

THIRTY-FIFTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2005



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.

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SUMMARY OF 2005 PANEL ACTIVITIES

During 2005 the Panel reviewed thirty-six new research study submissions. A total of thirty-three new research studies and one revision were approved by the Panel. Fourteen Independent studies were approved, of which nine were human studies and five were non-human studies. Eighteen Multicenter Clinical Drug Trial studies were approved. One Drug Abuse Treatment study was approved.

The Panel closed fifty-eight research studies during the year 2005. Twenty-one Independent studies were closed, of which eighteen were human studies and three were non-human studies. Thirty-four Multicenter Clinical Drug Trial studies were closed. Three Drug Abuse Treatment studies were closed..

At the end of 2005 the Panel was monitoring 140 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ongoing projects are monitored by means of annual reports, AE reports and site visits; and approval may be withdrawn if activities deviate significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2005 and Table 2 is a list of the studies closed by the Panel in 2005.

TABLE 1

**RESEARCH STUDIES
APPROVED IN 2005**

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Center 5858 Horton Street, Suite 200 Emeryville, CA 94608	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Ronald W. Barrett, Ph.D. XenoPort, Inc. 3410 Central Expressway Santa Clara, CA 95051	Gamma Hydroxybutyrate as an Agonist at the GABA-B Receptor

Cephalon, Inc.
Frazer, Pennsylvania

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Low Back Pain

Cephalon, Inc.
Frazer, Pennsylvania

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of ORAVESCENT Fentanyl Citrate in Opioid-Tolerant Patients With Cancer and Breakthrough Pain

Cephalon, Inc.
Frazer, Pennsylvania

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Neuropathic Pain

Cephalon, Inc.
Frazer, Pennsylvania

A 4-Week, Open-Label Extension Study of ACTIQ (Oral Transmucosal Fentanyl Citrate [OTFC ®] Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain

Cephalon, Inc.
Frazer, Pennsylvania

An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Noncancer Pain

Cephalon, Inc.
Frazer, Pennsylvania

Evaluation of Safety, Tolerability, and Pharmacokinetics of a 200 ug Single Dose of OraVescent Fentanyl Citrate Administered Buccally to Opioid-Tolerant Cancer Patients with or without Oral Mucositis

Table 1 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Douglas Fry NORAC, Inc. 405 South Motor Avenue Azusa, CA 91702-3232	Preparation of Ibogaine and Its Analogs and Derivatives
Grunenthal GmbH Research and Development Aachen, Germany	Randomized, multicenter, double blind, parallel-group study assessing analgesic efficacy & safety of different dosages of GRT0151Y bid compared to active comparator bid & placebo bid in subjects with chronic knee-joint osteoarthritis
Halozyne Therapeutics, Inc. San Diego, CA 92121	Increased Flow Using Subcutaneously Enhanced Morphine (INFUSE-Morphine) Study: A Phase IIIB, double-blind, randomized, crossover study comparing the pharmacokinetics, safety and tolerability of morphine administered subcutaneously with and without human recombinant hyaluronidase (HYLENEX) and intravenously
Reese T. Jones, M.D. Dept of Psych & Langley Porter 401 Parnassus Avenue San Francisco, CA 94143-0984	Double-Blind, Placebo-Controlled, Assessment of Intravenous Methamphetamine and Modafinil Interactions
Ari Kalechstein, Ph.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A8-144 NPI Los Angeles, CA 90024	Methamphetamine Dependence: Treating Neurocognitive Impairment
Jon D. Levine, M.D., Ph.D. UCSF Box 0440 San Francisco, CA 94143-0440	Mechanisms of Pain Control: V. Analgesic Combinations for Post-Operative Pain-Kappa Opioids and Morphine

John E. Mendelson, M.D.
California Pacific Med Center
Castro & Duboce Sts., Room #151
San Francisco, CA 94114 .

Bioavailability and Urinary Excretion of Oral
L-Methamphetamine

Robert O. Messing, M.D.
Ernest Gallo Clinic & Research Center
5858 Horton Street, Suite 200
Emeryville, CA 94608

Protein kinase C epsilon (PKCε) in Responses to
Cannabinoids

Thomas F. Newton, M.D. .
UCLA / ISAP Clinical Trials Ops
760 Westwood Plaza
Box 12, NPI 175919
Los Angeles, CA 90024

Phase 1, Double-Blind, Placebo-Controlled
Assessment of Potential Interactions between
Intravenous Methamphetamine and GBR 12909

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
760 Westwood Plaza
Box 12, NPI 175919
Los Angeles, CA 90024

Modafinil as a Treatment for Methamphetamine
Dependence: Initial Safety, Subjective Effects,
and Brain Functioning - Pilot study

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
760 Westwood Plaza
Box 12, NPI 175919
Los Angeles, CA 90024

The Effects of Modafinil on Tests of Inhibitory
Control in Methamphetamine Addiction

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
760 Westwood Plaza
Box 12, NPI 175919
Los Angeles, CA 90024

Laboratory Models of Cocaine Self
Administration

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Randomized, Double-Blind, Active- and Placebo-Controlled, Phase III, Efficacy and Safety Study of Oxycodone and Low-Dose Naltrexone (PTI-801) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Pain Therapeutics, Inc. South San Francisco, California	A Long-Term, Open-Label, Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCl (PTI-801) in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Mark Perrone, Ph.D. Genomics Inst Novartis Rsrch Fdn 10675 John Jay Hopkins Drive San Diego, CA 94608	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Ste 200 Emeryville, CA 94608	Pharmacological and genetic study of the effects of 3,4- methylenedioxymethamphetamine (MDMA) using a model organism, the nematode <i>Caenorhabditis elegans</i>
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase III, Multi-Center, Open-label Study of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Dvlpmt., Inc.
Rockville, Maryland

