

2021

Research Advisory Panel of California

51st Annual Report
to the Governor and
Legislature of California



RAPC
RESEARCH ADVISORY
PANAL OF CALIFORNIA

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.

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RESEARCH ADVISORY PANEL OF CALIFORNIA

California law, pursuant to Health and Safety Code Sections 11480 and 11481, requires proposed research studies using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances to be reviewed and authorized by the Research Advisory Panel of California (RAPC) in the Attorney General's Office.

RAPC primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel Members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

2021 PANEL MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

The RAPC consists of the Panel Chair, Executive Officer, and the Panel members.

Enid Camps, JD

Deputy Attorney General, State of California Office of the Attorney General, San Francisco
Panel Chair, Appointed by the California State Attorney General

Tanveer Khan, PharmD

Executive Officer
Appointed by the California State Attorney General

Angie Chen, MD, FACP

Clinical Associate Professor, Stanford University School of Medicine
Appointed by Stanford University

Patrick R. Finley, PharmD, BCPP

Professor of Clinical Pharmacy, University of California, San Francisco (UCSF) School of Pharmacy
Appointed by the California State Board of Pharmacy

James J. Gasper, PharmD, BCPP

Psychiatric and Substance Use Disorder Pharmacist, California Department of Health Care Services
Appointed by the California Department of Public Health

Andrew S. Kayser, MD, PhD

Professor of Neurology, UCSF School of Medicine
Appointed by the University of California

Jennifer Mitchell, PhD

Professor of Neurology and Psychiatry and Behavioral Sciences, UCSF School of Medicine
Appointed by the California State Governor

SUMMARY OF 2021 PANEL ACTIVITIES

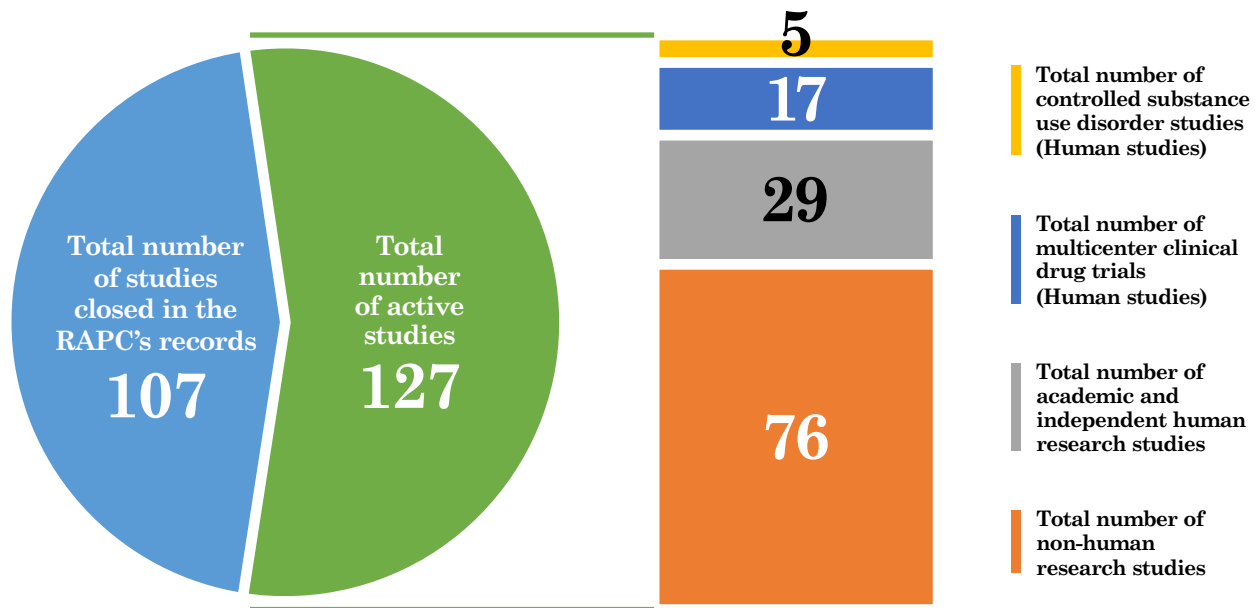
During calendar year 2021 (Jan 1 – Dec 31), RAPC reviewed 69 new and amended research submissions. RAPC approved 47 new studies and 18 amended studies. Four submissions reviewed by RAPC were not approved.

Among the new studies approved by RAPC, 18 studies were academic or independent human research studies, 18 studies were multi-center clinical drug trial research, and two studies were on the treatment of controlled substance use disorder. RAPC also approved 27 new non-human research projects.

One-hundred seven research studies were completed or terminated in 2021 and closed in RAPC's records. Of these, ten studies were closed in RAPC's records due to the descheduling of samidorphan. Samidorphan was removed from Drug Enforcement Agency (DEA) scheduling on April 19, 2021 (Federal Register/Vol.86, No.73/Monday, April 19, 2021). Many research projects that ended in 2021 cited difficulties initiating research, enrolling subjects, or securing funding during the COVID-19 pandemic.

Table 1 is a list of new studies approved by RAPC. Table 2 is a list of amended studies approved by RAPC. Table 3 is a list of studies closed by RAPC.

At the end of 2021, RAPC was monitoring 127 research projects. Please see Appendices A, B, C, and D for specific listings.



As part of RAPC's supervisory responsibilities, ongoing projects are monitored by means of annual progress reports, significant adverse event reports, and site visits. No site visits were performed between January 1, 2021 and December 31, 2021, due to the COVID-19 pandemic. Approval may be withdrawn if the study activities deviate significantly from the approved protocol.

SELECTED RESEARCH FINDINGS

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

Dr. Thomas Marcotte, PhD and colleagues at the University of California (UC) San Diego Center for Medicinal Cannabis Research have completed a human research project entitled “A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels.” The findings for this study are published in *JAMA Psychiatry* and *Journal of Analytical Toxicology*, and Dr. Marcotte has provided the following summary and key findings for this research:

Summary of Project:

This study was designed to evaluate the effects of different strengths of delta-9 tetrahydrocannabinol (THC) (varying %THC by weight) on driving performance, the time duration of any impairments, and whether whole blood, oral fluid or breath can provide information on impairment or time since use. Conducted at the Center for Medicinal Cannabis Research (CMCR) at UC San Diego, we enrolled 191 regular cannabis users who were subsequently randomized to smoke 5.9% THC, 13.4% THC, or placebo cannabis ad libitum (as they do at home) and complete 5 driving simulations (1 prior to smoking, 4 post-smoking), as well as evaluations of THC concentrations in blood, oral fluid, and breath.

Key findings emerging from this project include:

1. There was a significant impact of THC on driving (simulator) performance that was of a “medium” effect size. While there was a clear difference between the THC and Placebo groups, a portion of the THC group performed at a level similar to that seen in the Placebo group.
2. The effect of THC on driving measures was most pronounced after 30 minutes, persisted at 90 minutes, began dissipating at 3 hours and 30 minutes, and was no longer detectable at 4 hours 30 minutes.

While the THC group generally showed good agreement between subjective driving impairment and actual performance at 30 minutes, a subset of impaired participants said they would drive in their current state. There was a greater disconnect at the 1 hour 30 minute time point: participants increasingly rated themselves as safe to drive whereas simulator data indicated an on-going post-smoking reduction in driving performance in many of these participants.

3. There was no clear relationship between the amount of THC in the cigarette and simulator performance, nor the THC concentrations reached in whole blood.
4. There was no relationship between THC concentrations in whole blood, or oral fluid or breath, at any time point, and simulator performance. Blood, oral fluid, and breath assays for THC demonstrated different characteristics with respect to the time elapsed since smoking.

THC quickly dissipated in blood, and then exhibited a low-level, gradual decline, but was frequently detected at the end of the study.

Oral fluid (saliva) demonstrated a more gradual decline, whereas breath THC concentrations were mostly not present after the 30 minute time point, indicating rapid elimination. By the end of the observation period (approximately 5 hours), THC was more likely to be detectable in whole blood in the frequent users compared to occasional users, while there was no difference between the two groups in oral fluid or breath.

