

FORTY-SECOND ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2012



PREPARED FOR THE

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

**455 Golden Gate Avenue - Suite 11000
San Francisco, California 94102-7004**

www.ag.ca.gov/research

TABLE OF CONTENTS

	Page
LIST OF 2012 PANEL MEMBERS	2
SUMMARY OF 2012 PANEL ACTIVITIES	3
TABLE 1 - Research Studies approved in 2012	7
TABLE 2 - Research Studies closed in 2012	13
APPENDICES	
Appendix A - Currently Open Schedule I and II Non-Human & Academic Human Studies	25
Appendix B - Currently Open Schedule II Clinical Drug Trial Studies	31
Appendix C - Currently Open Research Studies on the Treatment of Controlled Substance Abuse	41
Appendix D - Pertinent Sections - California Health and Safety Code	
§ 11213 - Persons and researches using controlled substances	43
§ 11480 & 11481 - Research Advisory Panel	43
§ 11603 & 11604 - Attorney General	44
§ 24172 - Experimental subject's bill of rights	45
§ 24173 - Informed consent	46

2012 PANEL MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

Edward P. O'Brien, J.D.
Panel Chairman
Appointed by Attorney General

Y. Jennifer Ahn, Pharm.D.
Executive Officer

Patrick R. Finley, Pharm.D.
Appointed by the State Board of Pharmacy

Andrew S. Kayser, MD, PhD
Appointed by the University of California at San Francisco
Designated University of California

John E. Mendelson, M.D.
Appointed by the California Medical Association
Designated professional medical society

Michele T. Pato, M.D.
Appointed by the University of Southern California
Designated private university

Laurence R. Upjohn, Pharm.D.
Appointed by the Department of Public Health

RAPC Website : www.ag.ca.gov/research

E-mail contact: jennifer.ahn@doj.ca.gov

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.

SUMMARY OF 2012 PANEL ACTIVITIES

During 2012 the Panel reviewed twenty-five research study submissions. Twenty-four were approved by the Panel. Among approved studies, four studies were Academic research studies, two studies were Substance Abuse Treatment research protocols, and eighteen studies were Clinical Drug Trial research protocols.

Forty-three research studies were completed in 2012, and they were closed on the Panel's records.

At the end of 2012, the Panel was monitoring one hundred-twenty 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 2012 and Table 2 is a list of the studies closed by the Panel in 2012.

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 research projects currently ongoing in California:

Dr. Philip Bickler, MD, PhD, and colleagues at University of California, San Francisco have provided the Panel with the following summary of Human research titled "Detecting apnea in healthy volunteers receiving opiate or sedative medications"

The long-term objective of this study is to improve the safety of patients receiving opioids for post-operative pain control or conscious sedation outside the operating room. To achieve this objective, the study will determine if a new modification to a pulse oximeter is able to detect apnea by analyzing the waveform of the pulse oximeter photoplethysmography signal. As a safe test protocol, we will use our laboratories established apnea model involving intravenous sedation with propofol and remifentanyl in healthy volunteers. This apnea model was part of the previously approved study "Supplemental oxygen:

A reduction in pulse oximetry sensitivity or an increased margin of safety?", PI Mark Rollins, Approval # H8785-31490.

We will enroll up to 40 subjects per year in a protocol involving an infusion of propofol to produce sedation, followed by administration of the ultra-short acting opioid remifentanyl to produce apnea. Apneas of varying durations will be produced by varying the dose of remifentanyl. If the saturation drops below 85%, the anesthesiologists in attendance will provide airway support and/or positive pressure ventilation until spontaneous breathing is restored.

Sunovion Pharmaceuticals has submitted the Panel with the following summary of clinical drug trial study titled "A Randomized, Double-Blind, Parallel-Group, Multicenter Efficacy and Safety Study of SEP-225289 Versus Placebo in Adults with Attention Deficit Hyperactivity Disorder (ADHD)"

Study Objectives

Primary: To evaluate the efficacy of SEP-225289 (4 mg and 8 mg) compared with placebo in adult subjects with ADHD.

Secondary: To evaluate the safety and tolerability of SEP-225289 (4 mg and 8 mg).
To evaluate the effects of SEP-225289 (4 mg and 8 mg) compared with placebo on cognition in adult subjects with ADHD.
To assess the relationship between SEP-225289 plasma concentration and the primary and selected secondary clinical outcome measures, and 3, 4-dihydroxyphenylglycol (DHPG)/ norepinephrine (NE) concentrations and plasma concentration of SEP-225289 using population pharmacokinetic (PK)/pharmacodynamic (PD) methods.

This is a Phase 2, randomized, double-blind, parallel-group, multicenter, outpatient study evaluating the efficacy and safety of SEP-225289 in adults with ADHD using 2 dosages (4 or 8 mg SEP-225289 once daily [QD]) versus placebo over a 4-week treatment period. The study will consist of 3 periods including Screening, Treatment, and Washout/Follow-up, as described below.

