aided awareness among oncologists was 31% (vs. 58% in May 2001)
  - Aided awareness among pain specialists was 45% (vs. 60% in May 2001)

| Awareness of ACTIQ |                           |                            |                           |                            |
|--------------------|---------------------------|----------------------------|---------------------------|----------------------------|
|                    | ONCOLOGISTS               |                            | PAIN SPECIALISTS          |                            |
|                    | 5/01<br>Tracking<br>Study | 12/01<br>Tracking<br>Study | 5/01<br>Tracking<br>Study | 12/01<br>Tracking<br>Study |
| Physician Count    | 50                        | 51                         | 50                        | 51                         |
| Unaided Aware      | 22%                       | 47%                        | 14%                       | 29%                        |
| Aided Aware        | 58%                       | 31%                        | 60%                       | 45%                        |
| Total Aware        | 80%                       | 78%                        | 74%                       | 74%                        |

Source: December 2001 Baseline Tracking Study

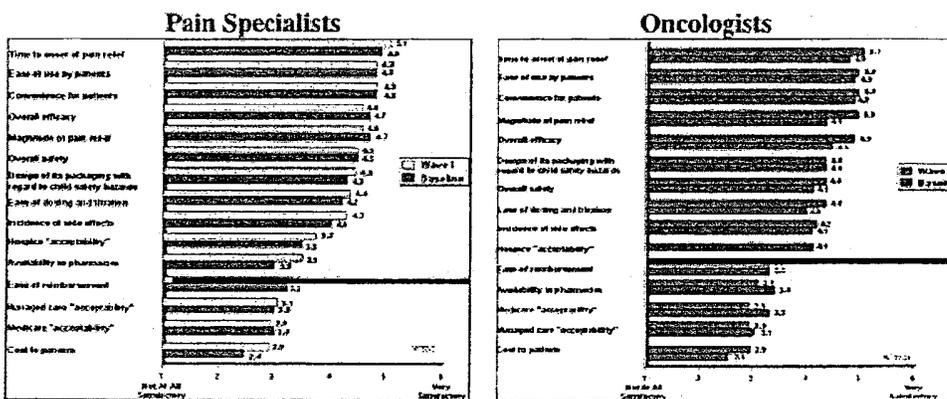
<sup>2</sup> "Unaided" awareness was assessed by asking physicians "Have you heard of any newer, rapid-acting, oral opioids either under development or launched within the past three years?"

<sup>3</sup> "Aided" awareness was assessed by asking physicians "Have you heard of ACTIQ, which is the brand name for oral transmucosal fentanyl?"

**Product Perception**

We also assessed physician perception of the core product characteristics and features of ACTIQ. On average, across all features, both pain specialists and oncologists indicated high satisfaction ratings. The highest satisfaction levels were reported for speed and magnitude of pain relief, ease of use and convenience for patients. The characteristics garnering the lowest satisfaction ratings were cost and reimbursement issues. Marketing must continue to differentiate ACTIQ from other shorter acting opioids based on its key patient benefits, including portability, convenience, control and most significantly, rapid onset of analgesia. See below for specific "satisfaction" ratings from both the May and December 2001 tracking studies.

**Physician Satisfaction of ACTIQ Product Characteristics**



Source: December 2001 Baseline Tracking Study

**G. REIMBURSEMENT UPDATE**

**Reimbursement Overview**

ACTIQ continues to operate under the radar screen of most managed care organizations and the vast majority of prescriptions are being reimbursed for both malignant and non-malignant pain patients. Currently, formulary status is not a critical factor with ACTIQ. The critical marker for this product is its reimbursement status. While ACTIQ is on the formulary of over 85 Managed Care Organizations (MCOs), the majority of plans classify the product as a non-formulary reimbursed drug. This reimbursement status (i.e., non-formulary reimbursed) is most commonly used for low volume specialty products and has been the largest determinant for ACTIQ reimbursement. In these plans, there are no specific efforts to control utilization through the prior authorization process.

Similarly, most MCOs with ACTIQ on formulary approve coverage for the treatment of BTCP and many approve coverage beyond BTCP to other pain diagnoses. Those that

deny reimbursement do so based primarily on the high acquisition cost of ACTIQ or a lack of clinical data and peer reviewed publications that do the following:

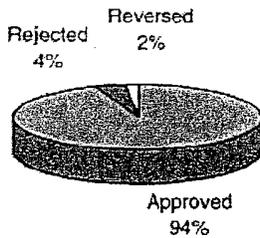
- Support efficacy and safety beyond the cancer patient population
- Illustrate pharmacoeconomic benefits to the health care system by preventing emergency room and hospital admissions for uncontrolled pain.

Although not observed often, some managed care organizations are utilizing some of the typical restrictions to limit coverage of ACTIQ such as:

- Prior authorizations (often based on BTCP diagnosis)
- Step-therapy protocols
- Tiered co-payment systems

An evaluation of five MCOs (payers/processors) performed by Quintiles Transnational over the time period December 1, 2001 to February 28, 2002 tracked a total of 5,232 ACTIQ prescriptions. Their investigation showed that 94% of the 5,232 ACTIQ prescriptions were approved, while only 4% were rejected.

**Percent of Claims Approved/Rejected/Reversed  
(12/1/01 - 2/28/02)  
5,232 ACTIQ TRx**



Source: Quintiles Transnational

Additionally, further investigation by Quintiles Transnational demonstrated that 87% of all co-pays associated with ACTIQ prescriptions are less than \$40.00.

| <b>Out of Pocket Costs (OPC) Distribution: For all ACTIQ Claims</b> |               |               |
|---|---------------|---------------|
| Cost Range  | # of Patients | % of Patients |
| \$0.00 - \$5.00   | 236           | 24%           |
| \$5.01 - \$10.00  | 103           | 10%           |
| \$10.01 - \$20.00   | 262           | 26%           |
| \$20.01 - \$40.00   | 270           | 27%           |
| \$40.00+  | 130           | 13%           |
| <b>TOTAL</b>  | <b>1,001</b>  | <b>100%</b>   |

\*OPC distribution is based on all non-rejected claims for 30-day prescriptions

Note: The average OPC/day is \$2.87  
 Source: Quintiles Transnational

**ACTIQ Reimbursement Hotline**

The following data represents data and trends obtained through ACTIQ Reimbursement Hotline activity YTD August 2001.

**Reimbursement Hotline Activity YTD June 2002**

|  |  |
|--|--|
| Total number of cases handled and resolved (not pending)         | 30   |
| Cases successfully resolved                                      | 50%  |
| Appeal rate for previously denied claims                         | 30%<br>17 cases pending appeal: 4 BTCP, 4 some form of back pain, 2 rheumatoid arthritis, 1 each sickle cell anemia, AIDS, multiple sclerosis, osteomyelitis, cerebrovascular disease, migraine headache and diabetic gastroparesis. |
| Percentage of covered claims with non-BTCP                       | 80%  |
| Most common non-BTCP diagnoses covered                           | Some form of back pain, neuralgia and fibromyalgia   |
| Percentage of plans covering ACTIQ requiring prior-authorization | 13% (100% non-BTCP diagnosis)  |
| Percentage of plans covering ACTIQ utilizing tiered co-pays      | 13% (2 cases)  |
| Percentage of plans covering ACTIQ utilizing step therapy        | 13% (2 cases)  |

**Trends:**

- Increasing number of insurers are setting dosage limits which require quantity overrides and additional documentation on the part of pharmacies and prescribers.
- Increasing number of non-opioid tolerant patients using ACTIQ for episodic pain diagnoses (i.e., back pain and fibromyalgia).
- Medicaid and some MCOs are covering for non-BTCP diagnoses but are requiring more frequent prior-authorizations. Some insurers require prior authorization for each ACTIQ prescription even though previously covered.

As the use of ACTIQ continues to expand beyond BTCP, the likelihood of the product appearing on MCO radar screens greatly increases. This may be inevitable in 2003, as factory sales for ACTIQ continue to grow at such a level that it will soon demand the attention of managed care. Although there are few barriers currently in place, physicians continue to perceive reimbursement as a major concern. In fact, the tracking studies conducted in May and December of 2001 illustrate that physicians' perception and

"satisfaction" with the cost and reimbursement of ACTIQ remain the most significant concerns when prescribing. As ACTIQ continues its remarkable growth, managed care and reimbursement will play a much greater role in the success of the product. The lack of peer-reviewed publications outside of BTCP and the deficiency of data demonstrating the pharmacoeconomic benefits of ACTIQ, in addition to the high acquisition cost and perceived reimbursement difficulty, could potentially hinder the phenomenal growth expected in 2003. Marketing will be putting plans into place to address these potential issues.

Throughout 2002, an evaluation of vendors/agencies capable of planning and executing a pharmacoeconomic study with ACTIQ has been performed. In addition, an assessment of the ability to mine payer data has been performed and looms as a potential option for generating useful pharmacoeconomic data. It will be critical to address this issue and have an executable plan prepared for 2003.

## H. MEDICAL EDUCATION AND PROMOTION RESPONSE

### *Continuing Medical Education*

CME played a vital role in the education of clinicians, including physicians, nurses and pharmacists, in 2002 regarding how and where to utilize ACTIQ in the context of pure education. The major CME initiatives in 2002 included 27 Regional CME Symposia, a tri-mesterly newsletter entitled *Emerging Solutions in Pain*, a repository website by the same name *EmergingSolutionsinPain.com* and the sponsorship of a breakthrough pain category on *pain.com*, the most popular pain website on the internet.

The 27 regional CME Symposia represented the greatest effort in 2002 and allowed us to communicate specific information on diagnosis and management of BTP to 449 physicians through the first 23 programs. The average attendance through the first 23 programs was 19.5 physicians/symposia. The tri-annual newsletter, *Emerging Solutions in Pain*, currently has a circulation of over 11,000 clinicians (8,000+ physicians and 2000+ nurses) and this includes over 1,100 additional, clinician-originated new subscriptions during 2002. Each newsletter allows for communication of information on diagnosis and management of BTP where applicable in two distinct media, written and CD-ROM. The accompanying website, launched in October 2001, serves as a repository for all CME programs created. Over 430 CME/CNE/CPE credits have been issued to physicians/nurses/pharmacists through June 2002.

### *Promotional Medical Education Programs*

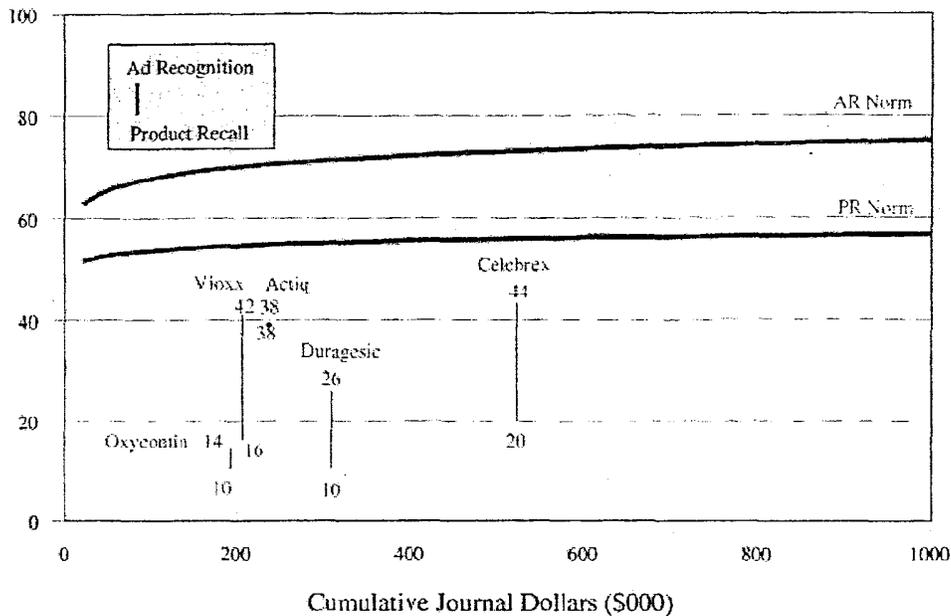
Sales-driven Medical Education Programs (MEPs) are also a critical component of the educational efforts for ACTIQ. In 2002, over 620 sales-driven MEPs will be executed with greater than 1500 clinicians exposed to ACTIQ promotional messaging.

