THIRTY-SEVENTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2007

Prepared for the

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

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SUMMARY OF 2007 PANEL ACTIVITIES

During 2007 the Panel reviewed fifty-nine research study submissions. Fifty-three were approved by the Panel. Among fifty-three approved studies, twenty-six studies were Academic research studies including ten Substance Abuse Treatment research protocols and twenty-seven studies were Multicenter Clinical Drug Trial protocols.

Fifty-four research studies were completed (or in a few cases - terminated) in 2007, upon which Panel approval was withdrawn and they were closed on the Panel's records.

At the end of 2007 the Panel was monitoring 134 active research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, AE reports and site visits; and approval may be withdrawn if activities deviate significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2007 and Table 2 is a list of the studies closed by the Panel in 2007.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance and substance abuse treatment research projects currently ongoing in California:

Dr. Sharon B. Wigal, Ph.D. and colleagues at the Child Development Center at UC Irvine, have completed a study titled "Pharmacokinetic and Pharmacodynamic Evaluation of Stimulant Drugs". The results of this study were recently published in the *Journal of the American Academy of Child and Adolescent Psychopharmacology.* and summarized with the following abstract:

> *Objective*: The aim of this study was to compare the pharmacokinetics of immediate-release methylphenidate (MPH) in preschool and school-aged children with attention-deficit/hyperactivity disorder (ADHD).
> *Methods*:, Preschool children 4-5 years (n = 14) and school-aged children 6-8 years (n = 9) with diagnose of ADHD were titrated to an effective dose of MPH based on parent, teacher, and clinician ratings in a protocol specified by the Preschoolers with ADHD Treatment Study (PATS) and then attended a laboratory school where the single morning dose of immediate release MPH was administered. Blood samples for measurement of MPH concentrations were obtained predose, and at 1,2,4, and 6 hours postdose. A nonlinear model was

used to derive three pharmacokinetic (PK) values for analysis: Peak plasma concentration (Cmax), half-life (t1/2), and clearance (CL).
Results: The two groups did not differ in the mean mg dose of MPH ($p = 0.33$), or in the weight-adjusted mg/kg dose ($p = 0.20$). Dose-normalized Cmax was significantly higher ($p = 0.003$), and clearance was significantly slower ($p = 0.0002$) in preschool than in school-aged children.
Conclusions: In this sample, age significantly affected absorption and metabolism of MPH, so that preschool children had greater exposure than school aged children to the same weight-adjusted dose. These data suggest additional studies should be performed to characterize age-related differences in PK properties of MPH that may inform practitioners about dosing strategies based on the age and size of children being treated.

Dr. Thomas F. Newton, M.D. and colleagues at the Stimulant Abuse and Addiction Research Group at the David Geffen School of Medicine at UCLA, have completed a study titled "Perindopril - Methamphetamine Interaction Study" and have provided the Panel with the following summary:

Angiotensin-converting enzyme (ACE) inhibitors are widely used for the treatment of hypertension. Perindopril is a centrally acting ACE inhibitor that has been shown to attenuate the neurotoxic effects of MPTP and to ameliorate symptoms in Parkinson's disease. We conducted an inpatient, double-blind, placebo-controlled, parallel design evaluation of potential interactions between oral perindopril and methamphetamine (MA). Non-treatment-seeking, MA-experienced volunteers were randomized to receive either perindopril (2,4,or 8mg daily) or matching placebo. On the 3rd and 5th day of perindopril or placebo treatment, subjects received intravenous doses of 15 and 30mg of MA or saline. Thirty participants completed the study. Perindopril treatment was well tolerated and did not accentuate cardiovascular effects produced by MA The preliminary analysis indicates that perindopril (2 and 4mg) dose-dependently reduced ratings of "any drug effect", "high", "stimulated", and "desire MA" following administration of MA ($p<0.05$). Taken together, the data indicate preliminary efficacy for perindopril in attenuating the positive subjective effects produced by MA implicating angiotensin II in mediating effects of stimulants. Further research is indicated to investigate the efficacy of perindopril for the treatment of MA dependence.

Mr. M. Douglas Winship at Catalyst Pharmaceuticals in Coral Gables, Florida has provided the Panel with the following summary of research & development this company is doing in their project titled "Vigabatrin Treatment of Cocaine Dependence"

CPP-109 vigabatrin, an irreversible inhibitor of GABA-transaminase, can block block the manifestations of cocaine consumption typically seen in animal models

without impairing the usual dopamine-based mechanisms necessary to maintain a stable affective equilibrium (Stromberg et al, 2001; Kushner et al, 1997; Kushner et al, 1999). Vigabatrin works by inhibiting GABA-transaminase, a key enzyme responsible for GABA catabolism. It is, therefore, postulated that vigabatrin might prevent the cocaine "high" and subsequent "craving" and reduces the "need" for repeated and increasing drug doses (Dewey et al, 1998). Perhaps more importantly, however, is the unique activity-dependent mechanism associated with vigabatrin-induced increases in intracelluar GABA. This activity dependence results in increased release of presynaptic stores only in the presence of significant excitatory stimulus. Unlike some other drugs currently being used to treat drug dependencies (e.g. methadone), vigabatrin does not have abuse potential.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2007

