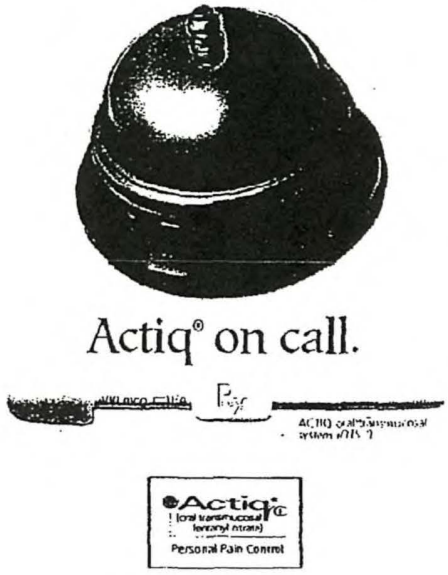
ACTIQ

2002 Marketing Plan



P. Andrew Pyfer, Product Manager – ACTIQ

PLAINTIFFS TRIAL EXHIBIT
P-03626_00001

CEPH-GM-00013241

Table of Contents

I. EXECUTIVE SUMMARY

2001 Performance Review

After the relaunch and repositioning of ACTIQ in February 2001, the Cephalon commercial organization performed exceptionally well causing ACTIQ to experience tremendous growth. Total prescriptions are projected to exceed 71,000 and total factory sales are projected to be greater than $50.5 MM, greater than three times the total sales of 2000 ($16.0 MM).

ACTIQ Performance: 2000 vs. 2001

	2000	2001 (YTD)	2001 Projected	% Growth Projected
TRx	21,823	37,428 (Aug)	71,017	325%
Factory Sales	$16.0 MM	$32.6 MM (Sept)	$50.5 MM	316%

Two key factors contributed to this tremendous growth. First, a new brand concept was developed and it repositioned ACTIQ to take advantage of its clear and considerable, differentiating feature and benefit (rapid onset of analgesia and personal pain control). Second, anesthesiologists/pain specialists became the primary physician group targeted for promotion.

Anesthesiologists/pain specialists are the second largest segment of the ACTIQ prescriber base, behind oncologists, and will be the largest segment by the end of 2001. They have proven to be the most receptive segment and have most readily adopted ACTIQ as a viable treatment option for breakthrough pain (BTP) in both malignant and non-malignant patients. They have also utilized ACTIQ in the treatment of episodic pain, a substantial segment of the pain market. Anesthesiologists/pain specialists have also proven to be the most productive segment of the ACTIQ prescriber base. Through July 2001, they comprised 25% of the ACTIQ prescriber base, yet accounted for 49% of TRx and 60% of demand sales.

ACTIQ increased its market share of the short-acting pure opioid market and is one of only two products to gain market share in 2001.

The competitive landscape has remained relatively static, however, increased scrutiny of opioid prescribing has occurred due to the abuse of OxyContin. Although OxyContin is not a direct competitor of ACTIQ, this increased scrutiny may negatively influence ACTIQ, and opioid prescribing overall, for the remainder of 2001 and 2002. In addition, new competitive BTP medications such as OraVescent (dissolvable tablet) are currently under investigation, which may pose a threat to ACTIQ in the future.

2002 Commercial Objectives

In 2002, ACTIQ will be positioned as the most rapid acting, non-invasive opioid available affording patients personal pain control for both BTP and episodic pain. To continue the extraordinary growth observed in 2001 and achieve the 2002 commercial objectives, marketing must continue a solid Phase IV / Case Series / Publications plan must be developed. Without a solid Phase IV / Case Series / Publications plan to support the use of ACTIQ in other pain types, we will be severely limiting its potential growth in the chronic pain market, a market with a large unmet need for a rapid-acting, non-invasive opioid.

ACTIQ 2002 Objectives: 2001 Actual vs. 2002 Budget

	2001 Projected	2002 Budget	% Increase
TRx	71,017	108,906	53%
Factory Sales	$50.5 MM	$84.3 MM	67%

2002 Issues

The key marketing issues facing ACTIQ in 2002 are:

- Low awareness of ACTIQ (linked to key benefits)
- Lack of knowledge in the assessment and treatment of BTP and episodic pain among targeted physician specialties
- Limited clinical data outside cancer patient population
- Low product and disease state awareness among targeted patient populations
- Limited direct promotional reach

2002 Strategy

The overall marketing strategy for 2002 will be similar to the 2001 strategy and will focus on differentiating ACTIQ from its competitors by utilizing the products primary strengths: rapid onset of analgesia and personal pain control. Efforts will be made to improve awareness of ACTIQ and strengthen the association with its differentiating benefits. Anesthesiologists/Pain Specialists will continue to be the primary targeted physician specialty. Each of the key marketing issues listed above will be addressed through targeted strategies and specific tactical initiatives.

2002 Tactical Summary

The ACTIQ marketing strategy will be executed through a variety of tactical initiatives that convey ACTIQ's key messages, such as: direct selling, sales-driven medical education programs, CME programs (teleconferences, symposia, newsletter, website), direct mailings, internet activity, journal advertisements, peer-reviewed publications of case series and/or phase IV research, patient education programs, consultant meetings and advisory boards.

Due to ACTIQ's narrow, limited indication, CME programs and peer-to-peer medical education programs will play a major role in the promotion of ACTIQ and will comprise 45% of the 2002 marketing budget. Pure promotional tactics such as journal advertisements and direct selling aids will comprise approximately 31% of the 2002 marketing budget.

Attaining the 2002 commercial objectives will be directly influenced by the following critical factors:

- Appropriate physician targeting
- Effective sales-driven medical education programs
- Successful CME programs
- Effective consultant meetings
- Timely publications (case series / phase IV research / posters / abstracts) that demonstrate potential uses and true onset of analgesia

The marketing team is confident that the aggressive growth targets for 2002 can be attained if the key elements outlined above occur.

II. SITUATION ANALYSIS

A. 2001 REVIEW

2001 Marketing Strategy Review
The 2001 ACTIQ marketing strategy centered on accomplishing several goals:

- Develop a new brand concept that delivers the key ACTIQ marketing messages (rapid onset of analgesia and personal pain control) to effectively reposition ACTIQ
- Increase ACTIQ prescriber productivity and prescriber retention
- Increase the number of ACTIQ prescribers through increased awareness of breakthrough pain (BTP) and ACTIQ among pain specialists (anesthesiologists, physiatrists, neurologists, etc.), oncologists, and targeted nurses
- Improve physician awareness of the primary differentiating feature and benefit of ACTIQ: rapid onset and personal pain control
- Establish a solid public relations plan to begin raising awareness of BTP and ACTIQ among targeted patient populations.

Overall, the promotional strategy implemented in 2001 has proven effective.

Brand Concept Development and Poor Product Positioning
Prior to 2001, ACTIQ was not positioned in the pain market to take advantage of its clear differentiating feature and benefit (i.e., rapid onset of analgesia and personal pain control). Former brand concepts focused solely on the "novel" oral transmucosal delivery system of ACTIQ or the clinical entity of breakthrough pain. They did not convey any of the new, key marketing messages and did not provide a meaningful reason to prescribe or inquire further. They did not effectively position ACTIQ as anything other than a product with a unique "delivery system." See appendix for 1999 and 2000 ACTIQ concepts.

Testing of four new and different concepts occurred in February 2001. The clear winner was the "bell" concept because it reflected the key ACTIQ marketing messages and supported the 2001 positioning of ACTIQ as a rapid acting analgesic that provides personal pain control.

Ownership Changes and Product Perception
Cephalon is now the third "owner" of ACTIQ and as it has passed through the hands of Abbott Laboratories and Anesta Corp. to Cephalon, Inc., the product has been launched/relaunched three times. There has also been tremendous turnover and a lack of continuity in both sales force and marketing personnel. These issues may have created negative perceptions of ACTIQ in the minds of some clinicians and were addressed in 2001. A direct mailing initiative sent to over 18,000 high opioid prescribers attempted to address these concerns. It will be important to be cognizant of these issues in 2002.

Breakthrough Pain Misunderstood

Breakthrough pain was first defined in 1990 yet is still misunderstood by many in the pain community. Many physicians are not aware of the prevalence and characteristics of BTP, such as the typical onset and duration of BTP episodes and the acceptable number of BTP episodes per day. Opinions differ on the acceptable number of breakthrough pain episodes per day ranging from zero to as high as six or seven. Many physicians maintain the belief that breakthrough pain can be controlled/eliminated by increasing the long-acting opioid to levels that often lead to overmedication and intolerable side effects. Many physicians must still be taught that most chronic pain patients (malignant and non-malignant) will experience an average of three BTP episodes per day even when their persistent pain is well controlled. Ideally, breakthrough pain must be assessed and treated independently and in coordination with the long-acting medication.

For those physicians that *believe* they understand how to treat BTP, the standard of care has become to prescribe a long-acting opioid to control persistent pain and a short-acting opioid to control BTP. These physicians believe that they are satisfactorily assessing and treating BTP. However, they may not effectively be managing BTP considering the delayed onset of action of currently available oral short-acting opioids. Additionally, many physicians follow the "mono-therapy" philosophy that the long and short-acting medications must be the same opioid. However, this was impossible for Duragesic prescribers until ACTIQ was launched and remains a problem for physicians who prescribe Dilaudid (hydromorphone). Purdue Frederick, the manufacturers of OxyIR (short-acting oxycodone), Percocet (short-acting oxycodone combo product) and OxyContin (long-acting oxycodone), has promoted this theory aggressively and effectively. As physicians continue to treat BTP and gain a better understanding of the common characteristics of BTP (rapid onset of pain, short duration of pain, average of 3 episodes per day), ACTIQ should become the clear choice in the treatment of BTP based on its primary differentiating feature.

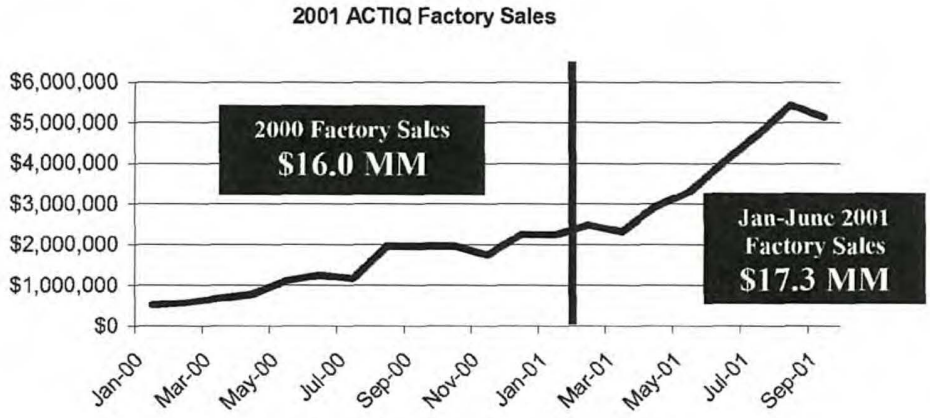
Why ACTIQ?

ACTIQ's clear differentiating feature is its rapid onset of analgesia. The use of oral short-acting pure opioids or combination products for the treatment of BTP is less than ideal due to a lack of rapidity of analgesic effect. Additionally, due to ACTIQ's rapid onset, it has a clear and distinct advantage over other products in the treatment of episodic or recurrent pain (e.g., sickle cell crisis, migraine headaches). This type of pain represents a substantial market opportunity.

B. SALES AND PRESCRIPTION UPDATE

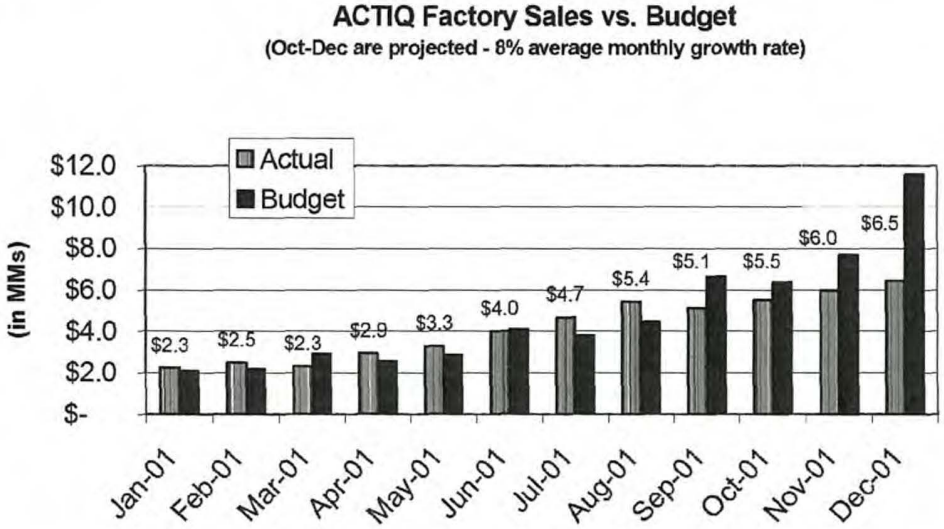
Sales

Upon relaunch and repositioning in February 2001, factory sales in the first six months of 2001 of $17.3 MM exceeded total sales of $16.0 MM in 2000.