### *Advertising Campaign*

The concept currently in use for ACTIQ is the "bell" concept and was developed early in 2001. This concept has been utilized in all branded promotional materials since and was incorporated into the advertising campaign initiated in June 2001. In December 2001, six months after launching the campaign, a Campaign Tracking Study was performed with PERQ/HCI to evaluate the advertisement's overall effectiveness. More specifically, the study looked to measure physicians' ability to recognize and recall the advertisement as well as the believability, relevance and uniqueness of specific messages within the advertisement. Participating physicians totaled 157, including 84 oncologists and 73 anesthesiologists.

### *Recognition and Recall*

The results of the study were mixed with both very positive and very negative findings. The findings regarding advertisement recognition and recall were tremendously positive, especially considering the level of spend for the ACTIQ media plan versus the other products tested. Thirty-eight percent of participating physicians recognized the ACTIQ advertisement (stated that they had seen it before) and *every* physician who recognized it recalled it was an advertisement specifically for ACTIQ and not another pain product. The recognition score of 38% was considered to be fantastic as it proved comparable to a few of the large pain brands such as Celebrex (44%) and Vioxx (42%), and scored much higher than other big players such as Duragesic (26%) and OxyContin (14%).



Norm based on 54 observations  
 Source: December 2005 FEROHIC Campaign Tracking Study

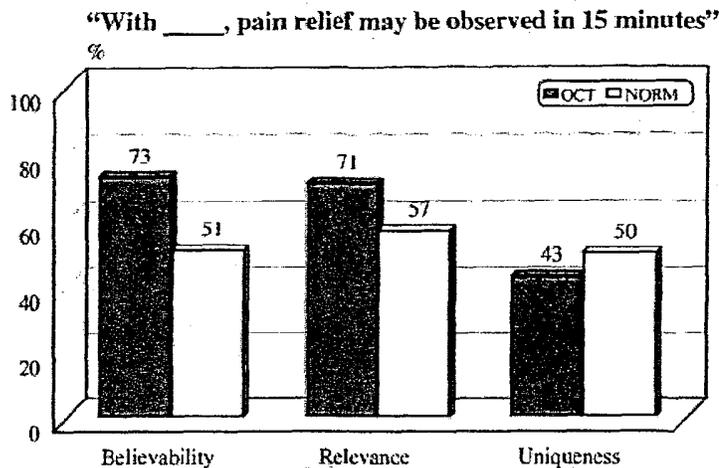
The recall score of 38% meant that the difference between recognition and recall was 0% for ACTIQ. Again, this score was considered to be excellent as the difference in recognition scores for the other products evaluated was 24% for Celebrex, 26% for Vioxx, 16% for Duragesic and 4% for OxyContin. Recognition and recall scores for ACTIQ measured lower than the norm, however, this is common among the opioid class overall, which directs its advertising toward a specialty audience and not a general practice audience.

#### Believability, Relevance and Uniqueness

The two messages we tested in this study included:

- “With \_\_\_\_\_, pain relief may be observed in 15 minutes”
  - The brand name ACTIQ was not included in the statement so as to evaluate message association with the brand.
- “Personal Pain Control”

The first statement listed above (“With \_\_\_\_\_, pain relief may be observed in 15 minutes”) tested exceptionally well with respect to believability, relevance and uniqueness. Seventy three percent of participating physicians found the statement to be believable, 71% found the statement to be relevant to their practice and finally, 43% felt the statement was unique to ACTIQ. The scores for this message tested much higher than the norm and are listed on the chart below.



Source: December 2001 PERQ/HCI Campaign Tracking Study

The second statement listed above (“Personal Pain Control”) was being utilized as a tagline because the original tagline (“Relief on Demand”) was found to be violative by the FDA. This statement tested terribly with respect to believability and relevance. Ultimately, participating physicians found this statement to be anything but unique as many of them associated this message with another leading product in the pain market, Duragesic.

Based on the results of the PERQ/HCI Campaign Tracking Study, we decided to implement additional market research to identify the most powerful and meaningful messages for ACTIQ. The evaluated messages were created within the guidelines and direction provided through FDA feedback over the last three years. The results of the market research message testing will be discussed within the Tactical Plan and the newly developed journal advertisements are attached as Appendix 6. These journal advertisements, which include a new headline (“When Onset Matters...ACTIQ on Call” and tagline (“When Onset Matters”) have been approved by the FDA and will be placed in journals starting in January 2003. Despite approval in August 2002, placement in 2002 was not possible due to insufficient funds in the 2002 ACTIQ marketing budget.

## I. MARKET DYNAMICS

### *Opioid Market*

The prescription opioid market can be divided into two major categories:

- Short-acting opioids
- Long-acting opioids

### *Short-Acting Opioids*

The short-acting opioid market can be further subdivided into two distinct categories:

- Short-acting pure opioids
- Combination product (e.g., opioid plus NSAID)

Currently, short-acting opioids (both pure opioids and combination products) are commonly used to treat opioid naïve patients suffering from acute pain and recurrent or episodic pain, as well as opioid tolerant patients suffering from breakthrough pain. **Acute pain** is loosely defined as pain of relatively short duration elicited by injury of body tissue and activation of nociceptors (e.g., injury, surgery). **Recurrent or episodic pain** refers to intermittent occurrences of pain, with episodes lasting for a relatively short duration but occurring across an extended period of time (e.g., migraine headaches, sickle cell crisis); there is not a persistent-background pain component. **Breakthrough pain** is defined as a transitory flare of pain that occurs on a background of otherwise stable, persistent pain in patients receiving chronic opioid therapy.

Currently available short-acting opioids provide onset of analgesia over a range of 30-60 minutes while the duration of action ranges from 4-6 hours. As the name implies, these products have a "shorter" duration of effect than longer acting agents. The pervasive misperception among pain physicians is that the onset of analgesia that they provide is more rapid than oral long acting opioids. This misperception is patently untrue. The onset of analgesia of short-acting agents (approximately 30-60 minutes) is practically identical to oral long-acting opioid products. A study published in the *Journal of Pain and Symptom Management* in October 1999 entitled "Can a Controlled-Release Oral Dose Form of Oxycodone Be Used as Readily as an Immediate-Release Form for the Purpose of Titrating to Stable Pain Control?" demonstrated that the median time to onset of pain relief was 46 minutes for 30mg of immediate-release oxycodone and 41 minutes for 30mg of controlled-release oxycodone. This data helps to prove that the currently available oral short-acting opioids do not offer any clear advantage over oral long-acting agents with respect to onset of analgesia. Furthermore, the term "immediate release" is often considered a misnomer. Immediate-release refers to the fact that these products do not provide a controlled-release of medication over an extended period of time, as do the long-acting opioids. A chart of the short-acting pure opioids is included in the appendix.

### *Long-Acting Opioids*

Long-acting opioids are most commonly prescribed to treat the persistent pain component of chronic pain in patients who are considered opioid tolerant. Chronic pain is loosely defined as pain that persists for a specified time that is arbitrarily determined (e.g., 3 months or 6 months), or beyond the expected period of healing. The duration of analgesia ranges from 8-72 hours, while onset of analgesia ranges from 45 minutes to 12 hours. The convenience afforded by the duration of analgesia is the key benefit of long-acting opioid products. The onset of analgesia is not a differentiating factor for long-acting opioids. A chart of the long-acting opioids is included in the appendix.

### *Evolving Pain Guidelines*

Opioid use is currently classified by potency by the WHO (World Health Organization) Three-Step Analgesic Ladder. The WHO ladder system of pain management is segmented by the degree of pain: mild to moderate, moderate to severe, and severe. The ladder matches each level of pain to the potency of medications with more potent medications at each step. Adjuvant medications are also incorporated into the WHO ladder.

Most key opinion leaders view the WHO Three-Step Analgesic Ladder as nearly outdated. For example, major flaws of the WHO ladder include the absence of the concept of BTP and the recommendation of combination product use for moderate to severe pain. The American Pain Society (APS), the WHO and other pain organizations will be publishing various pain treatment guidelines in 2003. Treatment guidelines for some chronic pain syndromes were completed and published in 2002 including, osteoarthritis (OA), rheumatoid arthritis (RA) and sickle cell anemia.

Public relations and marketing have worked throughout 2002 with various KOLs, including Dr. Christine Miaskowski, the out-going President of the American Pain Society, and encouraged them to:

- 1) Incorporate the concept and treatment options of BTP into new treatment guidelines
- 2) Discuss the use of pure opioid therapy (versus combination products and NSAIDS) at a much earlier point in treatment than the WHO ladder currently recommends. Pain assessment, continuous re-evaluation of therapy, and a multi-disciplinary approach will also be key components of many of the new pain treatment guidelines.

Overall, newly revised/developed guidelines should offer a vast improvement over the archaic WHO ladder and should be an important step in increasing awareness of the proper assessment and treatment of BTP and the use of opioids in pain disease states such as OA and RA. As these new aggressive guidelines are adapted, BTP becomes more widely accepted as a clinical entity in need of treatment, and the characteristics of BTP are better understood, we will have the opportunity to position ACTIQ as the ideal treatment in the management of BTP.

## **J. COMPETITION**

### *Competitive Companies*

The major companies in the pain market place currently marketing pain medications (i.e., not devices) include Purdue Pharma, Janssen, Abbott Laboratories, Elan, Ligand, Endo and Cephalon, with Purdue Pharma being the dominant market leader. These companies have primarily focused on the outpatient chronic pain market for long-acting, sustained release products (although most offer both long and short-acting products), but new

competitors, such as Watson Pharmaceuticals and CIMA are in various stages of development with short-acting compounds which may be indicated for BTP.

***Long-Acting Opioids: Competitor?***

The currently marketed long-acting products are not considered direct competitors of ACTIQ, however, in a certain sense they remain as a competitive barrier to additional ACTIQ use. In general, these products have indications for "moderate to severe" pain in opioid tolerant patients and are positioned for the treatment of all types of chronic pain, including both malignant and non-malignant. As mentioned previously, the duration of action for long-acting opioids ranges from 8-72 hours, while the onset of analgesia ranges from 45 minutes to 12 hours. All of the manufacturers of long-acting opioids, especially Purdue Pharma and Janssen, have been educating physicians over the last 3-5 years about the ability to reduce and/or eliminate the need for BTP medications by merely increasing the level of the persistent pain medication to cover episodes of BTP. In the rare instances that a patient experiences BTP (i.e., the long-acting medication is perceived to have "failed" at a specific moment), they espouse that a short-acting medication can be prescribed as a "rescue medication." Many of these long-acting, sustained release products have complementary short-acting products that have been traditionally promoted for acute and episodic pain. Although their use is indicated for moderate to severe pain only, many of these short-acting products are being promoted for use as "rescue medication" to be used along with the long-acting counterpart. As mentioned previously, the onset of analgesia of oral short-acting opioids ranges from 30-60 minutes. This delayed onset of analgesia may not provide relief rapidly enough to be effective to control a typical BTP or episodic pain episode.

Education regarding the independent assessment and treatment of both persistent pain and BTP will continue to be a major objective in 2003.

