



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 7, 2010**

**To: Communication and Public Education Committee**

**Subject: 2009 Report of the Research Advisory Panel of California**

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**For Information:**

The California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled substances. Section 11213 provides that:

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purposes 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.

A copy of the 2009 report of the panel that was recently received by the board follows this page.

Pages 39 – 44 of this report describe the statutory mandate of the panel. The Board of Pharmacy has one representative on this panel – Dr. Peter Koo of UCSF.

*Publi Ed*

Edward P. O'Brien, J.D.  
Chairman

Y. Jennifer Ahn, Pharm.D.  
Executive Officer



Panel Members

Antonello Bonci, M.D.  
Daniel P. Holschneider, M.D.  
Peter Koo, Pharm.D.  
John Mendelson, M.D.  
Laurence R. Upjohn, Pharm.D.

**RESEARCH ADVISORY PANEL  
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**MEMORANDUM**

Date: June 3, 2010

To: Recipients - Research Advisory Panel Annual Report

From: Y. Jennifer Ahn, Pharm.D.  
Panel Executive Officer

Subject: Thirty-Ninth Annual Report of the Research  
Advisory Panel of California

The Research Advisory Panel of California has recently submitted its annual report to the Legislature and Governor. Enclosed is a copy of this report, which provides a summary of the Panel's activities for the year 2009. Additional copies are available upon request.

# **THIRTY-NINTH ANNUAL REPORT**

of the

## **RESEARCH ADVISORY PANEL OF CALIFORNIA**

**2009**



Prepared for the

**LEGISLATURE AND GOVERNOR**

**RESEARCH ADVISORY PANEL OF CALIFORNIA**

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**Panel Chairman**  
**Appointed by Attorney General**

**Antonello Bonci, M.D.**  
**Appointed by the University of California at San Francisco**  
**Designated University of California**

**Daniel P. Holschneider, M.D.**  
**Appointed by the University of Southern California**  
**Designated private university**

**Peter Koo, Pharm.D.**  
**Appointed by the State Board of Pharmacy**

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

## TABLE OF CONTENTS

|  | Page |
|--|------|
| SUMMARY OF 2009 PANEL ACTIVITIES   | 3    |
| SELECTED RESEARCH FINDINGS   | 3    |
| TABLE 1 - Research Studies approved in 2009  | 7    |
| TABLE 2 - Research Studies closed in 2009  | 15   |
| APPENDICES   |      |
| Appendix A - Currently Open Schedule I and II<br>Non-Human & Academic Human Studies            | 21   |
| Appendix B - Currently Open Schedule II<br>Clinical Drug Trial Studies                         | 29   |
| Appendix C - Currently Open Research Studies<br>on the Treatment of Controlled Substance Abuse | 37   |
| Appendix D - Pertinent Sections - California Health and Safety Code                            |      |
| § 11213 - Persons and researches using controlled substances                                   | 39   |
| § 11480 & 11481 - Research Advisory Panel  | 39   |
| § 11603 & 11604 - Attorney General   | 40   |
| § 24172 - Experimental subject's bill of rights  | 41   |
| § 24173 - Informed consent   | 42   |

## SUMMARY OF 2009 PANEL ACTIVITIES

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

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

At the end of 2009, the Panel was monitoring 101 active research projects. Note Appendices A, B, and C for specific listings.

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

Table 1 is a list of the studies approved by the Panel in 2009 and Table 2 is a list of the studies closed by the Panel in 2009.

## SELECTED RESEARCH FINDINGS

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

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

Attention-deficit/hyperactivity disorder (ADHD) - characterized by symptoms of inattention and hyperactivity-impulsivity - is the most prevalent childhood psychiatric disorder that frequently persists into adulthood, and there is increasing evidence of reward-motivation deficits in this disorder.

To evaluate biological bases that might underlie a reward/motivation deficit by imaging key components of the brain dopamine reward pathway (mesoaccumbens). We used positron emission tomography to measure

dopamine synaptic markers in 53 nonmedicated adults with ADHD and 44 healthy controls between 2001-2009 at Brookhaven National Laboratory. We measured specific binding of positron emission tomographic radioligands for dopamine transporters (DAT) quantified as binding potential.

For both ligands, statistical parametric mapping showed that specific binding was lower in ADHD than in controls in regions of the dopamine reward pathway in the left side of the brain. Region-of-interest analyses corroborated these findings. As conclusion, a reduction in dopamine synaptic markers associated with symptoms of inattention was shown in the dopamine reward pathway of participants with ADHD.

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

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

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

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



TABLE 1

RESEARCH STUDIES  
APPROVED IN 2009

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

Table 1 Cont.

PI/ Sponsor

Title of Study / Clinical Drug  
Trial Protocol

Keith Heinzerling, MD, MPH  
UCLA Dept of Family Medicine  
Los Angeles, CA

Pilot Trial of Bupropion versus Placebo for  
Methamphetamine Abuse in Adolescents

Lorin Koran, M.D.  
Stanford University  
Stanford, CA

Functional MRI of D-amphetamine vs.  
Placebo in Obsessive-Compulsive Disorder

Adam Leventhal, Ph.D.  
USC Keck School of Medicine  
Alhambra, CA

Influence of Genes and Emotions on  
medication Effects

Linghui Li, Ph.D.  
APRL/CPMC Research Institute  
San Francisco, CA

An Open-Label Stud to Evaluate the Impact of  
Genetic Variation in CYP2D6 on the  
Pharmacokinetics and Pharmacodynamics of  
Methamphetamine in Healthy Adults

Edythe London, Ph.D.  
UCLA  
Los Angeles, CA

A Study to Assess the Cardiovascular,  
Cognitive, and Subjective Effects of  
Atomoxetine in Combination with Intravenous  
Amphetamine

John E. Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Role of Serotonin in Acute and Subacute  
MDMA Effects

John E. Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

A Phase-I, Two-Stage, Double-Blind,  
Placebo-Controlled, Pharmacokinetics and  
pharmacodynamic Trial of Low Doses of  
Intravenous 6B-Naltrexol (AIKO-150) in  
Opioid-Dependent Subjects

Table 1 Cont.

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

Table 1 Cont.

PI/ Sponsor

Title of Study / Clinical Drug  
Trial Protocol

NIAID/NIH  
Bethesda, MD

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Duloxetine and Methadone for the Treatment of HIV-Associated Painful Peripheral Neuropathy (DAIDS A5252)

OMJSA  
Titusville, NJ

A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate (OMJSA CONCERTA-ATT-3014)

Johnson & Johnson  
Malvern, PA

A Single-Dose Study to Evaluate the Relative Bioavailability of a 100mg tamper-Resistant Prolonged-Release Formulation (TRF) of Tapentadol with Respect to the PRI Prolonged-Release 100mg tablet Formulation Under Fasted Condition in Japanese Healthy Subjects (J&J R331333 PAI 1053)

Johnson & Johnson  
Titusville

A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety, and Tolerability, of Tapentadol Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN) (J&J R331333 PAI 3027)

Table 1 Cont.

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

Table 1 Cont.

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

Table 1 Cont.

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



TABLE 2

RESEARCH STUDIES CLOSED OR  
DISCONTINUED IN 2009

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

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

John Polich, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Marijuana CNS Effects in Low- and  
High-Risk Adults

Steven Shoptaw, Ph.D.  
UCLA  
Los Angeles, CA

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

AcelRx Pharmaceuticals  
Redwood City, CA

A Randomized, Double-Blind, Placebo-  
Controlled, Phase 2 Study to Evaluate the  
Clinical Efficacy, Safety, and Tolerability  
of ARX-F03 Sublingual  
Sufentanil/Triazolam Nanotabs in Patients  
Undergoing an Elective Abdominal  
Liposuction Procedure  
(AcelRx ARX-C-004)

BioDelivery Sciences International, Inc.  
Raleigh, NC

Open-Label, Long-Term Extension Study  
for Treatment of Breakthrough Cancer  
Pain with BEMA Fentanyl  
(BioDelivery FEN-290)

Endo Pharmaceuticals, Inc.  
Chadds Ford, PA

A Double-Blind, Randomized, Placebo-  
Controlled, multicenter Study to Evaluate  
the Efficacy and safety of EN3267 for the  
Treatment of Breakthrough Pain in Opioid  
Tolerant Cancer Patients Followed by a  
12-Month Non-Randomized, Open-label  
Extension to Assess Long-Term Safety  
(Endo EN3267-005)

Table 2 Cont.

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

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Neuromed Pharmaceuticals  
Raleigh, NC

A Phase III, Variable-Dose Titration  
Followed by a Randomized Double-Blind  
Study of Controlled-Release OROS®  
Hydromorphone HCl (NMED-1077)  
Compared to Placebo in Patients with  
Chronic Low Back Pain  
(Neuromed NMT 1077-301)

NextWave Pharmaceuticals  
Research Triangle Park, NC

NWP06 in Treatment of Children with  
ADHD: A laboratory Classroom Study  
(NextWave NWP06-ADD-100)

Ortho-McNeil Janssen Scientific Affairs,  
LLC  
Raritan, NJ

A Randomized, Double Blind, Placebo-  
and Oxycodone Immediate Release (IR) -  
Controlled Study of Tapentadol IR for the  
Treatment of Acute pain Caused by  
Vertebral Compression Fractures  
Associated with Osteoporosis  
(OMJSA R331333-PAI-3021)

Purdue Pharma L.P.  
Stamford, CT

A Multi-center, Randomized, Double-  
blind, Placebo-controlled Study with an  
Open-label Run-in to Assess the Efficacy,  
Tolerability, and Safety of BTDS 10 or  
BTDS 20 Compared to Placebo in Opioid-  
naive Subjects with Moderate to Severe,  
Chronic Pain due to Osteoarthritis of the  
Knee  
(Purdue BUP3025)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Shire Pharmaceuticals, Inc.  
Wayne, PA

A Phase IIIb, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Dose-Optimization, Cross-Over, Analog Classroom Study to Assess the Time of Onset of Vyvanse™ in Pediatric Subjects aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (Shire SPD489-311)

Shire Pharmaceuticals, Inc.  
Philadelphia, PA

A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)



APPENDIX A

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

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

Appendix A Cont.

