Joint Meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committees

Acurox®

(oxycodone HCl and niacin)

Tablets

April 22, 2010

King Pharmaceuticals

Acura PHARMACEUTICALS, INC. *Abuse Deterrent Products*

Introduction

Eric Carter, Ph.D., M.D.
Chief Science Officer
King Pharmaceuticals, Inc.

Opioid Abuse Liability and Acurox®

Acurox® is the first product designed to introduce limits and impediments to the oral, nasal, and injectable abuse associated with immediate release opioids

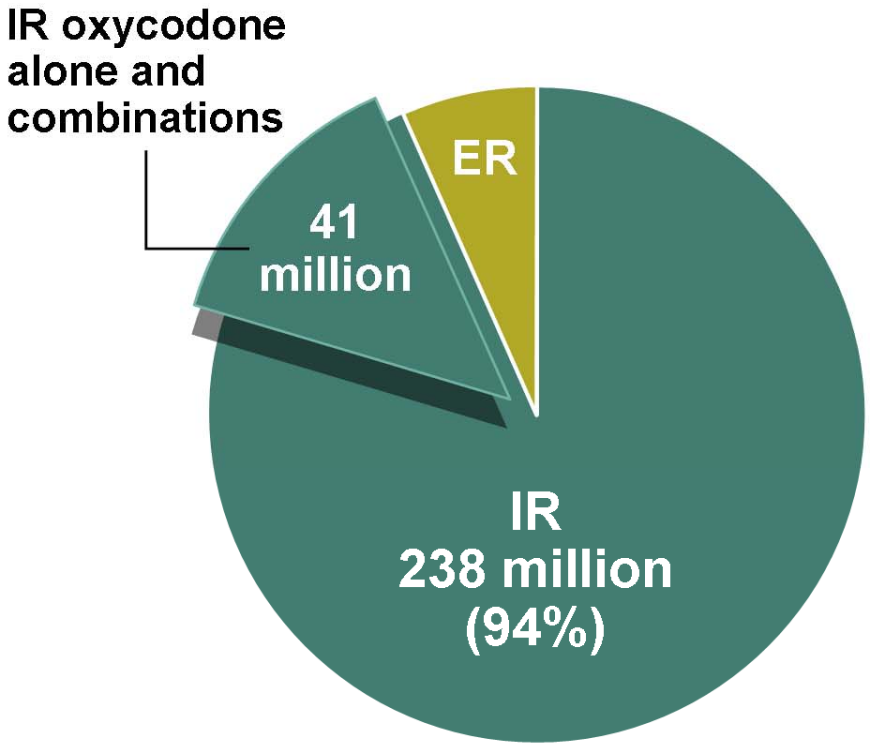
Non-medical Use of Prescription Opioid Analgesics

- Medical value of opioid analgesics long-recognized
- Non-medical use a growing and significant societal issue
  - 35 million people; >10% of U.S. population*
  - 250,000 emergency room visits per year**
  - 85,000 admissions per year to substance-abuse treatment**
- >13,000 fatal overdoses involving an opioid in 2006***
  - Over three-fold increase since 1999
- Societal cost of abuse ~$50 Billion annually†

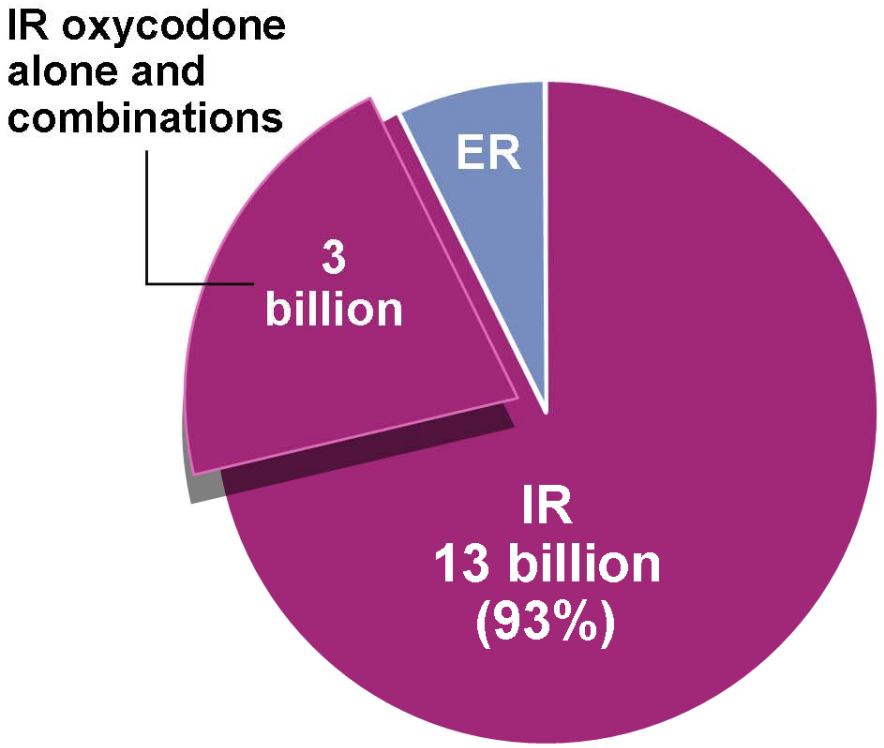
*SAMHSA (2009). Results from the 2008 National Survey on Drug Use and Health: National Findings. NSDUH Series H-36, HHS Publication No. SMA 09-4434.
**SAMHSA (2008). Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits. DAWN Series D 30, DHHS Publication No. (SMA) 08-4339.
***Warner M, Chen LH, Makuc DM. Increase in fatal poisonings involving opioid analgesics in the United States, 1999-2006. NCHS Data Brief. 2009 Sep;(22):1-8.
†Data on File; White AG, et al. Societal costs of opioid abuse, dependence, and misuse in the United States (October 2009); King Pharmaceuticals®, Inc.

Immediate Release (IR) and Extended Release (ER)
Opioid Analgesic Prescriptions

Prescriptions
254 million dispensed



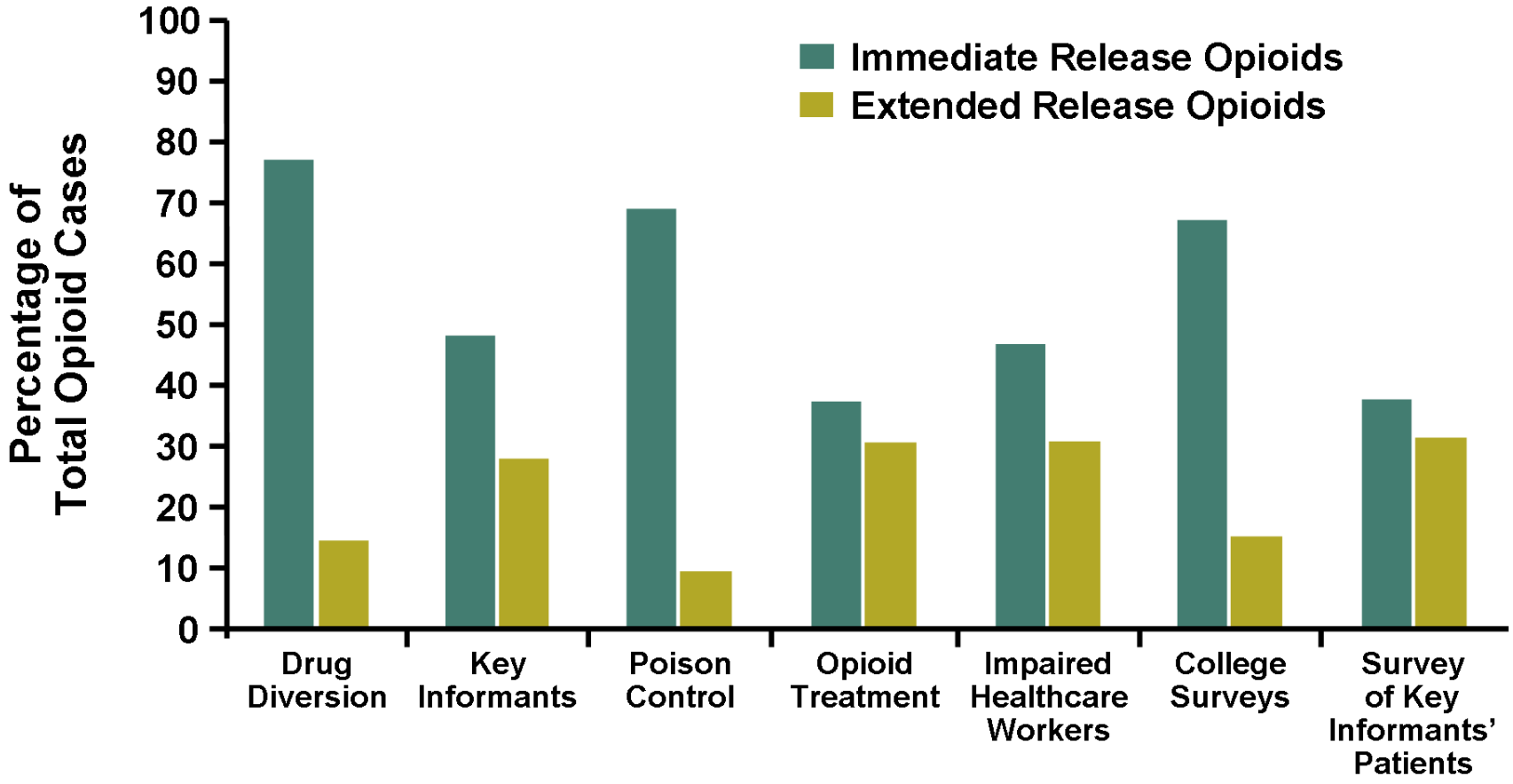
Tablets/Capsules
14 billion dispensed



IMS Health, National Prescription Audit, 2009

RADARS®

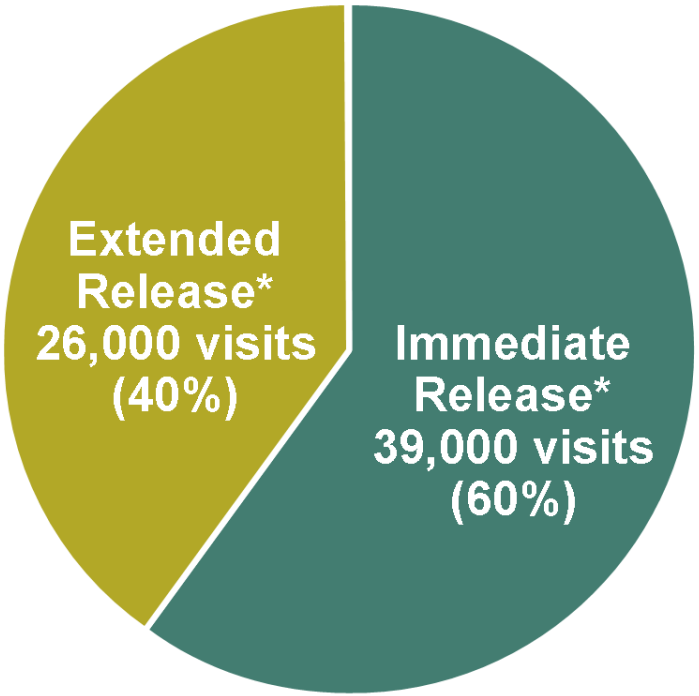
Researched Abuse, Diversion, and Addiction-Related Surveillance



RADARS® System News. Second Quarter 2009; Volume 4, Issue 2.

Oxycodone Emergency Room Visits (2006)

65,000 annual oxycodone-related emergency department visits



*Includes combination products.

Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits. DAWN Series D-30, DHHS Publication No. (SMA) 08-4339, Rockville, MD, 2008.

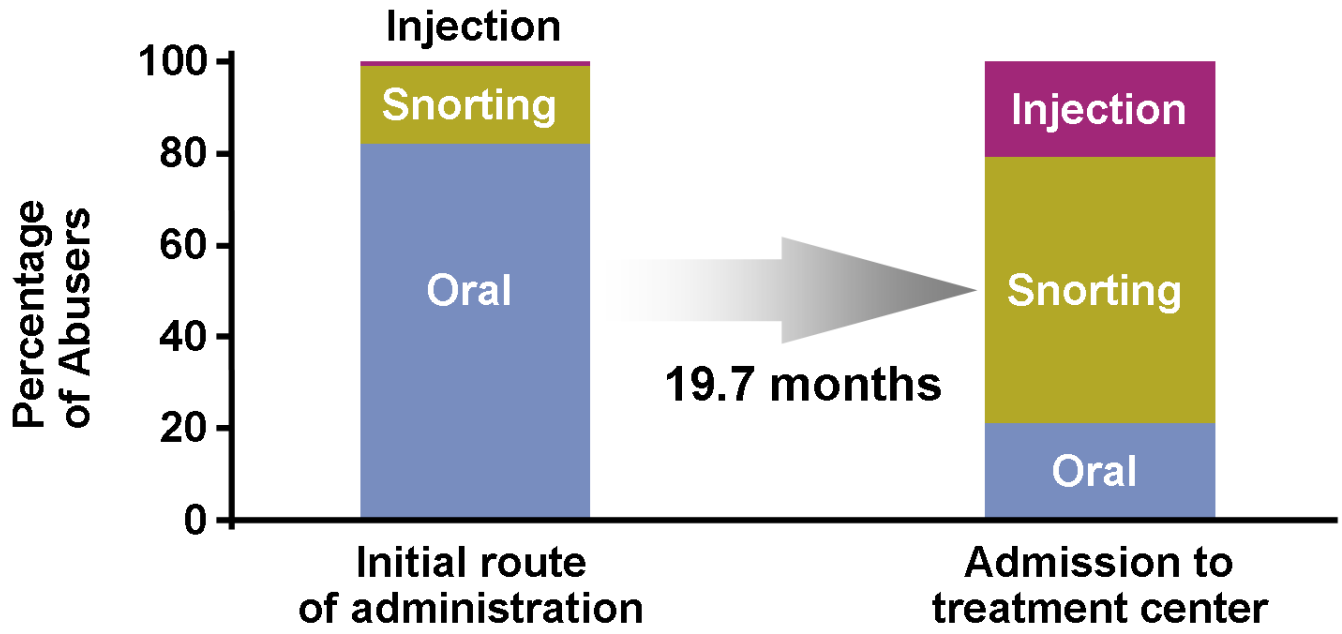
Availability and Consequences of IR Opioid Abuse and Misuse

- IR non-medical use estimated to be 10 times greater than ER*
  - Dispensed prescriptions
    - IR 15 times greater than ER**
  - Dispensed tablets and capsules
    - IR 13 times greater than ER**

*Derived from SAMHSA Issue 22, 2006.
**IMS Health, National Prescription Audit, 2009.