***ACTIQ's Competitors: Direct and Indirect***

ACTIQ's direct competitors are the short-acting pure opioids. The branded formulations of these opioids are listed in Appendix 1. The use of other currently available oral short-acting pure opioids for the treatment of BTP is less than ideal due to a lack of rapidity of analgesic effect that they afford. ACTIQ's clear and distinct advantage over the currently available products in this category is its rapidity of onset of analgesia.

Opioid combination products, although prescribed for the treatment of BTP, are not truly direct competitors of ACTIQ for the following reasons:

- Limited dosing flexibility due to low opioid dosage options (for use in mild to moderate pain only)
- Dose ceiling effect due to presence of NSAID (intolerable side effects)
- Not being aggressively promoted for the treatment of BTP
- Use in BTP and episodic pain occurring as a result of physician ignorance.

As previously stated, long-acting opioids are not considered a direct competitor in the BTP market; however, they may be viewed as an indirect competitor for ACTIQ. Various manufacturers have aggressively educated physicians that when appropriately medicated with a long-acting opioid, patients should not experience BTP, or should experience it minimally. Although not congruent with the opinions of most key opinion leaders, many community-based physicians currently adhere to this philosophy, thus turning the long-acting opioids into "pseudo competitors." Re-educating misled physicians will be a challenge.

A comprehensive competitive intelligence analysis was initiated in August 2002. Results are expected in November 2002 and should help to guide us in our strategy to defend our current market position.

**Pure Short-Acting Prescription Analysis**

Since Q1 2000, ACTIQ prescriptions have grown at a faster rate than any other pure short-acting opioid, branded or generic. ACTIQ prescriptions have grown 843% from Q1 2000 (4,467 TRx) to Q2 2002 (42,135 TRx). The only other two products with over 100% growth during this time period are generic oxycodone (257% growth) and generic morphine (112% growth). The total pure short-acting opioid market grew 69% over this same time period from 808,269 TRx in Q1 2000 to 1,363,553 TRx in Q2 2002.

**Analysis of Pure Short-Acting TRx Market**

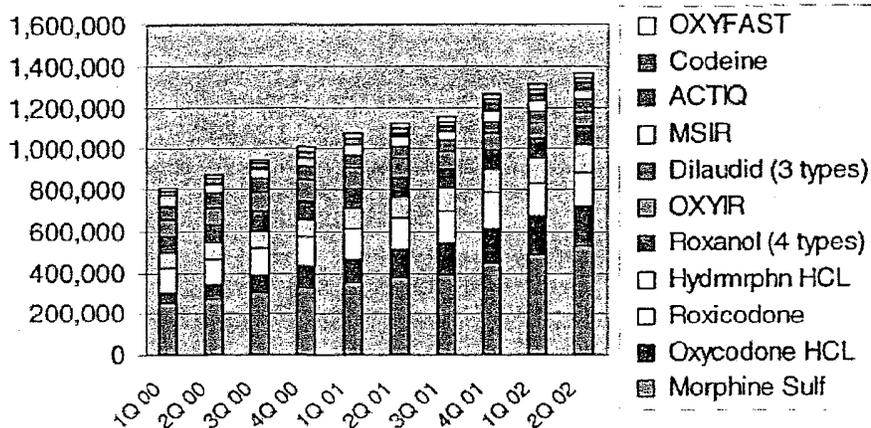
| Opioid Compound           | TRx Q1 2000 | TRx Q4 2001 | TRx Q2 2002 | % Growth Q1 2000 to Q2 2002 | % Growth Q4 2001 to Q2 2002 |
|---------------------------|-------------|-------------|-------------|-----------------------------|-----------------------------|
| <b>TOTAL SA Opioids</b>   | 808,269     | 1,258,961   | 1,363,553   | 69%                         | 8%                          |
| Morphine Sulfate          | 246,944     | 443,189     | 523,599     | 112%                        | 18%                         |
| Oxycodone HCL             | 55,569      | 174,713     | 198,222     | 257%                        | 13%                         |
| <b>ROXICODONE</b>         | 115,231     | 165,015     | 162,056     | 41%                         | -2%                         |
| Hydromorphone HCL         | 74,089      | 116,133     | 134,245     | 81%                         | 16%                         |
| <b>ROXANOL (4 types)</b>  | 83,702      | 97,306      | 88,537      | 6%                          | -9%                         |
| OXYIR                     | 81,337      | 78,949      | 67,837      | -17%                        | -14%                        |
| <b>DILAUDID (3 types)</b> | 62,270      | 59,992      | 59,036      | -5%                         | -2%                         |
| MSIR                      | 46,111      | 45,888      | 44,469      | -4%                         | -3%                         |
| <b>ACTIQ</b>              | 4,467       | 28,923      | 42,135      | 843%                        | 46%                         |
| Codeine                   | 23,571      | 25,267      | 24,690      | 5%                          | -2%                         |
| <b>OXYFAST</b>            | 14,978      | 23,586      | 18,727      | 25%                         | -21%                        |

Source: IMS NPA  
 Note: Branded products in caps and bolded.

Looking only at growth in 2002, YTD growth of total prescriptions grew 46% from Q4 2001 (28,923 TRx) to Q2 2002 (42,135). This was again by far the greatest increase in percentage growth among all pure short-acting opioids. In fact no other branded product

had more total prescriptions in Q2 2002 than in Q4 2001. Every branded competitor showed a decrease in TRx over this time period.

### Prescriptions for All Products in the Pure Short-Acting Opioid Market



Source: IMS NPA

#### Market Share Analysis

From Q1 2000 to Q2 2002, ACTIQ increased its market share by 2.5%, greater than all other pure short-acting opioids save generic morphine (7.8%) and generic oxycodone (7.7%). No other branded competitor increased market share over this time period. Looking at more recent data reveals similar results. From Q4 2001 to Q2 2002, ACTIQ again was the only branded pure short-acting opioid to increase market share, growing almost a full percentage point (0.8%) and running second only to generic morphine (3.2% growth).

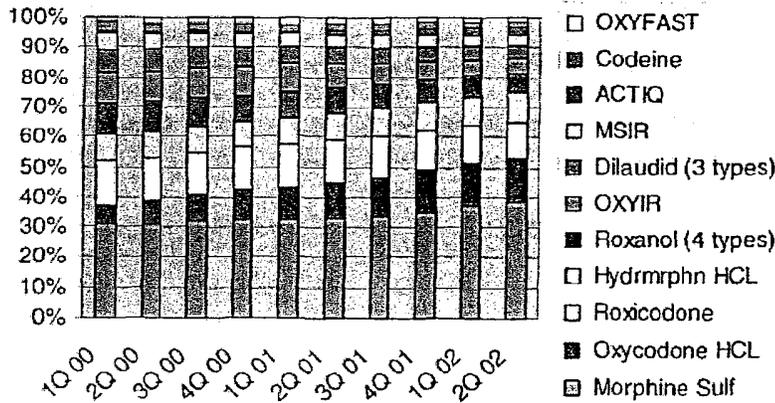
ACTIQ Market Share Analysis

| Opioid Compound           | Market Share Q1 2000 | Market Share Q4 2001 | Market Share Q2 2002 | Market Share Growth Q1 2000 to Q2 2002 | Market Share Growth Q4 2001 to Q2 2002 |
|---------------------------|----------------------|----------------------|----------------------|--|--|
| Morphine Sulfate          | 30.6%                | 35.2%                | 38.4%                | 7.8%                                   | 3.2%                                   |
| Oxycodone HCL             | 6.9%                 | 13.9%                | 14.5%                | 7.7%                                   | 0.7%                                   |
| <b>ROXICODONE</b>         | 14.3%                | 13.1%                | 11.9%                | -2.4%                                  | -1.2%                                  |
| Hydromorphone HCL         | 9.2%                 | 9.2%                 | 9.8%                 | 0.7%                                   | 0.6%                                   |
| <b>ROXANOL (4 types)</b>  | 10.4%                | 7.7%                 | 6.5%                 | -3.9%                                  | -1.2%                                  |
| <b>OXYIR</b>              | 10.1%                | 6.3%                 | 5.0%                 | -5.1%                                  | -1.3%                                  |
| <b>DILAUDID (3 types)</b> | 7.7%                 | 4.8%                 | 4.3%                 | -3.4%                                  | -0.4%                                  |
| <b>MSIR</b>               | 5.7%                 | 3.6%                 | 3.3%                 | -2.4%                                  | -0.4%                                  |
| <b>ACTIQ</b>              | 0.6%                 | 2.3%                 | 3.1%                 | 2.5%                                   | 0.8%                                   |
| Codeine                   | 2.9%                 | 2.0%                 | 1.8%                 | -1.1%                                  | -0.2%                                  |
| <b>OXYFAST</b>            | 1.9%                 | 1.9%                 | 1.4%                 | -0.5%                                  | -0.5%                                  |

Source: IMS NPA

Note: Branded products in caps and bolded.

All Product Market Shares in the Pure Short-Acting Opioid Market



Source: IMS NPA

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### III. COMMERCIAL INFRASTRUCTURE UPDATE

#### A. SALES AND MARKETING

While the size of the commercial infrastructure that supports ACTIQ remained fairly modest in 2002, Cephalon marketing and sales continued to excel and drive the product forward.

The PCS sales force expanded from 48 representatives in 2001 to 60 representatives in 2002. The addition of 12 PCS sales representatives created slightly smaller, more manageable sales territories and may have contributed to the continued success of ACTIQ. Additionally, an Associate Product Manager, with a clinical background, formidable ACTIQ sales experience and a solid understanding of the pain market was added to the ACTIQ marketing team. This addition allowed for the implementation and execution of a greater number of marketing initiatives, as well as optimizing financial resources placed behind the brand.

Further expansion of both the PCS sales force and ACTIQ marketing team will be required to move ACTIQ to the next level of productivity.

#### B. MEDICAL LIAISONS MANAGERS

The Medical Liaisons Managers support ACTIQ in three distinct manners:

- Direct promotional support
- ACTIQ Speaker Bureau development
- Case series advancement

Each of these functions played an important role in supporting and growing ACTIQ in 2002. As peer-to-peer education is critical in the promotion of ACTIQ, the continued development of quality ACTIQ speakers will be essential to continued ACTIQ growth. Additionally, case series development outside of the cancer patient population will also be vital to growing ACTIQ significantly beyond BTCP in 2003 and beyond.

