



## Communication and Public Education Committee

Ryan Brooks, Chair, Public Member  
Cheryl Butler, PharmD, Professional Member  
Ramón Castellblanch, PhD, Public Member  
Shirley Wheat, Public Member  
Albert Wong, PharmD, Professional Member

Report of the Communication and Public Education Committee Meeting Held October 7, 2013.

a. **FOR INFORMATION: Review and Discussion of the 42<sup>nd</sup> Annual Report of the Research Advisory Panel of California**

**Attachment 1**

Background

The Research Advisory Panel of California was established 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.*

Patrick R. Finley, Pharm.D., is the board's appointment to the seven member advisory panel. Mr. Weisser referenced the copy of the 42nd Annual Report of the Research Advisory Panel of California (July, 2012) provided with the meeting materials. The committee recommended that Dr. Finley come to a future meeting of the committee or board to tell them more about the Advisory Panel's activities and to share additional information on studies that may be of interest to the board or related to the pharmacy profession.

b. **FOR INFORMATION: Discussion on Requests from California Pharmacies for Exemption from Title 16 California Code of Regulations Section 1707.6(e) to Use Alternate Notice of Interpreter Availability Posters**

**Attachment 2**

Existing Board regulation requires pharmacies to prominently post the "Notice to Consumers" required by 16 CCR Section 1707.6. In addition, Section 1707.6(c) requires every pharmacy to

post or provide a “point to your language” notice so that consumers are aware that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the Board unless the pharmacy has received prior approval of another format or display methodology. The board has delegated to the Communication and Public Education Committee the authority to act on all requests to use another format or display methodology of these posters.

The committee considered and denied two requests to use an alternate format Notice of Interpreter Availability. One request was from Costco, and the other from Walmart Stores (for both Walmart and Sams Club pharmacies). While each request specified additional languages (in addition to the twelve mandated by board regulation), neither contained the specific language/phrasing that is required by 16 California Code of Regulations Section 1707.6(c): “Point to your language. Interpreter services will be provided to you upon request at no cost.” Copies of the alternate format notices considered by the committee are provided in Attachment 2. In addition, the committee would like to see any alternate format notice submitted for the committee’s approval to include the statement “This notice is required to be posted by the California Board of Pharmacy.”

Finally, board staff drafted a form that can be used for future requests for the committee’s consideration. Staff will add to that request form a reminder that any alternative format notice must contain the language required by 1707.6(c).

**c. FOR INFORMATION: Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by Title 16, California Code of Regulations Section 1707.5(e)**

**Attachment 3**

The board is in the process of securing bids to have the Emergency Contraception Fact Sheet (required by 16 CCR Section 1746(b)) translated into six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. These are the same six languages in which the board makes available its “Notice to Consumers” posters (upon request, or download). When available, the Fact Sheets will be available upon request, and will also be available for download from the board’s web site.

A copy of the updated Emergency Contraception Fact Sheet (English version) is provided in Attachment 3.

**d. FOR INFORMATION: Results of the Assessment of California’s Patient-Centered Labeling Requirements as Required by Title 16 California Code of Regulations Section 1707.5(e)**

**Attachment 4**

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

The committee reviewed the factors considered when developing the current regulatory requirements, as well as the board's efforts to date to review the patient-centered requirements, which was initiated by the committee in April 2013. The committee discussed the USP guidelines published in November 2012, noting the close resemblance to the board's requirements, and Ms. Herold indicated that staff continues to search for medical literacy research regarding standardized directions for use, noting the goal of such a schedule is to increase patient understanding, adherence to medication instructions and improving health outcomes. Board staff has been trying to build support among groups by highlighting the benefits of utilizing standardized directions for use, and that there may be educational opportunities to work with the prescribing boards to this end.

One of the recommendations in the NCPDP White Paper is to implement the use of universal medication instructions in an effort to help get the e-prescribing directions for use standardized. In its surveys, the board has looked at the use of font sizes, how interpretive services requirements are being implemented, patient satisfaction (a general framework of what patients are thinking) – noting they want larger font, and the purpose on the label.

The committee discussed the distribution of the surveys, noting that CPEHN had the survey translated and distributed among limited English and other groups. Results of a recent survey conducted by the board are provided in **Attachment 4**.

**Should the board modify what is considered “patient-centered”?**

Regulation currently requires that “patient-centered” items shall be clustered into one area of the label that comprises at least 50 percent of the label:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

In addition to these required elements, it is noted that some pharmacies include additional information within the 50% clustered area, such as the patient's address, expiration dates of drugs, or other information. The committee voted to clarify exactly what information is intended by the board to be included within the patient-centered clustered area.

**Committee Recommendation: Amend Section 1707.5(a)(1) to read as follows, to specify that only the four items listed in that paragraph are to be within the patient-centered clustered area.**

- (1) Each of the following items, and only those four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

The committee addressed whether or not there should be any change to “name of the patient,” and there was no committee or public comment.

**Should changes be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug”?**

**Is it worthwhile to list the name of the manufacturer in the patient-centered portion of the label?**

Current regulation at Section 1707.5(a)(1)(B) specifies that the name of the drug and strength of the drug be in the patient-centered portion of the label and that “for the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.” The committee discussed the value of having the manufacturer’s name as one of the patient-centered elements.

Recommendations provided in research are as follows:

- USP suggests that the drug name be spelled out fully (brand AND the generic name) – no abbreviations.
- NABP suggests inclusion of suffixes (CD, SR, XL, XR, etc.)

It was the consensus of the committee that having both the trade/brand name and the generic name fully spelled out was needed. In addition, there was consensus that the suffixes referenced in the NABP recommendation were part of the drug name and should be used.

- NABP suggests that if a prescription is written for a brand name and a generic drug is dispensed then “generic for [brand name]” appear on the label.

The committee noted that it is required that the manufacturer name be on a prescription label, and that they were considering whether or not it was to be within the patient-centered cluster or not.

Public comments suggested that “generic for” be on the label where a generic is dispensed for a trade name, to avoid patient and/or caregiver confusion as to what medication to take and to avoid adverse events. An example of dispensing hydrochlorothiazide (generic) for Hydrodiuril (trade name) was used, where the patient may get a generic at the pharmacy, and have a bottle (previously dispensed) at home with the trade name. The committee received comments in support of having a “check book” approach to the format of prescription labels, where the information is in the same place, no matter what pharmacy dispenses the drug.

There were comments in support of having the *strength of the drug* on the container, as it is important to emergency personnel.

It was the consensus of the committee that the “suffixes” referenced in the research are a part of the drug name and should be on the label.

**Committee Recommendation:** Modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name). Staff is working with counsel to develop this language.

**Should Purpose or Condition be in the patient-centered clustered items?**

There was wide consensus among the committee and the public that the purpose or condition should be on the prescription label within the clustered patient-centered items. Staff counsel commented that a statutory change may be needed, as Section 4076 states it is required to be on the label only if it is specified on the prescription.

Staff sought the committee’s input as to whether this should be a regulatory change, or perhaps a statutory change – noting that previous attempts to make a statutory change failed.

**Committee Recommendation:** Direct staff to work with legal counsel to draft language to amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

**What Font Size is Appropriate?**

Acknowledging the Governor’s recent veto of legislation that sought to mandate a 12-point font on prescription labels, the committee discussed the current requirements. Staff summarized surveys which indicated that pharmacies, by a wide preponderance, are using 12 point font as the primary font on prescription labels, and the committee noted that there are many reports, research and legislative efforts to increase the font size on a prescription label. It was the consensus of the committee that the regulation should be modified to require a minimum 12 point font.

**Committee Recommendation: Modify Section 1707.5(a)(1) to read as follows:**

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface or, if requested by the consumer, at least a 12-point sans serif typeface~~ typeface, and listed in the following order:

**Should the existing requirements for “added emphasis” be modified?**

Current regulation at Section 1707.5(a)(2) states “For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).”

The committee noted that not much research is available that addresses these items, however, there is a recommendation in the research that sentence casing not be in all capital letters.

The committee did not recommend any changes to this requirement.

**Translations**

The committee received public comment in support of translations on prescription labels. Ms. Sarah de Guia, CPEHN, expressed concern over the survey results that indicated that pharmacies were using on-line translation services, such as Google Translations, and she spoke in support of the professional field of translators that are certified to provide these services. She requested that as the board moves forward, it consider the use of such certified translators, and that where CPEHN can provide additional information to let her know. She said CPEHN is concerned about the quality of translations that are being provided. She spoke in support of establishing standards for providing translations.

The committee discussed the ways in which the board is advising pharmacies of regulatory requirements and the notices that are required to be posted in pharmacies. Staff noted that the board utilizes its newsletter, *The Script*, as well as e-mail subscriber alerts to share information with its licensees and interested parties. Staff asked one industry member if they would be willing to survey their member pharmacies to determine the types of services that are used for purposes of translating prescription drug labels.

The committee did not recommend any modifications to the current requirements at this time.

**e. DISCUSSION AND POSSIBLE ACTION: Initiate a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5**

**Attachment 5**

As a result of the committee’s discussion, the committee made the following recommendations to amend Title 16 California Code of Regulations Section 1707.5. Where applicable, the recommended changes are reflected (in underscore and ~~strikeout~~ text) on Attachment 5.

Regarding what should be considered “patient-centered”:

**Committee Recommendation:** Amend Section 1707.5(a)(1) to read as follows, to specify that

only the four items listed in that paragraph are to be within the patient-centered clustered area.

(1) Each of the following items, and only those four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

Regarding what type of information is within the “patient-centered” clustered area:

**Committee Recommendation:** Modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name). *Staff is working with counsel to develop this language.*

Regarding the “Purpose or Condition” on the prescription label:

**Committee Recommendation:** Direct *staff to work with legal counsel to draft language to amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.*

Regarding the minimum font size of the “patient-centered” components of the prescription label:

**Committee Recommendation: Modify Section 1707.5(a)(1) to read as follows:**

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface or, if requested by the consumer, at least a 12-point~~ sans serif typeface, and listed in the following order:

**f. FOR INFORMATION: Update on The Script**

The next issue of *The Script* is being finalized and prepared for being posted online. *The Script* includes information regarding disciplinary actions taken by the Board, answers questions to frequently asked questions, and contains an article about the Joint Forum to Promote Appropriate Prescribing and Dispensing held earlier this year in South San Francisco. Staff leaves of absences and other issues have delayed the publication, but it should be available by the end of the month.

