FORTY-FOURTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2014

PREPARED FOR THE

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA
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2014 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 2014 PANEL ACTIVITIES

During 2014 the Panel reviewed thirty-three research study submissions. Thirty-one were approved by the Panel. Among thirty-one approved studies, ten studies were Academic research studies, one study was Substance Abuse Treatment research protocol, and twenty studies were Clinical Drug Trial research protocols.

Thirteen research studies were completed or, in a few cases, terminated in 2014, and they were closed on the Panel's records.

At the end of 2014, the Panel was monitoring one hundred-thirteen active research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2014 and Table 2 is a list of the studies closed by the Panel in 2014.

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. Donald Abrams, M.D. and colleagues at University of California, San Francisco and San Francisco General Hospital Clinical Research Unit have provided the Panel with the following summary of research titled "Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease".

Our primary objective is to assess whether inhaling vaporized cannabis ameliorates chronic pain in patients with sickle cell disease (SCD). As these patients will all be on chronic opioid analgesics, we will also assess the possible synergistic affect between inhaled cannabis and opioids. We will also assess the clinical safety of the concomitant use of cannabinoids and these opioids in patients with SCD by monitoring the short-term side effects associated with combined therapy.

Chronic pain conditions remain problematic, especially in adult patients with SCD. Although opioids are effective analgesics, dose-limiting side effects in the form of

sedation, nausea and vomiting, and fear of dependence often limit their use at higher – and possibly more effective – doses. Of particular interest, however, is the potential for greater than additive analgesic effect of cannabinoids and opioids in combination that would allow for opioid analgesic effect to be achieved at lower dosages than are necessary alone (2–5), which could overcome problems with both tolerance and side effects for both drug classes. Safety data on the combination in humans is limited at this time, especially in patients with SCD. Among the plant's bioactive cannabinoids, delta-9-tetrahydrocannabinol (THC) is most known for its psychoactive effects, although analgesic effects have also been ascertained. Cannabidiol, a non-psychoactive cannabinoid, is becoming increasingly recognized as a potent anti-inflammatory and analgesic that may have a unique place in the armamentarium of potential pain medications. As patients with SCD may turn to cannabis to augment the effects of their opioid analgesics and for possible anti-inflammatory effects to alter disease progression, data on the clinical safety and possible effectiveness of the combinations should be evaluated in a controlled proof of principle setting.

Dr. Tanya Wallace, Ph.D. and colleagues at the SRI International Research Institute, Menlo Park, CA have provided the Panel with the following summary of research titled "Cannabinoid Regulation of Cognition".

The Translational Neuroscience Laboratory at SRI International is dedicated to investigating the effects of compounds on cognitive function in non-human primates. The goal of this specific project is to investigate the effects of short-term and long-term Δ9-Tetrahydrocannabinol exposure on cognitive function in Cynomolgus macaques. This project involves cognitive behavioral tasks measuring recognition and working memory, motor function, and visuo-spatial learning, as well as some physiological testing in adult monkeys given systemic Δ9-THC injections. The project also incorporates testing of several full agonist cannabinoid compounds found in the so-called synthetic marijuana or "herbal high" products marketed as Spice, Spike, K2, and a host of other names in convenience stores, head shops and cigar stores. We also wish to determine if cannabidiol, a constituent in marijuana, is capable of ameliorating or reversing the effects of cannabinoid agonist compounds.

Dr. Keith Heinzerling, M.D. and colleagues at University of California, Los Angeles has submitted Annual Progress Report titled "Randomized Trial of Ibudilast for Methamphetamine Dependence".

This study opened enrollment in October 2013 and we aim to randomize 140 participants in this trial. As of 31 Dec 2014, 161 participants have opened informed consent: 125 have screen failed and 34 have been randomized onto the study. Screen

fails have been due to: failure to complete baseline assessments (n=38), psychiatric exclusion (n=34), medical exclusion (n=20), voluntarily withdrew (n=12), not meth dependent/no meth positive (n=9), PI/MD discretion (n=7), suicidality (n=4) and medication non-adherent (n=1). Of the 34 randomized participants, 3 are currently active, 16 have completed the study and 15 have dropped. Reasons for dropping include: missed four consecutive visits (n=11), voluntarily withdrew (n=2), transferred to higher level of care (n=1) and due to serious adverse event (n=1).

