



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.

Communication and Public Education Committee
Meeting Materials for the December 10, 2014 Meeting

Members

Rosalyn Hackworth, Public Member, Chair
Albert Wong, PharmD, Professional Member
Ramon Castellblanch, PhD, Public Member
Allen Schaad, RPh, Professional Member

-
- 1. FOR DISCUSSION: Presentation on the 43rd Annual Report of the Research Advisory Panel of California by Dr. Laurence R. Upjohn, Pharm.D.**

Attachment 1

At the last committee meeting, members requested that a presentation be made on the 43rd Annual Report of the Research Advisory Panel of California. California law, pursuant to Health & Safety Code sections §11480 & §11481, requires proposed research projects using certain opioid, stimulant and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office. The Board of Pharmacy has an appointee on the panel.

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

Dr. Laurence R. Upjohn, Pharm.D.Chief, with the Science and Education Section of the California State Department of Public Health/Food and Drug Branch, will present the report.

Attachment 1 includes a copy of the report and Dr. Upjohn's biography.

2. FOR DISCUSSION: Future Board Forum on Elements of Quality Patient Consultation

Attachment 2

It was discussed at the last committee meeting and at the October board meeting that requirements for patient consultation were adopted by the board in the early 1990s and have not been revised since. The importance of patient consultation by a pharmacist was discussed and it was agreed that consultations are still not being conducted as they should be, despite studies that have shown there is better adherence with consultation.

The committee members discussed that consultation should include items of importance that aren't always on the label, such as storage requirements and number of refills left; and should never be just a recitation of what is already printed on the label. The committee felt pharmacists are in a position to dispel bad information that patients might find on the internet and since pharmacists are health care providers, pharmacists need to engage their patients.

It was also noted that the committee discussed that 25 years ago when the board adopted patient consultation requirements, the board extended implementation by 18 months to allow for enactment of legislation that permitted pharmacy technicians to work in pharmacies to "free" the pharmacist to perform consultation.

During the board meeting, it was stated that pharmacy schools must do more to train their students on how to do a proper consultation and not leave it up to the students to learn during their internships. Evidence of this is a past study that indicated California pharmacists are not comfortable doing consultations because they weren't trained on how to do them.

The committee further discussed that many improvements are needed in the area of pharmacist consultation. The board requested that patient consultation and the elements of quality consultation be further discussed by the committee.

The board asked that a future board meeting discussion be scheduled with California school of pharmacy deans to discuss how schools are educating students to perform patient consultation.

A copy of 16 California Code of Regulations Section 1707.2 and an excerpt of the discussion from the October Board Meeting is included in **Attachment 2**.

3. FOR DISCUSSION AND POSSIBLE ACTION: Social Media Participation by the Board of Pharmacy presented by Scott Paterson, Deputy Director of Enterprise Solutions for the California Department of Technology

Attachment 3

The Board of Pharmacy has not participated in social media and the committee will examine and discuss utilizing Facebook and Twitter to provide public outreach to consumers and the media. Scott Paterson, Deputy Director of Enterprise Solutions for the California Department of Technology, will present information on social media and state guidelines for participation.

Attachment 3 contains Mr. Paterson's presentations and his biography.

4. FOR DISCUSSION AND POSSIBLE ACTION: Assessment of California's Patient-Centered Labeling Requirement

Attachment 4

a. Should Purpose or Condition Be a General Requirement For Labels?

At the October Board Meeting, the addition of this component as a required element to the label was discussed.

Board members, especially those who have cared for an elderly parent, concurred that it is important to have purpose on the label; however, prescribers are not required to include it and may choose not to because of off-label use of medications.

Discussion also included whether or not a pharmacist could include purpose on the label, even though the prescriber didn't include it, if the patient requests it. It was also discussed that pharmacists should ask patients the purpose of the medication because that could prevent a medication error and the inclusion of purpose will be a new requirement for e-prescriptions.

Draft language was presented at the board meeting to determine whether there should be regulation/legislation and to see if there was support to proceed. The draft language is below.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, ~~if requested by the patient or patients.~~ unless the patient requests that this information not be added to the prescription.

Legal counsel informed the board that if it was not provided by the doctor, the pharmacist would need to call the prescriber or talk to the patient to determine the purpose.

The board asked that this item be sent back to the committee for additional discussion.

b. Translation of Labels and the Use of Translated Directions Available on the Board's Website

At the last committee meeting, members agreed that patients benefit when translated instructions are provided in their native language; however, there are liability issues for pharmacists when they cannot read or write the language on the label or in ancillary information.

The committee discussed that requiring translations could first begin by requiring the use of the vetted instructions on the board's website, which appear in English and five different languages; and then addressing the issue of liability through legislation. There was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescriber's prescription order.

At the October Board Meeting, discussion included comments that requiring complete translations in all languages could be difficult for many pharmacies and could negatively affect the workflow. It was noted that a board survey indicated that approximately 70 percent of the pharmacies indicated they already had a system in place to provide translations. Concerns were also raised about law enforcement or emergency medical workers needing to have the label printed in English.

It was explained that the initial intent of the proposal is to have pharmacists use the standardized directions for use which are on the board's website and are translated into five languages.

It was stated that the goal of the proposed language was not to provide translations for every language and for every possible type of prescription with complicated directions for use, but the goal was to provide translations for the 90 percent of medications that are dispensed with standard directions for use in the five languages spoken by the majority of Californians.

During the board meeting, board members were provided with draft language to consider, it was noted that the language specifically took the liability off the pharmacist if they used the translations provided on the board's website. The board asked that the item be brought back to the committee for further discussion and that the draft language be revised.

This revised language will be brought to the committee at the meeting.

Attachment 4 contains the discussion from the October Board Meeting on including purpose or condition on a label and translation of labels and use of translated directions.

5. FOR INFORMATION: Update on *The Script*

The Board of Pharmacy newsletter, *the Script*, is in the review process and should be distributed before the end of the year. The issue highlights new laws, board enforcement actions, hospital drug diversion, the Medical Board's release of their revised pain management guidelines and the board's recommendation on no tobacco sales in pharmacies.

6. FOR DISCUSSION: Redesign of the Board's Website

The Board of Pharmacy's transition to the new BreEZe system has been delayed. Thus in 2015, the board will upgrade the board's website to the new state agency format.

7. FOR INFORMATION: National Association of Boards of Pharmacy's .Pharmacy Suffix for Online Pharmacies

The National Association of Boards of Pharmacy (NABP) launched the .pharmacy Top-Level Domain (TLD) to provide consumers around the world with a means for identifying safe, legal and ethical online pharmacies and related resources.

During the initial application and registration phase, eligible trademark holders who have logged their brand names in the ICANN TMCH may apply to NABP for approval to register .pharmacy domain names that exactly match their trademark names. Once approved, these organizations will be able to register the domain with an approved registrar. The initial application phase will begin immediately following a special members-only registration period for NABP's member boards of pharmacy.

Following the initial application and registration phase, registration for .pharmacy domain names will be open to pharmacy websites that are accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) and Veterinary-Verified Internet Pharmacy Practice SitesCM (Vet-VIPPS®) programs, as well as for pharmacy websites that have received approval through the NABP e-Advertiser ApprovalCM Program.