Abusers Progress from Oral Ingestion to Snorting/Injecting

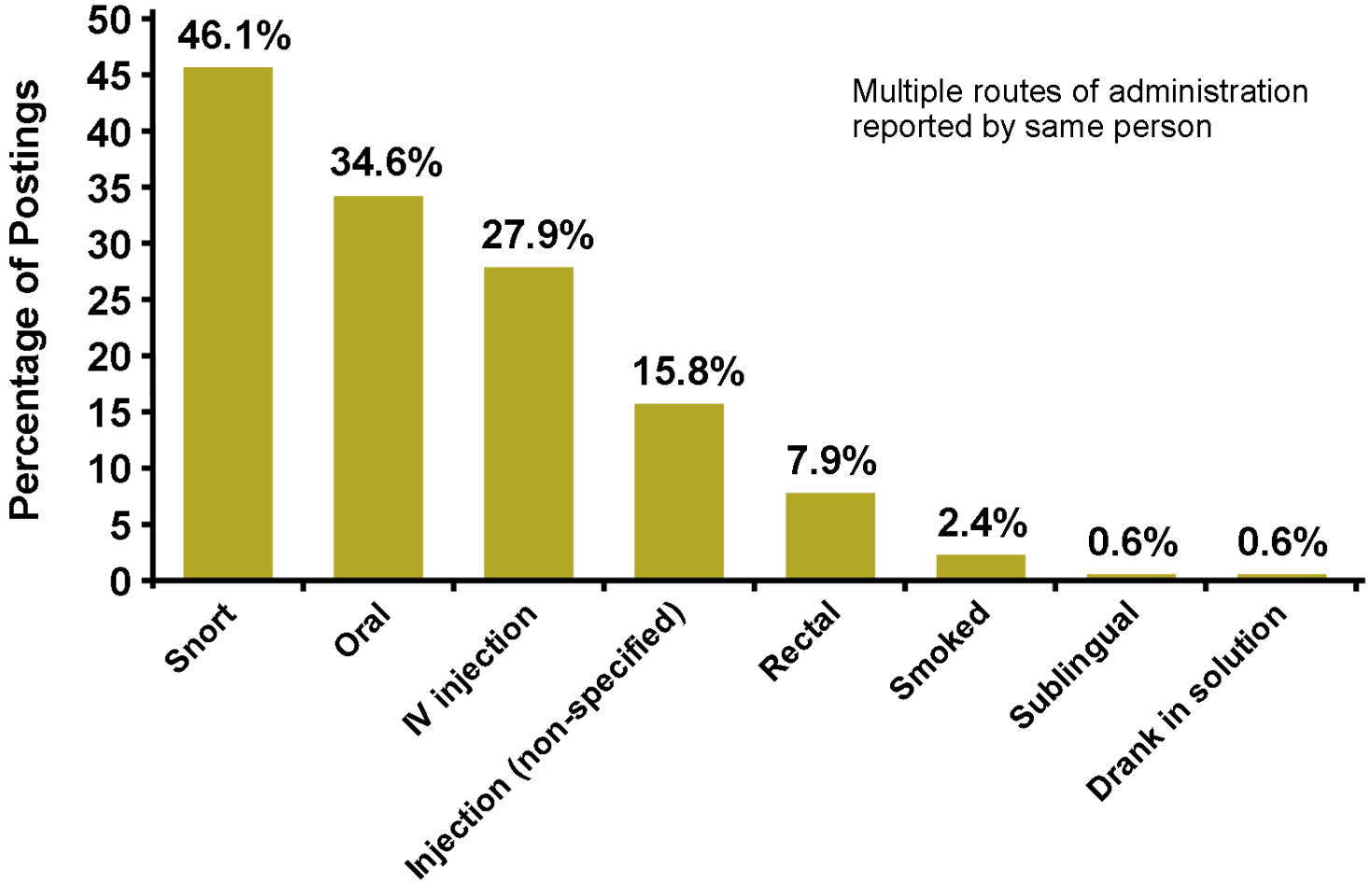
- Oral swallowing of excess quantities
- Nasal snorting
- Intravenous injection



Hays L, Kirsh KL, Passik SD. J Natl Compr Canc Netw. 2003;1(3):423-8.

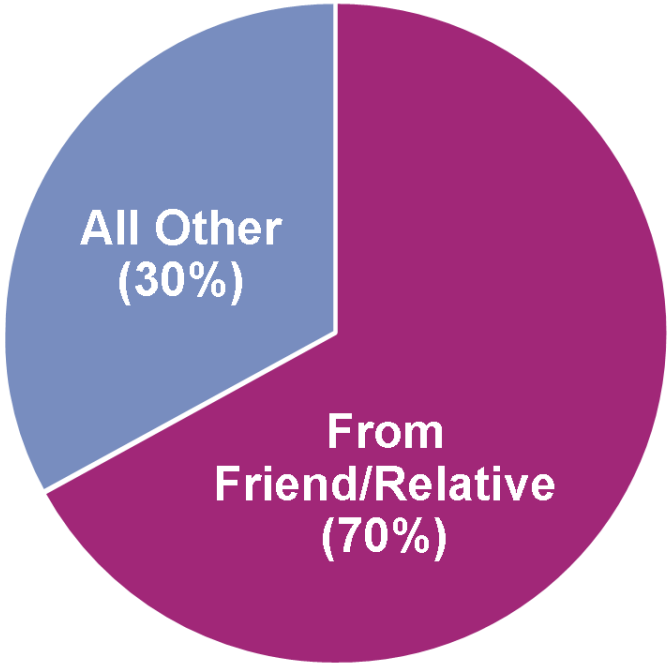
Internet Monitoring of IR Oxycodone Tablets

Routes of Administration (n = 165)



National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO™) – Internet Monitoring – Analysis of Web Informed Services (WIS™) Data for August 1, 2009 – January 31, 2010; Prepared for: King Pharmaceuticals®, by Inflexxion, Inc.

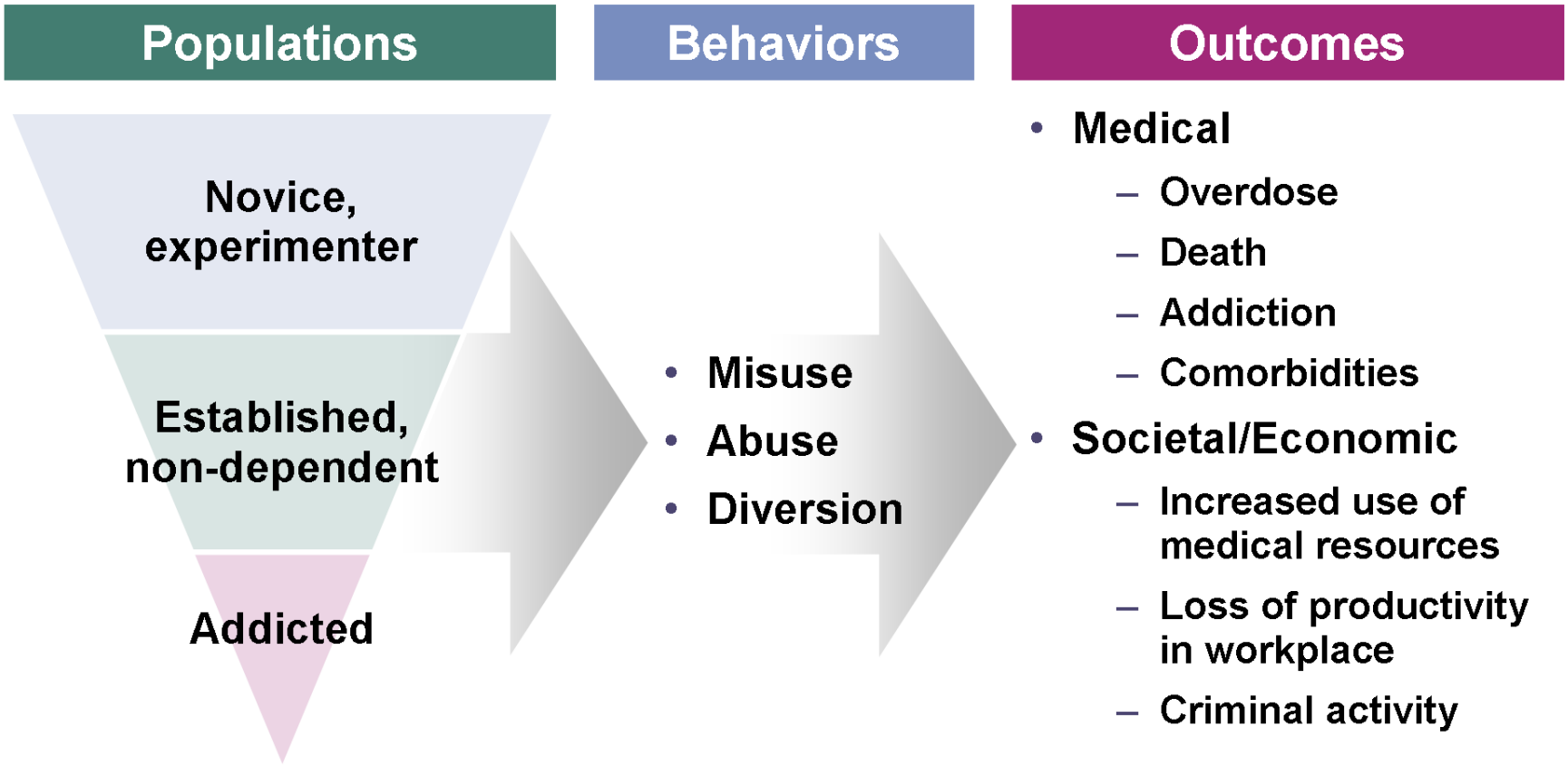
Source of Abused Painkillers



- Majority of abused painkillers diverted from legitimate prescriptions
- Friends/relatives are major source of diversion

SAMHSA (2009). Results from the 2008 National Survey on Drug Use and Health: National Findings. NSDUH Series H-36, HHS Publication No. SMA 09-4434.

Medical, Societal, and Economic Outcomes Associated with Misuse, Abuse, and Diversion of Opioids



FDA Goal

"Strike the Right Balance"

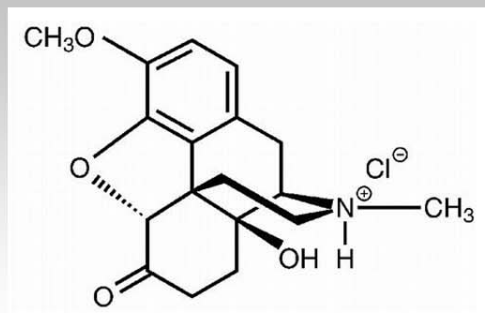
"We at the Food and Drug Administration (FDA) have been engaging physicians, pharmacy groups, patients, and other stakeholders in an ongoing effort to ***strike the right balance*** *between two important goals: on the one hand, providing access to pain medications for those who need them, and on the other hand, managing the variety of risks posed by analgesic drugs."*

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
A Difficult Balance – Pain Management, Drug Safety, and the FDA.
N Engl J Med. 2009 Nov 26;361(22):2105-7

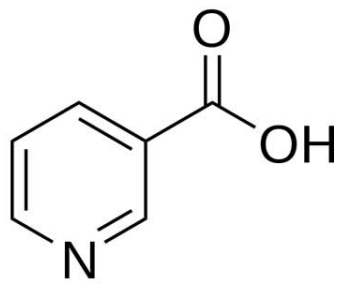
Acurox® Tablets
IR Combination Product

- Two active ingredients and a mixture of inactive ingredients

Oxycodone HCl



Niacin



- Well tolerated at proposed doses for treating pain
- Disliked when taken orally in excess to get high
- Disliked when snorted
- Designed to be difficult to administer intravenously
- Proposed dose – depends on severity of pain
  - 1 or 2 x Acurox® (oxycodone HCl/niacin) Tablets 5/30 mg q6h
  - 1 or 2 x Acurox® (oxycodone HCl/niacin) Tablets 7.5/30 mg q6h

Combination Drug Rule
21 CFR 300.50(a)

Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. **Special cases of this general rule are where a component is added:**

1. To enhance the safety or effectiveness of the principal active component; and
2. **To minimize the potential for abuse of the principal active component**

Populations Potentially Benefiting from Acurox®
Intended Patients and Unintended Populations

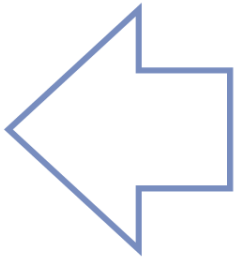
Intended Patients

Proposed Indication

- Relief of moderate-to-severe pain where use of an immediate release orally administered opioid analgesic tablet is appropriate

Limitations to use

- Should not be prescribed when dose escalation above proposed doses is anticipated



Recommended Dose

Up to 2 tablets every 6 hours. Equivalent to a maximum of 15 mg oxycodone and 60 mg niacin per dose.

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Unintended Populations

Pain Patients (Potential Misusers)

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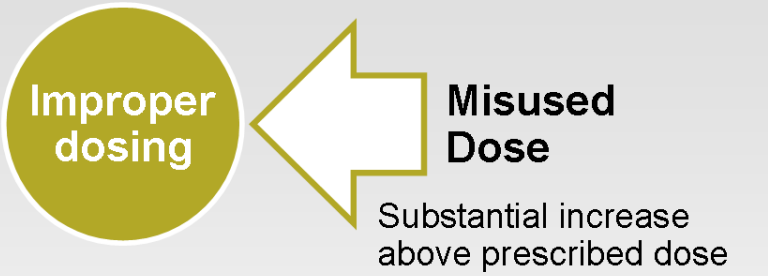
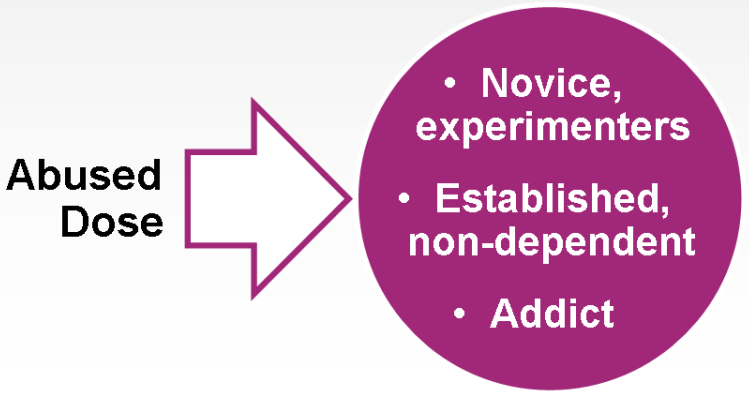
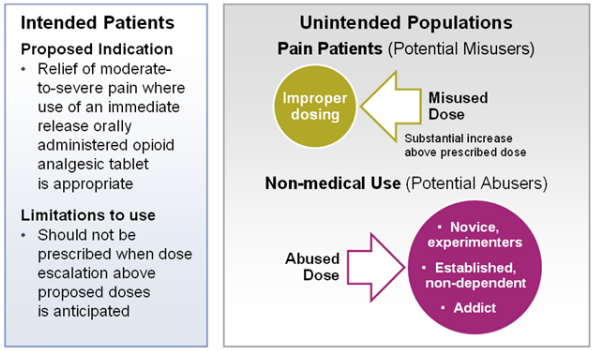


Non-medical Use (Potential Abusers)



Populations Potentially Benefiting from Acurox®
Intended Patients and Unintended Populations

- Acurox® would be anticipated to provide an incremental benefit by introducing limits and impediments to
  - Oral abuse: Disliking effects of niacin
  - Snorting: Irritant effects of excipients
  - Injection: Difficulty of extraction and IV administration
- Goal: Help decrease progression from occasional oral use towards addiction



Acurox® Tablets
Human Abuse Liability Studies

- Four studies conducted
  - Study 102: Oral niacin dose-ranging study
  - Study 111: First oral definitive study
  - Study 106: Nasal ‘snorting’ study
  - Study 114: Second oral definitive study

Opioid Abuse Liability and Acurox®

Acurox® is the first product designed to introduce limits and impediments to the oral, nasal, and injectable abuse associated with immediate release opioids

Sponsor Presentation

• Acurox® Development Program: Focus on Niacin	Kenneth Sommerville, M.D., FAAN Vice President, Clinical Development King Pharmaceuticals, Inc. Adjunct Assistant Professor of Medicine Duke University
• Clinical Abuse Liability Studies	Lynn R. Webster, M.D., FACPM, FASAM Medical Director Lifetree Clinical Research® and Pain Clinic
• Concluding Remarks	Eric Carter, Ph.D., M.D. Chief Science Officer King Pharmaceuticals, Inc.

Acurox® Development Program: Focus on Niacin

Kenneth Sommerville, M.D., FAAN

Vice President, Clinical Development
King Pharmaceuticals, Inc.

