FORTY-SIXTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2016

PREPARED FOR THE

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA
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2016 PANEL MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

The Research Advisory Panel of California (RAPC) consists of the Panel chairman, Executive officer, and the Panel members.

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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.

SUMMARY OF 2016 PANEL ACTIVITIES

During 2016 the Panel reviewed thirty-five research study submissions. Thirty-two were approved by the Panel. Among the approved studies, nineteen studies were Academic research studies and thirteen studies were Multi-Center Clinical Drug Trial research studies.

Twenty-eight research studies were completed or, in a few cases, terminated in 2016, and they were closed on the Panel's records.

At the end of 2016 the Panel was monitoring one hundred and eleven 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 Approval may be withdrawn if the study deviates significantly from the approved protocol.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 2016 and Table 2 is a list of the studies closed by the Panel in 2016.

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. Matthew Worley, Ph.D., MPH. and colleagues at University of California, San Diego have provided the Panel with the following summary of academic human research titled "Behavioral Economic Mechanisms of Prescription Opioid Addiction in Chronic Pain"

Over the last 10-15 years prescription opioid abuse has increased dramatically in the United States and other developed nations, and is currently a significant public health problem. Chronic pain patients are particularly vulnerable for opioid misuse, abuse, and addiction as they have greater rates of exposure to chronic opioid treatment and thus have greater risk for prescription opioid addiction than the general population. The syndrome of addiction is also difficult to recognize in this population, because opioid tolerance, persistent pain, and prescription opioid misuse behaviors (e.g., early refills, taking more than prescribed) have significant overlap. Specific neurobehavioral factors or "mechanisms" that influence the onset of prescription opioid addiction in chronic

pain patients have not been identified, which limits the safety and specificity of opioid treatment for pain.

Emerging research in substance use disorders (SUDs) prioritizes the identification of specific biologicallydriven phenotypes that may be causal mechanisms of SUDs. In pursuit of this goal, a significant body of research grounded in behavioral economics has identified behavioral markers of maladaptive reward valuation and decision-making that are common across SUDs. On such marker is excessive "drug demand", a tendency for persons with SUDs to allocate excessive amounts of personal resources (such as income or time) to obtain and use substances. Among adults with chronic pain who use prescribed opioid medications, opioids serve as a functional reinforcer as they reduce pain, activate neural reward systems, and can reduce aversive symptoms such as stress and negative affect. Excessive drug demand may also contribute to prescription opioid addiction in chronic pain patients, but behavioral economic methods have not been previously applied to prescription opioid addiction in chronic pain patients, due in part to the absence of valid experimental models of pain-related demand in this population. This project will establish a novel human laboratory model to examine behavioral economic markers of rewardrelated decision-making in chronic pain patients who use prescribed opioids for pain. The study will recruit adults with chronic pain currently in long-term opioid treatment (≥3 months) for pain management. The study will involve a screening visit and two experimental sessions, with procedures including pain testing, behavioral economic measures, and clinical measures of pain and opioid use. The primary objective of the study is establish a valid model of pain-related opioid demand, by comparing measures of in-vivo opioid reinforcement to opioid demand assessed under hypothetical conditions. Results will validate novel behavioral economic measures of decision-making with specific applications for patients with chronic pain. Resultant data will support future, larger studies on the behavioral economics of prescription opioid use disorders in adults with chronic pain chronic pain.

Rates of prescription opioid abuse have accelerated drastically in the past 15 years, especially among adults with chronic pain (Jones, Mack, & Paulozzi, 2013). The specific mechanisms that underlie prescription opioid addiction in chronic pain patients are not well-understood. Better understanding of such mechanisms would improve treatment of pain and reduce abuse of prescribed opioid pain medications. In prior research behavioral economics has been used to identify markers of dysfunctional decision-making that may underlie substance use disorders (Bickel, Johnson, Koffarnus, Mackillop, & Murphy, 2014). Typically, persons with substance use disorders exhibit excessive demand for their preferred "reinforcer", in that they continue to expend excessive amounts of personal resources to obtain and consume the reinforcer (e.g., cigarettes, alcohol) even in the presence of increasing costs or incentives against consumption. This excessive "drug demand" appears to be a translational marker of dysfunctional reward-seeking, with consistent evidence across multiple types of addiction and other reward-related disorders such as gambling disorder and obesity (Bickel, Jarmolowicz, Mueller, Koffarnus, & Gatchalian, 2012). Drug demand is

therefore a strong candidate mechanism of risk for prescription opioid abuse in chronic pain patients, but no prior studies have examined demand for opioid medications in adults with chronic pain, perhaps in part because no valid experimental models of drug demand for this population exist. The proposed study seeks to test and validate a human laboratory model of pain-related drug demand in chronic pain patients. Findings will establish methodology for future investigations of causal mechanisms of prescription opioid misuse and addiction in this population.

