



1996

BUDGET PLAN

Produced to: Connecticut  
Attorney General Richard Blumenthal

PP 00006

**OxyContin™**

Produced to: Connecticut  
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PP 00007

## II. ASSUMPTIONS

### A. Market Overview

The classic model utilized in treatment of cancer pain is the World Health Organization (W.H.O.) Three Step Analgesic Ladder. The recommendations of the W.H.O. are:

Step 1: Use NSAIDs to treat mild pain, i.e., aspirin.

Step 2: Use weak opioids to treat moderate pain, i.e., codeine, oxycodone and hydrocodone combinations.

Step 3: Use strong opioids to treat severe pain, i.e., morphine.

Opioid choices in treating moderate to moderately severe pain in Step 2 have been limited by oxycodone, hydrocodone, and codeine combination products. Their short-acting duration of action provides peaks and valleys in pain control. The combination of the opioid

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with APAP or ASA limits the maximum dosage because of potential liver toxicity. The APAP or ASA component also has the potential to mask a fever in the cancer patient. All these problems associated with the choice of opioid analgesics in Step 2 present an opportunity for the introduction of a single-entity, long-acting oxycodone product.

The introduction of long-acting morphine and the transdermal fentanyl patch provides the physician with two long-acting products to meet the needs of moderately severe to severe pain in Step 3.

Morphine/Fentanyl, available to treat Step 3, possess disadvantages, such as the patient stigmas that surround morphine, and the M.D., R.N., pharmacist reluctance to use.

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B. Fixed Combination Opioids

Fixed combination opioids (oxycodone, hydrocodone, and codeine combined with APAP or ASA) have been the drugs of choice for treating moderate to moderately severe cancer pain (W.H.O. Step 2). Because they contain APAP or ASA, these products are limited by a recommended dosing ceiling, as the non-opioid can cause renal or hepatic toxicities. Sales for generic combination opioids are expected to continue growing, while the branded products will be flat. Combination opioids are considered primary competition for OxyContin.

C. MS CONTIN

MS CONTIN has become the gold standard for treating moderately severe to severe cancer pain (W.H.O. Step 3). Although faced with stiff competition from Duragesic® and Oramorph SR™, MS CONTIN sales grew by 26.5% in 1994. It is expected that health care professionals will continue to support the use of MS CONTIN for severe pain in 1996.

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Because a bioequivalent AB-rated generic controlled-release morphine sulfate is expected to be available sometime during the latter part of 1996 or early 1997, one of the primary objectives is to switch patients who would have been started on MS CONTIN to OxyContin, as quickly as possible.

D. Duragesic

It is expected that Duragesic will continue heavy promotion in the cancer market for moderate to severe pain. The patch is mainly used for moderately severe to severe pain, but Janssen has been targeting the moderate to moderately severe market for the past two years. Their progress has been slow but steady in obtaining patients coming straight off of fixed combination opioids.

Janssen will continue to target primary care physicians (namely internists) as well as oncologists. In 1995,

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Janssen spent a significant amount of money advertising Duragesic in journals which target the internist and other primary care specialists.

Because OxyContin will be targeted for patients who would have been started on fixed combination opioids, from which Duragesic draws approximately 25% of its sales, it is expected that Janssen will try to counter the OxyContin position by stressing fewer side effects and easier titration. As a result, it will be critical that proper titration and treatment of side effects are stressed in the promotion of OxyContin.

E. Kadian<sup>™</sup>

It is expected that Faulding/Bristol-Myers-Squibb will receive FDA approval to market Kadian (morphine sulfate extended release capsules) during mid- to late-1996. It is anticipated that Kadian will receive a q24h dosing indication, but no less than a q12h approval. Although not bioequivalent to MS CONTIN, it is expected that

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Kadian will be positioned as a "better alternative." In Australia the product was launched by Glaxo whose promotional focus overseas has centered around the inference that flatter plasma concentrations equate to better efficacy than MS CONTIN.

It is unlikely that Kadian will be primary competition for OxyContin since the use of morphine for moderately to moderately severe pain has not been an accepted practice among health care professionals. Kadian will replace MS CONTIN and reduce the available prescriptions for switching from MS CONTIN to OxyContin. It is anticipated, however, that Kadian will position itself as the logical next step as patients no longer tolerate or receive adequate analgesia from OxyContin. Just as with Duragesic, it will be critical that proper titration and treatment of side effects are stressed when selling OxyContin, thereby reducing the number of patient failures.

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F. Oramorph SR

Roxane is expected to continue promotion of Oramorph SR positioning it as a cost effective alternative to MS CONTIN. They will spend a large portion of their marketing and sales promotion convincing formulary decision makers for hospitals, hospices, and state formulary committees that Oramorph SR is a less expensive, but just as effective replacement for MS CONTIN. It is expected that they will continue to spend a significant amount of promotional money for journal advertising and direct mail. As with Kadian, this product reduces the prescriptions available for switches to OxyContin.

G. Generic Morphine Sulfate Controlled-Release

It is possible that a generic morphine sulfate controlled-release product that is bioequivalent to MS CONTIN will be FDA approved in the latter part of 1996. This product is not considered primary

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competition for OxyContin as it will compete mainly with MS CONTIN. However, since it will be a twice-a-day, long-acting opioid, if it is priced considerably lower than OxyContin, it will likely be positioned as a cost-effective alternative to OxyContin. As with Kadian, this product reduces the prescriptions available for switches to OxyContin.