Conclusions:

In summary, when individuals smoke to a level of highness they desire, we see moderate effects on driving performance, with a subset of individuals clearly showing driving performance decline (e.g., ability to attend to the roadway while doing a secondary task), while others perform similar to the placebo group. Participants self-titrate, so that regardless of the THC content of the cigarette, they achieve similar concentrations of THC in blood, as well as showing comparable effects on driving.

Individuals under the influence are reasonably accurate regarding impairment soon after smoking, but this is not true for all participants who may be impaired. This disconnect is greater in the following hour or two, when they perceive their driving performance as recovering sooner than objective measures indicate, possibly putting them at risk for impaired driving. Recovery appears to begin a few hours post-smoking, with the THC group performing similarly to the Placebo group by 4-1/2 hours. THC concentration in blood, oral fluid, and breath were not correlated with degree of driving impairment.

Thus, they cannot be recommended as surrogates for impaired driving. In terms of specifically detecting recent cannabis intake, oral fluid and breath show some promise.

The fact that driving simulator performance of some participants who received THC-containing cannabis was indistinguishable from those receiving placebo indicates that much work is still needed in understanding impairment risks associated with factors such as individual biologic differences, personal experience with cannabis, and cannabis administration methods.

Dr. Karl Deisseroth, MD, PhD and colleagues in the Departments of Bioengineering and of Psychiatry and Behavioral Sciences at Stanford University are conducting a non-human study entitled “Neural Circuit Dynamics of LSD-Induced Psychosis.” An article related to this research has appeared in the journal *Nature*. Dr. Deisseroth has provided the following abstract of his research:

Advanced imaging methods now allow cell-type-specific recording of neural activity across the mammalian brain, potentially enabling the exploration of how brain-wide dynamical patterns give rise to complex behavioural states. Dissociation is an altered behavioural state in which the integrity of experience is disrupted, resulting in reproducible cognitive phenomena including the dissociation of stimulus detection from stimulus-related affective responses. Dissociation can occur as a result of trauma, epilepsy or dissociative drug use, but despite its substantial basic and clinical importance, the underlying neurophysiology of this state is unknown. Here we establish such a dissociation-like state in mice, induced by precisely dosed administration of ketamine or

phencyclidine. Large-scale imaging of neural activity revealed that these dissociative agents elicited a 1–3-Hz rhythm in layer 5 neurons of the retrosplenial cortex. Electrophysiological recording with four simultaneously deployed high-density probes revealed rhythmic coupling of the retrosplenial cortex with anatomically connected components of thalamus circuitry, but uncoupling from most other brain regions was observed—including a notable inverse correlation with frontally projecting thalamic nuclei. In testing for causal significance, we found that rhythmic optogenetic activation of retrosplenial cortex layer 5 neurons recapitulated dissociation-like behavioural effects. Local retrosplenial hyperpolarization-activated cyclic-nucleotide-gated potassium channel 1 (HCN1) pacemakers were required for systemic ketamine to induce this rhythm and to elicit dissociation-like behavioural effects. In a patient with focal epilepsy, simultaneous intracranial stereoencephalography recordings from across the brain revealed a similarly localized rhythm in the homologous deep posteromedial cortex that was temporally correlated with pre-seizure self-reported dissociation, and local brief electrical stimulation of this region elicited dissociative experiences. These results identify the molecular, cellular and physiological properties of a conserved deep posteromedial cortical rhythm that underlies states of dissociation.

Dr. Francesca Telese, PhD and colleagues in the Department of Medicine at UC San Diego are conducting a non-human research project entitled “Epigenetic Regulation of Gene Expression in the Brain.” Dr. Telese has provided the following summary of findings for this research project:

My laboratory investigates the effects of long-term cannabinoid exposure on the brain in mice. The overall goal of this project is to determine how different constituents of marijuana, including THC and cannabidiol, affect the function of different cells in the brain.

In April 2021, my research group published a manuscript in the journal *Neuropharmacology* entitled “Reelin deficiency contributes to long-term behavioral abnormalities induced by chronic adolescent exposure to Delta-9-tetrahydrocannabinol in mice.” In this manuscript, we demonstrated that adolescent exposure to high doses of THC led to persistent behavioral abnormalities, such as deficits in working memory and social interaction. Further, we showed that heterozygous mutation in the Reelin gene leads to increased behavioral disinhibition and increased stress reactivity following the adolescent exposure to THC in female and male mice, respectively. These results suggest that Reelin signaling may interact with the endocannabinoid signaling during brain maturation in adolescence.

Furthermore, we examined the sex differences in behavioral and molecular consequences of chronic adolescent exposure to THC in mice. Our results show that, compared to vehicle, THC-treated female mice have stronger memory deficits, and brain region-specific changes in the expression of genes involved in the endocannabinoid signaling and inflammation.

Hector Perez, MD and colleagues in the Department of Otolaryngology-Head and Neck Surgery at Loma Linda University Medical Center are conducting a human research study entitled “Assessing Perceived Quality of Care with Differing Pain Management Protocols after Outpatient Otolaryngology Procedures.” They have provided the following report on the progress of their research:

Background: It is routine practice to provide analgesic medications after surgical procedures to provide patients with adequate pain control. Prior studies at our institution have demonstrated that recommending non-narcotics as first line therapy significantly reduces the quantity of narcotic medication patients have to take. The purpose of this study is to assess patient satisfaction with the pain regimen as it relates to pain control and quality of life in the acute post-operative period.

Methods: Patients were recruited in the pre-operative unit prior to a scheduled outpatient procedure. Patients were randomized into one of three groups that altered the recommended plan for pain control. Group 1 was prescribed hydrocodone/acetaminophen as first line with ibuprofen as second line treatment. Group 2 was prescribed ibuprofen as first line with hydrocodone/acetaminophen as second line. Group 3 was prescribed ibuprofen as first line with acetaminophen as second line, with no narcotic prescription. Patients were then asked to fill out a post-operative questionnaire at their one week follow-up appointment.

Results: Ninety patients at this point have been recruited in the study. Of the 90 patients recruited, 37 patients were able to complete the questionnaire at their post-operative appointments. This data has not yet been analyzed as the study remains in the data collection phase.

Our study has been progressing, however we have suffered from difficulty coordinating with our clinic staff with regards to handing out post-operative questionnaires to recruited patients. For this reason, we have changed the protocol for post-operative follow-up on our patients to increase our completed dataset. We have now scheduled phone calls for purposes of gathering patients' answers for the questionnaires. This has been enacted in the last 30 days and has yielded a significant increase in completed subject data. We hope to complete this study with our increase in completed data sets by the end of 2022.

Ziva Cooper, PhD at the UC Los Angeles (UCLA) Cannabis Research Initiative provided the following abstract for the human research study entitled "Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women."

Rates of cannabis use and Cannabis Use Disorder (CUD) have doubled over the last ten years in the United States (US). While overall rates of cannabis use and CUD are still lower among women relative to men, epidemiological reports document a telescoping effect; women transition from first use to CUD at a faster rate than men. Preclinical studies demonstrate that relative to males, females are more sensitive to the reinforcing effects of cannabinoids, perhaps explaining the accelerated progression to CUD observed in the epidemiological reports.

To understand cannabis's acute effects that indicate increased risk for developing CUD among women, the proposed study will compare the dose-dependent effects of smoked cannabis on endpoints directly associated with abuse-liability between light- and heavy-cannabis using men and women. Findings from these studies will be instrumental in establishing sex as a biological variable in the prevention, intervention, and treatment of CUD.

Another emerging trend impacting women's vulnerability to developing CUD is the closing gender gap in the use of medical cannabis. Nearly 50% of medical cannabis users are women

with pain cited as the primary indication for treatment. This trend further establishes the critical need to identify potential differences between men and women related to cannabis-associated effects that contribute to the trajectory towards CUD (i.e., abuse-liability). Additionally, these findings raise questions about potential sex-dependent differences in the analgesic effects of cannabis and cannabinoids that may be a factor contributing to these high rates of use among women. This 3-session, within-subject and between-groups, outpatient study will compare cannabis's dose-dependent abuse liability (subjective-effect ratings and self-administration), analgesia, and THC and metabolite levels between men and women matched for current cannabis use. Menstrual cycle effects will be controlled for by testing women during the mid- late-follicular phase when estradiol levels are rising and progesterone levels are minimal.

