THIRTY-EIGHTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2008

Prepared for the

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

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2008 PANEL MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

Edward P. O'Brien, J.D.
Panel Chairman

Y. Jennifer Ahn, Pharm.D.
Executive Officer

Antonello Bonci, M.D.
Appointed by the University of California at San Francisco
Designated University of California

Daniel P. Holschneider, M.D.
Appointed by the University of Southern California
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John Mendelson, M.D.
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TABLE OF CONTENTS

SUMMARY OF 2008 PANEL ACTIVITIES

During 2008 the Panel reviewed thirty research study submissions. Twenty-eight were approved by the Panel. Among twenty-eight approved studies, thirteen studies were Academic research studies including six Substance Abuse Treatment research protocols and fifteen studies were Clinical Drug Trial research protocols.

Sixty research studies were completed or, in a few cases, terminated in 2008, Panel approval was withdrawn and they were closed on the Panel's records.

At the end of 2008 the Panel was monitoring 79 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, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2008 and Table 2 is a list of the studies closed by the Panel in 2008.

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. Jon D. Levine, M.D., Ph.D. and colleagues at the Department of Oral and Maxillofacial Surgery at UC San Francisco, have completed a study titled "Mechanisms Pain Control: V. Analgesic Combinations for Post-Operative Pain-Kappa Opioids and Morphine ". The results of this study were recently published in the *Journal of Pain* and summarized with the following findings:

> For the last several years we have studied the mechanism(s) that could explain sex differences in the analgesic effect of kappa opioids, which are known to produce significantly greater analgesia in women than in men. A major clue in this investigation was the finding that co-administration of a low dose of the opioid antagonist naloxone (Narcan) with a kappa opioid eliminates the sex differences and enhances the analgesia in both men and women. The current project was designed to investigate whether a low dose of the mu-opioid agonist morphine would enhance or diminish kappa-mediated analgesia. We found that

morphine enhanced nalbuphine analgesia at a dose that did not itself produce significant analgesia. Since the side-effect profile of kappa opioids compares favorably (including less addiction potential) to that of the more widely used mu-opioids, this research could lead to effective pain management alternatives where mu-opioids alone are contraindicated.

Dr. Lawrence Toll, Ph.D. and colleagues at the Receptor Pharmacology Department of SRI International, Menlo Park, California have completed a study titled "Biochemical Studies into Opiate Efficacies" The results of this study were recently published in the *British Journal of Pharmacology* and summarized with the following abstract:

> Compounds that activate both NOP and *u*-opioid receptors might be useful as analgesics and drug abuse medications. Studies were carried out to better understand the biological activity of such compounds.
> Binding affinities were determined on membranes from cells transfected with NOP and opioid receptors. Functional activity was determined by (35S)GTP*r*S binding on cell membranes and using the mouse was deferent preparation *in vitro* and the tail flick antinociception assay *in vivo.*
> Compounds that bind to both *u*-opioid and NOP receptors have antinociceptive activity but the relative contribution of each receptor is unclear. These experiments help characterize compounds that bind to both receptors, to better understand the mechanism behind their biological activities, and identify new pharmacological tools to characterize NOP and opioid receptors.

Dr. Walter Ling, M.D. and colleagues at the Integrated Substance Abuse Programs at UCLA have provided the Panel with the following summary of ongoing research titled "Optimizing outcomes using Suboxone for Opiate Dependence"

> The approval of buprenorphine (combined with naloxone as Suboxone) by the FDA enables physicians in the United States to provide a pharmacotherapy treatment to opioid-dependent patients in private medical settings. Buprenorphine's wide acceptance and implementation by physicians has been slower than expected, however, and this may be due in part to the nature and necessity of providing comprehensive treatment for opioid-dependent patients. Lessons learned from methadone maintenance make it clear that simply providing opioid substitution does not address the behavioral components of dependence. While there is no lack of behavioral treatment facilities for substance abuse in the United States, what is lacking is an integrative approach to the treatment of opioid dependence using pharmacotherapy in conjunction with proven behavioral treatment strategies. Following a two-week stabilization and baseline period, this project will randomize 240 participants into 4