Adjunct Assistant Professor of Medicine
Duke University

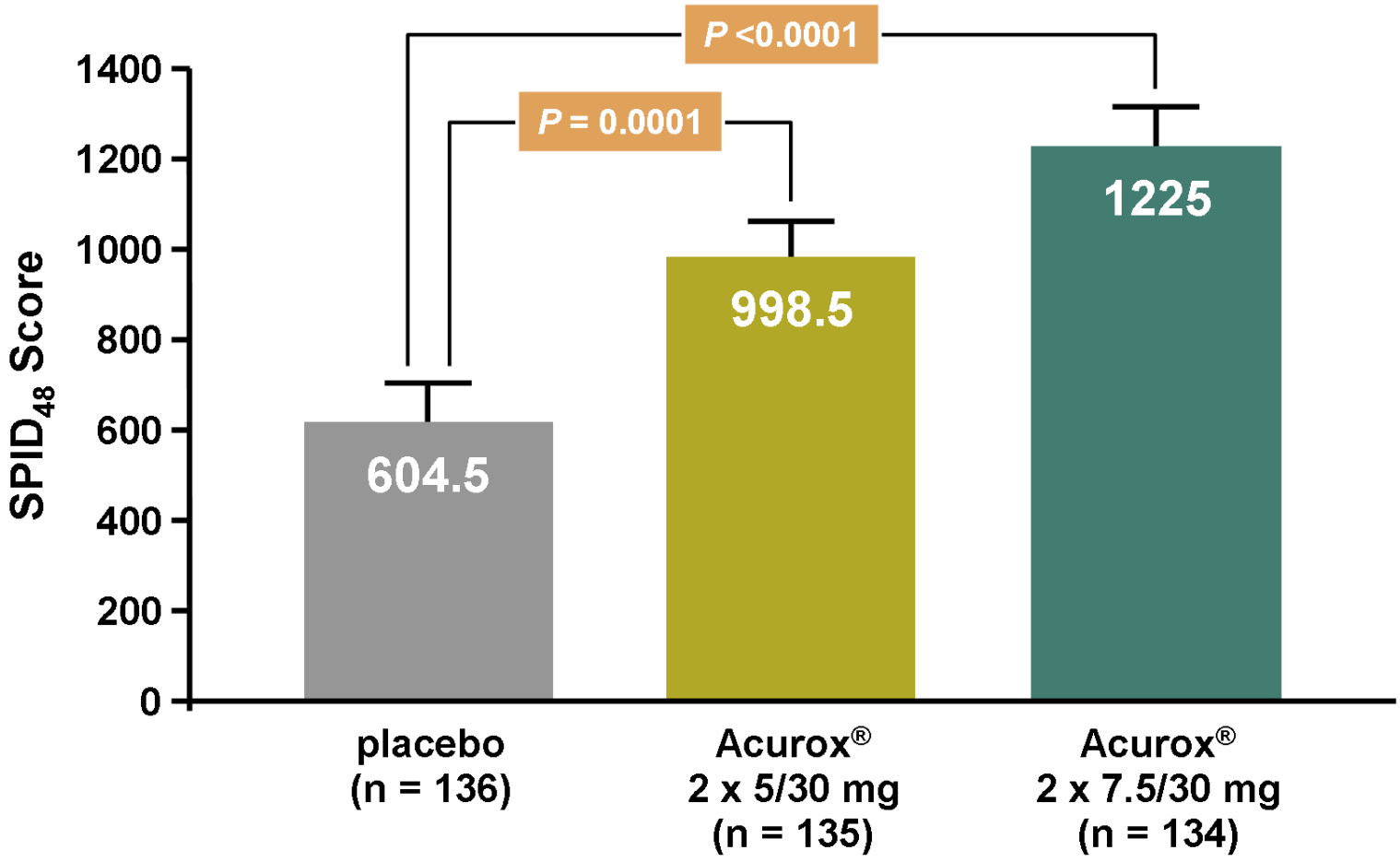
Acurox® Clinical Development Program

Trial type	Study number
Pharmacokinetic and bioequivalence studies in healthy subjects	104, 108, 109
Safety and tolerability studies of niacin alone in healthy subjects	101, 107
Safety and tolerability study of niacin with and without oxycodone in healthy subjects	103
Pivotal safety and efficacy study in patients with moderate-to-severe acute pain	105
Oral abuse liability studies in healthy subjects with a history of recreational opioid abuse	102, 111, 114
Intranasal abuse liability study in healthy subjects with a history of recreational opioid abuse	106
Laboratory studies (syringeability and extraction)	

Acurox® Tablets
Introduces Limits or Impediments to IV Abuse

- Novel mixture of functional inactive ingredients
  - Forms viscous gel if tablets are dissolved
  - Impedes extraction of oxycodone from tablets
  - Limits ability to draw viscous gel into a syringe
  - Functional inactive ingredients are generally recognized as safe

Study 105
Primary Analgesic Efficacy Results



$SPID_{48}$ = Sum of Pain Intensity Difference from 0 to 48 hours

Niacin in Acurox® Tablets

- Background of niacin
- Niacin in Acurox® clinical trials
  - Safety
  - NSAIDs
  - Food

Niacin (Vitamin B_3)

- Essential nutrient for energy metabolism and function of several tissues
- Recommended daily dietary allowance – 16 mg (men) and 14 mg (women)
- Found in nutritional supplements and in fortified cereals
- Rapid absorption from GI tract
- Peak plasma concentration within 1 hour
- Elimination half-life of 20-45 minutes

Niacin-induced Flushing

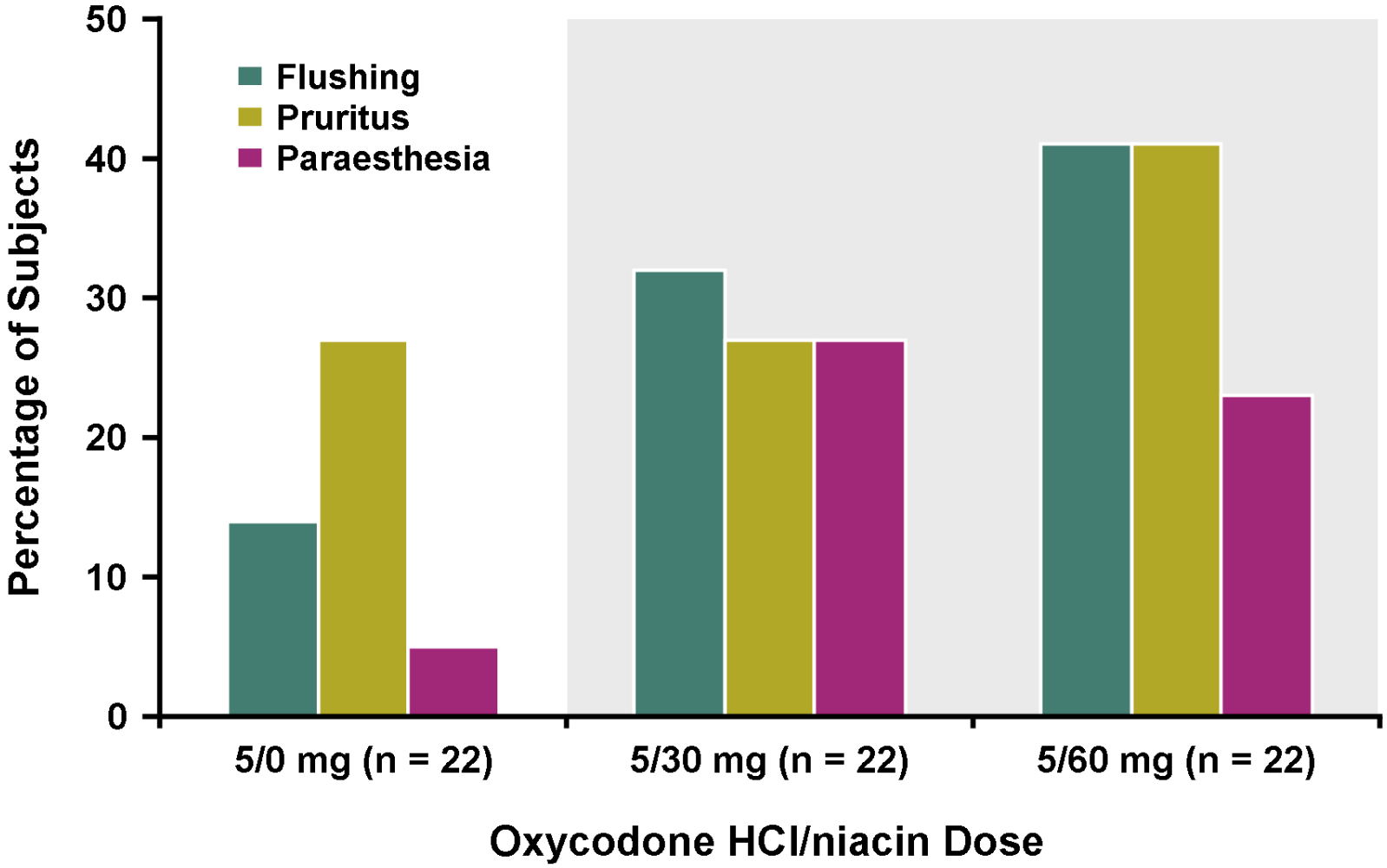
- Dose-related
- Rapid onset
- No clinically relevant effect on blood pressure
- Cutaneous signs and symptoms of redness, itching, tingling, and warmth
- Benign and transient
- Tolerance may develop over time

Niacin for Lipid Disorders

- Extensive clinical experience among millions of patients dosed chronically
- FDA approved products
  - Niacor® (IR niacin)
  - Niaspan® (ER niacin)
- FDA approved daily doses
  - IR 500 – 6,000 mg
  - ER 500 – 2,000 mg

Study 103: Multiple-dose Safety and Tolerability

Subject-reported Incidence of Flushing, Pruritus, and Paraesthesia



Study 105: Pivotal Phase 3

Adverse Events Possibly Related to Niacin in ≥3% of Patients

Adverse Event*	Placebo (N = 136) n (%)	Acurox® 2 x 5/30 mg (N = 135) n (%)	Acurox® 2 x 7.5/30 mg (N = 134) n (%)
Flushing	2 (1.5)	22 (16.3)	15 (11.2)
Pruritus	1 (0.7)	17 (12.6)	13 (9.7)
Pruritus generalized	1 (0.7)	8 (5.9)	10 (7.5)
Paraesthesia	0	4 (3.0)	3 (2.2)
Feeling hot	1 (0.7)	6 (4.4)	5 (3.7)
Hyperhidrosis	0	4 (3.0)	1 (0.7)

*Same patient may report multiple events

Bunionectomy Studies with IR Oxycodone
Incidence of Vomiting

Study	Medication	Dose/Regimen	N	Vomiting incidence
Study 105	Acurox® 5/30 mg	10 mg q6h for 48 hours	135	46 (34%)
Study 105	Acurox® 7.5/30 mg	15 mg q6h for 48 hours	134	67 (50%)
Stegmann et. al.*	IR oxycodone	10 mg q4-6hrs for 72 hours	67	26 (39%)
Daniels et. al**	IR oxycodone	15 mg q4-6hrs for 72 hours	125	52 (42%)
Daniels et. al***	IR oxycodone	10 mg q4-6hrs for 72 hours	279	72 (26%)

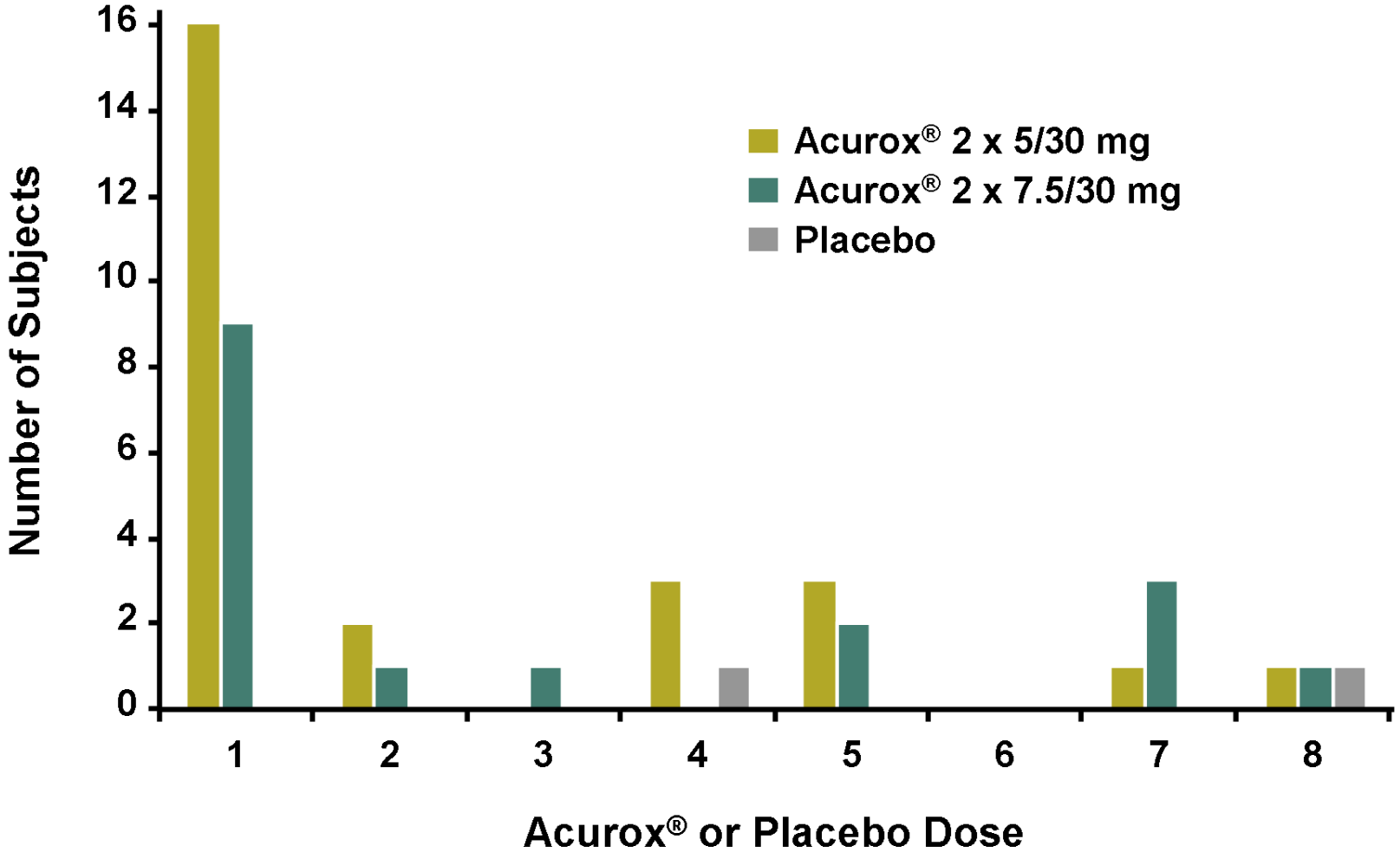
*Stegmann JU, Weber H, Steup A, Okamoto A, Upmalis D, Daniels S. The efficacy and tolerability of multiple-dose tapentadol immediate release for the relief of acute pain following orthopedic (bunionectomy) surgery. Curr Med Res Opin. 2008;24(11):3185-96.

**Daniels SE, Upmalis D, Okamoto A, Lange C, Häeussler J. A randomized, double-blind, phase III study comparing multiple doses of tapentadol IR, oxycodone IR, and placebo for postoperative (bunionectomy) pain. Curr Med Res Opin. 2009;25(3):765-76.

***Daniels S, Casson E, Stegmann JU, Oh C, Okamoto A, Rauschkolb C, Upmalis D. A randomized, double-blind, placebo-controlled phase 3 study of the relative efficacy and tolerability of tapentadol IR and oxycodone IR for acute pain. Curr Med Res Opin. 2009 Jun;25(6):1551-61.

Study 105: Pivotal Phase 3

Number of Patients Flushing by Dose and Time



NSAID Effects

- NSAIDs can potentially mitigate niacin-induced flushing or disliking
  - Literature indicates that mitigation is incomplete and time/dose dependent
  - Mitigation is inconsistent as noted in Niaspan® (ER niacin) Summary Basis of Approval

Jungnickel PW, Maloley PA, Vander Tuin EL, et al. Campbell JR. Effect of two aspirin pretreatment regimens on niacin-induced cutaneous reactions. J Gen Intern Med. 1997 Oct;12(10):591-6.

Whelan AM, Price SO, Fowler SF, Hainer BL. The effect of aspirin on niacin-induced cutaneous reactions. J Fam Pract. 1992;34(2):165-8.

Oberwittler H, Baccara-Dinet M. Clinical evidence for use of acetyl salicylic acid in control of flushing related to nicotinic acid treatment. Int J Clin Pract. 2006;60(6):707-15.