Dr. Robert C. Malenka, MD, PhD, and colleagues in the Department of Psychiatry and Behavioral Sciences at Stanford University are conducting non-human research entitled “The Role of Oxytocin in the Pathogenesis of Autism.” Dr. Malenka has provided the following summary on the progress of this study:

We aim to define the pathogenesis of social dysfunction in autistic spectrum disorders (ASDs) by investigating the mechanism of 3,4-Methylenedioxymethamphetamine's (MDMA) prosocial effects in both wild-type mice and mouse models of ASDs, which demonstrate abnormal social behavior. Acute MDMA administration is unique in its ability to promote pro-social and empathic behavior in humans, potentially pointing to therapeutic avenues for human ASDs. In our studies, we have modeled both the pro-social “affiliative” effect of MDMA in mice, as well as the nonsocial drug reward associated with MDMA. To elucidate the mechanism of this prosocial effect we have taken multiple complementary experimental approaches, combining conventional behavioral pharmacology with intracranial drug infusion, conditional gene knockout, in vivo imaging of neural activity, and electrophysiological recordings of acutely dissected brain slices. We found that MDMA's prosocial effect, but not its addictive effect, requires an interaction with the serotonin transporter, SERT, in the nucleus accumbens. Moreover, we found that serotonin released into the nucleus accumbens, or MDMA directly injected into this brain structure, are sufficient to produce prosocial behavior (Walsh et al, 2018, *Nature*; Heifets et al, 2019 *Science Translational Medicine*).

During 2021, we published the results of a comprehensive study showing MDMA consistently reverses social deficits in both models of genetic ASD syndromes (16p11 chromosomal deletion, Fragile X Syndrome, and *Arid1b* deletion), as well as a developmental toxicity model, valproate acid in pregnancy (Walsh et al, 2021, *Neuropsychopharm*). We also published the results of a multi-year study of how MDMA and the closely related psychostimulant methamphetamine (METH) impact excitatory synaptic transmission in the nucleus accumbens. We surveyed four different synaptic inputs to the accumbens, finding that MDMA, like serotonin, filters these inputs in a manner distinctly separate from the filtering produced by METH and dopamine (Christoffel et al, 2021, *Proc Natl Acad Sci U S A*).

During the coming year, we plan to continue our characterization of brain-wide networks with causal roles in MDMA mediated prosocial behavior, and continue our investigation into how MDMA-evoked dopamine and serotonin interact in the nucleus accumbens to regulate social and nonsocial reward. We have also expanded the scope of our studies by testing specific metabolites and enantiomers of MDMA in these same social assays and models. These compounds include R(-)-MDMA, S-(+)-MDMA, RS-MDA, R(-)-MDA and S-(+)-MDA.

TABLE 1

RESEARCH STUDIES APPROVED IN 2021

Absorption Systems, a Pharmaron Company | San Diego, CA

Determine Exposure of Sponsor's Test Article(s) After Intranasal (IN) and Oral (PO) Administration in Male Beagle Dogs (Crossover)

AnaBios Corp | San Diego, CA

CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl

AnaBios Corp | San Diego, CA

CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl + Noribogaine

Roberto C. Andresen Aguiluz, PhD | UC Merced | Merced, CA

Establishing the Role of Cannabinoids in Altering the Function of the Cardiovasculature

Kathleen Angkustsiri, MD | UC Davis Mind Institute | Sacramento, CA

Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome [NICHD (R61/R33)]

Aurora Fine Chemicals, LLC | San Diego, CA

Water Soluble Cannabinoids, Preparation and Use

Avadel | CRO: Advanced Clinical | Deerfield, IL

An Open Label Study to Evaluate Long-Term Safety and Tolerability of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) and the Ability to Switch from Twice-Nightly Immediate Release Sodium Oxybate to Once-Nightly FT218 for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy" (CLFT218-1901)

Nancy Buckley, PhD | California State Polytechnic University | Pomona, CA

Investigate the Effect of THC and Roles of CB2R and Sex on Resistance to a Secondary Systemic *C. albicans* Infection

Odmara Barreto Chang, MD, PhD | UC San Francisco | San Francisco, CA

Evaluation of BIS and Levels of Sedation with Common Inhalational Anesthetics in Healthy Volunteers

Phillip Coffin, MD | San Francisco Department of Public Health | San Francisco, CA

Phase 1 Safety-Interaction Study of Mirtazapine for the Treatment of Methamphetamine Use Disorder

Melanie J. Cocco, PhD | UC Irvine | Irvine, CA

Creation of an NMR Library of H1-C13 Atomic Fingerprints of Pure Cannabis Components for the Analysis and Characterization of Cannabis and Cannabis Extracts

Andrew Conley, PhD | Lygos, Inc. | Berkeley, CA

Developing Psilocybin-like Substituted Tryptamines (PLST) for In-vitro Binding Studies with G-Protein Coupled Receptors

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Evaluation of Smoked THC and CBD in Oral Fluid, Pharmacokinetics, and Subjective and Neurocognitive Effects in Men and Women (S-TACOFs)

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Analgesic, Appetite-Stimulating, and Subjective Effects of Cannabigerol Administered Alone and in Combination with Delta-9-tetrahydrocannabinol

John S. Cowart, PhD | Seacoast Science, Inc. | Carlsbad, CA

Modular Biomimetic Polymers, Rationally Programmed to Detect a Panel of Cannabinoids

Hugo Destailats, PhD | Lawrence Berkely National Laboratory | Berkeley, CA

Assessment of Secondhand and Thirdhand Exposures to Cannabis-Related Indoor Contaminants

Ei Ventures, Inc. | CRO: Tioga Research | San Diego, CA

Research and Early Pharmaceutical Development of a Transdermal Dosage Form of Psilocybin

Timothy Furnish, MD | UC San Diego | San Diego, CA

Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain

Brook Henry, PhD | UC San Diego | San Diego, CA

Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity

Walter Kaye, MD | UC San Diego | San Diego, CA

Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

Frank Kochinke, PhD | Mycrodose Therapeutics | San Diego, CA

Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT

Stephan Lammel, PhD | UC Berkeley | Berkeley, CA

Organization and Function of Neural Circuits in the Mammalian Brain

Daniel Levin, PhD | S&B Pharma, Inc. | Azusa, CA

Process Research towards the Manufacture of Sodium Oxybate, Potassium Oxybate, Magnesium Oxybate, and Calcium Oxybate

Pamela A. Maher, PhD | The Salk Institute | La Jolla, CA

Therapeutic Relevance of Cannabinoids for Alzheimer's Disease

Thomas Marcotte, PhD | UC San Diego | San Diego, CA

Effects of Cannabis/Alcohol on Simulated Driving Performance and Field Sobriety Tests

MAPS Public Benefit Corp (MAPS-PBC) | Santa Cruz, CA

MAPPUSX: A Multi-Site Open-Label Safety Extension Study of Manualized MDMA-Assisted Psychotherapy for the Treatment of Participants with Posttraumatic Stress Disorder (MAPPUSX)

MAPS Public Benefit Corp (MAPS-PBC) | Santa Cruz, CA

EAMP1 - An Intermediate size Multi-Site Expanded Access Program for MDMA-Assisted Psychotherapy for Patients with Treatment-Resistant PTSD

NIH/National Institute on Drug Abuse (NIDA) | CRO: Emmes | Rockville, MD

Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (RDD) (CTN-0100)

Khanh Nguyen, MD | Loma Linda University Medical Center | Loma Linda, CA

Assessing Perceived Quality of Care with Differing Pain Management Protocols after Outpatient Otolaryngology Procedures

Amir Raz, PhD | Chapman University | Irvine, CA

Psilocybin Microdosing in Healthy Volunteers: Comparative Effects on Sleep, Brain Activity, Psychosocial, and Cognitive Functioning

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

Efficacy and Safety of REL-1017 Monotherapy for Major Depressive Disorder (The RELIANCE-III Study) (REL-1017-303)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-I Study)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Open-Label Study to Assess the Long-Term Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-OLS)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-II Study)

Shannon Remick, MD | VA Loma Linda Healthcare System | Loma Linda, CA

Open-Label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD

Amanda Roberts, PhD | The Scripps Research Institute | La Jolla, CA

Effects of THC/alcohol Combinations In Utero on Adult Electrophysiology, Protein Levels, and Gene Expression