## IV. SWOT ANALYSIS AND KEY MARKETING ISSUES

### A. ACTIQ SWOT ANALYSIS

| STRENGTHS  | WEAKNESSES  |
|--|---|
| <ul style="list-style-type: none"> <li>• Rapid onset of analgesia</li> <li>• OTC delivery and onset of action provides patients with portability, convenience, and control</li> <li>• Well known opioid with proven efficacy and safety profile – (fentanyl)</li> <li>• Solid clinical database within cancer patient population</li> <li>• Large base of published product literature within cancer</li> <li>• Anecdotal positive impact on Quality of Life</li> <li>• Core product characteristics appropriate for treatment of BTP in chronic benign pain and episodic pain (sickle cell, migraines)</li> </ul> | <ul style="list-style-type: none"> <li>• Narrow indication</li> <li>• Limited promotional flexibility due to Subpart-H approval (Risk Management Plan and 30 day mandatory FDA review)</li> <li>• Lack of data and publications outside of cancer patient population</li> <li>• Cannot make the claim “rapid onset” despite being the most rapid acting “oral” agent and trials proving onset in 15 minutes</li> <li>• Lack of clinical data showing onset &lt; 15 minutes</li> <li>• High acquisition cost – value proposition not well understood</li> <li>• Perceived cumbersome titration process</li> <li>• No equianalgesic dosing</li> <li>• Opioid tolerant requirement limits drug selection in other pain diagnoses</li> <li>• Perceived safety concerns</li> </ul> |
| OPPORTUNITIES  | THREATS   |
| <ul style="list-style-type: none"> <li>• Physician eagerness to evaluate drug outside of BTCP; e.g., OA, RA, migraine, lower back pain, etc. creates opportunities to generate data in needed areas</li> <li>• Increased focus on pain management from JCAHO (5<sup>th</sup> vital sign)</li> <li>• Expansion of sales force to increase promotional reach</li> </ul>  | <ul style="list-style-type: none"> <li>• Continued Subpart H classification and RMP restrictions/obligations</li> <li>• Limited availability in retail pharmacies</li> <li>• Increased counter-detailing from competitors as ACTIQ gains market share</li> <li>• OxyContin abuse issue enhances opiophobia within pain market</li> <li>• Competitors continuing to make claims for BTP without having done any trials</li> <li>• Increased reimbursement difficulties</li> <li>• Minimal support with phase IV, publications, and case series in 2002</li> <li>• Dental caries issue becomes larger</li> <li>• Potential future competitors: E-Trans (Alza), Oravescent (Cima), etc.</li> </ul>   |

## B. KEY MARKETING ISSUES

There are seven key issues that need to be addressed for ACTIQ in 2003:

- **Low awareness in the assessment and treatment of BTP**

Many of our targeted physicians and healthcare providers (e.g., RNs, RPhs) believe that they are managing chronic pain adequately, despite the fact that most pain assessment tools do not include questions or pain scales specific to BTP. BTP must become recognized as a critical component of chronic pain that must be assessed and treated as distinct and separate entity from persistent pain.

- **Low product awareness among patients and prescribers**

Although unaided awareness of ACTIQ has improved amongst both pain specialists and oncologists, most remain uninformed about ACTIQ and its benefits in treating BTP. Increasing the awareness of ACTIQ and its key differentiating benefits of rapid onset of analgesia, portability, convenience and control will be critical to continuing the tremendous growth seen with ACTIQ in 2002.

- **Low awareness/lack of branding of ACTIQ/Cephalon within the pain community**

Marketing plans to greatly enhance the ACTIQ/Cephalon presence at all medical meetings attended in 2003. A minimum of seven national level medical meetings will be attended. The primary objectives will be to raise awareness/brand both ACTIQ and Cephalon within the pain community. This will be accomplished through the a larger booth dedicated solely to ACTIQ, CME symposia, consultant meetings and other medical meeting-specific promotional and educational efforts.

- **Launch of new formulation**

Launching the new formulation of ACTIQ must be done without interrupting the distribution, sales, and confidence of both patients and prescribers. Extensive education of physicians, nurses, pharmacists, wholesalers, and patients regarding the continued availability, bioequivalence and safety of the new formulation will be critical in preventing any disruption in the tremendous success seen with ACTIQ in 2002.

- **Limited KOL/advocates as well as BTP treatment guidelines**

Both marketing and public relations must develop/renew relationships with KOL in the field of pain management in order for ACTIQ to gain the exposure and support needed to become a first line treatment option for BTP in both malignant and non-malignant pain. Key opinion leaders must be made aware of the key messages and benefits of ACTIQ and be encouraged to incorporate ACTIQ as part of pain treatment guidelines. At this time, there are no guidelines specific to BTP and BTP is ignored or rarely mentioned in most pain treatment guidelines.

- **Limited clinical data and publications**

Developing efficacy data outside BTCP (e.g., OA, RA, chronic back pain, CRPS) that highlights the need for rapid pain relief, as well as producing pharmacoeconomic benefit data, will be crucial in growing the use of ACTIQ, as well as overcoming current and future reimbursement hurdles. Demonstrating Patient Reported Outcomes (PROs) in both BTCP and disease states outside of CA will also be critical in expanding the use of ACTIQ and overcoming reimbursement barriers.

- **New competitors**

ACTIQ's rapid onset of analgesia and unique delivery system are its key differentiating benefit and feature, respectively. It is expected that other products with similar benefits will become available and may claim to have an even faster onset than ACTIQ. Cephalon must anticipate and prepare for the launch of these products and proactively deliver the right messages regarding the onset and safety of ACTIQ to key targeted market segments.

- **Limited direct promotional reach**

With 60 pain care specialists, the current direct promotional reach for ACTIQ is very limited, especially in contrast to the sales forces of other market leaders. It will be crucial in 2003 for the ACTIQ marketing team to complement the efforts of the sales force with the successful implementation of appropriate and effective promotional and educational vehicles that will both increase ACTIQ's share of voice as well as drive prescriptions.

### C. ACTIQ DEVELOPMENT NEEDS

#### *ACTIQ's Differentiating Benefit*

ACTIQ's clear differentiating benefit is its rapid onset of analgesia. Currently available oral shorter acting pure opioids and combination products are sub-optimal for the treatment of breakthrough pain (BTP) due to their lack of rapidity of analgesic effect.

#### *ACTIQ's Limiting Factor*

ACTIQ's greatest limiting factor is its narrow, limited indication. ACTIQ's indication is narrow in that it is specific for "breakthrough cancer pain only" and it is limited in that patients must be "tolerant to opioid therapy." Every other oral shorter acting pure opioid has an open indication for "moderate to severe pain" which allows them to be prescribed for everything from acute, post-op pain to BTCP and by all types of physicians from pain specialists and oncologists to family practitioners.

#### *ACTIQ's Potential*

Rapid pain relief is a largely unmet need in patients suffering from malignant and non-malignant BTP, as well as chronic episodic pain (e.g., migraine, sickle cell, etc.). These types of pain represent a substantial market opportunity. The total market for pure short acting opioids and combination products has been \$906 million in 2000, \$1.15 billion in 2001 and \$649 million YTD through June 2002 (2002 projected total is \$1.3 billion).

#### *Strategic Market Development Issues that Must be Addressed*

There are three primary market development issues that must be addressed immediately. These needs were also highlighted in the 2002 ACTIQ marketing plan and they include:

1. Considerations for strategically maximizing ACTIQ's potential through phase IV research and publications
2. Patent extension considerations

3. Strategy regarding the creation of an enhanced formulation of ACTIQ (i.e., sugar free lozenge enhanced onset/bioavailability).

- Maximize Usage Potential Through Phase IV Research
  - Based on the direction and guidance received during consultant meetings and advisory panel meetings there is a critical need to evaluate ACTIQ within other pain types, to demonstrate simplified titration in clinical trials and to explore other potential uses for ACTIQ (i.e., monotherapy). Two phase IV trials are to begin in Q4 2002, including an open-label migraine trial and an evaluation of ACTIQ as monotherapy in cancer patients. Although the initiation of these two trials is an important step in the right direction, a much more aggressive approach to phase IV research must be taken immediately and in 2003 to maximize the potential usage of ACTIQ. Due to the fact that branded competition is anticipated in late 2004 and that the patent expires in May 2005, it will be imperative to generate clinical data as quickly as possible. Marketing will work with Steven Shoemaker, MD, our lead consultant in these matters to develop a phase IV program that generates the specific data needed (i.e., data outside CA, demonstrating patient benefits of rapid onset of pain relief, simplifying titration and illustrating potential use as a sole agent) as quickly as possible.
- Maximize Usage Potential Through Publication Efforts
  - In Q4 2001, a publications plan was developed with the simple goals of:
    - Generating awareness of BTP
    - Generating awareness of ACTIQ, its primary patient benefit (rapid onset of analgesia) and its potential therapeutic applications
    - Highlighting approaches to simplify titration/dosing

Several publication efforts have been initiated in 2002, including, but not limited to, one review article regarding relative potency/equianalgesic dosing and two distinct case series (migraine & sickle cell). Unfortunately, much of the efforts toward ACTIQ publications in 2002 were focused on publications with little to no commercial value. In addition, of the 20+ case series submitted to publications for potential write-up, only the two aforementioned case series were resourced, with none being published in 2002. In fact, most of the areas of need highlighted in the publications plan set forth in Q4 2001 and the 2001 ACTIQ marketing plan were not addressed in 2002. A much more aggressive and commercially focused effort with publications must be taken immediately and in 2003 to maximize the potential usage of ACTIQ. If efforts are not made to execute publications as soon as possible in 2003 demonstrating/discussing the following areas of need, we will have missed a large opportunity to maximize growth of the product:

- ACTIQ use in other potential therapeutic areas (where rapid pain relief is needed)

- Discussion of ACTIQ PK/PD information relative to competition and IV alternatives
  - Patient reported benefits of rapid pain relief with ACTIQ
  - Simplified titration/dosing
  - Pharmacoeconomic benefits of ACTIQ
- Creation of a new, enhanced formulation of ACTIQ
    - If it is determined that the development of an enhanced formulation of ACTIQ is possible given the anticipated arrival of branded competition in Q4 2004, prior to moving forward with the clinical development of a new formulation, a thorough assessment of the ideal clinical profile for an ACTIQ-type product must be performed. In addition, a thorough evaluation of the opportunities for patent extension resulting in market exclusivity advantages must be performed to plan and direct the potential creation of a new formulation (see below). Given the limited patent life of both the sugar-melt formulation (May 2005) and the compressed powder formulation (March 2006), the timing of the development and launch of an enhanced formulation should begin immediately. Considerations for the development of an enhanced formulation of ACTIQ have begun in Q3 2002. Possible considerations include:
      - Sugar free lozenge
      - Enhanced onset/bioavailability through alterations in pH and or a concentrated fentanyl coating
      - Combination of sugar free lozenge and enhanced onset
  - Patent Extension Considerations
    - A strategic and detailed assessment of patent extension considerations was recommended in the 2002 ACTIQ brand plan and must be performed immediately. Patent extension considerations may include, but may not be limited to, the following:
      - Sugar free formulation – This possibility has been under evaluation during 2002.
      - Manufacturing process – Patents around the manufacturing process (both sugar-melt and compressed powder) have been under evaluation in 2002.
      - Pediatric Exclusivity – Potential for an additional six months exclusivity is a potential.

Some consideration and planning has been dedicated to elucidating the potential for patent extension beginning in Q3 2002, however, this may be too little too late. Based on physician feedback and the fact that strong branded competition is expected in late 2004, any efforts made to extend the patent of ACTIQ should be done while also enhancing the product (i.e., making it sugar-free, etc.). In addition, the timeline for developing a new and improved ACTIQ (with or without a patent extension) should be evaluated in light of a Q4 2004 deadline of branded competition. Based

on the stronghold we are developing within the pain community as the breakthrough pain advocates and pioneers, we should also consider the feasibility of acquiring one of the expected branded competitors to replace ACTIQ as the patent expires.

***Other Clinical Development Challenges***

There are several additional issues that must be addressed by Regulatory and Clinical Operations/Medical Affairs.

- Subpart-H status – Is the removal this status and the accompanying obligations/restrictions possible?
- Risk Management Plan (RMP) – Is lessening the restrictions/obligations (which greatly limit promotional flexibility) possible.
- Inability to make claim “rapid onset of analgesia” – Can we utilize competitive pain medication claims regarding rapid onset (e.g., Avinza and Ultracet) to force FDA to consider our potential use of this claim? What can be done to make this claim?

***Recommendations for Immediate Needs to Maximize Business Potential***

ACTIQ will most likely more than double sales from 2001 to 2002. To continue this growth in 2003, marketing recommends that the following *minimal* needs be satisfied:

- Case Series development in non-cancer pain models such as chronic back pain, OA, RA, CRPS, migraine headaches, etc. submitted for publication within six months.
- Exploratory studies in other, high incidence pain models followed by strong publications and marketing driven medical education efforts.
- Research that clearly demonstrates the true time to onset of analgesia (< 15 minutes) and demonstrating the pharmacoeconomic benefits of ACTIQ.
- Rapid seeding publications to elucidate the relative potency of ACTIQ as well as simplifying the titration process.