H. PCA Pumps

During 1994, sales of injectables have stopped declining and actually showed some increases. This is likely due to the FDA problems that Duragesic faced as patients who could not swallow were placed on PCA Pump regimens in place of Duragesic. PCA Pumps are not considered primary or secondary competition for OxyContin since a large majority of these patients can no longer swallow.

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Post-Launch

After FDA approval is received, the OxyContin exhibit structure will feature graphic panels of the OxyContin core creative concept; "THE NEW WAY" depicting a.m. and p.m. dosing represented by two dosing cups. Various promotional activities will be conducted at the booth to draw attendees into a discussion with our representatives about OxyContin. The proposed convention schedule is listed at the end of the promotional plan.

F. Clinical Support/Dates

1. Study: Dosing Guidelines Test (Label Validation Study) (OC93-0704)  
  
Date of Completion: Third Quarter, 1996  
  
Date of Marketing Usage: Fourth Quarter, 1996  
  
Marketing Usage: To demonstrate how to obtain effective pain control by following the OxyContin package insert directions.
  
2. Study: Opioid Naive and Fixed Combination (PRN) Patients (OC94-0506)  
  
Date of Completion: First Quarter, 1997

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Date of Marketing Usage: Second Quarter, 1997

Marketing Usage: To demonstrate that OxyContin can be an effective analgesic in opioid naive patients or in patients currently taking fixed combination opioids.

3. Study: OxyContin vs. Percocet® in Osteoarthritis Patients (OC95-0103)

Date of Completion: Fourth Quarter, 1996

Date of Marketing Usage: First Quarter, 1997

Marketing Usage: A head-to-head comparative study to measure the safety, efficacy, and quality of life of OxyContin vs. Percocet in osteoarthritis patients.

4. Study: OxyContin vs. Placebo in Patients with Low Back Pain (OC95-0107)

Date of Completion: Second Quarter, 1997

Date of Marketing Usage: Third Quarter, 1997

Marketing Usage: Designed to demonstrate that OxyContin is effective and safe for patients with low back pain compared to placebo.

5. Study: OxyContin vs. Percocet Outcomes in Patients with Low Back Pain (OC95-0201)

Date of Completion: Third Quarter, 1997

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Date of Marketing Usage: Fourth Quarter, 1997

Marketing Usage: To demonstrate that OxyContin provides a better quality of life than Percocet for patients with low back pain.

6. Study: OxyContin vs. Percocet in Cancer Pain (OC95-0304)

Date of Completion: Fourth Quarter, 1997

Date of Marketing Usage: First Quarter, 1998

Marketing Usage: To prove that OxyContin is as safe and effective as Percocet in cancer patients but provides a better quality of life because of its q12h administration.

7. Study: OxyContin vs. Placebo Outcomes in Osteoarthritis Patients (OC95-0202)

Date of Completion: Second Quarter, 1997

Date of Marketing Usage: Third Quarter, 1997

Marketing Usage: Designed to demonstrate that OxyContin is safe and effective in patients with osteoarthritis and can provide outcomes benefits.

8. Study: Opioid Stigma Survey (OC95-0000)

Date of Completion: First Quarter, 1997

Date of Marketing Usage: Second Quarter, 1997

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- Marketing Usage: . To show the differences in stigma among various opioids when treating patients in pain. The intent is to prove that oxycodone is a more well accepted opioid than morphine.
9. Study: OxyContin vs. Duragesic Random Site (OC95-0804)
- Date of Completion: Second Quarter, 1998
- Date of Marketing Usage: Third Quarter, 1998
- Marketing Usage: An open label random site study designed to measure quality of life of OxyContin vs. Duragesic.
10. Study: OxyContin vs. Duragesic Double Blind (OC95-0806)
- Date of Completion: First Quarter, 1998
- Date of Marketing Usage: Second Quarter, 1998
- Marketing Usage: A double blind study designed to compare OxyContin and Duragesic with regards to efficacy safety and other outcomes to be determined.

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### III. PRODUCT STRATEGY

#### A. Objectives

- To achieve \$25 million in sales during the first full year, post launch.
- To generate 205,000 prescriptions in year 1, by capturing:
  - 15% of MS CONTIN Rxs written for cancer pain.
  - 10% of oxycodone combination Rxs written for cancer pain.
  - 10% of hydromorphone Rxs written for cancer pain.
  - 2.5% of Duragesic combination Rxs written for cancer pain.
- To convince health care professionals to replace 15% of MS CONTIN prescriptions (year 1) with OxyContin as their drug of choice for cancer pain.
- To establish OxyContin as the opioid of choice in Step 2 of the W.H.O. analgesic stepladder.

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- To displace MS CONTIN and Duragesic in Step 3 of the W.H.O. analgesic stepladder, by positioning OxyContin as the opioid to start with and stay with, thereby expanding the usage of Step 2. Hence, Step 3 products, i.e., MS CONTIN, Duragesic, will become drugs of last resort, as OxyContin is used throughout the clinical progression of the cancer pain.
- To increase the number of prescriptions for strong opioids by 10%. This will be accomplished by convincing health care professionals to use OxyContin earlier in the patient's treatment cycle.