A Phase IIIB, Rndmzd, Dbl-Blind, Multi-Ctr, Placebo-Cntrl'd, Dose-Optzmd, 3-way X-Over Study to Assess the Efficacy, Effect, Tolerability and Safety of 4 & 6 hour Wear Times of Methylphenidate Transderm Sys (MTS) in Pedi Sbjts aged 6-12 w/ ADHD

Shire Pharmaceutical Dvlpmt., Inc.
Rockville, Maryland

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Dvlpmt., Inc.
Rockville, Maryland

A Prospective, Open-Label, Multi-Center Study Evaluating the Safety and Tolerability of Methylphenidate Transdermal System (MTS) in Children Aged 6 - 12 Previously Treated with Extended Release Methylphenidate Product

Shire Pharmaceutical Dvlpmt., Inc.
Rockville, Maryland

A Phase II, Randomized, Double-blind, Multi-center, Placebo-controlled, Crossover Study of SPD464 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

Steven Shoptaw, Ph.D.
Semel Inst of Neurosci & Hum Behav.
11075 Santa Monica Blvd. #200
Los Angeles, CA 90025

A Randomized, Double-Blind, Placebo-Controlled Evaluation of Bupropion vs Placebo for the Treatment of Methamphetamine Dependence

Solvay Pharmaceuticals, Inc.

Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Efficacy, Safety, and Tolerability Study of Dronabinol MDI in the Acute Treatment of Migraine Headache

ZARS, Inc.
Salt Lake City, Utah

An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Osteoarthritis Pain

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

ZARS, Inc.
Salt Lake City, Utah

An Open-Label Safety Study to Evaluate the
Safety of the ZR-02-01 Matrix Transdermal
Fentanyl Patch for the Treatment of Moderate to
Severe, Non-malignant Chronic Pain

TABLE 2

**RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2005**

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	Marijuana in Combination with Opioid for Cancer Pain: Pilot Study.
ALZA Corporation Mountain View, California	ALZA Protocol M03-644
ALZA Corporation Mountain View, California	ALZA Protocol C-2003-008
ALZA Corporation Mountain View, California	ALZA Protocol C-2003-017
ALZA Corporation Mountain View, California	ALZA Protocol C-2004-016
Jed Black, M.D. Stanford Sleep Disorders Clinic 401 Quarry Road, Suite 3301 Stanford, CA 94305	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)
Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, Connecticut	A Phase I dbl-blind, dbl-dummy, rmdmzd 3 period cross-over study designed to assess the abuse potential of 2 doses of NS 2330 relative to placebo and 10mg methamphetamine in recreational stimulant users who demonstrate a response to methamphetamine

Cephalon, Inc.
Frazer, Pennsylvania

A Multicenter, Double-Blind,
Placebo-Controlled Study of
OraVescent® Fentanyl Citrate for the
Treatment of Breakthrough Pain in
Opioid-Tolerant Cancer Patients

Cephalon, Inc.
Frazer, Pennsylvania

Evaluation of Safety, Tolerability, and
Pharmacokinetics of a 200 ug Single Dose of
OraVescent Fentanyl Citrate Administered
Buccally to Opioid-Tolerant Cancer Patients
with or without Oral Mucositis

Peggy A. Compton, RN, Ph.D.
UCLA School of Nursing
Box 956918
Los Angeles, CA 90095-6918

Hyperalgesia in Methadone Maintained
Patients: Can it be Treated with Oxycodone?

Drug Abuse Sciences, Inc.
Germantown, Tennessee

A 6-month open-label, prospective,
multicenter safety study of Naltrexone Depot
as relapse prevention therapy of
heroin-dependent subjects following
detoxification with Suboxone®

Suzanne L. Dibble, DNSc, R.N.
UCSF School of Nursing
Box 0646, Laurel Heights, Rm 340
San Francisco, CA 94143-0646

Treating Chemotherapy-Induced Delayed
Nausea with Cannabinoids

Joel E. Dimsdale, M.D.
University of California, San Diego
9500 Gillman Drive
La Jolla, CA 92093-0804

Effects of Common Opioid Medications on
Sleep Architecture and Next-Day Fatigue

Elan Pharmaceuticals, Inc.
San Diego, CA 92121

An Open-label, Multicenter Study of the
Safety and Efficacy of Combined Intrathecal
Infumorph® and Ziconotide (Prialt™):
Addition of Infumorph® in Patients
Receiving Prialt™ for Severe Chronic Pain

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Elan Pharmaceuticals, Inc. San Diego, CA 92121	An Open-label, Multicenter Study of the Safety and Efficacy of Combined Intrathecal Infumorph® and Ziconotide (Prialt™): Addition of Prialt™ in Patients Receiving Infumorph® for Severe Chronic Pain
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Double-Blind, Randomized, Sham Procedure Controlled Study to Evaluate the Efficacy and Safety of a Single Epidural Dose of SKY0401 in the Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Double-Blind, Randomized, Sham Procedure Controlled Study to Evaluate the Efficacy and Safety of a Single Epidural Dose of SKY0401 in the Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Single-Dose Evaluation of the Safety and Efficacy of Oxycodone/Acetaminophen for Acute Postoperative Pain in Pediatric Patients
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	An Open-Label, Long-Term Effectiveness and Safety Study of Oxymorphone Extended Release Tablets in Patients with Cancer or Neuropathic Pain
Milton K. Erman, M.D. Pacific Sleep Medicine Svcs Inc. 9834 Genesee Avenue, Suite 328 La Jolla, CA 92037	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)