Study 105: Pivotal Phase 3

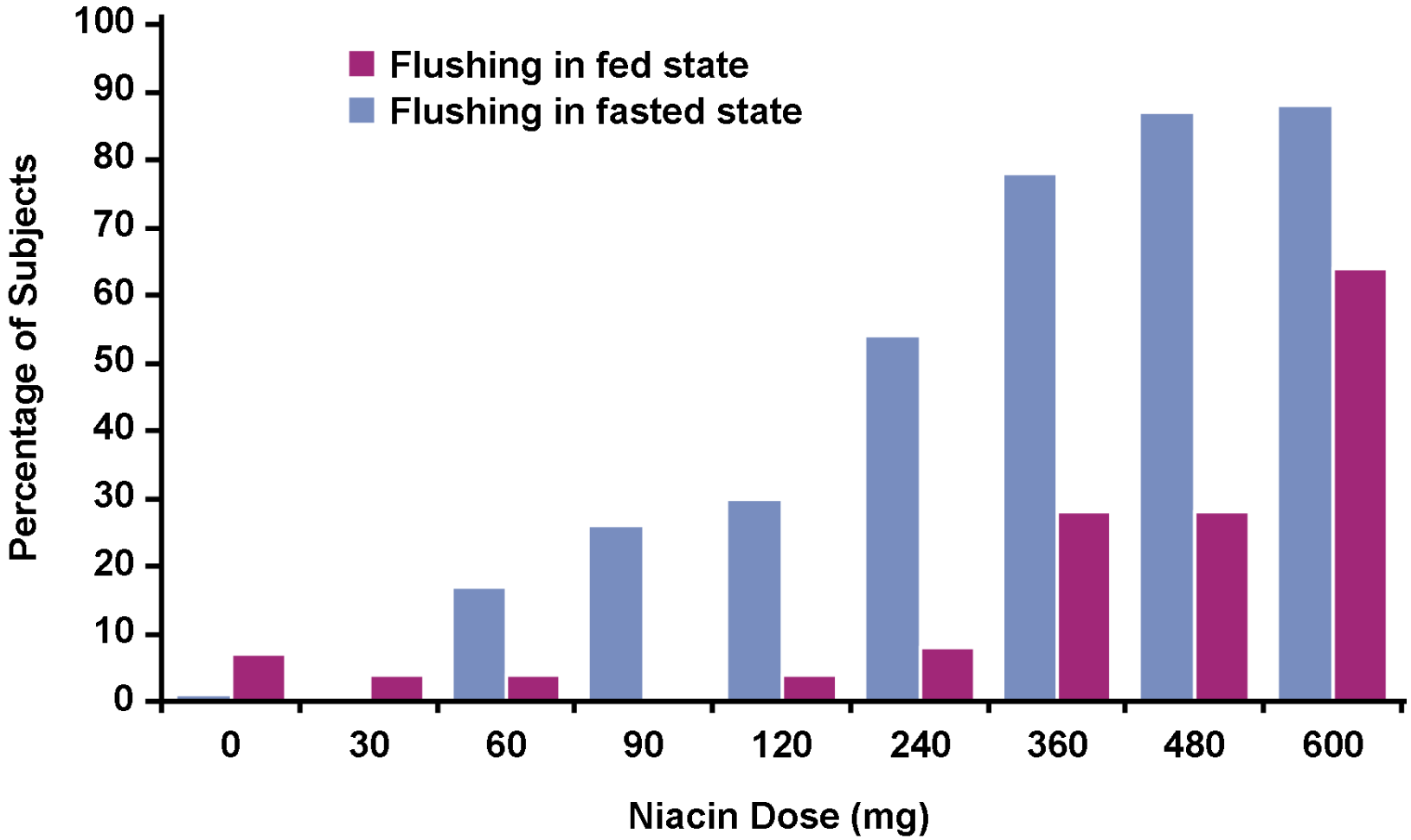
Ketorolac and Flushing – Acurox®-treated Patients

	Flushing	No flushing
Received ketorolac	32/231 (13.9%)	199/231 (86.1%)
No ketorolac	5/38 (13.2%)	33/38 (86.8%)

- Pattern and frequency of IV ketorolac administration similar between patients with flushing and without flushing

Food Effects

Study 107: Niacin Dose-ranging



Food Effects

Pharmacokinetics of Oxycodone in Acurox®

- Delayed time to peak oxycodone ~2 hours
- May delay oxycodone-induced euphoria

Summary of Niacin

- Safe and well-tolerated at proposed doses for Acurox®
- Safety well-documented with high doses
- Flushing
  - Rapid onset
  - Disliked at high doses
  - Unpleasant but benign
- NSAIDs and food have a variable and incomplete effect on niacin

Clinical Abuse Liability Studies

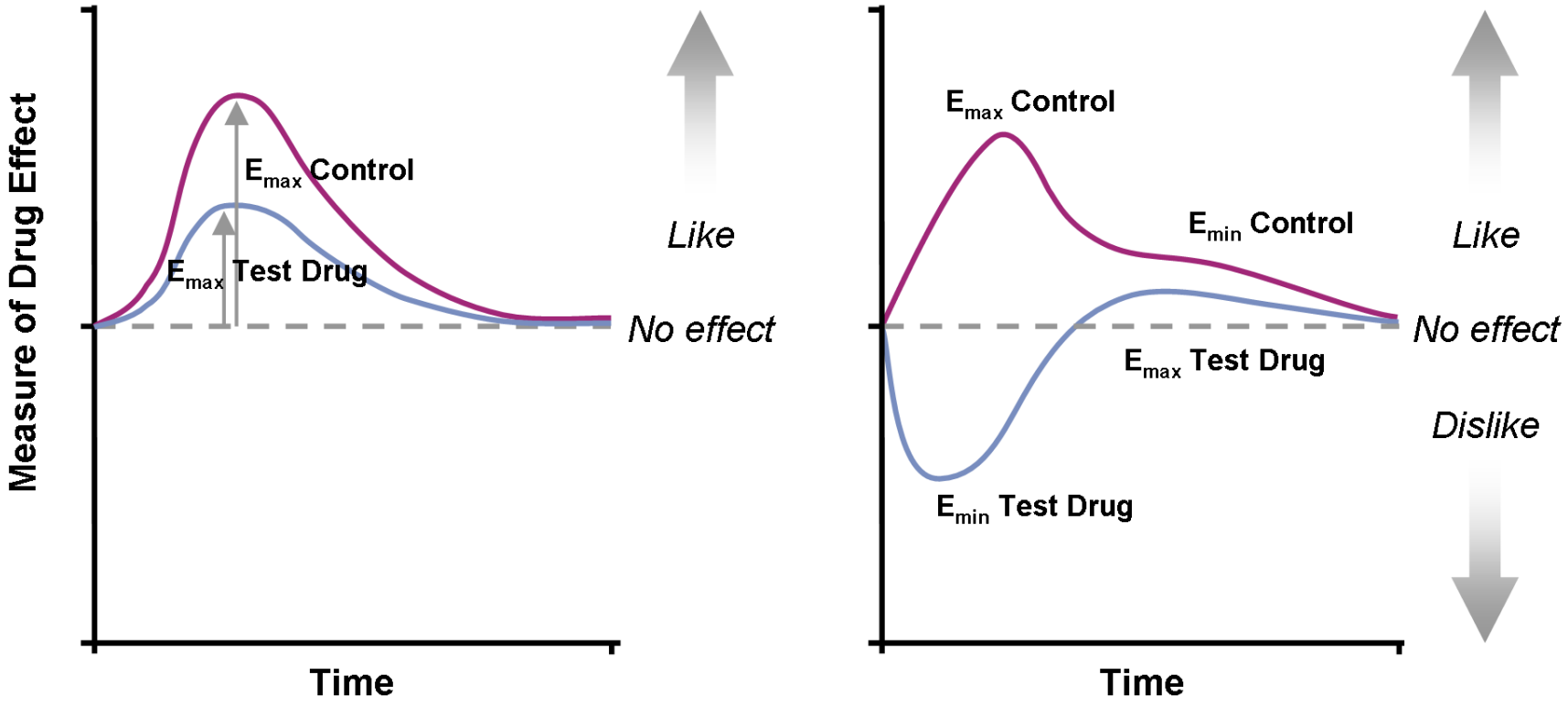
Lynn R. Webster, M.D., FACPM, FASAM

Medical Director
Lifetree Clinical Research® and Pain Clinic

Clinical Studies Evaluating Abuse Liability

- Key elements
  - Controlled, inpatient, clinical research setting
  - Double-blind, placebo- and positive-controlled crossover design
  - Study population of non-dependent recreational drug abusers
- Primary efficacy measures such as
  - Co-primary endpoints: Peak effects and effect over time
  - Subject Visual Analog Scale (VAS) ratings of drug liking/disliking
- Secondary efficacy measures such as
  - Treatment Enjoyment Assessment Question (TEAQ)
  - Take Drug Again Assessment (TDAA)
  - Global Assessment of Overall Drug Liking

Paradigm Shift in the Evaluation of Abuse Liability



E_{min} represents peak disliking

Abuse Liability Studies

Study No.	Description	Subjects randomized	Principal Investigator
106	• Nasal abuse liability	15	Edward Sellers, M.D., Ph.D. Vice President Early Stage, Kendle International
102	• Niacin dose-ranging study • Information for design and methods of subsequent oral studies	25	Donald Jasinski, M.D. Chief of the Center for Chemical Dependency Johns Hopkins Bayview Medical Center, MD
111	• Oral abuse liability with one excess dose	30	Donald Jasinski, M.D.
114	• Oral abuse liability with two excess doses	49	Lynn Webster, M.D. Medical Director Lifetree Clinical Research® and Pain Clinic, UT

Study 106: Nasal Abuse Liability

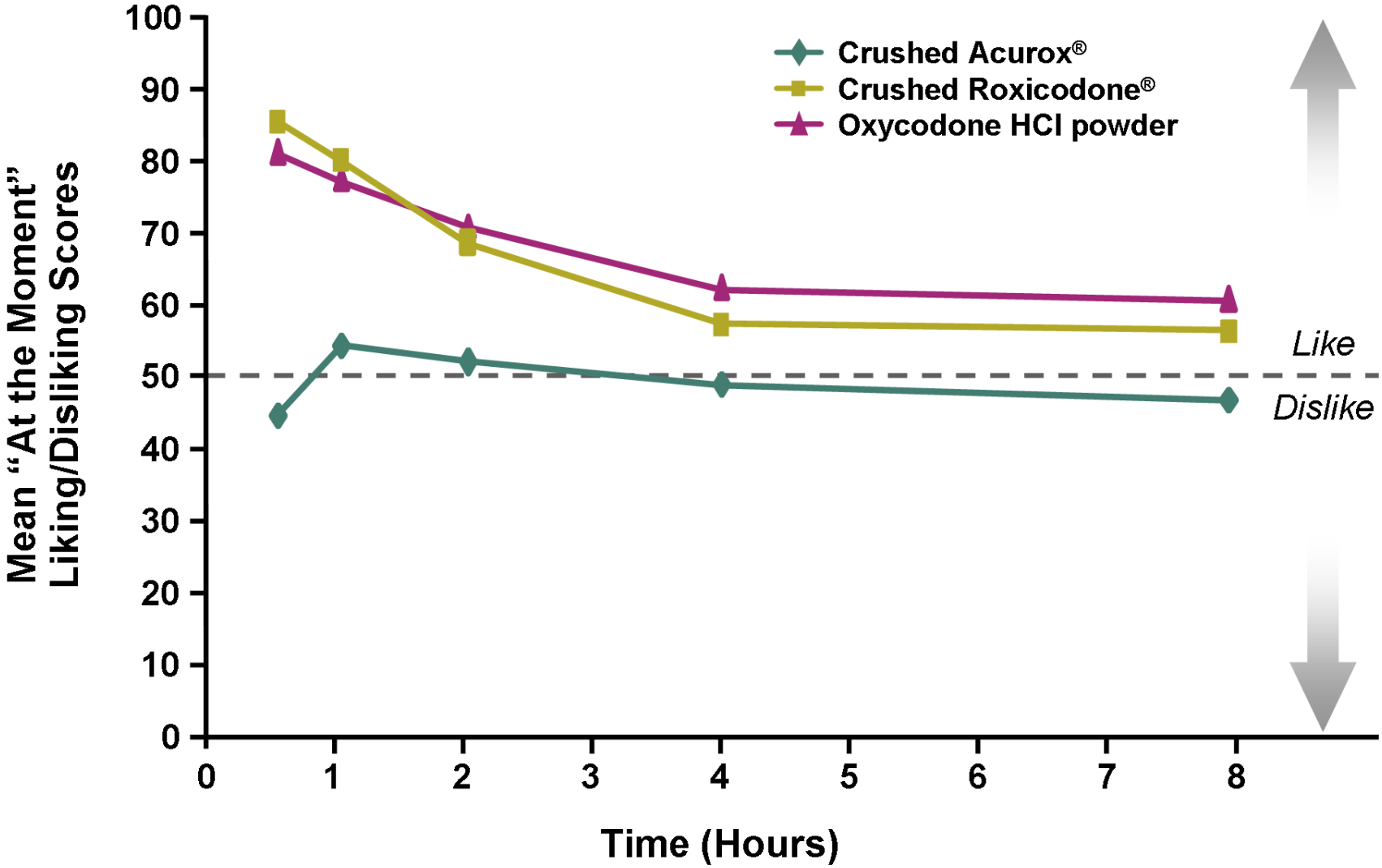
Intranasal doses in random order
(separated by at least 6 days)

Crushed Acurox® Tablets	Crushed Roxicodone® Tablets	Oxycodone HCl Powder
2 x 7.5/30 mg	1 x 15 mg	15 mg