Efficacy will primarily be evaluated using the ADHD Rating Scale Version IV (ADHD RS-IV) with adult prompts. Effects on cognition will be evaluated using the CDR System. Safety and tolerability will be monitored throughout the study by collection of physical examinations, 12-lead electrocardiograms (ECG), vital signs, adverse events (AEs), hematology, blood chemistry, urinalysis, Insomnia Severity Index (ISI), and Columbia – Suicide Severity Rating Scale (C-SSRS). Population pharmacokinetic methodology will be performed using the measured plasma SEP-225289 concentrations; the results of which will be reported separately. The relationship between SEP-225289 plasma concentration and the primary and selected secondary clinical outcome measures, and SEP-225289 plasma concentration and DHPG/NE concentrations using population PK/PD methods will be explored.

Subjects will provide information on subjective drug effects that would indicate abuse liability via the administration of the Drug Effects Questionnaire at each visit and the Brief Psychiatric Rating Scale and Physician Withdrawal Checklist will be administered. In addition a comprehensive Abuse Potential Monitoring Plan (APMP) for SEP-225289 has been designed to detect potential abuse of the compound and to more closely monitor AEs consistent with the pharmacology. (refer to Appendix VII)

Professor Raymond Stevens, PhD, and colleagues at the Scripps Research Institutes, La Jolla, CA have submitted the Panel with the following summary of Non-Human research titled "Microscale Extraction and Purification of Integral Membrane Proteins"

This Immobilized Metal Affinity Chromatography (IMAC)-based protein purification protocol is currently being used at the JCIMPT for small-scale preparation of purified proteins starting with biomass of SF9 cells containing over-expressed membrane proteins. Its main use is the early evaluation and characterization of expression, protein properties, and the design of strategies for large-scale production of samples for crystallization and functional studies. The protocol has been tested and extensively used in preparing and screening GPCR samples using 5 mL of biomass.

Overview of Steps:

- Cell lysis and production of membrane preparations containing over-expressed proteins
- Extraction and solubilization by detergents
- IMAC purification
- Quality check and characterization of products

TABLE 1

**RESEARCH STUDIES
APPROVED IN 2012**

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Jack Berger, M.D. LAC + USC Medical Center Los Angeles, CA	Prospective, Double-Blinded, and Randomized Control Trial of Multimodal Pain Relief with Intravenous Magnesium, Lidocaine and Ketorolac in Patients with Opiate Refractory, Post-Operative Pain
Philip E. Bickler, MD, PhD Dept of Anesthesia, UCSF San Francisco	Detecting Apnea in Healthy Volunteers Receiving Opiate or Sedative Medications
Raymond Stevens, Ph.D. The Scripps Research Institute La Jolla, CA	Structure Determination of the Hallucinogens LSD and Psilocin Bound to the Serotonin Receptor 5-HT2B
Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate ALKS 5461 in Subjects with Major Depressive Disorder and Inadequate Responses to Antidepressant Therapy (ALK5461-202)

Collegium / CRO-INC Research
Raleigh, NC

A Phase 3, Multi-Center, Randomized,
Double-Blind, Placebo-Controlled, Safety,
Tolerability, and Efficacy Study of Oxycodone
DETERx™ Versus Placebo in
Opioid-Experienced and Opioid-Naïve
Subjects with Moderate-to-Severe Chronic
Low Back Pain
(CO-OXYDET-08)

GW Pharmaceuticals
Mill Valley, CA

Panel Approved Resesarch

Mitsubishi / CRO-Quintiles
Overland Park, KS

A Phase 2, Randomized, Double-Blind,
Placebo-Controlled, Fixed-Dose,
Parallel-Group, Multicenter, Efficacy, and
Safety Study of MT-9938 for Treatment of
Uremic Pruritus in Subjects with End-Stage
Renal Disease Receiving Hemodialysis
(MT-9938-01)

Nektar
San Francisco, CA

A Phase 2, Enriched-Enrollment,
Randomized-Withdrawal, DB, PC, MC Study
to Assess the Efficacy, Tolerability, & Safety
of NKTR-181 in Opioid-Naïve Subjects w
Mod to Sev Chr Pain Due to Osteoarthritis of
the Knee
(12-181-04)