Ricahrd C. Gaul, Pharm.D.
682 29th Ave
San Francisco, CA 94121

Mechanisms of
3,4-methylenedioxymethamphetamine
Toxicities

Dennis M. Israelski, M.D.
San Mateo Medical Center
222 West 39th Avenue
San Mateo, CA 94403

A Pilot Study of the Feasibility and Safety of
Controlled Trials of Medical Marijuana to
Relieve HIV-Associated Distal Symmetric
Polyneuropathy; Other HIV-associated Pain;
and HIV-associated Nausea, Anorexia, and
Wasting

Dennis M. Israelski, M.D.
San Mateo Medical Center
222 West 39th Avenue
San Mateo, CA 94403

MMJ for HIV-associated DSPN: Adherence
& Compliance Sub-Study

Johnson & Johnson Pharm Rsrch & Dvl
Titusville, New Jersey

A 4-Week Multicenter, Phase IIB Study
Comparing Efficacy and Safety of
Ascending Doses of CG5503 PR Up To 233
mg BID and Oxycodone PR up to 20mg BID
to Placebo in Subjects with Moderate to
Severre Chronic Pain Due to Osteoarthritis
of the Knee

Lorin M. Koran, M.D.
Stanford Univ. School of Medicine
401 Quarry Road Rm. 2363
Stanford, CA 94305-5721

Oral Morphine in Treatment Resistant
Obsessive-Compulsive Disorder (OCD)

Ronald Kuczenski, Ph.D.
UCSD School of Medicine
9500 Gillman Drive
La Jolla, CA 92093-0603

Effects of GW Extracts on
Methamphetamine-Induced Neurotoxicity

Jelveh Lameh, Ph.D.
Molecular Research Institute
2495 Old Middlefield Way
Mountain View, CA 94043

Pharmacochemical Studies of Opiate
Narcotics

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
James T. McCracken, M.D. UCLA Neuropsychiatric Institute 300 UCLA Medical Plaza, Suite 1534A Los Angeles, CA 90095-6967	Methylphenidate in the Treatment of Hyperactivity and Impulsiveness in Children and Adolescents with Pervasive Developmental Disorder
Thomas F. Newton, M.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A7-372 NPI Los Angeles, CA 90024	Phase 1, Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and GBR 12909
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled, Dose Response Trial of Ondansetron for the Treatment of Methamphetamine Dependence
National Institute on Drug Abuse Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Selegiline for Methamphetamine Relapse Prevention
Noven Pharmaceuticals Inc. Miami, Florida	Open Label Study of MethyPatch in Children with ADHD / Extension Continuation
Orphan Medical Minnetonka, Minnesota	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)
Ortho-McNeil Pharmaceuticals Inc. Raritan, New Jersey	Comparison of the Safety and Efficacy of Patient Controlled Analgesia delivered by Fentanyl HCl Transdermal System versus Morphine IV Pump for Pain Management after Primary Unilateral Total Hip Replacement

Ortho-McNeil Pharmaceuticals Inc.
Raritan, New Jersey

Comparison of the Safety and Efficacy of
Patient Controlled Analgesia delivered by
Fentanyl HCl Transdermal System versus
Morphine IV Pump for Pain Management
after Non-emergent Lower Abdominal and
Pelvic Surgery

Pain Therapeutics, Inc.
South San Francisco, California

A Multicenter, Randomized
Placebo-Controlled, Phase III, Efficacy and
Safety Study of PTI-821 in Patients with
Moderate to Severe Chronic Pain Due to
Osteoarthritis of the Hip or Knee

Helen J. Parish, Director
Pharmaceutical Sciences laboratory
SRI International
333 Ravenswood Ave., PS 143
Menlo Park, CA 94025

Pulsatile Release/Controlled Release Dosage
Form Development of Xyrem

Karin L. Petersen, M.D.
UCSF Clinical Pain Research Center
1701 Divisadero Street, Suite 480
San Francisco, CA 94115

Randomized, Double-blind, Pilot Study to
Compare the Analgesic Efficacy of
Morphidex versus Morphine,
Dextromethorphan, and Placebo Using the
Heat/Capsaicin Sensitization Model

Progenics Pharmaceuticals
Tarrytown, New York

A Double-Blind Placebo Controlled Study of
Methylnaltrexone (MNTX) for the Relief of
Symptomatic Constipation Due to Chronic
Opioid Therapy in Patients with Advanced
Medical Illness

Purdue Pharma L.P.
Stamford, Connecticut

A Randomized, Multiple-dose,
Double-blind, Placebo-controlled,
Parallel-group Study Comparing the
Safety and Efficacy of Hydromorphone
HCl Extended-release and Duragesic® in
Subjects with Non-malignant Pain