**g. FOR INFORMATION: Public Outreach Activities Conducted by the Board**

Staff provided an update of public outreach activities since the July report:

- July 25, 2013: The Board of Pharmacy, in conjunction with the Los Angeles Field Division of the Drug Enforcement Administration, co-hosts a seminar for pharmacists on July 26 in Downey, CA. The seminar focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminar was well attended, with approximately 220 in attendance.
- August 13, 2013: Executive Officer Herold provides a webinar on e-Pedigree requirements at to a webinar audience hosted by the FDAnews.
- August 16, 17, 18, 19: The Board of Pharmacy, in conjunction with Washington Headquarters of the Drug Enforcement Administration, co-hosts four day-long seminars for pharmacists. Two were held in San Diego, and two in San Jose. The seminars focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminars were well attended, with at least 300 individuals in attendance each day.
- August 25: Supervising Inspector Janice Dang provides a presentation on corresponding responsibility of pharmacies to physicians attending the Napa Pain Conference.
- August 26: Executive Officer Herold provides a presentation via telephone connection to the New Mexico Board of Pharmacy on virtual wholesalers and wholesaler brokers and drug diversion.
- September 17: Executive Officer Herold provides a presentation via telephone connection on California's e-pedigree regulations to 300 attendees of a LogiPharma conference in Princeton, NJ.
- September 17: Executive Officer Herold provides a webinar on California's requirements for serialization to attendees of a PricewaterhouseCoopers virtual meeting.
- October 2: Executive Officer Herold provides a presentation on California's e-pedigree regulations to attendees at a GS1 conference held in San Francisco.

**h. Update on the Development of Committee Goals for 2012-2017 to Fulfill the Board's Strategic Plan**

Staff suggested that at a future meeting, the committee augment its goals for the Strategic Plan.

Draft minutes of the Public Education and Communication Committee meeting held October 7, 2013 are provided in **Attachment 6**.

# **Attachment 1**

**FORTY-SECOND ANNUAL REPORT**

**of the**

**RESEARCH ADVISORY PANEL  
OF CALIFORNIA**

**2012**



**PREPARED FOR THE**

**LEGISLATURE AND GOVERNOR**

**RESEARCH ADVISORY PANEL OF CALIFORNIA**

**455 Golden Gate Avenue - Suite 11000  
San Francisco, California 94102-7004**

**[www.ag.ca.gov/research](http://www.ag.ca.gov/research)**

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## MEMBERS

### RESEARCH ADVISORY PANEL OF CALIFORNIA

Edward P. O'Brien, J.D.  
Panel Chairman  
Appointed by Attorney General

Y. Jennifer Ahn, Pharm.D.  
Executive Officer

Patrick R. Finley, Pharm.D.  
Appointed by the State Board of Pharmacy

Andrew S. Kayser, MD, PhD  
Appointed by the University of California at San Francisco  
Designated University of California

John E. Mendelson, M.D.  
Appointed by the California Medical Association  
Designated professional medical society

Michele T. Pato, M.D.  
Appointed by the University of Southern California  
Designated private university

Laurence R. Upjohn, Pharm.D.  
Appointed by the Department of Public Health

**RAPC Website : [www.ag.ca.gov/research](http://www.ag.ca.gov/research)**

**E-mail contact: [jennifer.ahn@doj.ca.gov](mailto:jennifer.ahn@doj.ca.gov)**

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

## SUMMARY OF 2012 PANEL ACTIVITIES

During 2012 the Panel reviewed twenty-five research study submissions. Twenty-four were approved by the Panel. Among approved studies, four studies were Academic research studies, two studies were Substance Abuse Treatment research protocols, and eighteen studies were Clinical Drug Trial research protocols.

Forty-three research studies were completed in 2012, and they were closed on the Panel's records.

At the end of 2012, the Panel was monitoring one hundred-twenty 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 2012 and Table 2 is a list of the studies closed by the Panel in 2012.



TABLE 1

RESEARCH STUDIES  
APPROVED IN 2012

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Jack Berger, M.D. LAC + USC Medical Center Los Angeles, CA	Prospective, Double-Blinded, and Randomized Control Trial of Multimodal Pain Relief with Intravenous Magnesium, Lidocaine and Ketorolac in Patients with Opiate Refractory, Post-Operative Pain
Philip E. Bickler, MD, PhD Dept of Anesthesia, UCSF San Francisco	Detecting Apnea in Healthy Volunteers Receiving Opiate or Sedative Medications
Raymond Stevens, Ph.D. The Scripps Research Institute La Jolla, CA	Structure Determination of the Hallucinogens LSD and Psilocin Bound to the Serotonin Receptor 5-HT2B
Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate ALKS 5461 in Subjects with Major Depressive Disorder and Inadequate Responses to Antidepressant Therapy (ALK5461-202)

Collegium / CRO-INC Research  
Raleigh, NC

A Phase 3, Multi-Center, Randomized,  
Double-Blind, Placebo-Controlled, Safety,  
Tolerability, and Efficacy Study of Oxycodone  
DETERx™ Versus Placebo in  
Opioid-Experienced and Opioid-Naive  
Subjects with Moderate-to-Severe Chronic  
Low Back Pain  
(CO-OXYDET-08)

GW Pharmaceuticals  
Mill Valley, CA

Panel Approved Resesarch

Mitsubishi / CRO-Quintiles  
Overland Park, KS

A Phase 2, Randomized, Double-Blind,  
Placebo-Controlled, Fixed-Dose,  
Parallel-Group, Multicenter, Efficacy, and  
Safety Study of MT-9938 for Treatment of  
Uremic Pruritus in Subjects with End-Stage  
Renal Disease Receiving Hemodialysis  
(MT-9938-01)

Nektar  
San Francisco, CA

A Phase 2, Enriched-Enrollment,  
Randomized-Withdrawal, DB, PC, MC Study  
to Assess the Efficacy, Tolerability, & Safety  
of NKTR-181 in Opioid-Naïve Subjects w  
Mod to Sev Chr Pain Due to Osteoarthritis of  
the Knee  
(12-181-04)

NextWave Pharmaceuticals  
Chapel Hill, NC

A Multicenter, Dose-Optimized,  
Double-Blind, Randomized,  
Placebo-Controlled Study to Evaluate the  
Efficacy of NWP09 in Pediatric Patients with  
Attention Deficit Hyperactivity Disorder  
(ADHD) in a Laboratory Classroom  
(NWP09-ADHD-300)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Noven / CRO-PRA Lenexa, KS	A Randomized, DB, PC, Cross-Over, Lab Classroom Study to Evaluate the Safety & Efficacy of d-Amphetamine Transdermal Drug Delivery System (d-ATS) Compared to Placebo in Children & Adolescents w ADHD (N25-006)
Noven Pharmaceuticals New York, NY	An Investigational Study to Evaluate the Usability of Reformulated Methylphenidate Transdermal System in Children, Adolescents and Adults with ADHD and Caregivers (N17-030)
Pfizer, Inc. New York, NY	A MC, 12-week, DB, PC, Rand. Withdrawal Study to Determine The Efficacy & Safety of ALO-02 (Oxycodone HCl & Naltrexone HCl) ER Caps in Subjects w Mod to Sev Chr. Low Back Pain (B4531002)
QRxPharma / CRO-INC Research Austin, TX	A DB, Rand, P, & AC, PG Study to Evaluate the Safety, Tolerability & Efficacy of Q8011 Comped to OxyContin & Placebo in Pts w Mod to Sev Chr. Hip or Kneww Pain Due to Osteoarthritis (Q8011-201)
Roxane / CRO-Quintiles Durham, NC	A Multicenter, Open-Label, Safety & PK Study of Oral Codeine Sulfate Adm of Pediatric Subjects 2 yrs old thru 17 yrs old w Post-Procedural Pain (Code-OS+T-(2-17)-SPK-1)

Shire / CRO-Premier  
Research Group  
Bluff City, TN

A Phase 3, Multicenter, Open-Label,  
12-Month Extension Safety and Tolerability  
Study of SPD489 in the Treatment of Adults  
with Binge Eating Disorder  
(SPD489-345)

Shire / CRO-Premier  
Research Group  
Philadelphia, PA

A Phase 3, Multicenter, Randomized,  
Double-Blind, Parallel-Group,  
Placebo-Controlled, Dose-Optimization Study  
to Evaluate the Efficacy, Safety, and  
Tolerability of SPD489 in Adults Aged 18-55  
Years with Moderate to Severe Binge Eating  
Disorder  
(SPD489-344)

Shire Pharmaceuticals  
New York, NY

A Phase I, Rand, DB, PC Study to Evaluate  
the Safety, Tolerability, & PK of Single &  
Multiple-Doses of SPD489 in Japanese &  
Caucasian Healthy Adult Subjects  
(SPD489-121)

Shire / CRO-Premier  
Research Group  
Alexander, NC

A Phase 4, Rando, DB, MC, PG, AC,  
Forced-dose Titration, Safety & Efficacy  
Study of SPD489 (Vyvanse) Compared w  
OROS-MPH (Concerta) w a Placebo  
Reference Arm, in Adolescents Aged 13-17  
Years w ADHD  
(SPD489-406)

Shire / CRO-Premier  
Research Group  
Alexander, NC

A Phase 4, Rando, DB, MC, PG, AC,  
Dose-optimization Safety & Efficacy Study of  
SPD489 (Vyvanse) Compared w OROS-MPH  
(concerta) w a Placebo Reference Arm, in  
Adolescents Aged 13-17 Years w ADHD  
(SPD489-405)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire / CRO-Premier Research Group Philadelphia, PA	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Optimization Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder (SPD489-343)
Sunovion / CRO-INC Research Seattle, WA	A Randomized, Double-Blind, Parallel-Group, Multicenter Efficacy and Safety Study of SEP-225289 Versus Placebo in Adults with Attention Deficit Hyperactivity Disorder (ADHD) (SEP360-201)
Liza Gorgon NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial of Nepicastat for Cocaine Dependence (CS# 1031)
Edythe London, Ph.D. Semel Institute, UCLA Los Angeles, CA	Safety and Initial Efficacy of Buspirone for Methamphetamine Dependence