To establish the validity of a human laboratory model for examining the effects of pain on opioid demand in adult users of prescribed opioids with chronic pain. We propose to study approximately 15 adults (age 18 - 65) with chronic pain who are prescribed opioid medications on a chronic basis for pain management. The sample will include individuals who exhibit current misuse of prescribed opioid medications, as assessed by validated screening measures. In cases of early study withdrawal or termination, additional subjects will be recruited to complete the sample.

NIDA, NDAT, CTN has provided the Panel with the following summary of the substance abuse treatment research titled "Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT)"

This study was designed to assess the comparative effectiveness of extended release injectable naltrexone (XR-NTX, Vivitrol®), an opioid antagonist indicated for the prevention of relapse to opioid dependence, versus buprenorphine-naloxone (BUP-NX, Suboxone®), a high affinity partial agonist indicated for maintenance treatment of opioid dependence, as pharmacotherapeutic aids to recovery.

Study enrollment began on January 30, 2014 and concluded on May 25, 2016. Overall, 570 participants, both males and females over 18 years of age seeking treatment for opioid dependence (heroin or prescription opioids) were admitted to an inpatient (detoxification and/or short term residential treatment) program for treatment of substance dependence and randomized into the study.
The first participant at the Tarzana Treatment Center was enrolled on July 17, 2014, and the final participant was enrolled at the Tarzana site on May 19, 2016. Overall, a total of 66 participants were enrolled at the Tarzana site. All study dosing is now complete.

Twenty-eight Serious Adverse Events (SAEs) were reported in 2016, none of which were considered related to study drug and therefore were not subject to expedited reporting requirements.

The following publication regarding the design and methods of the X:BOT study was published in 2016, and is provided as Attachment 1 to this report:
- Lee JD, Nunes EV, Novo P, Bailey GL, Brigham GS, Cohen AJ, Fishman M, Ling W, Lindblad R, Shmueli-Blumberg D, Stablein D, May J, Salazar D, Liu D, Rotrosen J.

NIDA Clinical Trials Network CTN-0051, Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT):
Study design and rationale. *Contemporary Clinical Trials*, **2016**. 50: 253-264.

Dr. Heinz Moser, Ph.D. and colleagues at the Novartis Institute for Biomedical Research, Emeryville, CA have provided the Panel with the following summary of non-human research titled "Synthesis and Optimization of Novel Therapeutics"

The Novartis research site in Emeryville is dedicating its effort on the identification of novel anti-infective therapeutics to address unmet medical needs such as infections by multi-drug resistant bacteria or a variety of viruses. We typically identify compounds with the desired biological activity convert them in a complex, multi]step approach to potential clinical candidates. This process requires the synthesis of hundreds to thousands of compounds to refine a number of parameters (safety, selectivity, potency, efficacy, pharmacokinetic profile, solubility, etc.) of the original hit(s) to generate compounds for preclinical profiling, IND filing with FDA, and eventually clinical examination in humans. The realization of this chemical optimization requires a diverse set of chemical substances as either building blocks (intermediates) or reagents. Each project typically requires hundreds of chemicals during these optimization steps, some of which are controlled substances. The requirement of specific chemicals is impossible to predict as pathways or targets of these drug candidates are often novel and part of our work is to gain insight in how effective inhibitors are constructed. For this purpose we request the use of a subset of Schedule I compounds that are viewed by us as either versatile reagents (such as benzylpiperazine, see below) or building blocks (e.g. a subset of amphetamines and tryptamines). We typically use quantities of 100 mg or less and will only use larger quantities for the synthesis of valuable intermediates of interest. To the best of our possibilities, we will keep the use of Controlled Substances to a minimum but in certain circumstances, it will be difficult to avoid.

Corbus Pharmaceuticals has provided the Panel with the following rationale of multicenter clinical drug trial research titled "A Phase 2, Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Efficacy of JBT-101 in Cystic Fibrosis"