Mark Sussman, PhD | San Diego State University | San Diego, CA

Adolescent Vaping Accelerates Cardiac Aging

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-blind, Placebo-controlled, Dose-ranging Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy (VX21-548-101)

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-blind, Placebo-controlled, Multi-dose Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty (VX21-548-102)

Scott A. Wilke, MD, PhD | UCLA | Los Angeles, CA

Psychostimulant Augmentation of Repetitive TMS (rTMS) for the treatment of Major Depressive Disorder: A Randomized, Placebo-Controlled Clinical Trial

Leanne Williams, PhD | Stanford University | Palo Alto, CA

Randomized, Double-Blind, Placebo-Controlled, Within-Subject Study on the Influence of MDMA on Risk and Reward Circuits of the Brain

Waylan Wong, MD | UCI Health | Orange, CA

Outcomes of DSUVIA Administration for Retina Surgery: A Pilot Study

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

A Double-blinded, Active Placebo-Controlled, Randomized Trial Examining the Feasibility and Preliminary Efficacy of Psilocybin Therapy for People with Chronic Low Back Pain

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

An Open-Label Pilot Study Examining the Feasibility, Safety, and Effectiveness of Psilocybin Therapy for Depression in Bipolar II Disorder

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease: A Pilot Study

Fadel Zeidan, PhD | UC San Diego | La Jolla, CA

Brain Mechanisms of Cannabis-Based Analgesia

Yi Zuo, PhD | UC Santa Cruz | Santa Cruz, CA

Chemical Modulation of Neural Circuits and Plasticity

TABLE 2

RESEARCH STUDIES WITH AMENDMENTS APPROVED IN 2021

Kathleen Angkustsiri, MD | UC Davis Mind Institute | Sacramento, CA

Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome [NICHD (R61/R33)]

Avadel | CRO: Advanced Clinical | Deerfield, IL

An Open Label Study to Evaluate Long-Term Safety and Tolerability of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) and the Ability to Switch from Twice-Nightly Immediate Release Sodium Oxybate to Once-Nightly FT218 for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy” (CLFT218-1901)

Nelson Barton, PhD | Genomatica, Inc. | San Diego, CA

Microbial Processes for the Manufacture of Specialty Chemicals

Melissa Bauman, PhD | UC Davis | Sacramento, CA

Neurodevelopmental Impact of Prenatal Cannabis Exposure

Compass Pathfinder | CRO: World Wide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin as an Adjunctive Therapy in Participants with Treatment-Resistant Depression (COMP 003)

Compass Pathfinder | CRO: World Wide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (PTRD) (COMP 001)

Adam Halberstadt, PhD | UC San Diego | La Jolla, CA

The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Walter Kaye, MD | UC San Diego | San Diego, CA

Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

Stephen Mahler, PhD | UC Irvine | Irvine, CA

Neural Circuits Underlying Motivation and Addiction

Robert Malenka, MD | Stanford University | Palo Alto, CA

The Role of Oxytocin in the Pathogenesis of Autism

Daniele Piomelli, PhD | UC Irvine | Irvine, CA

1. Effect of Adolescent Cannabis Exposure in Adult Mice and Rats
2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Ivan Soltesz, PhD | Stanford University | Stanford, CA

Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

Usona Institute | CRO: The Emmes Company | Rockville, MD

A Randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD) (PSIL201)

Shannon Remick, MD | VA Loma Linda Healthcare System | Loma Linda, CA

Open-Label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD

Frank Kochinke, PhD | Mycrodose Therapeutics | San Diego, CA

Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT

Novartis Institute for Functional Genomics | San Diego, CA

Use of Selected DEA Schedule I Controlled Substances as Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Dose Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty (VX21-548-102)

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy (VX21-548-101)

TABLE 3

RESEARCH STUDIES
CLOSED IN 2021

Alkermes, Inc. | Waltham, MA

A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)

Alkermes, Inc. | Waltham, MA

A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALKS 3831-A303)

Alkermes, Inc. | Waltham, MA

A Phase 1 Study to Evaluate the Effect of Multiple Doses of ALKS 3831 on QTc interval in Subjects with Schizophrenia (ALK3831-A109)

Alkermes, Inc. | Waltham, MA

A Phase 3 Study to Assess the Long Term Safety, Tolerability, and Durability of Treatment Effect of ALKS 3831 in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder (ALK3831-A308)

Alkermes, Inc. | Waltham, MA

A Study to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform or Bipolar I Disorder Who are Early in Their Illness (ALK3831-A307)

Alkermes, Inc. | Waltham, MA

A Phase 3b Efficacy and Safety Study of Adjunctive ALKS 5461 in Treatment Refractory Major Depressive Disorder (ALK5461-217)

Alkermes, Inc. | Waltham, MA

A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A304)

Alkermes, Inc. | Waltham, MA

A Randomized, Double-Blind, Parallel-Group Study in Healthy Subjects to Characterize Insulin Sensitivity and Lipid Metabolism in Response to Treatment with ALKS3831 and Olanzapine (ALK3831-A108)

Alkermes, Inc. | Waltham, MA

A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALKS 3831-A306)

Arbor Pharmaceuticals | CRO: Rho Inc. | Chapel Hill, NC

A Multicenter, Fixed-Dose, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of AR19 (Amphetamine Sulfate) in Adult Subjects (Ages 18-55) with Attention Deficit Hyperactivity Disorder (ADHD)

Avenue Therapeutics | New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Three-Arm Study to Evaluate the Efficacy and Safety of Tramadol Infusion (AVE-901) Versus Placebo and Morphine in the Management of Postoperative Pain Following Abdominoplasty

Marc Azar, PhD | Behavioral Pharma | La Jolla, CA

Effects of Client's Test Compound on Cue-Induced Reinstatement of Heroin-Seeking Behavior

Marc Azar, PhD | Behavioral Pharma | La Jolla, CA

Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin

Neal Benowitz, MD | UC San Francisco | San Francisco, CA

Intake and Pharmacokinetics of THC Vaped from Electronic Cigarettes

Neal Benowitz, MD | UC San Francisco | San Francisco, CA

Vaping THC from Electronic Cigarettes: a Novel Evaluation of Intake and Pharmacokinetics

Neal Benowitz, MD | UC San Francisco | San Francisco, CA

Evaluating the Characteristics of Daily Cannabis Users

Devin K. Binder, MD, PhD | UC Riverside | Riverside, CA

Translational EEG Biomarkers in a Mouse Model of Fragile X Syndrome

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

Botanix | CRO: Premier Research | Research Triangle Park, NC

A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of BTX 1503 in Patients with Moderate to Severe Acne Vulgaris (BTX.2018.001)

Botanix | CRO: Premier Research | Research Triangle Park, NC

A Randomized, Double-Blind, Vehicle-Controlled Study of the Safety, Tolerability, and Efficacy of BTX 1204 in Patients with Moderate Atopic Dermatitis (BTX.2018.003)

Joshua Britton, PhD | Debut Biotechnology, Inc | Carlsbad, CA

Production of Cannabinoids and their Precursors and via Purified Enzymes in a Continuous System

Nicholas Butowski, MD | UC San Francisco | San Francisco, CA

CBD Developmental Research Project

Kent Chu, PhD | YJ Bio-Products | Rancho Cordova, CA

Immunochromatographic Test Device for THC and LSD

Luis Colon-Perez, PhD | UC Irvine | Irvine, CA

Determining the Effects of Drugs of Abuse on Cognitive Control and Functional Brain Connectivity

Compass Pathfinder | CRO: World Wide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin as an Adjunctive Therapy in Participants with Treatment-Resistant Depression (COMP 003)

Compass Pathfinder | CRO: World Wide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (PTRD) (COMP 001)

Andrew Conley, PhD | Lygos, Inc. | Berkeley, CA

Developing Psilocybin-Like Substituted Tryptamines (PLST) for In-vitro Binding Studies with G-Protein Coupled Receptors

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Blind, Placebo Controlled Phase 2 Trial to Evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis (JBT101-CF-002)

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis (JBT101-SSc-002)

Nissar Darmani, PhD | Western University of Health Sciences | Pomona, CA

Project 2: Dev Changes in Monoamine Function Following Prenatal and Early Postnatal Exposure to Serotonergic Altering Drugs in Mice

