THIRTY-NINTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2009

Prepared for the

LEGISLATURE AND GOVERNOR

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

TABLE OF CONTENTS

SUMMARY OF 2009 PANEL ACTIVITIES

During 2009 the Panel reviewed forty research study submissions. Thirty-six were approved by the Panel. Among thirty-six approved studies, fifteen studies were Academic research studies including five Substance Abuse Treatment research protocols and twenty-one studies were Clinical Drug Trial research protocols.

Twenty-one research studies were completed or, in a few cases, terminated in 2009, and they were closed on the Panel's records.

At the end of 2009, the Panel was monitoring 101 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 Approval may be withdrawn if the study deviates significantly from the approved protocol.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 2009 and Table 2 is a list of the studies closed by the Panel in 2009.

SELECTED RESEARCH FINDINGS

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

Dr. Timothy L. Wigal, Ph.D. and colleagues at the UCI Child Development center in Irvine, Californiá have completed a study titled "Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)" The results of this study were recently published in the Journal of the American Medical Association and summarized with the following findings:

> Attention-deficit/hyperactivity disorder (ADHD) - characterized by symptoms of inattention and hyperactivity-impulsivity - is the most prevalent childhood psychiatric disorder that frequently persists into adulthood, and there is increasing evidence of reward-motivation deficits in this disorder.
> To evaluate biological bases that might underlie a reward/motivation deficit by imaging key components of the brain dopamine reward pathway (mesoaccumbens). We used positron emission tomography to measure

dopamine synaptic makers in 53 nonmedicated adults with ADHD and 44 healthy controls between 2001-2009 at Brookhaven National Laboratory. We measured specific binding of positron emission tomographic radioligands for dopamine transporters (DAT) quantified as binding potential.
For both ligands, statistical parametric mapping showed that specific binding was lower in ADHD than in controls in regions of the dopamine reward pathway in the left side of the brain. Region-of-interest analyses corroborated these findings. As conclusion, a reduction in dopamine synaptic makers associated with symptoms of inattention was shown in the dopamine reward pathway of participants with ADHD.

Dr. Matthew Schreiber, MD, PhD and colleagues at the Ernest Gallo Clinic and Research Center in Emeryville, California have provided the Panel with the following summary of ongoing research titled "Pharmacological and Genetic Study of the Effects of 3,4-methylenedixoymethamphetamine (MDMA) using a moder organism, the nematode *Caenorhabditis elegans.*"

Amphetamines are among the most widely abused substances. From a public health standpoint, there is substantial concern about the toxicity of these substances, particularly MDMA, which is abused by an especially vulnerable population. The toxicity of MDMA has been shown in mammalian models, but the underlying molecular mechanisms mediating this toxicity are still only poorly understood. A better understanding of this toxicity would pirmit better treatment and prevention of the abuse of these substances. To this end, I am using a model organism, the nematode *C. Elegans*, to study MDMA toxicity. This organism's simple nervous system employs molecular components that are highly conserved with mammals. This makes study of these organisms relevant to the study of basic aspects of mammalian neurobiology, while offering the great advantage that genetic studies are possible that would be very difficult or impossible in mammals. Preliminary work indicates that MDMA has distinct behavioral effects on this organism, as well as toxicity to the organism as a whole. New computer-assisted techniques developed in this laboratory will allow more accurate and detailed investigation of the neurobehavioral toxicity of this substance. As these techniques are implemented, further efforts will be directed to the identification of the cellular targets responsible for this toxicity, as well as more detailed scrutiny of the neurobehavioral effects of the drug. In turn these studies will facilitate genetic tests to identify molecular components of the toxic effects of the substance. It is anticipated that these efforts will lead to a better understanding of this class of harmful, widely-abused substances.