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
John M. Roll, Ph.D. Friends Research Inst., Inc. 11075 Santa Monica Blvd., Suite 350 Los Angeles, CA 90025	Human Behavioral Pharmacology of GHB
John M. Roll, Ph.D. Friends Research Inst., Inc. 11075 Santa Monica Blvd., Suite 350 Los Angeles, CA 90025	Human Methamphetamine Use: A Modell
Murray H. Rosenthal, D.O. HealthQuest Clinical Trials 3625 Ruffin Road, Suite 100 San Diego, CA 92123	A Polysomnographic Study Measuring the Effect of Avinza on Sleep in Osteoarthritis Patients with Complaints of Sleep Disturbances Attributed to Moderate to Severe Chronic Pain
Michael C. Rowbotham, M.D. UCSF Pain Clinical Research Center 1701 Divisadero St., Suite 480 San Francisco, CA 94115	The effect of intravenous remifentanil on the experimental heat/ capsaicin sensitization model in chronic pain patients
Sention, Inc. Providence, Rhode Island	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety, Tolerability, and Efficacy of Titration and Treatment with C105 in Subjects with Mild Cognitive Impairment (MCI)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Multi-center, 18-month, Open-label Safety, Tolerability and Efficacy Study of Adderall XR® in the Treatment of Adolescents Aged 13-18 with Attention Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development
Rockville, Maryland

A Phase IIIb, Open-Label, Multi-Ctr Study to Assess Safety, Tolerability, and Effectiveness Associated with the use of ADDERALL XR® in Adults with Attention Deficit Hyperactivity Disorder and Evaluate an ADHD-specific Novel Quality of Life Measure

Shire Pharmaceutical Development
Rockville, Maryland

A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of ADDERALL XR® with an Open-label Extension, in Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development
Rockville, Maryland

A Phase 2, Randomized, Double-blind, Multi-center, Placebo- and Active-controlled, Crossover Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development
Rockville, Maryland

A Randomized, Double-Blind, Parallel-Group, Analog Classroom Study, Evaluating Adderall XR® vs. Strattera™, Dosed once-daily, in Children aged 6-12 with Attention Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development
Rockville, Maryland

A Phase II, Randomized, Double-blind, Multi-center, Placebo- and Active-controlled, Crossover Study of SPD465 in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development
Rockville, Maryland

A 24-Month, Open-Label Study of Adderall XR® in Adults with Attention Deficit Hyperactivity Disorder

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire Pharmaceutical Development Rockville, Maryland	A Phase II, Rndmzd, Dbl-Blind, Multi-Center, Placebo-Cntrld, Crossover Study, Designed to Assess the Time Course of Treatment Effect, Tolerability and Safety of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with ADHD
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Rndmzd, Dbl-Blind, Multi-Center, Parallel Grp, Placebo-Cntrld, Dose Optimization Study, Designed to Evalutate the Safety & Efficacy of Methylphenidate Transdermal System® (MTS) vs. CONCERTA® in Pediatric Patients aged 6-12 with ADHD
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-Group, Safety and Efficacy Study of SPD465 with an Open-label Extension in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)
SkyePharma, Inc. San Diego, California	SkyePharma Protocol SKY0401-020
Mark S. Wallace, M.D. UCSD Clinical Pain Research 9500 Gilman Drive # 0924 La Jolla, CA 92093-0924	Analgesic Efficacy of Smoked Cannabis in Refractory Cancer Pain

ZARS, Inc.
Salt Lake City, Utah

Double-Blind, Parallel, Randomized,
Placebo-Controlled, 12-Week Efficacy and
Safety Assessment of ZR-02-01 in the
Treatment of Chronic, Moderate to Severe
Osteoarthritis (OA) Pain

APPENDIX A

CURRENTLY APPROVED (*December 31, 2005*) INDEPENDENT SCHEDULE I AND SCHEDULE II CONTROLLED SUBSTANCE RESEARCH STUDIES

<u>Principal Investigator</u>	<u>Title of Study</u>
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	The Effects of Marijuana on Neuropathic Pain in HIV-Related Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Study
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	The Effect of Marijuana on Neuropathic Pain in HIV-Related Peripheral Neuropathy
Mark A. Agius, M.D. Dept. of Neurology University of California, Davis 1515 Newton Court Room 510 Davis, CA 95616	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
James T. Arnold, Ph.D. Systems and Techniques Lab. Varian Associates 3075 Hansen Way Palo Alto, CA 94304-1025	Chemical Vapor Analysis of Marijuana and Other Drugs of Abuse
Mark G. Barad, M.D., Ph.D. UCLA Dept Psych & Biobehav Sci 695 Charles E. Young Drive South Los Angeles, CA 90095-1761	Cannabinoids in Fear Extinction
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street, Suite 200 Emeryville, CA 94608	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction

Appendix A Cont.

Principal Investigator

Title of Study

Ronald W. Barrett, Ph.D.
XenoPort, Inc.
3410 Central Expressway
Santa Clara, CA 95051

Gamma Hydroxybutyrate as an Agonist at the
GABA-B Receptor

Phillip E. Bickler, M.D., Ph.D.
UCSF Dept. of Anes. & Periop. Care
513 Parnassus Ave.
San Francisco, CA 94143-0542

Inhaled carbon dioxide and apnea during
intravenous sedation

Nancy E. Buckley, Ph.D.
California State Polytechnic Univ.
3801 W. Temple Ave.
Pomona, CA 91768

The Role of the Peripheral Cannabinoid (CB2)
Receptor Activation in Immune Function

Jeremy S. Caldwell, Ph.D.
Genomics Inst Novartis Research Fdn
10675 John Jay Hopkins Drive
San Diego, CA 92121