With minimal clinical data and adequate marketing resources (i.e., personnel and financial resources), ACTIQ could be positioned to expand its share of the potential \$1 billion short-acting market in 2002.

## V. PRODUCT VISION AND POSITIONING

### A. ACTIQ VISION

*Short-Term Vision:* ACTIQ is a revolutionary and highly beneficial option to treat BTP as well as chronic episodic pain in patients who have been exposed to opioids.

*Middle-Term Vision:* ACTIQ is the ideal first-line option to treat BTP and chronic episodic pain.

*Long-Term Vision:* ACTIQ is the ideal first-line option to treat BTP and chronic episodic pain in patients exposed to opioids, as well as to be viewed and utilized similarly to all other shorter acting opioids.

Although ACTIQ prescriptions grew at an impressive rate in 2002, ACTIQ must still be established as a valid first-line treatment option for BTP. In order to accomplish the middle and long-term visions, the following needs have to be met:

- Development of clinical data and publications outside of cancer patient population
- Development of clinical data to support onset within 5 to 10 minutes to allow claims to be made about rapid onset of action
- Expanded and highly effective promotional and medical education efforts
- PRO and pharmaco-economic benefit studies to support reimbursement issues
- Increase size of sales force
- Increase ACTIQ marketing personnel and financial resources

### B. ACTIQ 2003 POSITIONING

ACTIQ's positioning will continue to focus on its key differentiating feature and benefit.

- **Key Feature:** ACTIQ utilizes a unique oral transmucosal delivery system (OTS) for rapid absorption of fentanyl
- **Primary Patient Benefit:** ACTIQ's oral transmucosal delivery system provides the most onset of action among all non-invasive, shorter acting opioids.

#### *ACTIQ 2003 Positioning Statement:*

The 2002 positioning statement for ACTIQ reflects the above key differentiating feature and benefit. The 2003 positioning statement for ACTIQ was created to be simple, direct and allow for broad therapeutic application.

**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.**

***Patient Profile***

The ideal patients for ACTIQ are those that will benefit from ACTIQ's rapid onset of analgesia as well as its portability, convenience and control. Any opioid tolerant patient suffering from BTP or chronic episodic pain, regardless of disease state, are potential ACTIQ patients.

## VI. MARKETING AND PROMOTIONAL STRATEGY

### A. MARKETING GOALS AND OBJECTIVES

#### *Marketing Goals*

The 2003 ACTIQ marketing plan will seek to achieve the following goals:

- Increase the number of ACTIQ prescribers
- Increase ACTIQ prescriber productivity and prescriber retention
- Increase awareness of ACTIQ and BTP among targeted physician specialties and patient populations
- Ensure successful transition to new formulation with minimal/no sales disruption
- Continue to develop relationships with KOL in pain management
- Generate clinical data and publications of ACTIQ to meet prescriber and advisor demands regarding:
  - Efficacy data in various pain types
  - Simplified titration/dosing
  - Onset in <15 minutes
  - Patient reported outcomes and pharmacoeconomic benefit data

#### *Marketing Objectives*

Factory sales and prescription volume objectives for 2003 are as follows:

| 2003              | Gross Sales           | TRx            |
|-------------------|-----------------------|----------------|
| Q1                | \$ 48,900,000         | 59,583         |
| Q2                | \$ 55,000,000         | 66,011         |
| Q3                | \$ 56,400,000         | 73,187         |
| Q4                | \$ 58,500,000         | 81,144         |
| <b>2003 TOTAL</b> | <b>\$ 218,800,000</b> | <b>279,880</b> |

### B. MARKETING STRATEGY

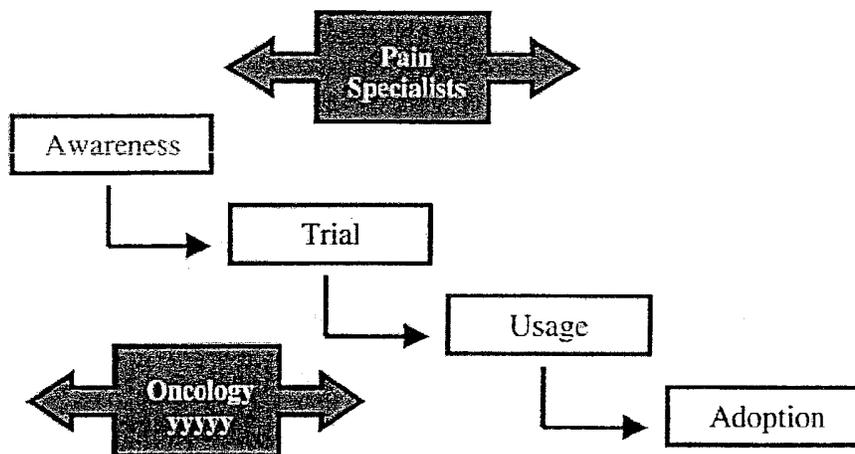
#### *Overall Promotional Strategy*

The marketing strategy for 2003 will continue to build on the successful platform in 2002 and will continue to attempt to drive physicians along the product adoption curve from awareness and trial to usage and adoption. In order to increase market share and achieve the aforementioned sales and prescription objectives, the marketing strategy for ACTIQ will be to continue to raise awareness of BTP and ACTIQ and differentiate the product from its competitors by educating clinicians about the primary product strengths: rapid onset of analgesia and portability, convenience and control. The phrase "personal pain control" will no longer be used to attempt to differentiate ACTIQ from its competitors due to the poor response it received during December PERQ/HCI campaign tracking

study. When physicians were asked to match the statement "personal pain control" with a specific pain medication, most physicians linked it to Duragesic.

When looking at the continuum of the product adoption curve, the majority of all ACTIQ prescribers fall into the trial range within the curve. An evaluation of the top five prescribing deciles for ACTIQ shows that 117 of the 200 prescribers among these deciles are pain specialists. This is a relatively small number of pain specialists, but nevertheless highlights that a small percentage of this specialty falls into the usage and/or adoption end of the curve. Oncologists make up only 2% of the top five prescribing deciles for ACTIQ and remain in the awareness and trial phase. This may be a product of ACTIQ's: 1) limited share of voice (e.g., direct sales force), 2) limited financial marketing support and 3) the previous and current targeting directives. The overall promotional strategy for 2003 will be to move pain specialists from trial and usage to usage and adoption and oncologists from awareness and trial to trial and usage.

### ACTIQ in the Product Adoption Curve



#### *Promotional Strategy by Key Marketing Issue*

**Issue:** Low awareness in the assessment and treatment BTP

**Strategy:** Educate key targeted physician specialties about the importance of assessing BTP and the benefits of treating it with ACTIQ.

Through promotional, educational and public relations efforts, marketing will strive to increase awareness of BTP amongst targeted physician specialties. Based on proven success, peer-to-peer promotional efforts and CME will be the primary means used to

educate physicians, pharmacists and nurses. In addition, an enhanced convention presence will be employed in 2003, including a larger, ACTIQ-dedicated booth.

**Issue: Low product awareness among patients and prescribers**

**Strategy: Strengthen the association of ACTIQ and its key patient benefits through improved awareness and medical education**

Market research was conducted to obtain feedback from physicians concerning which key messages best conveyed ACTIQ's key differentiating benefits. These key messages, along with the current brand concept (i.e., the bell concept), will be critical in raising awareness of ACTIQ. Marketing will implement high reach promotional efforts to contact as many potential ACTIQ prescribers as possible. Additionally, more specific targeted promotional efforts will be implemented to raise awareness among the highest potential prescribers. Additional concept testing will be done to determine if the bell concept along with the new headline (i.e., "When onset matters...ACTIQ on call") and tagline (i.e., "When onset matters") is conveying the desired messages and positioning ACTIQ appropriately. Lastly, to complement our enhanced convention presence in 2003, medical education programs, such as consultant meetings, CME symposia and advisory panels will be employed at several medical meetings. In order to maintain the tremendous growth seen in 2002, awareness of ACTIQ associated with its primary patient benefit of rapid analgesia must be accomplished.

**Issue: Low awareness/lack of branding of ACTIQ/Cephalon within the pain community**

**Strategy: Enhanced medical meeting presence**

Marketing plans to attend a minimum of seven national level conventions in 2003 and will focus on increasing and improving our presence at these meetings. The primary objectives will be to raise awareness/brand both ACTIQ and Cephalon within the pain community. This will be accomplished through the purchase and utilization of a larger booth dedicated solely to ACTIQ, CME symposia, consultant meetings and other medical meeting-specific promotional and educational efforts. Multiple new booth panels focusing on the mechanism of action, OTS delivery, BTP characteristics and titration messaging will help to deliver key marketing messages, raise awareness of ACTIQ and differentiate ACTIQ from its competitors. A separate and distinct Medical Affairs area within/without of the newly designed booth will be implemented in convention planning to allow for questions regarding use outside of BTCP. Specifically, marketing will sponsor symposia at the AAPM and possibly PM&R meetings on the topic of *Use of Opioids in Neuropathic Pain* and *Use of Opioids in Musculoskeletal Pain*, respectively. It is crucial that ACTIQ/Cephalon increase its presence at these key meetings in order to be seen as a major player in pain management.

As in 2002, Pain Care Area Managers will take responsibility for deciding when to attend regional medical symposia and/or local conventions. Marketing will continue to support the planning and logistics associated with these meetings when necessary.

**Issue: Launch of the compressed powder formulation**

**Strategy: Proactively inform all target audiences of the impending transition to the compressed powder formulation**

Marketing will implement a series of tactics to inform all target audiences including, physicians, nurses, pharmacists, wholesalers and patients of the transition to the compressed powder formulation. These tactics will explain why the change is taking place, (i.e., to meet increased demand, to provide a more consistent world wide product and to ensure safety and efficacy) through educational mailers, sales aids, etc. Marketing will reassure patients and physicians of bioequivalence, safety and efficacy to the previous, sugar melt formulation. ACTIQ prescribers and ACTIQ stocking pharmacies will receive information about the change in multiple forms of communication to ensure the changes are being communicated effectively. Special attention will need to be given to the pharmacy/wholesaler chain to ensure the NDC codes are changed/updated in a timely fashion. If not done correctly, "out of stock" messages may be delivered to pharmacies as they attempt to order product from wholesalers.

**Issue: Limited advocacy among KOLs as well as inclusion of BTP/ACTIQ in treatment guidelines**

**Strategy: Build/renew relationships with KOLs in pain management and targeted physician specialties through consultant meetings and advisory boards.** Marketing and product communications will initiate/renew contact with KOLs with the objectives of: 1) receiving guidance in CME, educational initiatives, and clinical development, and 2) empower advocates to incorporate BTP and ACTIQ into pain treatment guidelines. At this time, there are no guidelines specific to BTP and very few mentions of BTP are found among the various pain treatment guidelines.

**Issue: Limited clinical data and publications**

**Strategy: If adequate clinical support provided, drive the direction of phase IV research and publication efforts to be consistent with commercial needs**

ACTIQ's narrow indication is its most significant promotional limiting factor. There is substantial opportunity for ACTIQ in the treatment of BTP in opioid tolerant patients in a variety of pain diagnoses, as well as chronic episodic pain. In order to continue ACTIQ's growth outside of the cancer patient population, ACTIQ's safety, efficacy and true onset of analgesic effect must be demonstrated in other larger segments of the pain market (i.e., chronic back pain, OA, RA, CRPS, migraine headaches, etc.)