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Gayle C. Baldwin, Ph.D. UCLA Los Angeles, CA	Cocaine Dependency and Enhanced Susceptibility to HIV Infection
Mark Burk Genomics Institute San Diego, CA	Panel Approved Research Project
Gantt Galloway, Pharm.D. UCSF/CPMC San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Jean Gehricke, Ph.D. UC Irvine Irvine, CA	The Reinforcing Mechanisms of Smoking in Adult ADHD
Reese Jones, M.D. UCSF San Francisco, CA	Double-Blind, Placebo-Controlled, Crossover Assessment of Intravenous Methamphetamine and Sublingual Lobeline Interactions
Reese Jones, M.D. UCSF San Francisco, CA	Pilot Study of LSD in Healthy Volunteers

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Mark Leibowitz, M.D. California Clinical Trials Glendale, CA	A Randomized, Open-Label, Cross-Over Study to Characterize the Pharmacokinetics of Fentanyl From Single Doses of Non-Colored Fentanyl Buccal Tablets Over the Dose Range of 100 mcg through 800 mcg in Healthy Japanese Subjects Residing in the United States (Cephalon C25608/1054/PK/US)
Daniel Levin NORAC Pharma Azusa, CA	Panel Approved Research Project
Edythe D. London, Ph.D. UCLA Los Angeles, CA	A Human laboratory Assessment of the Safety and Potential Efficacy of Varenicline in Methamphetamine-Dependent Volunteers Receiving Methamphetamine
John E. Mendelson, M.D. UCSF/CPMC San Francisco, CA	Steady State Kinetics of l-Methamphetamine and Validation of Sensitivity of Dose Estimation
Pierre-Yves Michellys, Ph.D. Genomics Institute San Diego, CA	Use of Selected DEA Schedule I Controlled Substances as a Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies (Non-Human)
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Intranasal administration of gamma-hydroxybutyrate (Non-Human)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Assessment of GVG for the Treatment of Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	A Pilot Study of Prazosin for Cocaine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Phase I Clinical Trial with OROS-MPH for Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	A Human Laboratory Assessment of the Safety and Potential Efficacy of Nepicastat (SYN117) in Cocaine-Dependent Volunteers Receiving Cocaine
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Pharmacological Manipulation of Psychosocial Stress
Michael D. Roth, M.D. UCLA Los Angeles, CA	Evaluating the impact of habitual marijuana (MJ) use on humoral and cellular immune responses to a hepatitis B virus (HBV) vaccine
Steven Shoptaw, Ph.D. UCLA Los Angeles, CA	A Randomized, Double-Blind, Placebo-Controlled Evaluation of Modafinil vs Placebo for the Treatment of Methamphetamine Dependence