Principal Investigator

Title of Study

John R. Cashman, Ph.D.  
Human BioMolecular Research  
Institute  
San Diego, CA

Molecular Evolution of Human Cocaine  
Catalysis

Kent S. Chu, Ph.D.  
YJ Bio-Products  
Cordova, CA

Immunochromatographic Test Device for  
THC and LSD

Laura Colin  
Biostride, Inc.  
Redwood City, CA

Panel Approved Research Project

G. Patrick Dauert, M.D.  
UC Davis Medical Center  
Sacramento, CA

Does Oral Methadone Use in Opiate  
Replacement Therapy Prolong the QTc  
Interval?

Mohammad Diab, M.D.  
UC San Francisco  
San Francisco, CA

Comparison of Extended-Release Epidural  
Morphine, PC Epidural Analgesia, & PC  
Intravenous Analgesia for Post-Op Pain  
Management after Post. Spinal Fusion in  
Adolescents

Robert Edwards, M.D.  
UCSF School of Medicine  
San Francisco, CA

Panel Approved Research Project

Aaron Ettenberg, Ph.D.  
UC Santa Barbara  
Santa Barbara, CA

Dopamine Involvement in Opiate and  
Stimulant Drug Reinforcement

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

Appendix A Cont.

Principal Investigator

Title of Study

Edward T. Kisak, Ph.D.  
Fqubed, Inc.  
San Diego, CA

Transdermal Delivery of tetrahydrocannabinol

George F. Koob, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Central Mechanisms of Opiate Reinforcement  
and Dependence

Lorrin Koran, M.D.  
Stanford University,  
School of Medicine  
Stanford, CA

Double-Blind Trial of Acute &  
Intermediate-Term Dextro-Amphetamine  
versus Caffeine Augmentation in  
Treatment-Resistant Obsessive-Compulsive  
Disorder

Kimberley D. Lakes, Ph.D.  
UC Irvine  
Irvine, CA

The Effects of Vyvanse on Brain  
Hemodynamics and Reading

Adam Leventhal, Ph.D.  
USC Keck School of Medicine  
Alhambra, CA

Influence of Genes and Emotions on  
medication Effects

Linghui Li, Ph.D.  
APRL/CPMC Research Institute  
San Francisco, CA

An Open-Label Stud to Evaluate the Impact of  
Genetic Variation in CYP2D6 on the  
Pharmacokinetics and Pharmacodynamics of  
Methamphetamine in Healthy Adults

Marie Lin, Ph.D. R.Ph.  
Lin-Zhi International, Inc.  
Sunnyvale, CA

Lin-Zhi Immunoassay Development Study

Principal InvestigatorTitle of Study

Edythe London, Ph.D.  
UCLA  
Los Angeles, CA

A Study to Assess the Cardiovascular,  
Cognitive, and Subjective Effects of  
Atomoxetine in Combination with Intravenous  
Amphetamine

Sean D. McAllister, Ph.D.  
CPMC Research Institute  
San Francisco, CA

Panel Approved Research Project

James T. McCracken, M.D.  
UCLA NPI  
Los Angeles, CA

An 8-Week, Randomized, Double-Blind  
Comparison of Twice-Daily Guanfacine,  
Once-Daily d-Methylphenidate ER (Focalin  
XR) and the Combination, with a 12 Month  
Open-Label Extension for the Treatment of  
ADHD in Pediatric Subjects Aged 7 to 14  
years

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Is There an Acute MDMA Single Dose  
Withdrawal Syndrome?

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Steady State Kinetics of l-Methamphetamine  
and Validation of Sensitivity of Dose  
Estimation

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Bioavailability and Urinary Excretion of Oral  
L-Methamphetamine

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Interactions of Prazosin and MDMA

Appendix A Cont.

Principal Investigator

Title of Study

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Pilot Study of LSD in Healthy Volunteers

John Mendelson, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

Clinical Pharmacology of  
3,4-methylenedioxyamphetamine (MDA)

Robert Messing, M.D.  
Ernest Gallo Clinic & Research Ctr  
Emeryville, CA

Protein kinase C epsilon (PKCe) in Responses  
to Cannabinoids

Stanley M. Parsons, Ph.D.  
UC Santa Barbara  
Santa Barbara, CA

Panel Approved Research Project

Richard Reznicek, M.D.  
Harbor-UCLA Medical Center  
Torrance, CA

A prospective, randomized, double-blind  
study comparing the efficacy and safety of  
intra nasal fentanyl spray to placebo as an  
analgesic in patients undergoing outpatient  
cystoscopic procedures

Mark Rollins, MD, PhD  
UCSF Dept of Anesthesia  
San Francisco, CA

Supplemental Oxygen: A Reduction in Pulse  
Oximetry Sensitivity or an Increased Margin  
of Safety?

Dorit Ron, Ph.D.  
Ernest Gallo Clinic & Research Ctr  
Emeryville, CA

Signaling Pathways Involved in the  
Mechanism of Action of the Anti-Addictive  
Drug Ibogaine

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

Appendix A Cont.

Principal Investigator

Title of Study

Randall Wong  
Norac Pharma, Inc.  
Azusa, CA

Panel Approved Research Project

Randall Wong  
Norac Pharma, Inc.  
Azusa, CA

Panel Approved Research Project

APPENDIX B

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

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

Appendix B Cont.

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

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Johnson & Johnson  
Malvern, PA

A Single-Dose Study to Evaluate the Effect of Food on the Pharmacokinetics of a Tamper-Resistant prolonged-Release 100mg Tablet Formulation of Tapentadol in healthy Male Japanese Subjects  
(J&J R331333-PAI-1052)

Johnson & Johnson  
Malvern, PA

A Single-Dose Study to Evaluate the Relative Bioavailability of a 100mg tamper-Resistant Prolonged-Release Formulation (TRF) of Tapentadol with Respect to the PRI Prolonged-Release 100mg tablet Formulation Under Fasted Condition in Japanese Healthy Subjects  
(J&J R331333-PAI-1053)

Johnson & Johnson  
Titusville, NJ

A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate  
(OMJSA CONCERTA-ATT-3014)

Johnson & Johnson  
Titusville, NJ

A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety, and Tolerability, of Tapentadol Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN)  
(J&J R331333-PAI-3027)

Appendix B Cont.

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

King Pharmaceuticals R & D  
Austin, TX

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Multiple-dose Study of the Safety and Efficacy of Acuracet TM Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Subjects  
(King K228-08-3001)

Eli Lilly Pharmaceuticals  
Indianapolis, IN

A Fixed-Dose, Randomized, Double-Blind, Placebo-Controlled Study of LY2216684 in Pediatric Patients with Attention Deficit/Hyperactivity Disorder  
(Lilly H9P-MC-LNBF)

Neurologic AIDS Research  
Consortium (NARC) at Washington  
University in St. Louis  
St. Louis, MO

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Methadone and Combination of Methadone and SAB378 in HIV-Associated Painful Peripheral Neuropathy  
(NARC NARC011)

Neuromed Pharmaceuticals  
Conshohocken, PA

A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain  
(NMT 1077-302)

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

Appendix B Cont.

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

QRxPharma  
Chapel Hill, NC

A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)

QRxPharma  
Chapel Hill, NC

A Randomized, Double-blind, Multicenter, Repeat-dose, Comparison of Analgesic Efficacy and Safety of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-008)

QRxPharma  
Chapel Hill, NC

A Randomized, Double-blind Study of The Analgesic Efficacy and Safety of Flexible Dose Q8003 versus Low Dose Q8003 in Patients Who Have Undergone Primary Unilateral Total Knee Arthroplasty (QRxPharma Q8003-009)

Shire Pharmaceuticals  
Raleigh, NC

A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Shire Pharmaceuticals  
Raleigh, NC

A Phase III, Open-Label, Extension,  
Multicenter, Safety and Efficacy Study of  
Lisdexamfetamine Dimesylate (LDX) in  
Adolescents Aged 13-17 with Attention  
Deficit/Hyperactivity Disorder (ADHD)  
(Shire SPD 489-306)

Shire Pharmaceuticals  
Philadelphia, PA

A Phase 4, Double-Blind, Multi-center,  
Placebo-Controlled, Randomized Withdrawal,  
Safety and Efficacy Study of SPD489 in  
Adults Aged 18-55 with Attention  
Deficit/Hyperactivity Disorder (ADHD)  
(Shire SPD489-401)



APPENDIX C

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

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

Appendix C. Cont.

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

## APPENDIX D

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

§ 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

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

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

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

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

Appendix D Cont.

**§ 11480. Cont.**

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to Section 11478.

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

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

**§ 11481.** The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

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

**§ 11603.** The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

§ 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in Section 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

Appendix D Cont.

§ 24172. Cont.

(i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

§ 24173. Cont.

- (2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
- (3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
- (4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
- (5) An estimate of the expected recovery time of the subject after the experiment.
- (6) An offer to answer any inquiries concerning the experiment or the procedures involved.
- (7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
- (8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
- (9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
- (10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.
- (11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

Appendix D Cont.

§ 24173. Cont.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 7, 2010**

**To: Communication and Public Education Committee**

**Subject: Development of Consumer Education Videos**

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At the end of 2009, the Board of Pharmacy worked with the Department of Consumer Affairs and a private vendor to develop a three minute video for consumers about how patients can prevent receiving a medication error. This video is available from the board's Web site.

The board and department were pleased with this video.

Over the prior six months, the board's staff has expressed an interest with the Department of Consumer Affairs in developing additional videos. Meanwhile, the DCA has hired video staff of its own, and thus could produce the video in-house.