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

Karen Chang, Ph.D.
ALZA Corp.
1900 Charleston Road
Mountain View, CA 94039-7210

Purity Determination, Morphine and
Hydromorphone

Lin Chang, M.D.
W. Los Angeles VA Medical Center
11301 Wilshire, Bldg 115, Rm 223
Los Angeles, CA 90073

Neuroendocrine Alterations in Fibromyalgia and
IBS

Arthur K. Cho, Ph.D.
Dept./Pharmacology, 23-272 CHS
UCLA School of Medicine
10833 Le Conte Avenue
Los Angeles, CA 90024-1721

Studies on Distribution and Metabolism of
Narcotics in Animals

<u>Principal Investigator</u>	<u>Title of Study</u>
Kent S. Chu, Ph.D. YJ Bio-Products 11353 Pyrites Way, Suite 14 Cordova, CA 95670	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. 1201 Douglas Avenue Redwood City, CA 94063	Research of Novel Technologies for Development of Antibodies and Immunoassay Techniques to Drugs of Abuse and Controlled Compounds of Interest
Jody Corey-Bloom, M.D. UCSD Clinical Research Ctr. 9500 Gilman Drive La Jolla, CA 92093-0620	Short-Term Effects of Cannabis Therapy on Spasticity in MS
Sean Drummond, Ph.D. UCSD/San Diego VAMC 3350 La Jolla Village Drive La Jolla, CA 92161	Sleep and Medicinal Cannabis
Ronald J. Ellis, M.D. UCSD HIV Neurobehav. Rsch. Ctr. 150 W. Washington St., 2nd Floor San Diego, CA 92103	Placebo-controlled, Double-blind Trial of Medicinal Cannabis in Painful HIV-Neuropathy
Laura J. Esserman, M.D. UCSF Breast Care Center 1600 Divisadero St. Box 1710 San Francisco, CA 94143	Postoperative Pain Control with Fentanyl Patch in Patients undergoing Mastectomy and Tram Flap Reconstruction
Aaron Ettenberg, Ph.D. Dept. Psychology, UC Santa Barbara Santa Barbara, CA 93106-9660	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement

Appendix A Cont.

Principal Investigator

Title of Study

Frederick D. Frankel, Ph.D.
UCLA Department of Psychiatry
300 UCLA Medical Plaza
Los Angeles, CA 90095-6769

Social Skills Training for Medicated Children

Douglas Fry
The NORAC Co., Inc.
405 S Motor Ave., POB 577
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Research on the Synthesis of Schedule I
Controlled Substances: delta-9-THC and LAAM

Douglas Fry
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"Preparation of Ibogaine and Its Analogs and
Derivatives"

Alan Gevins
SAM Technology, Inc.
425 Bush Street 5th Floor
San Francisco, CA 94108,

Neurocognitive Index of Cannabis Effects System

Mark A. Geyer, Ph.D.
Dept. of Psychiatry - 0804
University of Calif, San Diego
9500 Gilman Drive
La Jolla, CA 92093-0804

Behavioral and Cytofluorimetric Studies of
Psychoactive Drugs in Rats

Terry E. Grimmer, M.S.
Berlex Biosciences
2600 Hilltop Drive
Richmond, CA 94804-0099

Synthesis of Pharmaceutical Research Compounds

Charles S. Grob, M.D.
Harbor UCLA Medical Center
1000 West Carson Street
Torrance, CA 90509

Effects of Psilocybin in Terminal Cancer Patients
with Anxiety

<u>Principal Investigator</u>	<u>Title of Study</u>
Kanthi F. Hettiarachchi, Ph.D. SRI International 333 Ravenswood Avenue Menlo Park, CA 94025	Analysis of Cannabinoids
Richard A. Houghten, Ph.D. Torrey Pines Inst./Molecular Study 3550 General Atomics Ct. San Diego, CA 92121	Biochemical Basis for the CNS Actions of Methaqualone
Michael Irwin, M.D. UCLA Neuropsychiatric Institute 300 UCLA Medical Plaza Ste 3109 Los Angeles, CA 90095-7076	Cocaine Dependence: Sleep and Cytokines
J. David Jentsch, Ph.D. UCLA Department of Psychology 405 Hilgard Ave; B630 Franz Hall Los Angeles, CA 90095-1563	Neurocognitive and Chemical Effects of Entactogenic and Cannabinoidergic Drugs
S.V. Penelope Jones, Ph.D. UCSD School of Medicine 9500 Gilman Drive La Jolla, CA 92093-0603	Effects of GHB on the Mesolimbic Dopaminergic System
Ari Kalechstein, Ph.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A8-144 NPI Los Angeles, CA 90024	Methamphetamine Dependence: Treating Neurocognitive Impairment"
Thomas B. King Alexza Molecular Delivery Corp. 1001 East Meadow Circle Palo Alto, CA 94303	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery

Appendix A Cont.