NextWave Pharmaceuticals
Chapel Hill, NC

A Multicenter, Dose-Optimized,
Double-Blind, Randomized,
Placebo-Controlled Study to Evaluate the
Efficacy of NWP09 in Pediatric Patients with
Attention Deficit Hyperactivity Disorder
(ADHD) in a Laboratory Classroom
(NWP09-ADHD-300)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Noven / CRO-PRA Lenexa, KS	A Randomized, DB, PC, Cross-Over, Lab Classroom Study to Evaluate the Safety & Efficacy of d-Amphetamine Transdermal Drug Delivery System (d-ATS) Compared to Placebo in Children & Adolescents w ADHD (N25-006)
Noven Pharmaceuticals New York, NY	An Investigational Study to Evaluate the Usability of Reformulated Methylphenidate Transdermal System in Children, Adolescents and Adults with ADHD and Caregivers (N17-030)
Pfizer, Inc. New York, NY	A MC, 12-week, DB, PC, Rand. Withdrawal Study to Determine The Efficacy & Safety of ALO-02 (Oxycodone HCl & Naltrexone HCl) ER Caps in Subjects w Mod to Sev Chr. Low Back Pain (B4531002)
QRxPharma / CRO-INC Research Austin, TX	A DB, Rand, P, & AC, PG Study to Evaluate the Safety, Tolerability & Efficacy of Q8011 Comped to OxyContin & Placebo in Pts w Mod to Sev Chr. Hip or Kneww Pain Due to Osteoarthritis (Q8011-201)
Roxane / CRO-Quintiles Durham, NC	A Multicenter, Open-Label, Safety & PK Study of Oral Codeine Sulfate Adm of Pediatric Subjects 2 yrs old thru 17 yrs old w Post-Procedural Pain (Code-OS+T-(2-17)-SPK-1)

Shire / CRO-Premier
Research Group
Bluff City, TN

A Phase 3, Multicenter, Open-Label,
12-Month Extension Safety and Tolerability
Study of SPD489 in the Treatment of Adults
with Binge Eating Disorder
(SPD489-345)

Shire / CRO-Premier
Research Group
Philadelphia, PA

A Phase 3, Multicenter, Randomized,
Double-Blind, Parallel-Group,
Placebo-Controlled, Dose-Optimization Study
to Evaluate the Efficacy, Safety, and
Tolerability of SPD489 in Adults Aged 18-55
Years with Moderate to Severe Binge Eating
Disorder
(SPD489-344)

Shire Pharmaceuticals
New York, NY

A Phase I, Rand, DB, PC Study to Evaluate
the Safety, Tolerability, & PK of Single &
Multiple-Doses of SPD489 in Japanese &
Caucasian Healthy Adult Subjects
(SPD489-121)

Shire / CRO-Premier
Research Group
Alexander, NC

A Phase 4, Rando, DB, MC, PG, AC,
Forced-dose Titration, Safety & Efficacy
Study of SPD489 (Vyvanse) Compared w
OROS-MPH (Concerta) w a Placebo
Reference Arm, in Adolescents Aged 13-17
Years w ADHD
(SPD489-406)

Shire / CRO-Premier
Research Group
Alexander, NC

A Phase 4, Rando, DB, MC, PG, AC,
Dose-optimization Safety & Efficacy Study of
SPD489 (Vyvanse) Compared w OROS-MPH
(concerta) w a Placebo Reference Arm, in
Adolescents Aged 13-17 Years w ADHD
(SPD489-405)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire / CRO-Premier Research Group Philadelphia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Optimization Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder (SPD489-343)
Sunovion / CRO-INC Research Seattle, WA	A Randomized, Double-Blind, Parallel-Group, Multicenter Efficacy and Safety Study of SEP-225289 Versus Placebo in Adults with Attention Deficit Hyperactivity Disorder (ADHD) (SEP360-201)
Liza Gorgon NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial of Nepicastat for Cocaine Dependence (CS# 1031)
Edythe London, Ph.D. Semel Institute, UCLA Los Angeles, CA	Safety and Initial Efficacy of Buspirone for Methamphetamine Dependence

TABLE 2

RESEARCH STUDIES CLOSED IN 2012

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Hussein Al-Shamma, Ph.D. Arena Pharmaceuticals San Diego, CA	Evaluation of lorcaserin for abuse liability using the Drug Discrimination Test in the Rat
Danilyn Angeles, Ph.D. Loma Linda Univeristy Medical Ct. Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
Mariusz Banaszczyk, Ph.D. Biosite Diagnostics San Marcos, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Selena Barrett, Ph.D. Ernest Gallo Clinic & Research Ct. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Marthias Behrends, M.D. Dept. of Anesthesia, UCSF San Francisco, CA	A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Jack Berger, Ph.D. LAC + USC Medical Center Los Angeles, CA	Prospective, Double-Blinded, and Randomized Control Trial of Multimodal Pain Relief with Intravenous Magnesium, Lidocaine and Ketorolac in Patients with Opiate Refractory, Post-Operative Pain
Nancy Buckley, Ph.D. Biological Sciences Dept CA State Polytechnic University	Effects of delta-9-tetrahydrocannabinol on Candida albicans infection
Peggy Compton, RN, Ph.D. UCLA School of Nursing Los Angeles, CA	Pain, Opioids, and Pro-inflammatory Immune Responses
Keith Flower, M.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP
Keith Heinzerling, MD, PhD UCLA Geffen School of Medicine Los Angeles, CA	Pilot Trial of Bupropion versus Placebo for Methamphetamine Abuse in Adolescents
Scott Irwin, MD, PhD San Diego Hospice and Institute for Palliative Medicine San Diego, CA	An Open label Trial of Oral Ketamine for the Rapid Treatment of Depression in Hospice Patients