B. Positioning Statement

- All the analgesic efficacy of immediate-release oxycodone. The importance of the familiarity of physicians with oxycodone cannot be overstated. This familiarity is a principal factor that should lead to acceptance of OxyContin.

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- All the ease of q12h dosing. All of our market research indicates that the most important feature of OxyContin beyond oxycodone is the q12h dosing schedule. In all seven market research projects conducted among 626 health care professionals, this was the most compelling reason to prescribe OxyContin.
- When a opioid naive patient needs an opioid analgesic, physicians are reluctant to begin therapy with MS CONTIN. Therefore, OxyContin is the opioid to start with (for patients who would otherwise be started on Percocet, Lortab, Vicodin or Tylenol #3; W.H.O. Step 2) and the opioid to stay with as the disease progresses (when patients may otherwise be switched to MS CONTIN or Duragesic; W.H.O. Step 3).
- At the time of launch, OxyContin will be marketed for cancer pain. The primary strategy in the cancer pain market will be to establish OxyContin

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for a broader range of use than is available to MS CONTIN.

- As soon as enough appropriate clinical studies are available for promotional claims, OxyContin will be launched into the chronic non-malignant pain market. The most common diagnoses for non-malignant pain are musculoskeletal pain, injury and trauma pain. The major competitors for these diagnoses will be oxycodone and hydrocodone combination products. OxyContin will be positioned as providing the equivalent efficacy and safety of oxycodone combinations, with the benefit of a q12h dosing schedule.

### 3. Primary Competition

Long-acting opioids (MS CONTIN, Duragesic and Kadian) used for moderately severe to severe cancer pain (Step 3 of the W.H.O. analgesic ladder). Long-acting opioids used for moderately severe to severe cancer pain (Step 3 of the W.H.O. analgesic ladder).

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4. Secondary Competition

Combination opioids (oxycodone, hydrocodone and codeine with APAP or ASA) used for moderate to moderately severe cancer pain (Step 2 of the W.H.O. ladder).

5. Communications Objective

To convince MDs to prescribe and RNs to recommend new OxyContin for opioid naive or opioid exposed patients with moderate to severe cancer pain instead of combination opioids, and thereby eliminate or delay the need for other long-acting opioids.

6. Selling Points

The One to Start With

- The logical "next step" for patients no longer tolerating or responding to nonopioids - conforms to the three-step W.H.O. analgesic ladder

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- The analgesic efficacy of immediate-release oxycodone - the ease of q12h dosing
- All the analgesic efficacy of immediate-release oxycodone - all the convenience of q12h dosing
- Pain relief begins promptly, within one hour
- Rapid onset of action
- Rapidly effective - upon initiation, most patients can expect relief within one hour
- Pain control lasts 12 hours; two to three times longer than each dose of short-acting products such as Percocet®, Percodan®, Tylox®, Vicodin®, Lortab®, Lorcet®, and Tylenol® with Codeine.
- Convenient q12h schedule won't interfere with patients' daytime activities or nighttime rest, and encourages compliance
- Patients less likely to anxiously "clock watch" when pain control is sustained over long periods
- Single-entity agent - avoids adding the potential toxicities of products containing aspirin or acetaminophen

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- Three dosage strengths, bioequivalent and dose-proportional, are appropriate for a broad range of pain
- Small color-coded tablets are easy to identify and swallow - an important benefit for elderly patients and those on multiple medications
- In studies of patients with non-malignant pain...
  - Rapid reduction in pain intensity over the first 24 hours
  - By day three, patients had achieved 94% of their total pain reduction
  - Patients reported improved ability to sleep, walk, perform normal work, get along with other people, enjoy life

#### The One to Stay With

- Q12h dosing provides smooth and sustained blood levels - fewer peaks and valleys than with immediate-release oxycodone

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- Smooth and reliable pain control - less frequent dosing than with Percocet®, Vicodin®, or Tylenol® with Codeine
- No "ceiling" to analgesic efficacy - may be titrated upward as necessary *With full agonists, such as oxycodone, "effectiveness with increasing doses is not limited by a 'ceiling'."*
- Higher doses deliver greater pain control; nearly 30% of cancer patients maintained on 160 mg or more per day.
- Patients avoid the added risk of gastric/hepatic/renal toxicity that can occur with products containing aspirin or acetaminophen
- Excellent compliance, high degree of patient acceptability during clinical trials

#### Ideal for Long-Term Therapy

- A single-entity oral agent, contains no APAP or ASA - allows independent coadministration and dosage adjustments with nonopioid of choice

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### Easy to Live With

- Convenient q12h schedule won't interfere with patients' daytime activities or nighttime rest, and encourages compliance
- Common opioid side effects may be anticipated and effectively managed or prevented
- A significant decrease in the percent of patients reporting adverse events (56.5% vs. 25.9%,  $P < 0.0001$ ) was seen between the first and last weeks of a cancer study - even as daily doses increased

### The 12-Hour ACROCONTIN® Delivery System Allows Both Rapid and Prolonged Absorption Over a 12-Hour Period

- Rapid absorption - pain relief begins promptly, within one hour
- Prolonged absorption - pain control continues as tablet matrix slowly releases oxycodone granules at a constant rate over a 12-hour period
- Special acrylic coating renders oxycodone granule "pH independent," allowing uniform release within

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an acid environment (the stomach) or an alkaline environment (the intestines).