Source: DDN

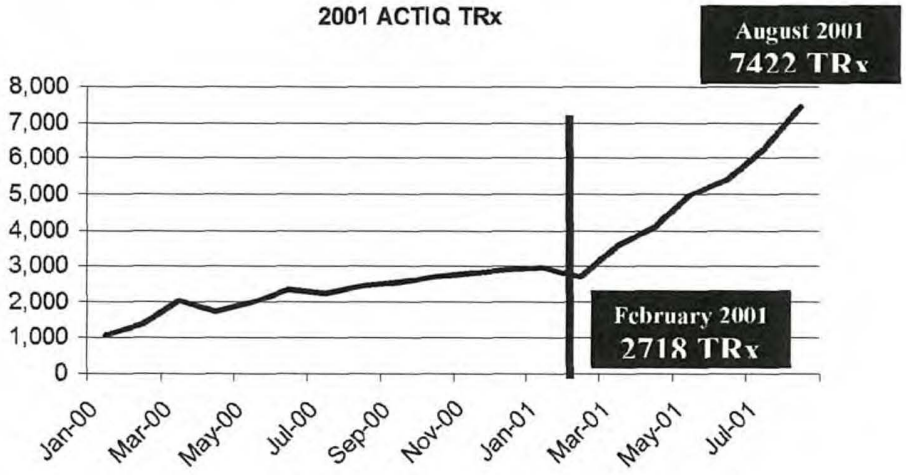
Year-to-date factory sales have exceeded budget in seven of the first nine months of 2001 and through September equaled $32.6 MM (103% of budget YTD). Factory sales are on pace to reach $50.5 MM, triple the total sales of $16.0 MM of 2000, just shy of the $57.4 MM year-end budget.



Source: IMS NPA

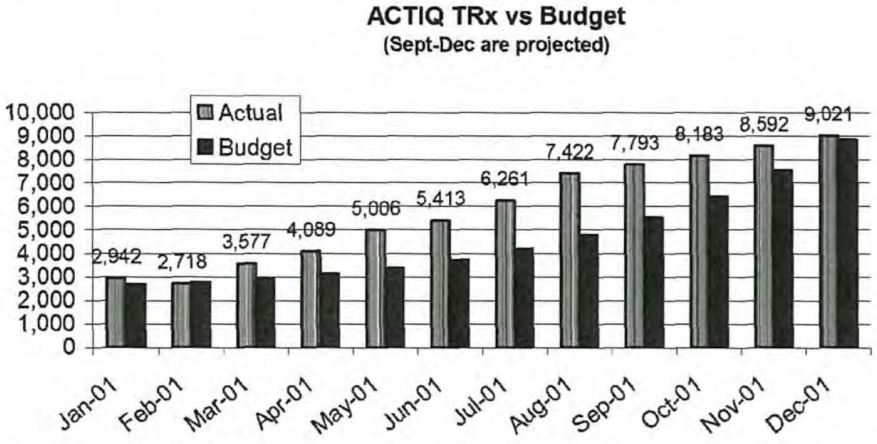
Prescriptions

Upon relaunch and repositioning in February 2001, ACTIQ prescriptions have grown enormously, with the number of TRx nearly tripling from February (2718 TRx) to August (7422 TRx).



Source: IMS NPA

ACTIQ prescriptions have exceeded budget in seven of the first eight months of 2001 and through August equaled 37,428 (135% of budget YTD). It is expected that 2001 TRx will exceed 71,000 and be 127% of total budgeted prescriptions.



Source: IMS NPA

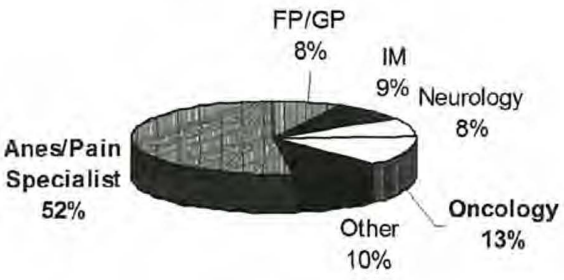
Sales and Prescriptions by Specialty

Targeting the correct physician specialties has been the primary reason for the significant growth in ACTIQ sales and TRx in 2001. Prior to the relaunch in February 2001, the marketing directive had been to target oncologists, hematologists and pain specialists, with the emphasis being placed on oncology. The indication for ACTIQ leads one to believe that oncologists should be the main focus of promotion; however, since the initial product launch in April 1999, oncologists have proven to be exceptionally slow in adopting ACTIQ as a viable alternative to treating BTP. This is primarily due to the fact that most oncologists are focused on delaying disease progression and are less concerned with symptom management.

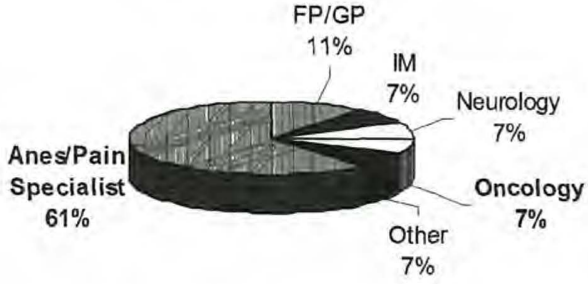
The physicians that have most readily adopted ACTIQ into their pain treatment regimen have been physicians that consider themselves "pain specialists." Therefore, the targeting directive for the 2001 relaunch called for promotional emphasis to be directed toward anesthesiologists and pain specialists. It is important to keep in mind that anesthesiologists/pain specialists are significant contributors in the treatment of cancer pain.

In fact, through August 2001, anesthesiologists/pain specialists accounted for 52% of TRx and 61% of demand sales, while oncologists have accounted for only 13% of TRx and 7% of demand sales. This also indicates that anesthesiologists/pain specialists are more productive prescribers. Additionally, the "other" group of physicians cited below consists primarily of physicians who specialize in pain yet have AMA specialties other than "anesthesiology" or what is normally considered a "pain" specialty. When combined with the anesthesiologists/pain specialists, the two physician groupings comprise 62% of TRx and 68% of demand sales.

TRx Count by Specialty
YTD August 2001



Demand Sales by Specialty
YTD August 2001



Source: NDC Source Prescriber

Sales and Prescriptions by Dosage Strength

Another key directive in the relaunch of 2001 was to focus on simplifying the titration process for clinicians. The goals of simplifying the titration process were to:

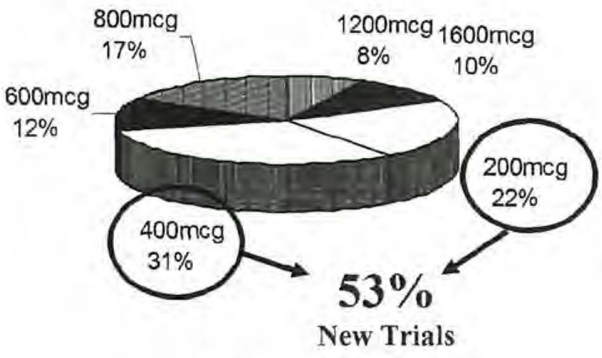
- Stress the importance of individualized dosing (dosing to effect)
- Educate physicians to begin titration at the 400mcg strength (versus 200mcg) to avoid treatment failures
- Educate physicians about the relative potency of ACTIQ to facilitate comfort when initiating treatment and titrating to the higher strengths.

This education was done primarily through peer-to-peer initiatives such as:

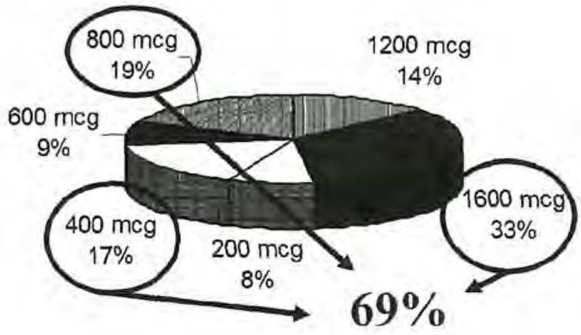
- Medical education programs (MEPs)
- Continuing medical education programs (CME)
- ACTIQ consultants meetings held in June 2001
- Direct selling efforts utilizing new promotional materials, including:
  - Dosing Guide
  - 2001 Sales Aid.

Through August, these education initiatives proved to be very successful. More prescriptions at the 400mcg strength (31% of TRx) were written than at any other strength, indicating that most new trials are being started at this strength. Overall, 53% of TRx have been written at the 200mcg (22%) and 400mcg (31%) through August 2001, indicating a solid growth trend in the overall number of new trials. Additionally, a significant number of prescriptions have been written for the three strengths that most correspond to the new titration direction; the 400mcg, 800mcg and 1600mcg strengths have accounted for 58% of TRx and 69% of total sales YTD. This is a significant indicator that ACTIQ prescribers are becoming increasingly comfortable with the titration process.

ACTIQ TRx by Strength
January - August 2001



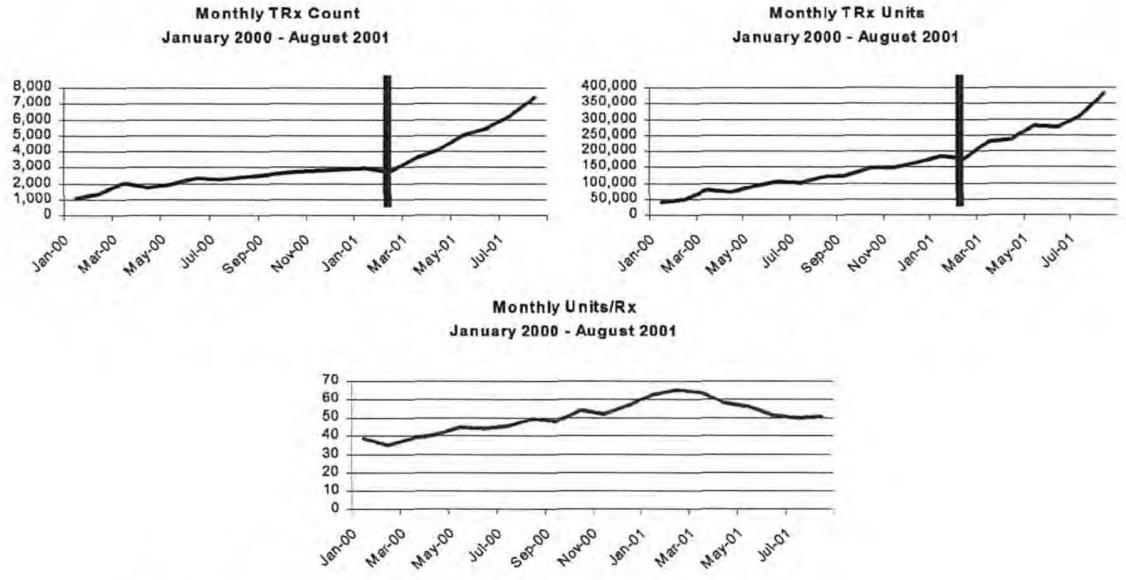
ACTIQ Factory Sales by Strength
January - August 2001



Source: IMS NPA

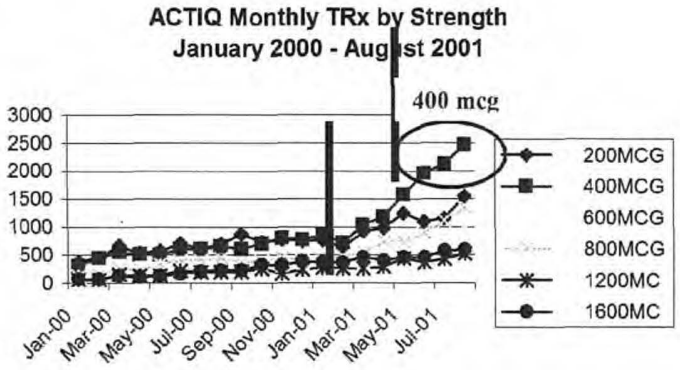
Prescription Characteristics

While TRx and TRx units have grown significantly since February 2001, it is also critical to measure the average prescription size as well. Since the 2001 relaunch, the TRx units has not increased commensurately with TRx and thus the average units/Rx has decreased steadily from a high of 64.3 units/Rx in January 2001 to an average of 53.1 units/Rx through June 2001.



Source: IMS NPA

Declining units/Rx may *appear* to be a concern; however, it is important to consider that 53% of TRx YTD have been either 200mcg or 400mcg prescriptions and that 400mcg prescriptions are currently growing at the fastest rate (see graph below). These are indicators that many of the prescriptions written since the 2001 relaunch are new trials of ACTIQ. New trials are almost always written for 24 units or fewer which would bring down the average units/Rx. As these new trials become maintenance prescriptions this number should slowly increase.



Source: IMS NPA

C. USAGE BY DISEASE AREA

The current source for disease usage data, PDDA from Scott-Levin, does not track anesthesiologists, the second largest and most productive segment of the ACTIQ prescriber base. PDDA does include oncologists and neurologists, also prescribers of ACTIQ, however the data is very limited. For example, there are no 2001 year-to-date uses reported in PDDA through August. Based on the preceding lack of data for anesthesiologists and the limited volume of ACTIQ prescriptions in PDDA, this data does not report an adequate representation of disease specific usage of ACTIQ.

As a result we implemented primary research to elucidate uses by pain type. The tracking study performed in May 2001 assessed awareness, perception and disease specific usage of ACTIQ among anesthesiologists/pain specialists (AMA specialty of "APM") and oncologists. While oncologists obviously use ACTIQ to treat BTCP, the participating APMs cited ACTIQ usage in the following disease states illustrating a wide spectrum of application and opportunity.