behavioral treatment groups featuring treatment that includes tools to address thinking and behavior (cognitive behavioral therapy; CBT) and treatment that rewards positive behavior change through the use of goods or services (contingency management therapy; CM). The four groups include: 1) CBT, 2) CM, 3) CBT + CM, 4) No CBT or CM (standard medical management). A universal, manual-guided psychosocial standard of care for buprenorphine pharmacological treatment allows for ethical inclusion of a "no-CBT or CM therapy" condition and closely resembles the current standard of psychosocial care delivered with opioid treatment using Suboxone. Behavioral therapies will be delivered for 16 weeks (to study week 18) in conjunction with continued care with Suboxone. An additional 16 weeks of treatment using Suboxone (to study week 34) will ensue during which no CBT or CM therapies are provided. All participants enter a buprenorphine taper and return at study week 52 for long-tern follow-up evaluations. Outcomes for the trial include illicit drug use (urine drug samples collected three times per week during the first 18 weeks), during craving, retention (days in the protocol), psychiatric status (depression, mood), HIV risk behaviors, and treatment feasibility ratings. Results will be used to recommend strategies to optimize buprenorphine treatment outcomes and promote integration of pharmacotherapy and psychosocial/behavioral treatment strategies for physicians and for behavioral treatment facilities treating opioid-dependent patients.

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This report represents a consensus among Panel members acting as individual experts. It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2008

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
Richard De La Garza, II, Ph.D. UCLA ISAP Los Angles, CA	Rivastigmine and Donepezil as Potential Treatments for Cocaine Addiction
Mohammad Diab, M.D. UCSF Dept of Orthopaedic Surgery San Francisco, CA	Panel Approved Research Project
Keith Heinzerling, M.D. UCLA Dept of Family Medicine San Francisco, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Scott Irwin, MD, PhD San Diego Hospice & Palliative Care San Diego, CA	Panel Approved Research Project
Ronald Krauss, M.D. Children's Hospital Oakland Oakland, CA	Rimonabant Effects on Hepatic Lipoprotein Production
Kimberley Lakes, Ph.D. UC Irvine Irvine, CA	The Effects of Vyvanse on Brain Hemodynamics and Reading

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
John E. Mendelson, M.D. CPMC APRL San Francisco, CA	Clinical Pharmacology of 3,4-methylenedioxyamphetamine (MDA)
Mark Rollins, MD, PhD UCSF Dept of Anesthesia San Francisco, CA	Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety?
AcelRx Pharmaceuticals Redwood City, CA	A Multi-Center, Randomized, Placebo-Controlled Phase II Study to evaluate the Clinical Efficacy, Safety, and Tolerability of ARX-F01 Sublingual Sufentanil Nanotabs TM in Patients Undergoing Major Abdominal Surgery (AcelRx ARX-C-005)
BioDelivery Sciences Raleigh, NC	Open-Label, Long-Term Extension Study for Treatment of Breakthrough Cancer Pain with BEMA Fentanyl (BioDelivery FEN-290)
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Methamphetamine Dependence: A Phase II Study (Catalyst CPP-02001)
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label, Ascending, Two-Part, Single- and Multiple-Dose Evaluation of the Safety, Pharmacokinetics, and Effectiveness of Oxymorphone For Acute Postoperative Pain in Pediatric Subjects (Endo EN3203-010)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxymorphone in Opioid-Tolerant pediatric Subjects with Chronic Pain (Endo EN3202-036)
Johnson & Johnson Cypress, CA	A Pivotal Bioequivalence Study Assessing Transdermal D-TRANS Fentanyl 100 *ug*/h Matrix System to DURAGESIC Fentanyl 100 *ug*/h Reservoir System After Single Application in Healthy Subjects (J & J FEN-PAI-1019)
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Placebo- and Active- Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated with Tapentadol IR and Oxycodone IR Using a Bowel Function Patient Diary (J&J R331333-PAI-3020)
Johnson & Johnson Austin, TX	A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy (J&J R331333-PAI-3018)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Neuromed Pharmaceuticals Conshohocken, PA	A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (Neuromed NMT 1077-302)
NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Bupropion for Methamphetamine Dependence (NIDA-MDS-Bupropion Meth-0001)
Ortho-McNeil Janssen Irvine, CA	Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)
Ortho-McNeil Janssen Irvine, CA	A Randomized, Double Blind, Placebo- and Oxycodone Immediate Release (IR) - Controlled Study of Tapentadol IR for the Treatment of Acute pain Caused by Vertebral Compression Fractures Associated with Osteoporosis (OMJSA R331333-PAI-3021)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
QRxPharma Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)
QRxPharma Bedminster, NJ	A Double-Blind, Randomized, Multi-Center, Repeat Dose, Placebo Controlled Study to Compare the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to Each of the Individual Milligram Components (Oxycodone and Morphine) and Placebo in the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-015)
Shire Pharmaceuticals Philadelphia, PA	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Shire Pharmaceuticals Philadelphia, PA	A Phase III, Open-Label, Extension, Multicenter, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-306)
Shire Pharmaceuticals Wayne, PA	A Phase IIIb Randomized, Double-Blind, Multi-center, Placebo-controlled, Dose Optimization, Crossover, Safety and Efficacy Workplace Environment Study of Lisdexamfetamine Dimesylate (LDX) in Adults with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD489-316)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-808)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-809)