- "pH independence" assures...Minimal effect of stomach contents on absorption - bioavailability unaffected by food or ingestion of other medications

#### Easy to Titrate

- Steady-state achieved in 24 - 48 hours and remains constant thereafter - if needed, pain assessment and titration are possible on a daily basis
- In cancer studies...
  - Titration enhanced efficacy of therapy - only 3.5% of cancer patients discontinued (due to inadequate pain control) when allowed to titrate and use rescue medication
  - Patients were titrated as quickly and easily with OxyContin as with immediate-release oxycodone

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- 92% of patients were titrated to stable pain control with OxyContin, compared with 79% for IR oxycodone
- Average time to stable pain control was 1.6 days
- The goal of titration - to effectively control pain with two or fewer rescue doses per day

#### Easy to Dose

- Small, color-coded tablets are easy to identify and swallow - an important benefit for patients on multiple medications
- Variety of strengths permit precise titration to an effective dose. Breakthrough or incident pain can be managed with OxyIR - avoids polypharmacy

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2. Secondary Audiences

Secondary Audiences	Site	Targets	Comments
A. Consultant Pharmacists	Long-term Care Facilities	≥6,000	Influence decision-makers at LTC facilities
B. Patients and Caregivers		6 - 7 million patients	<ul style="list-style-type: none"> <li>• 1.2 million new cancer cases annually</li> <li>• 30-40% experience pain (early/intermediate)</li> <li>• 65-90% experience pain (intermediate/late)</li> </ul>
C. Physicians	<ul style="list-style-type: none"> <li>• Office</li> <li>• Hospital</li> </ul>	33,000	<p><u>Target List #2</u></p> <p>Decile 10 for combo only; but not in Target List 1A, non-malignant market</p>
D. Residents/Fellows	Teaching Hospitals		

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IV. TACTICS

A. Sales Force Allocation

The deployment of our most valuable resource, the sales force, will be critical to the success of OxyContin. Heavy promotional support in the first three years of launch will ensure appropriate awareness of OxyContin in the opioid market. This sales force allocation is subject to change as the launch into chronic non-malignant pain becomes more eminent.

Sales force allocation should be implemented as follows:

YEAR	% OF PRIMARY SALES CALLS	# CALLS/QUARTER
1	70%	78,424 *
2	60%	67,221
3	50%	56,017
4	40%	44,814
5	40%	44,814

\* 1st Quarter will be lower as physician selling will not begin until March.

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B. Representative Delivered Promotional Materials

Distribution Plan to Trade

Pharmacists are generally reluctant to stock Class II opioid analgesics. This reluctance is based on the fears that drug abusers will try to obtain these drugs for other than medicinal purposes. The concerns for stocking Class II opioids are also related to the voluminous paperwork required for receiving, distributing, and returning these products. In nine states, triplicate prescription laws monitor the distribution of Class II opioids to patients.

As a result, stocking this product into the retail distribution channels may be somewhat problematic. Obviously, adequate distribution is one of the most essential factors to the successful launch of any product. Therefore, it will be critical for the Sales Department to coordinate efforts between the National Account Managers and the ethical field force.

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All promotional efforts for the retail distribution of OxyContin will focus on the incredible success that Purdue Frederick has achieved and sustained with the MS CONTIN<sup>®</sup> product line. Wholesale pharmaceutical buyers and retail pharmacists should be reminded of how MS CONTIN created such a large market for the use of sustained release opioids for the treatment of pain. This in turn created profits for pharmacists, helping to grow their businesses. Promotional copy should focus on the market potential for OxyContin and patient populations to be targeted, including the number of prescriptions written for Class II and Class III opioids every year.

The Executive Director of National Accounts should work with drug wholesalers in developing programs to utilize the wholesalers' sales representatives to ensure adequate distribution. Consideration should also be given to advertisements in drug wholesaler ad books or computer programs.

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A cooperative direct mail/advertising sales sheet offering a rebate on the initial order of OxyContin to retail pharmacists will be mailed every month during the first three months of launch. This promotion will increase awareness and supplement field force efforts in gaining adequate distribution.

#### Wholesalers

In an effort to ensure fast and adequate distribution of OxyContin, National Account Managers will begin making pre-launch sales calls during October, 1995. The objective of these sales calls is to obtain EPIC numbers for OxyContin and have the product down-loaded into computer systems so when FDA approval is granted, there is no delay in shipping product to wholesalers. A pre-launch wholesaler sell sheet will be developed, supplying all appropriate information (i.e., NDC numbers, package sizes, pricing, etc.). Since FDA does not allow promotion of a brand's effectiveness, safety, or indications during the pre-launch phase, no

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information other than product specifications (i.e., NDC numbers, dimensions, pricing, etc.) will be included in the pre-launch sell sheet.

A launch sell sheet will be developed for OxyContin. It will carry promotional messages about OxyContin and will explain the level of marketing and sales support that the brand will receive. A separate sell sheet will be developed for OxyIR. These materials will be provided to National Account Managers and the ethical field force as soon as possible after FDA approval is received to ensure adequate and fast distribution.