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Marylou V. Solbrig, Ph.D. UC Irvine Irvine, CA	Cannabinoids in viral-induced Parkinsonism and striatal neurogenesis
Mark S. Wallace, M.D. UCSD San Diego, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy
Timothy L. Wigal, Ph.D. UC Irvine Irvine, CA	Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)
ACURA Pharmaceuticals Austin, TX	A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety & Efficacy of OxyADF (oxycodone HCl and niacin) Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients (Acura AP-ADF-105).
ALPHARMA Pharmaceuticals Piscataway, NJ	A Long-Term, Open-Label, Safety Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Chronic Moderate to Severe Nonmalignant Pain (Alpharma ALO-KNT-302)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
ALPHARMA Pharmaceuticals Piscataway, NJ	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Efficacy Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended- Release) Capsules in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Alpharma ALO-KNT-301)
ALZA Corporation Mountain View, CA	A Pharmacokinetic Study of Three Strengths of Transdermal D-TRANS Fentanyl Matrix QD in Healthy Japanese Subjects (Alza C-2006-029)
ALZA Corporation Mountain View, CA	A Study Evaluating the Pharmacokinetics of D-TRANS Fentanyl Matrix QD 100mcg/h After Repeated Applications in Healthy Japanese Subjects (Alza C-2007-004)
CATALYST Pharmaceuticals Chapel Hill, NC	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study (Catalyst CPP 01004)
COGNITION Pharmaceuticals San Diego, CA	A Randomized, Double-Blind, Placebo-Controlled, Dose, Titration Study to Assess the Safety, Tolerability, and Efficacy of C105 in Persons with Multiple Sclerosis with Cognitive Impairment (Cognition 22029)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
ENDO Pharmaceuticals Chadds Ford, PA	An Open-Label, Two-Stage, Phase II Study to Explore the Titration Schedule for Transitioning Opioid-Experienced patients with Non-Malignant Moderate to Severe Chronic Pain from Current Opioid Therapy to the Sufentanil Transdermal Therapeutic System (STTS) (Endo EN3270-201)
GRUNENTHAL GmbH Austin, TX	A Randomized Withdrawal, Active- and Placebo-Controlled, Double-Blind, Multi-Center Phase III Trial Assessing Safety and Efficacy of Oral CG5503 PR* in Subjects with Moderate to Severe Chronic Malignant Tumor-Related Pain (Grunenthal KF5503/16)
GW Pharmaceuticals Mill Valley, CA	GW CA0701
INSYS Therapeutics, Inc. Phoenix, AZ	Open-Label, Multi-Center Safety Trial of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-06-007)
INSYS Therapeutics, Inc. Phoenix, AZ	A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-05-001)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
JOHNSON & JOHNSON Titusville, NJ	A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of CG5503 Extended-Release (ER) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee (J&J R331333-PAI-3008)
JOHNSON & JOHNSON Titusville, NJ	Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain (J&J R331333-PAI-3010)
JOHNSON & JOHNSON Titusville, NJ	A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Low Back Pain (J&J R331333-PAI-3011)
MEDGENEX Ellicott City, MD	A Double-Blind, Randomized, Placebo-Controlled Study of Modafinil and Morphine or Oxycodone in Patients with Excessive Daytime Sleepiness Due to Opioid Therapy (Medgenex MGX-001)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
NEUROMED Pharmaceuticals Raleigh, NC	A Phase III, Variable-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Chronic Low Back Pain (Neuromed NMT 1077-301)
National Institute on Drug Abuse (NIDA) Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Modafinil for the Treatment of Methamphetamine Dependence (NIDA/VA CSP #1026)
PURDUE Pharma, L.P. Stamford, CT	A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Low Back Pain (Purdue BUP3024)
PURDUE Pharma, L.P. Stamford, CT	A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Pain due to Osteoarthritis of the Knee (Purdue BUP3025)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
PURDUE Pharma, L.P. Stamford, CT	A Multi-Center, Inpatient, Open-Label, within Subject Dose Titration Study to Characterize the Pharmacokinetics/Pharmacodynamics, Safety and Efficacy of Hydromorphone HCl Oral Solution in Subjects from 28 Days to 16 Years of Age, Inclusive, Who Require Opioid Analgesics for Post-Operative Pain (Purdue HMP4009)
QRx Pharma, Inc. Austin, TX	A Double-Blind, Multi-Center Extension Study to Evaluate the Safety and Efficacy of Q8003 in Patients with Acute Moderate to Severe Pain (QRx Q8003-010)
QRx Pharma, Inc. Austin, TX	A Placebo-Controlled, Randomized, Double-Blind Study of the Safety and Efficacy of Q8003 in The Management of Post-Bunionectomy Pain (QRx Q8003-007)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose Optimization Study, Designed to Evaluate the Efficacy and Safety of Methylphenidate Transdermal System (MTS) in Adolescents aged 13-17 years with ADHD (Shire SPD485-409)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
SHIRE Pharmaceuticals Wayne, PA	A Phase IV, Multi-center, Open-label Study of DAYTRANA TM (Methylphenidate Transdermal System (MTS)) to Characterize the Dermal Reactions in Pediatric Patients aged 6-12 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-411)
SHIRE Pharmaceuticals Wayne, PA	An Open-Label, Randomized Study of the Pharmacokinetics of *d*-Methylphenidate and *l*-Methylphenidate After Single and Multiple Doses of Methylphenidate Transdermal System (MTS) or CONCERTA® Administered to Children and Adolescents Ages 6 to 17 Years with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD485-106)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Dose-Optimization, Cross-Over, Analog Classroom Study to Assess the Time of Onset of Vyvanse™ in Pediatric Subjects aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (Shire SPD489-311)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Long-Term, Open-Label, Multi-Center, Extension Study Designed to Evaluate the Safety and Efficacy of Methylphenidate Transdermal System (MTS) in Adolescents aged 13-17 years with Attention-Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-410)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
SHIRE Pharmaceuticals Wayne, PA	A Prospective, Open-Label, Multi-Center, Dose-Optimization Study Evaluating the Efficacy, Safety and Tolerability of Vyvanse™ 20-70mg in Children aged 6-12 Diagnosed with ADHD (Shire SPD489-310)
TITAN Pharmaceuticals Mississauga, Canada	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-805)
TITAN Pharmaceuticals Mississauga, Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-807)