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 2. Study of the Effect of Recombinant Syntheses and Cannabigerolic Acid (CBGA), Determination of CBGA and Cannabidiolic Acid (CBDA) Concentrations

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 1. Study of Cannabigerolic acid (CBGA) and Cannabidiolic acid (CBDA) Concentrations in Yeast Cultures Containing Engineered Recombinant Synthase Enzymes

Aaron Ettenberg, PhD | UC Santa Barbara | Santa Barbara, CA

Dopamine involvement in Opiate and Stimulant Reinforcement

Flamel Ireland, LTD | CRO: Syneos Health | Morrisville, NC

A DB, R, PC, Two Arm MC Study to Assess the E and S of a Once Nightly Formulation of Na Oxybate for ER Oral Suspension (FT218) for the Tx of Excessive Daytime Sleepiness & Cataplexy in Subjects w Narcolepsy

Alidad Ghiassi, MD | USC Keck School of Medicine | Los Angeles, CA

A Randomized Trial Comparing Ibuprofen Plus Acetaminophen Versus Oxycodone After Outpatient Soft Tissue Hand Surgery

Anushka Goonawardena, PhD | SRI International | Menlo Park, CA

Cannabinoid Regulation on Resting State Quantitative EEG, Sleep and Cognition

Grunenthal/Janssen | CRO: inVentiv Health Clinical | Cary, NC

An Evaluation of the Efficacy and Safety of Tapentadol Oral Solution in the Tx of Post-Operative Acute Pain Requiring Opioid Tx in Pediatric Subjects Aged from Birth to Less than 18 Y.O. (KF5503/65)

GW Pharmaceuticals | Carlsbad, CA

A Double-Blind, Randomized Placebo-Controlled Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P, CBD) as Add-On Therapy in Patients with Tuberous Sclerosis Complex Who Experience Inadequately-Controlled Seizures

GW Pharmaceuticals | Cambridge, UK

A Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P) in Children and Young Adults with Dravet Syndrome (GWEP 1424)

GW Pharmaceuticals | Carlsbad, CA

An Open Label Extension Study to Investigate the Safety of Cannabidiol (GWP42003-P; CBD) in Children and Adults with Inadequately Controlled Dravet or Lennox-Gastaut Syndrome (GWEP 1415)

Catherine Hagan, DVM, PhD | Valley Biosystems | West Sacramento, CA

Cannabis for Veterinary Use and Model Development

Keith Heinzerling, MD | UCLA | Santa Monica, CA

Phase 1 Safety-Interaction Study of Pomaglumetad Methionil for Methamphetamine Use Disorder

Keith Heinzerling, MD | UCLA | Santa Monica, CA

Randomized Trial of Ibudilast for Methamphetamine Dependence

Kanthi Hettiarachchi, PhD | SRI International | Menlo Park, CA

Analysis of Controlled Substances

INSYS Therapeutics, Inc. | Chandler, AZ

A Multicenter, Open-Label Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Patients with Prader-Willi Syndrome (INSOI 1-17-115)

INSYS Therapeutics, Inc. | Chandler, AZ

A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution for the Treatment of Patients with Prader-Willi Syndrome (INS011-16-085)

INSYS Therapeutics, Inc. | Chandler, AZ

An MC, Open-Label, Flexible Dose Study to Assess the Long-Term Safety of Pharmaceutical Cannabidiol Oral Solution as an Adjunctive Tx for Pediatric and Adult Subjects with a Treatment-Resistant Seizure Disorder Who Complete 024, 025, or 029 (INS011-14-030)

INSYS Therapeutics, Inc. | Chandler, AZ

A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution as Adjunctive Therapy with Vigabatrin as Initial Therapy in Patients with Infantile Spasms (INS011-16-082)

INSYS Therapeutics, Inc. | Chandler, AZ

A Multicenter, Open-Label, Flexible Dose Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution as in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS011-17-113)

INSYS Therapeutics, Inc. | Chandler, AZ

A Phase 2, Open-Label, Dose-Finding Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS011-17-103)

InterveXion Therapeutics | CRO: Pharmaceutical Research Assoc | Little Rock, AR

Study of Antibody for Methamphetamine Outpatient Therapy (M200C-1801)

Kim Janda, PhD | The Scripps Research Institute | La Jolla, CA

Vaccines for the Treatment of Opiate Addiction

Kim Janda, PhD | The Scripps Research Institute | San Diego, CA

Immunopharmacotherapy for Methamphetamine Addiction

Jazz Pharmaceuticals | CRO: IQVIA | Overland Park, KS

A Double-Blind, Placebo-Controlled, Randomized Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in the Treatment of Idiopathic Hypersomnia (IH) with an Open-Label Safety Extension

Jazz Pharmaceuticals | CRO: IQVIA | Overland Park, KS

A Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in Subjects with Narcolepsy with Cataplexy

Jay Keasling, PhD | Lawrence Berkeley National Lab | Berkeley, CA

Engineering the Industrial Microbe *Saccharomyces Cerevisiae* for Biosynthesis of Cannabinoids
9/23/2015

Heather Knych, DVM | UC Davis School of Veterinary Medicine | Sacramento, CA

Pharmacokinetics and Selected Pharmacodynamic Effects of Cannabidiol in Horses

Daniel Levin, PhD | S&B Pharma Inc. | Azusa, CA

Research on the Synthesis of Schedule I Controlled Substances delta-9-THC and LAAM

Daniel Levin, PhD | S&B Pharma Inc. | Azusa, CA

Process Research Towards the Manufacture of Sodium Oxybate, Potassium Oxybate, Magnesium Oxybate, and Calcium Oxybate

Daniel Levin, PhD | S&B Pharma Inc. | Azusa, CA

Process Research Towards the Manufacture of Ajulemic Acid

MAPS Public Benefit Corp (MAPS PBC) | Santo Cruz, CA

An Open-Label, Multi-Site Phase 2 Study of the Safety and Effect of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder

Thomas Marcotte, PhD | UC San Diego Health Care System | San Diego, CA

A Randomized, Cross-Over Controlled Trial of Dronabinol and Vaporized Cannabis in Neuropathic Low Back Pain

Thomas Marcotte, PhD | UC San Diego Health Care System | San Diego, CA

A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels

Sean McAllister, PhD | CPMC Research Institute | San Francisco, CA

Role of Cannabinoid Receptors in Central Nervous System Functions and Diseases

Rachel McKay, MD | UC San Francisco | San Francisco, CA

Evaluation of Pupillary Unrest in Prediction of Opioid Induced Respiratory Depression

Sara Mednick, PhD | UC Riverside | Riverside, CA

The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance

Lupe Mejorado, PhD | Alere San Diego | San Diego, CA

In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family

Stephen Morairty, PhD | SRI International | Menlo Park, CA

Dopamine involvement in Opiate and Stimulant Reinforcement

NIH/ National Institute on Drug Abuse (NIDA) | Rockville, MD

Medication Treatment for Opioid Use Disorder in Expectant Mothers (MOMs): A Pragmatic Randomized Trial Comparing Extended-Release and Daily Buprenorphine Formulations (NIDA CTN Protocol 0080)

NIH/ National Institute on Drug Abuse (NIDA) | Bethesda, MD

Phase 2, Multi-Center Trial of Lorcaserin for the Treatment of Cocaine Use Disorder (NIDA/ VACSP #1033)

NIH/ National Institute on Drug Abuse (NIDA) | Rockville, MD

Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT) (CTN 0051)

Novartis Institute | Emeryville, CA

Synthesis and Optimization of Novel Therapeutics

Noven | CRO: Covance | Nashville, TN

A Randomized, Multiple-Dose, Open-Label, 4-Week Study to Characterize the Pharmacokinetics, Cumulative Irritation, Safety, and Tolerability of d-Amphetamine Transdermal System (d-ATS) in Adults Diagnosed with ADHD

Pfizer, Inc. | San Diego, CA

Understanding the Translation of the Response of the CB1 Agonist

Pfizer, Inc. | CRO: ICON | New York, NY

An Open-Label Study to Evaluate the Safety and Pharmacokinetics of PF-06412528 in Children 7-17 Years for the Treatment of Moderate-to-Severe Pain (B4541006)

Pfizer, Inc. | CRO: ICON | New York, NY

An Open-Label Study to Evaluate the PK and Safety of ALO-02 EX Capsules in Children and Adolescents 7-17 Years of Age Who Require Opioid Analgesia (B4531015)