TABLE 2

RESEARCH STUDIES CLOSED IN 2012

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Hussein Al-Shamma, Ph.D. Arena Pharmaceuticals San Diego, CA	Evaluation of lorcaserin for abuse liability using the Drug Discrimination Test in the Rat
Danilyn Angeles, Ph.D. Loma Linda Univeristy Medical Ct. Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
Mariusz Banaszczyk, Ph.D. Biosite Diagnostics San Marcos, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Selena Barrett, Ph.D. Ernest Gallo Clinic & Research Ct. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Marthias Behrends, M.D. Dept. of Anesthesia, UCSF San Francisco, CA	A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Jack Berger, Ph.D.  
LAC + USC Medical Center  
Los Angeles, CA

Prospective, Double-Blinded, and  
Randomized Control Trial of Multimodal  
Pain Relief with Intravenous Magnesium,  
Lidocaine and Ketorolac in Patients with  
Opiate Refractory, Post-Operative Pain

Nancy Buckley, Ph.D.  
Biological Sciences Dept  
CA State Polytechnic University

Effects of delta-9-tetrahydrocannabinol on  
Candida albicans infection

Peggy Compton, RN, Ph.D.  
UCLA School of Nursing  
Los Angeles, CA

Pain, Opioids, and Pro-inflammatory  
Immune Responses

Keith Flower, M.D.  
APRL/CPMC Research Institute  
San Francisco, CA

A Pilot Trial of Naltrexone for  
Methamphetamine Addiction - Role of the  
A118G SNP

Keith Heinzerling, MD, PhD  
UCLA Geffen School of Medicine  
Los Angeles, CA

Pilot Trial of Bupropion versus Placebo  
for Methamphetamine Abuse in  
Adolescents

Scott Irwin, MD, PhD  
San Diego Hospice and  
Institute for Palliative Medicine  
San Diego, CA

An Open label Trial of Oral Ketamine for  
the Rapid Treatment of Depression in  
Hospice Patients

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Daniel Levin, Ph.D. Norac Pharma Azusa, CA	Evaluation of Cannabinoids derived from the Natural Product Marijuana
Walter Ling, M.D. UCLA Geffen School of Medicine Los Angeles, CA	Optimizing Outcomes Using Suboxone for Opiate Dependence
Edythe London, Ph.D. UCLA Geffen School of Medicine Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Oral Methamphetamine
James McCracken, M.D. APRL/CPMC Research Institute San Francisco, CA	An 8-Wk, Rndmzd, Dbl-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate ER (Focalin XR) and the Combination, with a 12 Month Open-Lbl Extension for the Treatment of ADHD in Pediatric Subjects Aged 7 to 14 years
John E. Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Bioavailability and Urinary Excretion of Oral L-Methamphetamine

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

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

The Effects of MDMA on Sleep  
Architecture, Water Homeostasis, and  
Cognitive Function

Loren Parsons, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Cognitive and Neurochemical Effects of  
 $\Delta^9$ -tetrahydrocannabinol and related  
cannabinoids in rodents

Lara Ray, Ph.D.  
UCLA  
Los Angeles, CA

Genetics of Naltrexone in  
Methamphetamine Users

Rajesh Venugopal  
NIDA, The EMMES Corp.  
Rockville, MD

Cocaine Use Reduction with  
Buprenorphine (CURB)  
(CTN-0048)

Ronald Victor, M.D.  
Cedars-Sinai Medical Center  
Los Angeles, CA

Cocaine and Sympathetic Nerve Activity  
in Humans - "Cocaine and the Heart"

Mark Wallace, M.D.  
Center for Pain Medicine, UCSD  
La Jolla, CA

Efficacy of Inhaled Cannabis for the  
Treatment of Painful Diabetic Peripheral  
Neuropathy

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA	The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain
Titan Pharmaceuticals, Inc. S. San Francisco, CA	A Randomized, Placebo and Active-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (PRO-806)
Titan Pharmaceuticals, Inc. S. San Francisco, CA	A Phase 3, Six-Month, Open-Label Re-Treatment Study of Probuphine in Opioid Addiction (PRO-811)
Astra Zenica / CRO-Quintiles Overland Park, KS	An Open-label, Parallel-group, Phase I Study to Compare the Pharmacokinetics of NKTR-118 Following a Single-Oral Dose in Subjects with Renal Impairment and Subjects with Normal Renal Function (D3820C00009)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

BRC Operations  
Ultimo, NSW

International Study to Predict Optimized  
Treatment in Attention  
Deficit/Hyperactivity Disorder

Cephalon, Inc.  
Fort Washington, PA

A 12 wk, Rand, Dbl-Blind, P-C. Study to  
Eval. the Efficacy & Safety of  
Hydrocodone Bitartrate ER Tabs  
(CEP-33237) at 15-90mg q12 hrs for  
Relief of Mod to Sev Pain in Pts w/ OA or  
Low Back Pain Who Require Opioid Tx  
for an Ext. Period of Time  
(C33237/3079)

Cephalon, Inc.  
Fort Washington, PA

A 12-Month, Open-Label Study to  
Evaluate the Long-Term Safety of  
Hydrocodone Bitartrate Extended-Release  
Tablets (CEP-33237) at 15 to 90mg Every  
12 Hours in Patients Who Require Opioid  
Treatment for an Extended Period of Time  
(Cephalon C33237/3080)

GW Pharmaceuticals  
Mill Valley, CA

Panel Approved Research

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Janssen / J&J Titusville, NJ	A Rand, DB, Parallel Arm, Clinical Trial to Compare the Clin Effectiveness of Tapentadol ER vs Oxycodone CR in Subjects w Mod to Sev Chronic Low Back Pain (R331333PAI4003)
Johnson & Johnson PRD Malvern, PA	Single-Dose, Open-Lbl. Ran. Two-Way Crossover Study to Assess the BE of Tapentadol Given as Two 50mg ER TRF Tabs Relative to One 100mg ER TRF Tab in Healthy Japanese Male Subjects (PAI 1063)
Johnson & Johnson PRD 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) (PAI 3027)
Johnson & Johnson PRD Malvern, PA	A Single-Dose, Open-Lbl, Ran. Two-Way Crossover Study to Assess the BE of Tapentadol Given as Two 25mg ER Tamper-Resistant Form (TRF) Tabs Relative to One 50mg ER TRF Tab in Healthy Japanese male Subjects (PAI 1062)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Johnson & Johnson PRD  
Malvern, PA

A Single-Dose, Open-Label, Rand. 4-Way  
Crossover Study to Assess the  
Dose-Proportionality of the PK of  
Tapentadol, Given as Tamper-Resistant  
Tabs, in Healthy Japanese & Korean Male  
Subjects  
(PAI 1064)

Mallinckrodt  
Hazelwood, MD

A Phase 3 MC, R, DB, PC, PG Evaluation  
of the Safety & Analgesia Efficacy of  
COV795 (Oxycodone HCl /  
Acetaminophen) ER Tablets in Mod to  
Sev Post-Operative Bunionectomy Pain  
Followed by an Open Label Extension  
(COV15000182US)

Mallinckrodt / CRO-INC Research  
Middleton, WI

An Open Label Safety Study of COV795  
in Subjects with Osteoarthritis or Chronic  
Low Back Pain  
(COV15000181US)

Mundipharma / CRO-Parex  
Woburn, MA

A Confirmatory, Placebo-Controlled,  
Rand, D-B, Single-Dummy, Parallel Gr,  
Ratio-Finding Study in Constipated Pain  
Pts to Establish an Optimal  
Hydromorphone-naloxone ratio w an  
Improved Bowel Funct & a Comp Analg  
Eff Comp to H-morphone alone  
(HMX3501)

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
NextWave Pharmaceuticals Chapel Hill, NC	A Multicenter, Dose-Optimized, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of NWP09 in Pediatric Patients with Attention Deficit Hyperactivity Disorder (ADHD) in a Laboratory Classroom (NWP09-ADHD-300)
Novartis Pharmaceuticals East Hanover, NJ	A 6-Month, Open-Label Extension to a 40-Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Study of Ratain LA in the Treatment of Adult Patients with Childhood-Onset ADHD (CRIT124D2302E1)
Novartis Pharmaceuticals East Hanover, NJ	A 40-Week, Randomized, Double-Blind, Placebo controlled, Multicenter Efficacy and Safety Study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (CRIT124D2302)
Purdue / CRO-PRA International Lenexa, KS	An Open-label, MC Study of the Safety of Twice Daily Oxycodone HCl CR Tabs in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, w/ Mod to Sev Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics (OTR3001)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Purdue / CRO-PRA International  
Lenexa, KS

An Open-label Study to Characterize the  
PK and Safety of Oxycodone HCl q12h  
CR (ORF) Tabs in Pediatric Pts Aged 6 to  
16 years inclusive, Who Require Opioid  
Analgesia  
(OTR 1020)

Rhodes / CRO-NuTec Inc.  
Boston, MA

A Random, Dbl-Blind Study of the Time  
Course of Response of Biphentin®  
Methylphenidate HCl ER Caps As  
Compared to Placebo in Children 6-12  
y.o. w/ ADHD in an Analog Classroom  
Setting  
(RP-BP-EF001)

Rhodes / CRO-NuTec Inc.  
Boston, MA

A Randomized, Parallel, Double-Blind  
Efficacy and Safety Study of Biphentin™  
Methylphenidate Hydrochloride Extended  
Release Capsules Compared to Placebo in  
Children and Adolescents 6 to 18 years  
with Attention Deficit Hyperactivity  
Disorder  
(RP-BP-EF002)

Roxane / CRO-Quintile  
Durham, NC

A Multicenter, Open-Label, Safety & PK  
Study of Oral Codeine Sulfate Adm of  
Pediatric Subjects 2 yrs old thru 17 yrs old  
w Post-Procedural Pain  
(Code-OS+T-(2-17)-SPK-1)