**Issue: Potential new competitors**

**Strategy: Proactively position ACTIQ to defend its market share against potential competition**

Marketing will attempt to proactively educate healthcare providers of the advantages ACTIQ has over any future potential competition. It will be imperative for the ACTIQ marketing team to remain flexible regarding a change in ACTIQ's key messaging and positioning as we become aware of new competition.

**Issue: Limited direct promotional reach**

**Strategy: Direct the most effective promotional efforts to the highest potential targeted physicians**

Marketing will direct the most effective (and often the most costly) promotional efforts (e.g., personal selling, medical education programs, CME programs) to the highest potential targeted physicians. Promotional programs with a greater reach (and often lower cost) will be directed toward lower potential targets (e.g., direct mailings, CME programs). Overall, the promotional strategy will be to provide an appropriate mix of promotional initiatives that complement the efforts of the 60 Pain Care Specialists and expand our reach to the vast number of potential prescribers that the PCS cannot directly influence.

## VII. TACTICAL PLAN

### A. ACTIQ KEY MESSAGES

Message and positioning testing was done in April 2002 to determine the key messages that most effectively convey ACTIQ's key differentiating benefits and appropriately position the product. ACTIQ will be positioned as fentanyl in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available through the communication of the following key product messages, which tested highest amongst physicians in April 2002:

- **Efficacy:** The main benefit of ACTIQ is its time to onset of analgesia.
- **Safety:** In clinical trials, the safety and efficacy of ACTIQ were established in opioid tolerant cancer patients receiving both long-acting oral and transdermal opioids.
- **Side Effects:** The adverse events seen with ACTIQ are typical opioid side effects. Frequently, these adverse events will cease or decrease in intensity with continued use of ACTIQ, as the patient is titrated to the proper dose.
- **Dosing and Titration:** ACTIQ should be taken along with the patients' longer-acting cancer pain medication.
- **Convenience/Ease of Use:** ACTIQ's oral transmucosal delivery system and onset of action provides patients with portability, convenience and control.
- **Delivery System:** ACTIQ utilizes a unique oral transmucosal system (OTS) for rapid absorption of fentanyl.
- **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.

### B. TARGET AUDIENCE

The ACTIQ target audience can be divided into two distinct market segments:

- Pain specialists
- Oncologists

The primary target for ACTIQ in 2003 will continue to be pain specialists. However, there will be a need to expand from our base of core physicians and begin to increase our target list. The pain specialist group consists of any physician, regardless of AMA specialty that treats pain as a primary function of their practice. A pain specialist is most often an anesthesiologist or physiatrist, but can also be a neurologist, psychiatrist or any of a multitude of other AMA specialties. AMA specialty can often be a poor way to target physicians for ACTIQ potential. Therefore, when targeting pain specialists, it will be critical to evaluate opioid prescribing habits. More specifically, it may be important to evaluate specific opioid usage.

Oncologists will remain a target as the labeling for ACTIQ remains static; for the management of BTCP in opioid tolerant cancer patients. Unfortunately, we have learned from experience since the launch of ACTIQ in April 1999, that oncologists are not as adept at pain management as once believed. Therefore, as in 2002, this segment of the target audience will be a secondary target for promotional efforts behind high opioid prescribing pain specialists. Oncologists that are truly "pain specialists" will obviously become a key target.

Most pain experts believe that "pain is pain" regardless of the source of pain or disease state. Therefore, messaging for both targeted segments (pain specialists and oncologists) will be identical and will include the key marketing messages previously listed.

### C. CORE TACTICAL PLAN

#### *Overall Tactical Approach*

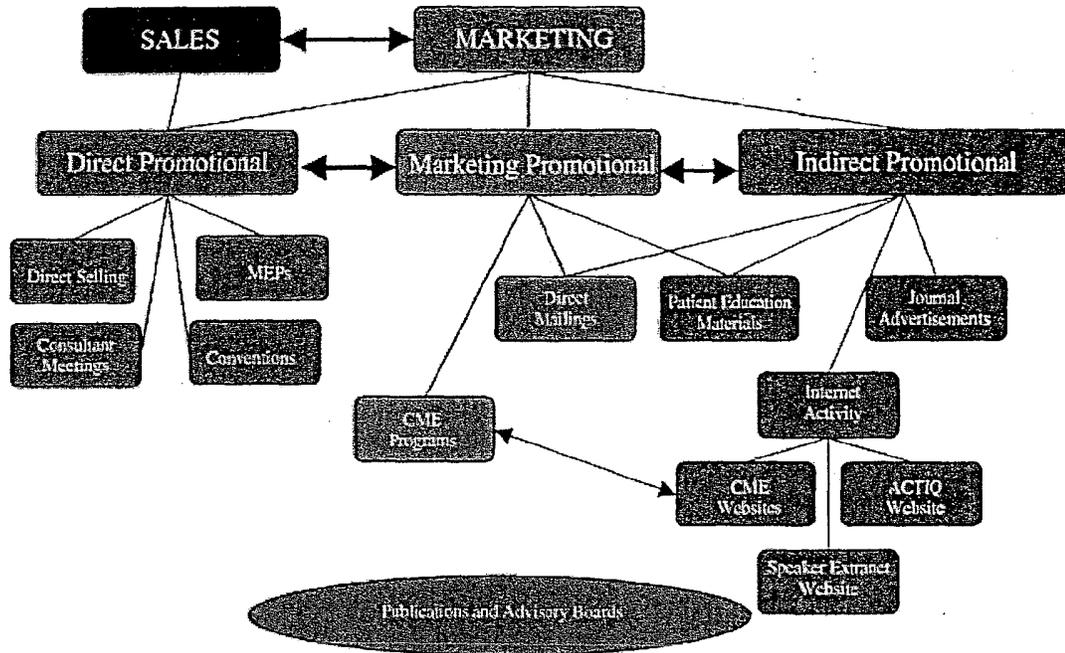
The majority of resources will be allocated to tactics that are considered *most* effective in delivering ACTIQ's key messages to our target audiences. Based on the current limitations in promotional flexibility, the most effective tactics will include peer-to-peer educational programs, such as consultant meetings, CME programs and sales-driven medical education programs (MEPs). As in 2002, physician and nursing advisory boards will be implemented to identify appropriate and effective tactical programs and formats, to assist in the development of a clinical research and publications plan, and to develop tactics to raise awareness of BTP/ACTIQ among both patients and clinicians.

The 2002 ACTIQ tactical initiatives can be broken down into three broad categories:

- Direct promotion
- Marketing promotion
- Indirect promotion

The following is a brief overview and description for each of the 2002 ACTIQ tactical initiatives. The complete tactical plan is presented in detail in the Appendix.

*Tactical Plan Overview*



*Direct Promotional Tactics*

• **Direct Selling Support Pieces**

With the anticipated transition to the compressed powder formulation of ACTIQ, it will be critical that marketing arm the PCS sales force with appropriate and effective sales support materials. All support pieces will contain ACTIQ key messages as listed previously, as well as the brand colors and current brand concept. Marketing will develop additional promotional pieces to support the sales force's efforts. PCS representatives will continue to receive a sufficient amount of coupons as they have proven incredibly effective in generating new patient starts. Each representative will receive 150 coupons/month for distribution.

• **Medical Education Programs (MEPs)**

As we have seen in 2001 and 2002, peer-to-peer selling is a highly effective means of developing new prescribers and ACTIQ advocates. MEPs have proved to be an effective way to convert ACTIQ dabblers into ACTIQ champions. Marketing will provide sufficient resources to the PCS sales force to drive the implementation of sales-driven MEPs in 2003.

- **Consultant Meetings**

Marketing plans to implement three national level ACTIQ consultants meetings for 2003. In addition, due to the incredible success of the national level meetings in 2002, marketing plans to implement a minimum of eight regional level consultant meetings. The addition of regional level meetings will assist in gleaning critical feedback from key target physicians.

**Marketing Promotional Tactics**

- **Direct Mail**

Direct mailing efforts for 2003 will focus on accomplishing the following key objectives:

- Deliver ACTIQ key messages to specific market segments
- Increase ACTIQ awareness among targeted market segments
- Maintain/continue communication with previous direct mail responders
- Notification to existing prescribers, as well as high opioid prescribers, of the pending change in formulation and packaging for ACTIQ

All direct mail targets will be both marketing and sales targets. Therefore, the PCS representatives will be given copies of each direct mail effort to utilize in physician offices to reinforce the key messages of each mailing.

- **CME programs**

Marketing will implement several new CME initiatives in 2003 as well as expand and improve initiatives from 2002. As we have seen in the past, these programs can be extremely effective in communicating key selling messages in the context of pure, balanced educational programs. Substantial resources will be applied to CME programs this year due to our limited promotional flexibility and inability to make certain claims.

The CME programs for 2003 include:

- Tri-Annual Newsletter
- Approximately 300 local/regional symposia
- WebMD/Medscape CME
  - Clinical Update – CME review article
  - CME Circles – Review of CME symposia
- Teleconferences
- *EmergingSolutionsinPain.com*
- *Pain.com/breakthrough*

- **Publications**

ACTIQ has tremendous growth potential in the treatment of BTP in opioid tolerant patients in a variety of non-malignant pain diagnoses, as well as chronic episodic pain in other disease states. If adequate internal medical support is provided, marketing will drive the direction and execution of publication plans and phase IV research.

- *Case series* in 2003 should target several of the largest potential segments of the pain market: BTP in non-malignant chronic pain (i.e., chronic back pain, CRPS, OA, RA, etc.) as well as episodic pain (i.e., migraine headaches, sickle cell pain, etc.).

- *Phase IV research* should include the following outcomes:
  - Efficacy outside of CA patient population
  - Onset of pain relief < 15 minutes
  - Patient preference
  - Simplified titration

- **Advisory Boards**

Marketing will implement two marketing advisory board meetings in 2003. The strategy and objectives of the meetings will be identified as needs arise throughout 2003.

*Indirect Promotional Tactics*

- **Journal Advertisements**

A PERQ/HCI campaign tracking study implemented in December 2001 and message testing performed in April 2002 provided critical feedback to improve our current campaign. The current concept will remain static, however, several key messages will be changed to enhance the effectiveness of the advertisement. A headline, "When onset matters...ACTIQ on Call," has been added, to enhance the advertisement and reinforce the key differentiating benefit of rapid onset of pain relief. Marketing will also develop a two page spread in addition to the one page journal advertisement to provide a new look and feel to the current campaign with the goal to re-attract physicians to the advertisement. Marketing plans to increase journal placements and ACTIQ's share of voice among the pain market. Concept and message testing will be conducted at the end of 2002/ beginning of 2003 to ensure key messages are effectively being delivered in the new campaign. The complete ACTIQ media plan is detailed in Appendix 7.

**Journal Advertising Distribution**

|                       |   |
|-----------------------|---|
| <b>Pain</b>           | <b>Journal of Pain</b><br><b>Journal of Pain Symptom Management</b><br><b>Pain Medicine</b><br><b>Pain Medicine News</b>  |
| <b>Anesthesiology</b> | <b>Anesthesia &amp; Analgesia</b><br><b>Anesthesiology</b><br><b>Anesthesiology News</b>  |
| <b>Oncology</b>       | <b>American Journal of Oncology Review</b><br><b>Journal of Clinical Oncology</b><br><b>Oncology</b><br><b>Oncology News International</b><br><b>Oncology Net Guide</b> |

- **Internet Activity**

As in 2002, marketing will employ three primary internet sources of information on BTP and/or ACTIQ. These sources are as follows:

- *ACTIQ.com*
  - Product specific information as well as FAQ's for physician and patients. Redesigned and launched in March 2002
- *Cephalonspeaker.com*
  - Product specific information with resources for ACTIQ speakers.
- *EmergingSolutionsinPain.com*
  - On-line repository of all CME programs created with Medicom, Inc. Launched September 2001.