Mark Peterman, PhD | OndaVia | Hayward, CA

Development of a Rapid and Field-Ready Heroin Analysis Tool

Joy Phillips, PhD | San Diego State | San Diego, CA

Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function

Piramal Critical Care, Ltd | CRO: Social & Scientific Systems

A Phase 3 Open-Label, Single-Arm Study to Assess the Safety of Hydromorphone HCl Delivered by Intrathecal Administration (CNS-HYD202US)

Piramal Critical Care, Ltd | 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 and Programmable Implantable Pump (CNS-HYD201US)

Purdue | CRO: PRA | Raleigh, NC

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Laboratory Classroom Study to Evaluate the Safety and Efficacy of PRC-063 Compared to Placebo in Children (6-12 years of age) with ADHD

Birgit Puschner, DVM, PhD | UC Davis School of Veterinary Medicine | Sacramento, CA

Analysis of Cannabinoids in Hemp Oil Veterinary Treats/Supplements

Richard Reznichuk, MD | Harbor-UCLA Medical Center

A Prospective Study Comparing the Efficacy and Safety of 100 mcg and 200 mcg of Intranasal Fentanyl Pectin Spray as an Analgesic in Adult Males Undergoing Outpatient Cystoscopic Procedures

Receptor Life Sciences | WCCT Global, Inc. | Cypress, CA

A Three Part, Open-Label Crossover Study of Oral and Inhaled Cannabidiol (CBD) in Healthy Adult Participants (1) (RC-2018/02)

Receptor Life Sciences | WCCT Global, Inc. | Cypress, CA

A Three Part, Open-Label, Crossover Study of Oral and Inhaled Cannabidiol (CBD) in Healthy Adult Participants (2) (RC-2018/02)

Receptor Life Sciences | WCCT Global, Inc. | Cypress, CA

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Healthy Adult Participants (2) (RC-2018/01)

Receptor Life Sciences | WCCT Global, Inc. | Cypress, CA

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Healthy Adult Participants (1) (RC-2018/01)

Benjamin Reese, PhD | UC Santa Barbara | Santa Barbara, CA

Cannabinoid Neuroprotection of Retinal Ganglion Cells in Glaucoma

Relmada Therapeutics | CRO: Syneos | Cary, NC

A Phase 2a, MC, R, DB, PC, 3 Arm Study to Assess the Safety, Tolerability, PK Profile, and Sx Response of a 7 Day Dosing with REL 1017 25mg QD and 50mg QD as Adj The in the Tx of Pt Dx with Major Depressive Disorder

Pierre Riviere, PhD | Peptide Logic | San Diego, CA

Opioid Antidotes (PL005)

Shire | CRO: PPD | Morrisville, NC

A Phase 3, Random, DB, MC, Parallel-Group, PC, Dose-Optimization Safety and Efficacy Study of SPD489 Compared with Placebo in Preschool Children Aged 4-5 Years with ADHD (SPD489-347)

Shire | CRO: PPD | Morrisville, NC

A Phase 3, Open-Label, Multicenter, 12-Month Safety and Tolerability Study of SPD489 in Preschool Children Aged 4-5 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (SPD489-348)

Shire | CRO: PPD | Morrisville, NC

A Phase 2, Open-label, Multicenter, Exploratory Safety, Tolerability, Pharmacokinetics, and Efficacy Study of SPD489 in Preschool Children Aged 4-5 Years with Attention-Deficit/Hyperactivity Disorder (SPD489-211)

David Schubert, PhD | The Salk Institute | La Jolla, CA

The Identification of Neuroprotective Compounds in Cannabis

Philip Schwartz, PhD | Children's Hospital of Orange County | Orange County, CA
Effect of Cannabinoid Receptor Activation on Human Neural Stem Cell Function

Steven Shoptaw, PhD | UCLA | Los Angeles, CA
Varenicline for Methamphetamine Dependence

Steven Shoptaw, PhD | UCLA | Los Angeles, CA
Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

SRI International | Menlo Park, CA
Identification and Isolation of Specific Pesticides from Cannabinoid oils

Nancy Tich, MS, PhD | Zynerba Pharmaceuticals | Devon, PA
(1) An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome (CONNECT-FX)
(2) Open Label Extension (OLE) Clinical study Of caNNabidiol in childrEn and adolesCentTs with Fragile X (CONNECT-FX OLE) (ZYN2-CL-017)

David Tompkins, MD,MHS | UC San Francisco | San Francisco, CA
Acute Pain Management in Patients on Opioid Replacement Therapy

Doris Trauner, MD | UC San Diego | La Jolla, CA
A Double-Blind, Crossover Trial of Cannabidiol to Treat Severe Behavior Problems in Children with Autism

Rama Voladri, PhD | Codexis, Inc. | Redwood City, CA
Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577

Friedbert Weiss, PhD | The Scripps Research Institute | La Jolla, CA
Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol

Friedbert Weiss, PhD | The Scripps Research Institute | La Jolla, CA
Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol

West-Ward | CRO: Premier Research | Research Triangle Park, NC
A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 Years Old Through 17 Years Old with Postoperative Pain (MORP-OS+T-(2-17)-SPK-2)

Matthew Worley, PhD | UC San Diego | La Jolla, CA
Behavioral Economic Mechanisms of Prescription Opioid Addiction in Chronic Pain

APPENDIX A

OPEN (through December 31, 2021) SCHEDULE I AND SCHEDULE II ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

Catherine Ayers, PhD & Brian Martis, MD, MBA | VA San Diego Healthcare System | San Diego, CA

Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Evaluation of Smoked THC and CBD in Oral Fluid, Pharmacokinetics, and Subjective and Neurocognitive Effects in Men and Women

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Analgesic, Appetite-Stimulating, and Subjective Effects of Cannabigerol Administered Alone and in Combination with Delta-9-tetrahydrocannabinol

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women

Ziva Cooper, PhD | UCLA | Los Angeles, CA

Subjective and Analgesic Effects of Terpene, Beta-Caryophyllene and Myrcene, Vaporized Alone and in Combination with THC

Randall Espinoza, MD, MPH | UCLA | Los Angeles, CA

Psilocybin Pilot for Treatment-Resistant Depression (TRD)

Timothy Furnish, MD | UC San Diego | San Diego, CA

Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain

Keith Heinzerling, MD | Pacific Neuroscience Institute | Santa Monica, CA

Pilot Trial of Visual Healing®, a Nature-Themed Virtual Immersive Experience, to Optimize Set and Setting in Psilocybin-Assisted Therapy for Alcohol Use Disorder

Brook Henry, PhD | UC San Diego | San Diego, CA

Effect of Cannabis Administration and Endocannabinoids on HIV Neuropathic Pain Study - Phase 2

Brook Henry, PhD | UC San Diego | San Diego, CA

Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity

Jared Inman, MD | Loma Linda University | Loma Linda, CA

Quantifying Narcotic Use in Outpatient ENT Procedures

William Jagust, MD | UC Berkeley | Berkeley, CA

Dopaminergic Mechanisms Underlying Decision Making: Academic Human Subjects Research with Schedule II Drug (methylphenidate)

Walter Kaye, MD | UC San Diego | San Diego, CA

Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

Sulggi Lee, MD, PhD | UC San Francisco | San Francisco, CA

Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study

Thomas Marcotte, PhD | UC San Diego | San Diego, CA

Effects of Cannabis/Alcohol on Simulated Driving Performance and Field Sobriety Tests

Fatta Nahab, MD | UC San Diego | La Jolla, CA

A Double-Blind, Cross-Over, Placebo-Controlled Efficacy and Tolerability Study of Oral Cannabidiol (CBD) and Tetrahydrocannabinol (THC) for Essential Tremor (ET)

Khanh Nguyen, MD | Loma Linda University | Loma Linda, CA

Assessing Perceived Quality of Care with Differing Pain Management Protocols after Outpatient Otolaryngology Procedures

Amir Raz, PhD | Chapman University | Irvine, CA

Psilocybin Microdosing in Healthy Volunteers: Comparative Effects on Sleep, Brain Activity, Psychosocial, and Cognitive Functioning