Applications from other dispensing pharmacies will be accepted beginning in mid-2015. General availability will begin in June 2015, at which time all entities providing pharmacy-related products, services or information that meet .pharmacy eligibility standards will be able to apply to register for the domain.

The .pharmacy domain application will be available at www.dotpharmacy.net beginning December 19, 2014. Additional information about the .Pharmacy TLD Program, as well as NABP's most recent research on rogue online drug sellers is also available on the site.

8. FOR INFORMATION: Update on Media Activity

Attachment 5

Attachment 5 contains an update on board media activity.

9. FOR INFORMATION: Public Outreach Activities Conducted by the Board

- Oct. 13: Ms. Emard attended the California Prescription Drug Abuse Work Group meeting
- Oct 17: Ms. Herold presented prescription drug abuse information to the California Dental Association
- Oct. 21: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Oct. 27: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Oct. 31: Dr. Amy Gutierrez and Ms. Herold provided a presentation on California Compounding to the California society of Health System Pharmacists Annual meeting “Seminar”
- Nov. 1: Dr. Guitierrez and Ms. Herold provided a presentation on the Board of Pharmacy at the CSHP nnuual meeting “Seminar”
- Nov. 3: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Nov. 4: Ms. Herold and Ms. Emard attended the California Prescription Drug Abuse Work Group meeting
- Nov. 15: Ms. Herold provided a presentation on California Sterile Compounding Pharmacies to the Sacramento Valley Society of Health System Pharmacies
- Dec. 2: Ms. Herold and Ms. Emard participated in the California Prescription Drug Abuse Work Group meeting

10. FOR REVIEW AND DISCUSSION: Articles on Issues of Interest

Attachment 6

Attachment 6 contains articles of interest for the Communication and Public Education Committee.

11. Public Comment for Items Not on the Agenda, Matters for Future Meetings*

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Attachment 1

Laurence R. Upjohn, Pharm.D.

*Chief, Science and Education Section
Ca. Dept. of Public Health/Food and Drug Branch
1500 Capitol Avenue, MS 7602
P.O. Box 997413
Sacramento, CA 95899-7413
916-650-6703
Email: Laurence.Upjohn@CDPH.CA.GOV*

Objective

My objective is to apply my skills, education and experience to assure that the public receive the best food, drug and medical device technologies from California manufacturing and retailing companies.

Academic Training

UNIVERSITY OF THE PACIFIC
Doctor of Pharmacy, Electropharmacology Emphasis, 1976
Dean's List, Faculty Community Service Award.

CHAPMAN UNIVERSITY
Bachelor of Science, Applied Mathematics-Computer Science, 1985
Dean's List

U.S. AIR FORCE
Officer's Training School

U.S. AIR FORCE
Squadron Officer's School Training Course

U.S. AIR FORCE
Pharmacy Officer's Management Training Course

U.S. AIR FORCE
Local Area Network Implementation Course

DEFENSE LANGUAGE INSTITUTE WEST COAST BRANCH
Diploma in Chinese Mandarin

U.S. NAVY
Promoted to Communications Technician Petty Officer 2nd Class Rank.

U.S. NAVY
Communications Technician Class A School

Relevant Profession Skills and Experience

CALIF. DEPARTMENT OF PUBLIC HEALTH FOOD AND DRUG BRANCH

- Research Scientist Supervisor II (*Food and Drug*), 2011-Present
- Current serve as the Chief, Science and Education Section managing a staff of 6 Ph.D. level scientists who are subject matter experts in the area of drugs, medical devices, foods and cosmetics.
- Continue to provide service to the branch as the subject matter expert on medical devices and drugs where needed.
- Supervise development and delivery of training modules for branch staff covering food, drugs, medical devices and cosmetics and applied technologies related to their manufacture.
- Serve as subject matter expert for analysis of proposed legislation dealing with drug, medical device and cosmetic regulation in California.
- Represent the California Department of Public Health on the CA. Dept. of Justice Research Advisory Panel that oversees all clinical research dealing with controlled substance taking place in California. (Since 2005-2006). Subject matter expert on Informed consent documents for both adults and children.
- Appointed as a member of the FDA Medical Device Good Manufacturing Practices Advisory Panel as a subject matter expert in pharmacology and software analysis. (My appointment term lasts through Federal FY 2017)

CALIF. DEPARTMENT OF PUBLIC HEALTH FOOD AND DRUG BRANCH

- Research Scientist IV (*Food and Drug*), 1990-2011
- Served in both Drug and Medical device Sections of the Food and Drug Branch.
- Served as the medical device subject matter expert dealing with device related software
- Was trained and participated as a medical device 510k application reviewer during the period that the FDA third party 510k approver program was piloted and instituted.
- Participated in the design team planning branch wide reorganization.
- Modernized and maintained all of the branch licensing software while serving as the administrator of Branch wide Local area network for 3 years.
- Successfully trained as an FDA Medical Device Inspector and performed inspections of Medical Device Manufacturers under FDA contract.
- Continually participated in the branch business process review.
- Developed and implement processes and systems to transfer from the CA. Board of Pharmacy the Medical Device Retail Licensing system. The Food and Drug Branch continues this program as the Home Medical Device Retail Program.
- Represent the California Department of Public Health on the CA. Dept. of Justice Research Advisory Panel that oversees all clinical research dealing with controlled substance taking place in California.
- Served as a voting member of the United States Pharmacopeial Convention (USP) from 2005-2008.

UNIV. OF CALIFORNIA, U.S. AIR FORCE, MERCY HEALTH CARE WEST (DIGNITY HEALTH)

- *Clinical Pharmacist, 1976 to Present*
- I have provided pharmaceutical care in the Acute Hospital settings throughout my professional career. I have focused on the provision of sterile parenteral drugs in routine and investigational forms. Developed research protocols for the clinical investigation of unique or

new drug active ingredients.

- Developed and instituted a pharmacy based investigational drug center overseeing all research drug protocols within the University of California Davis Medical Center.
- I have held both staff and management positions including chief pharmacist's positions at two of the above institutions.
- I have managed up to 25 persons and budgets upwards of \$6 million per annum.
- I have completed a number of management courses including supervisor's training at U.C. Davis, and Officer's Training School in the U.S. Air Force.
- I currently maintain my California Registered Pharmacist Certification and periodically work relief schedules with hospitals in the Dignity Healthcare (formerly Mercy Healthcare West) system in the local area.

Outcomes

- Developed and authored the pilot versions of the FDA TurboEIR field reporting system.
- Assisted the national effort to train FDA staff for implementation of the TurboEIR program as documented in the current FDA Investigations Operation Manual.
- Developed and authored the editor and database for the Citations used in TurboEIR. This database provides paraphrased regulatory citations for use in the FDA483 for documentation of observations noted during FDA inspections reported on the TurboEIR system and used by compliance officers for drafting FDA warning letters and other actions directly related to violations of Good Manufacturing Practices (GMP). This project gave me wide exposures to all areas of FDA GMP regulation with most intensive focus on Medical Device GMP regulation.
- Received extensive training in the Medical Device Quality System Regulations prior to their publication in October of 1996. This was incorporated directly in all pilot and operational versions of TurboEIR using the above Citation database.
- Consulted with FDA management during transfer of the TurboEIR pilot to the USDA Software Support team in Ft. Collins, CO.
- Received California Sustained Performance award for the TurboEIR and branch software efforts.
- Received Commendation from FDA commissioner for participation in the FDA TurboEIR development team.
- Received Commendation from FDA commissioner for participation in a joint FDA/FDB case regarding the adulteration of a cosmetic with a prescription drug.
- Continued development of FDB training modules relating complex scientific, technical and physical processes to GMP requirements for Drug and Medical Device manufacturers.
- Currently researching and developing methods to assess and monitor products using emerging biotech, nanotechnology and electronic technologies particularly those related to medical device manufacture.