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Daniel Levin, Ph.D.
Norac Pharma
Azusa, CA

Evaluation of Cannabinoids derived from
the Natural Product Marijuana

Walter Ling, M.D.
UCLA Geffen School of Medicine
Los Angeles, CA

Optimizing Outcomes Using Suboxone
for Opiate Dependence

Edythe London, Ph.D.
UCLA Geffen School of Medicine
Los Angeles, CA

A Study to Assess the Cardiovascular,
Cognitive, and Subjective Effects of
Atomoxetine in Combination with Oral
Methamphetamine

James McCracken, M.D.
APRL/CPMC Research Institute
San Francisco, CA

An 8-Wk, Rndmzd, Dbl-Blind
Comparison of Twice-Daily Guanfacine,
Once-Daily d-Methylphenidate ER
(Focalin XR) and the Combination, with a
12 Month Open-Lbl Extension for the
Treatment of ADHD in Pediatric Subjects
Aged 7 to 14 years

John E. Mendelson, M.D.
APRL/CPMC Research Institute
San Francisco, CA

Bioavailability and Urinary Excretion of
Oral L-Methamphetamine

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
John E. Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	The Effects of MDMA on Sleep Architecture, Water Homeostasis, and Cognitive Function
Loren Parsons, Ph.D. The Scripps Research Institute La Jolla, CA	Cognitive and Neurochemical Effects of Δ^9 -tetrahydrocannabinol and related cannabinoids in rodents
Lara Ray, Ph.D. UCLA Los Angeles, CA	Genetics of Naltrexone in Methamphetamine Users
Rajesh Venugopal NIDA, The EMMES Corp. Rockville, MD	Cocaine Use Reduction with Buprenorphine (CURB) (CTN-0048)
Ronald Victor, M.D. Cedars-Sinai Medical Center Los Angeles, CA	Cocaine and Sympathetic Nerve Activity in Humans - "Cocaine and the Heart"
Mark Wallace, M.D. Center for Pain Medicine, UCSD La Jolla, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Barth Wilsey, M.D.
UC Davis Medical Center
Sacramento, CA

The Analgesic Effect of Vaporized
Cannabis on Neuropathic Pain

Titan Pharmaceuticals, Inc.
S. San Francisco, CA

A Randomized, Placebo and
Active-Controlled, Multi-Center Study of
Probuphine in Patients with Opioid
Dependence
(PRO-806)

Titan Pharmaceuticals, Inc.
S. San Francisco, CA

A Phase 3, Six-Month, Open-Label
Re-Treatment Study of Probuphine in
Opioid Addiction
(PRO-811)

Astra Zenica / CRO-Quintiles
Overland Park, KS

An Open-label, Parallel-group, Phase I
Study to Compare the Pharmacokinetics
of NKTR-118 Following a Single-Oral
Dose in Subjects with Renal Impairment
and Subjects with Normal Renal Function
(D3820C00009)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

BRC Operations
Ultimo, NSW

International Study to Predict Optimized
Treatment in Attention
Deficit/Hyperactivity Disorder

Cephalon, Inc.
Fort Washington, PA

A 12 wk, Rand, Dbl-Blind, P-C. Study to
Eval. the Efficacy & Safety of
Hydrocodone Bitartrate ER Tabs
(CEP-33237) at 15-90mg q12 hrs for
Relief of Mod to Sev Pain in Pts w/ OA or
Low Back Pain Who Require Opioid Tx
for an Ext. Period of Time
(C33237/3079)

Cephalon, Inc.
Fort Washington, PA

A 12-Month, Open-Label Study to
Evaluate the Long-Term Safety of
Hydrocodone Bitartrate Extended-Release
Tablets (CEP-33237) at 15 to 90mg Every
12 Hours in Patients Who Require Opioid
Treatment for an Extended Period of Time
(Cephalon C33237/3080)

GW Pharmaceuticals
Mill Valley, CA

Panel Approved Research

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Janssen / J&J
Titusville, NJ

A Rand, DB, Parallel Arm, Clinical Trial
to Compare the Clin Effectiveness of
Tapentadol ER vs Oxycodone CR in
Subjects w Mod to Sev Chronic Low
Back Pain
(R331333PAI4003)

Johnson & Johnson PRD
Malvern, PA

Single-Dose, Open-Lbl. Ran. Two-Way
Crossover Study to Assess the BE of
Tapentadol Given as Two 50mg ER TRF
Tabs Relative to One 100mg ER TRF Tab
in Healthy Japanese Male Subjects
(PAI 1063)