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Roxane / CRO-Quintile Durham, NC	A MC, Open Label, Safety & PK Study of Oral Morphine Sulfate Admin. In Pediatric Subjects 2 yrs old thru 17 y.o. w/ Postoperative Pain (MORP-OS+T-(2-17)-SPK-1)
Shire Pharmaceuticals Wayne, PA	A Phase 1, R, DB, PC Study to Assess the Safety, Tolerability, PK, & PD of Ascending, Multiple Oral Doses of SPD489 in Clinically Stable Adults w Schizophrenia (SPD489-119)
Shire / CRO-Premium Research Bluff City, TN	A Phase 2 Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Forced-dose Titration Study to Evaluate the Efficacy, Safe, and Tolerability of SPD489 in Adults Aged 18-55 Years with Binge Eating Disorder (SPD489-208)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug  
Trial Protocol

Shire /Hampshire Intn'l  
Hampshire, UK

A Phase III, Db-Blind, Placebo-Cont.  
Randomized Withdrawal, M-C,  
Extension, Safety & Efficacy study of  
LDX in Children & Adoles. Aged 6-17 w/  
ADHD  
(SPD489-326)

Shire Pharmaceuticals  
New York, NY

A Phase I, Rand, DB, PC Study to  
Evaluate the Safety, Tolerability, & PK of  
Single & Multiple-Doses of SPD489 in  
Japanese & Caucasian Healthy Adult  
Subjects  
(SPD489-121)

Shire / CRO-INC Research  
Raleigh, NC

A Phase 2, MC, Rand, DB, PC,  
Parallel-gr. Study to Evaluate the  
Efficacy, Safety & Tolerability of SPD489  
in Adults w Clin. Signif. Persistent  
Executive Function Impairments (EFI) &  
Partial or Full Remission of Rec. Major  
Depressive Disorder  
(SPD489-205)

Zogenix Inc.  
Emeryville, CA

A Long-Term Open-Label Safety Study of  
Hydrocodone Bitartrate  
Controlled-Release Capsules with  
Flexible Dosing to Treat Subjects with  
Moderate to Severe Pain  
(Zx002-0802)

APPENDIX A

CURRENTLY OPEN (*through December 31, 2012*)  
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. UC. Davis Davis, CA	Cannabis for Spasticity in MS: Placebo- Controlled Study
Philip E. Bickler, MD, PhD Dept of Anesthesia, UCSF San Francisco, CA	Detecting Apnea in Healthy Volunteers Receiving Opiate or Sedative Medications
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research
Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats

Valerie Gruber, Ph.D.  
SF General Hospital  
UCSF  
San Francisco, CA

Investigation of Age Differences in Analgesic,  
Cognitive, and subjective effects of  
Oxycodone, Hydrocodone, and  
Acetaminophen

Kanthi Hettiarachchi, Ph.D.  
SRI International  
Menlo Park, CA

Analysis of Controlled Substances

Reese Jones, M.D.  
UCSF  
San Francisco, CA

Phase I Study of Interactions between Oral  
Naltrexone and Bupripion and Intravenous  
Methamphetamine in Mathamphetamine  
Experienced Volunteers

Thomas S. Kilduff, Ph.D.  
SRI International  
Menlo Park, CA

Neurobiological Studies of  
Gammahydroxybutyrate (GHB)

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

Influence of Genes and Emotions on  
medication Effects

Daniel Levin, Ph.D.  
NORAC Pharma  
Azusa, CA

Panel Approved Research

Daniel Levin, Ph.D.  
NORAC Pharma  
Azusa, CA

Panel Approved Research

Daniel Levin, Ph.D.  
NORAC Pharma  
Azusa, CA

Panel Approved Research

<u>Principal Investigator</u>	<u>Title of Study</u>
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development 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 Mackey, MD, PhD Stanford University Palo Alto, CA	Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients
Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA	Panel Approved Research Project
Ardis Moe, Ph.D. UCLA Center for AIDS Research Los Angeles, CA	Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta™) for Treatment of HIV Dementia
Richard Reznichak, 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
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans

Rajkumar J. Sevak, Ph.D.  
UCLA  
Los Angeles, CA

Human Methamphetamine  
Self-Administration in a Progressive-Ratio  
Paradigm

Matthew L. Springer, Ph.D.  
UCSF  
San Francisco, CA

Assessment of Impairment of Vascular  
Function in Rats by Environmental Exposure  
to Marijuana Second Hand Smoke

Raymond Stevens, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Structure Determination of the Hallucinogens  
LSD and Psilocin Bound to the Serotonin  
Receptor 5-HT<sub>2B</sub>

Michael Taffe, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Behavioral and physiological toxicities of  
cannabinoids

Michael Taffe, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Behavioral Toxicities of amphetamine and  
cathinone stimulant drugs

Michael Taffe, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Behavioral toxicities of amphetamine and  
cathinone stimulant drugs

Michael Taffe, Ph.D.  
The Scripps Research Institute  
La Jolla, CA

Behavioral and Physiological Toxicities of  
Cannabinoids: Effects of Cannabidiol

Stephen Van Dien, Ph.D.  
Genomatica, Inc.  
San Diego, CA

Panel Approved Research Project

Principal Investigator

Title of Study

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

Endocytosis and Opioid Receptors

Timothy Wigal, Ph.D.  
UC Irvine  
Irvine, CA

Brain Dopamine Function in Adults with  
Attention Deficit/Hyperactivity Disorder  
(ADHD)

Barth Wilsey, M.D.  
UC Davis Medical Center  
Sacramento, CA

The Effect of Vaporized Cannabis on  
Neuropathic Pain in Spinal Cord Injury



**APPENDIX B**

CURRENTLY OPEN (*through December 31, 2012*)  
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (SAP202)
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (IAP310)
AcelRx Redwood City, CA	A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (IAP309)
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate ALKS 5461 in Subjects with Major Depressive Disorder and Inadequate Responses to Antidepressant Therapy (ALK5461-2)

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Astra Zenica / CRO - Quintiles  
Overland Park, KS

A Randomized, Double-Blind, Placebo-  
Controlled Study to Assess the Efficacy and  
Safety of NKTR-118 in Patients with Non-  
Cancer-Related Pain and Opioid-Induced  
Constipation (OIC)  
(D3820C00004)

Astra Zenica / CRO - Quintiles  
Overland Park, KS

A Randomized, Double-Blind, Placebo-  
Controlled Study to Assess the Efficacy and  
Safety of NKTR-118 in Relieving Opioid-  
Induced Constipation (OIC) in Patients with  
Cancer-Related Pain  
(D3820C00006)

Astra Zenica / CRO - Quintiles  
Overland Park, KS

A Randomized, Double-Blind, Placebo-  
Controlled 12-Week Extension Study to  
Assess the Safety and Tolerability of NKTR-  
118 in Patients with Non-Cancer-Related Pain  
and Opioid-Induced Constipation (OIC)  
(D3820C00007)

Astra Zenica / CRO - Quintiles  
Overland Park, KS

An Open-Label 52 week Study to Assess the  
Long-Term Safety of NKTR-118 in Opioid-  
Induced Constipation (OIC) in Patients with  
Non-Cancer-Related Pain  
(D3820C00008)

Astra Zenica / CRO - Quintiles  
Overland Park, KS

An Open-label, Parallel-group, Phase I Study  
to Compare the Pharmacokinetics of NKTR-  
118 Following a Single-Oral Dose in Subjects  
with Renal Impairment and Subjects with  
Normal Renal Function  
(D3820C00009)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Collegium /CRO-INC Research Raleigh, NC	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of Oxycodone DETERx™ Versus Placebo in Opioid-Experienced and Opioid-Naive Subjects with Moderate-to-Severe Chronic Low Back Pain (CO-OXYDET-08)
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project.
INTRuST Clinical Consortium La Jolla, CA	Randomized Controlled Trial of Galantamine, Methylphenidate, and Placebo for the Treatment of Cognitive Symptoms in Patients with Mild Traumatic Brain Injury (mTBI) and/or Posttraumatic Stress Disorder (PISD) (“Cognitive REmediation After Trauma Exposure” Trial = CREATE Trial”)
Mitsubishi / CRO-Quintiles Overland Park, KS	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group, Multicenter, Efficacy, and Safety Study of MT-9938 for Treatment of Uremic Pruritus in Subjects with End-Stage Renal Disease Receiving Hemodialysis (MT-9938-01)

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Nektar  
San Francisco, CA

A Phase 2, Enriched-Enrollment,  
Randomized-Withdrawal, DB, PC, MC Study  
to Assess the Efficacy, Tolerability, & Safety  
of NKTR-181 in Opioid-Naïve Subjects w  
Mod to Sev Chr Pain Due to Osteoarthritis of  
the Knee  
(12-181-04)

Noven / CRO-PRA  
Lenexa, CA

A Randomized, DB, PC, Cross-Over, Lab  
Classroom Study to Evaluate the Safety &  
Efficacy of d-Amphetamine Transdermal  
Drug Delivery System (d-ATS) Compared to  
Placebo in Children & Adolescents w ADHD  
(N25-006)

Noven Pharmaceuticals  
New York, NY

An Investigational Study to Evaluate the  
Usability of Reformulated Methylphenidate  
Transdermal System in Children, Adolescents  
and Adults with ADHD and Caregivers  
(N17-030)

Pfizer Inc.  
New York, NY

An Investigational Study to Evaluate the  
Usability of Reformulated Methylphenidate  
Transdermal System in Children, Adolescents  
and Adults with ADHD and Caregivers  
(B4531002)

Purdue / CRO-INC Research  
Raleigh, NC

A MC, R, DB, PC Study w an OL Run-in to  
Assess the Efficacy & Safety of Hydrocodone  
Bitartrate (HYD) Tabs 20 to 120 mg  
Once-day in Subjects w Mod to Sev Chronic  
Low Back Pain  
(HYD3002)

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Purdue / CRO-PRA  
Raleigh, NC

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (ONU3701)

Purdue / CRO-Quintiles  
Overland Park, KS

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (ONU3704)

Sponsor

Description or Title  
of Clinical Drug Trial Protocol

Purdue / CRO-Quintiles  
Overland Park, KS

A Rand, DB, DD, PC, AC, PG, MC Trial of OXN to Assess the Analg Effic (Comp to Plac) & the Magm of Opioid-induc Const (Comp to OXY) in Opioid-exp Sub w Cont Mod to Sev Chr Low Back Pain & a His of Opioid-induc Const w Req ATC Opioid Therapy (ONU3705)