TABLE 2

RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2008

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Gayle Baldwin, Ph.D. UCLA ISAP Los Angeles, CA	Cocaine Dependency and Enhanced Susceptibility to HIV Infection
Phillip E. Bickler, MD, PhD UCSF Dept of Anesthesia San Francisco, CA	Inhaled carbon dioxide and apnea during intravenous sedation
Richard De La Garza, II, Ph.D. UCLA ISAP Los Angeles, CA	Rivastigmine and Donepezil as Potential Treatments for Cocaine Addiction
Ronald Ellis, MD, PhD UCSD HIV Neurobehavior Research Ct. San Diego, CA	Ronald Ellis, MD, PhD UCSD HIV Neurobehavior Research Ct. San Diego, CA
Douglas Fry NORAC Azusa, CA	Panel Approved Research Project
Richard A. Houghten, Ph.D. Torrey Pines Inst./Molecular Study San Diego, CA	Biochemical Basis for the CNS Actions of Methaqualone
Ari Kalechstein, Ph.D. UCLA ISAP Los Angeles, CA	Methamphetamine Dependence: Treating Neurocognitive Impairment

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
George F. Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Central Mechanisms of Opiate Reinforcement and Dependence
George F. Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Neuronal Substrates of Cocaine Reward
Ronald Krauss, M.D. Children's Hospital Oakland Oakland, CA	Rimonabant Effects on Hepatic Lipoprotein Production
Richard Lenart Innovacon San Diego, CA	Development of urine and/or oral-fluid based in-vitro diagnostic tests to detect the presence of the controlled substances MDMA, GHB and THC
Richard Lenart Innovacon San Diego, CA	Development of urine and/or oral-fluid based in-vitro diagnostic tests in the form of lateral flow rapid test format to detect controlled substances commonly abused and misused by individuals
Mark T. Leibowitz, M.D. CA Clinical Trials Medical Group Glendale, CA	A Randomized, Open-label, Cross-Over Study to Characterize the PK of Fentanyl From Single Doses of Non-colored Fentanyl Buccal Tabs over the Dose Range of 100mcg thru 800mcg in Healthy Japanese Subjects Residing in the US

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Jon Levine, MD, PhD UCSF San Francisco, CA	Mechanisms of Pain Control: V. Analgesic Combinations for Post-Operative Pain–Kappa Opioids and Morphine
Edythe London, Ph.D. UCLA ISAP Los Angeles, CA	Modafinil as a Treatment for Methamphetamine Dependence: Initial Safety, Subjective Effects, and Brain Functioning - Pilot study
John E. Mendelson, M.D. CPMC APRL San Francisco, CA	Is There an Acute MDMA Single Dose Withdrawal Syndrome?
Pierre-Yves Michellys, Ph.D. Genomics Institute of the Novartis 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
Karen Miotto, M.D. UCLA ISAP Los Angeles, CA	GHB: Effects, Withdrawal and Treatment
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	Phase I Clinical Trial with OROS-MPH for Methamphetamine Dependence

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	An evaluation of the presence of psychotic symptoms in response to experimental administration of methamphetamine or placebo in the laboratory
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	The Dual Deficit Hypothesis of Stimulant Dependence: An Experiment Assessment in Human Volunteers
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Laboratory Models of Cocaine Self Administration
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Double-Blind, Randomized, Placebo-Controlled Trial of Rivastigmine (Exelon) as a Potential Medication for Methamphetamine Abuse
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	Methamphetamine Dependence: A Novel Laboratory Model

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Karno Ng, Ph.D. California State University San Marcos San Marcos, CA	New Qualitative and Quantitative Methods for the Detection of Gamma-hydroxybutyrate (GHB)
Mark Perrone, Ph.D. Genomics Institute of the Novartis 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
Robert Ramage Microgenics Corporation Fremont, CA	Use of Schedule I Controlled Substances for Cross Reactant Studies and Investigation of Customer Inquiries
Marylou Solbrig, M.D. UC Irvine Irvine, CA	Panel Approved Research Project
David L. Valentine, Ph.D. UCSB Department of Earth Science Santa Barbara, CA	Perindopril - Methamphetamine Interaction Study
AcelRx Pharmaceuticals Redwood City, CA	A Multicenter, Randomized, Placebo-Controlled, Crossover Study for the Evaluation of the Safety and Efficacy of ARX-F02 Compared to Placebo in the Treatment of Cancer Breakthrough Pain (AcelRx ARX-C-003)

Table 2 Cont.