#### Pharmacies

Representative promotion to retail pharmacies will begin once adequate wholesaler distribution is attained. Representatives will be provided with a launch sell sheet for both OxyContin and OxyIR. Initial targets will be all 25,000 stores who stock MS CONTIN. Representatives will be provided with lists showing all stores purchasing MS CONTIN within the last 6 to

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12 months. Stocking will then be expanded to the additional 35,000 stores remaining in the market.

In an effort to create demand at the pharmacy level, a mailing will be sent to physicians announcing the introduction of OxyContin. A business reply card will be included, which they will return to Purdue Frederick if they are interested in having their local pharmacy stocked with OxyContin. These business reply cards will be distributed to the appropriate sales representative and used when stocking local retail pharmacies to create a pull-through demand program.

#### Hospitals

In an effort to gain formulary acceptance of OxyContin, representatives will make calls on all P&T committees to gain hospital formulary acceptance during the first three months of launch. This will entail contacting directors of pharmacies and P&T committee members in all hospitals of 100 beds or more.

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A hospital formulary kit and product data brochure will be utilized by the sales force to provide the appropriate clinical data necessary to add OxyContin to hospital formularies. In addition, representatives will be given tabletop hospital display panels. Speakers' Bureau lectures will be conducted during grand rounds, tumor boards, etc. The focus of these presentations will be the addition of a new opioid (OxyContin) to the analgesic treatment armamentarium.

#### Managed Care Organizations

Managed Care Account Executives will target all major PBMs and IPA plans in an effort to add OxyContin to their formularies. P & T committee members will be provided with a formulary kit that has been customized for their managed care organization, personalized with their name on the cover. In addition, they will be provided with product data brochures.

The Partners Against Pain™ Program will be expanded significantly for the managed care market, providing

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customized materials to meet their needs. Items such as a case manager education video, titration guideline cards, and conversion calculators will be offered to managed care organizations with their plan's indicia printed on them. In addition, various educational programs such as regional physician and nurse educators, consultations with pain management specialists, etc. are being explored as possible value-added services offered through the Partners Against Pain Program.

C. Direct Mail

Pre-Launch Mailings

Pre-launch mailings will be sent to wholesalers announcing that OxyContin is coming soon from Purdue. The objective of these mailings is to ensure that EPIC numbers are assigned to OxyContin by each wholesaler. This will speed up the distribution process, since it takes approximately 60 days to complete this task.

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### Approval Announcements

As soon as adequate retail distribution is attained, announcements will be sent to MDs, RNs, RPHs, MCOs, hospitals and hospices. The objective of these mailings is to build awareness of the OxyContin name.

### Launch Mailings

The focus of mailings at and after launch will be on "THE OLD WAY" versus "THE NEW WAY" of oxycodone pain control. The graphic of two cups representing a.m. and p.m. dosing will be the main message that is conveyed. These launch mailings will have the objective of creating brand awareness of OxyContin and also campaign awareness that carries the most important benefit OxyContin has to offer, q12h dosing.

### Representative Follow-up Mailings

Representatives will be given the ability to send follow-up mailings to MDs and RNs after making a call. This will be accomplished through the Precise System.

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D. Journal Advertising

Launch Advertising

The launch ad for OxyContin will contain the core creative concept of 24 hr. Oxycodone the "OLD WAY" (6 dosing cups) vs. the "NEW WAY" (2 dosing cups). This ad will be a 4-page insert placed in journals from February 1996 through July 1996.

Post-Launch Advertising

Starting in August, 1996, a three page run-of-book post launch ad will be utilized to reduce advertising space costs and to remind the physician of the main message of OxyContin, a.m. and p.m. dosing. It will carry the same graphic as the launch ad.

E. Conventions

A new exhibit structure has been constructed specifically for the OxyContin launch. This exhibit will be used during the pre-launch phase and in the

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first year after launch, just to promote OxyContin. After the first year, consideration will be given to converting the structure into the Purdue pain management exhibit, where all Purdue analgesics could be displayed.

#### Pre-Launch

Prior to FDA approval, in an effort to create broad awareness of the upcoming launch of OxyContin with large target audiences (primary care MDs), the OxyContin convention exhibit was displayed at the AAFP and AOA conventions. Since FDA guidelines do not allow promotion of effectiveness, safety, or indications prior to approval, the emphasis at the pre-launch booth focused on "coming soon from Purdue Pharma LP; OxyContin (oxycodone hydrochloride controlled release) Tablets. Attendees visiting this booth during the pre-launch phase will be entered into a database which will be used to send mailings when FDA approval is received.

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Post-Launch

After FDA approval is received, the OxyContin exhibit structure will feature graphic panels of the OxyContin core creative concept; "THE NEW WAY" depicting a.m. and p.m. dosing represented by two dosing cups. Various promotional activities will be conducted at the booth to draw attendees into a discussion with our representatives about OxyContin. The proposed convention schedule is listed at the end of the promotional plan.