Dr. Keith Flower, MD and colleagues at the Addiction Pharmacology Research Laboratory at CPMC Research Institute in San Francisco, California have provided the Panel with the following summary of ongoing research titled "A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP"

Methamphetamine addiction remains a significant public health problem with no known effective pharmacotherapies. Small clinical trials suggest that oral naltrexone, an opioid antagonist with known efficacy in treating alcoholism, has efficacy against amphetamine addiction. In alcoholics, use of sustained release naltrexone improves adherence and decreases drinking. Alcoholics who are carriers of the A11IG single nucleotide polymorphism (SNP) of the *u*-opioid receptor (OPRM1) respond better to naltrexone than do non-carriers. We propose conducting the first trial of naltrexone for methamphetamine addiction. We will use the injectable, sustained release formulation and focus on the role of the A118G Snp in response to naltrexone. The conventional approach to a full-scale outpatient efficacy trial would be to recruit equal numbers of A118G and wild type subjects and assign them randomly to naltrexone or placebo. However, the relative infrequency of the A118G polymorphism (10-30%) would require screening many subjects, and is not appropriate for a pilot trial. If naltrexone is effective for methamphetamine addiction, we anticipate a large difference in response to naltrexone based on the presence or absence of the A118G polymorphism. Finding such a difference would indicate that a larger, placebo-controlled trial should be conducted. Therefore, we plan to conduct an outpatient, pilot clinical trial of sustained release naltrexone s a pharmacotherapy for methamphetamine addiction, comparing responses to a sustained release formulation of naltrexone in subjects with and without the A118G polymorphism. Comparing the effects of naltrexone in these two groups will provide important data useful in guiding the design of subsequent, more definitive studies. In this pilot trial, we utilize several innovative methods to test naltrexone against methamphetamine addiction. First, we use sustained release naltrexone to improve compliance and decrease variability in drug response. Second, we recruit two pharmacogenomically-defined groups - carriers of the A118G SNP, and wild type - and compare response to naltrexone by pharmacogenomic status. Third, we utilize a non-randomized placebo control group from a similar, simultaneously running parallel study to permit effect size estimation at essentially no cost. Fourth, we investigate putative mechanisms of naltrexone action, which include reduction in craving and impulsivity.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2009

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Gayle C. Baldwin, Ph.D. UCLA Los Angeles, CA	Methamphetamine Dependence: A Novel Laboratory Model
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
G. Patrick Dauert, M.D. UC Davis Medical Center Sacramento, CA	Does Oral Methadone Use in Opiate Replacement Therapy Prolong the QTc Interval?
Keith Flower, M.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP
Gantt Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Modafinil for Methamphetamine Dependence
Gantt Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	Phase 1, Double-Blind, Placebo-Controlled Assessment of Potential Interactions Between Intravenous Cocaine and lofexidine
Edward T. Kisak, Ph.D. Fqubed, Inc. San Diego, CA	Transdermal Delivery of tetrahydrocannabinol

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Keith Heinzerling, MD, MPH UCLA Dept of Family Medicine Los Angeles, CA	Pilot Trial of Bupropion versus Placebo for Methamphetamine Abuse in Adolescents
Lorrin Koran, M.D. Stanford University Stanford, CA	Functional MRI of D-amphetamine vs. Placebo in Obsessive-Compulsive Disorder
Adam Leventhal, Ph.D. USC Keck School of Medicine Alhambra, CA	Influence of Genes and Emotions on medication Effects
Linghui Li, Ph.D. APRL/CPMC Research Institute San Francisco, CA	An Open-Label Stud to Evaluate the Impact of Genetic Variation in CYP2D6 on the Pharmacokinetics and Pharmacodynamics of Methamphetamine in Healthy Adults
Edythe London, Ph.D. UCLA Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine
John E. Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Role of Serotonin in Acute and Subacute MDMA Effects
John E. Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	A Phase-I, Two-Stage, Double-Blind, Placebo-Controlled, Pharmacokinetics and pharmacodynamic Trial of Low Doses of Intravenous 6*B*-Naltrexol (AIKO-150) in Opioid-Dependent Subjects