Purdue / CRO-INC Research  
Raleigh, NC

An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Non-malignant and Non-neuropathic Pain (HYD3003)

Purdue / CRO-PRA  
Charlottesville, VA

An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study (OTR3002)

QrxPharma / CRO-INC  
Austin, TX

A DB, Rand, P, & AC, PG Study to Evaluate the Safety, Tolerability & Efficacy of Q8011 Comped to OxyContin & Placebo in Pts w Mod to Sev Chr. Hip or Kneww Pain Due to Osteoarthritis (Q8011-201)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire / CRO-ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (489-322)
Shire / CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (SPD489-323)
Shire Pharmaceuticals Wayne, PA	A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (SPD 489-209)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire / CRO-Premier Research Group Alexander, NC	A Phase 4, Rando, DB, MC, PG, AC, Dose-optimization Safety & Efficacy Study of SPD489 (Vyvanse) Compared w OROS-MPH (concerta) w a Placebo Reference Arm, in Adolescents Aged 13-17 Years w ADHD (SPD489-405)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 4, Rando, DB, MC, PG, AC, Forced-dose Titration, Safety & Efficacy Study of SPD489 (Vyvanse) Compared w OROS-MPH (Concerta) w a Placebo Reference Arm, in Adolescents Aged 13-17 Years w ADHD (SPD489-406)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 3, Multicenter, Open-Label, 12-Month Extension Safety and Tolerability Study of SPD489 in the Treatment of Adults with Binge Eating Disorder (SPD489-345)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Optimization Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder (SPD489-344)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire / CRO-ICON Brentwood, TN	Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant (SPD489-329)
Shire / CRO-Premier Research Group Alexander, NC	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Optimization Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Moderate to Severe Binge Eating Disorder (SPD489-343)
Shire Pharmaceuticals Wayne, PA	A Phase 3b, Dbl-blind, Randomized, Active-controlled, Parallel-gr Study to Compare the Time to Response of Lisdexamfetamine to Atomoxetine in Children & Adolescents aged 6-17 w ADHD who have had an Inadequate Response to Methylphenidate Therapy (SPD489-317)
Sunovion / CRO-INC Seattle, WA	A Randomized, Double-Blind, Parallel-Group, Multicenter Efficacy and Safety Study of SEP-225289 Versus Placebo in Adults with Attention Deficit Hyperactivity Disorder (ADHD) (SEP360-20)



## APPENDIX C

### CURRENTLY OPEN (*December 31, 2012*) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

<u>Investigator or Sponsor</u>	<u>Description or Title of Research Study</u>
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Modafinil for Methamphetamine Dependence
Liza Gorgon NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial of Nopicastat for Cocaine Dependence (CS#1031)
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Sustained-Release Methylphenidate for management of Methamphetamine Dependence
Edythe London, Ph.D. Semel Institute, UCLA Los Angeles, CA	Safety and Initial Efficacy of Buspirone for Methamphetamine Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

Investigator or Sponsor

Description or Title  
of Research Study

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

Varenicline for Methamphetamine  
Dependence

Douglas Winship  
Catalyst  
Coral Gables, FI

Vigabatrin for Treatment of Cocaine  
Dependence: A Phase II Study Multi-Center  
Drug Trial

## APPENDIX D

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

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

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

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

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

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

Appendix D Cont.

**§ 11480. Cont.**

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

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

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

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

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

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

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

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

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

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

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

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

Appendix D Cont.

**§ 24172. Cont.**

- (i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

**§ 24173. Informed consent**

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

- (a) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.
- (b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.
- (c) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
  - (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

**§ 24173. Cont.**

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

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 § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

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

# **Attachment 2**



July 9, 2013

Jan Jamison  
California State Board of Pharmacy  
Public Information Officer  
1625 N Market Blvd N219  
Sacramento, CA 95834

Re: Notice of Interpreter Availability "Point to Your Language" Notice (Section 1707.6(c))

Dear Ms. Jamison:

This letter is a formal request by Costco Wholesale for approval from the Board for an alternative form of notice pursuant to 16 California Code of Regulations Section 1707.6(c). Costco would like to use our own form of notice of interpreter services. A sample of this is included in attachment two. We would be using this in color, on an 8 ½" by 11" easel.

Thank you,

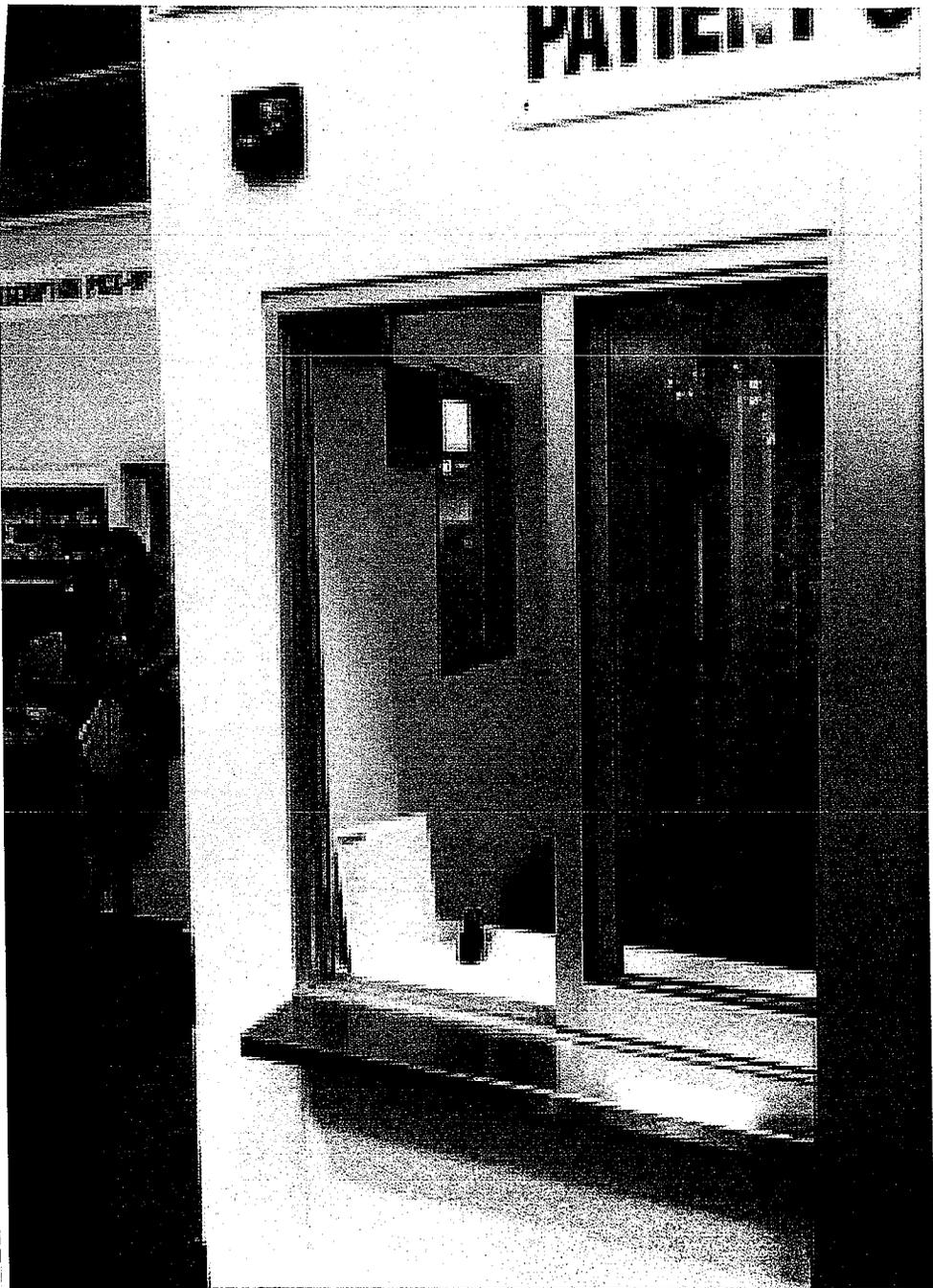
A handwritten signature in black ink that reads "Jon McArthur".

Jon McArthur  
Pharmacy Compliance  
Costco Wholesale  
999 Lake Drive  
Issaquah WA 98027

**English Translation:** Point to your language. An interpreter will be called. The interpreter is provided at no cost to you.

<b>Arabic</b> عربي <p>أشر إلى لغتك. وسوف يتم جلب مترجم فوري لك. سيتم تأمين المترجم الفوري مجاناً.</p>	<b>Japanese</b> 日本語 <p>あなたの話す言語を指して下さい。 無料で通訳を提供します。</p>
<b>Armenian</b> Հայերեն <p>Ցոյց տու՛ւք ո՞ր մէկ լեզուն կը խօսիք՝ Թարգմանիչ մը կանչել կը տանք. Թարգմանիչը կը տրամադրուի անվճար.</p>	<b>Korean</b> 한국어 <p>귀하께서 사용하는 언어를 지적하시면 해당 언어 통역 서비스를 무료로 제공해 드립니다.</p>
<b>Cambodian (Khmer)</b> កម្ពុជា (ខ្មែរ) <p>សូមចង្អុលភាសាអ្នក ។ យើងនឹងហៅអ្នកបកប្រែភាសាខ្មែរ ។ អ្នកបកប្រែភាសានឹងជួយអ្នកដោយមិនគិតថ្លៃ ។</p>	<b>Mandarin</b> 國語 <p>請指認您的語言， 以便為您提供免費的口譯服務。</p>
<b>Cantonese</b> 廣東話 <p>請指認您的語言， 以便為您提供免費的傳譯服務。</p>	<b>Polish</b> Polski <p>Proszę wskazać swój język i wezwiemy tłumacza. Tłumacza zapewnimy bezpłatnie.</p>
<b>Farsi</b> فارسي <p>زبان مورد نظر خود را مشخص کنید. یک مترجم برای شما درخواست خواهد شد. مترجم بصورت رایگان در اختیار شما قرار می گیرد.</p>	<b>Portuguese</b> Português <p>Indique o seu idioma. Um intérprete será chamado. A interpretação é fornecida sem qualquer custo para você.</p>
<b>French</b> Français <p>Pointez vers votre langue et on appellera un interprète qui vous sera fourni gratuitement.</p>	<b>Russian</b> Русский <p>Укажите язык, на котором вы говорите. Вам вызовут переводчика. Услуги переводчика предоставляются бесплатно.</p>
<b>German</b> Deutsch <p>Zeigen Sie auf Ihre Sprache. Ein Dolmetscher wird gerufen. Der Dolmetscher ist für Sie kostenlos.</p>	<b>Spanish</b> Español <p>Señale su idioma y llamaremos a un intérprete. El servicio es gratuito.</p>
<b>Hindi</b> हिंदी <p>अपनी भाषा पर इंगित करें और एक दुभाषिया बुलाया जाएगा। दुभाषिये का प्रबन्ध आप पर बिना किसी खर्च के किया जाता है।</p>	<b>Tagalog</b> Tagalog <p>Ituro po ang inyong wika. Isang tagasalin ang ipagkakaloob nang libre sa inyo.</p>
<b>Hmong</b> Hmoob <p>Taw rau koj hom lus. Yuav hu rau ib tug neeg txhais lus. Yuav muaj neeg txhais lus yam uas koj tsis tau them dab tsi.</p>	<b>Thai</b> ไทย <p>ช่วยชี้ที่ภาษาที่ท่านพูด แล้วเราจะจัดหาสามให้ท่าน การใช้สามไม่ต้องเสียค่าใช้จ่าย</p>
<b>Italian</b> Italiano <p>Puntare sulla propria lingua. Un interprete sarà chiamato. Il servizio è gratuito.</p>	<b>Vietnamese</b> Tiếng Việt <p>Hãy chỉ vào ngôn ngữ của quý vị. Một thông dịch viên sẽ được gọi đến, quý vị sẽ không phải trả tiền cho thông dịch viên.</p>