Additionally, two on-line CME initiatives will be employed in 2003:

- *Pain.com/breakthrough*
  - Unique URL on Pain.com containing educational information for physicians and patients about BTP as well as CME offerings. Pain.com is the most widely visited pain site on the internet with over 200,000 visits/year.
- Web MD/Medscape
  - On-line CME offerings focused on expanding awareness of BTP assessment and treatment.

- **Patient Education Materials and Programs**

Marketing and public relations will work to create and/or update appropriate patient education materials in 2003. Both branded and non-branded patient educational pieces were created in 2002. The focus in 2003 will be to create additional non-branded patient education materials. The nursing advisory board formed in 2002 will help to focus and drive this process. These materials will be created/updated in coordination with professional and/or patient support organizations as necessary and may be applicable across varying disease states and patient populations. Additionally, other programs will be implemented, such as teleconferences, aimed at raising awareness of BTP and ACTIQ among targeted patient populations.

#### **D. MARKET RESEARCH PLAN**

As the market for ACTIQ continues to grow in 2003, identifying and executing strategic market research programs is critical to identify trends and exploit future opportunities.

Some key opportunities for market research include:

- Learning more about the utilization of ACTIQ by various specialists and patient types
- Understanding which attributes are associated with ACTIQ and key competitors and which attributes drive brand choice

- Refining segments based on attitudinal and behavioral choices
- Selecting branding concepts, which best capture the "reason to believe" associated with ACTIQ.

### ***2003 Market Research Projects***

The aforementioned market research goals can be captured in the following proposed projects.

- **Market Structure Study (1Q 2003)**

This project will capture a snapshot of market dynamics regarding treatment choice and trends in the market that ACTIQ competes. Some key learnings include: attribute assessment, needs gap analysis and perceptual mapping of brand imagery. We will also uncover various measures of brand awareness.

The study will include high users of short-acting opioids and stratified to include high, low, and non-users of ACTIQ.

- **ACTIQ Messaging Study (1Q 2003)**

Based on the results of some of the above project, there may be a need to re-visit the key messages of ACTIQ. The above study will give us insight if ACTIQ is positioned optimally, and if so, if the messages are meaningful.

or

- **ACTIQ Segmentation Study (1Q 2Q 2003)**

If the messages are determined to be optimal, this project would help us understand in greater depth the reasons why certain doctors are using ACTIQ while others have do not. The results of this study will help refine the targeting for the product and understand how to reach those physicians who are not users.

- **ACTIQ Utilization/Patient Flow study (1Q 2003)**

This project will help us better stand how doctors and patients use ACTIQ and some key competing products. Key analysis will include acute vs. chronic use, titration patterns, compliance statistics, and various measures of physician trial, adoption, and drop-off rates.

The study will include high users of short-acting opioids and stratified to include high, low, and non-users of ACTIQ.

- **Re-Concepting (2Q or 3Q 2003)**

This study will help the brand team select the brand images that best convey the key product messages.

- **CTS – Media/Journal Ad Evaluation (3Q or 4Q 2003)**

This study will monitor the effectiveness of the re-conception effort.

## E. PUBLIC RELATIONS

The primary goals of the 2003 ACTIQ public relations (PR) plan are to increase awareness of BTP and ACTIQ among targeted physician and patient populations. Cancer patients and oncology professionals will be the primary focus for many of the 2003 PR initiatives to take advantage of the support network for cancer pain, which is much more established and organized than for other pain disease states. Additionally, although oncologists have proven to be less productive prescribers to date, they remain an important, targeted market segment and present a tremendous opportunity for sustained product growth. Cancer patient support organizations afford the most efficient path to raising awareness among these patients.

To guide the development of awareness campaign, a nursing advisory board was established in June 2002 with key, influential nurses including our Chairperson, Dr. Christine Miaskowski. The advisory board is comprised of both ACTIQ supporters who are actively involved in patient care, as well as KOLs involved in setting pain policies and treatment guidelines. The goals of the advisory board will be to assist with the content creation and implementation of several PR tactics, as well as to establish Cephalon as a solid member of the pain community supporting nursing efforts to improve pain management. Additional meetings will be planned for 2003.

The core PR strategies for 2003 are as follows:

- Establish/renew meaningful relationships with thought leaders and third party professional and patient groups
- Support educational programs on opioid use that incorporate or focus on BTP
- Emphasize safety and efficacy of opioids for chronic pain and BTP
- Emphasize importance of proper assessment and treatment of BTP as well as the ability of patients to speak with physicians and nurses about pain symptoms
- Generate ACTIQ visibility in the cancer and pain media
- Position ACTIQ and BTP effectively and in accordance with overall product positioning to physicians, nurses and patients

The following provides an overview of the 2003 ACTIQ PR tactical initiatives:

- **Constituency Relations**
  - Third party activities, underwrite APF reception at APS meeting and sponsor cancer care teleconference on dosing. Corporate contributions to professional organizations such as APF, Cancer Care, AACPI, NCCS and NPF will help to re-establish our relationships and show our commitment to the pain community.
- **Third Party Meetings**
  - Attend key meetings in order to coordinate and meet one-on-one with key thought leaders to assess views on BTP and ACTIQ and develop a rapport.
- **Website Updates**

- Update patient, third party health and medical websites to encourage inclusion of BTP and/or ACTIQ.
- **Nurses Advisory Board**
  - Organize additional nurses advisory board meetings. The nurses on the board will be an integral part in the design of two key educational pieces on BTP: a Patient Diary and Pocket Card BTP assessment tool for physicians and nurses.
- **ONS CE Program**
  - Create CE symposia on BTP to be held at ONS Institute of Learning meeting in November 2003. This CE effort will be coordinated with ACTIQ product management.
- **Media Relations**
  - Develop press materials, press release and media lists to announce the launch of the new ACTIQ formulation. Additionally, coordinate with investigators to develop press materials on Cephalon/ACTIQ news and publications.
- **Support upcoming book on pain**
  - Work with publisher to develop messages, press material development and distribution, pitching, audio news release, etc.

**APPENDIX**

1. Long-Acting Opioids and Short-Acting Pure Opioids
2. 2003 Tactical Plan by Marketing Strategy
3. 2003 Tactical Plan Implementation Timeline
4. 2003 Tactical Budget
5. 2002 ACTIQ Concept and Journal Advertisement
6. 2003 Journal Advertisements
7. 2003 Media Plan
8. 2003 ACTIQ Medical Meeting Plan

1. Long-Acting Opioids and Short-Acting Pure Opioids

Long-Acting Opioids

| Opioid    | Trade Name                     | Generic Name   | Manufacturer                        |
|-----------|--------------------------------|--|-------------------------------------|
| Fentanyl  | Duragesic                      | Fentanyl<br>Transdermal System                           | Janssen                             |
| Oxycodone | OxyContin                      | Oxycodone HCl<br>Controlled-Release                      | Purdue Pharma                       |
| Morphine  | MSContin<br>Oramorph<br>Kadian | Morphine Sulfate<br>Morphine Sulfate<br>Morphine Sulfate | Purdue Pharma<br>Roxane<br>Faulding |

Short-Acting Pure Opioids

| Opioid    | Trade Name      | Generic Name                          | Manufacturer            |
|-----------|-----------------|---------------------------------------|-------------------------|
| Fentanyl  | ACTIQ           | Oral Transmucosal<br>Fentanyl Citrate | Cephalon                |
| Oxycodone | OxyIR           | Oxycodone HCl<br>Immediate-Release    | Purdue Pharma           |
|           | OxyFast         | Oxycodone HCl<br>Immediate-Release    | Purdue Pharma           |
|           | Roxicodone      | Oxycodone HCl                         | Roxane                  |
| Morphine* | MSIR<br>Roxanol | Morphine Sulfate<br>Morphine Sulfate  | Purdue Pharma<br>Roxane |
|           | Dilaudid        | Hydromorphone<br>HCl                  | Knoll/Abbott Labs       |

\*Generic forms of short-acting morphine and hydromorphone also exist

2. 2003 Tactical Plan by Marketing Strategy

|                                   | Raise Awareness/Educate about BTP | Raise Awareness/Educate about ACTIQ | Enhanced Medical Meeting Presence | Proactive Communication of Transition to New Formulation | Build/Renew Relationship with KOLs | Limited Promotional Reach |
|-----------------------------------|-----------------------------------|-------------------------------------|-----------------------------------|--|------------------------------------|---------------------------|
| <b>CORE TACTICS</b>               |                                   |                                     |                                   |  |                                    |                           |
| Sales-Driven MEPs                 | X                                 | X                                   |                                   | X  | X                                  |                           |
| CME Symposia                      | X                                 | X                                   | X                                 |  | X                                  |                           |
| CME Teleconferences               |                                   | X                                   |                                   |  |                                    | X                         |
| ESP Newsletter/Website            | X                                 | X                                   |                                   |  |                                    |                           |
| Consultant Meetings               |                                   | X                                   | X                                 |  | X                                  | X                         |
| CME on WebMD/Medscape             | X                                 | X                                   |                                   |  |                                    | X                         |
| Transition Sales Tools            |                                   |                                     |                                   | X  |                                    |                           |
| Transition Mailings/Fax Campaigns |                                   |                                     |                                   | X  |                                    | X                         |
| Pain.com                          | X                                 | X                                   |                                   |  |                                    | X                         |
| Sample Coupons                    |                                   | X                                   |                                   |  |                                    | X                         |
| Medical Meetings                  | X                                 | X                                   | X                                 |  |                                    |                           |
| Public relations                  | X                                 | X                                   |                                   | X  | X                                  |                           |
| Publications                      | X                                 | X                                   | X                                 |  | X                                  | X                         |
| Journal Advertising               | X                                 | X                                   |                                   |  |                                    | X                         |

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3. 2003 Tactical Plan Implementation Timeline

|                                   | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec |
|-----------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|------|-----|-----|-----|
| <b>PROMOTIONAL TACTICS</b>        |     |     |     |     |     |     |     |     |      |     |     |     |
| Sales-Driven MEPS                 | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| CME Symposia                      | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| CME Teleconferences               |     |     | X   | X   | X   |     |     | X   | X    | X   |     |     |
| ESP Newsletter/Website            | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| Consultant Meetings               | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| CME on WebMD/Medscape             | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| Transition Sales Tools            |     | X   | X   | X   | X   | X   | X   |     |      |     |     |     |
| Transition Mailings/Fax Campaigns |     | X   | X   |     |     |     |     |     |      |     |     |     |
| Pain.com                          | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| Sample Coupons                    | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| Medical Meetings                  |     | X   | X   | X   | X   |     |     | X   | X    | X   | X   |     |
| Public relations                  | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |
| Publications                      |     |     |     |     |     |     |     |     |      |     |     |     |
| Journal Advertising               | X   | X   | X   | X   | X   | X   | X   | X   | X    | X   | X   | X   |