Usage of ACTIQ Cited by APMs in the May 2001 Baseline Tracking Study

USE OF ACTIQ	PAIN SPECIALISTS	
	Total	Of Those Prescribing, Mean # of Pts
(N) =	(25)	
	%	
% of MDs who have prescribed ACTIQ for:		
Lower back pain	48	11
Cancer pts	40	5
Reflex sympathetic dystrophy	36	3
Adhesions	24	8
Headache	24	7
Post-trauma	24	6
Osteoarthritis	20	7
Fibromyalgia	16	14
Diabetic neuropathy	16	3
Arachnoiditis	16	2
Rheumatoid arthritis	12	4
Systemic lupus	8	2
Other pt. Types	28	4

Source: May 2001 Baseline Tracking Study

ACTIQ usage by APMs in the aforementioned disease states may be due to several reasons:

- APMs are very familiar with fentanyl and may be comfortable with the application of fentanyl in a "unique" delivery system such as ACTIQ from their experience with Duragesic.
- APMs are accustomed to using many medications (especially adjuvants such as tricyclic antidepressants, anticonvulsants and corticosteroids) outside of their labeling and may feel comfortable with ACTIQ's potential in other pain states regardless of the narrow BTCP indication.

If these assumptions are correct, APMs may not require substantial clinical evidence in large numbers of patients to implement ACTIQ in disease states other than BTCP. Furthermore, these data may also suggest that small, exploratory studies to establish the clinical relevance of ACTIQ in the disease states listed above may encourage significant additional usage of ACTIQ in these and numerous other pain-related syndromes. Case series currently targeted for sickle cell anemia, migraine headache, RSD and chronic back pain should have a tremendous impact on physician prescribing habits. Rheumatoid and osteoarthritis represent other additional areas of great opportunity.

Using information from our baseline tracking study, we assume at least 37% of our 2001 prescriber base is prescribing ACTIQ to treat BTCP (see table below).[1] These numbers are small, and therefore the true percentage of physicians prescribing ACTIQ to treat BTCP may potentially be much higher.

Minimum Percentage of Prescribers Using ACTIQ to Treat BTCP

	Prescriber Count 2001 YTD (June)*	% of Prescriber Base	Multiple**	BTCP Prescriber Count	Minimum % of BTCP Prescribers
Oncology	561	27%	1.00	561	27%
Anes/Pain Spec	535	25%	.4	214	10%
Other	375	18%	0	0	0
IM	293	14%	0	0	0
FP/GP/OM	243	12%	0	0	0
Neurology	94	4%	0	0	0
TOTAL	**2101**	**100%**		**775**	**37%**

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

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

D. TARGET AUDIENCE AND PRESCRIBER ANALYSIS

Target Audience

An analysis of opioid prescription data shows that there are 24,000 potential ACTIQ targets. Applying further specific criteria to this active universe of 24,000 physicians narrows this universe to 7,921 targets that have been identified for more intense, marketing promotion and direct selling efforts. These 7,921 physicians represent roughly 165 physicians per Pain Care Specialist territory.

The specific criteria applied to the "active universe" to create the "target" list of 7,921 physicians included:

- Long-acting opioid prescribers (> decile 5)
- Short-acting opioid prescribers (> decile 6)
- Duragesic prescribers (> decile 7)
- ACTIQ prescribers (all)
- High opioid prescribing general surgeons, pediatricians and dentists were excluded

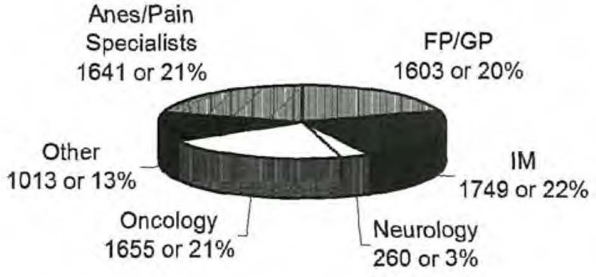
Sales and Marketing Targets

Source: NDC Source Prescriber

Targeting procedures for marketing promotional efforts in 2001 varied based on the objective of each initiative but ultimately involved one or all of the aforementioned criteria. Flexibility in targeting must be maintained in 2002 as the opportunities and target group for ACTIQ continue to evolve.

The 7,921 target physicians represent the following group specialties:

7,921 ACTIQ "Targets"



*Source: NDC Source Prescriber

Physician Targeting Research

Primary research and evaluation of the most effective methods of promotion was also performed in 2002. Significant results relevant to physician targeting include:

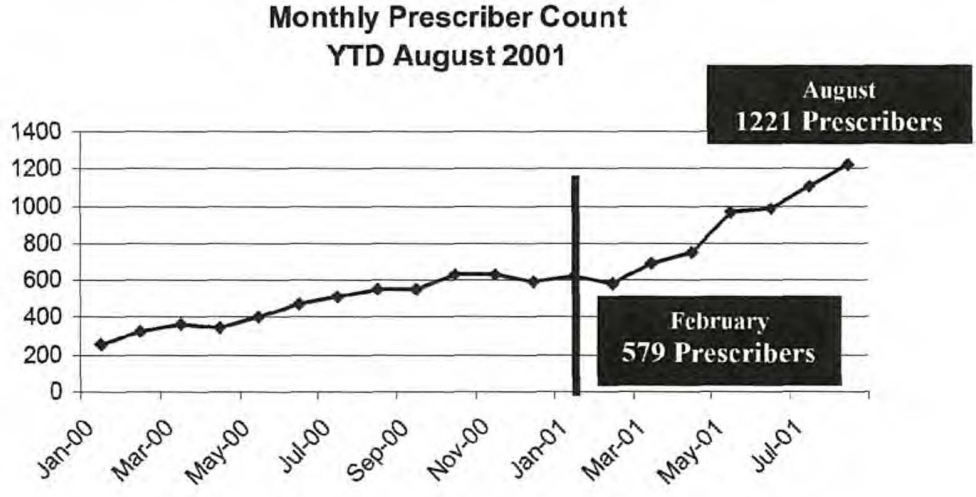
- ACTIQ prescribers were substantially more likely than non-prescribers to have been detailed
- Both oncologists and pain specialists claim detailing played a major role in prescribing ACTIQ
- Pain specialists and oncologists noted that after detailing, medical journals, medical meetings/symposia, colleagues and direct mailings are the most influential information sources

Pain Care Specialist Call Activity

Pain Care Specialists averaged 4.1 calls/day during 2001, representing over 27,000 target physician interactions through July 2001. This number is significantly lower than the number observed in the CNS sales force (5.7 calls/day). This can be primarily attributed to the large geographical territories many of the PCS sales representatives cover. Expansion of the PCS sales force will expand our direct promotional reach, shrink sales territories, and increase the call average.

Prescriber Base

Upon relaunch in 2001, the monthly prescriber count grew over a four-month period from 579 prescribers in February 2001 to 1221 in August 2001, and increase of 110%. The projected number of prescribers in December 2001 should exceed 1750.



*Source: NDC Source Prescriber

Prescriber Base Productivity

As a result of improved physician targeting, the total number of prescribers and TRx in the first six months of 2001 nearly equaled the total number of prescribers and TRx for the full year 2000. The most productive segment of the prescriber base is the anesthesiologist/pain specialist group. They far outpace every other prescriber base segment in TRx/prescriber (18.6 TRx/prescriber YTD June 2001). In fact, through June 2001, they comprised 25% of the ACTIQ prescriber base, yet produced 49% of all prescriptions. Conversely, oncologists prescribed the lowest number of TRx/prescriber (5.2 TRx/prescriber YTD June 2001); they accounted for 27% of all prescribers and a mere 14% of all prescriptions. It is also worth noting that although neurologists comprise a small percentage of the prescriber base (4.5%), they are very productive prescribers (17.1 TRx/prescriber) and have accounted for 8% of all TRx YTD June 2001.

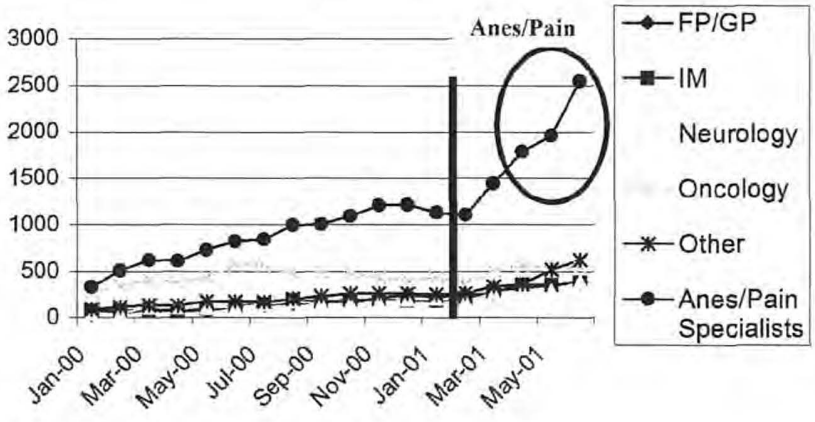
Prescriber Count, TRx and TRx/Prescriber Comparison by Specialty

	2000 Prescriber Count*	2000 TRx Count*	2000 TRx per Prescriber	2001 Prescriber Count YTD (June)*	2001 TRx YTD (June)*	2001 TRx per Prescriber
Oncology	855	5186	6.1	561	2921	5.2
Anes/Pain Spec	423	9965	23.6	535	9964	18.6
Other	385	2174	5.6	375	2339	6.2
IM	279	1551	5.6	293	1749	6.0
FP/GP/OM	210	1476	7.0	243	1761	7.2
Neurology	73	1471	20.2	94	1609	17.1
TOTALS	2225	21823	9.8	2101	20343	9.7

*Source: NDC Source Prescriber

Significant promotional efforts in 2001 were focused on the anesthesiology/pain specialist segment of the prescriber base.

TRx Count by Specialty Group
January 2000 - June 2001

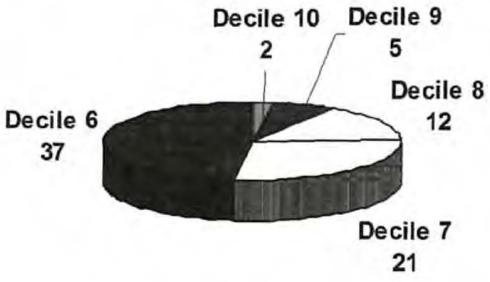


*Source: NDC Source Prescriber

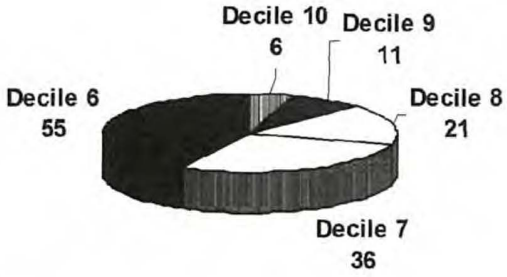
ACTIQ Decile Analysis

The number of top five decile ACTIQ prescribers has grown significantly since the relaunch and repositioning in February 2001. The number of physicians comprising the top five deciles for the six-month period September 2000 to February 2001 equaled 77 physicians. This number increased 68% to a total of 129 physicians for the six-month period immediately following the relaunch, March 2001 through August 2001. These 129 physicians have accounted for 13,784 TRx over this time period and have written and average of 18 TRx/month and 65 units/Rx. They have also prescribed over 59% of all units during this time period. This data supports the marketing direction to build ACTIQ from a smaller, core group of physicians. Additionally, 57% of the 129 physicians currently included in the top five deciles for ACTIQ are anesthesiologists/pain specialists, supporting the marketing direction to target this highly productive physician specialty.

# of Physicians - ACTIQ Top 5 Deciles
September 2000 - February 2001



# of Physicians - ACTIQ Top 5 Deciles
March 2001 - August 2001



Total 77 Physicians
(60% Anes/Pain)

→ **68% Increase** →

Total 129 Physicians
(57% Anes/Pain)

*Source: NDC Source Prescriber

E. PRODUCT AWARENESS AND PERCEPTION

Product Awareness

Unaided product awareness of ACTIQ is very low, as evidenced by our baseline tracking study performed in May 2001. Unaided awareness is notably higher among oncologists as a result of former targeting directives and promotional efforts. Awareness among APMs should improve in 2002 as promotional targeting evolves.

Specific results from the baseline tracking study include:

- Combined unaided awareness of ACTIQ is 18%[2]
  - Unaided awareness among oncologists is 22%
  - Unaided awareness among APMs is 14%
- Aided awareness levels increased for both oncologists (58%) and APMs (60%)
  - Aided awareness is significantly higher than unaided awareness, but these figures remain relatively low[3]

Awareness of ACTIQ

	ONCOLOGISTS			PAIN SPECIALISTS		
	Total	Users	Non-Users	Total	Users	Non-Users
(N) =	(50)	(25)	(25)	(50)	(21)	(29)
	%	%	%	%	%	%
Unaided aware	22	36	8	14	24	7
Aided aware	58	64	52	60	76	48
Total Aware:	80	100	60	74	100	55

*Source: May 2001 Baseline Tracking Study

Prior to 2001, ACTIQ was not positioned in the pain market to take advantage of its clear differentiating feature and benefit (i.e., rapid onset of analgesia and personal pain control). Former brand concepts focused solely on the oral transmucosal delivery system of ACTIQ and the clinical entity of breakthrough pain. These concepts, while focusing on the feature (delivery system), may have aided overall awareness, but it is unclear if they increased recognition of the benefits of ACTIQ. In 2002, we will continue to emphasize the differentiating feature and benefit of ACTIQ (i.e., rapid onset of analgesia and personal pain control) in an effort to strengthen the positioning of the product in physicians' minds. Market research in 2002 will be utilized to evaluate both the awareness of ACTIQ as well as recognition of its benefits.