PATIENT





## Health and Wellness Practice Compliance

Debbie Mack, R.Ph, CHC  
Sr. Director, Corporate Compliance

702 SW 8<sup>th</sup> Street  
Bentonville, AR 72716  
Phone 479.277.0491  
Fax 479-273-8675  
Debbie.Mack@wal-mart.com

July 26, 2013

California State Board of Pharmacy  
Jan Jamison, Public Information Officer  
1625 N. Market Blvd. N219  
Sacramento, CA 95834  
Phone: 916-574-7957  
Fax: 916-574-8618

**RE: Notice of Interpreter Availability**

Dear Ms. Jamison:

Thank you for considering this request for approval by the California State Board of Pharmacy for Walmart and Sam's Club Pharmacies to use the enclosed sign for the Notice of Interpreter Availability pursuant to 16 California Code of Regulations Section 1707.6(c).

The attached example is for Walmart Pharmacies only. We plan to co-brand the logo to include Walmart and Sam's Club.

Thank you again for considering this request. Should you have any questions or need additional information regarding this matter, please do not hesitate to contact me at 479-277-0491.

Sincerely,

Debbie Mack, R.Ph, CHC  
Walmart Stores, Inc.



Interpreter Services available at no cost to you. Please point to your language.

**Spanish**

Servicios de intérprete disponible sin costo alguno para usted. Por favor señale su idioma.

**Russian**

Вы имеете право на бесплатные услуги переводчика. Пожалуйста просим Вас указать на Ваш язык.

**Portuguese (Brazilian)**

Serviços de tradutor disponível para você gratuitamente. Favor apontar para o seu idioma.

**Polish**

Pacjenci mogą korzystać z bezpłatnych usług tłumacza. Proszę wskazać swój język.

**Hmong**

Peb yuav muaj tug paab txhais lug rua koj dlawb dlawb. Thov taw rua koj yaam lug.

**French (Canadian)**

Services d'interprète disponibles sans frais pour vous. Veuillez indiquer votre langue.

**German**

Sie können von kostenlosen Dolmetschdiensten Gebrauch machen. Bitte zeigen Sie auf Ihre Sprache.

**Vietnamese**

Dịch vụ Thông dịch luôn có sẵn miễn phí cho quý vị. Vui lòng cho biết ngôn ngữ của quý vị.

**Cantonese (Simplified)**

请点击这里以获得免费广东话口译服务

**Cantonese (Traditional)**

請點這裏以獲得免費廣東話口譯服務

**Mandarin (Traditional)**

請點這裏以獲得免費國語口譯服務

**Mandarin (Simplified)**

请点击这里以获得免费普通话口译服务

**Korean**

통역 서비스를 무료로 제공합니다.

**Cambodian/Khmer**

សំណើកម្មវិធីបកប្រែសេរី  
មានជូនដល់លោកអ្នកដោយមិនអស់លុយ។  
សូមចង្អុលទៅភាសារបស់លោកអ្នក។

**Tagalog**

Mga Serbisyo ng Tagasalin nang walang gastos sa iyo. Pakituro sana ang iyong lengguwahe.

**Arabic**

يمكننا توفير خدمات الترجمة الفورية مجاناً. الرجاء تحديد لغتك

**Farsi**

خدمات ترجمه رایگان برای شما موجود است.  
لطفاً به زبان خود اشاره کنید.

**Armenian**

Կարող ենք ապահովել անվճար արագ և ճշգրիտ լեզուների թարգմանություններ։  
Խնդրում ենք նշել Ձեր լեզուն։

**Italian**

Servizi di interpretariato gratuiti. Indicare la lingua.



**CERTIFIED LANGUAGES**  
INTERNATIONAL





**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834  
Phone: (916) 574-7900  
Fax: (916) 574-8618  
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

**Request for Approval of Alternate Format or Display Methodology  
“Point To Your Language” Notice (Notice of Interpreter Availability)**

Every pharmacy is required to post or provide a notice of interpreter availability in a place conspicuous to and readable by a consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Every pharmacy shall use the standardized notice provided by the board unless prior approval has been received to use another format or display methodology. *16 Cal. Code Reg. 1707.6(c).*

Completion of this form is not mandatory. You may submit a written request to the board at the address below. Unless approved by the board in advance, each pharmacy must use the standard notice provided by the board, available on the board’s website:

[http://www.pharmacy.ca.gov/publications/point\\_to\\_your\\_language.pdf](http://www.pharmacy.ca.gov/publications/point_to_your_language.pdf)

**IMPORTANT:** All twelve languages specified in the board’s regulation must be on the “Point To Your Language” notice.

Please send your request, a sample of your proposed notice, and any relevant / additional information to the board at the following address: California State Board of Pharmacy, 1675 North Market Blvd., Suite 219, Sacramento, CA 95834.

Name of Pharmacy: \_\_\_\_\_ License Number: \_\_\_\_\_

Address: \_\_\_\_\_

Contact Person: \_\_\_\_\_ Phone Number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**Please complete the following:**

**1. What are you requesting? (Check all that apply.)**

Print

- Approval of an alternate printed format of the notice of interpreter availability.
- Approval of a specific display methodology of the printed notice.

Video

- Approval of another video format of the notice of interpreter availability.
- Approval of a specific display methodology of the video notice.

**2. Are all twelve languages required by 16 California Code of Regulations Section 1707.6(c) on your notice?**

YES

NO

**3. Are additional languages (in addition to the twelve languages required by 16 CCR § 1707.6(c)) on your notice?**

YES

NO

a. If YES, what additional languages are listed?

b. How did you determine what additional languages to include?

**4. Did you contract with a translation service to provide translations for your notice?**

YES

NO

a. If YES, is the translation service certified or accredited?

b. If YES, what is the agency or agencies that certified or accredited the translation service?

c. Please provide the name, address and phone number of the translation service you used.

NAME:

ADDRESS:

PHONE NO:

**5. Additional Information:**

# **Attachment 3**

# Key Facts About Emergency Contraception



Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception (EC) if:

- You had unprotected sex, or
- You think your contraceptive didn't work.

**What are Emergency Contraceptive pills?**

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of Emergency Contraceptive pills:

- Progestin-only pills (Plan B® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- High doses of regular oral contraceptive pills

**Don't wait! Take EC as soon as possible.**

- It is best to take EC as soon as possible; the sooner you take EC the more effective it is.
- It has been shown to be effective for up to 5 days.
- For more information talk to your pharmacist or doctor.

**When taken as directed Emergency Contraception has been shown to be safe and effective.**

- Emergency Contraception may reduce the risk of pregnancy by up to 89 percent.
- The effectiveness of EC varies based on the type used and when it is taken.
- EC is only recommended as a backup and should not be used as your primary method of birth control.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

What EC does:

- Emergency Contraceptive pills prevent pregnancy.
- Emergency Contraceptive pills are not effective after pregnancy has occurred and they will not harm the developing fetus.
- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Using Emergency Contraceptive pills will not affect a woman's ability to become pregnancy in the future.

**Follow-up after taking Emergency Contraceptive pills:**

- If you vomit after taking emergency contraception you may need to take another dose. Before you do, contact a pharmacist or healthcare provider immediately.
- If you do not get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic for a regular birth control method and information about preventing sexually transmitted infections.
- Medical providers or your pharmacist can provide Emergency Contraception for future use if needed.

In California, women and men may receive free family planning services through Family PACT based on income.

If you don't have a doctor or clinic, call (800) 942-1054 to find a Family PACT provider near you.

Under the Affordable Care Act (ACA), Emergency Contraception may be covered with a prescription.



**BE AWARE AND TAKE CARE:**  
Talk to your pharmacist!  
CALIFORNIA STATE BOARD OF PHARMACY

California State Board of Pharmacy  
1625 North Market Blvd., Suite N-219  
Sacramento, CA 95834

www.pharmacy.ca.gov  
(916) 574-7900

# **Attachment 4**

## TABULATION OF SURVEY RESULTS

### Survey Results Regarding Pharmacy Compliance With Translated Labels and Interpreter Availability

A total of 239 surveys were collected by Board inspectors. The results are as follows:

1. Do you provide prescription container labels with translated directions?

a) Yes 185 (77.4%)    b) No 54 (22.6%)

Individual Comments:

Limited Spanish

No occasion has arisen

Spanish/French Canadian on label and as counseling information

Spanish

Spanish only

2. How do you provide the translation of the directions for use?

a) Pharmacy staff translates the labels: 69 (37.3%)

Individual Comment: Spanish Only

b) The pharmacy uses the Board of Pharmacy's online translated directions for use: 5 (2.7%)

c) The pharmacy uses computer software or online programs: 151 (81.67%)

Comments: Spanish only; by Sigs only; no free-form Sigs can be translated on label.

d) The pharmacy uses other means of providing translations (describe): 12 (6.5%)

Individual Responses:

1. Third party Language Line, although the occasion has never arisen

2. Language Line

3. Store employees (Spanish only). No other language translations have ever come up

3. If you translate the labels, do you also provide the English language equivalent on the label?

a) Yes 47 (26%)      b) No 134 (74%)

Individual Comments:

Optional

If the software is used correctly an additional leaflet prints in English, with label information and medication information

No room/space for both

Hard copy is in English

RPh translates based on Spanish experience

Some prescribers write both English and the foreign language, so the pharmacy puts both on the label

Has never come up

Don't use often

Don't know if label provides English translation.