Johnson & Johnson PRD
Titusville, NJ

A Randomized-Withdrawal,
Placebo-Controlled, Study Evaluating the
Efficacy, Safety, and Tolerability, of
Tapentadol Extended-Release (ER) in
Subjects with Chronic, Painful Diabetic
Peripheral Neuropathy (DPN)
(PAI 3027)

Johnson & Johnson PRD
Malvern, PA

A Single-Dose, Open-Lbl, Ran. Two-Way
Crossover Study to Assess the BE of
Tapentadol Given as Two 25mg ER
Tamper-Resistant Form (TRF) Tabs
Relative to One 50mg ER TRF Tab in
Healthy Japanese male Subjects
(PAI 1062)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Johnson & Johnson PRD
Malvern, PA

A Single-Dose, Open-Label, Rand. 4-Way
Crossover Study to Assess the
Dose-Proportionality of the PK of
Tapentadol, Given as Tamper-Resistant
Tabs, in Healthy Japanese & Korean Male
Subjects
(PAI 1064)

Mallinckrodt
Hazelwood, MD

A Phase 3 MC, R, DB, PC, PG Evaluation
of the Safety & Analgesia Efficacy of
COV795 (Oxycodone HCl /
Acetaminophen) ER Tablets in Mod to
Sev Post-Operative Bunionectomy Pain
Followed by an Open Label Extension
(COV15000182US)

Mallinckrodt / CRO-INC Research
Middleton, WI

An Open Label Safety Study of COV795
in Subjects with Osteoarthritis or Chronic
Low Back Pain
(COV15000181US)

Mundipharma / CRO-Parex
Woburn, MA

A Confirmatory, Placebo-Controlled,
Rand, D-B, Single-Dummy, Parallel Gr,
Ratio-Finding Study in Constipated Pain
Pts to Establish an Optimal
Hydromorphone-naloxone ratio w an
Improved Bowel Funt & a Comp Analg
Eff Comp to H-morphone alone
(HMX3501)

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

NextWave Pharmaceuticals
Chapel Hill, NC

A Multicenter, Dose-Optimized,
Double-Blind, Randomized,
Placebo-Controlled Study to Evaluate the
Efficacy of NWP09 in Pediatric Patients
with Attention Deficit Hyperactivity
Disorder (ADHD) in a Laboratory
Classroom
(NWP09-ADHD-300)

Novartis Pharmaceuticals
East Hanover, NJ

A 6-Month, Open-Label Extension to a
40-Week, Randomized, Double-Blind,
Placebo-Controlled, Multicenter Efficacy
and Safety Study of Ratain LA in the
Treatment of Adult Patients with
Childhood-Onset ADHD
(CRIT124D2302E1)

Novartis Pharmaceuticals
East Hanover, NJ

A 40-Week, Randomized, Double-Blind,
Placebo controlled, Multicenter Efficacy
and Safety Study of Ritalin® LA in the
Treatment of Adult Patients with
Childhood-Onset ADHD
(CRIT124D2302)

Purdue / CRO-PRA International
Lenexa, KS

An Open-label, MC Study of the Safety of
Twice Daily Oxycodone HCl CR Tabs in
Opioid Experienced Children from Ages 6
to 16 Years Old, Inclusive, w/ Mod to Sev
Malignant and/or Nonmalignant Pain
Requiring Opioid Analgesics
(OTR3001)

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Purdue / CRO-PRA International Lenexa, KS	An Open-label Study to Characterize the PK and Safety of Oxycodone HCl q12h CR (ORF) Tabs in Pediatric Pts Aged 6 to 16 years inclusive, Who Require Opioid Analgesia (OTR 1020)
Rhodes / CRO-NuTec Inc. Boston, MA	A Random, Dbl-Blind Study of the Time Course of Response of Biphentin ® Methylphenidate HCl ER Caps As Compared to Placebo in Children 6-12 y.o. w/ ADHD in an Analog Classroom Setting (RP-BP-EF001)
Rhodes / CRO-NuTec Inc. Boston, MA	A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder (RP-BP-EF002)
Roxane / CRO-Quintile Durham, NC	A Multicenter, Open-Label, Safety & PK Study of Oral Codeine Sulfate Adm of Pediatric Subjects 2 yrs old thru 17 yrs old w Post-Procedural Pain (Code-OS+T-(2-17)-SPK-1)

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Roxane / CRO-Quintile
Durham, NC

A MC, Open Label, Safety & PK Study of
Oral Morphine Sulfate Admin. In
Pediatric Subjects 2 yrs old thru 17 y.o. w/
Postoperative Pain
(MORP-OS+T-(2-17)-SPK-1)

Shire Pharmaceuticals
Wayne, PA

A Phase 1, R, DB, PC Study to Assess the
Safety, Tolerability, PK, & PD of
Ascending, Multiple Oral Doses of
SPD489 in Clinically Stable Adults w
Schizophrenia
(SPD489-119)