TABLE 2

RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2007

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Donald I. Abrams, M.D. UCSF Community Consortium San Francisco, CA	Opioid and Cannabinoid Pharmacokinetic Interactions: A Pilot Study
Ronald Barrett, Ph.D. XenoPort, Inc. Santa Clara, CA	Gamma Hydroxybutyrate as an Agonist at the GABA-B Receptor
Selena Barrett, Ph.D. Ernest Gallo Clinic & Research Center Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Oliver Civelli, Ph.D. UC Irvine Irvine, CA	Identify the receptor(s) for gamma-hydroxybutynic acid (GHB)
Richard DelaGarza, II, Ph.D. UCLA ISAP Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive and Subjective Effects of OROS-MPH in Combination with Oral Methamphetamine
Ivan Diamond, M.D., Ph.D. CV Therapeutics, Inc. Palo Alto, CA	Treatment of Experimental Heroin Addiction in Rats
Gantt Galloway, Pharm.D. UCSF/CPMC San Francisco, CA	A Rapid Screening Trial of Medications for Methamphetamine Dependence

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Gantt Galloway, Pharm.D. UCSF/CPMC San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Reese Jones, M.D. UCSF San Francisco, CA	Pilot Study of LSD in Healthy Volunteers
Reese Jones, M.D. UCSF San Francisco, CA	Double-Blind, Placebo-Controlled, Crossover Assessment of Intravenous Methamphetamine and Sublingual Lobeline Interactions
James McCracken UCLA Los Angeles, CA	An Eight-Week, Randomized, Double-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate Extended Release (Focalin XR) and the Combination, with a Twelve Month Open-Label Extension for the Treatment of Attention Deficit/ Hyperactivity Disorder in Pediatric Subjects Aged 7 to 14 years.
John E. Mendelson, M.D. UCSF/CPMC San Francisco, CA	Bioavailability and Urinary Excretion of Oral L-Methamphetamine

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
John E. Mendelson, M.D. UCSF/CPMC San Francisco, CA	Interactions of Prazosin and MDMA
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Perindopril - Methamphetamine Interaction Study
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Non-Specific COX Inhibitors as Treatment for Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA/NIDA Los Angeles, CA	Phase I, Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Cocaine and Ethanol and Oral Disulfiram (NIDA Study MDS-Disulfiram-0001)
Thomas F. Newton, M.D. UCLA/NIDA Los Angeles, CA	Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and Aripiprazole (NIDA Study NIDA-MDS-ARIPIP-0001)
Scott Novick, Ph.D. BioCatalytics Pasadena, CA	Panel Approved Research Project