Sponsor / PI	Title of Study / 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)

Table 2 Cont.

Sponsor / PI	Title of Study / 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 (Archimedes 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 (Archimedes CPO45/06/FCNS)
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study
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 2 Cont.

Sponsor / PI	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 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)
Javelin Pharmaceuticals Cambridge, MA	A Randomized, Double-Blind, Active- and Placebo-Controlled, Study of the Analgesic Efficacy & Safety of Repeated Dosing of MNS075 (Intranasal Morphine), IV Morphine and Placebo in Patients with Acute Post-Operative Pain after Elective Orthopedic Surgery (Javelin MOR-003)

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 Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease (J&J R331333-PAI-3002)
NIDA Rockville, MD	A Two-Phase Randomized Controlled Clinical Trial of Buprenorphine/Naloxone Treatment Plus Individual Drug Counseling for Opiod Analgesic Dependence (NIDA CTN Protocol 0030)
NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Topiramate for the Treatment of Methamphetamine Dependence (NIDA-MDS-Topiramate/meth0001)
NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Modafinil for the Treatment of Methamphetamine Dependence (NIDA/VA CSP #1026)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
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)
Purdue Pharma 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)
Purdue Pharma 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)
QRxPharma Austin, TX	A Placebo-Controlled, Randomized, Double-Blind Study of the Safety and Efficacy of Q8003 in The Management of Post-Bunionectomy Pain (QRxPharma Q8003-007)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
QRxPharma 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 (QRxPharma Q8003-010)
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)
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)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire Pharmaceuticals Wayne, PA	A Phase IIIb Randomized, Double-Blind, Multi-center, Placebo-controlled, Dose Optimization, Crossover, Safety and Efficacy Workplace Environment Study of Lisdexamfetamine Dimesylate (LDX) in Adults with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD489-316)
Titan Pharmaceuticals Mississauga, ON Canada	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-805)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-807)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-808)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-809)

APPENDIX A

CURRENTLY OPEN *(through December 31, 2008)*
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
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
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
James T. Arnold, Ph.D. Systems and Techniques Lab. Palo Alto, CA	Panel Approved Research Project
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768	The cannabinoid system and the modulation of T cell and macrophage Functions
Jeremy S. Caldwell, Ph.D. Genomics Institute San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
Karen Chang, Ph.D. ALZA Corporation Mountain View, CA	Purity Determination, Morphine and Hydromorphone

Appendix A Cont.

Principal Investigator	Title of Study
Arthur K. Cho, Ph.D. UCLA School of Medicine Los Angeles, CA	Studies on Distribution and Metabolism of Narcotics in Animals
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Project
Mohammad Diab, M.D. UCSF Dept of Orthopaedic Surgery San Francisco, CA	Panel Approved Research Project
Robert Edwards, M.D. UCSF School of Medicine San Francisco, CA	Panel Approved Research Project
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement
Frederick D. Frankel, Ph.D. UCLA ISAP Los Angeles, CA	Social Skills Training for Medicated Children
Douglas Fry The Norac Co., Inc. Azusa, CA	Panel Approved Research Project

Principal Investigator	Title of Study
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
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
Scott A. Irwin, MD, PhD San Diego Hospice/ Palliative Care San Diego, CA	Panel Approved Research Project
Reese Jones, M.D. UCSF Langley Porter Institute San Francisco, CA	Pilot Study of LSD in Healthy Volunteers
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

Appendix A Cont.

Principal Investigator	Title of Study
Kimberley D. Lakes, Ph.D. UC Irvine Irvine, CA	The Effects of Vyvanse on Brain Hemodynamics and Reading
Nancy M. Lee, Ph.D. CPMC Research Center San Francisco, CA	Panel Approved Research Project
Daniel Levin, Ph.D. Norac Pharma Azusa, CA	Panel Approved Research Project
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development Study
James T. McCracken, M.D. UCLA NPI Los Angeles, CA	An 8-Week, Randomized, Double-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate ER (Focalin XR) and the Combination, with a 12 Month Open-Label Extension for the Treatment of ADHD in Pediatric Subjects Aged 7 to 14 years
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

Principal Investigator	Title of Study
Robert Messing, M.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Protein kinase C epsilon (PKCe) in Responses to Cannabinoids
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Intranasal administration of gamma-hydroxybutyrate
Karel Z. Newman, Ph.D. Biosite Incorporated San Diego, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Stanley M. Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA	Rapid Detection of 4-hydroxybutyrate
John M. Polich, Ph.D. The Scripps Research Institute La Jolla, CA	Marijuana CNS Effects in Low- and High-Risk Adults
Mark Rollins, MD, PhD UCSF Dept of Anesthesia San Francisco, CA	Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety?
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

Appendix A Cont.