Under development as a board/DCA collaboration is development of a new video on the dangers of buying drugs from the Internet. A copy of the draft script is follows this page.

During this meeting, the committee will have an opportunity to comment on the manuscript.

# DCA's TakeCharge video series for consumer education

## *Online Drugs – Do you know what you're getting?*

### **Script**

Version 7/1/2010

**[Note: This is voice-over. We don't see the actor, except his/her hands. All visuals: text on screen (TOS), graphics, and camera directions are in italics]**

*Computer screen: we see a hand on the mouse – see the actor in profile, looking at the screen.*

*Screen shows rogue online pharmacy...*

*[Note to Paul: Fake Pharmacy site should have words like Half Price drugs! Get your order overnite! US licensed doctor. US licensed pharmacist. [Use clip art of smiling pharmacist.]*

We see the fake pharmacy site...

### **Voice Over**

Buying prescription drugs through an online pharmacy site can be fast, convenient and it can be done in the privacy of our own homes.

*Text on Screen ('TOS): Fast, convenient, private*

But many sites ...

—even up to 95% of all online pharmacy sites—

*TOS: 95% of Online Pharmacy Sites Not Licensed*

are not legitimate pharmacies licensed by the state.

Why should this matter to you?

There are a number of sites that sell counterfeit prescription drugs.

*TOS: Counterfeit Drugs*

These are drugs that are oftentimes manufactured outside of the US and out of sight of federal regulators.

# DCA's TakeCharge video series for consumer education

## *Online Drugs – Do you know what you're getting?*

### **Script**

Version 7/1/2010

When you buy prescription drugs from an unregulated site, there is no way of knowing what is really in the drug.

But here are some ingredients that have been found in counterfeit drugs.

*Close up on hand holding a brick being grated....and then hand picks up dust and lets it fall.  
If possible, get a pharmacist's compounder vessel.*

Brick dust.

*Close up on sack of cement mixer, with bag open and hand scoops up some mixer and drops it on table.*

Industrial cement mixer ...

*Close up on box of rat poison, with the pellets being poured out.*

Rat poison ...

*Close up on antifreeze container, being poured into a bottle of children's liquid Tylenol [obscure label name]*

And diethylene glycol, a syrupy poison that is used in antifreeze. It was found in counterfeit children's liquid fever reducer. Several children died as a result of taking it.

Too much of the active ingredient . . .

*Suggestion: we see the contents of capsules being poured out...can we get a slow motion shot of capsule ingredients falling in midair?*

Or too little of the active ingredient...

*Pan table with all the bad ingredients...*

So – what can you do to make sure the prescription drugs you are buying online are safe?

# DCA's TakeCharge video series for consumer education

## *Online Drugs – Do you know what you're getting?*

### **Script**

Version 7/1/2010

Know the “red flags,” the signs that alert you that the site may not be legitimate.

*Close up on screen to customer query form— a name is being typed in ...*

First red flag – no prescription is needed to purchase the drugs.

*Camera scans down the page,*

*We see a form that asks for: Name, Address, State, Zipcode, List any drug allergies patient may have*

Where does it ask for a prescription from your doctor or healthcare provider?

A legitimate site operating within the law will always require you to submit the prescription from your health care provider or provide your provider's phone number, so the pharmacy can confirm the prescription.

*We see a legitimate site where the prescription number is required.*

[\[https://www.familymeds.com/online-pharmacy/new-review-prescription.aspx \]](https://www.familymeds.com/online-pharmacy/new-review-prescription.aspx)

*NOTE: I made up an account at a legit pharm site, we can look at it to copy.*

Another red flag:

*Click into Contact Us – page has an 800 number and an email address.*

Can you find a physical address on the website?

*We see a post office box. PO Box 83567  
Los Angeles, CA 90..*

Not a post office box number, but a street address in the United States?

While a street address doesn't guarantee the site is legitimate, if you don't see one, beware.

# DCA's TakeCharge video series for consumer education

## *Online Drugs – Do you know what you're getting?*

### **Script**

Version 7/1/2010

How do you know where this business is located? What if you have a problem or complaint about the medications you've received?

Legitimate pharmacies will have a street address on their website.

But there's more that you can do to ensure the medications you are buying are genuine.

Look for the VIPPS seal.

*Close up on VIPPS seal.*

VIPPS stands for Verified Internet Pharmacy Practice Site.

*Show NABP.net site on screen*

And it's the seal of approval from the National Association of Boards of Pharmacy, which represents state boards of pharmacy. State boards are responsible for licensing and regulating pharmacies and pharmacists in each state.

Some sites have other types of seals:

*Close up on Verisign and McAfee safe sign*

But these don't have anything to do with whether a site is run by a licensed pharmacy. Always make sure the site you are using has this seal.

*Again, show VIPPS seal.*

Don't take risks with your health.

Counterfeit drugs with these kinds of ingredients ...

*Fast montage of brick dust, cement mixer, rat poison and antifreeze*

Could put you *in* the hospital rather than help you get better.

# **DCA's TakeCharge video series for consumer education**

## ***Online Drugs – Do you know what you're getting?***

### **Script**

Version 7/1/2010

*Logo of Pharmacy Board*

This message is from the California State Board of Pharmacy

*DCA logo*

and the Department of Consumer Affairs

*TakeCharge Logo*

Take Charge of your health care! Know your rights as a consumer.

*Have thumbnail of Right Drug, Right Dose [link to video]*



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 6, 2010**

**To: Communication and Public Education Committee**

**Subject: Update and Discussion on Consumer Fact Sheets**

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Several years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of the materials.

Initially the project was initiated with UCSF and their Center for Consumer Self-Care. Over the course of several years, approximately nine fact sheets were developed; however, funding issues prevented UCSF from continuing to do the project without a stipend from the board.

Next, the board decided to invigorate this program by offering other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and then have the developed fact sheets reviewed by an expert.

Over a period of some months, representatives from other California pharmacy schools expressed interest in this project for their students. The board then directed staff to proceed with the committee's recommendation for development of a template for future fact sheets, and work with the schools of pharmacy to initiate this intern project.

Earlier this year, board staff again contacted each of the California schools of pharmacy to initiate the project. We currently have four schools who have confirmed their participation.

A copy of the materials sent to the schools follows this page.

# California State Board of Pharmacy Consumer Fact Sheet Template/Guidelines

## PURPOSE

To provide quick and summary information about relevant health topics in a consumer-friendly format. Fact sheets are distributed to the public at community outreach events throughout California, and posted on the Board of Pharmacy (BOP) public web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). The fact sheets encourage discussion between consumers and their pharmacists who serve as health care providers.

## READING LEVEL AND SUGGESTED AUDIENCE

Health literacy and limited English proficiency of some consumers should be considered when drafting proposed language. Identify Flesch-Kincaid Grade Level to determine reading level of proposed wording by using Microsoft Word in "Tools, Options, Spelling & Grammar, and Show Readability Statistics." Ideal Flesch-Kincaid Grade Level is 8<sup>th</sup> Grade, but should not exceed 10<sup>th</sup> Grade Reading Level.

## TEMPLATE

Each proposed fact sheet must contain the following elements.

- Title
- General information on the health care topic
- Facts, or in some cases, common misunderstandings/myths about the topic
- Questions that consumers can discuss with their pharmacists about the topic
- Footnotes documenting origin of information referenced; applicable resource materials should be attached and references should be cited

## MAXIMUM LENGTH

Word count should not exceed 350.

## FORMAT

Submit draft wording in plain text format or Microsoft Word 12 point font. BOP will utilize a graphic designer to incorporate approved wording into applicable final format.

## Potential Topics for Consumer Fact Sheets

1. Different dosage form of drugs – ability for patients to request a specific type of product (for example, liquid or capsule) that would best fit needs of patients.
2. Flu shots – who should get them; when/where to get them; new strains of flu
3. Teens and abuse of prescription medicines
4. Accidental drug overdoses – dangers and ways to prevent
5. Medication errors – prevention
6. Steroids – warnings, precautions
7. Driving while taking prescription medicines or over-the-counter (OTC) medicines
8. Headaches – danger of taking too many OTC pain relievers for headaches
9. Hormone replacement therapy – synthetic or bioidentical; questions to ask
10. Poison control issues
11. Asking for drug product information and labels in your native language – new requirements in California
12. Cough/cold medicines and addiction issues, specifically dextromethorphan
13. Cough/cold medicines for children – precautions, FDA warnings
14. Rx (prescription) medicine labels – reading and understanding
15. OTC medicine labels – reading and understanding
16. Dietary Supplement labels – reading and understanding
17. Consumer reporting of adverse drug events – based on FDA advisement, “Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action.”

18. Taking medicines as directed – tips on how to take medicines safely
19. Questions to ask about a condition or medicine – cardiovascular disease
20. Questions to ask about a condition or medicine – depression
21. Questions to ask about a condition or medicine – arthritis and pain
22. Preventing disease – regular checkups, screenings, what Medicare offers
23. Childhood illnesses and conditions – head lice
24. Childhood illnesses and conditions – fevers
25. Drug-drug Interactions
26. Medicare Part D Prescription Drug benefits
27. Medication Therapy Management – what is it, and how your pharmacist can help
28. Drinking alcohol and taking medicines – dangerous interactions
29. Credible sources on the Internet – learning more about your medicine
30. Asthma – safe use of inhalers
31. Checking your blood pressure
32. Tips for parents – read the label, proper doses (i.e., teaspoons vs. tablespoons), and more medicine is not necessarily better
33. Allergies to medicines – what to look for and what to do; reading labels before purchase re: inactive ingredient sections; consumer reports to FDA (MedWatch)
34. Immunization schedules (pediatric) – what schools require
35. Immunization schedules (adult)
36. Immunizations – information regarding pharmacies that provide immunization services



BE AWARE & TAKE CARE:  
Talk to your pharmacist!