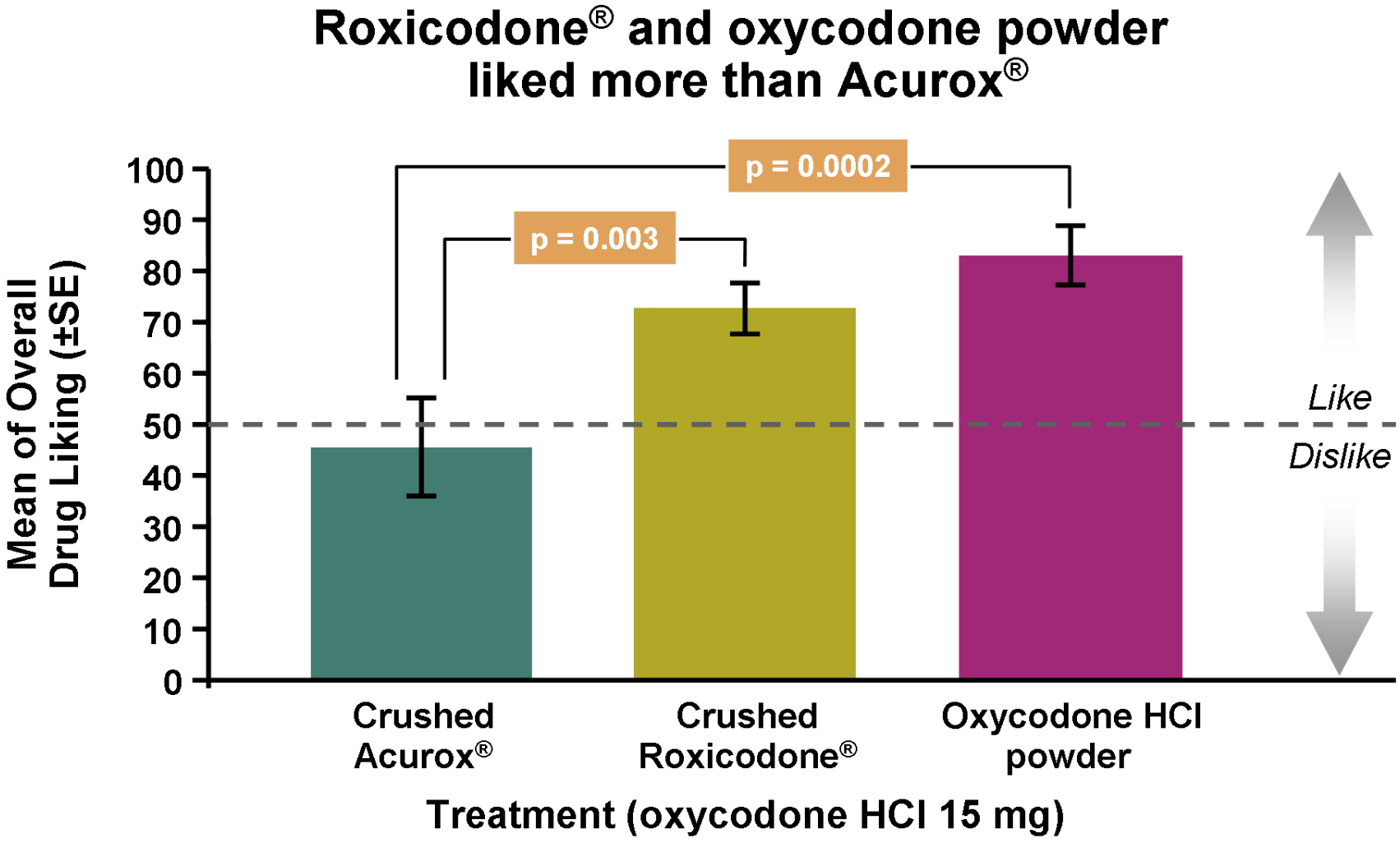
Crossover design

Study 106: Results

"At the Moment" Drug Liking/Disliking

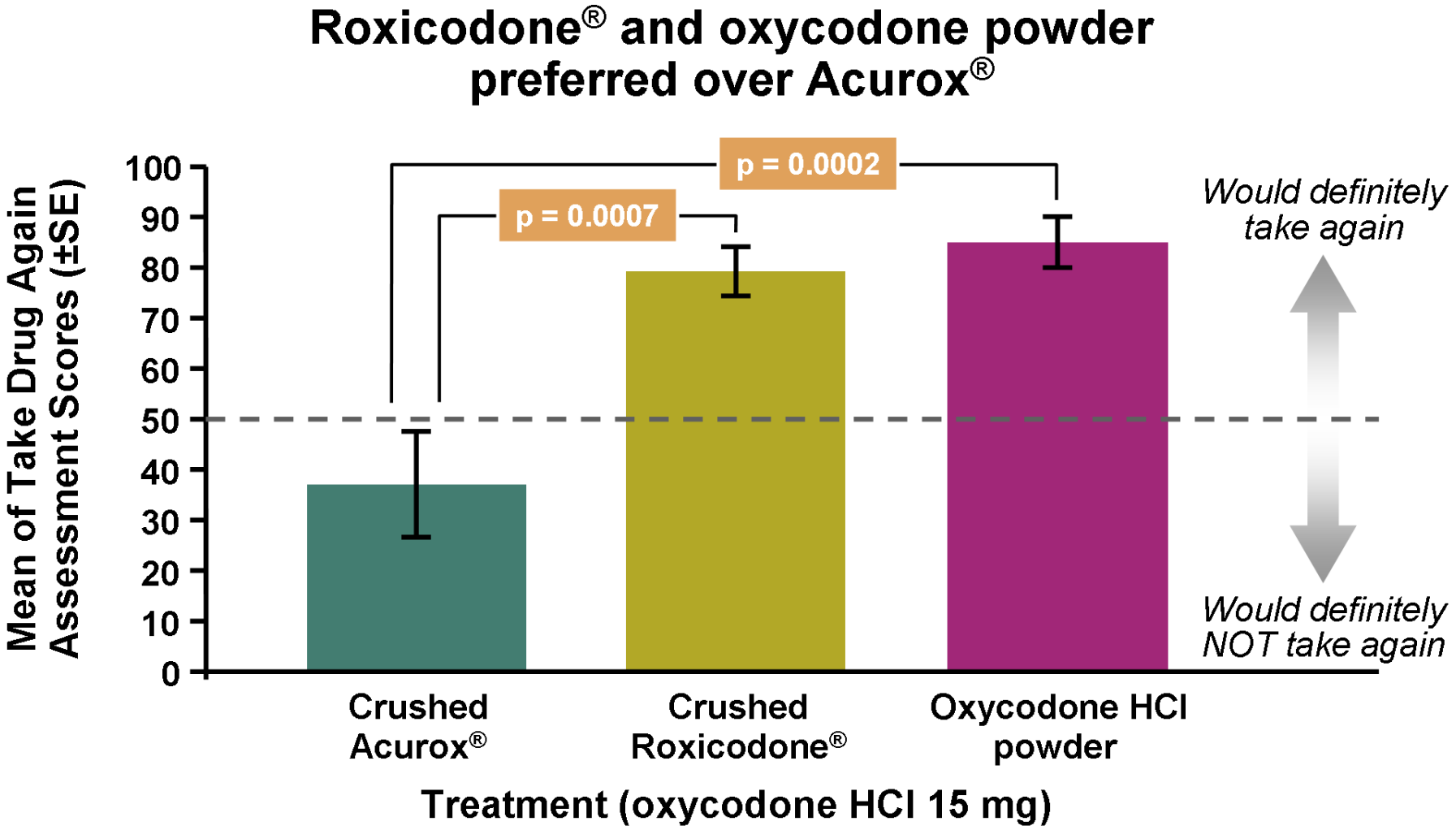


Study 106: Results
Overall Drug Liking



P-values = E_{max} for Acurox® vs. comparator treatments

Study 106: Results
Take Drug Again Assessment



P-values = E_{max} for Acurox® vs. comparator treatments

Oral Abuse Liability Studies 102, 111, and 114
Primary and Secondary Endpoints

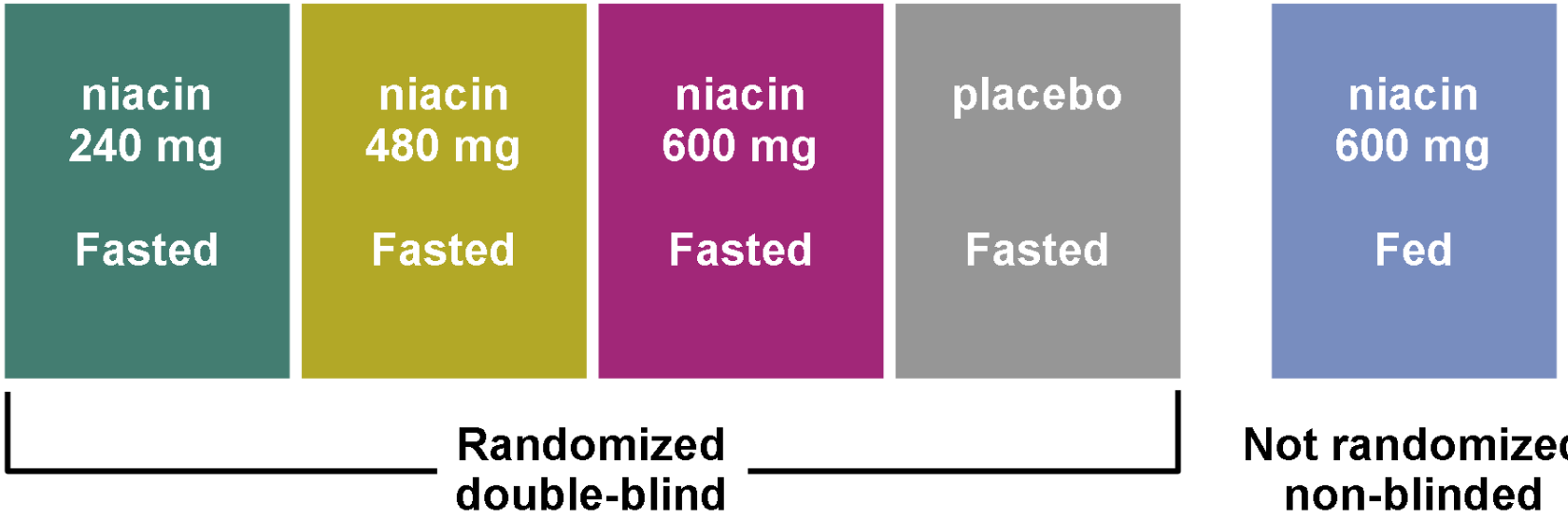
Selected study parameters		Study 102 N = 25	Study 111 N = 30	Study 114 N = 49
Primary endpoints	Drug *disliking* (unipolar scale)	✓		
	Drug *disliking/liking* (bipolar scales)		✓	✓
Secondary endpoints	Treatment Enjoyment Assessment Questionnaire (TEAQ)	✓	✓	
	Take Drug Again Assessment (TDAA)			✓
	Global Assessment of Overall Drug Liking			✓

Oral Abuse Liability Studies 102, 111, and 114
Selected Efficacy Parameters

Parameters		
Primary endpoints	E_{min} and $E_{0.5\ h}$	Peak (immediate) drug liking/disliking
	$AUE_{0\text{-}1\ h,\ 0\text{-}2\ h,\ 0\text{-}3\ h}$	Persistence of drug liking/disliking
Secondary endpoints	Treatment Enjoyment Assessment Questionnaire	Preference vs. IR oxycodone
	Take Drug Again Assessment Response at 1, 2, and 8 hours following drug administration	Preference vs. IR oxycodone
	Global Assessment of Overall Drug Liking Response at 12 hours following drug administration	Overall drug liking experience

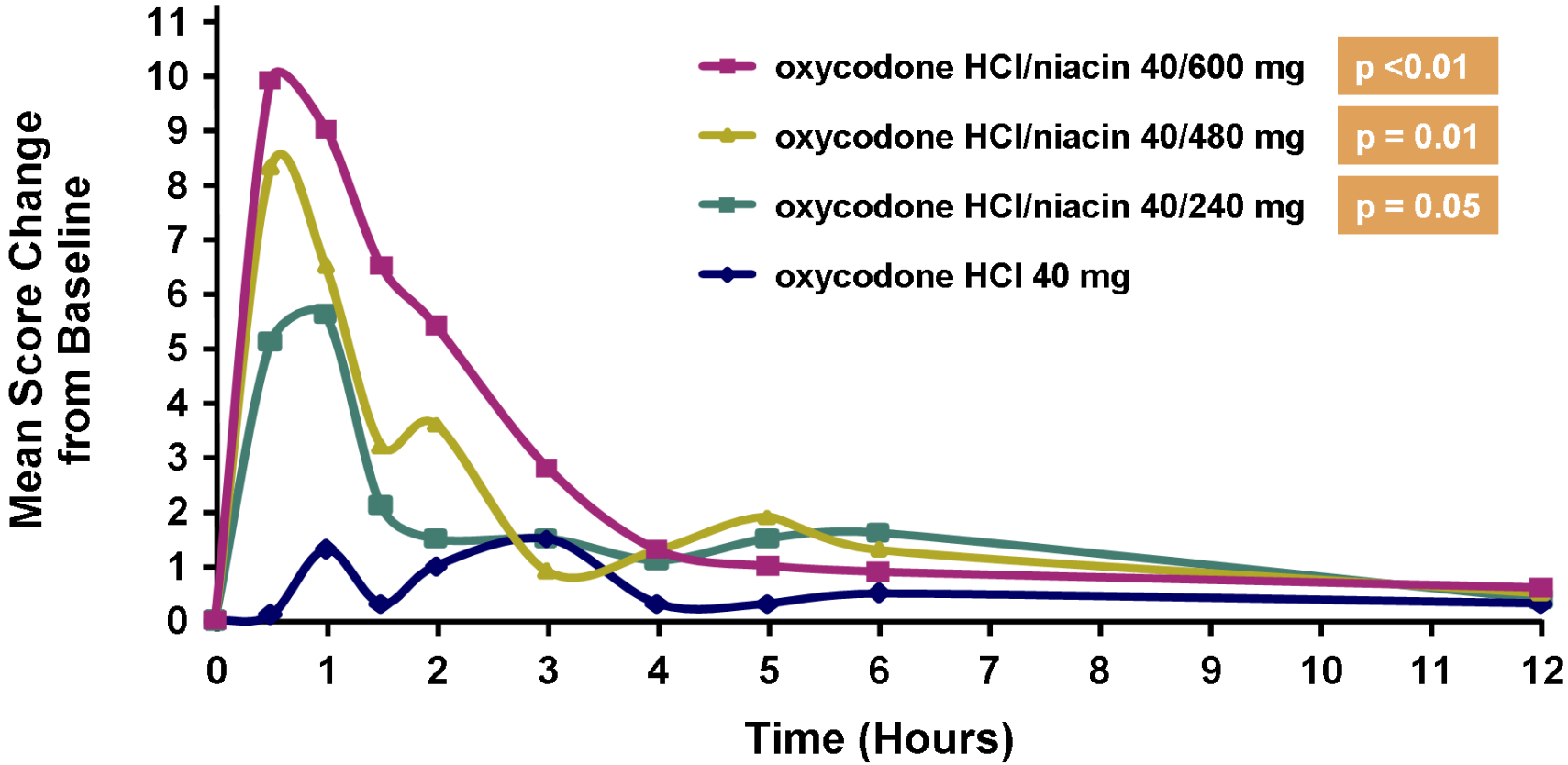
Study 102: Niacin Dose-ranging Abuse Liability
Design

Each subject administered oxycodone HCl 40 mg plus…



Study 102: Niacin Dose-ranging Abuse Liability
Primary Endpoint in Fasted Subjects

"Do You DISLIKE the Drug Effect You Are Feeling Now?"

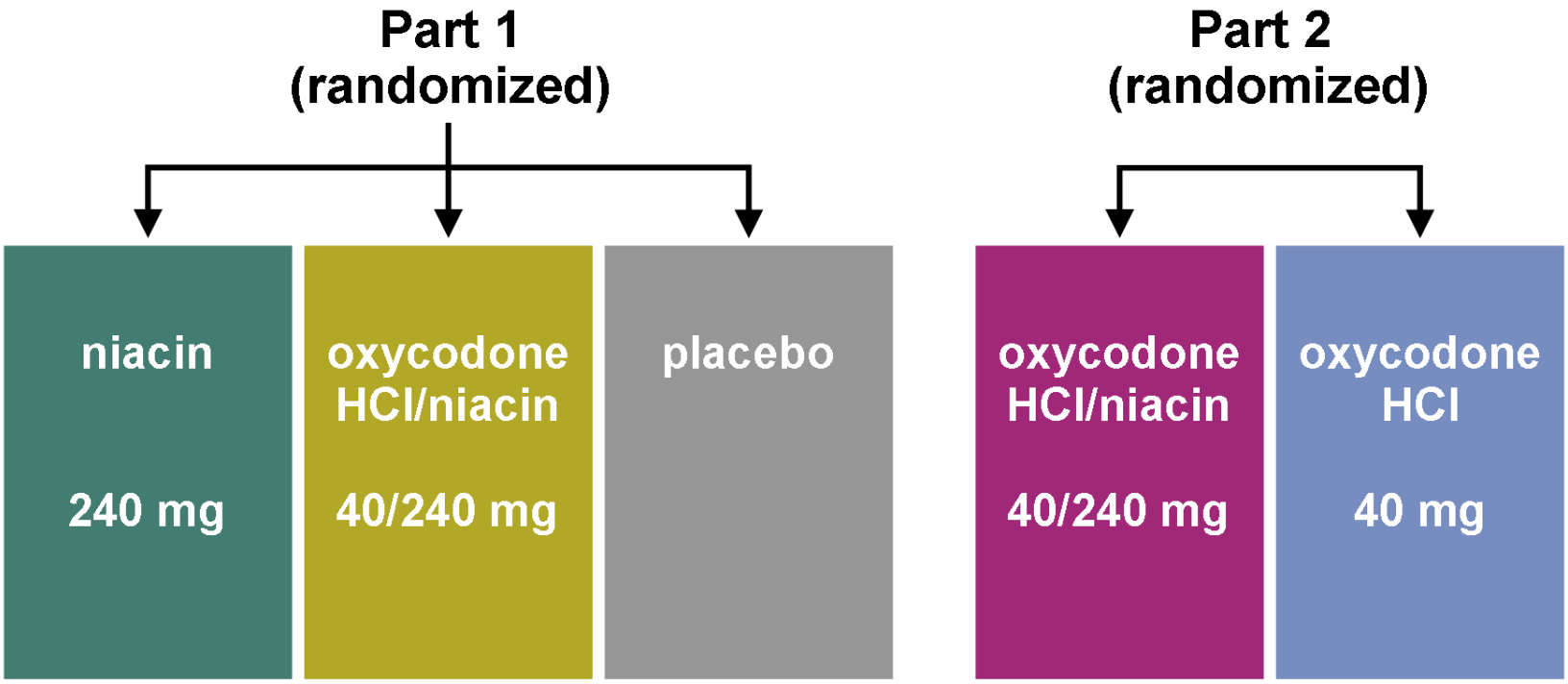


Baseline score established 0.5 hours prior to dosing and normalized to zero. For 0 mg niacin at 0.5 hour post-dose, actual value was -1.2, however for graphical clarity, 0.5-hour value plotted as 0.