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Richard Rawson, Ph.D. UCLA Los Angeles, CA	Double-Blind, Placebo-Controlled Trial of Bupropion for the Treatment of Methamphetamine Dependence
Michael Roth, M.D. UCLA Los Angeles, CA	Evaluating the impact of habitual marijuana (MJ) use on humoral and cellular immune responses to a hepatitis B virus (HBV) vaccine
Gary Scott, M.D. Childrens Hospital Los Angeles, CA	Comparison of On-Q PainBuster with Intrathecal Opioids for Postoperative Analgesia after Posterior Spinal Fusion
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Non-Specific COX Inhibitors as Treatment for Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA/NIDA Los Angeles, CA	Phase I, Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Cocaine and Ethanol and Oral Disulfiram (NIDA Study MDS-Disulfiram-0001)
Thomas F. Newton, M.D. UCLA/NIDA Los Angeles, CA	Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and Aripiprazole (NIDA Study NIDA-MDS-ARIPIP-0001)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Scott Novick, Ph.D. BioCatalytics Pasadena, CA	Panel Approved Research Project
Richard Rawson, Ph.D. UCLA Los Angeles, CA	Double-Blind, Placebo-Controlled Trial of Bupropion for the Treatment of Methamphetamine Dependence
Michael Roth, M.D. UCLA Los Angeles, CA	Evaluating the impact of habitual marijuana (MJ) use on humoral and cellular immune responses to a hepatitis B virus (HBV) vaccine
Gary Scott, M.D. Childrens Hospital Los Angeles, CA	Comparison of On-Q PainBuster with Intrathecal Opioids for Postoperative Analgesia after Posterior Spinal Fusion
CEPHALON, Inc. Frazer, PA	A 12-Week Open-Label Study With 3 Within-Patient Double-Blind Placebo-Controlled Periods to Evaluate the Efficacy and Safety of ORAVESCENT® Fentanyl Citrate Treatment for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Noncancer-Related Chronic Pain (Cephalon C25608/3052/BP/US)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
CEPHALON, Inc. Frazer, PA	A 4-Week Open-Label Study to Evaluate the Effect of Treatment With Fentanyl Buccal Tablets on Pain Anxiety Symptoms When Used for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Pain (Cephalon C25608/3054/BP/US)
GW Pharmaceuticals Mill Valley, CA	GW CA0501
HALOZYME Therapeutics San Diego, CA	Increased Flow Using Subcutaneously Enhanced Morphine (INFUSE-Morphine) Study: A Phase IIIB, double-blind, randomized, crossover study comparing p-kinetics, safety & tolerability of morphine administered SQ w & w/out human recom hyaluronidase & IV (Halozyme HZ2-05-06)
JOHNSON & JOHNSON Titusville, NJ	A Placebo-controlled, Double-blind, Parallel-group, Dose Titration Study to Evaluate the Efficacy and Safety of CONCERTA in Adults with Attention Deficit Hyperactivity Disorder at Doses of 36mg, 54mg, 72mg, 90mg, or 108mg per day (McNeil #02-159)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
JOHNSON & JOHNSON Titusville, NJ	A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of CG5503 Immediate-Release (IR) Formulation in the Treatment of Acute Pain From Total Hip Replacement Surgery Followed by a Voluntary Open-Label Extension (R331333-PAI-3001)
JOHNSON & JOHNSON Titusville, NJ	An Open-label, Dose-Titration, Long-Term Safety to Evaluate CONCERTA at Doses of 36mg, 54mg, 72mg, 90mg and 108mg per day in Adults with Attention Deficit Hyperactivity Disorder (McNeil Protocol 12-304)
JOHNSON & JOHNSON Titusville, NJ	A Randomized, Double-Blind, Active-Control, Parallel Arm, 90 Day Safety Study of CG5503 Immediate Release or Oxycodone Immediate Release in Subjects With Chronic Pain From Low Back Pain or Osteoarthritis of the Hip or Knee (J&J R331333-PAI-3004)
JOHNSON & JOHNSON Titusville, NJ	A One-Year, Randomized, Open-Label; Parallel-Arm, Phase III Long-Term Safety Trial, with Controlled Adjustment of Dose, of Multiple Doses of CG5503 PR* and Oxycodone in Subjects with Chronic Pain (J&J R331333-PAI-3007)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
JOHNSON & JOHNSON Titusville, NJ	A Randomized Double-Blind, Placebo- and Active-Control, Parallel-arm, Phase III Trial with Controlled Adjustment of Dose to Evaluate the Efficacy and Safety of CG5503 Extended-Release (ER) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee (J&J R331333-PAI-3008)
JOHNSON & JOHNSON Titusville, NJ	Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain (J&J R331333-PAI-3010)
MEDGENEX Ellicott City, MD	A Double-Blind, Randomized, Placebo-Controlled Study of Modafinil and Morphine or Oxycodone in Patients with Excessive Daytime Sleepiness Due to Opioid Therapy (Medgenex MGX-001)
PAIN Therapeutics, Inc. South San Francisco, CA	A Multicenter, Double-Blind, Active- and Placebo-Controlled Efficacy and Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCL (PTI-801) in Patients with Low Back Pain (Pain Therapeutics PTI-801-XG)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
PAIN Therapeutics, Inc. South San Francisco, CA	A Multicenter, Randomized, Double-Blind, Active- and Placebo-Controlled, Phase III, Efficacy and Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCl (PTI-801) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Pain Therapeutics PTI-801-XH)
PAIN Therapeutics, Inc. South San Francisco, CA	A Long-Term, Open-Label, Safety Study of Oxycodone HC1 and Low-Dose Naltrexone HC1 (PTI-801) in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Pain Therapeutics PTI-801-XI)
PAIN Therapeutics, Inc. South San Francisco, CA	A Long-Term, Open-Label, Safety Study of PTI-821 in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Pain Therapeutics PTI-821-CM)
PAIN Therapeutics, Inc. South San Francisco, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Efficacy & Safety Study of PTI-821 in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Pain Therapeutics PTI-821-CO)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
PRICARA Raritan, NJ	Time to Onset of Pain Relief Using a Standard Regimen of IV PCA Morphine Following Total Abdominal Hysterectomy (Pricara FENHYDPAI4003)
PROGENICS Pharmaceuticals Tarrytown, NY	A Compassionate Use Study of Methylnaltrexone in Patients with Opioid-Induced Side Effects (Progenics MNTX 901)
PURDUE Pharma, L.P. Stamford, CT	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Pilot Study to Evaluate the Analgesic Efficacy of BTDS on Postoperative Pain During Rehabilitation Following Total Knee Arthroplasty (Purdue BUP2003)
SHIRE Pharmaceuticals Austin, TX	A Phase III, Multi-Center, Open-label Study of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-303)
SHIRE Pharmaceuticals Wayne, PA	A Phase III, Multi-center, Open-label Safety Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD465-304

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
SHIRE Pharmaceuticals Lenexa, KS	A Phase IV, Multi-center, Open-label Study of DAYTRANA TM (Methylphenidate Transdermal System (MTS)) to Characterize the Dermal Reactions in Pediatric Patients aged 6-12 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-411)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Dose-Optimization, Cross-Over, Analog Classroom Study to Assess the Time of Onset of Vyvanse™ in Pediatric Subjects aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (Shire SPD489-311)

APPENDIX A

CURRENTLY APPROVED *(December 31, 2007)*
INDEPENDENT SCHEDULE I AND SCHEDULE II
CONTROLLED SUBSTANCE
RESEARCH STUDIES

Principal Investigator	Title of Study
Mark A. Agius, M.D. UC. Davis Davis, CA	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
James T. Arnold, Ph.D. Systems and Techniques Lab. Palo Alto, CA	Chemical Vapor Analysis of Marijuana and Other Drugs of Abuse
Phillip E. Bickler, M.D., Ph.D. UCSF San Francisco, CA	Inhaled carbon dioxide and apnea during intravenous sedation
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768	The cannabinoid system and the modulation of T cell and macrophage Functions
Mark Burk Genomatica, Institute San Diego, CA	Panel Approved Research Project
Jeremy S. Caldwell, Ph.D. Genomics Institute San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
Arthur K. Cho, Ph.D. UCLA School of Medicine Los Angeles, CA	Studies on Distribution and Metabolism of Narcotics in Animals

Appendix A Cont.