# Measuring Liquid Medicine

**Never guess the  
dose -- if you  
don't know, ask  
your pharmacist!**

It's important to measure liquid medicine accurately in order to get the right dose. Liquid medicine sometimes comes with a measuring device like a cup, spoon, or dropper. Be sure to use the right device in order to get the right dose.

Check the markings carefully on the measuring device. Most liquid medicine is measured by teaspoon (tsp) or milliliter (mL) or cc.



1 mL = 1 cc

2.5 mL = 2.5 cc = 1/2 teaspoon (tsp)

5 mL = 5 cc = 1 tsp

15 mL = 15 cc = 3 tsp = 1 tablespoon (tbl or Tbsp)

30 mL = 30 cc = 2 Tbsp = 1 fluid ounce (oz)

Using kitchen silverware instead of a measuring device that comes with a medicine can result in the wrong dosing -- too much or too little of the medicine. For example, a large kitchen spoon can hold twice as much liquid as a small kitchen spoon. Use the measuring device provided with the medicine instead of kitchen silverware.

If your liquid medicine doesn't come with a measuring device, ask for one at the pharmacy. Some of the most common measuring devices include:



dosing cup



measuring spoons



dosing spoon



dosing syringe

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Be sure to measure liquid medicine at eye level, and never guess at the dose. Use the dose shown on the prescription label. This is especially important when giving liquid medicine to children.

Ask your doctor or pharmacist if you have any questions about measuring liquid medicine.



## *Ever Miss a Dose of Your Medicine?*

*... here are some tips*

**FACT:** Many people miss taking one or more doses of their medicines.

**FACT:** Some people think they can make up for the missed doses by doubling up on their medicines.

**FACT:** Doubling up on your medication can cause serious, life-threatening side effects.

### *It can happen like this...\**

Mrs. Chase has been taking the same medicine for the last 3 months. Recently she has been very busy with work and other pressures, and she accidentally missed a dose of her medicine. She realized that she had skipped her regular dose, so she took two capsules to “make up for it.” A few hours later Mrs. Chase startled her coworkers...her eyes were moving back-and-forth, her speech was slurred. She staggered and stumbled when she tried to walk, became drowsy, vomited, had involuntary muscle twitches and then became unconscious. She was rushed to the emergency room.

*\*Based on a case series review on a commonly used prescription medication.*

### *If you missed your regular dose of medicine, here's what to do:*

1. Do not just double up on your medicine.
2. Read the drug information that was given to you when you got your medicine,. Some medicines come with directions on what to do if you miss your regular dose.
3. If you are still not sure, call your **pharmacist** or **doctor** for advice.
4. Work out a plan for your next dose with your pharmacist or doctor.
5. Talk with your pharmacist or doctor about any concerns you might have.

**HINT:** *Keep the phone numbers of your pharmacist and doctor in your wallet.*





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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 6, 2010**

**To: Communication and Public Education Committee**

**Subject: Public Education Materials Under Development**

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Publications under development, review or revision are:

- Revisions to an existing publication: "What you Should know Before Buying Drugs from Foreign Countries or Over the Internet," last revised in 2007, is targeted to be revamped into three publications – "Bringing Prescription Drugs into the Us From Foreign Countries," "Counterfeit Drugs" and "What You Should Know Before Buying Prescription Drugs on the Internet."

Copies of the old brochure and the three fact sheets are provided in this tab section for your quick review and comment.

- Later this fall, we hope to release new fact sheets developed by California interns.
- For board licensees, we have the following items being developed:
  - Questions and answers on the board's compounding regulations, following a discussion held at the June 2010 Enforcement Committee, and an ongoing number of questions being asked of the board regarding the compounding regulations.
  - Development of separate fact sheets from two articles published by the CPhA and CSHP in their newsletters -- on "The Pharmacists Recovery Program" and "Becoming a Licensed Pharmacist in California" (both attached).
- Development of a public education and outreach campaign on the patient-centered prescription container labels is needed. Staff from the Department of Consumer Affairs Press Office will attend this meeting to assist the board in this.



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## What You Should Know Before Buying Drugs From Foreign Countries or Over the Internet



September 2007

### Purchasing Prescription Drugs from Foreign Countries and Reducing Drug Costs

The prices of prescription drugs are high. Some patients go without food in order to purchase their medications or reduce the quantity of prescription drugs they are supposed to take to make a supply of medication last longer. Other patients simply don't purchase medication prescribed for them because it is too expensive.

Today, many patients are seeking lower priced drugs from nontraditional sources – places other than their local pharmacies. Some patients are purchasing prescription drugs from foreign countries, typically Canada or Mexico, because the prices are lower. Other patients are purchasing drugs online, from companies they do not know. Some patients purchase these drugs online without a prescription written for them by a health care provider.

Can you purchase drugs for lower prices? What should you know about purchasing drugs from foreign countries? What about purchasing drugs over the Internet? Do you really need a prescription before you obtain prescription drugs? The following information may help you in making wise choices.



### Frequently Asked Questions

**Q** Can I bring prescription drugs I buy outside the USA into the country legally?

**A** The Federal Food and Drug Administration

(the FDA) regulates prescription drugs made in the USA. Under federal law it is illegal for anyone except a drug manufacturer to import prescription drugs into the USA. There are strict requirements on drug manufacturers who import drugs.

These import laws were established for consumer protection – so that the only drugs available in the USA have been made by companies approved by the FDA, and have been manufactured at locations inspected by the government to produce the specific drugs. These laws are important for consistency – and uniformity – so that a specific drug has the same ingredients, strength, and will act in the same way regardless of who manufactures the drug or when the drug was made.

“Over the Counter Drugs” (or OTC drugs) are the drugs that you can buy without a prescription (for example, aspirin or cold medicines). Consumers can go to a store and select OTC drugs themselves.

“Prescription drugs” means those drugs that are considered so dangerous that they may be sold only after a health care provider (for example, a doctor or nurse) has examined a patient and ordered the drug for the patient. The order is typically called a prescription. Consumers cannot legally purchase the prescription drugs without an order or prescription from a health care provider who has examined the

This is important because it means the strength of the drug will be the same for every dose.

## Frequently Asked Questions (continued)



Such consistency in your medication is important for health care providers to treat you, and for you to receive the drug treatment planned and prescribed for you.

However, the FDA does not always enforce provisions for importing prescription drugs. Sometimes prescription drugs that are not FDA approved for sale in the USA are allowed in the USA on “humanitarian grounds” to treat serious conditions such as AIDS before the drugs are approved for use in the USA. Also, in the past the FDA has not enforced provisions against those who obtain a 90-day supply of medication for their personal use.

**Q** Why are prescription drug prices lower in other countries than here at home?

**A** There are a number of reasons. Among them: some governments set maximum drug prices for prescription drugs which holds down drug prices. In the USA, the government does not set maximum prices overall for prescription drugs. Also, typically the costs of researching and developing new drugs are passed on to American customers as part of a drug’s price.



**Q** Why are prescription drug prices different at the local pharmacies in my neighborhood?



**A** There are a number of reasons – among them:

- ♦ *Volume discounts* -- some pharmacies can purchase drugs from wholesalers at lower prices than other pharmacies, based on the quantities of drugs sold or whether the pharmacy is part of a buying group with other pharmacies.
- ♦ *Rebates* – money is sometimes paid to pharmacies by drug manufacturers for sales of particular drugs. Not all pharmacies may get these rebates.
- ♦ *Overhead* -- charges that cover the expenses for the operations of the pharmacy and the services provided by the pharmacy.

**Q** Are the drugs I get from a foreign country lower in quality or strength?

**A** The drugs you obtain this way may be of the same quality as those you get in the USA – the prescription drugs may even have been manufactured here. However, you cannot tell what the drug is just by looking at it. If the drugs are counterfeit, are of a different strength, have been stored improperly or are not really the drugs the label says they are, a patient using such drugs could suffer serious health problems.

## Is the Internet a good way to purchase prescription drugs?

Sometimes. Be cautious and careful.

- ♦ Make certain you are dealing with a pharmacy, and not another type or unknown form of drug supplier. Some businesses operating what appear to be Internet pharmacies are not pharmacies at all.
- ♦ Learn where the company is located – it may be located outside the USA in a country you know little about and where there is little government regulation of drug supplies.
- ♦ Beware if you do not need a prescription to purchase prescription drugs. The requirement for a prescription from a health care provider who has examined you is a legal requirement that exists to protect your health.
- ♦ Be careful if you must provide personally identifiable information (health information, social security number, credit card numbers) -- identity theft is a growing problem and you may not know to whom you are providing this sensitive and important personal information.
- ♦ Evaluate all costs for purchasing the drugs this way – it may not be cheaper after all.
- ♦ Purchase prescription drugs only from sites that are certified by national organizations – like the National Association of Boards of Pharmacy VIPPS seal on the Web site (the California Board of Pharmacy can help you with this information).
- ♦ Advise your health care provider if you obtain prescription drugs this way.

## Before buying drugs from a foreign country or over the Internet, carefully consider your options.

- ♦ Beware of any changes in your health after taking any drug obtained this way. If there is a change or if you feel differently, talk to your health care provider.
- ♦ Consider whether you want to give a credit card number to a company that is making these purchases for you.
- ♦ Determine the handling and other extra fees you pay for imported prescription drugs. How much will you really save?
- ♦ Ask any company that orders prescription drugs for you what it will do if there is a problem with the medication you receive.
- ♦ Keep your health care provider informed.

CALIFORNIA STATE  
BOARD OF PHARMACY



BE AWARE & TAKE CARE:  
Talk to your pharmacist!

For further assistance, please contact:

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Or visit us on the web at:  
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# Bringing prescription drugs into the U.S. from foreign countries

**CAUTION:** If you're hoping to save money by buying prescription drugs in a foreign country and bringing them back to the United States, know the rules.