Study 102: Niacin Dose-ranging Abuse Liability
Learnings for Subsequent Studies

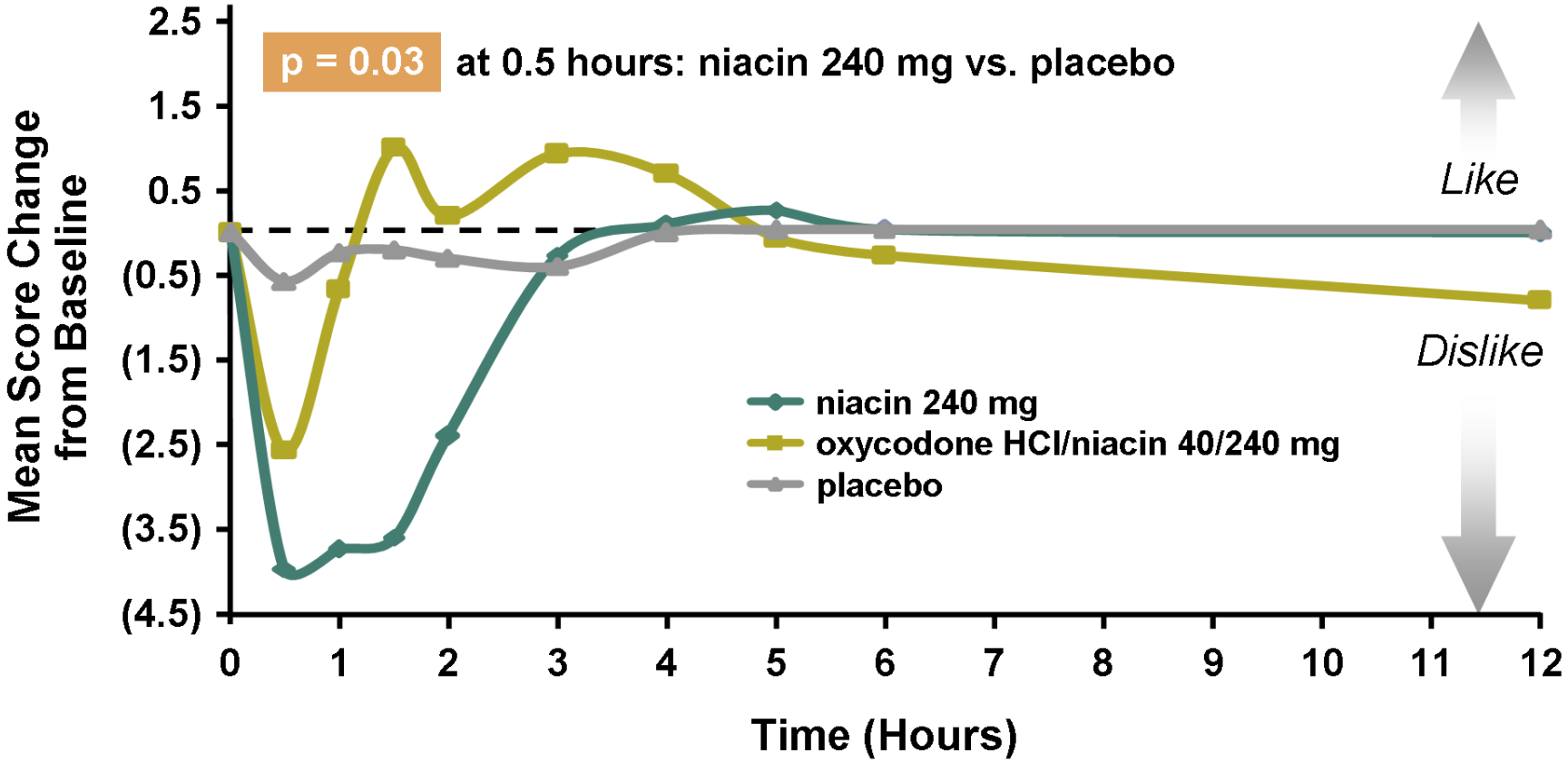
- Treatment Enjoyment Assessment Questionnaire only appropriate for assessing drug preference across 2 treatments
- Tolerability Rating Scale not appropriate for assessing abuse liability

Study 111: Oral Abuse Liability
Design



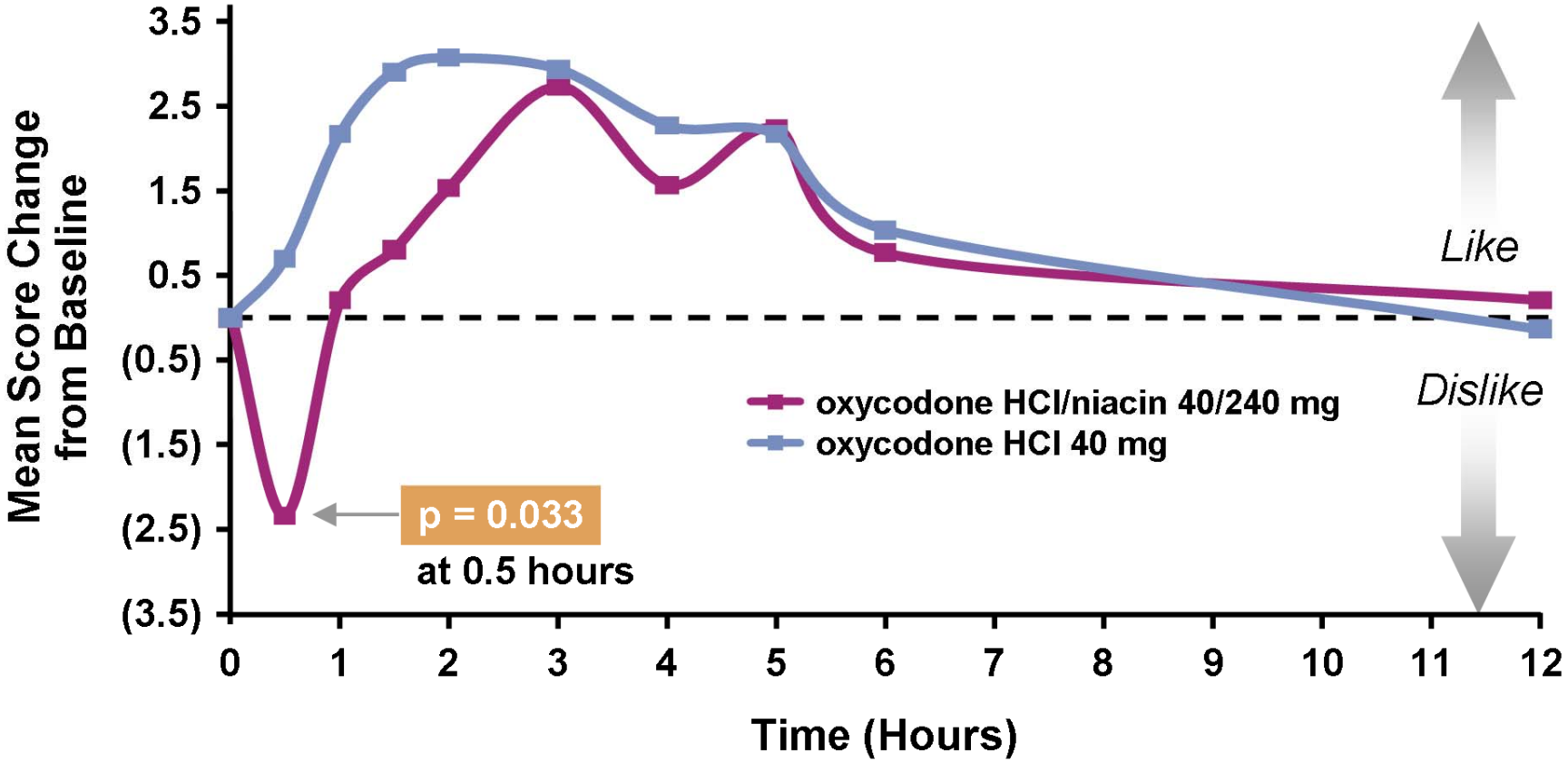
Study 111: Results Part 1
Primary Efficacy Measure

"Do You DISLIKE or LIKE the Drug Effect You Are Feeling Now?"



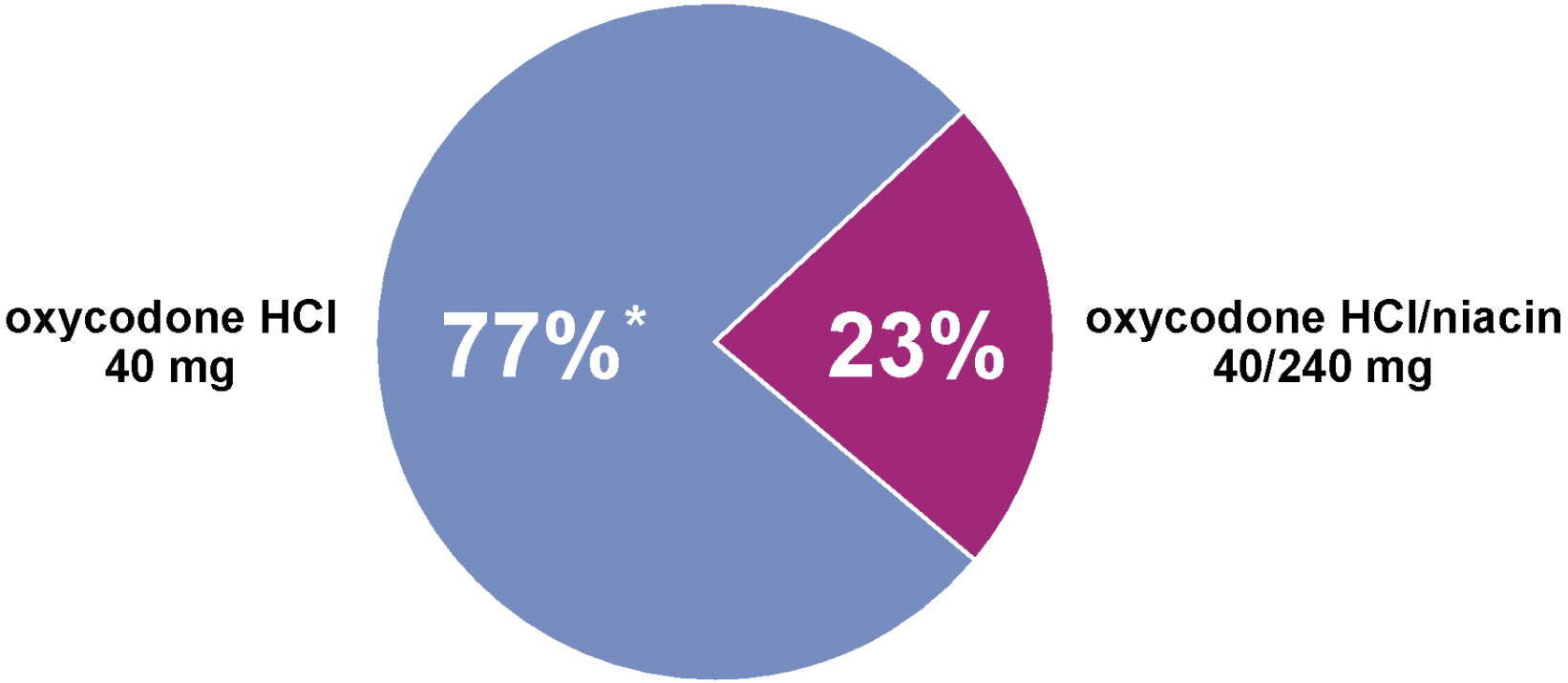
Study 111: Results Part 2
Primary Efficacy Measure

"Do You DISLIKE or LIKE the Drug Effect You Are Feeling Now?"



Study 111: Results Part 2
Secondary Efficacy Measure

"Which Treatment Would You LIKE to Take Again?"



*p <0.005 relative to preference for oxycodone HCl/niacin 40/240 mg

Study 111: Oral Abuse Liability
Conclusions

- In recreational opioid abusers
  - Acurox® significantly disliked at 30 minutes compared to oxycodone
  - Overall oxycodone significantly preferred over Acurox®
  - Treatment Enjoyment Assessment Questionnaire used to predict real-world behavior

Study 114: Oral Abuse Liability
Objectives

- Primary objective
  - Compare relative abuse potential of Acurox® Tablets to IR oxycodone in non-dependent recreational opioid users
- Secondary objectives
  - Assess dose-response for relative abuse potential of 40/240 mg and 80/480 mg oral doses
  - Assess safety of Acurox® in high doses

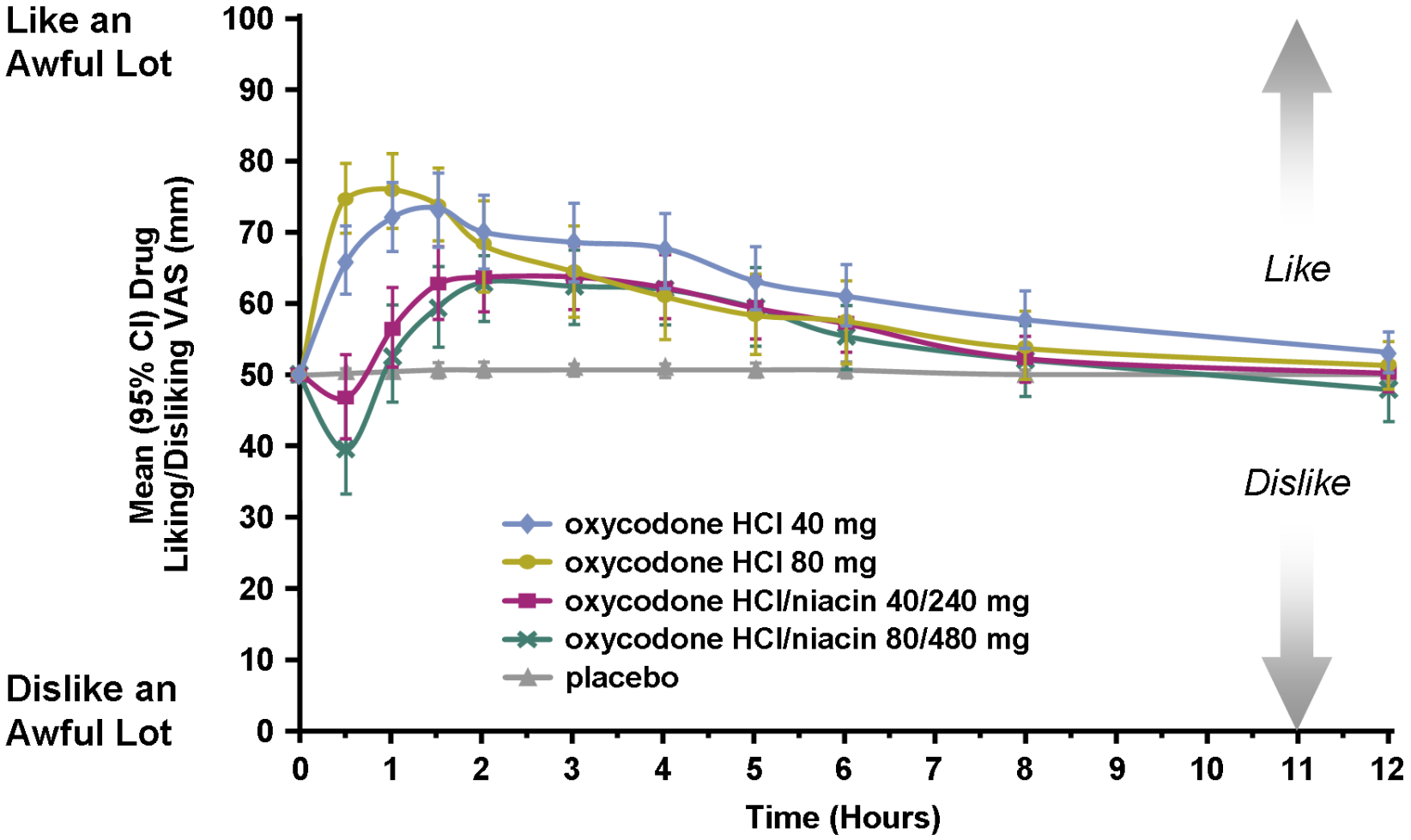
Study 114: Oral Abuse Liability
Design

- Randomized, double-blind, active- and placebo-controlled, 5-way crossover study
- Primary comparisons

Oxycodone HCl/niacin (mg)		Oxycodone HCl/niacin (mg)
40/240	vs.	40/0
80/480	vs.	80/0
40/0	vs.	0/0
80/0	vs.	0/0