JBT-101 has effects on soluble mediators and cell types implicated in the pathogenesis of lung disease in CF, providing evidence that JBT-101 may provide clinical benefit in CF as a novel, orally administered anti-inflammatory and anti-fibrotic treatment. Results from the proposed clinical trial will be used to power a future Phase 2 clinical trial to better characterize the clinical efficacy of JBT-101 in CF.
The hypothesis is that JBT-101 will provide clinical efficacy in CF patients by triggering pathways that resolve adverse innate immune responses and blunt pro-fibrotic processes in the lungs. Based on preclinical data, there is a component of the study to

evaluate the expectation that JBT-101 increases production of pro-resolving lipids, including but not limited to lipoxin A4 and anti-inflammatory eicosanoids PGD2 and PGJ2. Conversely, JBT-101 is expected to decrease production of pro-inflammatory eicosanoids, including leukotriene B4. JBT-101 is expected to inhibit production of pro-inflammatory adhesion molecules, chemokines, and cytokines, neutrophil infiltration of lung tissue, myofibroblast transformation, fibroblast proliferation and the production of extracellular matrix components that leads to tissue fibrosis. Further, JBT-101 is expected to activate apoptosis in activated immune cells and fibroblasts and induce clearance of cellular debris by non-inflammatory macrophages. Through production of lipoxin A4, JBT-101 also may increase mucus fluidity, survival of airway epithelial cells, and reduce pathogen-induced disruption of the airway epithelium. Through these mechanisms, JBT-101 is expected to provide efficacy in CF.

The first-in-CF study, proposed for conduct after results in healthy normal and pain were obtained in humans, is to assess safety, tolerability, PK, efficacy and mechanism of action of JBT-101 in CF subjects. The target population is adults with CF > 18 and < 65 years of age at the time of signing the Informed Consent Form, with FEV1 ≥ 40% predicted, corrected. Adults are selected as the target population because neither toxicology studies in juvenile animals nor safety or efficacy assessments in adults with CF have been done yet.

To reduce risk to subjects in this first-in-CF study, subjects will be excluded who have severe organ damage or require intravenous antibiotics in the 14 days prior to first dose. JBT-101 or placebo will be administered as "add-on" to standard of care, allowing subjects to continue to receive what their treating physicians deem most appropriate baseline therapy for their disease, to reduce risk of disease exacerbations. The 84 days duration of dosing is supported by findings in 13-week toxicology studies in rats and dogs. This study will provide data on safety, tolerability, plasma concentrations, and clinical efficacy of JBT-101 over a longer exposure than in a shorter study. The feasibility of enrolling 70 subjects into this study within 12 months at about 24 sites in the EU and US is judged acceptable, based on input from the principal investigators, the Cystic Fibrosis Foundation in the US, and the EU Cystic Fibrosis Society.

The JBT-101 oral doses selected for this study are 1 mg qd, 5 mg qd, 20 mg qd, and 20 mg twice a day (bid). All of these doses are expected have an acceptable safety profile, be well-tolerated, and provide some clinical benefit, based on previous animal or human testing and the nature of the inflammatory components of CF. Based on preclinical data and early higher dose clinical data, it is expected that any safety risk and clinical efficacy of JBT-101 in humans will be related to exposure. To maximize opportunity to detect an early safety signal and clinical efficacy in this study, subjects will receive JBT-101 20 mg bid on Days 29-84. The JBT-101 20 mg bid dose is expected to provide maximal or near maximal levels of clinical benefit, based on extrapolation from animal models of inflammation. Finally, the availability of data from individual subjects who have been exposed to two different doses of JBT-101 or two intervals of dosing increases the robustness of the modeling of relationships between plasma concentrations of JBT-101 and safety outcomes, efficacy outcomes, biomarkers and lipoxin A4 levels.

Parallel dose assignment to JBT-101 in doses up to 20 mg bid is supported by a previous multiple ascending dose study and a Phase 2 study in humans in which JBT-101 doses up to 40 mg bid showed acceptable safety profiles and were well tolerated. Efficacy will be explored with FEV1, LCI, CFQ-R Respiratory Symptoms score, and biomarkers of disease activity. Changes from baseline in these efficacy outcomes are expected to occur and be in the direction of improvement, although the changes are not expected to reach statistical significance after 84 days exposure in this first small pilot trial in CF. Changes in biomarkers of disease activity are expected to happen more quickly than changes in clinical efficacy outcomes, within a few weeks.
The mechanism of action will be evaluated by measuring metabolipidomic profiles, to determine whether JBT-101 increases SPMs, especially lipoxin A4, and anti-inflammatory eicosanoids, both in absolute amounts and relative to pro-inflammatory eicosanoid mediators. The downstream consequences of this activity on biologic pathways relevant to disease pathology in CF will be tested, looking for beneficial effects of JBT-101 on adhesion molecules, cytokines and chemokines, as well as gene transcripts indicating activation of inflammatory pathways. Changes in the metabolipidomic profile are expected within days and changes in these biomarkers of inflammation are expected within days to weeks.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2016