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Richard Reznichek, M.D. Harbor-UCLA Medical Center Torrance, CA	A prospective, randomized, double-blind study comparing the efficacy and safety of intra nasal fentanyl spray to placebo as an analgesic in patients undergoing outpatient cystoscopic procedures
Steven Shoptaw, Ph.D. UCLA Los Angeles, CA	Varenicline vs Placebo in Conjunction with Cognitive Behavioral Therapy for the Treatment of Methamphetamine Dependence
AcelRx Pharmaceuticals, Inc. Redwood City, CA	A Multicenter, Randomized, Placebo-Controlled, Crossover Study for the Evaluation of the Safety, Tolerability and Efficacy of ARX-F02 compared to Placebo in the Treatment of Cancer Breakthrough Pain (AcelRx ARX-C-003)
BRC Operations Pty Ltd. Ultimo, NSW, Australia	International Study to Predict Optimized Treatment in Attention Deficit/.Hyperactivity Disorder (BRC iSPOT-A)
Cephalon, Inc Frazer, PA	A Randomized, Double-Bind, Active-Controlled Crossover Study to Evaluate the Efficacy and Safety of Fentanyl Buccal Tablets Compared With Immediate-Release Oxycodone for the Management of Breakthrough Pain in Opioid-Tolerant patients With Chronic Pain, Followed by a 12-Week Open-Label Extension to Evaluate the Impact of Fentanyl Buccal Tablets on Patient Outcomes (Cephalon C25608/3056/BP/US)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
NIAID/NIH Bethesda, MD	A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Duloxetine and Methadone for the Treatment of HIV-Associated Painful Peripheral Neuropathy (DAIDS A5252)
OMJSA Titusville, NJ	A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate (OMJSA CONCERTA-ATT-3014)
Johnson & Johnson Malvern, PA	A Single-Dose Study to Evaluate the Relative Bioavailability of a 100mg tamper-Resistant Prolonged-Release Formulation (TRF) of Tapentadol with Respect to the PRI Prolonged-Release 100mg tablet Formulation Under Fasted Condition in Japanese Healthy Subjects (J&J R331333 PAI 1053)
Johnson & Johnson Titusville	A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety, and Tolerability, of Tapentadol Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN) (J&J R331333 PAI 3027)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Johnson & Johnson Titusville	A Randomized, Double Blind, Placebo- and Active-Controlled, Parallel-Group, Multicenter Study of Three Dosages of JNJ-31001074 in the Treatment of Adult Subjects with Attention Deficit/Hyperactivity Disorder (J&J 31001074-ATT-2001)
Johnson & Johnson Malvern, PA	A Single-Dose Study to Evaluate the Effect of Food on the Pharmacokinetics of a Tamper-Resistant prolonged-Release 100mg Tablet Formulation of Tapentadol in healthy Male Japanese Subjects (J&J R331333 PAI 1052)
King Pharmaceuticals R & D Austin, TX	A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Multiple-dose Study of the Safety and Efficacy of Acuracet TM Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Subjects (King K228-08-3001)
Eli Lilly Pharmaceuticals Indianapolis, IN	A Fixed-Dose, Randomized, Double-Blind, Placebo-Controlled Study of LY2216684 in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (Lilly H9P-MC-LNBF)

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Neurologic AIDS Research Consortium (NARC) at Washington University in St. Louis. St. Louis, MO	A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Methadone and Combination of Methadone and SAB378 in HIV-Associated Painful Peripheral Neuropathy (NARC NARC011)
NextWave Pharmaceuticals Research Triangle Park, NC	NWP06 in Treatment of Children with ADHD: A laboratory Classroom Study (NextWave NWP06-ADD-100)
Ortho-McNeil Janssen Scientific Affairs, LLC Raritan, NJ	A Randomized, Double-Blind, Multi-Center, Parallel-Group Study of Tapentadol Immediate Release (IR) vs. Oxycodone IR for the Treatment of Subjects with Acute Post-Operative Pain Following Elective Arthroscopic Shoulder Surgery (OMJSA R331333 PAI 3022)
QRxPharma Chapel Hill, NC	A Randomized, Double-blind, Multicenter, Repeat-dose, Comparison of Analgesic Efficacy and Safety of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-008)
QRxPharma Chapel Hill, NC	A Randomized, Double-blind Study of The Analgesic Efficacy and Safety of Flexible Dose Q8003 versus Low Dose Q8003 in Patients Who Have Undergone Primary Unilateral Total Knee Arthroplasty (QRxPharma Q8003-009)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Shire Philadelphia, PA	A Phase 4, Double-Blind, Multi-center, Placebo-Controlled, Randomized Withdrawal, Safety and Efficacy Study of SPD489 in Adults Aged 18-55 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD489-401)
Shire Raleigh, NC	A Phase II, Multicenter, Randomized, Double-blind, parallel-group, Placebo-controlled Exploratory Efficacy and Safety Study of SPD489 in Adults 18-55 years with Major Depressive Disorder (MDD) as Augmentation Therapy to an Antidepressant (Shire SPD489-203)
Shire Raleigh, NC	A Phase II, Multicenter Study with Open-label and Randomized Double-blind Placebo-Controlled Withdrawal Phases to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Schizophrenia and Predominant Negative Symptoms Who Are Clinically Stable and Taking Stable Doses of Atypical Antipsychotic Medication (Shire SPD489-204)