Principal Investigator	Title of Study
Lawrence Toll, Ph.D. SRI International Menlo Park, CA	Biochemical Studies into Opiate Efficacies
Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA	Panel Approved Research Project
Mark Wallace, M.D. UC San Diego San Diego, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	Endocytosis and Cannabinoid Receptors
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	Endocytosis and Opioid Receptors
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 OPEN *(through December 31, 2008)*
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
AcelRx Pharmaceuticals Redwood City, CA	A Multi-Center, Randomized, Placebo-Controlled Phase II Study to evaluate the Clinical Efficacy, Safety, and Tolerability of ARX-F01 Sublingual Sufentanil NanoTabs TM in Patients Undergoing Major Abdominal Surgery (AcelRx ARX-C-005)
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 FEN-202)
Endo Pharmaceuticals Chadds Ford, PA	A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy & Safety of EN3267 for the Treatment of Breakthrough Pain in Opioid Tolerant Cancer Patients Followed by a 12-Months Non-Randomized, Open-Label Extension to Assess LT Safety (Endo EN3267-005)
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 EN3267-007)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxymorphone in Opioid-Tolerant pediatric Subjects with Chronic Pain (Endo EN3202-036)
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label, Ascending, Two-Part, Single- and Multiple-Dose Evaluation of the Safety, Pharmacokinetics, and Effectiveness of Oxymorphone For Acute Postoperative Pain in Pediatric Subjects (Endo EN3203-010)
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)
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)

Sponsor	Description or Title of Clinical Drug Trial Protocol
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 Austin, TX	A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy (J&J R331333-PAI-3018)
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Placebo- and Active- Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated with Tapentadol IR and Oxycodone IR Using a Bowel Function Patient Diary (J&J R331333-PAI-3020)
Johnson & Johnson Titusville, NJ	A Pivotal Bioequivalence Study Assessing Transdermal D-TRANS Fentanyl 100 *u*g/h Matrix System to DURAGESIC Fentanyl 100 *u*g/h Reservoir System After Single Application in Healthy Subjects (J&J FEN-PAI-1019)

Appendix B Cont.

Sponsor	Description or Title of 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)
Neuromed Pharmaceuticals Conshohocken, PA	A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (Neuromed NMT 1077-302)
OMJSA Irvine, CA	Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)
OMJSA Raritan, NJ	A Randomized, Double Blind, Placebo- and Oxycodone Immediate Release (IR) - Controlled Study of Tapentadol IR for the Treatment of Acute pain Caused by Vertebral Compression Fractures Associated with Osteoporosis (OMJSA R331333-PAI-3021)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue Pharma 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)
QRxPharma Bedminster, NJ	A Double-Blind, Randomized, Multi-Center, Repeat Dose, Placebo Controlled Study to Compare the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to Each of the Individual Milligram Components (Oxycodone and Morphine) and Placebo in the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-015)
QRxPharma Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Shire Pharmaceuticals Wayne, PA	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)
Shire Pharmaceuticals Wayne, PA	A Phase III, Open-Label, Extension, Multicenter, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-306)
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 C

CURRENTLY OPEN *(through December 31, 2008)* RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Gantt P. Galloway, Pharm.D. CPMC APRL San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Gantt P. Galloway, Pharm.D. CPMC APRL San Francisco, CA	A Pilot Trial of Dextroamphetamine for Treatment of Methamphetamine Dependence
Alan Gevins, D. Sc. SAM Technology San Francisco, CA	Realtime Neural Monitor for Drug Abuse Research
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
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	A Human laboratory Assessment of the Safety and Potential Efficacy of Varenicline in Methamphetamine-Dependent Volunteers Receiving Methamphetamine

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 Methamphetamine Dependence: A Phase II Study (Catalyst CPP-02001)
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 Bupropion for Methamphetamine Dependence (NIDA-MDS-Bupropion Meth-0001)

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.

Sec. 11480. Cont.

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.