Under federal law, it is illegal for anyone except drug manufacturers to import into the U.S. any prescription drug that has not been approved for sale by the Food and Drug Administration (FDA).

In almost all cases, individual citizens are prohibited from importing prescription drugs into the U.S. However, the FDA provides guidance for "Coverage of Personal Importations" of unapproved new drugs.



The FDA may allow an individual entering the U.S. to import a three-month supply of an unapproved drug, but only if the following conditions are met:

- The intended use of the drug is for a serious condition for which effective treatment may not be available domestically, either through commercial or clinical means
- The drug will not be distributed commercially by the importer
- The product is considered not to represent an unreasonable risk
- The individual seeking to import the drug affirms that the drug is for the patient's own use and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for continuation of treatment begun in a foreign country

The FDA regulates prescription drugs made in the U.S., and is also responsible for pharmaceutical admissibility determinations.

If you have any questions about whether a specific drug may be imported into the U.S., contact the FDA Division of Import Operations and Policy directly at (301) 443-6553.

You can get more information from the FDA regarding the importation of prescription drugs at [www.fda.gov/ora/import/traveler\\_alert.htm](http://www.fda.gov/ora/import/traveler_alert.htm).

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# Counterfeit Drugs

Counterfeit drugs are fake or 'copycat' medicines, deliberately mislabelled with respect to their identity or source. Counterfeit drugs may look like the real thing, but have too much (or not enough) of the medicine you need.

The fraudulent practice of making counterfeiting drugs can apply to (both) brand name and generic products. If you take counterfeit drugs, you may have an allergic reaction or your medical condition can get worse.

Your risk of buying counterfeit drugs increases by buying medicine on Internet websites because there's no face-to-face contact between buyers and sellers. According to the World Health Organization, 50% of medicines bought on the Internet *from sites that conceal their physical address* are counterfeit.

Counterfeit drugs may be contaminated, or contain the wrong active ingredient, or the wrong *amounts* of an active ingredient. They may contain no active ingredients at all.

## IMPORTANT INFORMATION:

- Buy medicine only from U.S. state-licensed pharmacies. Find your state's contact information from the National Association of Boards of Pharmacy (NABP) at [www.nabp.info](http://www.nabp.info). For California, go to [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and click on 'Verify a License' to determine whether the pharmacy is currently licensed.
- Beware if the medicine tastes (or looks) differently than the last time you had the prescription filled; check the appearance of the medicine including color, texture, and shape; pay attention to altered containers or changes in the packaging.
- Check containers for broken seals or changes on the label. If you suspect the drug is counterfeit, contact the pharmacy where you bought the medicine, and be sure to talk to your doctor. Also, notify the Food and Drug Administration by calling (800) FDA-1088 or go to [www.fda.gov/cder/consumerinfo/counterfeit\\_text.htm](http://www.fda.gov/cder/consumerinfo/counterfeit_text.htm).
- Prescription drugs are considered so dangerous they may be sold only after a health care provider (for example, a physician) has examined the patient and ordered a drug for the patient. The 'order' is typically called a prescription. **NOTE:** It is illegal to dispense prescription drugs without a valid prescription.
- Beware of Internet websites offering to prescribe medication based only on a questionnaire -- you may receive an incorrect diagnosis or receive drugs that are inappropriate for your use.

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BE AWARE & TAKE CARE:  
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# What you should know before buying prescription drugs on the Internet

You may be tempted to buy prescription drugs using an Internet website, but be careful, and know your source. Buying prescription drugs on the Internet from an unknown source increases the risk of receiving a drug that is contaminated, diluted, or repackaged to show the wrong expiration date.

Check to see if the pharmacy's website contains the Verified Internet Pharmacy Practice Sites (VIPPS™) seal. A VIPPS™ seal means the website is a licensed pharmacy where FDA-approved medicines can be bought.



## TIPS TO CONSIDER

- Beware if no physical address of the pharmacy is provided on the pharmacy's website, as it could be located outside the U.S.
- Reputable Internet pharmacies will require a prescription from your doctor or other health care professional that is licensed in the U.S.
- Be careful if asked to provide personally identifiable information like a social security number, because of the risk of identity theft.
- Evaluate all costs to purchase on-line. With shipping, handling, and other costs, it may not be cheaper than buying your prescription drugs at a local pharmacy.
- Beware of changes in your health after taking a drug purchased on-line and if you feel differently, talk to your health care provider.



- Ask what the Internet pharmacy will do for you if you have a problem with the medication. Legitimate website pharmacies provide consumers with consultations with a licensed pharmacist, like in traditional storefront pharmacies.

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# The Pharmacists Recovery Program

## of the California State Board of Pharmacy

by the Staff of the California State Board of Pharmacy

In 1985, legislation became effective creating the Pharmacists Recovery Program (PRP). This legislation requires the California State Board of Pharmacy to seek ways to identify and rehabilitate pharmacists and interns whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety.

The law requires the board to contract with one or more employee assistance programs to administer the PRP. Currently the board contracts with Maximus to provide the program. The parameters for the program are provided for in California Business and Professions Code sections 4360-4373.

Today, the program is open to interns and pharmacists, but not open to other board licensees such as pharmacy technicians and designated representatives.

As required by California law, the

program fulfills two distinct functions. The PRP serves as a monitoring program to which the board may refer pharmacists and interns, and under which they can participate in recovery while being monitored to ensure public safety. Additionally, the PRP is also a confidential source of treatment for pharmacists and interns who enter the program on a voluntary basis and without the knowledge of the board.

Regardless of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Once the board learns that a pharmacist or

intern may be a candidate for the program – typically at the early stages of an investigation – board policy is to encourage the licensee's entry into the PRP rather than wait until the completion of the investigation. This is most often done by a board inspector who will refer the pharmacist or intern informally into the PRP at the time an investigation for self use is initiated. While the choice to contact the program is a voluntary one for the pharmacist or intern under investigation, this early intervention assists the licensee in recovery, but more importantly protects the public. Early intervention and referral results in the pharmacist or intern initiating treatment and being monitored while the case is being investigated. Meanwhile, the board will continue to complete the investigation, which may result in formal discipline mandating participation in the PRP, or in some cases license revocation.

All participants entering the PRP are evaluated by a licensed clinician. The initial evaluation identifies the nature and severity of the problem. Initial recommendations are made regarding the treatment and an initial treatment contract between Maximus and the participant is created based on the

## While ensuring licensees afflicted with mental illness or chemical dependency are treated and rehabilitated so they can return to the practice of pharmacy safely, this cannot be done at the expense of the board's mandate to protect the public.

recommendations. Failure to follow the signed treatment contract can result in the participant being reported to the board as a public risk. At this point, the board initiates or accelerates the investigation.

The treatment contract for a chemically dependent participant typically includes total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance each week at 3-5 self-help groups such as Alcoholics Anonymous and/or Narcotics Anonymous and at least 1-2 additional support groups. The support groups are conducted under the guidance of a licensed clinician and are comprised of health care professionals in recovery. These support groups serve as a forum for a health care professional to discuss recovery and may be used to confront a participant who may be acting inappropriately or who is not embracing recovery.

Random body fluid testing is established at frequent intervals to ensure sobriety. Failure to maintain sobriety results in an immediate cease to practice even for voluntary participants under terms of the Maximus contract (to protect the public). Many times such relapse results in referral to a 30-90 day residential treatment program. Upon completion of this residential treatment, outpatient treatment is typically required in addition to support group attendance and attendance at Alcoholics Anonymous and/or Narcotics Anonymous meetings.

The Pharmacy Review Committee (PRC), a committee comprised of senior board staff, the contract manager, and a supervising inspector, evaluate all board mandated participants' progress in the program every quarter. Through these meetings and reports, and from board inspections and reports, the PRC recommends when it is appropriate for the participant to return to work; but the board's executive officer must sign off on every change. The participant's contract will typically contain pharmacy practice restrictions (e.g., the participant must work with another pharmacist at all times, cannot supervise interns, serve as a

pharmacist-in-charge). Prior to returning to work the participant must designate a work site monitor — typically a pharmacist, who is in a supervisory capacity or at least one management step above the participant. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the PRC members. Monitoring and abstinence are important components of the program.

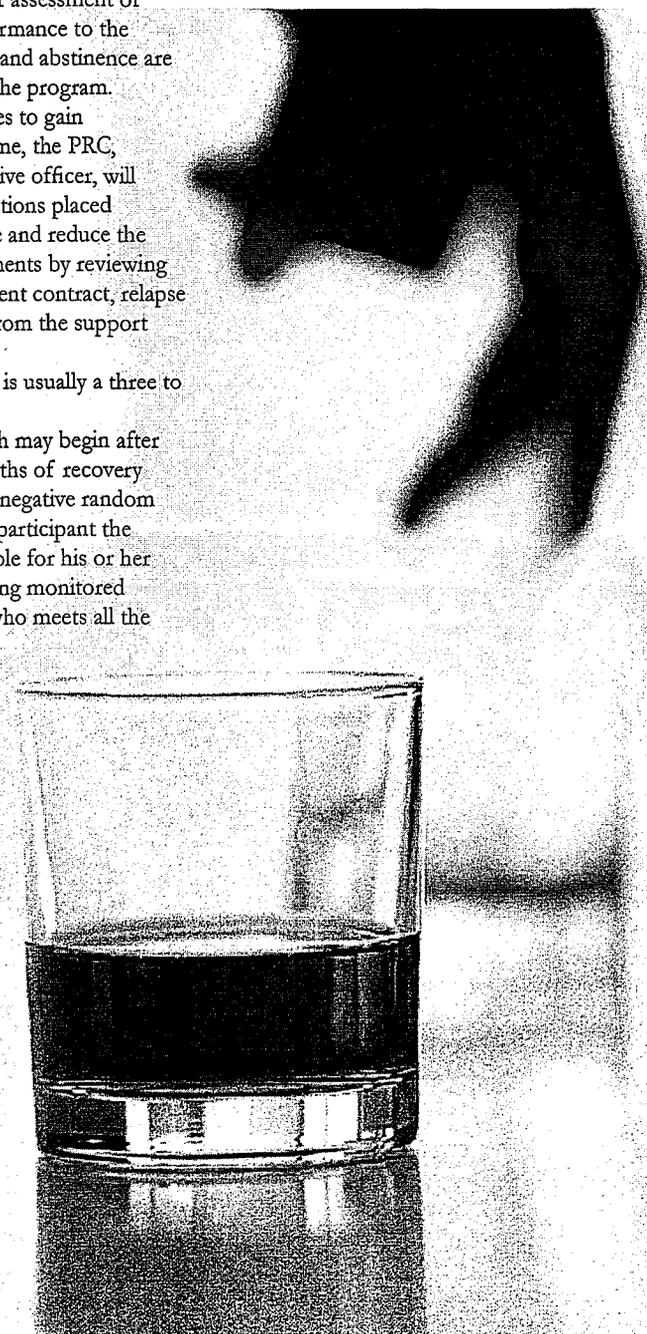
As a participant continues to gain strength in recovery over time, the PRC, with approval of the executive officer, will gradually remove the restrictions placed on the pharmacist's practice and reduce the treatment contract requirements by reviewing compliance with the treatment contract, relapse history, and seeking input from the support group leader.