---

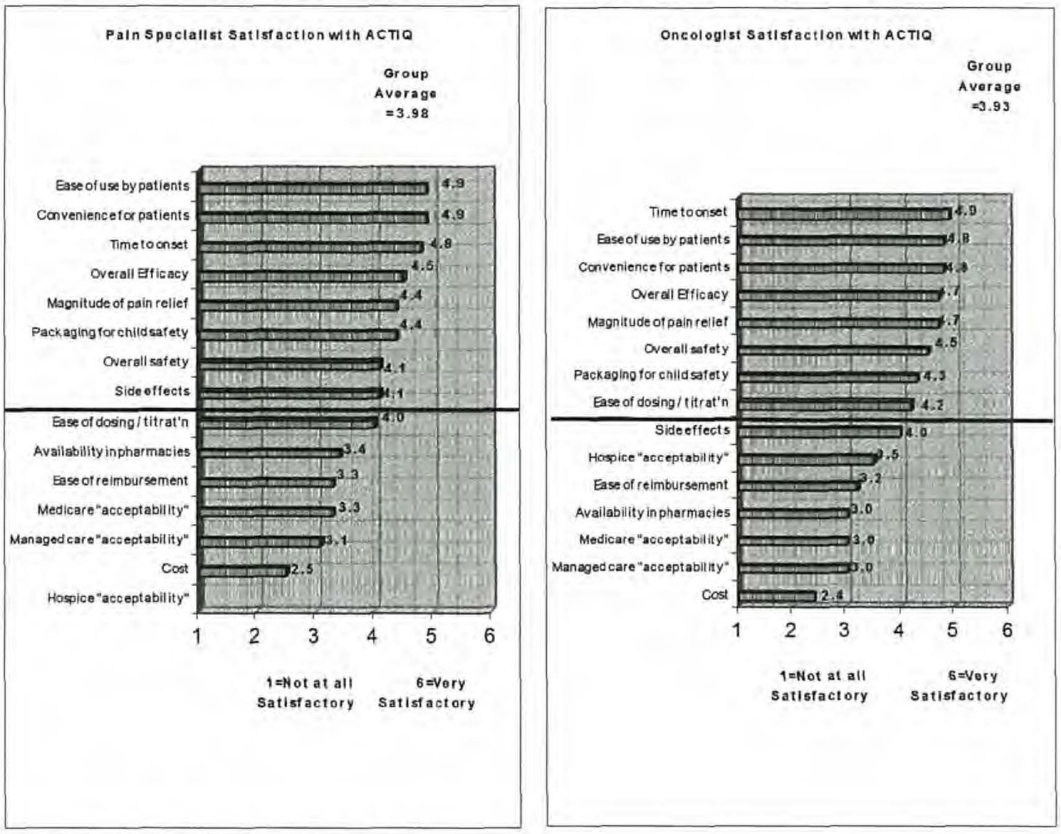
[2] "Unaided" awareness was assessed by asking physicians "Have you heard of any newer rapid-acting oral opioids under development or launched within the past two years?"

[3] "Aided' awareness was assessed by asking physicians "Have you heard of ACTIQ which is the brand name for oral transmucosal fentanyl?"

Product Perception

We evaluated the perception of ACTIQ's benefits by evaluating satisfaction levels with characteristics that drive the prescribing decision. On average, across all features, both APMs and oncologists indicated high satisfaction ratings. The highest satisfaction levels were reported for ACTIQ's speed and magnitude of pain relief, and it's ease of use and convenience for patients. The characteristics garnering the least satisfaction were cost and reimbursement issues. Marketing must continue to differentiate ACTIQ from other short-acting opioids based on its advantages; its ability to provide personal pain control through rapid onset of analgesia and ease of use/convenience. See below for specific "satisfaction" ratings.

Physician Satisfaction of ACTIQ Product Characteristics



Source: May 2001 Baseline Tracking Study

Other significant results relevant to product perception include:

- APMs noted ACTIQ's restrictive labeling ("only" for BTCP) as a moderate barrier to use
- APMs were notably more concerned with ACTIQ's abuse potential

F. REIMBURSEMENT UPDATE

ACTIQ continues to operate under the radar screen of most managed care organizations and the 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 managed care organizations 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 and a lack of clinical data and peer reviewed publications that do the following:

- Support ACTIQ's efficacy and safety beyond the cancer patient population
- Illustrate ACTIQ's cost effectiveness to the health care system by preventing emergency room and hospital admissions for uncontrolled pain.

Although not observed too 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

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

Reimbursement Hotline Activity

Total number of cases handled and resolved (not pending)	22
Cases successfully resolved	73%
Appeal rate for previously denied claims	31% (5 cases pending appeal: 2 BTCP, 1 each sickle cell, diabetic neuropathy, spinal stenosis)
Percentage of covered claims with non-BTCP diagnosis	50%
Most common non-BTCP diagnoses covered	some form back pain, sickle cell anemia
Percentage of plans covering ACTIQ requiring prior-authorization	25% (50% non-BTCP diagnosis)
Percentage of plans covering ACTIQ utilizing tiered co-pays	0%
Percentage of plans covering ACTIQ utilizing step therapy	0% (1 case pending)

Trends:

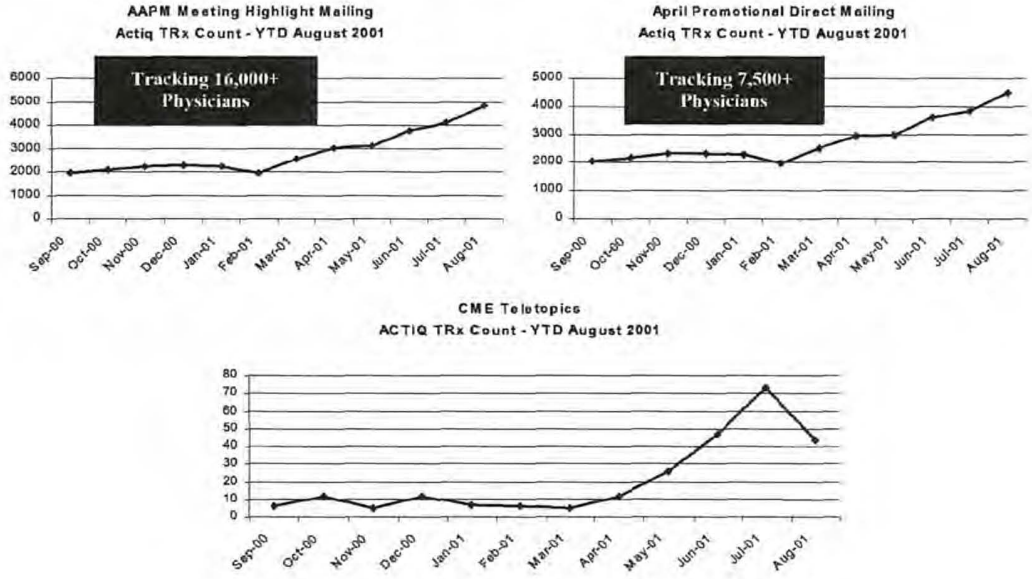
- **Increasing number of non-opioid tolerant patients using ACTIQ for episodic pain diagnoses (i.e., sickle cell)**
- **Medicaid and some MCOs are covering for both BTCP and non-BTCP diagnoses, but are requiring prior-authorizations more frequently. Previously covered patients are being forced to pre-authorize for continued coverage.**

As the use of ACTIQ continues to expand beyond BTCP, the likelihood of the product appearing on MCO radar screens increases. Although there are few barriers currently in place, physicians continue to perceive reimbursement as a major concern. In fact, the baseline tracking study conducted in May 2001 illustrates 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, the high acquisition cost, and the perceived reimbursement difficulty could hinder ACTIQ's growth in 2002.

G. MEDICAL EDUCATION AND PROMOTION RESPONSE

Multiple medical education and promotion initiatives were implemented in 2001. Two consultant meetings were held in June in San Diego. Over 330 sales driven medical education programs have been held YTD through August 2001. Lastly, multiple CME programs were implemented, including a CME website, teleconferences, newsletters, direct mailings, and symposia.

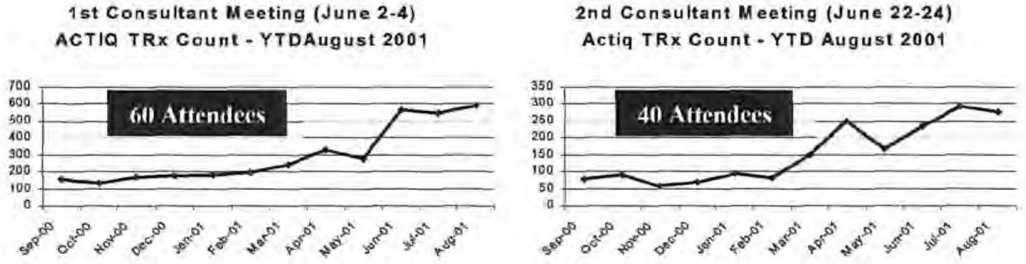
Many of these initiatives were executed and tracking mechanisms have been implemented to evaluate effectiveness. Early promotion response assessments indicate these programs are working to increase prescriptions. All programs will be monitored throughout the remainder of 2001. The most effective education mechanisms to broaden reach and drive prescriptions will be utilized in the final selection of tactics in 2002.



Source: NDC Source Prescriber

Although over 750 clinicians (physicians, nurses and pharmacists) have participated in the CME teletopics programs YTD September, only 18 physicians have requested CME credits and are possible to track. The CME teletopics program has been proven to be fairly effective in driving prescriptions (see graph above); however, implementation and successful recruitment of physicians proved somewhat difficult. The content of the teletopics program has been proven to be effective and will be applied to more effective implementation mechanisms. Future CME programs will not be implemented in this format.

While the AAPM meeting highlight summary mailing was sent to approximately 18,000 total physicians, both the AAPM mailing and the April promotional direct mailing efforts were distributed to the roughly 7,900 ACTIQ targets. Therefore, the two prescription tracking graphs appear very similar. The AAPM mailing was intended to raise awareness of ACTIQ and it's potential uses outside of BTCP among key, targeted high opioid prescribing physicians. The April direct mailing was intended to reaffirm physicians' confidence in ACTIQ, to introduce Cephalon as a player in the pain market, and to aid in ACTIQ prescriber retention. The increase in TRx seen among these targeted physicians is most likely a combination of many factors including these two direct mailing efforts as well as an enhanced, targeted direct selling presence.



Source: NDC Source Prescriber

Both consultant meetings proved incredibly effective in driving prescription growth among the 100 total attendees. Physicians attending the first consultant meeting (June 2-4) increased monthly prescriptions 108% from May (283 TRx) to August 2001 (590 TRx), while physicians attending the second meeting (June 22-24) increased 65% over this same period (168 TRx to 278 TRx). These meetings also proved effective in identifying and training ACTIQ speakers. Fifty-three additional speakers were added to the ACTIQ speaker bureau as approved speakers as a result of these meetings. It is interesting to note the growth in prescriptions from many attendees immediately *prior* to the meetings. Most likely, these physicians increased their use and experience with the product in anticipation of the potential of becoming an ACTIQ speaker.

Advertising Campaign

The ACTIQ advertising campaign was launched in June 2001. This campaign will be evaluated in December 2001, six months post launch, to evaluate key attributes of the campaign such as, message conveyance, uniqueness, believability, and prescribing impact. The 2001 journal advertisement is included in the appendix.

H. MARKET DYNAMICS

Opioid Market
The prescription opioid market can be divided into two major categories of medications:

- Short-acting opioids
- Long-acting opioids

Short-Acting Opioids
The short-acting opioid market can be subdivided into two distinct categories:

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

Currently, short-acting opioids (pure 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 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. In fact, this is untrue; the onset of analgesia of short acting agents (30-60 minutes) is very similar to oral long-acting opioid products. They do not offer any clear advantage over oral long-acting agents with respect to onset of analgesia. Furthermore, the term "immediate release" refers to the fact that these products do not have a controlled release of medication 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 (and should be) prescribed for patients that are considered opioid tolerant. These patients suffer from chronic, persistent pain which 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. Obviously, 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 obsolete. 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) and the WHO will be publishing new pain management guidelines in 2002. These new guidelines will incorporate the concept of BTP and will encourage pure opioid therapy at a much earlier point in treatment than the WHO ladder currently recommends. This is a much more aggressive approach to managing pain. Pain assessment, continuous re-evaluation of therapy, and a multi-disciplinary approach will also be key components of these new guidelines. Overall, the APS's new guidelines will be 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 episodic pain.

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 have the opportunity to position ACTIQ as an ideal treatment in the management of BTP.

I. COMPETITION

Competitive Companies

The major companies in the pain market place are few. They include Purdue Frederick, Janssen, Abbott Laboratories (acquisition of Knoll) and Roxane, with Purdue Frederick 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). These long-acting products have indications for "moderate to severe" pain and are positioned for both malignant and non-malignant chronic pain. 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.