To date, there has been 1 SAE on this trial. A report detailing this SAE was submitted to the panel on 22 Dec 2014. Briefly, participant 5147 is a 40 year old male who experienced a Serious Adverse Event, seizure (preferred term: convulsion). This adverse event is deemed a **serious adverse event** as meeting criteria as described in 21CFR312.32(a) as an important medical event. We have not unblinded the participant and are not able to confirm if this is an adverse drug reaction. However; given the temporal association with the drug, it was deemed "possibly related". This adverse event is not commonly associated with drug exposure and is uncommon in the population exposed to the drug, indicating that the adverse event is a **suspected adverse reaction** (21CFR312.32(a)). In regards to the study medication, seizures are not a known adverse event associated with ibudilast. According to the Japanese package insert for ibudilast "One reported case of "convulsions" was reported in a multicenter, double-blind, placebo-controlled study of 238 subjects with dizziness after stroke (Shinohara and Nakashima, 2002)" but seizures are not listed as an adverse event associated with ibudilast in the investigator's brochure. Therefore, this adverse event is considered **unexpected** (21CFR312.32(a)) in regards to study medication. However; the participant has a known history of seizures but reported no seizures since 2008. The participant had reported falling off a ladder 3 weeks prior to the adverse event (on 11/23/2014 prior to first study medication dose). The participant was assessed by study staff at the time, denied any seizure-like activity during the fall, and it was determined that this was not a seizure. The participant now reports that in retrospect the fall off the ladder may have been a seizure. Therefore, given the medical history and the baseline event, this adverse event is deemed **anticipated** (21CFR312.32(c)(5)) in regards to the underlying disease, disorder or condition of the participant experiencing the adverse event and is a re-emergence or worsening of a condition relative to pre-treatment baseline. In light of this, we do not feel that this event increases the risk to other participants nor are changes in the study protocol needed. Based on our assessment, this SAE does **NOT** meet criteria for submission to FDA as an IND Safety Report, nor to the UCLA IRB as an unanticipated problem. The SAE report was submitted to the DSMB, NIDA, RAP-C and study drug manufacturer, MediciNova, per reporting guidelines.

To date, all other adverse events reported have been as expected for this study. All regulatory approvals are current and in place. The study is currently active and recruiting, there are no results to report at this time.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2014

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Donald Abrams, M.D. UCSF / SFGH San Francisco, CA	Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease
Kevin Chu, D.O. 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
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.
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine involvement in Opiate and Stimulant Reinforcement
Judith Hellman, M.D. UCSF San Francisco, CA	Cannabinoid-Dependent Modulation of the Innate Immune Response to Infection and Injury
Kim D. Janda, Ph.D. The Scripps Research Institute La Jolla, CA	Vaccines for the Treatment of Opiate Addiction

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Byung-Sook Moon ARK Freemont, CA	Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing
N.V. Myung, M.D. Nano Engineered Applications Riverside, CA	Marijuana Active Ingredient Quantification via Volatilized Sample
Douglas Sears, M.D. Encino, CA	A Double-Blind, Placebo-Controlled Study of Combination Therapy in Children with ADHD
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
Tanya Wallace, Ph.D. SRI International Menlo Park, CA	Cannabinoid Regulation of Cognition
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy & Safety of the Sublingual Sufentanil Tablet 30 mcg for the Treatment of Post-Operative Pain in Patients after Abdominal Surgery (SAP301)

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Alkermes Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Tx of Major Depressive Disorder (Study I) (ALKS5461-205)
Alkermes Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Treatment of Major Depressive Disorder (Study II) (ALKS5461-206)
Alkermes Waltham, MA	A Phase 3 Efficacy & Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-207)
Alkermes Waltham, MA	A Phase 3 E & S Study of ALKS5461 for the Adjunctive Tx of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)
Alkermes 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)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
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)
Grunenthal/Janssen CRO - inVentiv Cary, NC	An Evaluation of the Efficacy & Safety of Tapentadol Oral Solution in the Treatment of Post-Operative Acute Pain Requiring Opioid Treatment in Pediatric Subjects Aged from Birth to Less than 18 Years old (KF5503/65)
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Study
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Study
Ironshore Camana Bay, Grand Cayman	A Phase 3 Clinical Endpoint Evaluation Study Examining the Safety & Efficacy of HLD200 in Pediatric Subjects with ADHD (CEES ADHD) (HLD200-106)