TABLE 2

RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2009

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Jeremy S. Caldwell, Ph.D. Genomics Institute Novartis Research Foundation San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
Karen Chang, Ph.D. ALZA Corporation Mountain View, CA	Purity Determination, Morphine and Hydromorphone
Arthur Cho, Ph.D. UCLA Los Angeles, CA	Studies on Distribution and Metabolism of Narcotics in Animals
Alan Gevins, D.Sc. SAM Technology San Francisco, CA	Panel Approved Research
Lorrin Koran, M.D. Stanford University Stanford, CA	Double-Blind Trial of Acute & Intermediate-Tern Dextro-Amphetamine versus Caffeine Augmentation in Treatment-Resistant Obsessive-Compulsive Disorder
Walter Ling, M.D. UCLA Los Angeles, CA	Double-Blind, Placebo-Controlled Trial of Prometa Pharmacotherapy for the Treatment of Methamphetamine Abuse

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
John Polich, Ph.D. The Scripps Research Institute La Jolla, CA	Marijuana CNS Effects in Low- and High-Risk Adults
Steven Shoptaw, Ph.D: UCLA Los Angeles, CA	A Randomized, Double-Blind, Placebo-Controlled Evaluation of Modafinil vs Placebo for the Treatment of Methamphetamine Dependence
AcelRx Pharmaceuticals Redwood City, CA	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Evaluate the Clinical Efficacy, Safety, and Tolerability of ARX-F03 Sublingual Sufentanil/Triazolam Nanotabs in Patients Undergoing an Elective Abdominal Liposuction Procedure (AcelRx ARX-C-004)
BioDelivery Sciences International, Inc. Raleigh, NC	Open-Label, Long-Term Extension Study for Treatment of Breakthrough Cancer Pain with BEMA Fentanyl (BioDelivery FEN-290)
Endo Pharmaceuticals, Inc. Chadds Ford, PA	A Double-Blind, Randomized, Placebo-Controlled, multicenter Study to Evaluate the Efficacy and safety of EN3267 for the Treatment of Breakthrough Pain in Opioid Tolerant Cancer Patients Followed by a 12-Month Non-Randomized, Open-label Extension to Assess Long-Term Safety (Endo EN3267-005)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Endo Pharmaceuticals, Inc. Chadds Ford, PA	A Multiple-Dose, Non Randomized, Open-Label, Multicenter Study to Evaluate the Long-Term Safety and Effectiveness of EN3267 in the Treatment of Breakthrough Pain in Cancer patients (Endo Protocol EN3267-007)
Johnson & Johnson Austin, TX	A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy (J&J R331333-PAI-3018)
Johnson & Johnson Cypress, CA	A Pivotal Bioequivalence Study Assessing Transdermal D-TRANS Fentanyl 100 *u*g/h Matrix System to DURAGESIC Fentanyl 100 *u*g/h Reservoir System After Single Application in Healthy Subjects (J&J FEN-PAI-1019)
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Placebo- and Active- Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated with Tapentadol IR and Oxycodone IR Using a Bowel Function Patient Diary (J&J R331333-PAI-3020)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Neuromed Pharmaceuticals Raleigh, NC	A Phase III, Variable-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Chronic Low Back Pain (Neuromed NMT 1077-301)
NextWave Pharmaceuticals Research Triangle Park, NC	NWP06 in Treatment of Children with ADHD: A laboratory Classroom Study (NextWave NWP06-ADD-100)
Ortho-McNeil Janssen Scientific Affairs, LLC Raritan, NJ	A Randomized, Double Blind, Placebo- and Oxycodone Immediate Release (IR) - Controlled Study of Tapentadol IR for the Treatment of Acute pain Caused by Vertebral Compression Fractures Associated with Osteoporosis (OMJSA R331333-PAI-3021)
Purdue Pharma L.P. Stamford, CT	A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naive Subjects with Moderate to Severe, Chronic Pain due to Osteoarthritis of the Knee (Purdue BUP3025)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire Pharmaceuticals, Inc. Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Dose-Optimization, Cross-Over, Analog Classroom Study to Assess the Time of Onset of Vyvanse™ in Pediatric Subjects aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (Shire SPD489-311)
Shire Pharmaceuticals, Inc. Philadelphia, PA	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)