Shire / CRO-Premium Research
Bluff City, TN

A Phase 2 Multicenter, Randomized,
Double-blind, Parallel-group,
Placebo-controlled, Forced-dose Titration
Study to Evaluate the Efficacy, Safe, and
Tolerability of SPD489 in Adults Aged
18-55 Years with Binge Eating Disorder
(SPD489-208)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Shire /Hampshire Intn'l
Hampshire, UK

A Phase III, Db-Blind, Placebo-Cont.
Randomized Withdrawal, M-C,
Extension, Safety & Efficacy study of
LDX in Children & Adoles. Aged 6-17 w/
ADHD
(SPD489-326)

Shire Pharmaceuticals
New York, NY

A Phase I, Rand, DB, PC Study to
Evaluate the Safety, Tolerability, & PK of
Single & Multiple-Doses of SPD489 in
Japanese & Caucasian Healthy Adult
Subjects
(SPD489-121)

Shire / CRO-INC Research
Raleigh, NC

A Phase 2, MC, Rand, DB, PC,
Parallel-gr. Study to Evaluate the
Efficacy, Safety & Tolerability of SPD489
in Adults w Clin. Signif. Persistent
Executive Function Impairments (EFI) &
Partial or Full Remission of Rec. Major
Depressive Disorder
(SPD489-205)

Zogenix Inc.
Emeryville, CA

A Long-Term Open-Label Safety Study of
Hydrocodone Bitartrate
Controlled-Release Capsules with
Flexible Dosing to Treat Subjects with
Moderate to Severe Pain
(Zx002-0802)

APPENDIX A

CURRENTLY OPEN (*through December 31, 2012*)
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 in MS: Placebo-
Controlled Study

Philip E. Bickler, MD, PhD
Dept of Anesthesia, UCSF
San Francisco, CA

Detecting Apnea in Healthy Volunteers
Receiving Opiate or Sedative Medications

John R. Cashman, Ph.D.
Human BioMolecular
Research Institute
San Diego, CA

Molecular Evolution of Human Cocaine
Catalysis

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

Mark A. Geyer, Ph.D.
Dept of Psychiatry, UCSD
La Jolla, CA

Behavioral and Cytofluorimetric Studies of
Psychoactive Drugs in Rats

Valerie Gruber, Ph.D.
SF General Hospital
UCSF
San Francisco, CA

Investigation of Age Differences in Analgesic,
Cognitive, and subjective effects of
Oxycodone, Hydrocodone, and
Acetaminophen

Kanthi Hettiarachchi, Ph.D.
SRI International
Menlo Park, CA

Analysis of Controlled Substances

Reese Jones, M.D.
UCSF
San Francisco, CA

Phase I Study of Interactions between Oral
Naltrexone and Bupripion and Intravenous
Methamphetamine in Mathamphetamine
Experienced Volunteers

Thomas S. Kilduff, Ph.D.
SRI International
Menlo Park, CA

Neurobiological Studies of
Gammahydroxybutyrate (GHB)

Adam Leventhal, Ph.D.
USC Keck School of Medicine
Alhambra, CA

Influence of Genes and Emotions on
medication Effects

Daniel Levin, Ph.D.
NORAC Pharma
Azusa, CA

Panel Approved Research

Daniel Levin, Ph.D.
NORAC Pharma
Azusa, CA

Panel Approved Research

Daniel Levin, Ph.D.
NORAC Pharma
Azusa, CA

Panel Approved Research

<u>Principal Investigator</u>	<u>Title of Study</u>
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development Study
Edythe London, Ph.D. UCLA Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine
Sean Mackey, MD, PhD Stanford University Palo Alto, CA	Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients
Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA	Panel Approved Research Project
Ardis Moe, Ph.D. UCLA Center for AIDS Research Los Angeles, CA	Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta TM) for Treatment of HIV Dementia
Richard Reznicek, M.D. Harbor-UCLA Medical Center Torrance, CA	A prospective, randomized, double-blind study comparing the efficacy and safety of intra nasal fentanyl spray to placebo as an analgesic in patients undergoing outpatient cystoscopic procedures
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans

Rajkumar J. Sevak, Ph.D.
UCLA
Los Angeles, CA

Human Methamphetamine
Self-Administration in a Progressive-Ratio
Paradigm

Matthew L. Springer, Ph.D.
UCSF
San Francisco, CA

Assessment of Impairment of Vascular
Function in Rats by Environmental Exposure
to Marijuana Second Hand Smoke

Raymond Stevens, Ph.D.
The Scripps Research Institute
La Jolla, CA

Structure Determination of the Hallucinogens
LSD and Psilocin Bound to the Serotonin
Receptor 5-HT_{2B}

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral and physiological toxicities of
cannabinoids

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral Toxicities of amphetamine and
cathinone stimulant drugs

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral toxicities of amphetamine and
cathinone stimulant drugs