Many of these long-acting, sustained release products have complementary short-acting, immediate release or concentrated solution products that have been traditionally promoted for acute and episodic pain. Although their use is indicated for moderate to severe pain only, these short-acting products are being promoted for the treatment of breakthrough pain as well. 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.

ACTIQ's Competitors: Direct and Indirect

ACTIQ's direct competitors are the short-acting pure opioids. Opioid combination products, although sometimes erroneously prescribed for the treatment of BTP, are not legitimate direct competitors of ACTIQ for the following reasons:

- Limited dosing flexibility due to low opioid dosage options
- 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.

ACTIQ's clear differentiating factor is its rapid onset of analgesia. The use of oral short-acting pure opioids or combination products for the treatment of BTP is less than ideal due to a lack of rapidity of analgesic effect. Additionally, due to ACTIQ's rapid onset, it has a clear and distinct advantage over other products in the treatment of episodic or recurrent pain (e.g., sickle cell crisis, migraine headaches). This type of pain represents a substantial market opportunity.

Long-acting opioids are not considered a direct competitor in the BTP market; however, they may be viewed as an indirect competitor for ACTIQ. Purdue Frederick has aggressively educated pain 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 physicians currently adhere to this philosophy, thus creating OxyContin into a "pseudo competitor." Re-educating misled physicians will be a challenge.

Future Competition

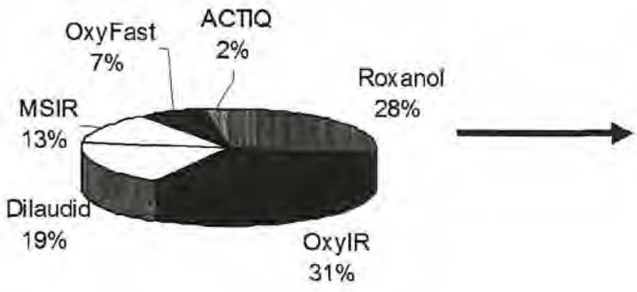
CIMA, a Minneapolis based manufacturer of prescription and OTC medications in a proprietary, fast-dissolve drug delivery system, is evaluating a new BTP medication called OraVescent. OraVescent is a buccal tablet containing fentanyl that allows for improved bioavailability and accelerated onset of action through absorption-enhancing ingredients. CIMA is presently in Phase II clinical trials of OraVescent; the targeted approval date is unknown.

A thorough evaluation of new BTP medications currently in development must occur in 2002.

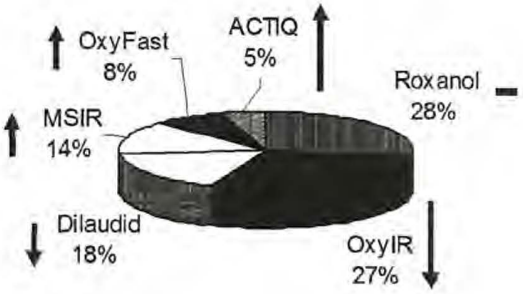
Market Share

Evaluation of the pure short-acting opioid prescription market since the February 2001 relaunch of ACTIQ shows that ACTIQ has increased its market share greater than any other product in its class. ACTIQ increased its market share 3% from the six-month time period September2000-February 2000 to March 2001-August 2001. This increase in market share can be primarily attributed to the successful repositioning of ACTIQ and improved physician targeting. The number of anesthesiologists/pain specialists, our most productive prescriber base segment, prescribing ACTIQ is growing significantly and steadily.

ACTIQ TRx Market Share
September 2000 - February 2001



ACTIQ TRx Market Share
March 2001 - August 2001



III. COMMERCIAL INFRASTRUCTURE UPDATE

A. SALES AND MARKETING

While the size of the commercial infrastructure that supports ACTIQ remained static from 2000 to 2001, Cephalon significantly upgraded the quality of personnel in the Pain Care sales and marketing organization.

In May 2000, Anesta Corp. reacquired the promotional rights of ACTIQ and relaunched it with the contract sales organization Innovex. At that time, Anesta more than doubled the sales force from 20 representatives to 48 representatives, but the overall quality of sales personnel was poor. In February 2001, a higher quality, newly hired Cephalon Pain Care Specialty sales force was fully trained and relaunched ACTIQ. Cephalon, in effect, achieved an expanded promotional reach through its higher quality sales organization. In addition, this was complemented by revised marketing direction and new target audience definition. These changes have been key factors behind the product performance to date.

B. MEDICAL LIAISONS

The Medical Liaisons 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 2001. 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 2002 and beyond.

IV. SWOT ANALYSIS AND KEY MARKETING ISSUES

A. ACTIQ SWOT ANALYSIS

STRENGTHS	WEAKNESSES
• Rapid onset of analgesia providing relief on demand • Well known opioid with proven efficacy and safety profile – fentanyl • Solid clinical database within cancer patient population • Large base of published product literature within cancer • Anecdotal positive impact on Quality of Life • Core product characteristics appropriate for treatment of BTP in chronic benign pain and episodic pain (sickle cell, migraines)	• Narrow indication • Limited promotional flexibility due to Subpart-H approval (Risk Management Plan and 30 day mandatory FDA review) • Lack of data and publications outside of cancer patient population • Cannot make the claim "rapid onset" despite being the most rapid acting "oral" agent and trials proving onset in 15 minutes • Lack of clinical data showing onset < 15 minutes • High acquisition cost – value proposition not well understood • Perceived cumbersome titration process • No equianalgesic dosing • Opioid tolerant requirement limits drug selection in other pain diagnoses • Perceived safety concerns
OPPORTUNITIES	**THREATS**
• Strong, supportive base of core prescribers • Physician eagerness to evaluate drug outside indication BTCP • Increased focus on pain management from JCAHO • Expansion of sales force to increase promotional reach • Initiation of case series • Poster presentations at national meetings and developing publications	• Continued Subpart H classification and RMP restrictions/obligations • Limited availability in retail pharmacies • Increased counter-detailing from competitors as ACTIQ gains market share • OxyContin abuse issue may bring further scrutiny to opioid market • Competitors continuing to make claims for BTP without having done any trials • Increased reimbursement difficulties • Slow start in 2001 with clinical trials and case series • Accidental ingestion of ACTIQ resulting in serious injury/death of a child or opioid naïve person • Dental caries issue becomes larger

ACTIQ's primary differentiating feature, rapid onset of analgesia, distinguishes it from every other currently available, oral short-acting opioid. It is this differentiating factor, and the benefits of rapid onset of analgesia (i.e., personal pain control, improved functionality and Quality of Life, decreased ER and hospital admissions, etc.) that must be maximized and highlighted through clinical studies, case series, promotional efforts and medical education programs in 2002. By illustrating the true onset of analgesia and proving ACTIQ safe and effective in the treatment of other pain diagnoses, including both opioid tolerant and opioid naïve patients, ACTIQ will be poised for tremendous growth in 2002 in both the BTP and episodic pain segments of the opioid market.

ACTIQ's narrow indication and subpart-H approval status are the greatest hindrances to continued growth. ACTIQ's subpart-H classification and the accompanying Risk Management Plan (RMP) limit our promotional flexibility as well as increase our expenditures in medical education. Efforts must be made in 2002 to decrease/eliminate ACTIQ's subpart-H classification and the restrictions and obligations imposed by the RMP.

B. KEY MARKETING ISSUES

There are five key issues that need to be addressed for ACTIQ in 2002:

- **Low product awareness among key targeted physician specialties**

Unaided awareness of ACTIQ (18%) is exceptionally low. In order to maintain the same type of growth seen in 2001, Cephalon must make the most potentially productive prescribers, anesthesiologists and pain specialists, aware of ACTIQ and it's potential benefits to their BTP and episodic pain patient populations. Because brand awareness has been negatively affected by poor concepting and messaging in the past, it will be necessary to evaluate awareness as it relates to the key benefits of the product.

- **Lack of knowledge in the assessment and treatment of BTP and episodic pain among key targeted physician specialties**

Many anesthesiologists and pain specialists believe that they are satisfactorily assessing and treating BTP. These under-informed physicians must be educated to understand the typical characteristics of BTP and made aware that ACTIQ's key differentiating feature (rapid onset of analgesia) will greatly benefit these patients. Also, physicians treating patients suffering from episodic pain episodes must also be made aware of the benefits of ACTIQ. There is a large, unmet need for rapid treatment of recurrent pain associated with such disease states as migraine headaches and sickle cell disease.

- **Limited clinical data and publications outside of the cancer patient population**

ACTIQ's narrow indication is it's most significant promotional limiting factor. There is tremendous opportunity for ACTIQ in the treatment of BTP in opioid tolerant patients in a variety of pain diagnoses (not only BTCP) as well as episodic pain in other disease states. In order to continue ACTIQ's growth, ACTIQ's safety, efficacy and true onset of analgesic effect must be demonstrated in other large segments of the pain market (e.g., chronic back pain, RSD).

- **Low product and disease state awareness among pain patients**

Most pain patients, regardless of disease state, are not aware of the term "breakthrough pain." Additionally, many patients have difficulty discussing their pain with their physician for a variety of reasons; ignorance of BTP, inability to describe their pain adequately, and fear of appearing weak or drug seeking are leading reasons. Cephalon must attempt to increase awareness of BTP and empower patients to speak openly with their physicians about their pain.

- **Limited direct promotional reach**

With 48 sales representatives, the current direct promotional reach for ACTIQ is limited. ACTIQ marketing must complement the efforts of these 48 representatives but must also focus

on expanding our promotional reach and share of voice significantly beyond these 48 representatives. To date, no sales force expansion is planned.

C. ACTIQ DEVELOPMENT NEEDS

ACTIQ's Differentiating Feature
ACTIQ's clear differentiating feature is its rapid onset of analgesia. Currently available oral short-acting pure opioids and combination products are not optimal for the treatment of breakthrough pain (BTP) and episodic pain (e.g., sickle cell crisis, migraine headaches) due to their lack of rapidity of analgesic effect.

ACTIQ's Limiting Factor
ACTIQ's greatest limiting factor is its limited, narrow 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 short-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 both BTP and episodic pain. These types of pain represent a substantial market opportunity. The total market for pure short acting opioids and combination products has been $753 MM in 1999 and $872 MM in 2000 and is $568 MM YTD through July 2001.

Big Questions that Must be Answered Immediately
To maximize ACTIQ's potential, Cephalon must first answer the following questions.

- What are our options for extending the patent life for ACTIQ beyond 2005?
    - Would a sugar-free formulation extend the patent? Is getting a sugar-free formulation approved a possibility given the limited amount of time prior to patent expiration?
- What can be done to expand the label beyond BTCP?
    - If patent extension is not viable, a label change that would expand the indication may invite generic competition.
- What can be done to alter the label to remove the contraindication in acute or post-op pain?
    - If the FDA will not budge on this aspect because they believe that ACTIQ delivers drug to quickly to the CNS and therefore must have this contraindication, then we must push back and request the ability to make the claim of "rapid onset of analgesia." The FDA's current stance on this issue can be summarized as follows: ACTIQ requires warnings because it may be unsafe in certain patient populations because it acts quickly, however, it is not permissible to make a positive claim about ACTIQ that states it acts quickly.

Other Challenges

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

- Research in non-malignant pain populations – How can this be accomplished in targeted disease areas?
- Subpart-H status – What must be done to remove this status and the accompanying obligations/restrictions?
- Risk Management Plan (RMP) – Its restrictions/obligations greatly limit promotional flexibility (i.e., 30 day FDA review of all promotional items).
- Inability to make claim "rapid onset of analgesia" – What must be done to make this claim?

A separate product issue that also should be addressed is the increased incidence of dental caries being reported. As this problem persists and continues to grow as we see ACTIQ prescribed for more and more chronic non-malignant, non-terminal pain patients, it could negatively influence prescribing habits of physicians. Oral hygiene warnings have been added to all new promotional materials. Is a sugar-free lozenge an option?

Recommendations:

Minimal Needs to Continue to Grow Business

ACTIQ will most likely triple sales from 2000 to 2001. To continue this growth in 2002, *minimal* needs must be met, including:

- **Case Series** development in non-cancer pain models such as chronic back pain, RSD, sickle cell disease, migraine headaches, etc.
- **Exploratory studies** in other, high incidence pain models followed by strong publications and medical education efforts.
  - Studies to demonstrate the efficacy in BTP (non-CA) and episodic pain.
  - Studies to demonstrate safety in opioid naïve and post-op patients.

Case series and open-label exploratory studies will be critical as we continue to grow our prescriber base beyond oncology. Currently, we offer no data for ACTIQ use outside cancer. If we do not generate clinical data in other areas we will be forced to continue to rely on physicians making the jump from cancer on their own. Some aggressive pain specialists have already made this leap but many of them will require additional clinical support. Simple case studies and open-label exploratory studies are not the strongest means of clinical support, but they may be all that we need to keep sales growing at the current pace.

- Studies to clearly demonstrate the true time to onset in order to make claims of "rapid onset" and change labeling to more accurately reflect this feature.
- Reduce obligations and requirements of RMP to enhance promotional flexibility.
- Consider new sugar-free formulation.

Brief Outline of Next Steps

- Internal Cephalon meeting to decide:
  - Is it possible to extend the patent? Do we wish to extend the patent?
    - If **"no"** to either question – What type of research can we do within the constraints of a subpart-H drug to continue to grow the business? Phase IV? Research filed under an IND? Case series only?
    - If **"yes"** to both questions – What are the next steps?
  - Meet with FDA and outline what change in label and claims we would like along with protocols for research required for such changes/claims.
  - Allocate adequate funds and personnel to generate minimal clinical support for ACTIQ in 2002.