Principal Investigator	Title of Study
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Research of Novel Technologies for Development of Antibodies and Immunoassay Techniques to Drugs of Abuse and Controlled Compounds of Interest
Robert Edwards, M.D. UCSF School of Medicine San Francisco, CA	Role of glutamate release by monoamine neurons
Ronald Ellis, M.D., Ph.D. UCSD San Diego, CA	Placebo-controlled, Double-blind Trial of Medicinal Cannabis in Painful HIV-Neuropathy
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement
Douglas Fry The NORAC Co., Inc. Azusa, CA	Research on the Synthesis of Schedule I Controlled Substances: delta-9-THC and LAAM
Jean Gehricke, Ph.D. UC Irvine Irvine, CA	The Reinforcing Mechanisms of Smoking in Adult ADHD
Mark A. Geyer, Ph.D. UC San Diego La Jolla, CA	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats

Principal Investigator	Title of Study
Charles S. Grob, M.D. Harbor UCLA Medical Center Torrance, CA	Effects of Psilocybin in Terminal Cancer Patients with Anxiety
Kanthi F. Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Cannabinoids
Thomas B. King Alexza Molecular Delivery Corp. Palo Alto, CA	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery
Lorrin Koran, M.D. Stanford University, School of Medicine Stanford, CA	Double-Blind Trial of Acute & Intermediate-Tern Dextro-Amphetamine versus Caffeine Augmentation in Treatment-Resistant Obsessive-Compulsive Disorder
Nancy M. Lee, Ph.D. CPMC Research Center San Francisco, CA	Role of Cannabinoid Receptors in Central Nervous System Functions and Diseases
Mark Leibowitz, M.D. CA Clinical Trials Medical Group Glendale, CA	A Randomized, Open-Label, Cross-Over Study to Characterize the Pharmacokinetics of Fentanyl From Single Doses of Non-Colored Fentanyl Buccal Tablets Over the Dose Range of 100 mcg through 800 mcg in Healthy Japanese Subjects Residing in the United States (Cephalon Protocol C25608/1054/PK/US)
Daniel Levin, Ph.D. NORAC Pharma Azusa, CA	Panel Approved Research Project

Appendix A Cont.

Principal Investigator	Title of Study
Jon Levine, M.D., Ph.D. UCSF San Francisco, CA	Mechanisms of Pain Control: V. Analgesic Combinations for Post-Operative Pain–Kappa Opioids and Morphine
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development Study
John Mendelson, M.D UCSF/CPMC San Francisco, CA	Is There an Acute MDMA Single Dose Withdrawal Syndrome?
John Mendelson, M.D UCSF/CPMC San Francisco, CA	Steady State Kinetics of l-Methamphetamine and Validation of Sensitivity of Dose Estimation
Robert Messing, M.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Protein kinase C epsilon (PKCe) in Responses to Cannabinoids
Pierre-Yves Michellys, Ph.D. Genomics Institute San Diego, CA	Use of Selected DEA Schedule I Controlled Substances as a Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies (Non-Human)
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Intranasal administration of gamma-hydroxybutyrate (Non-Human)
Karel Z. Newman, Ph.D. Biosite Incorporated San Diego, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances

Principal Investigator	Title of Study
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Laboratory Models of Cocaine Self Administration
Stanley M. Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA	Rapid Detection of 4-hydroxybutyrate
Mark Perrone, Ph.D. Genomics Institute San Diego, CA	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
John M. Polich, Ph.D. The Scripps Research Institute La Jolla, CA	Marijuana CNS Effects in Low- and High-Risk Adults
Dorit Ron, Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Signaling Pathways Involved in the Mechanism of Action of the Anti-Addictive Drug Ibogaine
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Pharmacological and genetic study of the effects of 3,4-methylenedioxymethamphetamine (MDMA) using a model organism, the nematode Caenorhabditis elegans
Lawrence Toll, Ph.D. SRI International Menlo Park, CA	Biochemical Studies into Opiate Efficacies
Mark Wallace, M.D. UC San Diego San Diego, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy

Appendix A Cont.