Licenses and Certificates

- California Registered Pharmacist
 - Diabetes Educator Certificate
 - Immunization Certificate(Pending update)
- Commissioned Officer, U.S. Public Health Service, Food and Drug Administration
- FDA Certified Third Party Medical Device Reviewer
- Medical Device Inspection Certification, U.S.F.D.A.
- Quality System Regulation Certification, U.S.F.D.A.
- Amateur Radio License, Federal Communication Commission

Skills

- Excellent written and oral communication skills
- Excellent "People" skills.
- Extensive Computer Programming experience using multiple computer languages.
- Extensive Laboratory skills in the chemical, biological and physical sciences.
- Extensive Foreign Language skills, with academic courses German, Chinese Mandarin, Japanese, and classical Latin.
- Advanced Applied mathematical skills

Published Articles, Speeches, Lectures and Software

SOFTWARE:

Upjohn, L.R.

"TurboEIR'

Inspection Report Writing System. Production version adopted throughout U.S.FDA for worldwide inspections of food, drug, biologics, veterinary, and medical device manufacturing firms.

1996

Upjohn, L.R.

"FELARS"

FDB Electronic Alert Reporting System. Designed to demonstrate integration of laptop computers and cell phone for field investigator use. Resulted in FDB adopting cell phone, laptop and printers for all field inspectors.

1995

Upjohn, L.R.

"Organic Food Processors Licensing System"

FDB database management system

1995

Upjohn, L.R.

"Petfood Cannery Licensing System"

FDB database management system

1994

Upjohn, L.R.

"Export Certificate System"

FDB database management system

1994

Upjohn, L.R.

"CCRCALC"

Renal function calculation program for clinical pharmacists

1995

Upjohn, L.R.
"BFI Scheduler"
Small contractor scheduling system
1993

PUBLISHED ARTICLES AND SPEECHES:

Upjohn, L.R.
"GMP Validation of Software for Medical Device Use"
FDB Training course for Field Inspection Staff
2009
Revised in 2013

Upjohn, L.R., Wallace, J.A.
"GMP Sterilization Technology for Drugs and Medical Devices"
2009
Revised in 2013
Includes modules for Steam, ETO, Radiation, Dry Heat, etc.

Upjohn, L.R.
"The Architecture of the Cray I Computer"
Senior Project Report
Chapman College. 1985

Upjohn, L.R.
"A Telemetric Electromyographic Switch for Microcomputer Control for the Severely Disabled"
Proceedings of the I.E.E.E., 1981

Stengert, K., Grehl, T., Klein, E., Upjohn, L.
"Use of Intravenous Nitroglycerin to Reduce Cardiac Afterload During Myocardial Revascularization Therapy."
Anesthesia, 1978

Upjohn, L.R.
"Appropriate Dosing of Aminoglycoside Antibiotics"
Professional Staff Lecture
USAF Hospital, Mather AFB, CA.
1985

Upjohn, L.R.
"Biofeedback for Rehabilitation Medicine"
University of California Davis College of Medicine
1977-1982

FORTY-THIRD ANNUAL REPORT

of the

**RESEARCH ADVISORY PANEL
OF CALIFORNIA**

2013



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

TABLE OF CONTENTS

	Page
LIST OF 2013 PANEL MEMBERS	2
SUMMARY OF 2013 PANEL ACTIVITIES	3
TABLE 1 - Research Studies approved in 2013	9
TABLE 2 - Research Studies closed in 2013	15
APPENDICES	
Appendix A - Currently Open Schedule I and II Non-Human & Academic Human Studies	19
Appendix B - Currently Open Schedule II Clinical Drug Trial Studies	25
Appendix C - Currently Open Research Studies on the Treatment of Controlled Substance Abuse	35
Appendix D - Pertinent Sections - California Health and Safety Code	
§ 11213 - Persons and researches using controlled substances	37
§ 11480 & 11481 - Research Advisory Panel	37
§ 11603 & 11604 - Attorney General	38
§ 24172 - Experimental subject's bill of rights	39
§ 24173 - Informed consent	40

2013 PANEL 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

E-mail contact: 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 2013 PANEL ACTIVITIES

During 2013 the Panel reviewed thirty-two research study submissions. Twenty-eight were approved by the Panel. Among twenty-eight approved studies, ten studies were Academic research studies, nine studies were Substance Abuse Treatment research protocols, and nine studies were Clinical Drug Trial research protocols.

Thirteen research studies were completed or, in a few cases, terminated in 2013, and they were closed on the Panel's records.

At the end of 2013, the Panel was monitoring eighty-nine active research projects. Note Appendices A, B, and C for specific listings.

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

Table 1 is a list of the studies approved by the Panel in 2013 and Table 2 is a list of the studies closed by the Panel in 2013.

SELECTED RESEARCH FINDINGS

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

Alkermes has submitted Annual Progress Report titled "A Phase II Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, A Component of ALKS3831, in Adults with Schizophrenia Treated with Olanzapine" (ALKS3831-302)

ALKS3831 is composed of two active substance: olanzapine and samidorphan and is under investigation for the treatment of schizophrenia. Olanzapine is FDA-approved for the treatment of schizophrenia and bipolar disorder and is not a controlled substance by the Drug Enforcement Agency (DEA). Samidorphan is a new chemical entity, under development by Alkermes for the treatment of reward disorders. Samidorphan was classified as a Schedule II substance by the DEA under the Controlled Substances Act ("CSA") (CSCN 9668).

To date, over 600 subjects have been exposed to samidorphan, either as a single agent, a co-formulation with buprenorphine or co-administered with olanzapine. Samidorphan is prepared from the uncontrolled substance naltrexone and retains the structural features of naltrexone that result in μ -opioid receptor antagonist activity. This activity likely underlies the effect of samidorphan to block subjective and physiological effects of opioid drugs, as seen in clinical and nonclinical studies. No evidence of withdrawal has been observed after discontinuing samidorphan.

ALKS3831-302 is a Phase II, randomized, placebo-controlled multicenter study, which is being conducted in 2 parts: Part A and Part B. Part A begins with screening and includes a 1-week olanzapine lead-in period followed by a 12 week double-blind, placebo-controlled treatment period where subjects receive samidorphan or placebo (in addition to the olanzapine prescribed on Study Day 1). Part B includes an additional 12-week treatment period where all subjects receive active olanzapine + samidorphan (ie, ALKS3831). At the end of Part B, samidorphan dosing stops, but olanzapine dosing continues uninterrupted through a 4-week follow-up period, which includes 2 safety visits.