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Nancy E. Buckley, Ph.D. CA State Polytech University Pomona, CA	Investigating the effect of delta-9-tetrahydrocannabinol (THC) on the susceptibility to systemic C. Albicans infection in mice treated with an anti-cancer drug
Davide Dulcis, Ph.D. UCSD La Jolla, CA	Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments
Roy Gerona, Ph.D. UCSF, Dept OBGYN San Francisco, CA	Real Time Surveillance of Designer Drug Intoxications using Enhanced High Resolution Mass Spectrometry (HRMS) based Drug Screening and Confirmation
Su Guo, Ph.D. UCSF San Francisco, CA	A novel RNA-Guided Platform for Dissecting Cannabinoid Signaling in Reward Circuit Development

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Kim D. Janda, Ph.D. The Scripps Research Institute San Diego, CA	Immunopharmaco Therapy for Methamphetamine Addiction
Gunjan Junnarkar, Ph.D. Jazz Pharmaceuticals Menlo Park, CA	Oxybate Research
Edward Kisak, Ph.D. Tioga Research Inc. San Diego, CA	Research of a Topical Cannabinoid Formulation to Treat Pain and Inflammatory Disorders
David Kokel, Ph.D. UCSF	Behavior Based Neuroactive Drug Discovery in Zebrafish
Thomas Marcotte, Ph.D. UCSD Health Care System San Diego, CA	A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels
Mark Peterman, Ph.D. OndaVia Hayward, CA	Development of a Rapid and Field-Ready Heroin analysis Tool
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids
Ivan Soltesz, Ph.D. Stanford University Stanford, CA	Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy
Matthew L. Springer, Ph.D. UCSF San Francisco, CA	Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers
Francesca Telese, Ph.D. UCSD La Jolla, CA	Epigenetic Regulation of Gene Expression in the Brain
Matthew Worley, Ph.D. UCSD La Jolla, CA	Behavioral Economic Mechanisms of Prescription Opioid Addiction in Chronic Pain
Xinmin Simon Xie, Ph.D. Afasci Research Laboratories Redwood City, CA	Pharmacological and Toxicological Effects of Aerosolized Δ9-Tetrahydrocannabinols (Δ9-THC) on Rodents
Cathy Zhang, M.S. Pfizer La Jolla La Jolla, CA	Induction of Myeloid-Derived Suppressor Cells (MDSC) by Tetrahydrocannabinol (THC)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Brandon Zipp, Ph.D. Vitality Biopharma, Inc. Los Angeles, CA	Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation
Alkermes Waltham, MA	A Randomized, Double-Blind, Parallel-Group Study in Healthy Subjects to Characterize Insulin Sensitivity and Lipid Metabolism in Response to Treatment with ALKS 3831 and Olanzapine (ALK3831-A108)
Alkermes Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A304)
Egalet CRO: PPD Wilmington, NC	Panel Approved Research Study

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Flamel Ireland CRO: INC Research Austin, TX	A Double-Blind, Randomized, Placebo-Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy (CLFT218-1501)
GW Cambridge, UK	Panel Approved Research Study
INSYS Chandler, AZ	A Phase 2 Multicenter, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of Fentanyl Sublingual Spray for the Treatment of Moderate to Severe Post-Operative Pain (INS002-16-092)
Opioid PMR Consortium (OPC) CRO: Endo Pharmaceuticals Raleigh, NC	Panel Approved Research Study
Pfizer CRO: ICON New York, NY	Panel Approved Research Study

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Rhodes CRO: MedSource Spokane Valley, WA	A Pharmacokinetic Study of Aptensio XR™ (Methylphenidate Hydrochloride) Extended-Release Capsules in Male or Female Preschool Children 4 to under 6 Years of Age with ADHD in Fed Condition (RP-BP-PK003)
Rhodes CRO: MedSource Spokane Valley, WA	A 12 Month Open Label Safety Study of Methylphenidate Hydrochloride Extended-Release Capsules (Aptensio XR™) in Children Ages 4-5 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD) (RP-BP-EF004)
Trevena King of Prussia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of Oliceridine (TRV130) for the Treatment of Moderate to Severe Acute Pain After Bunionectomy (CP130-3001)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Trevena King of Prussia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of Oliceridine (TRV130) for the Treatment of Moderate to Severe Acute Pain After Abdominoplasty (CP130-3002)
Trevena King of Prussia, PA	A Phase 3, Open-Label Study to Evaluate the safety of Oliceridine (TRV130) in Patients with Acute Pain for Which Parenteral Opioid Therapy is Warranted (CP130-3003)
Braeburn Princeton, NJ	A Phase III, Randomized, Double-Blind, Active-Controlled, Parallel Group, Multicenter Trial Assessing the Efficacy and Safety of a Once-Weekly and Once-Monthly, Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in Treatment of Adult Outpatients with Opioid Use Disorder (HS-11-421)