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1996 PROMOTIONAL PLANOXYCONTIN™

	<u>FIRST</u> <u>QUARTER</u>	<u>SECOND</u> <u>QUARTER</u>	<u>THIRD</u> <u>QUARTER</u>	<u>FOURTH</u> <u>QUARTER</u>
<u>PROMOTIONAL MATERIALS:</u>				
Launch Visual Aid	X			
File Card	X			
Pharmacy Stocking List	X			
OxyContin Prescription Pad Portfolio	X			
Cost Comparison Card	X			
Titration Guideline Card	X			
Conversion Calculator	X			
Phone Message Pads	X			
OxyContin In-Service Slide Module	X			
OxyIR File Card	X			
OxyContin Wholesaler/Chain Sell Sheet	X			
OxyIR Wholesaler/Chain Sell Sheet	X			
Pull Through Demand Program	X			
OxyContin Retail Pharmacy Sell Sheet	X			
OxyIR Retail Pharmacy Sell Sheet	X			

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	<u>FIRST</u> <u>QUARTER</u>	<u>SECOND</u> <u>QUARTER</u>	<u>THIRD</u> <u>QUARTER</u>	<u>FOURTH</u> <u>QUARTER</u>
<u>PROMOTIONAL MATERIALS cont:</u>				
Hospital Formulary Kit	X			
AT&T Make-A-Wish Phones	X			
Tabletop Displays	X			
Product Data Brochure	X			
Formulary Kit (customized)	X			
Formedics Patient Chart Forms	X			
Physician Reminders	X			
OxyContin/OxyIR Flash Card		X		
Office Premiums		X		
Reprint Fund		X		
Reprint Binder		X		
File Card (reorder remove the word new)			X	
Slim Jim			X	
Side Effect Management Slim Jim			X	
PAP Assessment Scale			X	
PAP Assessment Record Form			X	
Case Studies Brochure			X	

1996 PROMOTIONAL PLANOXYCONTIN™

	<u>FIRST</u> <u>QUARTER</u>	<u>SECOND</u> <u>QUARTER</u>	<u>THIRD</u> <u>QUARTER</u>	<u>FOURTH</u> <u>QUARTER</u>
<u>PROMOTIONAL MATERIALS cont:</u>				
"Start with Stay With" Premium			X	
Case Manager Video			X	
Life Style Detailer				X
PAP Professional Newsletter				X
<u>DIRECT MAIL:</u>				
PDR Addendum	X			
MD Approval Announcement	X			
RN Approval Announcement	X			
Consultant RPH Approval Announcement	X			
Managed Care Approval Announcement	X			
Hospital Approval Announcement	X			
Hospice Approval Announcement	X			
Wholesaler/Chain Launch Announcement	X			
Pharmacy Power Pack Mailing	X			
Managed Care Launch Mailer	X			

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	<u>FIRST</u> <u>QUARTER</u>	<u>SECOND</u> <u>QUARTER</u>	<u>THIRD</u> <u>QUARTER</u>	<u>FOURTH</u> <u>QUARTER</u>
<u>DIRECT MAIL cont:</u>				
Rep Follow-Up Mailings	X			
Physician Direct Mail Services: Features and Benefits (3 waves)		X		
RN Direct Mail Series: Features Benefits (3 waves)		X		
<u>JOURNAL ADVERTISING:</u>				
Journal Advertising	X	X	X	X
<u>SPECIAL PROMOTIONS:</u>				
Push Monies for Drug Wholesaler Incentives	X			
Rebates on Initial Retail Drugstore Orders	X			
Drug Wholesaler Advertising Programs	X			
<u>CONVENTIONS:</u>				
American College of Osteopathic Family Physicians	X			
Oncology Nursing Society		X		
American Society of Clinical Oncology		X		
American Academy of Physicians Assistants		X		

1996 PROMOTIONAL PLANOXYCONTIN™

	<u>FIRST</u> <u>QUARTER</u>	<u>SECOND</u> <u>QUARTER</u>	<u>THIRD</u> <u>QUARTER</u>	<u>FOURTH</u> <u>QUARTER</u>
<u>CONVENTIONS cont:</u>				
American Academy of Hospice Physicians		X		
International Association Study of Pain			X	
American Academy of Family Physicians				X
American Osteopathic Association				X
American College of Rheumatology				X
National Hospice Organization				X
Oncology Nursing Society Fall Teaching Institute				X
American Society of Consultant Pharmacists				X
American Pain Society				X
American Society Health System				X

PP 00049

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>FIRST QUARTER</b>				
<u>Promotional Materials:</u>				
Launch Visual Aid	New	5,000	\$45,000	A 20-page retained visual that will be the cornerstone sales aid for the representatives.
File Card	New	150,000	\$55,000	A mini visual/file card to be used as a leave-behind, includes package insert.
Pharmacy Stocking List	New	25,000	\$5,000	Leave-behinds to let health care professionals know which pharmacies stock OxyContin.
OxyContin Prescription Pad Portfolio	New	12,000	\$100,000	A portfolio bearing the "Partners Against Pain" and OxyContin logos, designed to hold the physician's prescription pad. These will be given to the physician with a OxyContin file card, conversion calculator, titration guidelines card, and conversion pen in them.

PP 00050

Produced to: Connecticut Attorney General Richard Blumenthal

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Promotional Materials cont:</u>				
Cost Comparison Card	New	100,000	\$40,000	A flash card used to demonstrate the daily cost of OxyContin versus Duragesic, Percocet, and MS Contin.
Titration Guideline Card	New	300,000	\$80,000	A two-sided flash card explaining the TIME principles of titration to ensure appropriate titration is carried out with OxyContin.
Conversion Calculator	New	200,000	\$225,000	A slide rule calculator providing appropriate conversions from other opioids to OxyContin.
Phone Message Pads	New	100,000	\$35,000	Pads given to the receptionist for recording phone messages for physicians. Because it bears the OxyContin logo, physicians will constantly be reminded of OxyContin every time they get a phone message.