Due to the blinded nature of the study, no efficacy results are available at this time. No subjects have died during the course of the study and there were no serious adverse events during the report period.

Dr. Friedbert Weiss, PhD, and colleagues at the Scripps Research Institutes, La Jolla, CA have provided the Panel with the following summary of research titled "Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol"

Drug addiction is a chronically relapsing disorder. Susceptibility to relapse can be traced to multiple factors including craving elicited by drug-related clues, heightened anxiety and hypersensitivity to stress, as well as drug-induced impairments in impulse control. Thus, treatment drugs that target more than a single factor or vulnerability state for relapse are likely to offer significant clinical advantages. Our findings suggest that cannabidiol (CBD), the main non-psychoactive and non-addictive component of the cannabis sativa plant, may provide such a profile of actions. A factor limiting the therapeutic potential of CBD is the drug's low oral bioavailability in man due to a major first-pass effect. This limitation can be overcome by transdermal administration, which eliminates the first-pass effect and reduces variability in bioavailability. In collaboration with our coinvestigator, Dr. Stinchcomb, we therefore developed a transdermal CBD formulation (tCBD) suitable for behavioral testing in rats, consisting of a fast drying CBD gel applied to a shaved area of skin.

The effects of tCBD were examined in animal models of relapse (cue and stress),

anxiety, and impulsivity. Rats with a history of ethanol or cocaine self-administration were treated with tCBD (15mg/kg) at 24h intervals for 7 days.

tCBD significantly reduced cue-induced reinstatement of ethanol and cocaine seeking, as well as stress-induced reinstatement by yohimbine or electric footshock, without producing tolerance. Remarkably, both stress- and cue-induced reinstatement remained fully attenuated as late as 138 days after termination of tCBD treatment. In tests of anxiety (using the elevated plus maze), all rats showed significantly reduced anxiety-like behavior. To study tCBD's effects on impulse control, rats were subjected to a 7d ethanol intragastric intoxication procedure during which they were treated at 24h intervals with tCBD (15mg/kg). In subsequent delay discounting tests, rats with an intoxication history showed significantly reduced preference for large delayed reward indicative of heightened impulsivity. This profile of high impulsivity was fully reversed in tCBD-treated rats. In tests of nonspecific behavioral effects, tCBD neither with reinstatement motivated by a palatable sweet solution, nor altered spontaneous locomotor activity.

Although presently limited to a single dose, the results are consistent with the hypothesis that tCBD has therapeutic potential for multiple vulnerability states underlying relapse risk. Particularly significant was the observation that cue- and stress-induced ethanol seeking remained effectively reduced as late as =5 months (138 days) post-treatment. This observation, paired with the finding that tCBD attenuates impulsivity in rats with a severe ethanol intoxication history, is of substantial interest both from a medication development and neurobiological perspective in that it is suggestive of diverse neuroregulatory actions that restore normal function to brain circuitries regulating reward, incentive motivation, impulsivity, stress and anxiety.

Dr. Walter Ling, M.D. and colleagues at University of California, Los Angeles have provided the Panel with the following summary of research titled "Analgesic Response to Opioid Analgesics in Buprenorphine-Maintained Individuals"

The extensive and detrimental effects of unrelieved pain are well described, with negative physiological and psychological consequences (see Brennan et al., 2007; Leykin et al., 2007). Fortunately, opiates and synthetic opioids provide powerful and effective treatment for pain. Recent national indicators show that rates of prescription opioid abuse have risen dramatically over the past decade (McCabe et al., 2008; NIDA, 2008; SAMHSA, 2009), presenting a pressing need to effectively and safely manage pain in opioid-dependent patients. To effectively treat pain and maximize health outcomes in patients at high risk for poor pain management, clinicians need a more comprehensive understanding of the effects of ongoing opioid use on pain outcomes.

Patients treated with opioids, including buprenorphine, for extended periods may develop physical dependence, and opioid-induced hyperalgesia. Managing acute pain in these patients has been hampered by misunderstanding and misinformation, and by a genuine lack of systematically gathered controlled study data. Many physicians believe that the ceiling effect of buprenorphine makes it a poor analgesic and that patients maintained on buprenorphine will not benefit from the analgesic effects of added opioids, although anecdotal reports from physician experience and observational—largely uncontrolled—data suggest otherwise. There is a dearth of data to provide guidance for clinicians for an evidence-based approach to providing meaningful analgesia using opioids in treating acute pain in buprenorphine-maintained patients.

The favorable clinical safety profile gives buprenorphine considerable latitude in practice settings and in method of medication dispensing and prescribing. Clinicians may have taken advantage of buprenorphine's off-label use to treat a variety of painful conditions. This practice in itself is within the scope of usual and customary clinical practice, but because, at least in the United States, analgesia is not the primary approved indication for buprenorphine, relevant and critical information of such use is rarely available to clinicians.

This project intends to provide information on analgesic responses to single doses of various opioid analgesics, including buprenorphine, in study participants maintained on buprenorphine. Study findings will provide needed data for an empirically based approach to using opioids in managing acute pain in buprenorphine-maintained patients. The study will also collect data related to mu receptor blockade of buprenorphine when combined w additional opioids.

The aim of this study is to examine the effects of opioid analgesics on acute pain in participants maintained on buprenorphine+naloxone (Suboxone) for opioid use disorders.

Study design is a single-blind examination of the analgesic effects of a single dose of seven test medications provided in an experimental pain paradigm using a cold pressor test (CPT). Test medication conditions include buprenorphine, morphine, hydromorphone, hydrocodone, oxycodone, and two placebo conditions to match test medication formulations (oral tablet, sublingual tablet). Each medication condition will be tested on separate days (seven total days, completing within 12 weeks), with random assignment to order of study medications.

Participants will be 12 males, age 20-50, who are currently prescribed buprenorphine maintenance treatment and are under the care of a physician not associated with the study. Presence of buprenorphine and buprenorphine metabolites will be confirmed in baseline urine toxicology tests. Participants must not require regular daily use of any other medications for pain or have any other condition that could interfere with participation, study procedures, or the interpretation of study findings.

After screening, eligible participants will be scheduled for 7 days of testing with test days at least 3 days apart to provide a sufficient medication wash-out period. Pain testing will utilize cold pressor tests (CPT), in which the participant submerges his arm and hand in a bath of ice cold water to determine pain threshold and tolerance. Participants will be given a practice trial to provide familiarity with the test and reduce test anxiety. Two CPTs will occur on each test day, and pre- and post-CPT assessments will be administered. Blood samples will be taken on each test day to measure blood levels of buprenorphine. Daily procedures include: (1) A baseline CPT (BL-CPT), (2) Administration of the test medication (active drug or placebo), (3) CPT administered at the time of maximum drug effect (Tmax-CPT) specific to medication (range 30-120 minutes), (4) Pupillometry conducted at baseline (before BL-CPT), and at time of maximum drug effect (before Tmax-CPT). Each participant will be discharged after clinical determination of the participant's safety and well-being.