4. If you do not provide translated directions on the label, why?

a) The pharmacy has no requests for translated labels 28 (51.9%)

b) The pharmacy has too many patients with diverse language needs 4 (7.4%)

c) The pharmacy's software will not print in foreign language fonts 18 (33.3%)

d) The pharmacy is concerned that errors on the label will go undetected 14 (25.9%)

e) Other:

Individual Responses:

Pharmacy has not contracted with any software vendor to provide labels yet (new pharmacy).

Pharmacy has no prescription processing software at this time (new pharmacy).

5. How does the pharmacy comply with the interpreter requirements?

a) Uses pharmacy staff at this or other pharmacies to interpret 138 (57.7%)

b) Uses a telephone language service 190 (77.5%)

c) Is not compliant with current requirements to have access to an interpreter 15 (6.3%)

Individual Comments:

Is not in full compliance. Only has Spanish-speaking staff.

Both staff and rarely Language Line

# **Attachment 5**

## CURRENT REGULATIONS (2013)

### ➡ § 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

## CURRENT REGULATIONS (2013)

- (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take \_\_\_ [insert appropriate dosage form] at a time. Wait at least \_\_\_ hours before taking again. Do not take more than \_\_\_ [appropriate dosage form] in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
- (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if

## CURRENT REGULATIONS (2013)

interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

# **Attachment 6**



**California State Board of Pharmacy**  
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

## Communication and Public Education Committee Minutes

**Date:** Monday, October 7, 2013  
**Location:** Department of Consumer Affairs  
First Floor Hearing Room  
1625 N. Market Boulevard  
Sacramento, CA 95834

### **Committee Members Present:**

Stan Weisser, Professional Member (Chairing)  
Cheryl Butler, Professional Member  
Ramon Castellblanch, Public Member  
Albert Wong, Professional Member

### **Committee Members Absent:**

Ryan Brooks, Public Member (Chair)  
Rosalyn Hackworth, Public Member  
Shirley Wheat, Public Member

### **Staff Present:**

Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Kristy Shellans, DCA Sr. Staff Counsel  
Carolyn Klein, Manager  
Laura Hendricks, Administrative Analyst

Stan Weisser, President of the Board, appointed himself to serve as Chair of the meeting for this date. He called the meeting to order at 12:33 p.m. and conducted a roll call of the members.

### **1. Review and Discussion of the 42<sup>nd</sup> Annual Report of the Research Advisory Panel of California**

The Research Advisory Panel of California was established 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.*

Patrick R. Finley, Pharm.D., is the board's appointment to the seven member advisory panel. Mr. Weisser referenced the copy of the 42nd Annual Report of the Research Advisory Panel of California (July, 2012) provided with the meeting materials. He recommended that Dr. Finley come to a future meeting of the committee or board to tell them more about the Advisory Panel's activities and to share additional information on studies that may be of interest to the board or related to the pharmacy profession.

## **2. Discussion and Action on Requests from California Pharmacies for Exemption from 16 California Code of Regulations Section 1707.6(e) to Use Their Own Notice of Interpreter Availability Posters**

Existing Board regulation requires pharmacies to prominently post the "Notice to Consumers" required by 16 CCR Section 1707.6. In addition, Section 1707.6(c) requires every pharmacy to post or provide a "point to your language" notice so that consumers are aware that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the Board unless the pharmacy has received prior approval of another format or display methodology. The board has delegated to the Communication and Public Education Committee the authority to act on all requests to use another format or display methodology of these posters.

The committee discussed the two requests to utilize their own Notices of Interpreter Availability. Sr. Staff Counsel Kristy Shellans advised the committee that neither request met the requirements of the regulation – in that neither contained the language required by subdivision (c) of Section 1707.5: "Point to your language. Interpreter services will be provided to you upon request at no cost." Ms. Shellans noted that without the required language, she believes the committee does not have the authority to approve the notices. She reminded the committee that the board authorized the committee to approve alternate *formats* of the notice, but that each would need to meet the requirements of the regulation.

Dr. Albert Wong expressed concern over different posters, in that consumers may not be able to recognize it as a board-required notice if they were different. He approached the idea of having a company place their company's banner on the board-approved poster so that they would be consistent. Dr. Ramon Castellblanch stated that he looks for a state seal on any notice to determine if it is a mandated notice. Ms. Herold stated that the regulation requires the notice to be within easy reach of the consumer at the pharmacy counter. She stated that requesters would know what languages are needed in their settings, thus, adding languages (to the twelve required by the regulation) ultimately serves the consumer. She said a regulation change would be required if the board determined that only the board's notice, customized with an entity's banner, should be required.

Mr. Weisser asked counsel if adding a company's name to the board-approved poster is a deviation from the regulation. Ms. Shellans stated it was not a deviation; that the committee

would just need to approve such a change.

Dr. Castellblanch asked if the board should require that the board logo be required to be on any notice posted pursuant to the regulation. Counsel stated that the current requirements do not require the board's logo on such a notice.

Counsel reference a draft request form provided in the meeting materials. She stated she would like to see the form reference the required text that shall be on each notice.

**Motion/Second (Castellblanch/Wong):**

Do not approve the alternate formats presented by Walmart and Costco because the required language "Point to your language. Interpreter services will be provided to you upon request at no cost" is not on each of the alternate formats. In addition, the committee would like to see any alternate format notice submitted for the committee's approval to include the statement "This notice is required to be posted by the California Board of Pharmacy."

Public Comment: There was no public comment.

Support: 4      Oppose: 0      Abstain: 0

**3. Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by 16 California Code of Regulations Section 1746**

Mr. Weisser referred to the updated Emergency Contraception Fact Sheet provided in the meeting materials, adding that the board is currently securing bids to have the Fact Sheet reproduced in six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. These are the same six languages in which the board makes available its "Notice to Consumers" posters (upon request, or download). When available, the Fact Sheets will be available upon request, and will also be available for download from the board's web site.

There was no further committee or public comment on this matter.

**4. Assessment of California's Patient-Centered Labeling Requirements as Required by 16 California Code of Regulations Section 1707.5(e)**

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

The committee reviewed the factors considered when developing the current regulatory requirements, as well as the board's efforts to date to review the patient-centered requirements, which was initiated by the committee in April 2013. The committee discussed the USP guidelines published in November 2012, noting the close resemblance to the board's

requirements. Ms. Herold indicated that staff continues to search for medical literacy research regarding standardized directions for use, noting the goal of such a schedule is to increase patient understanding, adherence to medication instructions and improving health outcomes. She stated she has been trying to build support among groups by highlighting the benefits of utilizing standardized directions for use, and that there may be educational opportunities to work with the prescribing boards to this end. One of the recommendations in the NCPDP White Paper is to implement the use of universal medication instructions in an effort to help get the e-prescribing directions for use standardized. In its surveys, the board has looked at the use of font sizes, how interpretive services requirements are being implemented, patient satisfaction (a general framework of what patients are thinking) – noting they want larger font, and the purpose on the label. Mr. Weisser discussed the distribution of these surveys, noting that CPEHN had the survey translated and distributed among limited English and other groups. Dr. Wong indicated the survey was available in Chinese in his pharmacy. Ms. Herold provided the results of a recent survey conducted by the board, the results of which will be appended to the minutes of the meeting.

**Should the board modify what is considered “patient-centered”?**

Regulation currently requires that “patient-centered” items shall be clustered into one area of the label that comprises at least 50 percent of the label:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Ms. Herold noted that in addition to these required elements, some pharmacies include additional information within the 50% clustered area, such as the patient’s address, expiration dates of drugs, or other information. She asked the board to clarify exactly what they intend be included within the patient-centered clustered area. Dr. Castellblanch spoke in support of having “only the four items” (specified at Section 1707.5(a)(1)(A)-(D)) – and nothing else – within the clustered area.

**Motion/Second (Castellblanch/Butler):** Recommend that Section 1707.5(a)(1) be modified to read as follows to indicate the prominence of the patient-centered clustered items:

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label, and only those four items. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

There was no public comment.

Support: 4      Oppose: 0      Abstain: 0

**Does the committee wish to discuss any changes to the requirement that the “name of the patient” be in the patient-centered cluster portion of the label?**

There was no committee or public discussion.

**Should changes be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug”?**

**Is it worthwhile to list the name of the manufacturer in the patient-centered portion of the label?**

Current regulation at Section 1707.5(a)(1)(B) specifies that the name of the drug and strength of the drug be in the patient-centered portion of the label and that “for the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.” The committee discussed the value of having the manufacturer’s name as one of the patient-centered elements. Dr. Wong stated his support of having the manufacturer’s name on the label, but not necessarily within the patient-centered elements.

Ms. Herold noted recommendations provided in the research:

- USP suggests that the drug name be spelled out fully (brand AND the generic name) – no abbreviations.
- NABP suggests inclusion of suffixes (CD, SR, XL, XR, etc.)

It was the consensus of the committee that having both the trade/brand name and the generic name fully spelled out was needed. In addition, there was consensus that the suffixes referenced in the NABP recommendation were part of the drug name and should be used.

- NABP suggests that if a prescription is written for a brand name and a generic drug is dispensed then “generic for [brand name]” appear on the label.

Ms. Herold stated it is required that the manufacturer name be on a prescription label, and that the committee is considering whether or not it should be within the patient-centered cluster or not.