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Lannett CRO - Parexel Waltham, MA	A Phase 3 Investigation of Topical Application of Cocaine 4% and 10% on Safety & Efficacy in Local Anesthesia for Dx Procedures & Surgeries on or through Accessible Mucous Membranes of the Nasal Cavities (COCA4vs10-001)
MAPS Santa Cruz, CA	A Randomized, Double-Blind, Placebo-Controlled Study of MDMA-Assisted Psychotherapy for Anxiety Associated with a Life-Threatening Illness (MDA-1)
Purdue Pickering, 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, Canada	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multicenter Study Measuring the Efficacy and Safety of PRC-063 in Adolescent ADHD Patients (063-009)
Purdue Pickering, Canada	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multicenter Study Measuring the Efficacy and Safety of PRC-063 in Adult ADHD Patients (063-010)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Purdue Pickering, Canada	A Six-month, Open-label, Multicenter Study of the Safety and Efficacy of PRC-063 in Adults and Adolescents with ADHD (063-012)
Shire CRO - Premier Philadelphia, PA	A Phase 3, Multicenter, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study to Evaluate the Maintenance of Efficacy of SPD489 in Adults Aged 18-55 years with Moderate to Severe Binge Eating Disorder (SPD489-346)
Trevena CRO - Premier Austin, TX	A Phase 2, Multicenter, Randomized, Double-Blind, Multiple-Dose, Adaptive, Placebo- and Active-Controlled Study of TRV130 for the Treatment of Acute Postoperative Pain after Buinionectomy (CP130-2001)
Tris CRO - Rho Chapel Hill, NC	Amphetamine Extended-Release Oral Suspension in the Treatment of Children with ADHD: A Laboratory School Study (TRI102-ADD-001)
NIDA Rockville, MD	Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (0051)

TABLE 2

RESEARCH STUDIES CLOSED IN 2014

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Sean Mackey, MD, PhD Stanford University Palo Alto, CA	Neural and Immune Effects of Sort-term Opioid Use in Chronic Pain Patients
Forest Research Jersey City, NJ	A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Safety and Efficacy of GRT6005 in Patients with Moderate tot Severe Chronic Pain Due to Osteoarthritis of the Knee (GRT-MD-101)
Mitsubishi CRO - Quintiles Overland, 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)
Shire Wayne, PA	A Phase 2, Multicenter, Double-Blind, Parallel-Group, Randomized, Placebo-Controlled, Forced-dose Titration, Dose-ranging Efficacy & 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 (SPD489-209)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire CRO - ICON Brentwood, TN	Phase 3, Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible Dose Titration, Efficacy & 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 (SPD489-322)
Shire CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible Dose Titration, Efficacy & 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 CRO - ICON Brentwood, TN	Phase 3, Open-Label, Multicenter, 12-months Extension Safety & Tolerability Studying 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)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire CRO - Premier Research 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 CRO - Premier Research Philadelphia, PA	A Phase 3, Multicenter, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study to Evaluate the Maintenance of Efficacy of SPD489 in Adults Aged 18-55 years with Moderate to Severe Binge Eating Disorder (SPD489-346)
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)
TEVA	A 6 months, Open-Lable, Extension Study to Evaluate the Safety of Hydrocodone Bitartrate ER tabs (CEP-33237) at 15mg-90mg every 12 hours for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (C33237/3104)

APPENDIX A

CURRENTLY OPEN *(through December 31, 2014)*
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

Principal Investigator	Title of Study
Donald Abrams, M.D. UCSF / SFGH San Francisco, CA	Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease
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
Kevin Chu, D.O. 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

Appendix A Cont.

Principal Investigator	Title of Study
Laura Colin Biostride, Inc. Redwood City, CA	Research of Novel Technologies for Development of Antibodies and Immunoassay Techniques to Drugs of Abuse and Controlled Compounds of Interest
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
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine involvement in Opiate and Stimulant Reinforcement
Michael Fischbach UCSF San Francisco, CA	Engineering a human gut bacteria to produce dimethyltryptamine
Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA	Effects of Cannabidiol on Mania-relevant Locomotor and Investigatory Behavior
Judith Hellman, M.D. UCSF San Francisco, CA	Cannabinoid-Dependent Modulation of the Innate Immune Response to Infection and Injury

Principal Investigator	Title of Study
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
Thomas S. Kilduff, Ph.D. SRI International Menlo Park, CA	Neurobiological Studies of Gammahydroxybutyrate (GHB)
George Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Prescription Opioid Addiction: Neurobiological Mechanisms
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

Appendix A Cont.