TABLE 1
RESEARCH STUDIES
APPROVED IN 2013

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Michael Fischbach, Ph.D. Dept of Anesthesia, UCSF San Francisco, CA	Engineering a human gut bacteria to produce dimethyltryptamine
George Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Prescription Opioid Addiction: Neurobiological Mechanisms
Walter Ling, M.D. Integrated Substance Abuse Programs, UCLA Los Angeles, CA	Analgesic Response to Opioid Analgesics in Buprenorphine-Maintained Individuals
Robert Malenka, M.D. School of Medicine Stanford University Palo Alto, CA	The Role of Oxytocin in the Pathogenesis of Autism
Florian Rader, M.D. Cedars-Sinai Med Center Los Angeles, CA	Mechanisms and Modulation of Cocaine Effects on Blood Flow to the Heart
Richard Reznicek, M.D. Harbor-UCLA Los Angeles, CA	Panel approved research

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Paolo Sassone-Corsi, Ph.D. Center for Epigenetics UC Irvine Irvine, CA	The Role of Liver CB1 Receptor in Regulation of the Circadian Metabolism
Ronald Victor, M.D. Cedars-Sinai Med Center Los Angeles, CA	Effects of Cocaine on Blood Flow to the Heart
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol"
Roya Yumul, MD, PhD Cedars-Sinai Med Center Los Angeles, CA	Intraoperative ketamine and methadone for laminectomy: effect on recovery, postoperative pain, and opioid requirements
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 Pain in Patients after Knee or Hip Replacement Surgery (IAP311)
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, A Component of ALKS 383, in Adults with Schizophrenia Treated with Olanzapine (ALK3831-302)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
CNS Therapeutics / CRO: Pacific-Link Consulting	A Controlled, Two-Arm Parallel Group, Randomized Withdrawal Study to Assess the Safety and Efficacy of Hydromorphone HCl Delivered by intrathecal Administration a Programmable Implantable Pump (HYD201US)
CNS Therapeutics / CRO: Pacific-Link Consulting	A Phase 3 Open-Label, Single-Arm Study To Assess The Safety of Hydromorphone HCl Delivered by Intrathecal Administration (HYD202US)
Forest Research Institute Jersey City, NJ	A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Safety and Efficacy of GRT6005 in Patients with Moderate tot Severe Chronic Pain Due to Osteoarthritis of the Knee (GRT-MD-101)
GW Pharmaceutics Mill Valley, CA	Panel approved research
MAPS Santa Cruz, CA	A Placebo-Controlled, Randomized, Blinded, Dose Finding Phase 2 Pilot Safety Study of MDMA-Assisted Therapy for Social Anxiety in Autistic Adults (MAA-1)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

Teva Pharmaceuticals
Frazer, PA

A 12-week, Randomized, Double-Blind, Placebo-Controlled, R-Withdrawal Study to Evaluate the Efficacy & Safety of Hydrocodone Bitartrate ER Tabs (CEP-33237) at 30-90mg q12 hrs for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (C33237/3103)

Teva Pharmaceuticals /
CRO: RPS
Upper Darby, PA

A 6 months, Open-Label, Extension Study to Evaluate the Safety of Hydrocodone Bitartrate ER tabs (CEP-33237) at 15mg-90mg q12h for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (C33237/3104)

NIDA
Rockville, MD

Achieving Cannabis Cessation-Evaluating N-Acetylcysteine Treatment (ACCENT) (CTN-0053)

Courtney Kelly, M.S.
UCLA
Los Angeles, CA

Effects of Naltrexone on Methamphetamine Cue-Induced Brain Activity in Methamphetamine Dependence

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
US WorldMeds, LLC Louisville, KY	A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Efficacy, Safety, and Dose-Response Study of Lofexidine in the Treatment of Opioid Withdrawal (Days 1-7) Followed by Open-Label, Variable Dose Lofexidine Treatment (Days 8-14) (USWM-LX1-300)
Keith Heinzerling, M.D. UCLA Los Angeles, CA	Randomized Trial of Ibudilast for Methamphetamine Dependence
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Naltrexone on Alcohol-Dependent Asian Americans
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Ibudilast on Non-treatment Seeking Patients Who Meet Criteria for Alcohol Abuse or Dependence
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Ivermectin on Non-Treatment Seeking Patients Who Meet Criteria for Alcohol Abuse or Dependence
NIDA Rockville, MD	Accelerated Development of Addictive Pharmacotherapy (ADAPT) (CNS Protocol 0054)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

Teva Pharmaceuticals
Frazer, PA

A 12 week, Multicenter, Randomized,
Double-Blind, Placebo-Controlled, Parallel-
Group Study to Evaluate the Efficacy & Safety
of 1-week IM Injection of TV-1380
(150mg/wk or 300mg/wk) as a Treatment for
Facilitation of Abstinence in
Cocaine-Dependent Subjects
(TV1380-COA-20)

TABLE 2

RESEARCH STUDIES CLOSED IN 2013

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Valerie Gruber, Ph.D. UCSF / SF General Hospital San Francisco, CA	Investigation of Age Differences in Analgesic, Cognitive, and subjective effects of Oxycodone, Hydrocodone, and Acetaminophen
Reese Jones, M.D. Drug Dependence Research Ct. UCSF San Francisco, CA	Phase I Study of Interactions between Oral Naltrexone and Bupripion and Intravenous Methamphetamine in Mathamphetamine Experienced Volunteers
Edith London, Ph.D. UCLA Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine
Richard Reznichuk, M.D. Harbor-UCLA Medical Center Torrance, CA	Panel approved research
Acel Rx 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 Pain in Patients after Knee or Hip Replacement Surgery (IAP311)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

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 (ALKS5461-202)

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)

Purdue / CRO: PRA
Raleigh, NC

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy & Safety of Oxycodone/Naloxone C-R Tabs (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require A-T-C Opioid Therapy (ONU3701)

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Shire / CRO: INC Research
Cincinnati, OH

A Phase 3 Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, 25-week, DO Study to Eval the Efficacy, Safety, & Tolerability of SPD489 Low Dose Range 40 80 100mg & Hi Dose Range 120 140 160mg as Adj Treatment to Establish Mt Doses of Antipsychotic Medications on Neg Symptoms in Clinically Stable Adults with Persistant Predominant Neg Symptoms of Schizophrenia (SPD489-335)

Shire / CRO: INC Research
Cincinnati, OH

A Phase 3 LT, Open-Label, Multicenter, 52-week Flex-D Safety Study of SPD489 as Adj Treatment of Establish Maintenant Dose of Antipsychotic Medications on Neg Symptoms in Clinically Stable Adults with Persistent Pred Neg Symptoms of Schizophrenia (SPD489-336)

Shire / CRO: INC Research
Cincinnati, OH

A Phase 3 Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled 12-wk, Forc-D Tat Study to Evaluate the Efficacy, Safety, & Tolerability of SPD489 40 100 or 160mg as Adj Treatment to Establish Maintenant Dose of Antipsychotic Medications on Neg Symptoms in Clinically Stable Adults with Persistent Pred Neg Symptoms of Schizophrenia (SPD489-338)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Shire Pharmaceuticals
Wayne, PA

A Phase 3b, Double-blind, Randomized,
Active-controlled, Parallel-group Study to
Compare the Time to Response of
Lisdexamfetamine to Atomoxetine in
Children & Adolescents aged 6-17 with
ADHD who have had an Inadequate
Response to Methylphenidate Therapy
(SPD489-317)

APPENDIX A

CURRENTLY OPEN (*through December 31, 2013*)
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
Michael Fischbach UCSF San Francisco, CA	Engineering a human gut bacteria to produce dimethyltryptamine
Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA	Behavioral and Cytofluorimetric Studies of Psychoactive Drugs in Rats

Appendix A Cont.