With minimal clinical data and adequate sales support, ACTIQ could be positioned to expand its share of the potential $1 billion short-acting pure opioid, combination product market in 2002. Additionally, a more liberal indication might allow for tremendous growth.

V. PRODUCT VISION AND POSITIONING

A. ACTIQ VISION

The following statements summarize the short, medium and long-term commercial direction for ACTIQ:

Short-Term Vision:	Establish ACTIQ as a valid, first-line option for the treatment of BTP.
Medium-Term Vision:	Establish ACTIQ as a revolutionary, highly beneficial and valid option for the treatment episodic pain as well as BTP.
Long-Term Vision:	Establish ACTIQ as the ideal, first-line option for the treatment of BTP and episodic pain.

Despite the marked increase in total prescriptions and sales in 2001, ACTIQ must still be established as a valid treatment option for BTP in 2002 in the minds of most anesthesiologists and pain specialists. To accomplish the medium and long-term visions for ACTIQ, a number of things may need to occur in the future, including, but not limited to, the following:

- Development of clinical data and publications outside of the cancer patient population
- Expansion of labeling and ability to make claims about rapidity of onset
- Removal/relaxation of current subpart-H classification and RMP requirements
- Expanded and highly effective promotional and medical education efforts

B. ACTIQ POSITIONING

Current physician use of ACTIQ suggests that ACTIQ has great potential beyond the treatment of BTCP. The key differentiating features/benefits that contribute to ACTIQ's potential outside of the current narrow indication are as follows:

- ACTIQ has a novel delivery system that allows for rapid absorption of fentanyl
- ACTIQ provides the most rapid onset of analgesia of any currently available, non-invasive opioid product (e.g., oral formulation, sublingual formulation)
- ACTIQ provides relief on demand and personal pain control and thus improves patient functionality and Quality of Life

Positioning Statement
The 2002 positioning statement for ACTIQ reflects these key, differentiating factors:

ACTIQ is a medication in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available and affords patients personal pain control for BTP or episodic pain.

Patient Profile

Any opioid tolerant patient suffering from BTP, regardless of disease state, is a potential candidate for ACTIQ. Additionally, any patients suffering from moderate to severe episodic pain due to migraine headaches, sickle cell pain crises, etc. are potential candidates for ACTIQ. Lastly, ACTIQ may also be appropriate as a pre-procedural pain medication for any opioid naïve or opioid tolerant patient about to undergo radiation therapy, wound dressing changes, physical therapy, etc. in a monitored setting.

VI. MARKETING AND PROMOTIONAL STRATEGY

A. MARKETING GOALS AND OBJECTIVES

Marketing Goals
Specifically, the 2002 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 patient populations
- Expand the clinical data and publications of ACTIQ beyond BTCP

Marketing Objectives
Factory sales and prescription volume objectives for 2002 are as follows:

2002	TRx	Factory Sales
Q1	24,850	$ 18,717,157
Q2	26,371	$ 21,253,192
Q3	27,986	$ 22,554,057
Q4	29,699	$ 23,934,546
TOTAL	108,906	$ 86,458,952

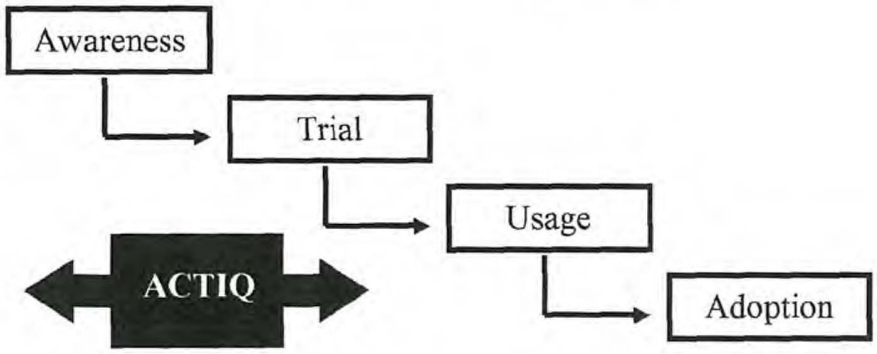
The monthly sales and prescription budgets are attached as an appendix.

B. MARKETING STRATEGY

Overall Promotional Strategy
To increase market share and achieve the aforementioned sales and prescription objectives, the marketing strategy for ACTIQ will be to differentiate the product from its competitors by utilizing the primary product strengths: rapid onset of an analgesia and personal pain control.

When looking at the continuum of the product adoption curve, ACTIQ currently falls between awareness and trial. The overall promotional strategy in 2002 will be to move more physicians, and thus ACTIQ, to trial and usage. To meet the 2002 sales and prescription objectives, ACTIQ must move in this direction.

ACTIQ in the Product Adoption Curve



Because it does not require an exorbitant number of prescribers to make a tremendous impact in prescriptions and sales with ACTIQ, one of the keys to success in 2001 was a much more focused targeting effort. At the territory level, the Pain Care Specialists focused on a smaller "core" group of physicians to build their territories from the inside-out. This is a different approach than what is traditionally used in big-pharma, but this strategy is essential to the success of ACTIQ. At a national level, this same type of approach has been utilized in 2001 and will again be utilized in 2002. The highest potential prescribing physicians in specialties that have been fastest to adopt ACTIQ in their treatment of BTP and episodic pain (anesthesiologists/pain specialists) will be the key targets in 2002. Additionally, we will evaluate the potential of high decile Duragesic prescribers more thoroughly and may target these physicians more aggressively.

The 2002 ACTIQ promotional strategy will be similar to the 2001 strategy. Each promotional effort will be focused on addressing the five key marketing issues and achieving one or more of the four key strategic objectives. Each promotional effort will be incorporated into the overall strategic framework to maximize promotional efficiency. Lastly, the current branding elements of the 2001 campaign such as the "bell" and the "mountain graphs" will continue to be used in a variety of branded and non-branded promotional efforts.

Promotional Strategy by Key Marketing Issue

Issue: **Low product awareness among key targeted physician specialties**
Strategy: **Strengthen the association of ACTIQ and its key benefits of rapid onset of analgesia and personal pain control through improved awareness**

Conveying ACTIQ's key, differentiating benefits to physicians through the brand concept and messaging will be critical to raising "awareness." 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. Because brand awareness has been negatively affected by poor concepting in the past, it will be necessary to evaluate awareness as it relates to the key benefit of the product. Testing will be done to see if the "bell" concept has been effective in raising physician awareness. Additional testing will be done to see if "OT-PCA" (Oral Transmucosal Patient Controlled Analgesia) effectively links ACTIQ's key benefits with the product in the minds of physicians. In order to maintain the same type of growth seen in 2001, Cephalon must improve awareness of ACTIQ and strengthen its association with its differentiating benefits.

Issue: **Lack of knowledge in the assessment and treatment of BTP and episodic pain among key targeted physician specialties**
Strategy: **Educate key targeted physician specialties about the benefits of treating breakthrough and episodic pain with ACTIQ**

Marketing will educate physicians through a variety of educational efforts. Because promotional flexibility is limited and the claim of "rapid onset of analgesia" cannot be stated, an emphasis will be placed on Continuing Medical Education as a primary means to educate physicians.

CME programs will be complemented by other peer-to-peer promotional efforts, as these types of programs have proven very effective.

Issue: **Limited clinical data and publications outside of the cancer patient population**
Strategy: **Marketing and Medical Affairs will develop a Phase IV / Case Series / Publication plan for 2002**

ACTIQ's narrow indication is it's 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 (not only BTCP) as well as episodic pain in other disease states. 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 large segments of the pain market (e.g., chronic back pain, RSD, fibromyalgia, migraine headaches, sickle cell disease).

Minimum Requirements:

- Phase IV study to evaluate true time to onset of analgesic effect in a clinical setting in opioid tolerant cancer patients and/or in a controlled laboratory environment. Previous studies have evaluated pain relief no sooner than 15 minutes thus limiting our ability to make claims.
- Exploratory phase IV studies and/or case series for the following non-malignant pain states:
  - Chronic back pain
  - Reflex sympathetic Dystrophy (RSD) or Complex regional pain syndrome (CRPS)
  - Rheumatoid and/or osteoarthritis arthritis
  - Fibromyalgia
  - Sickle cell disease
  - Migraine headaches
  - Incident related BTP (including any/all disease types)

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**

Because most pain patients are not aware of the term "breakthrough pain," the public relations and marketing strategy will focus on increasing awareness. Additionally, public relations and marketing will attempt to increase the awareness of ACTIQ among pain patients. Promotional efforts will be coordinated with targeted patient support and professional organizations.

Issue: **Limited direct promotional reach (48 PCSs)**
Strategy: **Direct the most effective promotional efforts to the highest potential targeted physicians**

As this issue is common to all three currently marketed Cephalon products, the promotional strategy applied to address this issue with ACTIQ will be similar to the strategy utilized by the

other product teams. 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 48 Pain Care Specialists and expand our reach to the vast number of potential prescribers that the PCSs cannot directly influence.

VII. TACTICAL PLAN

A. ACTIQ KEY MESSAGES

The promotional messages for ACTIQ in 2002 will remain consistent with the core messages already developed. These messages will be applied similarly to both of the targeted segments of the pain market, BTP and episodic pain.

ACTIQ will be positioned as valid, first-line treatment option for BTP and episodic pain through the communication of the following key product messages:

Key Messages
• ACTIQ provides rapid onset of analgesia
• ACTIQ has a unique, revolutionary drug delivery system
• ACTIQ is safe and highly effective
• ACTIQ is easy and convenient to use
• ACTIQ provides personal pain control and improves functionality and Quality of Life
• ACTIQ is most effective when titration is initiated at the 400mcg strength
• ACTIQ is the only product specifically studied and indicated for BTCP

The most significant change in the positioning of ACTIQ in 2002 is the incorporation of "episodic pain" as a segment of the targeted pain market. ACTIQ will be positioned to greatly expand use in both the BTP and the episodic pain segments of the pain market by applying the key messages listed above.

B. TARGET AUDIENCE

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

- Pain specialists
- Oncologists

The primary target for ACTIQ in 2002 will be pain specialists. 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; a high decile prescriber of Duragesic, another product utilizing fentanyl and a unique delivery system, may be an excellent ACTIQ target.

The pain specialist segment can be further subdivided into two segments based on the type of pain a physician specializes in treating:

- Focused pain specialist
- General pain specialist

A "focused" pain specialist specializes in the treatment of pain associated with a single disease process (i.e., hematologist specializing in sickle cell pain, neurologists specializing in migraine

headaches or RSD). A "general" pain specialist treats a vast array of pain-related disease states. Although both subdivisions of the pain specialist segment can be promoted to similarly, those that specialize in treating episodic pain may require different proof sources and promotional efforts (i.e., CME programs, peer-to-peer education, publications) since data is lacking.

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. They are much more focused on delaying disease progression than pain and symptom management. Therefore, as in 2001, 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 part of the pain specialist segment by virtue of their opioid prescribing history.

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 almost identical similar and will include the key marketing messages previously listed.

C. CORE TACTICAL PLAN

Overall Tactical Approach

The 2002 ACTIQ tactical plan will incorporate the seven key promotional messages listed previously that directly support the overall ACTIQ promotional strategy. The goal will be to distribute the total promotion budget appropriately and effectively across all tactical initiatives. The majority of resources will be allocated to tactics that are considered *most* effective in delivering these key messages to our target audience. 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). Additionally, the use of physician advisory boards will also be implemented in 2002 to help establish more focused product positioning and messaging, to establish the most effective tactical approaches, programs and formats, and to assist in the development of a clinical research plan.

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**

Forty-eight PCS representatives (plus 10 MLs) will be detailing ACTIQ to a core group of targeted physicians within their territories. Marketing will develop additional promotional pieces to support the sales force's efforts in delivering the key ACTIQ messages. Most branded pieces will continue to utilize the "bell" concept. Promotional support pieces planned for 2002 are included in the appendix.

Marketing will make available sufficient coupons for new trial generation of ACTIQ in 2002. Each Pain Care Specialist will receive 120 coupons per month. These coupons will only be distributed through the sales force.

- **Medical Education Programs (MEPs)**

As stated previously, peer-to-peer educational programs have proven to be incredibly effective in promoting ACTIQ. Marketing will provide ample resources to allow for an adequate number of sales-driven MEPs in 2002.

- **Consultant Meetings**

Marketing will plan a minimum of two ACTIQ consultant meetings for 2002. The goal will be to hold the first meeting in the January-February timeframe and the second in June. Based on the success of the two 2001 ACTIQ consultant meetings, a third meeting may be planned if financially possible.

- **Convention Presence**

Marketing plans to attend a minimum of six national level conventions in 2002. With the creation of new, branded booth panels ACTIQ's presence at these meetings in 2002 should be much more noticeable than in 2001. Additionally, marketing will consider the use of enticements and booth convention kiosks to drive clinicians to the ACTIQ booth for detailing purposes, but also to collect valuable market research information. Cost will be the primary consideration. The complete ACTIQ 2002 convention schedule is detailed in the Appendix.