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral and Physiological Toxicities of
Cannabinoids: Effects of Cannabidiol

Stephen Van Dien, Ph.D.
Genomatica, Inc.
San Diego, CA

Panel Approved Research Project

Principal Investigator

Title of Study

Jennifer L. Whistler, Ph.D.
Ernest Gallo Clinic & Research Ct.
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 Effect of Vaporized Cannabis on
Neuropathic Pain in Spinal Cord Injury

APPENDIX B

CURRENTLY OPEN (*through December 31, 2012*) SCHEDULE II CLINICAL DRUG TRIAL STUDIES

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (SAP202)
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (IAP310)
AcelRx Redwood City, CA	A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (IAP309)
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate ALKS 5461 in Subjects with Major Depressive Disorder and Inadequate Responses to Antidepressant Therapy (ALK5461-2)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled Study to Assess the Efficacy and
Safety of NKTR-118 in Patients with Non-
Cancer-Related Pain and Opioid-Induced
Constipation (OIC)
(D3820C00004)

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled Study to Assess the Efficacy and
Safety of NKTR-118 in Relieving Opioid-
Induced Constipation (OIC) in Patients with
Cancer-Related Pain
(D3820C00006)

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled 12-Week Extension Study to
Assess the Safety and Tolerability of NKTR-
118 in Patients with Non-Cancer-Related Pain
and Opioid-Induced Constipation (OIC)
(D3820C00007)

Astra Zenica / CRO - Quintiles
Overland Park, KS

An Open-Label 52 week Study to Assess the
Long-Term Safety of NKTR-118 in Opioid-
Induced Constipation (OIC) in Patients with
Non-Cancer-Related Pain
(D3820C00008)

Astra Zenica / CRO - Quintiles
Overland Park, KS

An Open-label, Parallel-group, Phase I Study
to Compare the Pharmacokinetics of NKTR-
118 Following a Single-Oral Dose in Subjects
with Renal Impairment and Subjects with
Normal Renal Function
(D3820C00009)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Collegium /CRO-INC Research Raleigh, NC	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of Oxycodone DETERx™ Versus Placebo in Opioid-Experienced and Opioid-Naive Subjects with Moderate-to-Severe Chronic Low Back Pain (CO-OXYDET-08)
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project
INTRuST Clinical Consortium La Jolla, CA	Randomized Controlled Trial of Galantamine, Methylphenidate, and Placebo for the Treatment of Cognitive Symptoms in Patients with Mild Traumatic Brain Injury (mTBI) and/or Posttraumatic Stress Disorder (PTSD) ("Cognitive REmediation After Trauma Exposure" Trial = CREATE Trial")
Mitsubishi / CRO-Quintiles Overland Park, KS	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group, Multicenter, Efficacy, and Safety Study of MT-9938 for Treatment of Uremic Pruritus in Subjects with End-Stage Renal Disease Receiving Hemodialysis (MT-9938-01)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Nektar
San Francisco, CA

A Phase 2, Enriched-Enrollment,
Randomized-Withdrawal, DB, PC, MC Study
to Assess the Efficacy, Tolerability, & Safety
of NKTR-181 in Opioid-Naïve Subjects w
Mod to Sev Chr Pain Due to Osteoarthritis of
the Knee
(12-181-04)

Noven / CRO-PRA
Lenexa, CA

A Randomized, DB, PC, Cross-Over, Lab
Classroom Study to Evaluate the Safety &
Efficacy of d-Amphetamine Transdermal
Drug Delivery System (d-ATS) Compared to
Placebo in Children & Adolescents w ADHD
(N25-006)

Noven Pharmaceuticals
New York, NY

An Investigational Study to Evaluate the
Usability of Reformulated Methylphenidate
Transdermal System in Children, Adolescents
and Adults with ADHD and Caregivers
(N17-030)

Pfizer Inc.
New York, NY

An Investigational Study to Evaluate the
Usability of Reformulated Methylphenidate
Transdermal System in Children, Adolescents
and Adults with ADHD and Caregivers
(B4531002)

Purdue / CRO-INC Research
Raleigh, NC

A MC, R, DB, PC Study w an OL Run-in to
Assess the Efficacy & Safety of Hydrocodone
Bitartrate (HYD) Tabs 20 to 120 mg
Once-day in Subjects w Mod to Sev Chronic
Low Back Pain
(HYD3002)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Purdue / CRO-PRA
Raleigh, NC

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (ONU3701)

Purdue / CRO-Quintiles
Overland Park, KS

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (ONU3704)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Purdue / CRO-Quintiles
Overland Park, KS

A Rand, DB, DD, PC, AC, PG, MC Trial of
OXN to Asses the Analg Effic (Comp to Plac)
& the Magm of Opioid-induc Const (Comp to
OXY) in Opioid-exp Sub w Cont Mod to Sev
Chr Low Back Pain & a His of Opioid-induc
Const w Req ATC Opioid Therapy
(ONU3705)