Principal Investigator

Title of Study

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

Analysis of Controlled Substances

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

Neurobiological Studies of
Gammahydroxybutyrate (GHB)

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

Prescription Opioid Addiction: Neurobiological
Mechanisms

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

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

Lin-Zhi Immunoassay Development Study

<u>Principal Investigator</u>	<u>Title of Study</u>
Walter Ling, M.D. Integrated Substance Abuse Programs, UCLA Los Angeles, CA	Analgesic Response to Opioid Analgesics in Buprenorphine-Maintained Individuals.
Sean Mackey, MD, PhD Stanford University Palo Alto, CA	Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients
Robert Malenka, M.D. School of Medicine Stanford University Palo Alto, CA	The Role of Oxytocin in the Pathogenesis of Avtism
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
Florian Rader, M.D. Cedars-Sinai Med Center Los Angeles, CA	Mechanisms and Modulation of Cocaine Effects on Blood Blow to the Heart
Richard Reznichak, M.D. Harbor-UCLA Los Angeles, CA	Panel approved research

Appendix A Cont.

Principal Investigator

Title of Study

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

Human Methamphetamine
Self-Administration in a Progressive-Ratio
Paradigm

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

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_{2B}

Paolo Sassone-Corsi, Ph.D.
Center for Epigenetics
UC Irvine
Irvine, CA

The Role of Liver CB1 Receptor in Regulation
of the Circadian Metabolism

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

<u>Principal Investigator</u>	<u>Title of Study</u>
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
Ronald Victor, M.D. Cedars-Sinai Med Center Los Angeles, CA	Effects of Cocaine on Blood Flow to the Heart
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol"
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
Roya Yumul, MD, PhD Cedars-Sinai Med Center Los Angeles, CA	Intraoperative ketamine and methadone for laminectomy: effect on recovery, postoperative pain, and opioid requirements

APPENDIX B

CURRENTLY OPEN (*through December 31, 2013*)
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, Open-Label, Parrell-Group Trial to Compare the Efficacy & Safety of the Sufentanil Nano Tab PCA System 15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Post-Operative Pain (IAP309)
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)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

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 Pain in Patients after Knee or Hip Replacement Surgery (IAP311)

Alkermes, Inc.
Waltham, MA

A Phase 2, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, A Component of ALKS 383, in Adults with Schizophrenia Treated with Olanzapine (ALK3831-302)

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)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
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)
CNS Therapeutics / CRO: Pacific-Link Consulting	A Controlled, Two-Arm Parallel Group, Randomized Withdrawal Study to Assess the Safety and Efficacy of Hydromorphone HCl Delivered by intrathecal Administration a Programmable Implantable Pump (HYD201US)
CNS Therapeutics / CRO: Pacific-Link Consulting	A Phase 3 Open-Label, Single-Arm Study To Assess The Safety of Hydromorphone HCl Delivered by Intrathecal Administration (HYD202US)
Forest Research Institute Jersey City, NJ	A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Safety and Efficacy of GRT6005 in Patients with Moderate tot Severe Chronic Pain Due to Osteoarthritis of the Knee (GRT-MD-101)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

GW Pharmaceuticals
Mill Valley, CA

Panel approved research

GW Pharmaceuticals
Mill Valley, CA

Panel approved research

GW Pharmaceuticals
Milly Valley, CA

Panel Approved Research Project

GW Pharmaceuticals
Mill 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")

MAPS
Santa Cruz, CA

A Placebo-Controlled, Randomized, Blinded,
Dose Finding Phase 2 Pilot Safety Study of
MDMA-Assisted Therapy for Social Anxiety in
Autistic Adults
(MAA-1)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
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)
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 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study with an Open-Label Run-in to Assess the Efficacy & Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-day in Subjects with Moderate to Severe Chronic Low Back Pain (HYD3002)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Purdue / CRO-INC Research
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)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Purdue / CRO-Quintiles Overland Park, KS	A Randomized, Double-Blind, DD, Placebo-controlled, AC, Parallel-Group, Multicenter Trial of OXN to Assess the Analgesic Efficacy (Compare to Placebo) and the management of Opioid-induced Const (Compare to OXY) in Opioid-exp Sub with Cont Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Const with 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)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

QrxPharma / CRO-INC
Austin, TX

A Double-Blind, Randomized, Placebo, & Active-Controlled, Parallel-Group Study to Evaluate the Safety, Tolerability & Efficacy of Q8011 Compared to OxyContin & Placebo in Patients with Moderate to Severe Chronic Hip or Knew with Pain Due to Osteoarthritis (Q8011-201)

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)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

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)

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)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Shire Pharmaceuticals
Wayne, PA

A Phase 3b, Double-Blind, Randomized, Active-Controlled, Parallel-Group Study to Compare the Time to Response of Lisdexamfetamine to Atomoxetine in Children and Adolescents Aged 6-17 with ADHD who have had an Inadequate Response to Methylphenidate Therapy (SPD489-317)

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 ADHD (SEP360-20)

Teva Pharmaceuticals
Frazer, PA

A 12-week, Randomized, Double-Blind, Placebo-Controlled, R-Withdrawal Study to Evaluate the Efficacy & Safety of Hydrocodone Bitartrate ER Tabs (CEP-33237) at 30-90mg q12 hrs for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (C33237/3103)

Teva Pharmaceuticals /
CRO: RPS
Upper Darby, PA

A 6 months, Open-Label, Extension Study to Evaluate the Safety of Hydrocodone Bitartrate ER tabs (CEP-33237) at 15mg-90mg q12h for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (C33237/3104)

APPENDIX C

CURRENTLY OPEN (*December 31, 2013*)
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, Multicenter Trial of Nepicastat for Cocaine Dependence (CS#1031)
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

Appendix C Cont.

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

Excerpt From October Board Meeting Minutes: Discussion of Patient Consultation

President Weisser expressed the importance of consultations and called on the pharmacy schools to better train their students on consultation. He added that as the scope of pharmacy is increased, communication between pharmacists and patients will become even more important.

Chair Hackworth asked if the board should conduct a survey of recent pharmacy grads to see what type of training the schools provide and if the students felt the training adequately prepared them for practice.

Ms. Herold commented that the board is still working with the district attorneys' office in three counties to conduct undercover prescription buys to determine if proper consultations are being given when the medication is dispensed. She reported that in one of the large chains only 50 percent received the required consultation. Ms. Herold added that two large chains have already paid fines under the Unfair Business Practices statutes.

Ms. Herold commented that pharmacists often say that they are not compensated for providing consultations. She added that the public does not know the wealth of knowledge that pharmacists have because they do not talk with their pharmacist.