In 2002 marketing will also ask the Pain Care Area Managers to take responsibility for deciding when to attend other, smaller national conventions and regional medical symposia throughout the year. Allowing the Pain Care Area Managers to make these decisions should encourage them to "take ownership" of the smaller national and regional meetings held in their respective areas. Marketing will continue to support the planning and logistics associated with these meetings when necessary. Additional funds will be provided to each of the Pain Care Area Managers in 2002.

Marketing Promotional Tactics

- **Direct Mail**

Direct mailing efforts in 2002 will be specifically designed to focus on accomplishing one of the following objectives:

- Raise awareness of ACTIQ among targeted high opioid prescribers
- Raise awareness of ACTIQ among top decile Duragesic prescribers
- Improve retention rates among existing ACTIQ prescribers
- Notification to existing prescribers of the pending change in formulation and packaging for ACTIQ

Marketing will also utilize direct mailings in 2002 as they were employed in 2001, which allows them to be utilized in a direct promotional manner. With each direct mailing effort focused on high opioid prescribing potential targets (many of whom are direct selling targets) and/or existing ACTIQ prescribers, a copy of the direct mail piece will also be forwarded to each PCS representative. The representatives will also receive a copy of the physician mailing list. A representative can utilize the direct mailing piece to gain access to difficult to see targets or to reinforce key selling messages with a physician that received the mailing

- **CME Programs**

Peer-to-peer educational programs such as CME programs can be tremendously effective. Marketing will employ numerous CME programs, many of which will be ongoing programs initiated in 2001 (i.e., website and trimesterly newsletter); substantial resources will be applied to these types of programs. The primary reason CME programs will be largely employed in 2002 is due to the limited promotional flexibility and ability to make claims that accompany ACTIQ's subpart-H classification. CME programs allow us to utilize peer-to-peer medical education to raise awareness of the proper assessment and treatment of BTP and episodic pain and to convey ACTIQ's key selling messages. CME programs planned for 2002 include:

  - Trimesterly Newsletter
  - Regional Symposia
  - Teleconferences

- Website
- Adaptation of all previous CME programs to on-line self-study

Some program formats that proved to be less effective than hoped in 2001, such as the teletopics program, will not be utilized in the future. The content from this specific program was, however, excellent and will be repackaged into more effective formats in other enduring CE programs.

- **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 episodic pain in other disease states. Marketing will work with Medical Affairs and Publications to develop phase IV, case series, and publication plans for 2002. Case series in 2002 should target several of the largest potential segments of the pain market: BTP in non-malignant chronic pain (i.e., spinal stenosis, chronic back pain, reflex sympathetic dystrophy, fibromyalgia, etc.) as well as episodic pain (migraine headaches, sickle cell pain, etc.). The phase IV plan should include, at a minimum, an evaluation of ACTIQ's "true" onset of analgesia (i.e., pain relief evaluations at 3, 5, 7, 10, and 15 minutes) in opioid tolerant cancer patients in a clinical setting and/or an evaluation in a controlled laboratory setting.

- **Advisory Boards**

Two advisory boards will be assembled in 2002, a Key Opinion Leader Advisory Board and a Marketing Advisory Board. The objective of the first advisory board will be to determine future direction for potential uses, studies, etc. of ACTIQ from key opinion leaders in the pain community. The objective of the second advisory panel will be to obtain strategic marketing direction (i.e., key messaging, positioning, evaluation of promotional and CME ideas, etc.) from current ACTIQ prescribers. Individual meetings with additional key opinion leaders and ACTIQ prescribers will occur throughout 2002 to assist in these and other areas.

Indirect Promotional Tactics

- **Journal Advertisements**

The current 2001 journal ad campaign will be evaluated in December 2001. If the current campaign tests successfully, the present plan sill be to continue use if this advertisement in 2002. Additional concept and message testing in 2002 may allow for enhancement of the current campaign, or the creation of a new campaign if deemed necessary. The complete ACTIQ media plan is detailed in the Appendix.

Journal Advertising Distribution

Pain	Journal of Pain Journal of Pain and Symptom Management Pain Medicine
Anesthesiology	Anesthesiology News Anesthesiology Anesthesia & Analgesia American Journal of Anesthesiology
Oncology	Journal of Clinical Oncology Oncology Oncology News International

- **Internet Promotional Activity**

Marketing will employ three primary internet sources of information for BTP and/or ACTIQ in 2002. These three sources will include:

  - *ACTIQ.com* – product specific information
    - Newly redesigned and completed in November 2001
  - *Cephalonspeaker.com* – product specific information
    - ACTIQ included in May 2001
  - *EmergingSolutionsinPain.com* – CME programs providing information on BTP, episodic pain and ACTIQ
    - Launched September 2001

Additionally, two other internet promotional initiatives will be employed in 2002:

  - *Pain.com* – An ACTIQ/BTP CME program will be installed on *pain.com* during 2002. Pain.com is the most widely physician visited pain site on the internet. The planned duration of the program will be six months.
  - *Cancer-Pain.org* – As in 2001, marketing and public relations will continue to support *Cancer-Pain.org*. In 2002, we will be primarily sponsoring the "Ask the Pain Expert" section of the site, which allows patients to interact with leading cancer pain experts.

- **Patient Education Materials and Programs**

Marketing and public relations will work to create and/or update appropriate patient education materials in 2002. The 2002 ACTIQ tactical plan will focus on creating/updating non-branded patient education materials. These materials will be created/updated in coordination with professional and/or patient support organizations and may be applicable across disease states and patient populations. Additionally, the tactical plan will incorporate specific programs, such as teleconference, to increase BTP awareness among targeted patient populations.

D. MARKET RESEARCH PLAN

As the market for ACTIQ continues to evolve in 2002, implementing appropriate market research will be critical in sustaining present and future promotional effectiveness. Maintaining flexibility throughout 2002 will be important; nonetheless, the following market research activities should be implemented:

- Title: Promotional Message Audit
  - Timing: January 2002 (covers Jul-Dec 2001) and August 2002 (covers Jan-June 2002)
  - Vendor: Strategic Business Research (SBR)
  - Target Audience: Oncologists/Anesthesiologist Pain Management Specialists detailed by the Pain Care sales force within the last 3 months (sample size = 50)
  - Primary Objective: To ensure that the Pain Care Specialists are accurately delivering the key safety messages of ACTIQ.
  - Primary Use of the Information: To fulfill section 8.6 of the ACTIQ Risk Management Program.

- Title: Positioning and message testing
  - Results: February 2002
  - Vendor: TBD
  - Type: Qualitative
  - Target Audience: Oncologists and Anesthesiologist Pain Management Specialists (sample size = approx 30)
  - Primary Objective: To test the current and possible alternative positioning statements and messages which communicate ACTIQ's benefits of rapid relief and personal pain control.
  - Primary Use of the Information: To choose the best positioning statement and messages to convey ACTIQ's benefits.

- Title: Convention Research at American Pain Society (APS)
  - Results: March 2002
  - Vendor: Strategic Business Research (SBR)
  - Type: Quantitative
  - Target Audience: Anesthesiologist Pain Management (sample size = approx 100)
  - Primary Objective: To gauge APMs awareness and perceptions of ACTIQ's benefits and to determine other diseases for which they are likely to prescribe ACTIQ. To determine which pain states ACTIQ is used in and which episodic types, now and in the future.
  - Primary Use of the Information: To understand if/how APMs perceive ACTIQ's benefits of rapid relief and personal pain control.

- Title: Tracking study – Wave II
  - Results: November 2002
  - Vendor: National Analysts
  - Type: Quantitative / Qualitative
  - Target Audience: Oncologists and Anesthesiologists/Pain Management Doctors (sample size = 50 + 50 = 100)
  - Primary Objective: To track physician awareness and perceptions of ACTIQ, how they rate the benefits/disadvantages of ACTIQ versus other short-acting opioids, and to help determine other diseases for which they are likely to prescribe ACTIQ. To determine which pain states ACTIQ is used in and which episodic types, now and in the future.
  - Primary Use of the Information: To monitor the effectiveness of the marketing efforts aimed at raising awareness of ACTIQ as an agent that provides rapid relief and personal pain control and at differentiating ACTIQ from competitors.

E. PUBLIC RELATIONS PLAN

The primary goals of the 2002 ACTIQ PR plan are to increase awareness of BTP and ACTIQ among targeted physician and patient populations. The targeted patient populations will be both cancer patients and chronic non-malignant pain patients, as well as patients suffering from episodic pain such as migraine headaches and sickle cell disease. Cancer patients will be the

primary focus for many of the 2002 PR initiatives because the support network for cancer pain is much more established and organized than for other pain disease states. Additionally, although oncologists have proven to be less productive prescribers, they still represent the largest segment of the ACTIQ prescriber base. Cancer organizations afford the most efficient path to raising awareness among patients.

A nursing advisory board will be established in 2002 with key, influential nurses. These nurses will be ACTIQ supporters, involved in setting pain policies, and well respected in the pain community. The purpose 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. The nursing advisory board meeting is tentatively targeted for February 2001.

The core PR strategies for 2002 are as follows:

- Establish 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 and the ability to speak to physicians about pain
- Generate ACTIQ visibility in the cancer and pain media
- Position ACTIQ and BTP effectively and in accordance with overall product positioning to physicians and patients

The following provides an overview of the 2002 ACTIQ PR tactical initiatives:

- Third Party Meetings – Meet with key opinion leaders.
- "Request for Proposal" (RFP) Program – Launch an open call for grants to support institutional education on BTP. Partner with professional organization.
- Patient Education Literature – Update and/or create third party materials with accurate and comprehensive information on BTP and/or ACTIQ.
- CancerCare Teleconferences – Conduct teleconferences on BTP for medical professionals and patients.
- Website Updates – Update patient, third party, health and medical websites to encourage inclusion of BTP and/or ACTIQ.
- Grass Roots" Support Group Strategy – Identify and train pain experts to present to various patient support group meetings.
- Nursing Advisory Board Meeting – Create strategy and criteria for the RFP Program. Develop tools needed for the "Grass Roots" Program (slide kit, video).

G. 2002 TACTICAL BUDGET

The 2002 ACTIQ tactical budget is attached as an appendix.

VIII. APPENDIX

1. Long-Acting Opioids and Short-Acting Pure Opioids
2. 2002 Tactical Plan by Marketing Strategy
3. 2002 Tactical Plan Implementation Timeline
4. 2002 Tactical Budget
5. 1999-2000 ACTIQ Concepts
6. 2001 ACTIQ Concept
7. 2001 Journal Advertisement
8. 2002 Media Plan
9. 2002 Convention Plan
10. 2002 Monthly Sales and Prescription Budget

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

Long-Acting Opioids

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

Short-Acting Pure Opioids

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

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

2. 2002 Tactical Plan by Marketing Strategy

PROMOTIONAL TACTICS	Improve Physician Awareness	Educate Physicians	Develop Clinical Data	Improve Patient Awareness	Expand Promotional Reach
DIRECT					
Medical Education					
Consultant Meetings	x	x			
Sales Driven MEPs	x	x			
Conventions	x	x			x
Sales Literature					
Pharmacokinetic Comparison SA		x			
Patient Profile Flash Cards		x			
Dosing/Titration Pocket Card		x			
Redesigned PCS Coupons	x	x			
Formulary Kit		x			
Non-branded BTP Wall Chart	x	x		x	
Patient Use Tear Sheet	x			x	
Pain Ass. Tear Sheet Holder	x	x		x	
MARKETING					
CME					
Teleconferences	x	x	x		x
Regional/Local Symposia	x	x	x		x
Trimesterly newsletter	x	x	x		x
Website (see below)	x	x	x		x
Direct Mailings					
High Decile Duragesic MDs • Comparative PK Data	x	x			x
Oncology and Pain RNs • 2nd Opinion of Journal Ad • 2nd Opinion – Results	x x	x x			x x
MD Retention • Opinion – ACTIQ Messaging • Opinion – Results	x x	x x			x x
Publications & Advisory Boards					
Case Series/Phase IV Studies			x		
Advisory Boards			x		
INDIRECT					
Journal Advertisements					
Current Journal Ad	x	x			x
New Journal Ad	x	x			x
Internet Activity					
ACTIQ.com	x	x		x	x
EmergingSolutionsinPain.com					
Cephalonspeaker.com					
Cancer-Pain.org					
Pain.com (CME program)					
Patient Education					
ACS BTCP Brochure - update				x	
APF BTP Brochure – create				x	
Sickle Cell Pain Aware. Brochure				x	
CancerCare Teleconference	x			x	
Update Health/Medical Websites				x	
RFP – Education Program		x		x	