TABLE 2

RESEARCH STUDIES CLOSED IN 2016

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Donald I. Abrams, M.D. UCSF/SFGH San Francisco, CA	Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease
Philip Bickler, MD, PhD Dept of Anesthesia & Perioperative Care UCSF San Francisco, CA	Detecting Apnea in Healthy Volunteers Receiving Opiate or Sedative Medications
Kevin Chu, DO Lotus Clinical Research, LLC Pasadena, CA	A Phase 2, Randomized, Double-Blind, Placebo- and Active-Controlled Study of TRV130 for the Treatment of Acute Postoperative Pain Following Abdominoplasty (CP130-2002)
Kevin Chu, DO Lotus Clinical Research, LLC Pasadena, CA	A Phase 1, Open-Label, Single Ascending Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Fentanyl Sublingual Spray and Fentanyl Citrate Intravenous (IV) in Opioid Naive Subjects (INS002-15-049)
Judith Hellman, Ph.D. UCSF San Francisco, CA	Cannabinoid-Dependent Modulation of the Innate Immune Response to Infection and Injury

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Ardis Ann Moe, M.D. UCLA Los Angeles, CA	Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta ™) for Treatment of HIV Dementia
Loren Parsons, Ph.D. Scripps La Jolla, CA	Cognitive and Neurochemical Effects of Δ9-tetrahydrocannabinol and Related Cannabinoids in Rodents
Joel E. Schlosburg, Ph.D. The Scripps Research Institute La Jolla, CA	Treatment of Opiate Dependence Through Inhibition of Fatty Acid Amide Hydrolase
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
Xinmin Simon Xie, Ph.D. Afasci Research Laboratories Redwood City, CA	Pharmacological and Toxicological Effects of Aerosolized Δ9-Tetrahydrocannabinols (Δ9-THC) on Rodents

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Alkermes Waltham, MA	A Phase 3 Multicenter Extension Study of ALKS 5461 to Assess the Long-Term Safety and Tolerability of ALKS 5461 for the Adjunctive Treatment of Major Depressive Disorder in Adults Who Have an Inadequate Response to Antidepressant Therapy (ALK5461-208EXT)
Alkermes Waltham, MA	A Phase 2, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, A Component of ALKS 383, in Adults with Schizophrenia Treated with Olanzapine (ALK3831-302)
GW Pharmaceuticals Cambridge, UK	Panel Approved Research Study
GW Pharmaceuticals Cambridge, UK	Panel Approved Research Study
GW Pharmaceuticals Cambridge, UK	Panel Approved Research Study
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Janssen R&D, LLC Raritan, NJ	A Randomized, Partially-Blind, Two-Arm, Single-Application, 3-Way Crossover Study to Evaluate the Adherence of 2 Strengths of Newly Manufactured Samples and Aged Samples of a New Formulation (JNJ-35685-AAA-G016 and JNJ-35685-AAA-G021) of Fentanyl Transdermal System Compared with DURAGESIC® Fentanyl Transdermal Patch in Healthy Subjects (FENPAI1025)
Lannett CRO: Parexel Waltham, MA	A Phase III Investigation of Topical Application of Cocaine HCl 4% and 10% on Safety and Efficacy in Local (Topical) Anesthesia for Diagnostic Procedures and Surgeries on or Through Accessible Mucous Membranes of the Nasal Cavities (COCA4vs10-001)
Purdue Pickering, Ontario Canada	A Randomized, Double-blind Study of the Time Course of Response of PRC-063 in Adults with ADHD in a Simulated Adult Workplace Environment (063-008)
Purdue Pickering, Ontario Canada	A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-arm, Multi-center Study Measuring the Efficacy and Safety of PRC-063 in Adolescent ADHD Patients

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Purdue Pickering, Ontario Canada	A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-arm, Multi-center Study measuring the Efficacy and Safety of PRC-063 in Adult ADHD Patients (063-010)
Purdue Pickering, Ontario Canada	A Six-month, Open-label, Multi-center Study of the Safety and Efficacy of PRC-063 in Adults and Adolescents with ADHD (063-012)
Shire CRO: Premier Research Philadelphia, PA	A Phase 3, Randomized, Double-blind, Multi-center, Placebo-controlled, Dose-Optimization, Safety and Efficacy Study of SHP465 in Children and Adolescents Aged 6-17 Years with Attention-Deficit Hyperactivity Disorder (ADHD) (SHP465-305)
Shire CRO: Premier Research San Diego, CA	A Phase 3, Multicenter, Opoen-label Treatment-optimized, Double-blind, Randomized, Placebo-controlled, Forced-withdrawal, parallel Group Study to Evaluate the Safety and Efficacy of Evening Dosed HLD200, a Novel Delayed and Extended Release Formulation (DELEXIS) of Methylphenidate Hydrochloride, in Children Aged 6-12 with Attention Deficit Hyperactivity Disorder (ADHD) in a Laboratory Classroom Setting (HLD200-107)