Shannon Remick, MD | VA Loma Linda Healthcare System | Loma Linda, CA

Open-Label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD

Nathaniel M. Schuster, MD | UC San Diego | La Jolla, CA

Efficacy of Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: A Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

Trisha Suppes, MD, PhD | VA Palo Alto Health Care System | Palo Alto, CA

The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P-TRD)

Scott A. Wilke, MD, PhD | UC Los Angeles | Los Angeles, CA

Psychostimulant Augmentation of Repetitive TMS (rTMS) for the Treatment of Major Depressive Disorder: A Randomized, Placebo-Controlled Clinical Trial

Leanne Williams, PhD | Stanford University | Palo Alto, CA

Randomized, Double-Blind, Placebo-Controlled, Within-Subject Study on the Influence of MDMA on Risk and Reward Circuits of the Brain

Waylan Wong, MD | UCI Health | Orange, CA

Outcomes of DSUVIA Administration for Retina Surgery: A Pilot Study

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

A Double-Blinded, Active Placebo-Controlled, Randomized Trial Examining the Feasibility and Preliminary Efficacy of Psilocybin Therapy for People with Chronic Low Back Pain

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

An Open-Label Pilot Study Examining the Feasibility, Safety, and Effectiveness of Psilocybin Therapy for Depression in Bipolar II Disorder

Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA

Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease: A Pilot Study

Roya Yumul, MD, PhD | Cedars-Sinai Medical Center | Los Angeles, CA

Intraoperative Ketamine and Methadone for Laminectomy: Effect on Recovery, Postoperative Pain, and Opioid Requirements

Fadel Zeidan, PhD | UC San Diego | La Jolla, CA

Brain Mechanisms of Cannabis-Based Analgesia

APPENDIX B

OPEN (through December 31, 2021) SCHEDULE I AND SCHEDULE II MULTICENTER CLINICAL DRUG TRIAL RESEARCH STUDIES

Kathleen Angkustsiri, MD | UC Davis Mind Institute | Sacramento, CA

Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome [NICHD (R61/R33)]

Avadel Ireland | CRO: Advanced Clinical | Deerfield, IL

An Open Label Study to Evaluate Long-Term Safety and Tolerability of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) and the Ability to Switch from Twice-Nightly Immediate Release Sodium Oxybate to Once-Nightly FT218 for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy” (CLFT218-1901)

MAPS Public Benefit Corporation (MAPS-PBC) | Santa Cruz, CA

MAPPUSX: A Multi-Site Open-Label Safety Extension Study of Manualized MDMA-Assisted Psychotherapy for the Treatment of Participants with Posttraumatic Stress Disorder (MAPPUSX)

MAPS Public Benefit Corporation (MAPS-PBC) | Santa Cruz, CA

EAMP1 - An Intermediate Size Multi-Site Expanded Access Program for MDMA-Assisted Psychotherapy for Patients with Treatment-Resistant PTSD (EAMP1)

MAPS Public Benefit Corporation (MAPS-PBC) | Santa Cruz, CA

A Phase 1, Open-Label, Multi-Site Study to Assess Psychological Effects of MDMA-Assisted Psychotherapy When Administered to Healthy Volunteers (MT2)

MAPS Public Benefit Corporation (MAPS-PBC) | Santa Cruz, CA

A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder of Moderate or Greater Severity (MAPP2)

MAPS Public Benefit Corporation (MAPS-PBC) | Santa Cruz, CA

A Phase 1, Open Label, Study of 3,4-Methylenedioxymethamphetamine (MDMA) Tolerability and Pharmacokinetics in Subjects with Moderate Hepatic Impairment Compared to Matched Control Subjects with Normal Hepatic Function (MPKH)

Medtronic | Boulder, CO

Evaluation of BIS and Levels of Sedation with Common Inhalational Anesthetics in Healthy Volunteers (OLIVER)

Neo Therapeutics | CRO: Premier Research | Covington, LA

A Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose Study of Adzenys XR-ODT™ in Children Aged 4 to Less Than 6 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD) (NT0202.1009)

NIH/National Institute of Allergy and Infectious Diseases (NIAID) | Rockville, MD

A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate Efficacy, Safety, and Tolerability of JBT-101 in Systemic Lupus Derythematosus (ALE09)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

Efficacy and Safety of REL-1017 Monotherapy for Major Depressive Disorder (The RELIANCE-III Study) (REL-1017-303)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Open-Label Study to Assess the Long-Term Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-OLS)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-II Study)

Relmada Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-I Study)

Usona Institute | CRO: The Emmes Company | Rockville, MD

A randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD) (PSIL201)

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Dose Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty (VX21-548-102)

Vertex Pharmaceuticals, Inc. | ICON Global Strategic Solutions | Boston, MA

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy (VX21-548-101)

APPENDIX C

OPEN (through December 31, 2021) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE USE DISORDER

Phillip Coffin, MD | San Francisco Department of Public Health | San Francisco, CA

Phase 1 Safety-Interaction Study of Mirtazapine for the Treatment of Methamphetamine Use Disorder

Edythe London, PhD | UCLA | Los Angeles, CA

Cannabidiol as Adjunctive Treatment for Opioid Use Disorder

NIH/National Institute on Drug Abuse (NIDA) | Rockville, MD

Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (RDD) (CTN-0100)

NIH/National Institute on Drug Abuse (NIDA) | Rockville, MD

Emergency Department-Initiated Buprenorphine Validation Network Trial (ED-INNOVATION) (CTN-0099)

Rajkumar Sevak, PhD | UCLA | Los Angeles, CA

Human Methamphetamine Self-Administration in a Progressive-Ratio Paradigm

APPENDIX D

OPEN (through December 31, 2021) SCHEDULE I NON-HUMAN RESEARCH STUDIES

Absorption Systems, a Pharmaron Company | San Diego, CA

Determine Exposure of Sponsor's Test Article(s) After Intranasal (IN) and Oral (PO) Administration in Male Beagle Dogs (Crossover)

AnaBios Corp | San Diego, CA

CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl + Noribogaine

AnaBios Corp | San Diego, CA

CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl

Stephan Anagnostaras, PhD | UC San Diego | La Jolla, CA

MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression: A Dose-Effect Analysis

Roberto C. Andresen Aguiluz, PhD | UC Merced | Merced, CA

Establishing the Role of Cannabinoids in Altering the Function of the Cardiovasculature

Aurora Fine Chemicals, LLC | San Diego, CA

Water Soluble Cannabinoids, Preparation and Use

Richard Baldwin, PhD | nanoComposix | San Diego, CA

Biosensor for the Detection of Synthetic Cannabinoids

Nelson Barton, PhD | Genomatica, Inc. | San Diego, CA

Microbial Processes for the Manufacture of Specialty Chemicals

Melissa Bauman, PhD | UC Davis | Sacramento, CA

Neurodevelopmental Impact of Prenatal Cannabis Exposure

Ryan Baxter, PhD | UC Merced | Merced, CA

Cannabinoid Isolation, Purification, and Structure Diversification

Brian Brandley, PhD | Biopharmaceutical Research Company | Castroville, CA

Characterization of Model Systems for Longevity Studies, Genetics and Neuroscience; Simple Model Systems for Examination of Cannabinoid Effects on Genetics, Development and Nervous Systems Using Roundworms (*C. elegans*) and/or Killifish (*Nothobranchius*)

Ellen Breen, PhD | UC San Diego | La Jolla, CA

In Defense Against Vaping Nicotine and Cannabis - Alarmins

Nancy Buckley, PhD | California State Polytechnic | Pomona, CA

Investigating the Effect of delta-9-tetrahydrocannabinol (THC) on the Susceptibility to Systemic C. Albicans Infection in Mice Treated with an Anti-Cancer Drug

Nancy Buckley, PhD | California State Polytechnic | Pomona, CA

Investigate the Effect of THC and Roles of CB2R and Sex on Resistance to a Secondary Systemic C. Albicans Infection

Joseph Califano, MD | UC San Diego | La Jolla, CA

THC-Cannabinoid Receptor Pathway and CBD Activation of GPCRs on Cannabinoid Signaling Pathways in Head and Neck Squamous Cell Carcinoma (HNSCC)