Participation in the PRP is usually a three to five year commitment.

A transition phase, which may begin after at least 24 consecutive months of recovery and a consistent history of negative random body fluid tests, allows the participant the opportunity to be responsible for his or her own recovery while still being monitored by the PRP. A participant who meets all the criteria set by the PRC for completion and who has demonstrated that he or she is rehabilitated will be successfully completed from the PRP after completing this transition phase.

The board is responsible for public protection first and foremost. While ensuring licensees afflicted with mental illness or chemical dependency are treated and rehabilitated so they can return to the practice of pharmacy safely, this cannot be done at the expense of the board's mandate to protect the public.

The first steps to entering the program require the pharmacist or intern to contact Maximus — to do this, a pharmacist or intern must call 1-800-522-9198. Calls to Maximus are confidential. There are costs a participant must pay for being in the PRP. ☎



# Becoming a Licensed Pharmacist in California

## *An Insider's View*

■ Virginia Herold

Executive Office, California State Board of Pharmacy

The California State Board of Pharmacy licenses pharmacists in California. The goal of licensing is consumer protection: the board is required to ensure that before practicing pharmacy, every applicant meets the minimum requirements. Once proof of achievement of the requirements is provided to and approved by the board, the board issues the individual a pharmacist license.

Pharmacy is regulated at the state level, so states have their own licensure requirements, although most states have similar requirements. Each requirement has a purpose. The requirements themselves have their origin in California statutory laws (enacted by the Legislature) or in regulations (rules promulgated by the board).

For many applicants, the process will take four to five months. For others it will take six months, and for a few, longer than six months. Most applicants can take steps to minimize the timeframe required to become licensed to the shorter end of the range. This article describes these steps.

Here are the basic components (note: please use the directions for the online examination application to provide you with the specifics of each component). The more complete your application is when you submit it, the shorter the process will be for you.

### I. Becoming Eligible to take the Examinations

1. **Education:** each applicant must be either:
  - A graduate of an ACPE-accredited school of pharmacy, or
  - If a foreign-educated pharmacist, certified by the Foreign Pharmacy Graduate Education Committee.
2. **Experience:** each applicant must provide proof of experience working as an intern pharmacist or if licensed in another state, experience as a pharmacist. Satisfactory evidence of experience must be one of the following:
  - 1,500 hours of intern experience provided on affidavits available from the board if registered in California as an intern.
  - 1,500 hours of intern experience earned as a pharmacist intern in another state - these hours must be certified by the board of pharmacy in the state where the hours were earned.
  - Proof of licensure as a pharmacist in another state for one year – this requires a license certification from the board of pharmacy in the state where the individual is licensed.
3. **Criminal Background Check:** All pharmacist applicants must undergo a criminal background check by submitting finger-

prints for evaluation by the California Department of Justice and Federal Bureau of Investigation. Even if you have previously submitted prints to the California board for an intern or pharmacy technician license, you must submit new prints with the classification of "pharmacist" listed on the fingerprint form. There are two ways to submit fingerprints:

- If you are located in California, you must submit prints via LiveScan. This is faster, and the California Department of Justice is insistent that LiveScan be used for those residing in California.
  - If you are outside California, request that the board mail you fingerprint cards. You need to submit two cards along with a separate fee (made payable to the board).
4. **License Verification:** we require a license verification from every state in which you are licensed as a pharmacist. The state boards of pharmacy in the respective states need to provide these certifications.

### II. Being made Eligible for the Examinations

Once the board has a complete application, the board will make you eligible to take the CPJE and NAPLEX exams. We will send you a letter notifying you that you are "eligible," and how to schedule your CPJE and NAPLEX exams. You can take the exams in any order.

- The board does provide some leeway for fingerprint clearances: if we have proof you have submitted prints for a pharmacist license, we will make you eligible without having the background clearances (however, you will not be licensed until we receive the clearances).
- If you passed the NAPLEX after January 1, 2004, you will not need to retake this examination if NABP can transfer the score to California. Contact NABP ([www.nabp.net](http://www.nabp.net)) for more information on how to share prior NAPLEX scores with California.
- Unless we have a quality assurance review (see below) underway for the CPJE, we will mail the scores to you typically within 14 days of when you take the exams.

### III. Becoming Licensed

After the board has the two passing scores on the required examinations, the board will send you a green sheet titled "Request for Issuance of Pharmacist License." You will be asked for a license fee and advised of any deficiencies remaining in your application. Typically the only deficiencies at this stage are results to the background clearances. If you believe that you have already

corrected the deficiency, use the "Contact Us" feature from the board's website to email us or attach a note to the green sheet when you return it to the board.

We try to process these applications very quickly. The fastest way to know you are licensed is to use the license verification feature on the website ([http://www.pharmacy.ca.gov/verify\\_lic.htm](http://www.pharmacy.ca.gov/verify_lic.htm)) and checking your name. Once your name appears as a licensed pharmacist, you are licensed. California law provides that verification of licensure from the website is proof you are licensed. You will receive a green, wallet-size license in about 8 weeks (another agency prints and mails these for the board). The large wall license will be mailed within four months.

### TIPS for faster and smoother processing, remember:

1. Use one of the processes we suggest for verifying that the board received your application.
2. Status checks are a problem for the board to perform. It diverts limited staff away from processing activities to simply answering a question for someone. We will not generally respond to status inquiries on applications that are less than 60 days old with the board. Instead we direct staff to process applications. Please be patient – and use a technique listed elsewhere in this article to make certain you know we received your application.
3. However, there are times when applicants need to reach us. Use the appropriate email address under "Contact Us" on the website. Certainly email the board if it has been more than 60 days, and you have heard nothing from the board – this is a problem you need to call to our attention. Also, if it has been more than 30 days after you believe your deficiency has been corrected, contact us.
4. If you receive a letter advising you that the board is missing some items (what we call a "deficiency letter") – this truly means we do not have the listed items. To get through the system faster, you need to provide the item, even if you may think we already have it. So what is most often missing?
  - Transcripts from colleges with the pharmacy degree posted (these must come directly from the school of pharmacy to the board). Oddly, some colleges do not post the PharmD degree to transcripts until 2-3 months after graduation.
  - Fingerprint clearances are sometimes a problem (we run both federal and state background checks). Sometimes we need to ask applicants to resubmit prints because something is preventing the board from receiving the documentation; the board will contact you if additional information is required.
  - Intern hours are missing or less than the 1,500 hours required.
5. Make certain your name matches identically on your government identification, with your social security card and with your name of record that you file with the board (this is the name that will appear on your pharmacist license). Identically

means identically (see the board's website for more information). Resolving name conflicts is the one area where you should not wait 60 days before resolving the problem.

6. The board periodically conducts quality assurance reviews of the CPJE. When this occurs, no CPJE scores are released until the assessment is completed. The board makes every effort to release scores as soon as we can, but a quality assurance check usually runs 2-3 months or until approximately 400 individuals take the test. We know this is frustrating, but it is necessary. We post this information on the website.
7. Background checks - if you have a prior conviction, you need to disclose it in the required place on the application and describe it fully. (You need to do this if you have reported the conviction on prior applications.) Even if you think a conviction has been expunged or set aside and dismissed, the clearance check usually picks up these records. If you state you have no convictions and yet a background check shows you do, this will become an "enforcement issue." Enforcement issues will delay the processing of your application or issuance of a license until all enforcement matters are resolved (typically this adds at least two months).

### What can you do?

1. Submit as complete an application as you can. This means you should submit in one package:
  - All required application forms
  - The required fee
  - Proof of at least 1,500 hours of intern experience
  - Verifications of pharmacist licensure from all states in which you are licensed
  - LiveScan Receipt showing submission of your fingerprints or if you are out-of-state, enclosing the fingerprint cards and additional processing fee.
2. How to verify the board has received your application:
  - Enclose a self-addressed, stamped post card, or simply an envelope addressed to you with your application package. Board staff will mail these to you when the board receives your application – so you know we have your application.
  - Check to see if the bank has cashed your check. The board cashes all checks it receives very quickly – within two working days of receipt. If the check has been cashed, we received your application.
3. Contact us if it has been more than 60 days since you submitted your application and you have heard nothing from the board, or more than 30 days since you have taken steps to correct a deficiency and you have had no response from the board.

The board wants all qualified applicants to become licensed as quickly and effortlessly as possible. Use the information above to aid you in getting through the process as expediently as possible. ♦



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 6, 2010**

**To: Communication and Public Education Committee**

**Subject: Future Assessment of Public Education Materials**

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As the board begins the fiscal year, this would seem a good time for this committee to assess and identify its public education materials and determine priorities for the next year or so. The outcome of this evaluation needs to be blended into the board's strategic plan eventually.