4. 2003 ACTIQ Tactical Budget

| 2003 ACTIQ Tactical Budget        |                      |                     |                     |                     |                     |
|-----------------------------------|----------------------|---------------------|---------------------|---------------------|---------------------|
|                                   | Total                | Q1                  | Q2                  | Q3                  | Q4                  |
| Market Research                   | \$ 815,000           | \$ 215,000          | \$ 225,000          | \$ 75,000           | \$ 100,000          |
| Consultants                       | \$ 10,000            | \$ 5,000            | \$ 5,000            |                     |                     |
| Journal Reprints                  | \$ 400,000           | \$ 300,000          | \$ 100,000          |                     |                     |
| Conversion                        | \$ 481,000           | \$ 271,000          | \$ 98,000           | \$ 50,000           | \$ 50,000           |
| Advertising/Promotional Materials | \$ 2,905,000         | \$ 1,180,000        | \$ 875,000          | \$ 450,000          | \$ 400,000          |
| Sample Coupons                    | \$ 1,165,000         | \$ 312,500          | \$ 272,500          | \$ 307,500          | \$ 272,500          |
| Public Relations                  | \$ 1,000,000         | \$ 250,000          | \$ 250,000          | \$ 250,000          | \$ 250,000          |
| Field Driven Speaker Programs     | \$ 2,750,000         | \$ 687,500          | \$ 687,500          | \$ 687,500          | \$ 687,500          |
| Medical Education                 | \$ 7,784,000         | \$ 1,703,000        | \$ 2,344,000        | \$ 1,884,000        | \$ 1,853,000        |
| Corporate Contributions           | \$ 150,000           | \$ 37,500           | \$ 37,500           | \$ 37,500           | \$ 37,500           |
| RMP Requirements                  | \$ 460,000           | \$ 40,000           | \$ 350,000          | \$ 40,000           | \$ 30,000           |
| <b>Totals</b>                     | <b>\$ 17,700,000</b> | <b>\$ 5,001,500</b> | <b>\$ 5,236,500</b> | <b>\$ 3,781,500</b> | <b>\$ 3,680,500</b> |

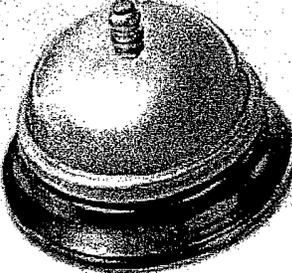


6. 2003 ACTIQ Journal Advertisements

ACTIQ One-Page Advertisement

www.actiq.com

## When onset matters...



### Actiq on call.



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

|  |   |
|--|---|
| <p><b>Rapid transdermal absorption</b></p> <ul style="list-style-type: none"> <li>• The rapid onset of action and longer duration of ACTIQ allows for rapid and sustained absorption and longer duration of analgesia.</li> <li>• Patients may begin experiencing pain relief while the ACTIQ patch is being applied, and may be able to get up in 15 minutes and begin to do ACTIQ work.</li> <li>• Studies have shown that onset of analgesia is observed within 15 to 30 minutes of the CS in patients with a 5- to 6-second half-life.</li> <li>• Lower or higher concentrations than the recommended 12 mg/24 hours may be used when appropriate in clinical studies.</li> </ul> <p><b>No pharmacologically active metabolites</b></p> <ul style="list-style-type: none"> <li>• Safety and efficacy have been established in opioid-naïve and opioid-tolerant patients based on the safety and efficacy of oxycodone.</li> </ul> <p><b>Typical opioid side effects</b></p> <ul style="list-style-type: none"> <li>• The most common side effects observed were constipation, drowsiness, and dizziness.</li> </ul> <p><b>Tolerability, discontinuation control</b></p> <ul style="list-style-type: none"> <li>• The use of oxycodone 5 mg/24 hours and 12 mg/24 hours in opioid-naïve patients with postoperative, cancer, and chronic pain.</li> </ul> | <p><b>Important Warnings</b></p> <ul style="list-style-type: none"> <li>• The safety and efficacy of ACTIQ have been established in patients with moderate to severe pain. The safety and efficacy of ACTIQ have not been established in patients with mild to moderate pain.</li> <li>• Oxycodone has the potential for abuse and addiction. The use of ACTIQ may lead to the development of tolerance and physical dependence.</li> <li>• The product must be used as directed for the intended purpose.</li> <li>• Alcohol consumption may increase the CNS effects of oxycodone and may lead to respiratory depression.</li> <li>• The most common side effects observed in clinical studies were constipation, drowsiness, and dizziness.</li> </ul> <p><small>*Based on clinical studies of oxycodone 5 mg/24 hours and 12 mg/24 hours in opioid-naïve patients with postoperative, cancer, and chronic pain.</small></p> |
|--|---|

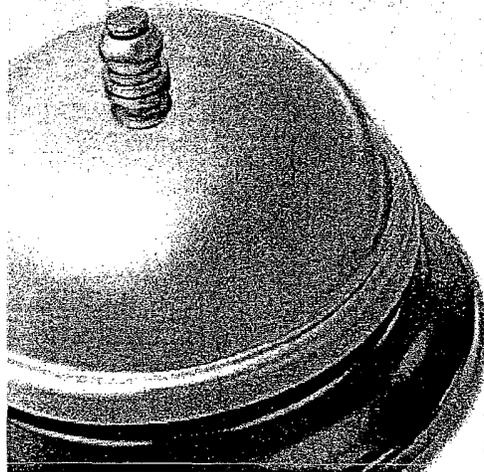


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6. 2003 ACTIQ Journal Advertisements (continued)

ACTIQ Two-Page Spread Advertisement



**When onset matters...**

**Actiq on call.**

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

**Rapid, nonopioid analgesia**

- \* The median time to onset of pain relief with ACTIQ was 15 minutes.
- \* The median time to onset of pain relief with ACTIQ was 15 minutes.
- \* The median time to onset of pain relief with ACTIQ was 15 minutes.

**No pharmacologically active metabolites**

- \* ACTIQ is a prodrug that is rapidly converted to its active form, rofecoxib.
- \* The only active metabolite of ACTIQ is rofecoxib.

**Typical opioid side effects**

- \* The most common side effects of ACTIQ were nausea, vomiting, and constipation.

**Pharmacokinetics, pharmacodynamics, and safety**

- \* The median time to onset of pain relief with ACTIQ was 15 minutes.

**Important Warnings:**

- \* Do not take ACTIQ if you are taking any other NSAIDs.
- \* Do not take ACTIQ if you have a history of ulcers or gastrointestinal bleeding.
- \* Do not take ACTIQ if you are pregnant or breastfeeding.
- \* Do not take ACTIQ if you are taking any other medications that may interact with ACTIQ.

**ACTIQ**

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7. 2003 Media Plan

ACTIO 2003 Recommended Media Plan  
Option #3 \$800,000 budget

| 2003                             | Total     | Jan      | Feb      | Mar      | Apr      | May      | Jun      | Jul      | Aug      | Sept     | Oct      | Nov      | Dec      |     |
|----------------------------------|-----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----|
| Number of Insertions             | 97        | 10       | 7        | 12       | 7        | 10       | 8        | 8        | 5        | 10       | 5        | 8        | 7        |     |
| Avg. Exposure per MD             | 18.77     | 1.41     | 1.32     | 1.80     | 1.32     | 1.41     | 1.48     | 1.36     | 1.25     | 1.54     | 1.26     | 1.25     | 1.45     |     |
| Journal Spend                    | \$757,218 | \$10,852 | \$51,913 | \$95,558 | \$51,913 | \$92,298 | \$44,377 | \$74,207 | \$33,424 | \$76,913 | \$33,424 | \$74,207 | \$36,130 |     |
| CMI Fee \$                       | 152,634   |          |          |          |          |          |          |          |          |          |          |          |          |     |
| Total \$                         | \$809,852 |          |          |          |          |          |          |          |          |          |          |          |          |     |
| Publications                     |           |          |          |          |          |          |          |          |          |          |          |          |          |     |
|                                  | Spend     | # Ins    | Jan      | Feb      | Mar      | Apr      | May      | Jun      | Jul      | Aug      | Sept     | Oct      | Nov      | Dec |
| <b>ANESTHESIOLOGY</b>            | Exp/Mth   | 1.5      | 1.4      | 1.4      | 1.7      | 1.4      | 1.4      | 1.7      | 1.4      | 1.4      | 1.7      | 1.4      | 1.4      | 1.7 |
|                                  | \$201,879 | 40       | 2        | 3        | 4        | 2        | 3        | 4        | 2        | 3        | 4        | 3        | 3        | 4   |
| Anesthesia & Analgesia           | \$58,048  | 12       | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1   |
| Anesthesiology                   | \$114,240 | 16       | 1        | 1        | 2        | 1        | 1        | 2        | 1        | 1        | 2        | 1        | 1        | 2   |
| Anesthesiology News              | \$129,591 | 12       | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1   |
| <b>ONCOLOGY</b>                  | Exp/Mth   | 0.6      | 1.3      | 0.5      | 1.3      | 0.5      | 1.3      | 0.3      | 0.7      |          | 0.7      |          | 0.7      |     |
|                                  | \$234,895 | 28       | 5        | 2        | 3        | 2        | 5        | 1        | 3        |          | 3        |          | 3        |     |
| American Jnl. Of Oncology Review | \$80,461  | 6        | 1        |          | 1        |          | 1        |          | 1        |          | 1        |          | 1        |     |
| Jnl. Of Clinical Oncology        | \$49,480  | 6        | 1        | 1        | 1        | 1        | 1        | 1        |          |          |          |          |          |     |
| MD Net Guide Onc. Est.           | \$60,217  | 6        | 1        |          | 1        |          | 1        |          | 1        |          | 1        |          | 1        |     |
| Oncology                         | \$48,011  | 5        | 1        | 1        | 1        | 1        | 1        |          |          |          |          |          |          |     |
| Oncology News Intl.              | \$55,826  | 6        | 1        |          | 1        |          | 1        |          | 1        |          | 1        |          | 1        |     |
| <b>PAIN SPECIALIST</b>           | Exp/Mth   | NA       |     |
|                                  | \$84,041  | 28       | 1        | 2        | 2        | 2        | 1        | 3        | 1        | 2        | 2        | 1        | 3        |     |
| Journal of Pain                  | \$18,207  | 8        |          | 1        |          | 1        |          | 1        |          | 1        |          | 1        | 1        |     |
| Jnl. Of Pain Symptom Management  | \$65,010  | 12       | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        | 1        |     |
| Pain Medicine                    | \$10,824  | 4        |          |          |          |          |          | 1        |          |          |          |          | 1        |     |
| Pain Medicine News               | \$65,402  | 6        | 1        |          | 1        |          | 1        |          | 2        |          | 1        |          | 1        |     |

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8. 2003 ACTIQ Medical Meeting Plan

| NAME & DATE   | BOOTH SIZE | SPECIALTY       | # OF ATTENDEES |
|---|------------|-----------------|----------------|
| <b>AAHPM - American Academy of Hospice and Palliative Medicine</b><br>February 6-9<br>Orlando, FL               | 10x20      | Palliative Care | 500            |
| <b>AAPM - American Academy of Pain Medicine</b><br>February 18-23<br>New Orleans, LA                            | 20x20      | Pain            | 600            |
| <b>APS - American Pain Society</b><br>March 20-23<br>Chicago, IL  | 20x20      | Pain            | 2,000          |
| <b>ONS - Oncology Nursing Society</b><br>May 1-4<br>Denver, CO  | 20x20      | Oncology        | 8,500          |
| <b>ASCO - American Society of Clinical Oncology</b><br>May 31-June 3<br>Chicago, IL                             | 10x20      | Oncology        | 22,000         |
| <b>AAPM - American Academy of Pain Management</b><br>September 4-7<br>Denver, CO                                | 20x20      | Pain            | 1,000          |
| <b>AAPM&amp;R - American Academy of Physical Medicine &amp; Rehabilitation</b><br>October 9-12<br>Chicago, IL   | 10x10      | Rehab Medicine  | 2,000          |
| <b>ASA - American Society of Anesthesiology</b><br>October 11-15<br>San Francisco, CA                           | 20x20      | Anesthesiology  | 16,000         |
| <b>ASTRO - American Society for Therapeutic Radiology &amp; Oncology</b><br>October 19-22<br>Salt Lake City, UT | 20x20      | Oncology        | 9,000          |

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