John Cashman, PhD | Human BioMolecular Research Institute | San Diego, CA

Molecular Evolution of Human Cocaine Catalysis

Melanie J. Cocco, PhD | UC Irvine | Irvine, CA

Creation of an NMR Library of H1-C13 Atomic Fingerprints of Pure Cannabis Components for the Analysis and Characterization of Cannabis and Cannabis Extracts

John S. Cowart, PhD | Seacoast Science, Inc. | Carlsbad, CA

Modular Biomimetic Polymers, Rationally Programmed to Detect a Panel of Cannabinoids

Nissar Darmani, PhD | Western University Health Sciences | Pomona, CA

Project 1: Mechanisms of Vomiting Induced by Chemotherapeutics, Related Emetics, and GI Disorders

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA

Neural Circuit Dynamics of LSD-Induced Psychosis

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA

Effects of LSD on Brain-Wide Neural Activity and Behavior

Hugo Destailats, PhD | Lawrence Berkely National Laboratory | Berkeley, CA

Assessment of Secondhand and Thirdhand Exposures to Cannabis-Related Indoor Contaminants

Michael W. DeGregorio, Pharm.D. | Immuno Tess, Inc. | Roseville, CA

Effects of Cannabinoids on Immune Response in Combination with Immunomodulators: Potential Utility in Cancer Immunotherapy

Nicholas DiPatrizio, PhD | UC Riverside | Riverside, CA

Mechanism of Endocannabinoid Control of Feeding and Energy Balance

Davide Dulcis, PhD | UC San Diego | La Jolla, CA

Effects of Neonatal Nicotine Exposure on Dopamine Neurons

Ei Ventures, Inc. | CRO: Tioga Research | San Diego, CA

Research and Early Pharmaceutical Development of a Transdermal Dosage Form of Psilocybin

Christie Fowler, PhD | UC Irvine | Irvine, CA

Mechanisms of Drug Reinforcement

Neil Garg, PhD | UCLA | Los Angeles, CA

Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Preclinical Testing of CBD for the Treatment of Nicotine Dependence

Adam Halberstadt, PhD | UC San Diego | La Jolla, CA

The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Boris Dov Heifets, MD, PhD | Stanford University | Palo Alto, CA

Effects of Classical Hallucinogens on Learning and Memory

Judith Hellman, MD | UC San Francisco | San Francisco, CA

Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA

Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse)

Frank Kochinke, PhD | Mycrodose Therapeutics | San Diego, CA

Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT

David Kokel, PhD | UC San Francisco | San Francisco, CA

Assessment of Zebrafish Phenotypic Assays to Model the Toxicology and Behavioral Pharmacology of Synthetic Cannabinoids and Other Psychoactive Compounds

Stephan Lammel, PhD | UC Berkeley | Berkeley, CA

Organization and Function of Neural Circuits in the Mammalian Brain

Charles Lee, PhD | USDA-ARS | Albany, CA

Low THC Industrial Hemp Cultivars

Peter Leeming, PhD | S & B Pharma, LLC | Azusa, CA

Process Research and Development for the Synthesis and Purification of Cannabidiol (CBD) and Cannabidivarin (CBDv)

Marie Lin, PhD, RPh | Lin-Zhi International, Inc. | Sunnyvale, CA

Lin-Zhi Immunoassay Development Study

Stephen Mahler, PhD | UC Irvine | Irvine, CA

Neural Circuits Underlying Motivation and Addiction

Pamela A. Maher, PhD | The Salk Institute | La Jolla, CA

Therapeutic Relevance of Cannabinoids for Alzheimer's Disease

Robert Malenka, MD | Stanford University | Palo Alto, CA

The Role of Oxytocin in the Pathogenesis of Autism

Faith Kennedy McDaniel, PhD | Koniku, Inc. | Berkeley, CA

Development of a Device that Detects Controlled Substances

Alysson Muotri, PhD | UC San Diego | La Jolla, CA

The Impact of CBD/THC on Human Neurodevelopment

Novartis Institute for Functional Genomics | San Diego, CA

High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays

Novartis Institute for Functional Genomics | San Diego, CA

Use of Selected DEA Schedule I Controlled Substances as Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies

David Olson, PhD | UC Davis | Davis, CA

Chemical Modulation of Neural Plasticity, Learning and Memory

Rudy M. Ortiz, PhD, FAPS, FAHA | UC Merced | Merced, CA

Potential CBD Benefits in Type 2 Diabetes

Dilworth Parkinson, PhD | Lawrence Berkeley National Laboratory | Berkeley, CA

X-ray Microtomography of Pharmaceuticals at the Advanced Light Source for Avadel

Jeanne Paz, PhD | UC San Francisco | San Francisco, CA

Role of Cannabidiol (CBD) in Inflammation in Generic and Acquired Epilepsy

Daniele Piomelli, PhD | UC Irvine | Irvine, CA

1. Effect of Adolescent Cannabis Exposure in Adult Mice and Rats
2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Amanda Roberts, PhD | The Scripps Research Institute | La Jolla, CA

Effects of THC/Alcohol Combinations In Utero on Adult Electrophysiology, Protein Levels, and Gene Expression

Pietro Sanna, MD | The Scripps Research Institute | La Jolla, CA

Neural Substrates of Opiate-HIV Interactions

Christopher Savile, PhD | Epimeron USA, Inc. | Mt. View, CA

Development of a Cannabidiol (CBD) Producing Yeast Strain and Fermentation-Based Production Process

Mehrdad Shamloo, PhD | Stanford University | Palo Alto, CA

Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases

Ivan Soltesz, PhD | Stanford University | Stanford, CA

Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

Stephen A. Spector, MD | UC San Diego | La Jolla, CA

Function of the Brain's Endocannabinoid System and its Role in Neuro-AIDS and Neuro-inflammation

Matthew Springer, PhD | UC San Francisco | San Francisco, CA

Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers

Mark Sussman, PhD | San Diego State University | San Diego, CA

Adolescent Vaping Accelerates Cardiac Aging

Mark Sussman, PhD | San Diego State University | San Diego, CA

Prenatal Nicotine Tetrahydrocannabinol Exposure Promotes Myocardial Damage: A Brain-Heart Parallel

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral and Physiological Toxicities of Cannabinoids

Deepti Tanjore, PhD | Lawrence Berkeley National Lab | Emeryville, CA

Expression of Phytocannabinoids in Yeast: A High Yield Platform for Low Abundance Natural Products (Phase II)

Francesca Telese, PhD | UC San Diego | La Jolla, CA

Epigenetic Regulation of Gene Expression in the Brain

Jeff Ubersax, PhD | Demetrix, Inc. | Emeryville, CA

Production of Natural and Modified Cannabinoids using Engineered, Industrial Microorganisms

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of Psilocybin in Baker's Yeast

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of DMT and Related Substituted Tryptamine Compounds in Baker's Yeast

Joseph Wu, MD, PhD | Stanford University | Palo Alto, CA

Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

Jianmin Xu, PhD | Latitude Pharmaceuticals, Inc. | San Diego, CA

Development of Oral and Injectable Formulation Technologies for CBD and THC

Moonbin Yim, PhD | ARK Diagnostics, Inc. | Fremont, CA

Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing

Brandon Zipp, PhD | Malachite Innovations | Los Angeles, CA

Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

Yi Zuo, PhD | UC Santa Cruz | Santa Cruz, CA

Chemical Modulation of Neural Circuits and Plasticity

APPENDIX E

STATUTORY AUTHORITY CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE

Health and Safety Code section 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 Section 11480 and Section 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.

Health and Safety Code section 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.

(b) 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, the State Public Health Officers, 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.

(c) The Research Advisory Panel shall appoint two special members to the Research Advisory Panel, who shall serve at the pleasure of the Research Advisory Panel only during the period Article 6 (commencing with Section 11260) of Chapter 5 remains effective. The additional members shall be physicians and surgeons, and who are board certified in oncology, ophthalmology, or psychiatry.

- (d) The panel shall annually select a chairperson from among its members.
- (e) The panel may hold hearings on, and in other ways study, research projects concerning cannabis 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.
- (f) The panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of cannabis or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of cannabis pursuant to Section 11478.
- (g) 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 cannabis to the Attorney General.
- (h) 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.

Health and Safety Code section 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.

Health and Safety Code section 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.

Health and Safety Code section 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.

Health and Safety Code section 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.
- (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.

Health and Safety Code section 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.
 - (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.
- (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.