APPENDIX A

CURRENTLY OPEN *(through December 31, 2016)*
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
Nancy E. Buckley, Ph.D. CA State Polytech University Pomona, CA	Investigating the effect of THC on the susceptibility to systemic C. Albicans infection in mice treated with an anti-cancer drug
Nicholas Butowski, M.D. UCSF Neurological Surgery San Francisco, CA	CBD Developmental Research Project
Jeremy Caldwell, Ph.D. Genomics Institute Novartis Foundation San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
Kent Chu YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD

Appendix A Cont.

Principal Investigator	Title of Study
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Study
Nissar A. Darmani, Ph.D. Western University Pomona, CA	Project 1: mechanisms of vomiting induced by chemotherapeutics, related emetics, & GI disorders. Project 2: Dev changes in monoamine function following prenatal & early postnatal exposure to serotonergic altering drugs in mice
Davide Dulcis, Ph.D. UCSD La Jolla, CA	Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine involvement in Opiate and Stimulant Reinforcement
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments

Principal Investigator	Title of Study
Roy Gerona, Ph.D. UCSF, Dept OBGYN San Francisco, CA	Real Time Surveillance of Designer Drug Intoxications using Enhanced High Resolution Mass Spectrometry (HRMS) based Drug Screening and Confirmation
Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA	Effects of Cannabidiol on Mania-relevant Locomotor and Investigatory Behavior
Su Guo, Ph.D. UCSF San Francisco, CA	A novel RNA-Guided Platform for Dissecting Cannabinoid Signaling in Reward Circuit Development
Kanthi Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Controlled Substances
Kim D. Janda, Ph.D. The Scripps Research Institute La Jolla, CA	Vaccines for the Treatment of Opiate Addiction
Kim D. Janda, Ph.D. The Scripps Research Institute San Diego, CA	Immunopharmaco Therapy for Methamphetamine Addiction
Gunjan Junnarkar, Ph.D. Jazz Pharmaceuticals Menlo Park, CA	Oxybate Research

Appendix A Cont.

Principal Investigator	Title of Study
Jay Keasling, Ph.D. Joint Bioenergy Institute Emeryville, CA	Engineering the Industrial Microbe Sacccharomyces Cerevisiae for Biosyntheris of Cannabinoids
Thomas S. Kilduff, Ph.D. SRI International Menlo Park, CA	Neurobiological Studies of Gammahydroxybutyrate (GHB)
Edward Kisak, Ph.D. Tioga Research Inc. San Diego, CA	Research of a Topical Cannabinoid Formulation to Treat Pain and Inflammatory Disorders
Christian Adam Kekoa Koch, MD Lotus Clinical Research, Inc. Pasadena, CA	A Phase I, Multiple Ascending Dose Study to Evaluate the Pharmacokinetics, Pharmaco-dynamics, Safety and Tolerability of Fentanyl Sublingual Spray in Opioid Naive Subjects
David Kokel, Ph.D. UCSF San Francisco, CA	Behavior Based Neuroactive Drug Discovery in Zebrafish
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study

Principal Investigator	Title of Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Walter Ling, M.D. Integrated Substance Abuse Programs, UCLA Los Angeles, CA	Analgesic Response to Opioid Analgesics in Buprenorphine-Maintained Individuals
Robert Malenka, M.D. School of Medicine Stanford University Palo Alto, CA	The Role of Oxytocin in the Pathogenesis of Avtism
Thomas Marcotte, Ph.D. UCSD Health Care System San Diego, CA	A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels
Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA	Panel Approved Research Study

Appendix A Cont.

Principal Investigator	Title of Study
Sara Mednick, Ph.D. UC Riverside Riverside, CA	The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance
Byung-Sook Moon ARK Freemont, CA	Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Panel Approved Research Study
Heinz Moser, Ph.D. Novartis Institute Emeryville, CA	Synthesis and Optimization of Novel Therapeutics
David E. Olson, Ph.D. UC Davis Davis, CA	Chemical Modulation of Neural Plasticity, Learning and Memory
Jeanne Paz, Ph.D. The J. David Gladstone Institutes San Francisco, CA	The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats
Mark Peterman, Ph.D. OndaVia Hayward, CA	Development of a Rapid and Field-Ready Heroin analysis Tool

Principal Investigator	Title of Study
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids
Florian Rader, M.D. Cedars-Sinai Med Center Los Angeles, CA	Mechanisms and Modulation of Cocaine Effects on Blood Blow to the Heart
Richard Reznichek, M.D. Harbor-UCLA Los Angeles, CA	Panel Approved Research Study
Douglas Sears, M.D. Encino, CA	A Double-Blind, Placebo-Controlled Study of Combination Therapy in Children with ADHD
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Human Methamphetamine Self-Administration in a Progressive-Ratio Paradigm
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

Appendix A Cont.