Principal Investigator	Title of Study
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development 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
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 ™) for Treatment of HIV Dementia
Byung-Sook Moon ARK Freemont, CA	Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing
N.V. Myung, M.D. Nano Engineered Applications Riverside, CA	Marijuana Active Ingredient Quantification via Volatilized Sample

Principal Investigator	Title of Study
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
Paolo Sassone-Corsi, Ph.D. Center for Epigenetics & Metabolism UC Irvine Irvine, CA	The Role of Liver CB1 Receptor in Regulation of the Circadian Metabolism
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
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 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
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol

Principal Investigator	Title of Study
Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA	Panel Approved Research Project
Ronald Victor, M.D. Cedars-Sinai Med Center Los Angeles, CA	Effects of Cocaine on Blood Flow to the Heart
Tanya Wallace, Ph.D. SRI International Menlo Park, CA	Cannabinoid Regulation of Cognition
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol
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 A Cont.

Principal Investigator	Title of Study
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

APPENDIX B

CURRENTLY OPEN *(through December 31, 2014)*
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
AcelRx Redwood City, CA	A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy & Safety of the Sufentanil Nano Tab PCA System 15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Post-Operative Pain (IAP309)
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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy & Safety of the Sublingual Sufentanil Tablet 30 mcg for the Treatment of Post-Operative Pain in Patients after Abdominal Surgery (SAP301)
Alkermes, Inc. 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)
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Tx 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 Waltham, MA	A Phase 3 Efficacy & Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-207)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes Waltham, MA	A Phase 3 E & S Study of ALKS5461 for the Adjunctive Tx of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)
Astra Zenica CRO : Quintiles Overland Park, KS	A Radomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain & Opioid-Induced Constipation (OIC) (D3820300004)
Astra Zenica CRO : Quintiles Overland Park, KS	A Radomized, 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) (D3820300005)
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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
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)
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	A Controlled, Two-Arm Parallel Group, Randomized Withdrawal Study to Assess the Safety and Efficacy of Hydromorphone HCl Delivered by intrathecal Administration a Programmable Implantable Pump (HYD201US)

Sponsor	Description or Title of Clinical Drug Trial Protocol
CNS Therapeutics CRO: Social & Scientific Systems	A Phase 3 Open-Label, Single-Arm Study To Assess The Safety of Hydromorphone HCl Delivered by Intrathecal Administration (HYD202US)
Collegium CRO : INC Research	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)
Grunenthal/Janssen CRO : inVentiv Cary, NC	An Evaluation of the Efficacy & Safety of Tapentadol Oral Solution in the Treatment of Post-Operative Acute Pain Requiring Opioid Treatment in Pediatric Subjects Aged from Birth to Less than 18 Years old (KF5503/65)
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
INTRuST Clinical Consortium Purdue / CRO-INC Research Raleigh, NC	Randomized Controlled Trial of Galantamine, Methylphenidate, & Placebo Tx of Cognitive Symptoms in Pts w Mild Traumatic Brain Injury and/or Posttraumatic Stress Disorder (PISD) ["Cognitive REmediation After Trauma Exposure" Trial = CREATE Trial"]
Ironshore Camana Bay, Grand Cayman	A Phase 3 Clinical Endpoint Evaluation Study Examining the Safety & Efficacy of HLD200 in Pediatric Subjects with ADHD (CEES ADHD) (HLD200-106)
Lannett CRO : Parexel Waltham, MA	A Phase 3 Investigation of Topical Application of Cocaine 4% and 10% on Safety & Efficacy in Local Anesthesia for Dx Procedures & Surgeries on or through Accessible Mucous Membranes of the Nasal Cavities (COCA4vs10-001)