APPENDIX A

CURRENTLY OPEN *(through December 31, 2009)*
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

Principal Investigator	Title of Study
Mark A. Agius, M.D. UC. Davis Davis, CA	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
James T. Arnold, Ph.D. Systems and Techniques Lab. Palo Alto, CA	Panel Approved Research Project
Gayle C. Baldwin, Ph.D. UCLA Los Angeles, CA	Methamphetamine Dependence: A Novel Laboratory Model
Mariusz G. Banaszczyk, Ph.D. Biosite Diagnostics San Marcos, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768	The cannabinoid system and the modulation of T cell and macrophage Functions

Appendix A Cont.

Principal Investigator	Title of Study
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Project
G. Patrick Dauert, M.D. UC Davis Medical Center Sacramento, CA	Does Oral Methadone Use in Opiate Replacement Therapy Prolong the QTc Interval?
Mohammad Diab, M.D. UC San Francisco San Francisco, CA	Comparison of Extended-Release Epidural Morphine, PC Epidural Analgesia, & PC Intravenous Analgesia for Post-Op Pain Management after Post. Spinal Fusion in Adolescents
Robert Edwards, M.D. UCSF School of Medicine San Francisco, CA	Panel Approved Research Project
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement

Principal Investigator	Title of Study
Frederick D. Frankel, Ph.D. UCLA ISAP Los Angeles, CA	Social Skills Training for Medicated Children
Gantt Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	Phase 1, Double-Blind, Placebo-Controlled Assessment of Potential Interactions Between Intravenous Cocaine and lofexidine
Jean Gehricke, Ph.D. UC Irvine Irvine, CA	Panel Approved Research Project
Mark A. Geyer, Ph.D. UC San Diego La Jolla, CA	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats
Charles S. Grob, M.D. Harbor UCLA Medical Center Torrance, CA	Effects of Psilocybin in Terminal Cancer Patients with Anxiety
Kanthi F. Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Cannabinoids
Scott A. Irwin, MD, PhD San Diego Hospice/ Palliative Care San Diego, CA	Panel Approved Research Project
Thomas B. King Alexza Molecular Delivery Corp. Palo Alto, CA	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery

Appendix A Cont.

Principal Investigator	Title of Study
Edward T. Kisak, Ph.D. Fqubed, Inc. San Diego, CA	Transdermal Delivery of tetrahydrocannabinol
George F. Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Central Mechanisms of Opiate Reinforcement and Dependence
Lorrin Koran, M.D. Stanford University, School of Medicine Stanford, CA	Double-Blind Trial of Acute & Intermediate-Tern Dextro-Amphetamine versus Caffeine Augmentation in Treatment-Resistant Obsessive-Compulsive Disorder
Kimberley D. Lakes, Ph.D. UC Irvine Irvine, CA	The Effects of Vyvanse on Brain Hemodynamics and Reading
Adam Leventhal, Ph.D. USC Keck School of Medicine Alhambra, CA	Influence of Genes and Emotions on medication Effects
Linghui Li, Ph.D. APRL/CPMC Research Institute San Francisco, CA	An Open-Label Stud to Evaluate the Impact of Genetic Variation in CYP2D6 on the Pharmacokinetics and Pharmacodynamics of Methamphetamine in Healthy Adults
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development Study

Principal Investigator	Title of Study
Edythe London, Ph.D. UCLA Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine
Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA	Panel Approved Research Project
James T. McCracken, M.D. UCLA NPI Los Angeles, CA	An 8-Week, Randomized, Double-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate ER (Focalin XR) and the Combination, with a 12 Month Open-Label Extension for the Treatment of ADHD in Pediatric Subjects Aged 7 to 14 years
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Is There an Acute MDMA Single Dose Withdrawal Syndrome?
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Steady State Kinetics of l-Methamphetamine and Validation of Sensitivity of Dose Estimation
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Bioavailability and Urinary Excretion of Oral L-Methamphetamine
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Interactions of Prazosin and MDMA

Appendix A Cont.