PP 00051

Produced to: Connecticut  
Attorney General Richard Blumenthal

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Promotional Materials cont:</u>				
OxyContin In-Service Slide Module	New	500	\$15,000	A set of 20 slides to be used by representatives for in-services on OxyContin.
OxyIR File Card	New	100,000	\$50,000	A mini visual/file card used as a leave-behind for OxyIR.
OxyContin Wholesaler/Chain Sell Sheet	New	10,000	\$30,000	To be used with wholesalers/chains to stock OxyContin and offer terms of sale.
OxyIR Wholesaler/Chain Sell Sheet	New	10,000	\$25,000	To be used with wholesalers/chains to stock OxyIR and offer terms of sale.
Pull Through Demand Program	New	N/A	\$5,000	A program to encourage physicians to return a business reply card requesting that their local pharmacy be stocked with OxyContin. Representatives will then use this card to stock the local pharmacy for the physician.

PP 00052

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Attorney General Richard Blumenthal

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<u>FIRST QUARTER cont.</u>				
<u>Promotional Materials cont:</u>				
OxyContin Retail Pharmacy Sell Sheet (300,000 for Power Pack Mailing - 50,000 for sales force)	New	350,000	\$50,000	To be used when stocking retail pharmacies with OxyContin. It will offer a rebate on the initial order of OxyContin. A mailing of 200,000 of the sell sheets will be made to all retail pharmacies across the country through Pharmacy Power Pack.
OxyIR Retail Pharmacy Sell Sheet (300,000 for Power Pack Mailing - 50,000 for sales force)	New	350,000	\$50,000	To be used when stocking retail pharmacies with OxyIR. It will offer a rebate on the initial order of OxyIR. A mailing of 200,000 of the sell sheets will be made to all retail pharmacies across the country through Pharmacy Power Pack.

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PP 00053

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Promotional Materials cont:</u>				
Hospital Formulary Kit	New	25,000	\$60,000	A binder given to P&T committee members when requesting the addition of OxyContin to a hospital formulary. This binder will contain all relevant clinical data for OxyContin.
AT&T Make-A-Wish Phones	New	100	\$100,000	Video conferencing phones to be given to the top 100 cancer centers across the nation as a donation. These phones are used by patients in isolation to speak with loved ones.
PP 00054				
Tabletop Displays	New	1,000	\$15,000	Display panels used by representatives when exhibiting at hospitals, hospices, etc.
Product Data Brochure	New	50,000	\$100,000	A brochure summarizing all PK/PD and clinical studies.
Formulary Kit (customized)	New	1,000		

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Promotional Material cont:</u>				
Formedics Patient Chart Forms	New	N/A	\$35,000	Patient record forms given to physicians free of charge. These forms will contain an advertisement for OxyContin.
Physician Reminders	New	TBD	\$300,000	Various giveaways to constantly remind the physician of the availability of q12h OxyContin.
<u>Direct Mail:</u>				
PDR Addendum	New	50,000	\$55,000	Once adequate retail distribution is attained, a mailing will be sent to physicians announcing the launch of OxyContin, and providing them with a package insert to be inserted into their Physicians' Desk Reference manual.

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PP 00055

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>FIRST QUARTER cont.</b>				
<u>Direct Mail:</u>				
MD Approval Announcement	New	30,000	\$41,000	Once adequate retail distribution is attained, a one-page letter will be sent to all high prescribers of opioids announcing the launch of OxyContin.
RN Approval Announcement	New	25,000	\$30,000	Once adequate retail distribution is attained, a one-page letter will be sent to all members of the Oncology Nursing Society announcing the launch of OxyContin.
Consultant R.Ph. Approval Announcement	New	6,000	\$10,000	Once adequate retail distribution is attained, a one-page letter will be sent to all members of the American Society of Consultant Pharmacists announcing the launch of OxyContin.

PP 00056

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>FIRST QUARTER cont.</b>				
<u>Direct Mail cont:</u>				
Managed Care Approval Announcement	New	12,000	\$15,000	Once adequate retail distribution is attained, a one-page letter will be sent to all members of Managed Care P&T Committees announcing the launch of OxyContin.
Hospital Approval Announcement	New	20,000	\$25,000	Once wholesaler distribution is attained, a one-page letter will be sent to all members of Hospital P&T Committees announcing the launch of OxyContin.
Hospice Approval Announcement	New	2,000	\$5,000	Once adequate retail distribution is attained, a one-page letter will be sent to all hospice directors announcing the launch of OxyContin.

PP 00057

Produced to: Connecticut  
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1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Direct Mail cont:</u>				
Wholesaler/Chain Launch Announcement	New	300	\$4,000	Once FDA approval is attained, a launch announcement will be sent all wholesalers/chain pharmaceutical buyers announcing the availability of OxyContin.
Pharmacy Power Pack Mailing (2 waves) (Retail, Hospital, Consultant Pharmacies)	New	100,000	\$20,000	A mailing of our sell sheet to all retail, hospital, consultant pharmacies announcing the availability of OxyContin.
Managed Care Launch Mailer	New	15,000	\$30,000	A mailing sent to managed care administrators explaining the features and benefits of OxyContin.
Rep Follow-Up Mailings	New	200,000	\$150,000	A series of letters that representatives can send to MDs, RNs and RPhs as a follow-up to their sales call. This program is administered through the Precise system.