Principal Investigator	Title of Study
Neil Singla, M.D. Lotus Clinical Research, LLC Pasadena, CA	A Randomized, Open Label, Prospective Study of the Analgesic Efficacy of Oral MNK795 Compared to Generic Oxycodone/APAP in the Treatment of Mod to Severe Post Operative Pain
Ivan Soltesz, Ph.D. Stanford University Stanford, CA	Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy
Matthew L. Springer, Ph.D. UCSF San Francisco, CA	Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers
Raymond Stevens, Ph.D. The Scripps Research Institute La Jolla, CA	Structure Determination of the Hallucinogens LSD and Psylocin Bound to the Serotonin Receptor 5-HT2B
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
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

Principal Investigator	Title of Study
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
Francesca Telese, Ph.D. UCSD La Jolla, CA	Epigenetic Regulation of Gene Expression in the Brain
Jennifer Thomas, Ph.D. San Diego State University San Diego, CA	The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats
Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA	Panel Approved Research Study
Ronald Victor, M.D. Cedars-Sinai Med Center Los Angeles, CA	Effects of Cocaine on Blood Flow to the Heart
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol

Appendix A Cont.

Principal Investigator	Title of Study
Timothy Wigal, Ph.D. UC Irvine Irvine, CA	Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)
Bart Wilsey, M.D. UC Davis Medical Center Sacramento, CA	A Randomized, Cross-Over Controlled Trial of Dronabinol and Vaporized Cannabis in Neuropathic Low Back Pain
Matthew Worley, Ph.D. UCSD La Jolla, CA	Behavioral Economic Mechanisms of Prescription Opioid Addiction in Chronic Pain
Roya Yumul, MD, PhD Cedars-Sinai Med Center Los Angeles, CA	Intra-operative ketamine and methadone for laminectomy: effect on recovery, post-operative pain, and opioid requirements
Xinmin Simon Xie, Ph.D. Afasci Research Laboratories Redwood City, CA	Pharmacological and Toxicological Effects of Aerosolized Δ9-Tetrahydrocannabinols (Δ9-THC) on Rodents
Cathy Zhang, M.S. Pfizer La Jolla La Jolla, CA	Induction of Myeloid-Derived Suppressor Cells (MDSC) by Tetrahydrocannabinol (THC)
Brandon Zipp, Ph.D. Vitality Biopharma, Inc. Los Angeles, CA	Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

APPENDIX B

CURRENTLY OPEN *(through December 31, 2016)*
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Treatment of Major Depressive Disorder (Study I) (ALKS5461-205)
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Treatment of Major Depressive Disorder (Study II) (ALKS5461-206)
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind Study to Evaluate Efficacy, Safety, and Tolerability of ALKS3831 in Subjects with Schizophrenia with Alcohol Use Disorder (ALKS3831-401)
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-207)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	A Phase 3 E & S Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)
Alkermes, Inc. Waltham, MA	A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALK3831-A303)
Alkermes, Inc. Waltham, MA	A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects with Acute Exacerbation of Schizophrenia (ALK3831-A305)
Alkermes, Inc. Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	A Randomized, Double-Blind, Parallel-Group Study in Healthy Subjects to Characterize Insulin Sensitivity and Lipid Metabolism in Response to Treatment with ALKS 3831 and Olanzapine (ALK3831-A108)
Alkermes, Inc. Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A304)
Braeburn Pharmaceuticals Princeton, NJ	A Randomized, Double-Blind, Double-Dummy, Active-Controlled Multi-Center Study of Adult Outpatients with Opioid Dependence Transitioned from a Daily Maintenance Dose of 8mg or Less of SL Buprenorphine or Buprenolphine/Naloxone to Four Probuphine Subdermal Implants (PRO-814)
CNS Therapeutics CRO: Social & Scientific Systems	Panel Approved Research Study
CNS Therapeutics CRO: Social & Scientific Systems	Panel Approved Research Study