Principal Investigator	Title of Study
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Pilot Study of LSD in Healthy Volunteers
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Clinical Pharmacology of 3,4-methylenedioxyamphetamine (MDA)
Robert Messing, M.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Protein kinase C epsilon (PKCe) in Responses to Cannabinoids
Stanley M. Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA	Panel Approved Research Project
Richard Reznichek, M.D. Harbor-UCLA Medical Center Torrance, CA	A prospective, randomized, double-blind study comparing the efficacy and safety of intra nasal fentanyl spray to placebo as an analgesic in patients undergoing outpatient cystoscopic procedures
Mark Rollins, MD, PhD UCSF Dept of Anesthesia San Francisco, CA	Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety?
Dorit Ron, Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Signaling Pathways Involved in the Mechanism of Action of the Anti-Addictive Drug Ibogaine

Principal Investigator	Title of Study
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Pharmacological and genetic study of the effects of 3,4-methylenedioxymethamphetamine (MDMA) using a model organism, the nematode Caenorhabditis elegans
Lawrence Toll, Ph.D. SRI International Menlo Park, CA	Biochemical Studies into Opiate Efficacies
Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA	Panel Approved Research Project
Mark Wallace, M.D. UC San Diego San Diego, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	Endocytosis and Cannabinoid Receptors
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	Endocytosis and Opioid Receptors
Timothy Wigal, Ph.D. UC Irvine Irvine, CA	Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA	The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain

Appendix A Cont.

Principal Investigator	Title of Study
Randall Wong Norac Pharma, Inc. Azusa, CA	Panel Approved Research Project
Randall Wong Norac Pharma, Inc. Azusa, CA	Panel Approved Research Project

APPENDIX B

CURRENTLY OPEN *(through December 31, 2009)*
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
BRC Operations Pty Ltd. Ultimo, NSW, Australia	International Study to Predict Optimized Treatment in Attention Deficit/.Hyperactivity Disorder (BRC iSPOT-A)
Cephalon, Inc Frazer, PA	A Randomized, Double-Bind, Active-Controlled Crossover Study to Evaluate the Efficacy and Safety of Fentanyl Buccal Tablets Compared With Immediate-Release Oxycodone for the Management of Breakthrough Pain in Opioid-Tolerant patients With Chronic Pain, Followed by a 12-Week Open-Label Extension to Evaluate the Impact of Fentanyl Buccal Tablets on Patient Outcomes (Cephalon C25608/3056/BP/US)
DAIS/NIH Bethesda, MD	A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Duloxetine and Methadone for the Treatment of HIV-Associated Painful Peripheral Neuropathy (DAIDS A5252)
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label, Ascending, Two-Part, Single- and Multiple-Dose Evaluation of the Safety, Pharmacokinetics, and Effectiveness of Oxymorphone For Acute Postoperative Pain in Pediatric Subjects (Endo EN3203-010)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxymorphone in Opioid-Tolerant pediatric Subjects with Chronic Pain (Endo EN3202-036)
GW Pharmaceuticals Wiltshire, UK	Panel Approved Research Project
Insys Therapeutics Phoenix, AZ	A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-05-001)
Insys Therapeutics Phoenix, AZ	Open-Label, Multi-Center Safety Trial of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-06-007)
Johnson & Johnson Titusville, NJ	A Randomized, Double Blind, Placebo- and Active-Controlled, Parallel-Group, Multicenter Study of Three Dosages of JNJ-31001074 in the Treatment of Adult Subjects with Attention Deficit/Hyperactivity Disorder (J&J 31001074-ATT-2001)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Johnson & Johnson Malvern, PA	A Single-Dose Study to Evaluate the Effect of Food on the Pharmacokinetics of a Tamper-Resistant prolonged-Release 100mg Tablet Formulation of Tapentadol in healthy Male Japanese Subjects (J&J R331333-PAI-1052)
Johnson & Johnson Malvern, PA	A Single-Dose Study to Evaluate the Relative Bioavailability of a 100mg tamper-Resistant Prolonged-Release Formulation (TRF) of Tapentadol with Respect to the PRI Prolonged-Release 100mg tablet Formulation Under Fasted Condition in Japanese Healthy Subjects (J&J R331333-PAI-1053)
Johnson & Johnson Titusville, NJ	A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate (OMJSA CONCERTA-ATT-3014)
Johnson & Johnson Titusville, NJ	A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety, and Tolerability, of Tapentadol Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN) (J&J R331333-PAI-3027)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
King Pharmaceuticals R & D Austin, TX	A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Multiple-dose Study of the Safety and Efficacy of Acuracet TM Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Subjects (King K228-08-3001)
Eli Lilly Pharmaceuticals Indianapolis, IN	A Fixed-Dose, Randomized, Double-Blind, Placebo-Controlled Study of LY2216684 in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (Lilly H9P-MC-LNBF)
Neurologic AIDS Research Consortium (NARC) at Washington University in St. Louis St. Louis, MO	A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Methadone and Combination of Methadone and SAB378 in HIV-Associated Painful Peripheral Neuropathy (NARC NARC011)
Neuromed Pharmaceuticals Conshohocken, PA	A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (NMT 1077-302)