Dr. Wong asked if the board could require schools to make consultation part of their core curriculum. Ms. Herold responded that it already is part of the curriculum. The board asked that at the January Board Meeting, schools of pharmacy come and report to the board on their current consultation curriculum, how it has changed over the years and if the Internet has changed consultations practices.

Mr. Brooks asked if the board could publicize the pharmacies that did not provide consultations. Ms. Herold responded that the two chains that have already paid their fines have been publicized through subscriber alerts and press releases. She added that the two chains also signed agreements saying they will provide consultations as required in California. Ms. Herold noted that if the DA goes into these pharmacies and finds that consultations are still not being provided, then additional fines could be assessed.

Mr. Brooks asked if the board could work with counsel to determine if schools of pharmacy could be required to notify their students that any criminal convictions will increase the chance that the board will deny them licensure. Ms. Herold stated that she would work with DCA counsel to create language and bring it to the Licensing Committee for discussion.

Ms. Butler commented that pharmacists are educated to provide consultations. She noted that in the problem is pharmacists are so busy that they are not providing the consultations.

Dr. Ratcliff described the process inspectors use to determine if a pharmacy is providing appropriate consultations. Inspectors often find that the pharmacy technicians screen for consultations in order to help keep the lines short in the pharmacy.

Dr. Ratcliff commented that in his opinion consultations often lack substance. He noted that the Indian Health Service offered an excellent training program on consultations.

Dr. Ratcliff explained that he often finds that pharmacies are understaffed which leads to pharmacists not providing required consultations.

Dr. Wong commented that another factor in providing consultations is that the reimbursement rates are so low that pharmacies have to fill a certain number of prescriptions per day to stay in business.

Ms. Herold reported that recently all of the board inspectors came to Sacramento for training. During the training, she reminded the inspectors that they need to be looking at consultations when they go into pharmacies.

Doug Hillbloom commented that at the next CHPA Exchange Meeting they will agendize a discussion on consultation. He added that he will look to see if they could also offer a continuing education course during their meeting. Dr. Gutierrez asked if there was a possibility of providing a web-based presentation. Mr. Hillbloom confirmed that they had the technology to do this.

Chair Hackworth commented that the board should consider creating a consultation video that could be available on the board website.

Holly Strom commented an effective technique for consultations is to first ask what the patient already knows about the medications. Often a patient's information is incomplete or incorrect; the pharmacist can then provide the patient with complete and accurate information. Ms. Strom also provided the board with personal experiences that illustrated how much of a positive impact consultation can have on a patient's health.

A pharmacist commented that he believes that similar to other states, California should be an "offer to counsel" state. This would allow a pharmacy technician to ask a patient if they would like a consultation. Mr. Brooks responded that he strongly disagrees with the pharmacist's opinion that staff should be able to screen patients for consultation. Mr. Brooks explained that patients often go online to gain information about their medications, but this information is often inaccurate or incomplete. By screening for consultations the patient will leave the pharmacy with inaccurate information about their medications, and this is a recipe for disaster. Mr. Brooks concluded that he does not care that other states allow screening, as California should be a leader in this area.

John Cronin, pharmacy attorney, commented that consultation should be a topic on future agenda items for additional discussion. He added that economics makes it difficult for pharmacists to offer consultations. Mr. Cronin encouraged the board to look at all sides of issue, including economics. Mr. Cronin concluded that when asked patients are not willing to pay for consultations. He said it begs the question as to how much consumers value consultations. Mr. Brooks agreed that economics should be part of the discussion, but he disagreed that patients should have to pay for consultations.

Robert Lee, area supervisor for Walgreens, commented that Walgreens does not time their pharmacists. They expect that for new prescriptions their pharmacists provide the appropriate consultation.

Ms. Herold commented that patients don't value consultation because they don't get them often enough and when they do, it maybe just the pharmacist reading them the label.

Mr. Cronin encouraged the board to publicize the next time consultations will be discussed.

Note: Mr. Schaad left the room at 10:47 a.m. and returned at 10:54 a.m.

Neshoba McCarum, pharmacist, commented that since she graduated fourteen years ago she has seen a culture change in regards to the value that is placed on consultations. She reported that now when she works in a pharmacy she has to specifically tell the technicians not to screen for consultations. Ms. McCarum stated that in her opinion the shift in culture was the result of the board announcing that they would no longer be doing random inspections.

Rebecca Cupp encouraged the board to continue the discussion on this topic. Ms. Cupp reported that Ralph's has a system in place that ensures pharmacists provide consultations for all new therapy.

Mr. Law commented that in his opinion a major issue contributing to the lack of consultation is the reimbursement rate decreasing each year. This puts pressure on pharmacy owners to fill as many prescriptions as possible each day.

1707.2 Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: of his or her right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Attachment 3



Scott Paterson: Deputy Director, Enterprise Solutions

California Department of Technology

Scott Paterson is the Deputy Director over Enterprise Solutions within the California Department of Technology and is responsible for the development and support of the *California Mobile Program* as well as various statewide enterprise information technology initiatives.

Scott has worked for the State of California for over 27 years within various departments which include; the Department of Public Health, Health Care Services and the California Department of Corrections prior to joining the Office of the State Chief Information Officer in 2008. Scott is responsible for enterprise initiatives related to mobile, website development, human resources, transparency, and reporting.

Top 10 Pharmacist Influencers on Twitter

Twitter is the #1 social media channel to connect with influential pharmacists. If you connect with the right pharmacist, you can learn about news, tools, great opportunities, or even land a job.

There are hundreds of pharmacists on Twitter, but who should you follow? Here, I have listed the top 10 pharmacist influencers, in no particular order:

1. Anyssa Garza @anyssa_garza

Anyssa is a [contributor at PharmacyTimes.com](#) and RxWiki, an online resource for medication information for patient and health care professionals. She posts great info about the latest news on pharmacy and new medications, and she also shares great advice for future PharmDs!

2. Jason Poquette @jasonpoquette

Jason is another [PharmacyTimes.com contributor](#) and the founder of The Honesty Apothecary, a website dedicated to helping pharmacists throughout all points of their career, with a focus on community pharmacy.

I love Jason's blog because he has a well-balanced view on current health care news, the pharmacy profession, and career development. Despite the fact Jason has more than 14,000 Twitter followers, he often says thank you to those who retweet him. Mad respect, Jason.

3. Dave Walker @drwalker_rph

Dave is the Pharmacist King of Twitter. He is always posting great things to help move the pharmacy profession forward. I have spoken with Dave many times over the last year and, each time, I leave the conversation with a million new ideas on how to improve my career and our profession.

4. Blonde pharmacist @blondepharmacist

Interested in the life of a clinical pharmacist? Check out the Blonde Pharmacist.

Beth has a wealth of clinical pharmacist information, specifically surrounding all things needed to become a board-certified pharmacotherapy specialist (BCPS). She's very active on her website, publishing content geared towards helping readers pass the BCPS exam.

5. Eric Christianson @Mededucation101

Eric, the man behind Meded101, is a long-term care pharmacist who is driven to provide more detailed information on medication management. He has a passion for long-term care patients and creating medication information that's super helpful!

I spoke with Eric over 4 months ago for the first time, and I could tell he had a passion for helping people.