The board's has one part-time staff person assigned to this function. Recently this part-time staffer has been reassigned to report disciplinary data to the Health Practitioner Data Bank. A retired annuitant develops the board's newsletter *The Script* twice annually. The executive officer and other staff prepare periodic reports to the department, administration, legislature and public (e.g., Addressing Drug and Device Recalls in Hospitals, SB 472's Implementation Report to the Legislature, Board-Sponsored Legislation Report, Annual Report).

The committee may want to designate one or two board members to work with staff on this assessment and bring the report back to the committee for a thorough discussion.

A copy of the consumer education materials available from the board, as listed on the board's Web site, follows this page.

# DEPARTMENT OF CONSUMER AFFAIRS BOARD OF PHARMACY

## Publications

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- [Addressing Drug and Device Recalls in Hospitals \(PDF\)](#)
- [Antibiotics - A National Treasure \(PDF\)](#)
- [Applications and Forms](#)
- [Consumer Fact Sheet Series](#)
- [Consumer Tips](#)
- [Department of Consumer Affairs One Stop Search for Documents](#)
- [Disciplinary Guidelines \(PDF\)](#)
- [Educational Materials](#)
- [Emergency Contraception Information](#)
- [Enforcement Actions and Policies](#)
- [Filing a Complaint \(PDF\)](#)
- [Medicare Part D Information \(PDF\)](#)
- [Health Notes \(PDF\)](#)
- [NCPIE - Background Information on New Drug Facts Label \(PDF\)](#)
- [NCPIE - New Drug Facts Label](#)
- [Notice to Consumers](#)
- [Patient Consultation](#)
- [Patients' Bill of Rights](#)
- [Pharmacist Fact Sheet](#)
- [Preserve a Treasure](#)
- [Public Disclosure Policy](#)
- [Registrant letter regarding electronic DEA 106 form update](#)
- [Reports](#)
- [Request a Publication](#)
- [Request Fingerprint Cards](#)
- [The Script Newsletter](#)

## Pharmacy Law with Rules and Regulations

[California Pharmacy Law and Index \(PDF\)](#)

California Pharmacy Law is available for purchase from [LawTech Publishing Co., Ltd.](#)

[Table of Contents](#) of the **California Pharmacy Law** with links to the sites where you can view the text of the various sections. Also included are selected sections of the Health and Safety Code.

**The Script Newsletters (PDF)** [Index of Newsletters from July 1998 - February 2010](#)

|                               |                                |                              |                               |                              |
|-------------------------------|--------------------------------|------------------------------|-------------------------------|------------------------------|
| <a href="#">February 2010</a> | <a href="#">February 2009</a>  | <a href="#">July 2008</a>    | <a href="#">January 2008</a>  | <a href="#">July 2007</a>    |
| <a href="#">January 2007</a>  | <a href="#">September 2006</a> | <a href="#">January 2006</a> | <a href="#">October 2005</a>  | <a href="#">January 2005</a> |
| <a href="#">March 2004</a>    | <a href="#">March 2003</a>     | <a href="#">October 2003</a> | <a href="#">January 2002</a>  | <a href="#">October 2001</a> |
| <a href="#">July 2001</a>     | <a href="#">April 2001</a>     | <a href="#">January 2001</a> | <a href="#">November 2000</a> | <a href="#">July 2000</a>    |
| <a href="#">April 2000</a>    | <a href="#">January 2000</a>   | <a href="#">July 1999</a>    | <a href="#">April 1999</a>    | <a href="#">January 1999</a> |
| <a href="#">October 1998</a>  |                                |                              |                               |                              |

**Notice to Consumers (PDF)**

- [Notice to Consumers - English](#) Pharmacies must display the full size posters provided by the Board of Pharmacy. To request your full size posters use the Board's [Publication Request Page](#) or contact the Board of Pharmacy.
- [Notice to Consumers - Spanish](#) Please print on legal size paper (8.5inches x 14inches) for legibility
- [Notice to Consumers - Chinese](#) Please print on legal size paper (8.5inches x 14inches) for legibility
- [Notice to Consumers - Vietnamese](#) Please print on legal size paper (8.5inches x 14inches) for legibility
- [Notice to Consumers - Tagalog](#) Please print on legal size paper (8.5inches x 14inches) for legibility

**Tips to Save You Money When Buying Prescription Drugs (PDF)**

- [Tips to Save You Money When Buying Prescription Drugs - English](#)
- [Tips to Save You Money When Buying Prescription Drugs - Spanish](#)
- [Tips to Save You Money When Buying Prescription Drugs - Chinese](#)
- [Tips to Save You Money When Buying Prescription Drugs - Vietnamese](#)

**Buying Drugs from Foreign Countries or Over the Internet (PDF)**

- [Buying Drugs from Foreign Countries or Over the Internet - English](#)
- [Buying Drugs from Foreign Countries or Over the Internet - Spanish](#)
- [Buying Drugs from Foreign Countries or Over the Internet - Chinese](#)
- [Buying Drugs from Foreign Countries or Over the Internet - Vietnamese](#)

**Health Notes (PDF)**

- [Pain Management](#)
- [Alternative Medicines](#)
- [References to the Alternative Medicines Health Notes](#)
- [Women's Health](#)

- [Quality Assurance](#)
- [Pharmacist Involvement in Anticoagulant Therapy](#)
- [Care of Children & Adults with Developmental Disabilities](#)
- [Drug Therapy Considerations in Older Adults](#)

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## Consumer Fact Sheet Series

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- [Diabetes - Engage Your Health Team](#)  
[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
- [Did You Know? Good Oral Health Means Good Overall Health](#)  
[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
- [Do you understand the directions on your Rx medicine label?](#) (PDF)
- [Drug discount programs](#) (PDF)
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[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
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[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
- [Lower Your Drug Costs so You can Keep on Taking Your Medicines](#)  
[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
- [Measuring Liquid Medicine](#) (PDF)
- [Pill Splitting](#) (PDF)
- [Thinking of Herbals? Check Carefully Before You Take Them With Medicines](#)  
[Spanish](#) [Chinese](#) [Vietnamese](#) (PDF)
- [Traveling Medicine Chest](#) (PDF)
- [Vaccinations and Travel Outside the U.S.](#) (PDF)
- [What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!](#)  
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# DEPARTMENT OF CONSUMER AFFAIRS BOARD OF PHARMACY

## Consumer Tips

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- [New Prescription Drug Discount Program for Medicare Recipients](#)
- [Things You Always Wanted to Know About the Board of Pharmacy...](#)
- [Get the Answer](#)
- [How to Take Your Pain Medications Effectively and Safely](#)
- [Side Effects of Narcotic Pain Relievers](#)
- [Older Adults and Medicines](#)
- [About Your Child's Medication](#)
- [Does the pharmacist have to talk to the patient about prescription medication?](#)
- [Can a pharmacist refuse to fill my prescription?](#)
- [Can the pharmacy refuse to take back my prescription medication?](#)
- [Can the pharmacist give out my personal medical information?](#)
- [Why does the pharmacy need my address, social security number, and date of birth?](#)



### GET THE ANSWERS

Talk with a pharmacist. Ask these questions about your medicines:

1. What is the name of the medicine and what is it supposed to do?
2. How and when do I take it and for how long?
3. What do I do if I forget to take my medicine?
4. Are there any side effects, and what do I do if they occur?
5. Is there any written information available about the medicine?



### HOW TO TAKE YOUR PAIN MEDICATIONS EFFECTIVELY AND SAFELY

Are you getting the pain relief you want?

- If you are not getting pain relief or are having side effects that you cannot tolerate, call your doctor or pharmacist.
- It is better to take your pain medication on a schedule if you are having constant pain. Do not wait until the pain is severe before taking your pain medication.



### **SIDE EFFECTS OF NARCOTIC PAIN RELIEVERS**

What to watch for and how to decrease side effects

1. Being sleepy, drowsy, dizzy or lightheaded is an expected side effect of narcotic pain relievers. The reaction is different for each person.
2. Make sure you know how you react to this medicine before you drive, use machines, or do other jobs that require you to be alert and clearheaded.
3. Do not drink alcohol while you are taking this medication.

These drugs may cause constipation. To prevent this from becoming a problem you can:

1. Drink plenty of fluids
2. Take over-the-counter (prescription not required) laxatives such as Senokot, Colace, and Milk of Magnesia if needed for constipation.
3. If you have not had a bowel movement within three days after starting your pain medication, contact your doctor immediately.
4. Your pain medication may also cause an upset stomach.



### **OLDER ADULTS AND MEDICINES**

Key factors contributing to the improper use of prescription medicines among older Americans include:

1. Poor communication between older patients and health professionals;
2. Taking several medicines at the same time, including prescription and nonprescription medicines;
3. Seeing and receiving prescriptions from more than one health care provider;
4. With advancing age, the body's response to medicine changes; and
5. The inability to take the medication as prescribed.

Adults involved in the care of older parents should know:

1. What medicines their parents take and for what conditions;
2. How often are they supposed to take their medicines;
3. Whether their parents feel the medicine is helping; and
4. If there are any problems with the medicine.

Older patients taking multiple medicines should ask their health care providers about having a medicine "check up." It can help uncover problems they may be having taking their medicines, and it's a good time for asking questions.

Years of training have made your pharmacist the health professional best qualified to help you understand the proper use of prescription and nonprescription drugs. Talk to your pharmacist!



## YOUR CHILD'S MEDICATION

Four common mistakes children make with medicines are:

1. Stopping too soon.
2. Taking too little.
3. Taking too much.
4. Refusing to take the medicine.

Parents should know the following things about the medicines their children take:

- What condition the medicine is for, and what it is supposed to do;
- How much to give;
- If there are any side effects and what to do if they occur; and
- What to do if a dose is missed.