Principal Investigator

Title of Study

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Dept of Neuropharmacol. CVN-7
The Scripps Research Institute
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Central Mechanisms of Opiate Reinforcement and
Dependence

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La Jolla, CA 92037

Neuronal Substrates of Cocaine Reward

Helen Lavretsky, M.D.
UCLA Neuropsychiatric Institute
760 Westwood Plaza Rm 37-425
Los Angeles, CA 90024

Intervention Clinical Trial for Geriatric
Depression: A Double-blind Placebo-Controlled
Trial of Methylphenidate (Ritalin) Augmentation
of Citalopram (Celexa) in Depressed Patients at
Least 70 Years of Age

Nancy M. Lee, Ph.D.
Forbes Norris ALS/MDA Rsrch Ctr.
2351 Clay Street Suite 416
San Francisco, CA 94115

Role of Cannabinoid Receptors in Central
Nervous System Functions and Diseases

Jon D. Levine, M.D., Ph.D.
UCSF
Dept. Oral&Maxillofac Surgery
San Francisco, CA 94143-0440

Mechanisms of Pain Control: V. Analgesic
Combinations for Post-Operative Pain—Kappa
Opioids and Morphine.

Marie Lin, Ph.D. R.Ph.
Lin-Zhi International, Inc.
687 North Pastoria Ave
Sunnyvale, CA 94085

Lin-Zhi Immunoassay Development Study

Thomas D. Marcotte, Ph.D.
UCSD HIV Neurobehav. Rsch. Ctr.
150 W. Washington St., 2nd Floor
San Diego, CA 92103

Impact of Repeated Cannabis Treatments on
Driving Abilities

<u>Principal Investigator</u>	<u>Title of Study</u>
James J. McGough, M.D. UCLA Child Treatment Rsch Grp 300 UCLA Medical Plaza # 1534A Los Angeles, CA 90095-6967	Response Variability in Stimulant Treatment of ADHD
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Pharmacokinetics of Intranasal and Smoked Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Pharmacokinetic Interactions between the Selegiline Transdermal Delivery System and d- Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Effects of Cocaine Agonist Therapy on Cocaine Self-Administration, Tolerance, and Craving
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Clinical Pharmacology of l-Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Interaction Between Oral Reserpine and Intravenous Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Interaction Between the Serotonin Reuptake Blocker Paroxetine and Methamphetamine

Appendix A Cont.

Principal Investigator

Title of Study

Karen Miotto, M.D.
UCLA Neuropsychiatric Inst.
760 Westwood Plaza Room 37-384C
Los Angeles, CA 90095

GHB: Effects, Withdrawal and Treatment"

Karel Z. Newman, Ph.D.
Biosite Incorporated
9975 Summers Ridge Road
San Diego, CA 92121

Development of In-vitro Immunoassays for the
Detection of Abused Substances

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
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Los Angeles, CA 90024

Perindopril - Methamphetamine Interaction Study

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
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Los Angeles, CA 90024

Modafinil as a Treatment for Methamphetamine
Dependence: Initial Safety, Subjective Effects,
and Brain Functioning - Pilot study

Thomas F. Newton, M.D.
UCLA / ISAP Clinical Trials Ops
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Los Angeles, CA 90024

Double-Blind, Placebo-Controlled Assessment of
Potential Interactions between Intravenous
Methamphetamine and Oral Bupropion

Thomas F. Newton, M.D.
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Los Angeles, CA 90024

Laboratory Models of Cocaine Self
Administration

Karno Ng, Ph.D.
California State University San Marcos
San Marcos, CA 92096-0001

New Qualitative and Quantitative Methods for the
Detection of Gamma-hydroxybutyrate (GHB)

<u>Principal Investigator</u>	<u>Title of Study</u>
Stanley M. Parsons, Ph.D. Dept Chem & Biochem, UCSB Santa Barbara, CA 93106-9510	Rapid Detection of 4-hydroxybutyrate
Mark Perrone, Ph.D. 10675 John Jay Hopkins Drive San Diego, CA 92121	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
John M. Polich, Ph.D. Dept. of Neuropharmacology The Scripps Research Institute 10550 North Torrey Pines Rd TPC10 La Jolla, CA 92037	Marijuana CNS Effects in Low- and High-Risk Adults
Robert Ramage Microgenics Corporation 46360 Fremont Boulevard Fremont, CA 94538	Use of Schedule I Controlled Substances for Cross Reactant Studies and Investigation of Customer Inquiries
Dorit Ron, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Suite 200 Emeryville, CA 94608	Signaling Pathways Involved in the Mechanism of Action of the Anti-Addictive Drug Ibogaine
Michael C. Rowbotham, M.D. UCSF Pain Clinical Res. Cntr. 2233 Post St. Suite 104 San Francisco, CA 94115	The effect of intravenous remifentanyl on the experimental heat/capsaicin sensitization model in chronic pain patients
Michael C. Rowbotham, M.D. UCSF Pain Clinical Res. Cntr. 2233 Post St. Suite 104 San Francisco, CA 94115	Evolution of Analgesic Tolerance During Long Term Treatment of Chronic Pain with Opioids

Appendix A Cont.

Principal Investigator

Title of Study

Matthew A. Schreiber, M.D., Ph.D.
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5858 Horton Street Ste 200
Emeryville, CA 94608

Pharmacological and genetic study of the effects
of 3,4- methylenedioxymethamphetamine
(MDMA) using a model organism, the nematode
Caenorhabditis elegans

Rachel D. Schrier, Ph.D.
UCSD Medical Center
200 W Arbor Drive MC 8416
San Diego, CA 92103-8416

Effects of Medicinal Cannabis on CD4 Immunity
in Aids

Steven Shoptaw, Ph.D.
Semel Inst of Neurosci & Hum Behav
11075 Santa Monica Blvd. #200
Los Angeles, CA 90025

A Randomized, Double-Blind, Placebo-Controlled
Evaluation of Bupropion vs Placebo for the
Treatment of Methamphetamine Dependence