Principal Investigator	Title of Study
Timothy Wigal, Ph.D. UC Irvine Irvine, CA	Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA	The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain

APPENDIX B

CURRENTLY APPROVED *(December 31, 2007)*
SCHEDULE II MULTICENTER
CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
ACURA Pharmaceuticals Austin, TX	A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety & Efficacy of OxyADF (oxycodone HCl and niacin) Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients (Acura AP-ADF-105)
ALPHARMA Pharmaceuticals Piscataway, NJ	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Efficacy Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee (Alpharma ALO-KNT-301)
ALPHARMA Pharmaceuticals Piscataway, NJ	A Long-Term, Open-Label, Safety Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Chronic Moderate to Severe Nonmalignant Pain (Alpharma ALO-KNT-302)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
ARCHIMEDES Development Nottingham, UK	A Multicenter, Placebo-Controlled, Double-Blind, Two-Phase Crossover Study of Nasalfent (Fentanyl Citrate Nasal Spray) in the Treatment of Breakthrough Cancer Pain (BTCP) in Subjects Taking Regular Opioid Therapy (CPO43/06/FCNS)
ARCHIMEDES Development Nottingham, UK	An Open-Label Study Investigating Long-Term Safety and Tolerability of Nasalfent (Fentanyl Citrate Nasal Spray) in the Treatment of Breakthrough Cancer Pain (BTCP) in Subjects Taking Regular Opioid Therapy (CPO45/06/FCNS)
BIODELIVERY Sciences Morrisville, NC	An open label, long-term treatment evaluation of the safety of BEMA fentanyl use for breakthrough pain in cancer subjects on chronic opioid therapy (BioDelivery Protocol FEN-202)
ENDO Pharmaceuticals Chadds Ford, PA	A Double-Blind, Randomized, Placebo-Controlled, multicenter Study to Evaluate the Efficacy and safety of EN3267 for the Treatment of Breakthrough Pain in Opioid Tolerant Cancer Patients Followed by a 12-Month Non-Randomized, Open-label Extension to Assess Long-Term Safety (Endo Protocol EN3267-005)

Sponsor	Description or Title of Clinical Drug Trial Protocol
ENDO Pharmaceuticals Chadds Ford, PA	A Multiple-Dose, Non Randomized, Open-Label, Multicenter Study to Evaluate the Long-Term Safety and Effectiveness of EN3267 in the Treatment of Breakthrough Pain in Cancer patients (Endo Protocol EN3267-007)
ENDO Pharmaceuticals Chadds Ford, PA	An Open-Label, Two-Stage, Phase II Study to Explore the Titration Schedule for Transitioning Opioid-Experienced patients with Non-Malignant Moderate to Severe Chronic Pain from Current Opioid Therapy to the Sufentanil Transdermal Therapeutic System (STTS) (Endo EN3270-201)
GRUNENTHAL GmbH Austin, TX	A Randomized Withdrawal, Active- and Placebo-Controlled, Double-Blind, Multi-Center Phase III Trial Assessing Safety and Efficacy of Oral CG5503 PR* in Subjects with Moderate to Severe Chronic Malignant Tumor-Related Pain (Grunenthal KF5503/16)
GW Pharmaceuticals Wiltshire, UK	A double blind, randomized, placebo controlled, parallel group dose-range exploration study of Sativex® in relieving pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy (GW GWCA0701)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
INSYS Therapeutics Phoenix, AZ	A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-05-001)
INSYS Therapeutics Phoenix, AZ	Open-Label, Multi-Center Safety Trial of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-06-007)
JOHNSON & JOHNSON Titusville, NJ	Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain (J&J R331333-PAI-3010)
NEUROMED Pharmaceuticals Raleigh, NC	A Phase III, Variable-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Chronic Low Back Pain (Neuromed NMT 1077-301)
NOVARTIS Pharmaceuticals East Hanover, NJ	An open-label, behavioral-treatment-controlled evaluation of the effects of extended release methylphenidate (Ritalin LA) on the frequency of cytogenetic abnormalities in children 6-12 year of age with ADHD (Novartis CRIT 124D2201)

Sponsor	Description or Title of Clinical Drug Trial Protocol
PURDUE Pharma L.P. Stamford, CT	A Multi-Center, Inpatient, Open-Label, within Subject Dose Titration Study to Characterize the Pharmacokinetics/Pharmacodynamics, Safety and Efficacy of Hydromorphone HCl Oral Solution in Subjects from 28 Days to 16 Years of Age, Inclusive, Who Require Opioid Analgesics for Post-Operative Pain (Purdue HMP4009)
PURDUE Pharma L.P. Stamford, CT	A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Low Back Pain (Purdue (Purdue BUP3024)
PURDUE Pharma L.P. Stamford, CT	A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Pain due to Osteoarthritis of the Knee (Purdue BUP3025)
QRX Pharma Austin, TX	A Double-Blind, Multi-Center Extension Study to Evaluate the Safety and Efficacy of Q8003 in Patients with Acute Moderate to Severe Pain (Qrx Q8003-010)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
SHIRE Pharmaceuticals, Wayne, PA	A Prospective, Open-Label, Multi-Center, Dose-Optimization Study Evaluating the Efficacy, Safety and Tolerability of Vyvanse™ 20-70mg in Children aged 6-12 Diagnosed with ADHD (Shire SPD489-310)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Parallel-Group, Placebo-Controlled, Dose Optimization Study, Designed to Evaluate the Efficacy and Safety of Methylphenidate Transdermal System (MTS) in Adolescents aged 13-17 years with ADHD (Shire SPD485-409)
SHIRE Pharmaceuticals Wayne, PA	An Open-Label, Randomized Study of the Pharmacokinetics of *d*-Methylphenidate and *l*-Methylphenidate After Single and Multiple Doses of Methylphenidate Transdermal System (MTS) or CONCERTA® Administered to Children and Adolescents Ages 6 to 17 Years with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD485-106)
SHIRE Pharmaceuticals Wayne, PA	A Phase IIIb, Long-Term, Open-Label, Multi-Center, Extension Study Designed to Evaluate the Safety and Efficacy of Methylphenidate Transdermal System (MTS) in Adolescents aged 13-17 years with Attention-Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-410)