## Public Comment

Dr. Steve Gray speaking for CSHP and as an individual/pharmacist noted that CSHP and CHA had a joint task force on “transitions for care” which addressed medication reconciliation. The task force noted too high a percentage of confusion among patients and their care givers regarding the names of drugs. He provided examples where brand names were prescribed and where generic substitutions were made (and communicated to the patient). He provided an example of a verbal consult where a patient is told that hydrochlorothiazide is substituted for Hydrodiuril, and the patient goes home with a prescription label that indicates hydrochlorothiazide. When the patient gets home, they also have a vial of Hydrodiuril (previous Rx) and they take both and have an adverse event – because they didn’t know they should have taken only one of those. He supported the use of “Generic for...” on the label so that the patient or care giver would not be confused as to what medication should be taken. He said *something* needs to change, and that the board may want to look into this further by having others address the board. He also spoke in support of prescription labels that are formatted the same, using a “check book” example (where specific items are always found in the same place no matter the bank).

With regard to directions for use, Dr. Gray provided that the name and *strength of the drug* is important to emergency personnel.

It was the consensus of the committee that the “suffixes” referenced in the research are a part of the drug name and should be on the label.

The committee discussed the use of generic drug names (when a generic is substituted for a trade name drug, or when a generic is prescribed) and reached consensus that when a generic is dispensed for a trade name drug that the label specify “Generic for *(trade name)*.” Dr. Wong conveyed the importance of having the manufacturer’s name, because that information was important to persons who might have drug allergies to a particular generic.

**Motion/Second (Wong/Castellblanch):** Modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name). Staff will work with counsel to bring back languages that would accomplish this recommendation.

There was no additional public comment on this item.

Support: 4      Oppose: 0      Abstain: 0

**Should Purpose or Condition be in the patient-centered clustered items?**

There was wide consensus that the purpose or condition should be on the prescription label within the clustered patient-centered items. Staff counsel commented that a statutory change may be needed, as Section 4076 states it is required to be on the label only if it is specified on the prescription.

**Public Comment**

Dr. Gray stated that a pharmacist may indicate the purpose or condition on the label if the patient requests it. He suggested a modification to the regulation that would clarify that a pharmacist can use professional judgment as to whether or not the purpose or condition should be on the label. With regard to patient consultation, a pharmacist needs to know what the drug is being used for in order to provide a full consultation, so the pharmacist has to figure that out somehow. Ms. Anne Sodergren, AEO, sought the committee’s input on suggesting a statutory amendment, and noted challenges in previous years when trying to make a statutory change to require the purpose or condition on the prescription label. Jonathan Nelson, CSHP, spoke in support of having the purpose or condition on the label, within the patient-centered clustered area. Dr. Gray suggested modifying the regulation language that would more clearly indicate that a pharmacist could use his or her professional judgment to include the purpose or condition on the label.

**Motion/Second (Butler/Castellblanch):** Direct staff to work with legal counsel to draft language to either amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

Dr. Steve Gray, Kaiser Permanente, and Jonathan Nelson, CSHP, spoke in support of having the “purpose or condition” as one of the patient-centered required items.

Support: 4      Oppose: 0      Abstain: 0

**What Font Size is Appropriate?**

Stan Weisser read the Governor’s recent veto letter for SB 205 related to the minimum font size on a prescription label, indicating the Governor’s preference to wait for the findings of the board’s review before making a statutory change to the font size on a prescription label.

Ms. Herold reviewed the current requirement for font size (10 point minimum, with 12 point required if requested by the patient) and as previously discussed at this meeting pharmacies, by a wide preponderance, are using 12 point font as the primary font on prescription labels. It was the consensus of the committee that the regulation should be modified to require a minimum 12 point font.

Dr. Castellblanch recognized the many reports, research, and legislative efforts to address the minimum font size on prescription labels.

**Motion/Second (Castellblanch/Butler):** Modify Section 1707.5(a)(1) to read as follows:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans-serif typeface~~ or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

#### Public Comment

Mandy Lee, California Retailers Association, expressed concern that if translations will be required at some point, and that if the patient-centered items are required to be printed in 12-point font, there could be issues with fitting everything on the label.

Jonathan Nelson, CSHP, sought clarification on exactly which patient-centered items would be impacted by the motion. Counsel referred to the four items currently referenced in Section 1707.5(a)(1)(A) – (D).

Support: 4      Oppose: 0      Abstain: 0

#### **Should the existing requirements for “added emphasis” be modified?**

Current regulation at Section 1707.5(a)(2) states “For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).”

Ms. Herold noted that there is not much available in the research that addresses these items, however, there is a recommendation in the research that sentence casing not be in all capital letters.

There was no further committee or public discussion on this item.

#### **Translations**

Ms. Sarah de Guia, CPEHN, thanked the board for its efforts to encourage translations for prescription labels. She noted that translation services are provided in health care settings on a regular basis. She expressed concern over the survey results that indicated that pharmacies were using on-line translation services, such as Google Translations. Ms. de Guia spoke in support of the professional field of translators that are certified to provide these

services. She requested that as the board moves forward that it considers the use of such certified translators, and that where CPEHN can provide additional information to let her know. She said CPEHN is concerned about the quality of translations that are being provided. She spoke in support of establishing standards for providing translations.

Dr. Castellblanch asked how the board has been advising pharmacies of the patient-centered requirements. Ms. Herold noted that the board has utilized its newsletter, *The Script*, as well as e-mail subscriber alerts.

Ms. Mandy Lee, California Retailers Association, indicated they are not aware that any of their member pharmacies that use on-line translations, as described at the meeting. Ms. Herold indicated that two member pharmacies indicated they used “on-line computer software” to provide the translations. Ms. Sodergren asked if Ms. Lee might be able to survey their members to clarify the types of services that are used for the purpose of translating prescription drug labels.

There was no further discussion on this item.

5. Update on the Committee’s Goals for 2012-2017 To Fulfill the Board’s Strategic Plan

Ms. Herold stated that the committee goals need to be augmented.

6. Update on The Script

Mr. Weisser referred to the update provided in the meeting materials.

7. Public Outreach Activities Conducted by the Board

A listing of public outreach activities are appended to these minutes.

8. Public Comment for Items Not on the Agenda

There were no public comments.

Mr. Weisser adjourned the meeting at 2:25 p.m.

## TABULATION OF SURVEY RESULTS

### Survey Results Regarding Pharmacy Compliance With Translated Labels and Interpreter Availability

A total of 239 surveys were collected by Board inspectors. The results are as follows:

1. Do you provide prescription container labels with translated directions?

a) Yes 185 (77.4%)      b) No 54 (22.6%)

Individual Comments:

Limited Spanish

No occasion has arisen

Spanish/French Canadian on label and as counseling information

Spanish

Spanish only

2. How do you provide the translation of the directions for use?

a) Pharmacy staff translates the labels: 69 (37.3%)

Individual Comment: Spanish Only

b) The pharmacy uses the Board of Pharmacy's online translated directions for use: 5 (2.7%)

c) The pharmacy uses computer software or online programs: 151 (81.67%)

Comments: Spanish only; by Sigs only; no free-form Sigs can be translated on label.

d) The pharmacy uses other means of providing translations (describe): 12 (6.5%)

Individual Responses:

1. Third party Language Line, although the occasion has never arisen

2. Language Line

3. Store employees (Spanish only). No other language translations have ever come up

3. If you translate the labels, do you also provide the English language equivalent on the label?

a) Yes 47 (26%)      b) No 134 (74%)

Individual Comments:

Optional

If the software is used correctly an additional leaflet prints in English, with label information and medication information

No room/space for both

Hard copy is in English

RPh translates based on Spanish experience  
Some prescribers write both English and the foreign language, so the pharmacy puts both on the label  
Has never come up  
Don't use often  
Don't know if label provides English translation.

4. If you do not provide translated directions on the label, why?

- a) The pharmacy has no requests for translated labels 28 (51.9%)
- b) The pharmacy has too many patients with diverse language needs 4 (7.4%)
- c) The pharmacy's software will not print in foreign language fonts 18 (33.3%)
- d) The pharmacy is concerned that errors on the label will go undetected 14 (25.9%)
- e) Other:

Individual Responses:

Pharmacy has not contracted with any software vendor to provide labels yet (new pharmacy).

Pharmacy has no prescription processing software at this time (new pharmacy).

5. How does the pharmacy comply with the interpreter requirements?

- a) Uses pharmacy staff at this or other pharmacies to interpret 138 (57.7%)
- b) Uses a telephone language service 190 (77.5%)
- c) Is not compliant with current requirements to have access to an interpreter 15 (6.3%)

Individual Comments:

Is not in full compliance. Only has Spanish-speaking staff.

Both staff and rarely Language Line

## **PUBLIC OUTREACH ACTIVITIES (July – September 2013)**

The following are public outreach activities we have participated in since the July report to the board:

- July 25, 2013: The Board of Pharmacy, in conjunction with the Los Angeles Field Division of the Drug Enforcement Administration, co-hosts a seminar for pharmacists on July 26 in Downey, CA. The seminar focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminar was well attended, with approximately 220 in attendance.
- August 13, 2013: Executive Officer Herold provides a webinar on e-Pedigree requirements at to a webinar audience hosted by the FDAnews.
- August 16, 17, 18, 19: The Board of Pharmacy, in conjunction with Washington Headquarters of the Drug Enforcement Administration, co-hosts four day-long seminars for pharmacists. Two were held in San Diego, and two in San Jose. The seminars focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminars were well attended, with at least 300 individuals in attendance each day.
- August 25: Supervising Inspector Janice Dang provides a presentation on corresponding responsibility of pharmacies to physicians attending the Napa Pain Conference.
- August 26: Executive Officer Herold provides a presentation via telephone connection to the New Mexico Board of Pharmacy on virtual wholesalers and wholesaler brokers and drug diversion.
- September 17: Executive Officer Herold provides a presentation via telephone connection on California's e-pedigree regulations to 300 attendees of a LogiPharma conference in Princeton, NJ.
- September 17: Executive Officer Herold provides a webinar on California's requirements for serialization to attendees of a PricewaterhouseCoopers virtual meeting.
- October 2: Executive Officer Herold provides a presentation on California's e-pedigree regulations to attendees at a GS1 conference held in San Francisco.