Sponsor	Description or Title of Clinical Drug Trial Protocol
OMJSA Irvine, CA	Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)
OMJSA Raritan, NJ	A Randomized, Double-Blind, Multi-Center, Parallel-Group Study of Tapentadol Immediate Release (IR) vs. Oxycodone IR for the Treatment of Subjects with Acute Post-Operative Pain Following Elective Arthroscopic Shoulder Surgery (OMJSA R331333-PAI-3022)
Purdue Pharma Stamford, CT	A Multi-Center, Inpatient, Open-Label, within Subject Dose Titration Study to Characterize the Pharmacokinetics/Pharmacodynamics, Safety and Efficacy of Hydromorphone HCl Oral Solution in Subjects from 28 Days to 16 Years of Age, Inclusive, Who Require Opioid Analgesics for Post-Operative Pain (Purdue HMP4009)
QRxPharma Bedminster, NJ	A Double-Blind, Randomized, Multi-Center, Repeat Dose, Placebo Controlled Study to Compare the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to Each of the Individual Milligram Components (Oxycodone and Morphine) and Placebo in the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-015)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
QRxPharma Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)
QRxPharma Chapel Hill, NC	A Randomized, Double-blind, Multicenter, Repeat-dose, Comparison of Analgesic Efficacy and Safety of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-008)
QRxPharma Chapel Hill, NC	A Randomized, Double-blind Study of The Analgesic Efficacy and Safety of Flexible Dose Q8003 versus Low Dose Q8003 in Patients Who Have Undergone Primary Unilateral Total Knee Arthroplasty (QRxPharma Q8003-009)
Shire Pharmaceuticals Raleigh, NC	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Shire Pharmaceuticals Raleigh, NC	A Phase III, Open-Label, Extension, Multicenter, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-306)
Shire Pharmaceuticals Philadelphia, PA	A Phase 4, Double-Blind, Multi-center, Placebo-Controlled, Randomized Withdrawal, Safety and Efficacy Study of SPD489 in Adults Aged 18-55 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD489-401)

APPENDIX C

CURRENTLY OPEN *(December 31, 2009)* RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Keith E. Flower, M.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Dextroamphetamine for Treatment of Methamphetamine Dependence
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Modafinil for Methamphetamine Dependence
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pilot Trial of Bupropion versus Placebo for Methamphetamine Abuse in Adolescents
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Optimizing Outcomes Using Suboxone for Opiate Dependence

Appendix C. Cont.

Investigator or Sponsor	Description or Title of Research Study
John E. Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Role of Serotonin in Acute and Subacute MDMA Effects
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline vs Placebo in Conjunction with Cognitive Behavioral Therapy for the Treatment of Methamphetamine Dependence
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Methamphetamine Dependence: A Phase II Study (Catalyst CPP-02001)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Topiramate for the Treatment of Methamphetamine Dependence (NIDA-MDS-Topiramate/meth0001)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Modafinil for the Treatment of Methamphetamine Dependence (NIDA/VA CSP #1026)
National Institute on Drug Abuse (NIDA) Bethesda, Maryland	Starting Treatment with Agonist Replacement Therapies (START) (NIDA CTN Protocol 0027)

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 Sections 11480 and 11481.

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

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

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

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

§ 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 Section 11478.

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

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

§ 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 Section 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 Section 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 Section 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 Section 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 Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 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 Section 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 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 Section 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 Section 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 Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.