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Cortbus Norwood, MA	A Phase 2, Double-Blind, randomized, Placebo-Controlled Multicenter Study to Evaluate safety, Tolerability, Efficacy, and Pharmacokinetics of JBT-101 in Cystic Fibrosis (BT101-CF-001)
Cortbus Norwood, MA	A Phase 2, Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Evaluate Safety, Tolerability, Efficacy, and Pharmacokinetics of JBT-101 in Diffuse Cutaneous Systemic Sclerosis (JBT101-SSc-001)
Egalet CRO: PPD Wilmington, NC	Panel Approved Research Study
Flamel Ireland CRO: INC Research Austin, TX	A Double-Blind, Randomized, Placebo-Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy (CLFT218-1501)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Grunenthal/Janssen CRO : inVentiv Cary, NC	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
INSYS Therapeutics Chandler, AZ	A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Lennox-Gastaut Syndrome (INS011-14-024)
INSYS Therapeutics Chandler, AZ	A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Dravet Syndrome (INS011-14-025)
INSYS Therapeutics Chandler, AZ	A multicenter, open-label, flexible dose study to assess the long-term safety of pharmaceutical Cannabidiol Oral Solution as an adjunctive treatment for pediatric and adult subjects with a treatment-resistant seizure disorder who complete INS011-14-024, INS011-14-025, or INS011-14-029 (INS011-14-030)

Sponsor	Description or Title of Clinical Drug Trial Protocol
INSYS Therapeutics Chandler, AZ	A Phase 2 Study to Assess the Efficacy and Safety of Cannabidiol Oral Solution for the Treatment of Refractory Infantile Spasms (NIS011-15-054)
INSYS Therapeutics Chandler, AZ	A Phase I/II Study to Assess the Pharmacokinetics and Safety of Multiple Doses of Pharmaceutical Cannabidiol Oral Solution in Pediatric Subjects with Treatment-Resistant Seizure Disorders (INS011-14-029)
INSYS Therapeutics Chandler, AZ	A Phase 2 Multicenter, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of Fentanyl Sublingual Spray for the Treatment of Moderate to Severe Post-Operative Pain (INS002-16-092)
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study
MAPS Santa Cruz, CA	Panel Approved Research Study

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
MAPS Santa Cruz, CA	Panel Approved Research Study
Opioid PMR Consortium (OPC) CRO: Endo Pharmaceuticals Raleigh, NC	Panel Approved Research Study
Pfizer CRO: ICON New York, NY	Panel Approved Research Study
Pfizer CRO: ICON New York, NY	Panel Approved Research Study
Rhodes CRO: MedSource Spokane Valley, WA	A Pharmacokinetic Study of Aptensio XR™ (Methylphenidate Hydrochloride) Extended-Release Capsules in Male or Female Preschool Children 4 to under 6 Years of Age with ADHD in Fed Condition (RP-BP-PK003)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Rhodes CRO: MedSource Spokane Valley, WA	A 12 Month Open Label Safety Study of Methylphenidate Hydrochloride Extended-Release Capsules (Aptensio XR™) in Children Ages 4-5 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD) (RP-BP-EF004)
Shire CRO: PPD San Diego, CA	Panel Approved Research Study
Trevena King of Prussia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of Oliceridine (TRV130) for the Treatment of Moderate to Severe Acute Pain After Bunionectomy (CP130-3001)
Trevena King of Prussia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of Oliceridine (TRV130) for the Treatment of Moderate to Severe Acute Pain After Abdominoplasty (CP130-3002)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Trevena King of Prussia, PA	A Phase 3, Open-Label Study to Evaluate the safety of Oliceridine (TRV130) in Patients with Acute Pain for Which Parenteral Opioid Therapy is Warranted (CP130-3003)

APPENDIX C

CURRENTLY OPEN *(December 31, 2016)*
RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Keith Heinzerling, M.D. UCLA Los Angeles, CA	Randomized Trial of Ibudilast for Methamphetamine Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline for Methamphetamine Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine
Alkermes Waltham, MA	A Phase 3 Study of Evaluate the Safety, Tolerability, and Efficacy of Naltrexone for use in Conjunction with Buprenorphine in Adults with Opioid Use Disorder Prior to First Dose of Vivitrol (ALK6428-A301)

Appendix C Cont.

Investigator or Sponsor	Description or Title of Research Project
Braeburn Princeton, NJ	A Phase III, Randomized, Double-Blind, Active-Controlled, Parallel Group, Multicenter Trial Assessing the Efficacy and Safety of a Once-Weekly and Once-Monthly, Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in Treatment of Adult Outpatients with Opioid Use Disorder (HS-11-421)
NIDA The EMMES Corp. Rockville, MD	Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT) (0051)

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.

§ 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.

§ 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.

§ 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.