### Does the pharmacist have to talk to the patient about prescription medication?

The pharmacist is required to talk to you about all new prescription medications that have not been provided to you before. You should know the answers to at least the following questions before taking prescription medications:

1. What is the name of the medicine and what is it supposed to do?
2. How and when do I take it and for how long?
3. What do I do if I forget to take my medicine?
4. Are there any side effects, and what do I do if they occur?
5. Is there any written information available about the medicine?

### Can a pharmacist refuse to fill my prescription?

Yes, a pharmacist in his or her professional judgment may refuse to fill a prescription.

### Can the pharmacy refuse to take back my prescription medication?

Yes, the pharmacy is not required by law to take back prescriptions that have been dispensed.

### Can the pharmacist give out my personal medical information?

California law places strict requirements on what information can be released. In most cases, the patient must approve release of any personal medical information.

### Why does the pharmacy need my address, social security number, and date of birth?

This information is used to identify patients to avoid any error in dispensing medication to the wrong patient.

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 6, 2010**

**To: Communication and Public Education Committee**

**Subject: Update on *The Script***

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Work on the July 2010 issue of *The Script* has been completed by staff and the text is undergoing legal review. The issue will focus on implementation and questions and answers about pharmacy law. This issue will also include an update to licensees about the requirements for patient-centered prescription container labels.

The future publication of *The Script* will be done electronically, rather than in print. This will allow the board to comply with budget restrictions, and save at least \$25,000 annually. This redirection is possible since existing law requires that all licensed facilities join the board's email subscriber list; hence, we can readily contact licensed sites and interested individual licensees (as well as others) who are interested in receiving these notices.

Work will soon begin on the January 2010 edition. This issue will highlight new pharmacy law that takes effect on January 1.



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 7, 2010**

**To: Communication and Public Education Committee**

**Subject: Readiness Articles for Emergency Responders for Disaster Response**

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The California Pharmacists Association's Emergency Response Committee recently contacted the board with two requests:

1. First, can the committee provide the board with an emergency preparedness survey (rather a link to it) that can be sent to your listserve (aka "subscriber alert")? The committee is trying to gauge what licensed pharmacists know/ what actions they have taken to get prepared for emergencies, so the committee can better tailor its next set of messages.
2. Also, the committee would like to prepare some emergency response communications specifically for pharmacists on how to respond to specific disasters, such as fire, earthquake, etc. They are to be in advisory nature, and are intended to answer the inevitable questions that come up when disasters strike, such as "how can I help? ). Since the board has direct access to all licensed pharmacists, the committee would like to provide the board with these messages that have been appropriately vetted with disaster response officials, to be sent out in times of need.

This is a specific request for a topic listed on the agenda for this meeting as item 9, under use of the subscriber alert system.

The CPhA is planning on attending this meeting to provide additional information on this request that was not available at the time this memorandum is being written.



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 9, 2010**

**To: Communication and Public Education Committee**

**Subject: Update on Public and Licensee Outreach**

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Public and licensee outreach activities performed during the fourth quarter of Fiscal Year 09/10 include:

- April 12, 2010 -- Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Board of Directors Meeting in Sacramento.
- May 5, 2010 - Executive Officer Herold and Supervising Inspector Ratcliff presented information about the Board of Pharmacy and answered questions about pharmacy law to 60 Costco Northern California pharmacy managers.
- May 13, 2010 – Board Member Kajioka provided presentations to students at the University of the Pacific about new pharmacy law and projects at the Board of Pharmacy.
- May 21, 2010 – Supervising Inspector Nurse made a presentation about drug thefts and robberies from pharmacies at a day-long San Diego Pharmacy Conference hosted by the federal Drug Enforcement Administration. Over 100 pharmacy representatives attended.
- May 23, 2010 -- Board President Schell and Executive Officer Herold hosted a booth at the annual National Association of Boards of Pharmacy Meeting in Orange County.
- May 29, 2010 -- Inspector Toevs provided a presentation about lowering drug costs at a community meeting hosted by Senator Liu in Los Angeles
- June 2, 2010 - Executive Officer Herold presented information about the board's compounding requirements and other key board issues to a meeting of the Bay Area Pharmacy Directors at Stanford.
- June 7, 2010 - Executive Officer Herold attended a conference hosted by the California Endowment on Building Quality and Equitable Health Care Systems in Los Angeles.
- June 17, 2010 – Board Member Schell and Executive Officer Herold participated in a High Risk Drug Task Force Meeting, hosted by the California Hospital Association.
- June 25, 2010 – Executive Officer Herold attended a Medication Safe Alliance Conference in San Francisco hosted by the Pharmacy Foundation of California.
- June 29, 2010 – Executive Officer Herold presented information on the role of the executive officer at the Department of Consumer Affairs Board Member Orientation in Sacramento.



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 8, 2010**

**To: Communication and Public Education Committee**

**Subject: Policy on Subscriber Alerts**

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For at least four years, the board has had an email “subscriber alert” system, by which those interested in receiving email notices from the board about information the board believes is important can receive such notices. Over the last few years, the board has used the subscriber alert system to advise licensees (and other interested parties) about:

- Drug recalls, where the drug is being recalled from the pharmacy or patient
- Emergency response declarations
- Board meeting agendas and meeting materials being released to the public
- Publication and availability of the board’s newsletter, *The Script*
- New materials being added to the board’s Web site
- “All Facility Letters” released by the California Department of Public Health
- Changes in the CURES program affecting board licensees

The board has also developed a special subscriber list of pharmacies that are able to compound drugs in emergency response or declared disaster areas, fulfilling a request of the California Department of Public Health for an immediate way to contact these pharmacies.

In July 2010, the California law was amended to require that all sites licensed by the board become subscribers to the board’s subscriber alert system. (Individuals who are licensed by the board can become subscribers voluntarily; they are not required to do so.) Currently pending in the California Legislature is SB 1489, is an amendment that would allow pharmacy “chains” with multiple pharmacies with the same owner to use a company’s internal email notification system for the board’s subscriber alert system so long as the headquarters becomes a subscriber, and immediately disseminates the board’s subscriber alert message to all of its component pharmacies.

The board also has begun to use the subscriber alert system as the primary way to notify licensees about changes in pharmacy laws and regulations, and to distribute the newsletter.

Periodically outside groups request to use the board’s subscriber alert system to notify our licensees about surveys, job opportunities, continuing education and conferences they are hosting. The board’s staff has declined to send such messages over the

subscriber alert system. Only messages from another state agency or notices involving recalls have been released over the subscriber alert system.

Given the number of requests the board is beginning to receive, staff request that a policy statement be developed by the board about the use of the subscriber alert system. Here is a draft:

The Board of Pharmacy's subscriber alert system is an email notification system used by the board to advise its licensees and other interested parties who are self subscribers about California State Board of Pharmacy policies, publications and activities that impact the board's regulatory jurisdiction or public protection mandate. On occasion, the board will release notices about other matters impacting public health of wide appeal or urgency (such as drug product recalls, notices from other state or federal agencies, emergency declarations).

Under California law, all sites licensed by the board are required to become subscribers and maintain their current email addresses with this system so that they can receive these board notices. However, the board recognizes the potential to overload licensees and subscribers with less important or unwanted notices, with the ultimate impact that all subscriber alerts sent by the board become viewed with less focus and discernment. As such, the board's executive staff will approve each subscriber alert before release to ensure that the notice advances the board's public protection mandate or relates to the board's regulatory jurisdiction.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 8, 2010**

**To: Communication and Public Education Committee**

**Subject: Web Casting of Meetings**

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The Department of Consumer Affairs now has technology and staff to facilitate the web casting of board and committee meetings. At this time, one board meeting (October 2009) has been web cast.

As an agency organized to promote consumer protection, the department is strongly encouraging boards to Web cast their meetings.

The committee is asked to develop a policy for referral to the board on whether to web cast some or all of its board meetings and committee meetings.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 6, 2010**

**To: Communication and Public Education Committee**

**Subject: Update of the Committee's Strategic Plan for 2010/11**

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In July 2006, the board finalized its strategic plan for 2006-2011. However, each year the board revises its plan to keep it current.

At this meeting, the committee will have the opportunity to revise its strategic plan, if warranted.

During the July Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for development of the 2010-11 strategic plan (completing the annual updating process).

## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

|               |   |
|---------------|---|
| Objective 4.1 | Develop a minimum of 10 communication venues to the public by June 30, 2011.  |
| Measure:      | Number of communication venues developed to the public.   |
| Tasks:        | <ol style="list-style-type: none"> <li>1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired.</li> <li>2. Restructure the board's Web site to make it more user friendly.</li> <li>3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics.</li> <li>4. Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics.</li> <li>5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation) on patients' rights to secure legitimately prescribed medication from pharmacies.</li> <li>6. Evaluate the practice of pill splitting as a consumer protection issue.</li> <li>7. Evaluate the SCR 49 Medication Errors Report for implementation.</li> <li>8. Develop patient-centered standardized prescription container labels by 2011.</li> <li>9. Address and promote licensee and public education on minimizing prescription errors.</li> <li>10. Educate consumers about steps they can take to prevent receiving a medication error.</li> </ol> |
| Objective 4.2 | Develop 10 communication venues to licensees by June 30, 2011.  |
| Measure:      | Number of communication venues developed to licensees   |
| Tasks:        | <ol style="list-style-type: none"> <li>1. Publish <i>The Script</i> two times annually.</li> <li>2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.</li> <li>3. Maintain important and timely licensee information on Web site.</li> </ol>   |
| Objective 4.3 | Participate in 12 forums, conferences and public education events annually.   |
| Measure:      | Number of forums participated.  |
| Tasks:        | <ol style="list-style-type: none"> <li>1. Participate in forums, conferences and educational fairs.</li> </ol>  |