3. 2002 Tactical Plan Implementation Timeline

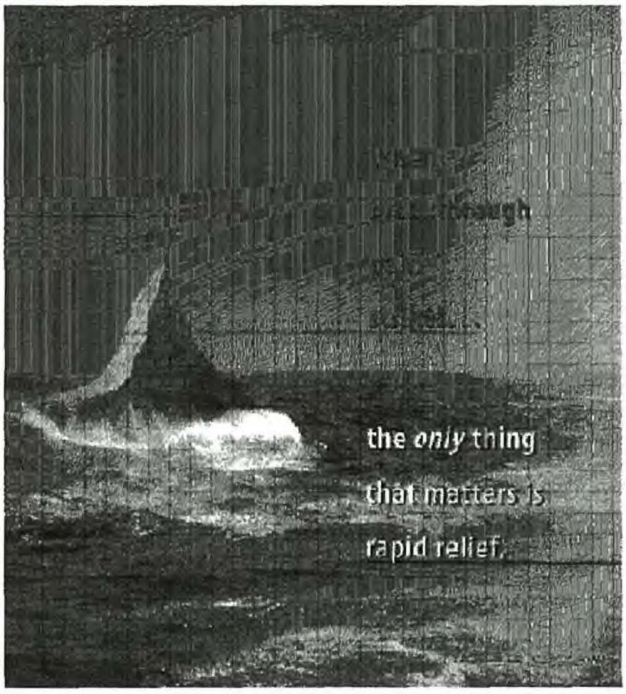
PROMOTIONAL TACTICS	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
DIRECT												
Medical Education												
Consultant Meetings	x					x						
Sales Driven MEPs	x	x	x	x	x	x	x	x	x	x	x	x
Conventions		x	x	x	x				x	x		
Sales Literature												
Pharmacokinetic Comparison SA			x									
Patient Profile Flash Cards				x								
Dosing/Titration Pocket Card				x								
Redesigned PCS Coupons		x										
Formulary Kit		x										
Non-branded BTP Wall Chart	x											
Patient Use Tear Sheet		x										
Pain Ass. Tear Sheet Holder	x											
MARKETING												
CME												
Teleconferences		x	x	x	x	x			x	x	x	
Regional/Local Symposia		x	x	x	x	x			x	x	x	
Trimesterly newsletter				x				x				x
Website (see below)	x	x	x	x	x	x	x	x	x	x	x	x
Direct Mailings												
High Decile Duragesic MDs • Comparative PK Data					x							
Oncology and Pain RNs • 2nd Opinion of J Ad • 2nd Opinion – Results	x			x								
MD Retention • Opinion – Messaging • Opinion – Results		x			x							
Publications & Advisory Boards												
Case Series/Phase IV Studies	x	x	x	x	x	x	x	x	x	x	x	x
Advisory Board Meetings	x					x						
INDIRECT												
Journal Advertisements												
Current Journal Ad	x	x	x	x	x	x	x	x	x	x	x	x
New Journal Ad				x	x	x	x	x	x	x	x	x
Internet Activity												
ACTIQ.com	x	x	x	x	x	x	x	x	x	x	x	x
EmergingSolutionsinPain.com	x	x	x	x	x	x	x	x	x	x	x	x
Cephalonspeaker.com	x	x	x	x	x	x	x	x	x	x	x	x
Cancer-Pain.org	x	x	x	x	x	x	x	x	x	x	x	x
Pain.com (CME program)		x	x	x	x	x	x					
Patient Education												
ACS BTCP Brochure - update			x									
APF BTP Brochure – create				x								
Sickle Cell Pain Aware. Brochure					x							
CancerCare Teleconference			x							x		
Update Medical Websites	x	x	x	x	x	x	x	x	x	x	x	x
RFP – Education Program				x								

4. 2002 ACTIQ Tactical Budget

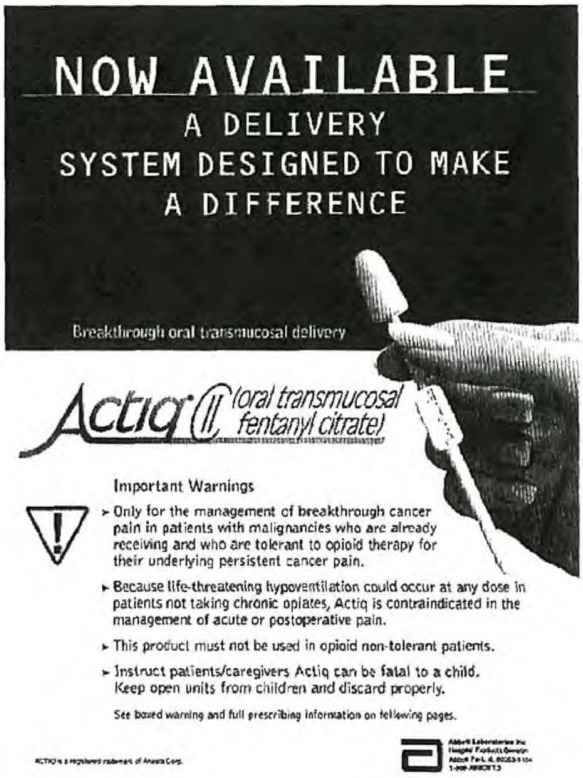
ACTIQ 2002 Tactical Budget	Total	Q1	Q2	Q3	Q4
Market Research					
Tracking Studies	$ 180,000	$ 90,000		$ 90,000	
Miscellaneous	$ 40,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000
Market Research Total	**$ 220,000**				
Consulting Requirements	**$ 20,000**	$ 5,000	$ 5,000	$ 5,000	$ 5,000
Journal Reprints	**$ 100,000**	$ 50,000	$ 50,000		
Convention					
Registration Fees	$ 25,000	$ 1,500	$ 12,000	$ 8,000	$ 3,500
Booth Transfer/Set-up	$ 90,000	$ 11,000	$ 44,000	$ 25,000	$ 10,000
Convention Advertisement	$ 5,000		$ 5,000		
Giveaways	$ 40,000	$ 5,000	$ 20,000	$ 10,000	$ 5,000
Convention Total	**$ 160,000**				
Advertising and Promotion					
Advertising Agency Fees	$ 300,000	$ 75,000	$ 75,000	$ 75,000	$ 75,000
Promotional Materials Development	$ 440,000	$ 150,000	$ 100,000	$ 100,000	$ 90,000
Promotional Materials Reprinting	$ 300,000	$ 50,000	$ 150,000	$ 50,000	$ 50,000
Media Planning Agency Fees	$ 48,000	$ 12,000	$ 12,000	$ 12,000	$ 12,000
Advertising Space	$ 555,000	$ 150,000	$ 145,000	$ 145,000	$ 115,000
Fulfillment Agency Fees	$ 100,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Sample Coupons - Product Costs	$ 55,000	$ 13,750	$ 13,750	$ 13,750	$ 13,750
Physician's Desk Reference	$ 80,000	$ 80,000			
Advertising & Promotion Total	**$ 1,878,000**				
Public Relations	**$ 400,000**	$ 150,000	$ 100,000	$ 100,000	$ 50,000
Medical Education Programs					
PCS Sales force Driven MEPs	$ 960,000	$ 240,000	$ 240,000	$ 240,000	$ 240,000
Medical Liaison MEPs	$ 100,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Consultant Meetings (two)	$ 600,000	$ 300,000	$ 300,000		
Speaker Materials	$ 10,000	$ 5,000	$ 5,000		
CME Programs ($1 MM)	$ 1,000,000	$ 250,000	$ 250,000	$ 250,000	$ 250,000
Advisory Board Meetings	$ 50,000	$ 25,000		$ 25,000	
Med Ed Total	**$ 2,720,000**				
Grants & Corporate Contributions					
Discretionary Field Grants	$ 96,000	$ 24,000	$ 24,000	$ 24,000	$ 24,000
RML Grants	$ 50,000	$ 12,500	$ 12,500	$ 12,500	$ 12,500
Discretionary Marketing Grants	$ 50,000	$ 12,500	$ 12,500	$ 12,500	$ 12,500
Grants & Corp Contributions Total	**$ 196,000**				
RMP Requirements					
Welcome Kit and Other Promo Materials	$ 200,000	$ 50,000	$ 50,000	$ 50,000	$ 50,000
Welcome Kit Order Fulfillment	$ 80,000	$ 20,000	$ 20,000	$ 20,000	$ 20,000
RMP Market Research	$ 25,000		$ 12,500		$ 12,500
RMP Requirements Total	**$ 305,000**				
Totals	**$ 6,000,000**	$ 1,842,250	$ 1,718,250	$ 1,327,750	$ 1,110,750

5. 1999-2000 ACTIQ Concepts

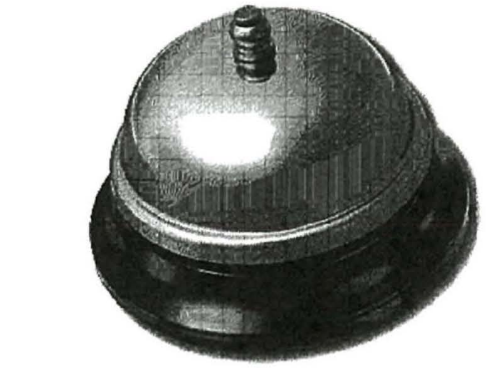
"BTP – Iceberg" Concept



"Unit – Delivery System" Concept



6. 2001 ACTIQ Concept



Actiq® on call.

Actiq®
(oral transmucosal fentanyl citrate)
Personal Pain Control

7. 2001 Journal Advertisement

Actiq® on call.

Actiq®
(oral transmucosal fentanyl citrate)
Personal Pain Control

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

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

Important Warnings

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

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

8. 2002 Media Plan

2002 ACTIQ MEDIA PLAN (Page 4C/ 2 PBW Film Unit & King P4C/ King PBW in Tabloids)

OPTION #1: Minimum Audience Coverage/NO NON-JNL - Targeting Only to ANES & ONC Univ & Pain Phys.

2002 Budget of $600K ($552.6 Jnl, $47.4 CMI fees [$32 CTS not in Media Budget])

	Totals		Jan 2002	Feb 2002	Mar 2002	Apr 2002	May 2002	Jun 2002	Jul 2002	Aug 2002	Sept 2002	Oct 2002	Nov 2002	Dec 2002
Number of Insertions	77		7	5	8	6	7	7	7	6	8	6	7	3
Avg. Exps/MD/Mo.	0.72		0.76	0.66	0.76	0.92	0.76	0.92	0.76	0.92	0.76	0.92	0.76	
Jrnl Space Spend	$552,455		$54,252	$32,865	$56,974	$43,588	$54,252	$46,310	$54,252	$43,588	$56,974	$43,588	$54,252	$11,562
CMI Est. Fees	$47,400													
Total '02 Investment	**$599,855**													
Publications	**Spend**	**# Ins**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
ONCOLOGY	$148,158	18	3		3		3		3		3		3	
Journal of Clinical Oncology	$43,492	6	1		1		1		1		1		1	
Oncology	$56,644	6	1		1		1		1		1		1	
Oncology News International	$48,022	6	1		1		1		1		1		1	
ANESTHESIOLOGY	$307,161	37	3	3	3	4	3	4	3	4	3	4	3	
Anesthesiology News	$108,049	11	1	1	1	1	1	1	1	1	1	1	1	
Anesthesiology	$97,794	11	1	1	1	1	1	1	1	1	1	1	1	
Anesthesia & Analgesia	$58,426	11	1	1	1	1	1	1	1	1	1	1	1	
American Jnl Anesthesiology	$42,892	4				1		1		1		1		
PAIN	$97,136	22	1	2	2	2	1	3	1	2	2	2	1	3
Journal of Pain	$19,836	6		1		1		1		1		1		1
Jrnl Pain & Symptom Mngt	$66,412	12	1	1	1	1	1	1	1	1	1	1	1	1
Pain Medicine	$10,889	4			1			1			1			1

9. 2002 Convention Plan

NAME & DATE	BOOTH SIZE	SPECIALTY	# OF ATTENDEES	# STAFF
AAPM American Academy of Pain Medicine Feb 28-March2 San Fran, CA	10x20	Pain	600	2 Mktg. 1 ML 3 TSS
APS American Pain Society March 12-17 Baltimore, MD	10x 20	Pain	2,000	2 Mktg. 1 ML 3 TSS
ONS Oncology Nursing Society April 18-21 Washington, DC	10x10	Oncology	8,500	2 Mktg. 1 ML 2 TSS
ASCO American Society of Clinical Oncology May 18-21 Orlando, FL	10x10	Oncology	22,000	2 Mktg. 1 ML 2 TSS
IASP 10th World Congress on Pain International Association for the Study of Pain Aug. 17-22 San Diego, CA	10x10	Pain	10,000	2 Mktg. 1 ML 2 TSS Int'l Partners
AAPM American Academy of Pain Management Sept. 26-29 Reno, NV	10x10	Pain	1,000	2 Mktg. 1 ML 2 TSS
ASTRO American Society for Therapeutic Radiology & Oncology Oct. 6-10 San Fran, CA	10x10	Oncology	9,000	2 Mktg. 1 ML 2 TSS
ASA American Society of Anesthesiology October 12-16 Orlando, FL	10x10	Anesthesiology	14,000	2 Mktg. 1 ML 2 TSS

10. 2002 Monthly Sales and Prescription Budget

	Jan-02	Feb-02	Mar-02	Apr-02	May-02	Jun-02
TRx	8,120	8,282	8,448	8,617	8,789	8,965
Demand Sales	$ 5,810,122	$ 5,926,325	$ 6,044,851	$ 6,165,748	$ 6,289,063	$ 6,477,735
Factory Sales	$ 6,115,918	$ 6,238,236	$ 6,363,001	$ 6,490,261	$ 6,620,066	$ 6,818,668

	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02
TRx	9,144	9,327	9,514	9,704	9,898	10,096
Demand Sales	$ 6,775,029	$ 6,978,280	$ 7,187,628	$ 7,403,257	$ 7,625,355	$ 7,854,115
Factory Sales	$ 7,057,322	$ 7,269,041	$ 7,487,113	$ 7,711,726	$ 7,943,078	$ 8,181,370

	2002 Totals
TRx	108,906
Demand Sales	$80,537,507
Factory Sales	$84,295,801