Sponsor	Description or Title of Clinical Drug Trial Protocol
MAPS Santa Cruz, CA	A Placebo-Controlled, Randomized, Blinded, Dose Finding Phase 2 Pilot Safety Study of MDMA-Assisted Therapy for Social Anxiety in Autistic Adults (MAA-1)
MAPS Santa Cruz, CA	A Randomized, Double-Blind, Placebo-Controlled Study of MDMA-Assisted Psychotherapy for Anxiety Associated with a Life-Threatening Illness (MDA-1)
Pfizer Inc. New York, NY	A Multicenter, 12-Week, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study to Determine the Efficacy and Safety of ALO-02 (Oxycodone Hydrochloride and Naltrexone Hydrochloride) Extended-Release Capsules in Subjects with Moderate to Severe Chronic Low Back Pain (B4531002)
Purdue CRO : PRA Lenexa, KS	An Open-Label, Multicenter Study of the Safety of Twice Daily Oxycodone HCl Controlled-Release Tablets in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, with Moderate to Severe Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics (OTR 3001)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue CRO : PRA Lenexa, KS	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)
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 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 Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (ONU3705)
Purdue / CRO-INC Research Raleigh, NC	A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain (HYD3002)
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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue Pickering, 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, Canada	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multicenter Study Measuring the Efficacy and Safety of PRC-063 in Adolescent ADHD Patients (063-009)
Purdue Pickering, Canada	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm, Multicenter Study Measuring the Efficacy and Safety of PRC-063 in Adult ADHD Patients (063-010)
Purdue Pickering, Canada	A Six-month, Open-label, Multicenter Study of the Safety and Efficacy of PRC-063 in Adults and Adolescents with ADHD (063-012)

Sponsor	Description or Title of Clinical Drug Trial Protocol
QrxPharma CRO : INC Research Austin, TX	A Double-Blind, Randomized, Placebo and Active-Control, Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of Q8011 Compared to OxyContin® and Placebo in Patients with Moderate to Severe Chronic Hip or Knee Pain Due to Osteoarthritis (Q8011-201)
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)
Purdue 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)
Purdue CRO : Premier Research Group Little Egg Harbor, NJ	A Phase 4, Randomized, Double-blind, Multicenter, Parallel-group, Active-controlled, Dose-optimization Safety and Efficacy Study of SPD489 (Vyvanse®) Compared with OROS-MPH (Concerta®) with a Placebo Reference Arm, in Adolescents Aged 13-17 Years with Attention-deficit/Hyperactivity Disorder (ADHD) (SPD489-405)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue CRO : Premier Research Group Little Egg Harbor, NJ	A Phase 4, Randomized, Double-blind, Multicenter, Parallel-group, Active-controlled, Forced-dose Titration, Safety and Efficacy Study of SPD489 (Vyvanse®) Compared with OROS-MPH (Concerta®) with a Placebo Reference Arm, in Adolescents Aged 13-17 Years with Attention-deficit/Hyperactivity Disorder (ADHD) (SPD489-406)
Tris CRO : Rho Chapel Hill, NC	Amphetamine Extended-Release Oral Suspension in the Treatment of Children with ADHD: A Laboratory School Study (TRI102-ADD-001)

APPENDIX C

CURRENTLY OPEN *(December 31, 2014)*
RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Catalyst Coral Gables, FI	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study Multi-Center Drug Trial
Kelly Courtney, M.S. UCLA Los Angeles, CA	The Effects of Naltrexone on Neural Responses to Methamphetamine Cues
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, Multicenter Trial of Nepicastat for Cocaine Dependence (CS#1031)
Keith Heinzerling, M.D. UCLA Los Angeles, CA	Randomized Trial of Ibudilast for Methamphetamine Dependence
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Sustained-Release Methylphenidate for management of Methamphetamine Dependence

Appendix C Cont.

Investigator or Sponsor	Description or Title of Research Project
NIDA Rockville, MD	Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (0051)
NIDA Rockville, MD	Achieving Cannabis Cessation - Evaluating N-Acetylcysteine Treatment (ACCENT) (CTN-0053)
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Naltrexone on Alcohol-Dependent Asian Americans
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Ibudilast on Non-treatment Seeking Patients Who Meet Criteria for Alcohol Abuse or Dependence
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Ivermectin on Non-Treatment Seeking Patients Who Meet Criteria for Alcohol Abuse or Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline for Methamphetamine Dependence

Investigator or Sponsor	Description or Title of Research Project
Teva Pharmaceuticals Frazer, PA	A 12-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of One-Weekly Intra-Muscular Injections of TV-1380 (150mg/week or 300mg/week) as a Treatment for Facilitation of Abstinence in Cocaine-Dependent Subjects (TV1380-COA-201)
US WordMeds, LLC Louisville, KY	A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Efficacy, Safety, and Dose-Response Study of Lofexidine in the Treatment of Opioid Withdrawal (Days 1-7) Followed by Open-Label, Variable Dose Lofexidine Treatment (Days 8-14) (USWM-LX1-3003-1)

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.

§ 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.