# **Xyrem Prescription and Distribution Process**

Video Script 2/2/01)

#### Audio

1. [Fade in music]

[Up music.]

Video Graphic texture of oranges and yellows

logo of Xyrem emerges

### Titles

Fade in first title/logo graphic.

Xyrem<sup>®</sup> (Sodium **Oxybate**) Oral Solution

Fade out first title/logo graphic. Fade in video title.

**Prescription and** Distribution Process

2. Narcolepsy, it is a serious debilitating condition that diminishes the quality of life for approximately 125,000 Americans.

Fade to head-to chest shot of narrator.

3. Xyrem is a promising new medication that, for some patients with narcolepsy, can significantly reduce the incidence of cataplexy, as well as improve symptoms of daytime sleepiness.

Fade to table-top shot of Xyrem box and a display of its contents.

Fade back to shot of narrator sitting on desk.

- 4. But, because Xyrem is a controlled substance, Orphan
  - Medical wants to make certain that "only" patients for whom it is prescribed have ongoing access to this important treatment.

DOCKE.

RM

[Fade out music.]

- 5. Orphan Medical is committed to a distribution plan that is both safe and effective for patients and also protects the general public by minimizing opportunities for the diversion of Xyrem to unauthorized individuals.
- 6. To achieve that goal, Orphan Medical--after extensive consultation with law enforcement, prosecutors, field law enforcement personnel, pharmaceutical distribution experts, forensic experts, DEA consultants, and drug diversion experts-- has developed a comprehensive, restrictive distribution program.

- In addition to thorough patient and physician education about Xyrem,
- 8. As well as multiple security checks before, during and after prescription fulfillment.

DOCKE.

RM

Fade to shot of Orphan representative making a presentation about success plans—perhaps pointing to a bullet point on an overhead screen.

Fade to build graphic that begins with shot of Xyrem box in center of screen. Fade in titles as mentioned.

- law enforcement
- prosecutors
- field law enforcement personnel
- pharmaceutical distribution experts
- forensic experts
- DEA consultants
- drug diversion experts

Fade to shot of narrator holding up a variety of patient/physician education material and, then, setting it down on the desk.

Cut to split-screen shot showing a) pharmacist assistant verifying doctor's license b) pharmacist unlocking cabinet, c) patient signing for delivery by Federal Express.

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

9. The purpose of this video is to outline, step-by-step, all of the security measures that will occur whenever a prescription of Xyrem is written and filled.

10.

DOCKET

RM

When Xyrem first becomes available, a select group of physicians with a documented history of prescribing medications for patients with narcolepsy will receive an educational module, in the mail, called the Physician Success Program.

11. This program will introduce these selected physicians to Xyrem and includes a videotape, Physician Success Program contact information, a patient education presentation, templates for medical records and patient contracts, and information about third-party payor reimbursement.

This mailing will be documented and no medication samples will ever be provided. Cut back to narrator.

Fade to freeze-frame shot of a physician consulting with a patient.

Fade to table-top display of

Physician Success Program

Begin action

materials.

Fade in title with freeze frame.

Notify A Select Group of Physicians about Xyrem®

Fade out title

Fade in titles when mentioned in narration.

- Documented mailing
- No physician samples

3

12. Complementing this effort, a representative from Orphan Medical will visit each targeted physician and reinforce the information provided in the Physician Success Program.

The representative will ask the physician to sign a receipt if any additional Physician Success Program materials are left for the physician's office.

13.

DOCKE

RM

A crucial component of the secure distribution of Xyrem is the use of a specialty pharmacy. The specialty pharmacy is a single, centrally-located facility that will have a variety of distribution, documentation, and security responsibilities.

14. A staff of dedicated pharmacists, reimbursement specialists, and customer service representatives will provide a closed-loop distribution system that will not only serve patients and prescribers, but will also be able to generate data, recording prescribers, patients and dosing that could provide information for any possible investigations and prosecutions for state and federal authorities. Fade to shot of rep and physician meeting and discussing Physician Success Program materials.

Fade in title

#### Specialty Pharmacy

Fade out title.

Fade in narrator

Fade to shot of pharmasist

Fade to shot of pharmacy employee unlocking holding warehouse to reveal Xyrem supply.	
	Fade in benefit title.
	Secure inventory storage
Cut to shot of pharmacy employees transferring inventory.	
Slow fades shot of a) pharmacy personnel signing some transaction documentation b) Orphan personnel at computer screen documenting the same.	
Fade to shot of narrator.	
Fade to shot of physician in the office using Orphan Medical's materials to educate a patient about Xyrem.	
Fade to shot of physician faxing prescription.	
	<ul> <li>employee unlocking holding warehouse to reveal Xyrem supply.</li> <li>Cut to shot of pharmacy employees transferring inventory.</li> <li>Slow fades shot of a) pharmacy personnel signing some transaction documentation b) Orphan personnel at computer screen documenting the same.</li> <li>Fade to shot of narrator.</li> <li>Fade to shot of physician in the office using Orphan Medical's materials to educate a patient about Xyrem.</li> <li>Fade to shot of physician</li> </ul>

# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

# **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

# API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.