APPENDIX C

CURRENTLY APPROVED *(December 31, 2007)* RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Gantt P. Galloway, Pharm.D. UCSF/CPMC San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Alan Gevins, D. Sc. SAM Technology San Francisco, CA	Realtime Neural Monitor for Drug Abuse Research
Ari Kalechstein, Ph.D. UCLA Neuropsychiatric Institute Los Angeles, CA	Methamphetamine Dependence: Treating Neurocognitive Impairment
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Optimizing Outcomes Using Suboxone for Opiate Dependence
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Double-Blind, Placebo-Controlled Trial of Prometa Pharmacotherapy for the Treatment of Methamphetamine Abuse
Edythe London, Ph.D. UCLA Los Angeles, CA	Modafinil as a Treatment for Methamphetamine Dependence: Initial Safety, Subjective Effects, and Brain Functioning - Pilot study
Edythe London, Ph.D. UCLA Los Angeles, CA	A Human laboratory Assessment of the Safety and Potential Efficacy of Varenicline in Methamphetamine-Dependent Volunteers Receiving Methamphetamine

Appendix C Cont.

Investigator or Sponsor	Description or Title of Research Project
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Assessment of GVG for the Treatment of Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Methamphetamine Dependence: A Novel Laboratory Model
Steven Shoptaw, Ph.D. Semel Inst of Neuroscience & Human Behavior 11075 Santa Monica Blvd. Los Angeles, CA 90025	A Randomized, Double-Blind, Placebo-Controlled Evaluation of Bupropion vs Placebo for the Treatment of Methamphetamine Dependence
CATALYST Pharmaceuticals Chapel Hill, NC	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study (Catalyst CPP 01004)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	A Two-Phase Randomized Controlled Clinical Trial of Buprenorphine/Naloxone Treatment Plus Individual Drug Counseling for Opiod Analgesic Dependence (NIDA CTN Protocol 0030)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Starting Treatment with Agonist Replacement Therapies (START) (NIDA CTN Protocol 0027)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Topiramate for the Treatment of Methamphetamine Dependence (NIDA-MDS-Topiramate/meth0001)

Investigator or Sponsor	Description or Title of Research Study
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Modafinil for the Treatment of Methamphetamine Dependence (NIDA/VA CSP #1026)
TITAN Pharmaceuticals Mississauga, Canada	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-805)
TITAN Pharmaceuticals Mississauga, Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-807)

APPENDIX D

SECTIONS CONCERNING THE RESEARCH ADVISORY PANEL
FROM THE CALIFORNIA HEALTH AND SAFETY CODE

Sec. 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Sec. 11362.9. California Marijuana Research Program; legislative intent; creation; research proposals; establishment; powers and duties; Scientific Advisory Council (In pertinent part)

(d) If the program is administered by the Regents of the University of California any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, marijuana. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

Sec. 11374. Every person who violates or fails to comply with any provisions of this division, except one for which a penalty is otherwise in this division specifically provided, is guilty of a misdemeanor punishable by a fine in a sum not less than thirty dollars ($30) nor more than five hundred dollars ($500), or by imprisonment for not less than 15 nor more than 180 days, or by both.

Sec. 11392. Spores or mycelium capable of producing mushrooms or other material which contains psilocyn or psyoclyin may be lawfully obtained and used for bona fide

research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Sec. 11478. Marijuana may be provided by the Attorney General to the heads of research projects which have been registered by the Attorney General, and which have been approved by the Research Advisory Panel pursuant to Section 11480.

The head of the approved research project shall personally receipt for such quantities of marijuana and shall make a record of their disposition. The receipt and record shall be retained by the Attorney General. The head of the approved research project shall also, at intervals and in the manner required by the Research Advisory Panel, report the progress or conclusions of the research project.

Sec. 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

The Panel shall annually select a chairman from among its members.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to Section 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

Sec. 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

Sec. 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

Sec. 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.