Purdue / CRO-INC Research
Raleigh, NC

An Open-label, Multicenter Study to Assess
the Long-Term Safety of Hydrocodone
Bitartrate (HYD) Tablets 20 to 120 mg Once-
daily in Subjects with Moderate to Severe
Chronic Non-malignant and Non-neuropathic
Pain
(HYD3003)

Purdue / CRO-PRA
Charlottesville, VA

An Open-label, Extension Study to Assess the
Long-Term Safety of Twice Daily Oxycodone
Hydrochloride Controlled-release Tablets in
Opioid Experienced Children Who Completed
the OTR3001 Study
(OTR3002)

QrxPharma / CRO-INC
Austin, TX

A DB, Rand, P, & AC, PG Study to Evaluate
the Safety, Tolerability & Efficacy of Q8011
Comped to OxyContin & Placebo in Pts w
Mod to Sev Chr. Hip or Kneww Pain Due to
Osteoarthritis
(Q8011-201)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Shire / CRO-ICON
Brentwood, TN

Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (489-322)

Shire / CRO - ICON
Brentwood, TN

Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (SPD489-323)

Shire Pharmaceuticals
Wayne, PA

A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (SPD 489-209)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire / CRO-Premier Research Group Alexander, NC	A Phase 4, Rando, DB, MC, PG, AC, Dose-optimization Safety & Efficacy Study of SPD489 (Vyvanse) Compared w OROS-MPH (concerta) w a Placebo Reference Arm, in Adolescents Aged 13-17 Years w ADHD (SPD489-405)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 4, Rando, DB, MC, PG, AC, Forced-dose Titration, Safety & Efficacy Study of SPD489 (Vyvanse) Compared w OROS-MPH (Concerta) w a Placebo Reference Arm, in Adolescents Aged 13-17 Years w ADHD (SPD489-406)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 3, Multicenter, Open-Label, 12-Month Extension Safety and Tolerability Study of SPD489 in the Treatment of Adults with Binge Eating Disorder (SPD489-345)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Optimization Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder (SPD489-344)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Shire / CRO-ICON
Brentwood, TN

Phase 3, Open-label, Multicenter, 12-month
Extension Safety and Tolerability Study of
SPD489 in Combination with an
Antidepressant in the Treatment of Adults
with Major Depressive Disorder with
Residual Symptoms or Inadequate Response
Following Treatment with an Antidepressant
(SPD489-329)

Shire / CRO-Premier
Research Group
Alexander, NC

A Phase 3, Multicenter, Randomized,
Double-Blind, Parallel-Group,
Placebo-Controlled, Dose-Optimization Study
to Evaluate the Efficacy, Safety, and
Tolerability of SPD489 in Adults Aged 18-55
Years with Moderate to Severe Binge Eating
Disorder
(SPD489-343)

Shire Pharmaceuticals
Wayne, PA

A Phase 3b, Dbl-blind, Randomized,
Active-controlled, Parallel-gr Study to
Compare the Time to Response of
Lisdexamfetamine to Atomoxetine in
Children & Adolescents aged 6-17 w ADHD
who have had an Inadequate Response to
Methylphenidate Therapy
(SPD489-317)

Sunovion / CRO-INC
Seattle, WA

A Randomized, Double-Blind,
Parallel-Group, Multicenter Efficacy and
Safety Study of SEP-225289 Versus Placebo
in Adults with Attention Deficit Hyperactivity
Disorder (ADHD)
(SEP360-20)

APPENDIX C

CURRENTLY OPEN (*December 31, 2012*) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

<u>Investigator or Sponsor</u>	<u>Description or Title of Research Study</u>
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Modafinil for Methamphetamine Dependence
Liza Gorgon NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial of Nopicastat for Cocaine Dependence (CS#1031)
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	Sustained-Release Methylphenidate for management of Methamphetamine Dependence
Edythe London, Ph.D. Semel Institute, UCLA Los Angeles, CA	Safety and Initial Efficacy of Bupirone for Methamphetamine Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

Investigator or Sponsor

Description or Title
of Research Study

Steven Shoptaw, Ph.D.
UCLA.
Los Angeles, CA

Varenicline for Methamphetamine
Dependence

Douglas Winship
Catalyst
Coral Gables, FI

Vigabatrin for Treatment of Cocaine
Dependence: A Phase II Study Multi-Center
Drug Trial

APPENDIX D

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

§ 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 § 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 § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

§ 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 § 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.

Appendix D Cont.

§ 11480. Cont.

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 § 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.

§ 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.

§ 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.

§ 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.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in § 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

Appendix D Cont.

§ 24172. Cont.

- (i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to § 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

- (a) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.
- (b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.
- (c) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
 - (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

§ 24173. Cont.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

Appendix D Cont.

§ 24173. Cont.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.