Donald P. Tashkin, M.D.
D Geffen School of Med at UCLA
10833 Le Conte Ave 37-131 CHS
Los Angeles, CA 90095-1690

Cocaine Smoking Effects on Lung Immunity and
Host Defense

Lawrence Toll, Ph.D.
Neuroscience Department
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

Biochemical Studies into Opiate Efficacies

Lawrence Toll, Ph.D.
Receptor Pharmacology
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

Receptor binding assays of blind and coded
schedule I controlled substances pursuant to
contracts with the National Institute on Drug
Abuse

Edward Tung, Ph.D.
Acon Laboratories
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San Diego, CA 92121

Development of urine and/or oral-fluid based
in-vitro diagnostic tests to detect the presence of
the controlled substances MDMA, GHB and THC

Principal Investigator

Title of Study

Edward Tung, Ph.D.
AZURE Institute
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Development of urine and/or oral-fluid based
in-vitro diagnostic tests in the form of lateral flow
rapid test format to detect controlled substances
commonly abused and misused by individuals

David L. Valentine, Ph.D.
Department of Earth Science
U.C. Santa Barbara
Santa Barbara, CA 93116

Isolation of bacteria capable of growth on
gamma-hydroxybutyric acid (GHB) and its
analogs

Jennifer L. Whistler, Ph.D.
Ernest Gallo Clinic & Research Ctr
5858 Horton Street Suite 200
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Endocytosis and Cannabinoid Receptors

Jennifer L. Whistler, Ph.D.
Ernest Gallo Clinic & Research Ctr
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Emeryville, CA 94608

Endocytosis and Opioid Receptors

Sharon B. Wigal, Ph.D.
UCI Child Development Center
19722 MacArthur Blvd.
Irvine, CA 92612

Pharmacokinetic and Pharmacodynamic
Evaluation of Stimulant Drugs

Barth L. Wilsey, M.D.
UC Davis Medical Center
4860 Y Street Suite 2700
Sacramento, CA 95817

A Double Blind, Active Placebo Controlled
Crossover Trial of the Antinociceptive Effect of
Smoked Marijuana on Subjects with Neuropathic
Pain; Correlation with Changes in Mood,
Cognition, and Psychomotor Performance

Justin A. Zivin, M.D., Ph.D.
Dept. of Neurosciences, 0624
UCSD School of Medicine
9500 Gilman Drive
La Jolla, CA 92093-0624

Therapy of Central Nervous System Ischemia

APPENDIX B

CURRENTLY APPROVED (*December 31, 2005*) SCHEDULE II MULTICENTER CLINICAL DRUG TRIAL STUDIES

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Low Back Pain
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of ORAVESCENT Fentanyl Citrate in Opioid-Tolerant Patients With Cancer and Breakthrough Pain
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Neuropathic Pain
Cephalon, Inc. Frazer, Pennsylvania	A 4-Week, Open-Label Extension Study of ACTIQ (Oral Transmucosal Fentanyl Citrate [OTFC ®] Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain
Cephalon, Inc. Frazer, Pennsylvania	A Multicenter, Open-Label, Long-Term Study of OraVescent® Fentanyl Citrate for the Treatment of Breakthrough Pain in Opioid-Tolerant Cancer Patients

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Placebo-Comparison Study to Evaluate the Efficacy and Safety of ACTIQ® (Oral Transmucosal Fentanyl Citrate[OTFC®]) Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain
Cephalon, Inc. Frazer, Pennsylvania	An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Noncancer Pain
Elan Pharmaceuticals Inc. San Diego, California	Elan Protocol ELN92045-205
Grunenthal GmbH, Research and Development Aachen, Germany	Randomized, multicenter, double blind, parallel-group study assessing analgesic efficacy & safety of different dosages of GRT0151Y bid compared to active comparator bid & placebo bid in subjects with chronic knee-joint osteoarthritis
Halozyne Therapeutics, Inc. San Diego, California	Increased Flow Using Subcutaneously Enhanced Morphine (INFUSE-Morphine) Study: A Phase IIIB, double-blind, randomized, crossover study comparing the pharmacokinetics, safety and tolerability of morphine administered subcutaneously with and without human recombinant hyaluronidase (HYLENEX) and intravenously
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and Aripiprazole (NIDA Study MDS-ARIP-0001)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Double-Blind, Active- and Placebo-Controlled Efficacy and Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCL (PTI-801) in Patients with Low Back Pain (Pain Therapeutics Protocol PTI-801-XG)
Pain Therapeutics, Inc. South San Francisco, California	A Long-Term, Open-Label, Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCl (PTI-801) in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Randomized, Double-Blind, Active- and Placebo-Controlled, Phase III, Efficacy and Safety Study of Oxycodone and Low-Dose Naltrexone (PTI-801) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
PARAXEL International Corp. Waltham, Massachusetts	A Randomized, Double-Blind Comparison of Atomoxetine, Augmented with either Extended-Release Methylphenidate (Concerta™) or Placebo in Children with Attention-Deficit/Hyperactivity Disorder (ADHD) Who Have Not Responded to Stimulant Mono Therapy
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase IIIB, Rndmzd, Dbl-Blind, Multi-Ctr, Placebo-Cntrl'd, Dose-Optzmd, 3-way X-Over Study to Assess the Efficacy, Effect, Tolerability and Safety of 4 & 6 hour Wear Times of Methylphenidate Transderm Sys (MTS) in Pedi Sbjts aged 6-12 w/ ADHD