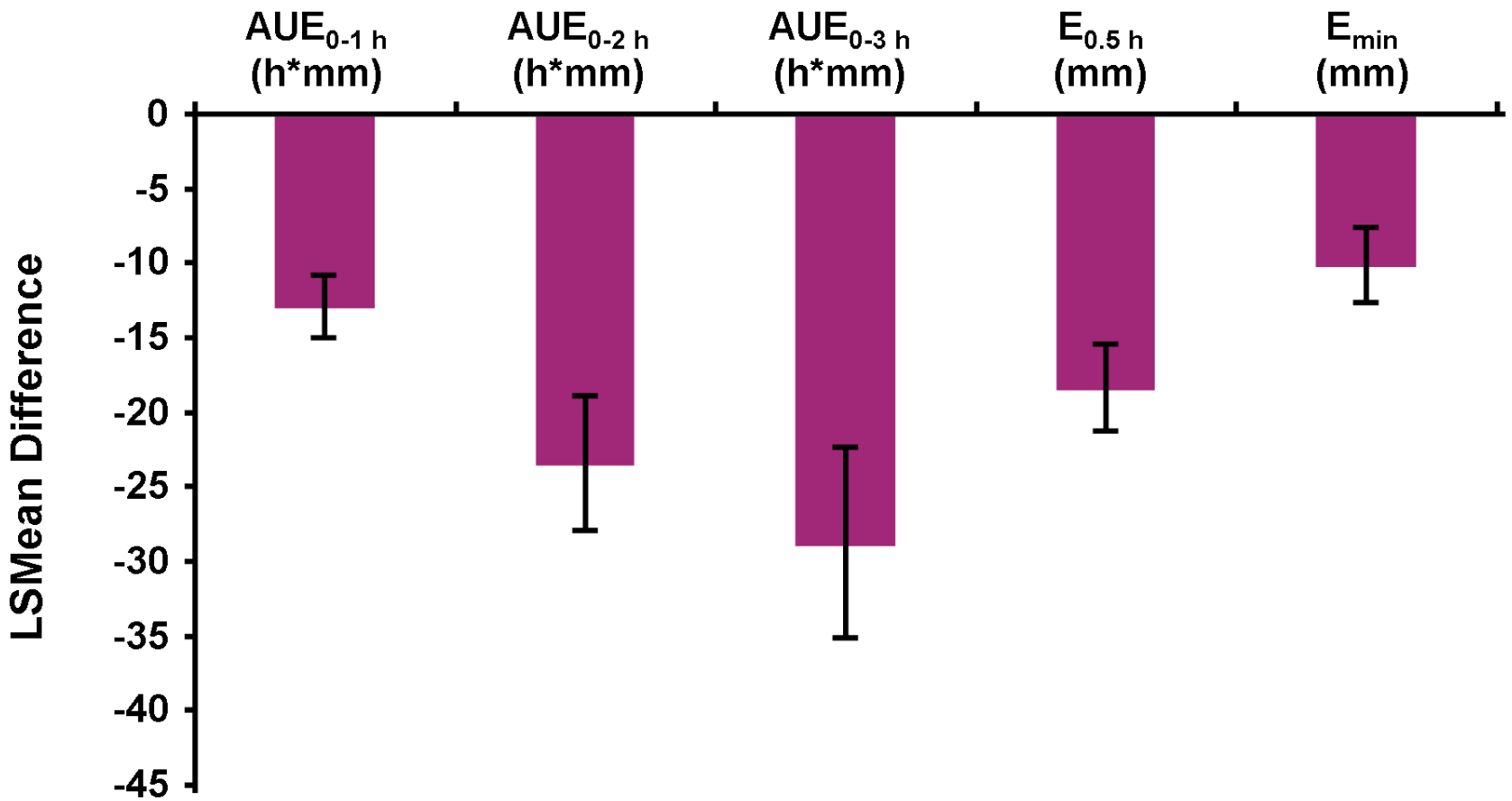
Study 114: Oral Abuse Liability
Primary Efficacy Results

"Do You DISLIKE or LIKE the Drug Effect You Are Feeling Now?"



Study 114: Oral Abuse Liability

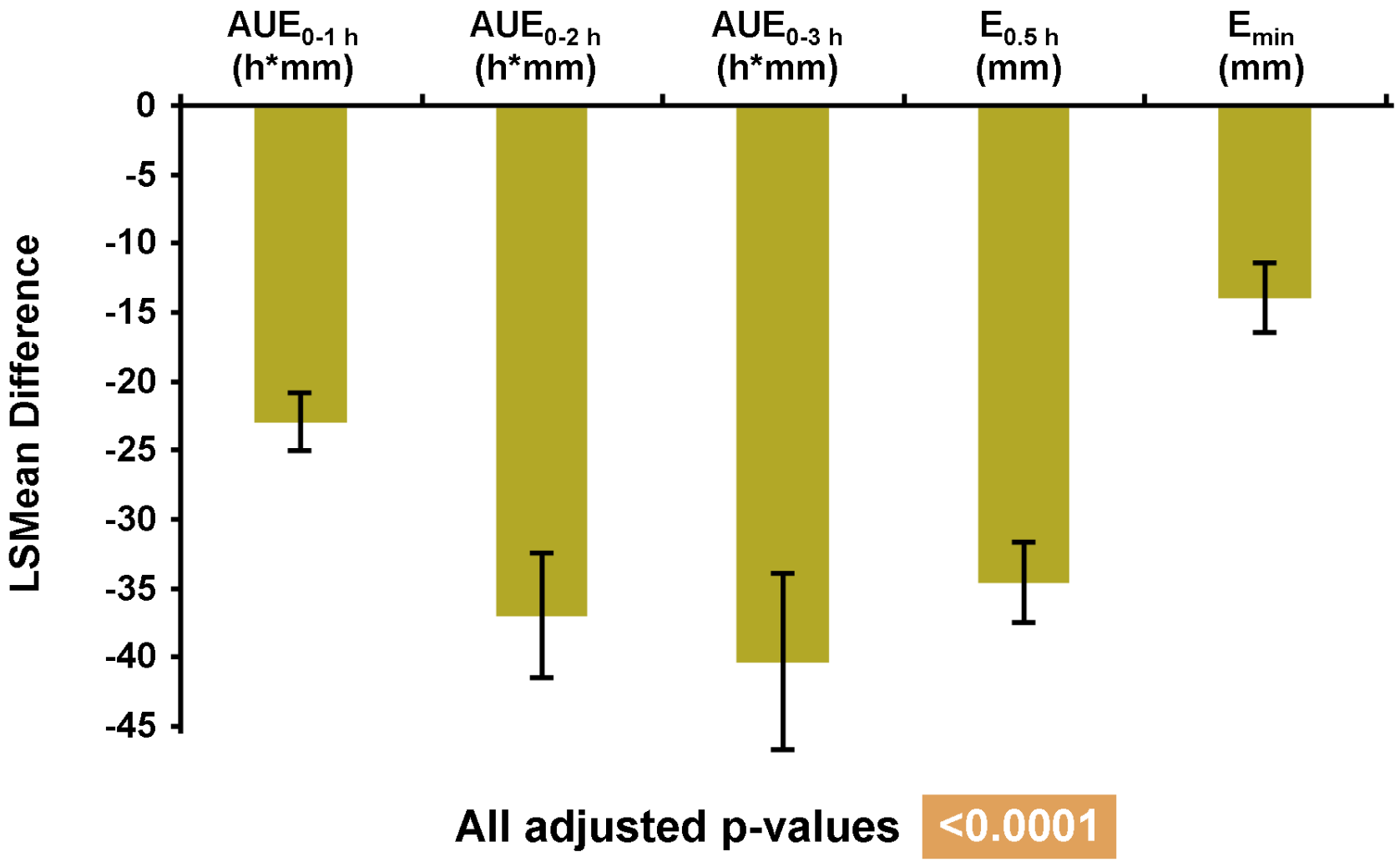
Summary of Primary Efficacy Assessments (40/240 mg vs. 40/0 mg)



All adjusted p-values <0.0001

Study 114: Oral Abuse Liability

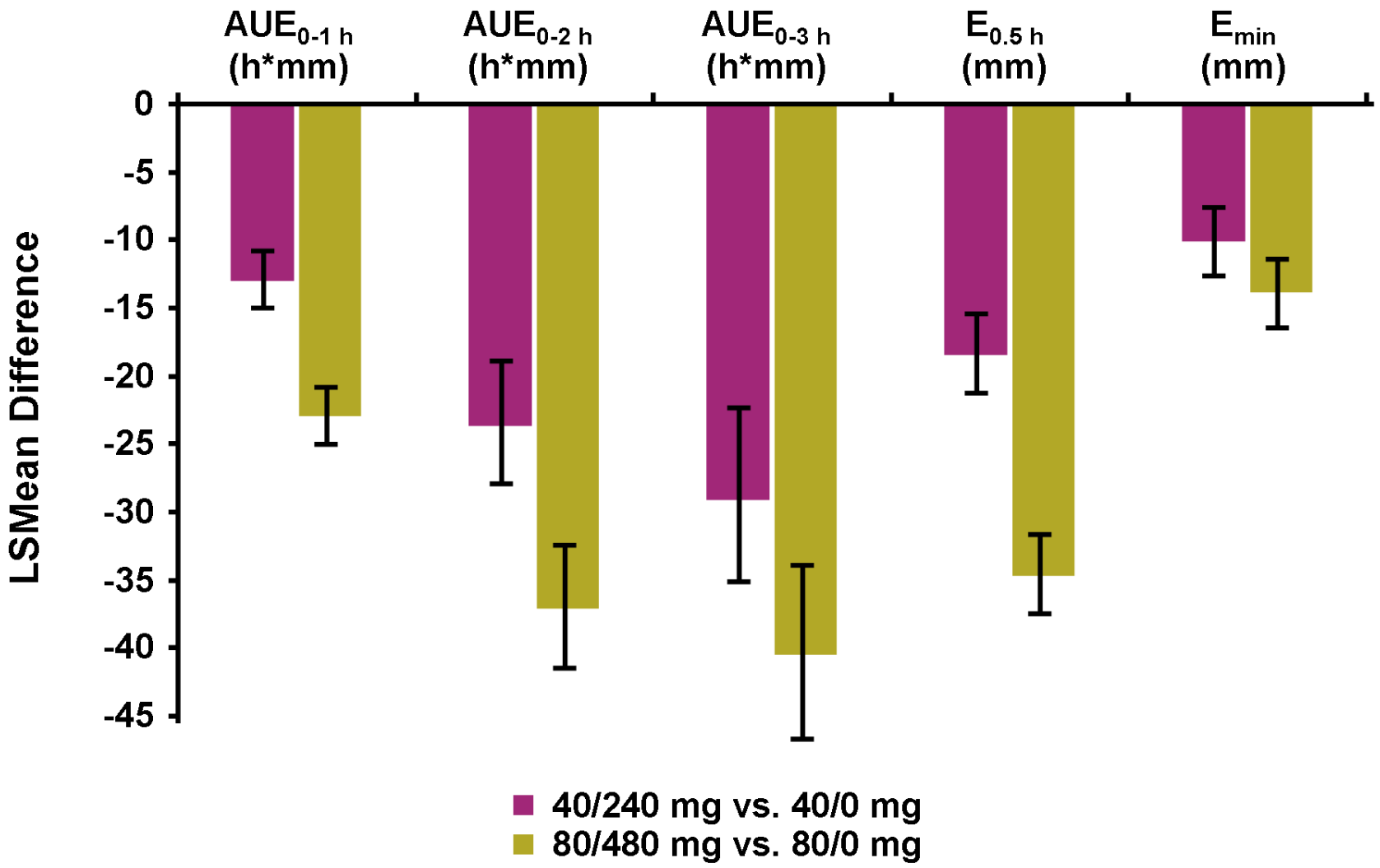
Summary of Primary Efficacy Assessments (80/480 mg vs. 80/0 mg)



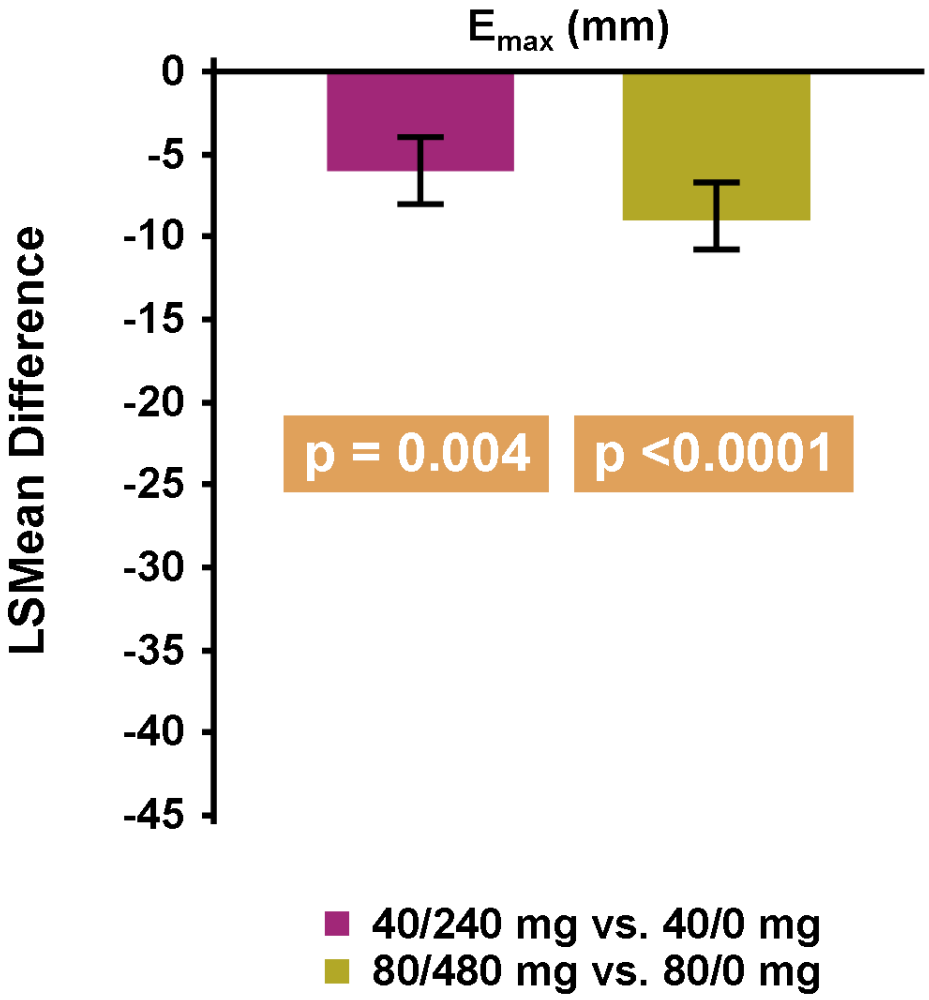
All adjusted p-values <0.0001

Study 114: Oral Abuse Liability

Summary of Dose-response – Primary Efficacy Assessments



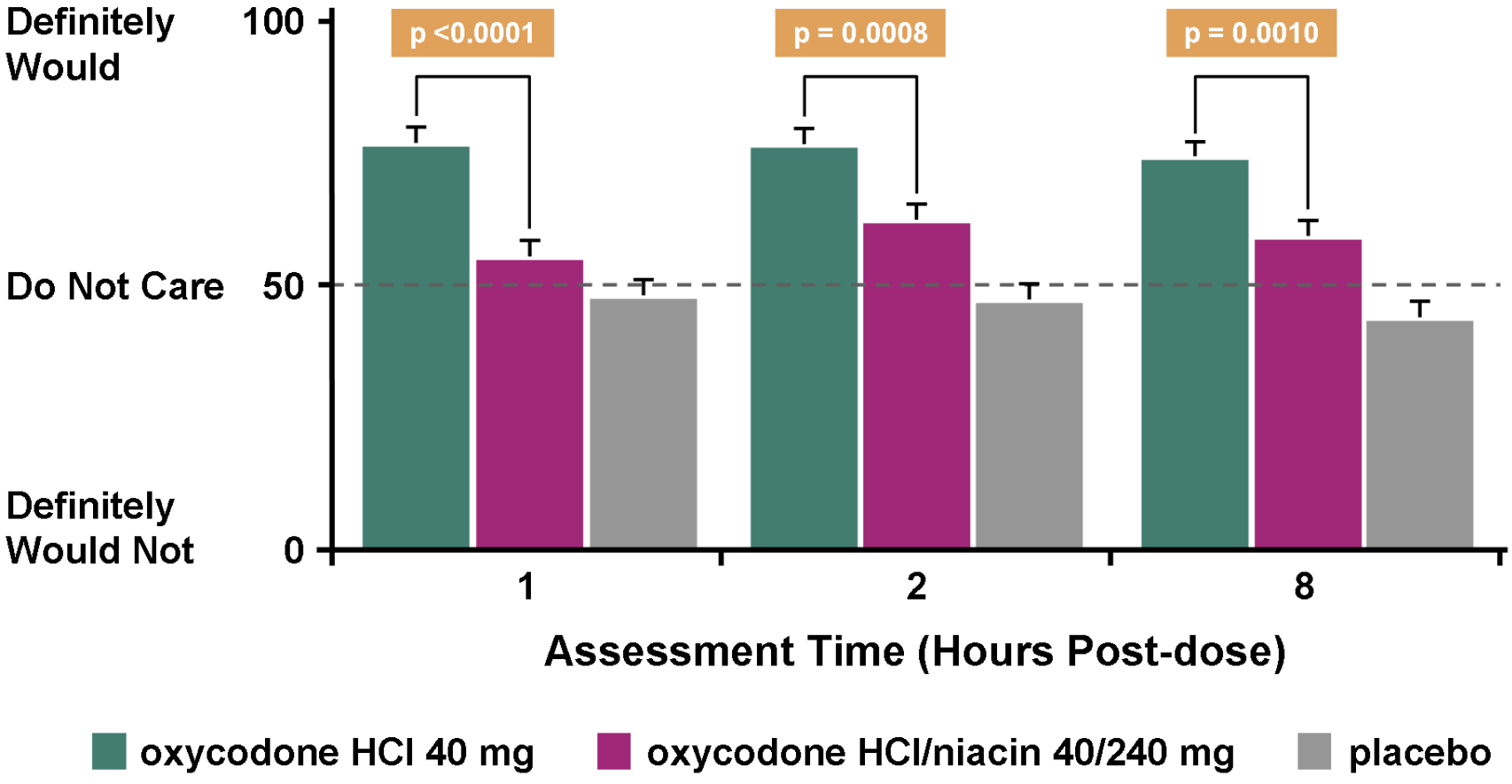
Study 114: Oral Abuse Liability
Secondary Efficacy Parameter (E_{max})