PP 00058

Produced to: Connecticut Attorney General Richard Blumenthal

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
FIRST QUARTER cont.				
<u>Journal Advertising:</u>				
Journal Advertising	New	N/A	\$187,500	Budget used to advertise OxyContin in journals.
<u>Special Promotions:</u>				
Push Monies for Drug Wholesaler Incentives	New	N/A	\$100,000	A budget used to provide wholesalers, with an incentive for stocking OxyContin into pharmacies.
Rebates on Initial Retail Drugstore Orders	New	N/A	\$70,000	A fund used to pay rebates to retail pharmacies on their initial order of OxyContin.
Drug Wholesaler Advertising Programs	New	N/A	\$100,000	Budget used to advertise OxyContin in wholesaler advertising booklets and computer programs.

PP 00059

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1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>SECOND QUARTER</b>				
<u>Promotional Material:</u>				
OxyContin/OxyIR Flash Card	New	200,000	\$100,000	A simple two-sided flash card used to explain the benefits of using OxyContin and OxyIR together.
Office Premiums	New	TBD	\$120,000	Premium giveaways for the physician's office constantly reminding them to prescribe OxyContin.
Reprint Fund	New	N/A	\$75,000	A fund used to purchase reprints as OxyContin manuscripts are published.
Reprint Binder	New	400	\$25,000	A binder used to hold all published abstracts and studies for OxyContin when making presentations.

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>SECOND QUARTER cont.</b>				
<u>Direct Mail:</u>				
Physician Direct Mail Series: Features and Benefits (3 waves)	New	25,000	\$215,000	A three-wave, three-dimensional mailing to high-prescribing opioid physicians explaining the unique features and benefits of OxyContin.
RN Direct Mail Series: Features Benefits (3 waves)	New	25,000	\$150,000	A three-wave mailing to all members of the Oncology Nursing Society explaining the unique features and benefits of OxyContin.
<u>Journal Advertising:</u>				
Journal Advertising	New	N/A	\$187,500	Budget used to advertise OxyContin in journals.

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PP 00061

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>THIRD QUARTER</b>				
<u>Promotional Material:</u>				
File Card (reorder remove the word new)	New	150,000	\$55,000	Reorder of the OxyContin file card removing the word "new" from the headline and logo per FDA regulations.
Slim Jim	New	100,000	\$170,000	Reduced version of the OxyContin retained visual in slim jim size for reps to use in a stand-up selling situation and as a leave-behind piece.
Side Effect Management Slim Jim	New	100,000	\$95,000	Handy reference guide for physicians and nurses to use when treating opioid side effects. This piece will emphasize the aggressive and prophylactic treatment of side effects caused by all opioids.

1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
THIRD QUARTER cont.				
<u>Promotional Materials cont:</u>				
PAP Assessment Scale	New	30,000	\$75,000	A pain assessment scale incorporating the faces of pain visual analog and 0-10 scales onto one standardized piece. This will be a "Partners Against Pain" value-added service tool.
PAP Assessment Record Form	New	30,000	\$60,000	A form for progress notes in patient charts. This form will help physicians identify and document the reason for giving an opioid to avoid any complications with the DEA for prescribing a Class II narcotic. This will be a value-added service tool through "Partners Against Pain."

PP 00063

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1996 PROMOTIONAL PLAN BY QUARTER

2-10

OXYCONTIN™

<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
THIRD QUARTER cont.				
<u>Promotional Materials cont:</u>				
Case Studies Brochure	New	50,000	\$50,000	A brochure presenting patient case studies in both malignant and non-malignant pain describing the benefits of OxyContin therapy.
"Start with Stay With" Premium	New	36,000	\$75,000	A premium reminder item to position OxyContin as the opioid to start with and stay with for the treatment of moderate to severe pain.
Case Manager Video	New	10,000	\$100,000	An educational videotape designed to teach case managers at managed care organizations the most appropriate pain management techniques.
<u>Journal Advertising:</u>				
Journal Advertising	New	N/A	\$187,500	Budget used to advertise OxyContin in journals.

PP 00064

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1996 PROMOTIONAL PLAN BY QUARTER

OXYCONTIN™

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<u>ITEM</u>	<u>NEW OR REPEAT</u>	<u>NO. OF PIECES</u>	<u>COST (EST.)</u>	<u>USAGE</u>
<b>FOURTH QUARTER</b>				
<u>Promotional Material:</u>				
Life Style Detailer	New	TBD	\$50,000	A sales aid demonstrating the quality of life benefits that OxyContin offers to patients through its q12h dosing schedule. The "Cups" campaign will be incorporated into this visual aid.
PAP Professional Newsletter	New	40,000/Qtr	\$180,000	A newsletter for health care professionals updating them on the latest advances in pain management. This newsletter will be geared as an educational tool to teach them the most appropriate ways to manage pain.
<u>Journal Advertising:</u>				
Journal Advertising	New	N/A	\$187,500	Budget used to advertise OxyContin in journals.

PP 00065