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase III, Multi-Center, Open-label Study of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)
Progenics Pharmaceuticals Tarrytown, New York	A Compassionate Use Study of Methylnaltrexone in Patients with Opioid-Induced Side Effects (Progenics Protocol MNTX 901)
Progenics Pharmaceuticals Tarrytown, New York	A Double-Blind Phase 3, Two-Week, Placebo Controlled Study of Methylnaltrexone (MNTX) for the Relief of Symptomatic Constipation Due to Chronic Opioid Therapy in Advanced Medical Illness; Three-Month Open Label Treatment Extension Option (Progenics Protocol MNTX 302, 302EXT)
Purdue Pharma L.P. Stamford, Connecticut	A Randomized Placebo-Controlled Crossover Trial Evaluating the Effect of Naltrexone at 1, 3, and 6 mg Dose Levels on the Abuse Potential of 40 mg Oxycodone in Non-dependent, Opioid-preferring Subjects
Purdue Pharma L.P. Stamford, Connecticut	Randomized, Double-blind, Multicenter, Active Comparator Study to Determine the Efficacy and Safety of BTDS 20 or Oxy IR® versus BTDS 5 in Subjects with Moderate to Severe Osteoarthritis (OA) Pain
Purdue Pharma L.P. Stamford, Connecticut	A Multicenter, Randomized, Double-blind, Active Comparator Study to Determine the Efficacy and Safety of BTDS 20 or Oxy IR® versus BTDS 5 in Subjects with Moderate to Severe Low Back Pain

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Purdue Pharma L.P. Stamford, Connecticut	A Rndmzd, Dbl-Blind, Placebo-Cntrl'd, Parallel Grp, Multicenter Study to Determine the Efficacy and Safety of Buprenorphine Transdermal System (BTDS) in Subjects with Moderate to Severe Osteoarthritis (OA) Pain Requiring Daily Treatment with Opioids
Shire Pharmaceutical Development Rockville, Maryland	A Phase II, Randomized, Double-blind, Multi-center, Placebo-controlled, Crossover Study of SPD464 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Multi-center, Open-label Safety Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Prospective, Open-Label, Multi-Center Study Evaluating the Safety and Tolerability of Methylphenidate Transdermal System (MTS) in Children Aged 6 - 12 Previously Treated with Extended Release Methylphenidate Product
Solvay Pharmaceuticals, Inc.	Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Efficacy, Safety, and Tolerability Study of Dronabinol MDI in the Acute Treatment of Migraine Headache

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
ZARS, Inc. Salt Lake City, Utah	An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Osteoarthritis Pain
ZARS, Inc. Salt Lake City, Utah	An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR-02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Moderate-to-Severe Cancer Pain
ZARS, Inc. Salt Lake City, Utah	An Open-Label Safety Study to Evaluate the Safety of the ZR-02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Moderate to Severe, Non-malignant Chronic Pain

APPENDIX C

CURRENTLY APPROVED (*December 31, 2005*) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Sponsor / PI

Description or Title of Research Study

National Institute on Drug Abuse
Bethesda, Maryland

Double-Blind, Placebo-Controlled Trial of
Bupropion for the Treatment of
Methamphetamine Dependence
(NIDA Study CTO-0008)

National Institute on Drug Abuse
Bethesda, Maryland

Double-Blind, Placebo-Controlled Assessment of
Potential Interactions Between Intravenous
Methamphetamine And Aripiprazole
(NIDA Study NIDA-MDS-ARIPIP-0001)

National Institute on Drug Abuse
Bethesda, Maryland

Single-Blind, Placebo-Controlled Assessment of
Potential Interactions Between Intravenous
Cocaine, Ethanol and Oral Disulfiram
(NIDA Study NIDA-MDS-Disulfiram-001)

Thomas F. Newton, M.D.
UCLA/ISAP Clinical Trials Operations
760 Westwood Plaza, Box 12, NPI 175919
Los Angeles, CA 90024

Double-Blind, Randomized, Placebo-Controlled
Trial of Rivastigmine (Exelon) as a Potential
Medication for Methamphetamine Abuse

APPENDIX D

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

Sec. 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.

Sec. 11362.9. **California Marijuana Research Program; legislative intent; creation; research proposals; establishment; powers and duties; Scientific Advisory Council**
(In pertinent part)

(d) If the program is administered by the Regents of the University of California any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, marijuana. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

Sec. 11374. Every person who violates or fails to comply with any provisions of this division, except one for which a penalty is otherwise in this division specifically provided, is guilty of a misdemeanor punishable by a fine in a sum not less than thirty dollars (\$30) nor more than five hundred dollars (\$500), or by imprisonment for not less than 15 nor more than 180 days, or by both.

Sec. 11392. Spores or mycelium capable of producing mushrooms or other material which contains psilocyn or psilocylin may be lawfully obtained and used for bona fide

research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Sec. 11478. Marijuana may be provided by the Attorney General to the heads of research projects which have been registered by the Attorney General, and which have been approved by the Research Advisory Panel pursuant to Section 11480.

The head of the approved research project shall personally receipt for such quantities of marijuana and shall make a record of their disposition. The receipt and record shall be retained by the Attorney General. The head of the approved research project shall also, at intervals and in the manner required by the Research Advisory Panel, report the progress or conclusions of the research project.

Sec. 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.

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.

Sec. 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.

Sec. 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.

Sec. 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.