Study 114: Oral Abuse Liability

Take Drug Again Assessment (40/0 mg vs. 40/240 mg)

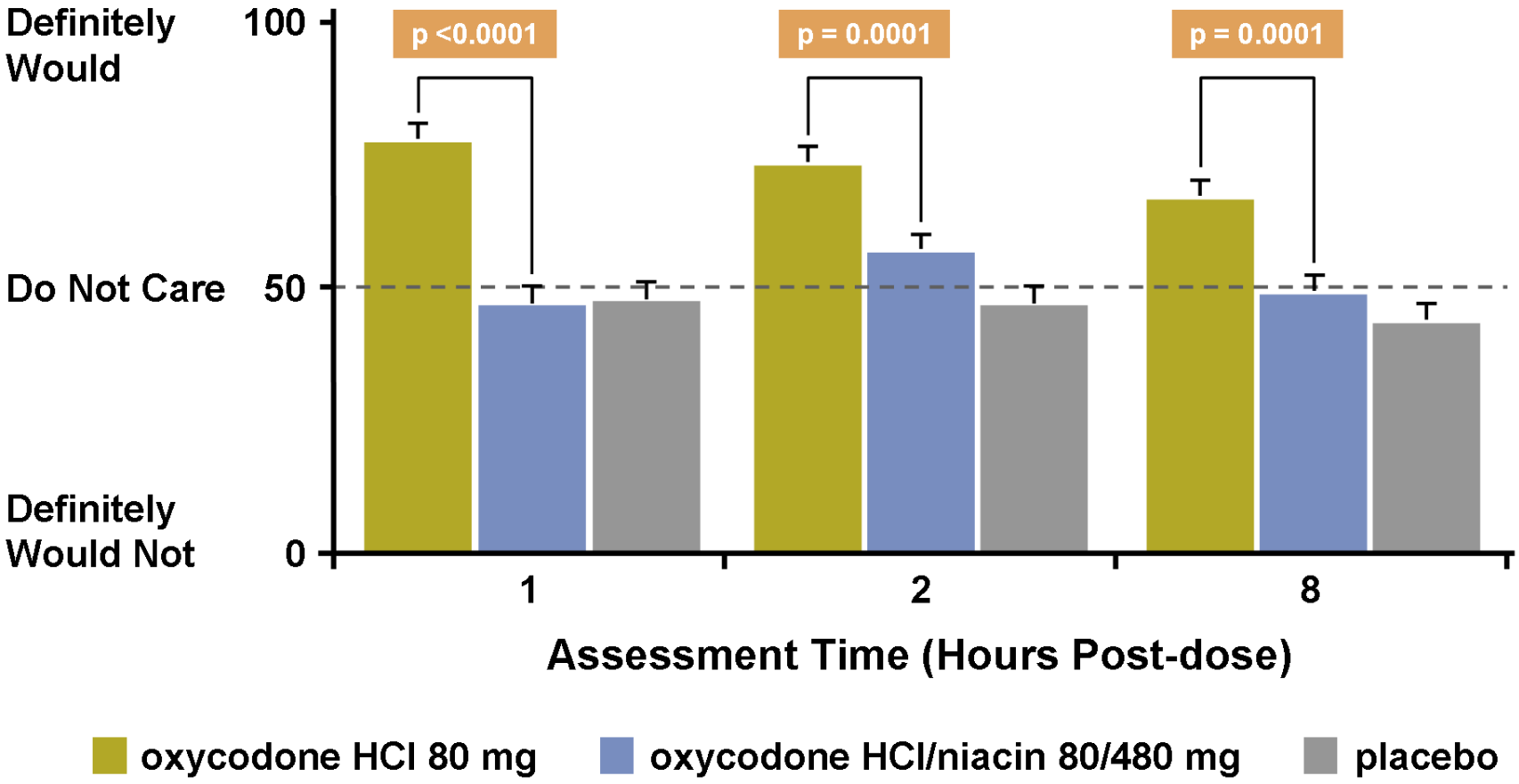
"Would You Want to Take the Drug You Just Received Again, if Given the Opportunity?"



Study 114: Oral Abuse Liability

Take Drug Again Assessment (80/0 mg vs. 80/480 mg)

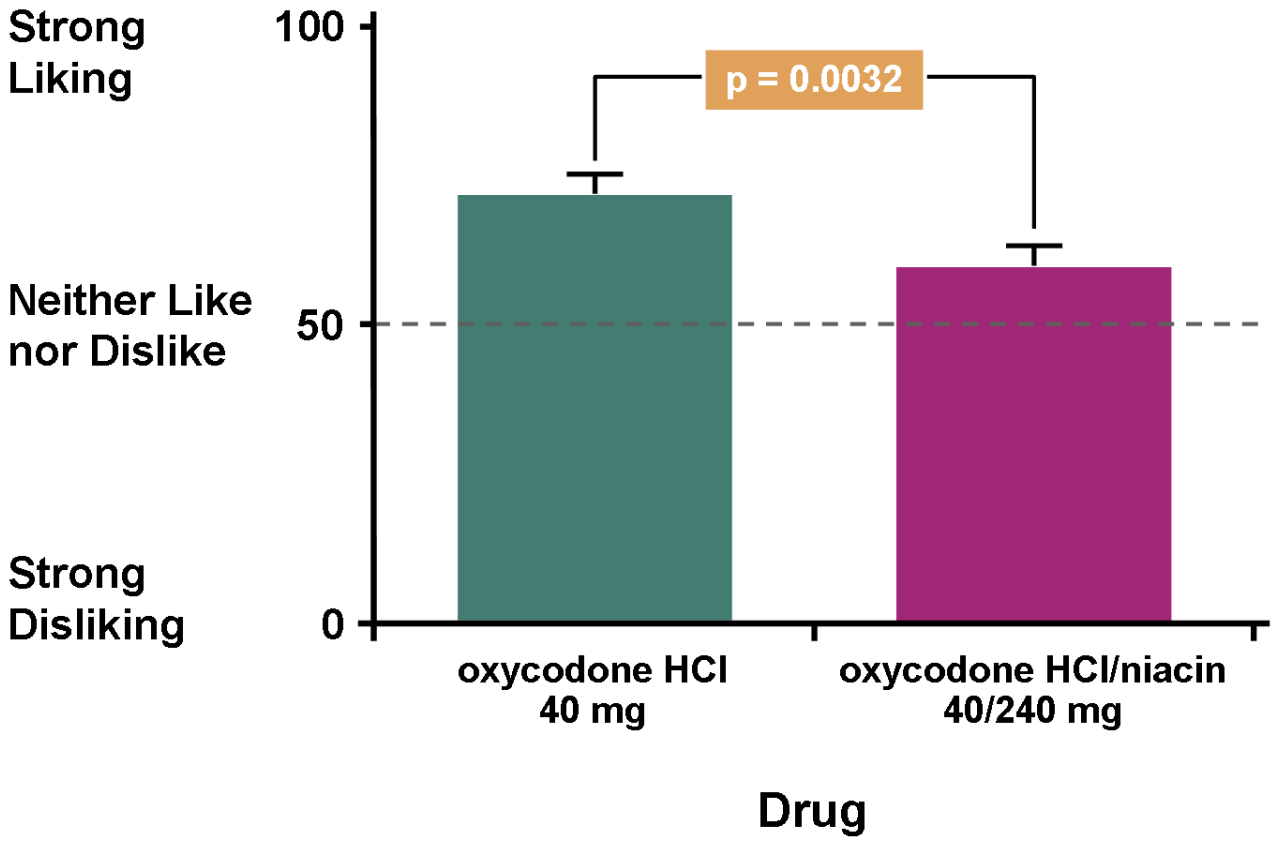
"Would You Want to Take the Drug You Just Received Again, if Given the Opportunity?"



Study 114: Oral Abuse Liability

Global Assessment of Overall Drug Liking at 12 Hours (40/0 mg vs. 40/240 mg)

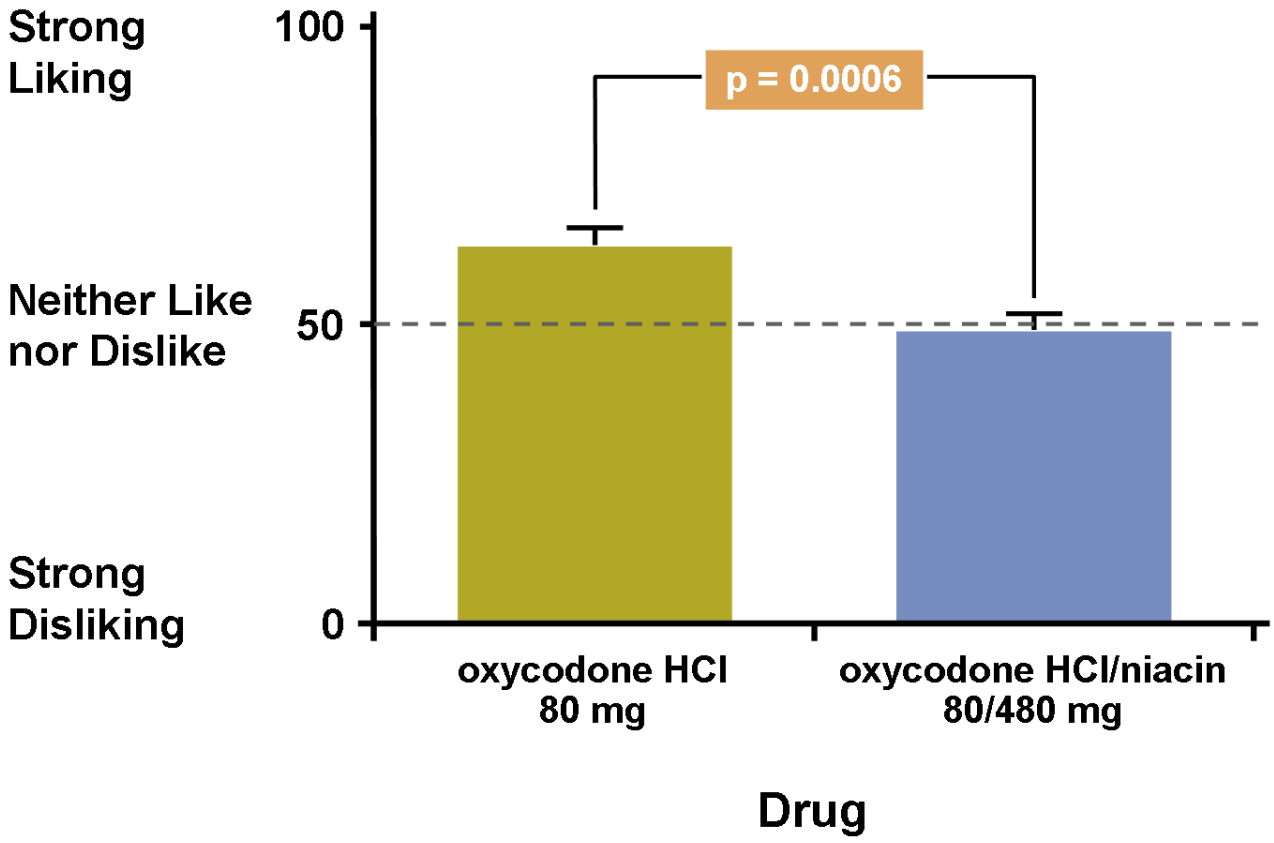
"My Overall LIKING of the Drug is…"



Study 114: Oral Abuse Liability

Global Assessment of Overall Drug Liking at 12 Hours (80/0 mg vs. 80/480 mg)

"My Overall LIKING of the Drug is…"



Study 114: Oral Abuse Liability
Conclusions

- Acurox® significantly disliked compared to oxycodone
  - Disliking effects of niacin increased with dose
  - Increasing doses of oxycodone failed to offset increased disliking of niacin
- Recreational opioid abusers preferred IR oxycodone to Acurox® in a highly significant manner
- Early disliking effects predicted later overall global assessment of drug liking

Clinical Evidence of Reduced Abuse Liability
Summary

- Oral and nasal administration
  - Acurox® significantly disliked compared to oxycodone
  - IR oxycodone significantly preferred over Acurox®
- Reproducibility of primary endpoint across three oral abuse liability studies

Concluding Remarks

Eric Carter, Ph.D., M.D.
Chief Science Officer
King Pharmaceuticals, Inc.

Acurox® Tablets Merit NDA Approval

- IR opioid misuse and abuse is a growing public health crisis
- Acurox® has proven safe and effective for relief of moderate-to-severe pain
- Acurox® functional inactive ingredients introduce limits and impediments to nasal and IV abuse
- Acurox® minimizes potential for oral abuse of oxycodone by using niacin as a second active ingredient
- Flushing may be partially mitigated by pre-treatment with food or NSAID but not in everybody
- Acurox® has a favorable benefit-to-risk profile
  - Potential risk of benign niacin-induced flushing that may occur in some pain patients is more than offset by benefit of niacin conclusively demonstrated in oral abuse liability studies

Post-approval Commitments

Monitoring and Surveillance

- Passive
  - Spontaneous adverse event reporting
  - Scientific literature
  - MedWatch to manufacturer
- Active
  - AERS/DAWN
  - Internet/Media
- Evaluation/Reporting

Education

- Educational materials
  - Full prescribing information
  - Information for patients
  - Educational brochure
- Communications
  - Dear healthcare professional letter to physicians
  - Dear pharmacist letter
  - Medical and pharmacy associations
  - State medical and pharmacy boards

Clinical Research

- Post-approval epidemiological studies
- Supportive surveys

Community Outreach

- 'Lock Your Meds' program
- Drug take back programs
- PainBalance® educational initiative

Acurox® Tablets
Label Considerations

- Abuse liability studies and extraction/syringeability studies demonstrated a decrease in abuse potential of Acurox® relative to oxycodone
- Not seeking an explicit abuse-deterrent claim
- Abuse deterrence claim requires long-term community observational studies demonstrating decreases in abuse
- Inclusion of selected results of experiments demonstrating abuse potential of Acurox® to provide important information for healthcare professionals
- Addition of disclaimer language to ensure that results on decrease in abuse potential are not overstated

Acurox® Tablets
Conclusions

- Acurox® Tablets provide incremental benefits by introducing limits or impediments to misuse and abuse
- These benefits represent the first advancement that addresses the significant and growing societal issue of immediate release opioid product abuse
- Niacin proven to be safe based on decades of long-term clinical use in doses far exceeding those in the Acurox® proposed maximum daily dose for relief of moderate-to-severe pain
- Niacin skin flushing, in a small percentage of pain patients taking low niacin doses, is clinically benign

Experts Available to Advisory Committee

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Johns Hopkins Bayview Medical Center

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Kendle International

John R. Guyton, M.D.
Associate Professor of Medicine
Director, Duke Lipid Clinic
Duke University Medical Center
Current President of American Board of Lipidology

Joint Meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committees

Acurox®

(oxycodone HCl and niacin)

Tablets

April 22, 2010

King Pharmaceuticals

Acura PHARMACEUTICALS, INC. *Abuse Deterrent Products*