6. Mel Seabright @pbmpharmacist

Mel Seabright is a managed care pharmacy expert (one of few on Twitter). If that wasn't enough, he finished his MBA shortly after pharmacy school. I follow Mel to stay updated on the world of pharmacy benefits management (PBM). I need to know an expert in this field, because I'm not!

It's great to make connections in various pharmacy fields, especially to know someone like Mel who is a third-party payment and drug price expert.

7. Tim Aungst @TDAungst

Tim is a new [PharmacyTimes.com contributor](#) and an assistant professor of pharmacy and founder of The Digital Apothecary. He has one of the best blogs about pharmacy that I have read. I enjoy Tim's blog because he doesn't hold back the truth and provides great insights on technology. I'm certain this Renaissance man will be leading our profession forward.

8. Joel Thornbury @JoelThornbury

Joel is president of the Kentucky Board of Pharmacy and an independent pharmacy owner. He is an inspiring man who pushes the profession forward. I saw him speak once for students and felt like I needed to open up my own independent pharmacy, and I don't even desire to work in retail! That's how energetic and inspiring Joel is!

9. Jamie Mitchell @pharmacistjamie

Jamie is a community pharmacist who's rocking the Twittersphere. I love her perspective on patient care and the pharmacy profession. Her tweets just make me smile.

Here's a tweet she wrote for the #rethinkpharmacy Twitter chat that I love:

"When a #pharmacist is close to burnout ask them to share a story of helping someone. Brings it back #rethinkpharmacy"

10. Daniel Kudryashov @Daniel_Kudro

Every time I see a tweet from Dan, a smile appears on my face. His Twitter account is filled with the most positive and encouraging posts, and he inspires me to do more with my

Twitter profile.

If you're a pharmacy student, and you need encouragement through those exams (because every future PharmD needs that), then I urge you to follow Dan. I'm also impressed that he's able to stay so active on Twitter as a pharmacy student.

If you have an interest in getting into pharmacy school, get a pharmacy residency, or rocking your PharmD career, I would be honored if you checked out my Twitter profile **@pharmschoolhq**.

Top 10 Pharmacist Influencers on Twitter

Twitter is the #1 social media channel to connect with influential pharmacists. If you connect with the right pharmacist, you can learn about news, tools, great opportunities, or even land a job.

There are hundreds of pharmacists on Twitter, but who should you follow? Here, I have listed the top 10 pharmacist influencers, in no particular order:

1. Anyssa Garza @anyssa_garza

Anyssa is a [contributor at PharmacyTimes.com](#) and RxWiki, an online resource for medication information for patient and health care professionals. She posts great info about the latest news on pharmacy and new medications, and she also shares great advice for future PharmDs!

2. Jason Poquette @jasonpoquette

Jason is another [PharmacyTimes.com contributor](#) and the founder of The Honesty Apothecary, a website dedicated to helping pharmacists throughout all points of their career, with a focus on community pharmacy.

I love Jason's blog because he has a well-balanced view on current health care news, the pharmacy profession, and career development. Despite the fact Jason has more than 14,000 Twitter followers, he often says thank you to those who retweet him. Mad respect, Jason.

3. Dave Walker @drwalker_rph

Dave is the Pharmacist King of Twitter. He is always posting great things to help move the pharmacy profession forward. I have spoken with Dave many times over the last year and, each time, I leave the conversation with a million new ideas on how to improve my career and our profession.

4. Blonde pharmacist @blondepharmacist

Interested in the life of a clinical pharmacist? Check out the Blonde Pharmacist.

Beth has a wealth of clinical pharmacist information, specifically surrounding all things needed to become a board-certified pharmacotherapy specialist (BCPS). She's very active on her website, publishing content geared towards helping readers pass the BCPS exam.

5. Eric Christianson @Mededucation101

Eric, the man behind Meded101, is a long-term care pharmacist who is driven to provide more detailed information on medication management. He has a passion for long-term care patients and creating medication information that's super helpful!

I spoke with Eric over 4 months ago for the first time, and I could tell he had a passion for helping people.

6. Mel Seabright @pbmpharmacist

Mel Seabright is a managed care pharmacy expert (one of few on Twitter). If that wasn't enough, he finished his MBA shortly after pharmacy school. I follow Mel to stay updated on the world of pharmacy benefits management (PBM). I need to know an expert in this field, because I'm not!

It's great to make connections in various pharmacy fields, especially to know someone like Mel who is a third-party payment and drug price expert.

7. Tim Aungst @TDAungst

Tim is a new [PharmacyTimes.com contributor](#) and an assistant professor of pharmacy and founder of The Digital Apothecary. He has one of the best blogs about pharmacy that I have read. I enjoy Tim's blog because he doesn't hold back the truth and provides great insights on technology. I'm certain this Renaissance man will be leading our profession forward.

8. Joel Thornbury @JoelThornbury

Joel is president of the Kentucky Board of Pharmacy and an independent pharmacy owner. He is an inspiring man who pushes the profession forward. I saw him speak once for students and felt like I needed to open up my own independent pharmacy, and I don't even desire to work in retail! That's how energetic and inspiring Joel is!

9. Jamie Mitchell @pharmacistjamie

Jamie is a community pharmacist who's rocking the Twittersphere. I love her perspective on patient care and the pharmacy profession. Her tweets just make me smile.

Here's a tweet she wrote for the #rethinkpharmacy Twitter chat that I love:

"When a #pharmacist is close to burnout ask them to share a story of helping someone. Brings it back #rethinkpharmacy"

10. Daniel Kudryashov @Daniel_Kudro

Every time I see a tweet from Dan, a smile appears on my face. His Twitter account is filled with the most positive and encouraging posts, and he inspires me to do more with my

Twitter profile.

If you're a pharmacy student, and you need encouragement through those exams (because every future PharmD needs that), then I urge you to follow Dan. I'm also impressed that he's able to stay so active on Twitter as a pharmacy student.

If you have an interest in getting into pharmacy school, get a pharmacy residency, or rocking your PharmD career, I would be honored if you checked out my Twitter profile **@pharmschoolhq**.

Social Media

Scott Paterson

*California Department of
Technology*

Enterprise Solutions

Social Media

Social Media Revolution

- <http://www.youtube.com/watch?v=DYedZth9ArM>

Social Media Statistics

- **Blogs**

1m new Blogs **PER MONTH**

- **Twitter**

1m new accts. **EACH DAY**

- 165m active users
- 107m users in the **US**
- **55% mobile access**

Social Media Statistics

- **Facebook**

900m users

- 93% of **US adults** on Facebook
- **500m mobile access**

- **LinkedIn**

2 new members **EVERY SECOND**

Social Media Statistics

- **YouTube**

72 HOURS of video uploaded **EVERY MINUTE**

- Average user spends **15 mins. per day** on YouTube
- **2nd most used** search engine

What is Social Media?

- Social Network Sites
- Blogs
- News Site Comment Sections
- Photo & Video Sharing Sites
- Chat Rooms

Social Media Evolution

- One way - Websites
- One to One - email
- One to Many - Blogs, Wikis
- Many to Many - Twitter, Facebook, etc.

Many to Many

During and incident or Issue

- Requires quick response
 - Fact vs. Assumption

***If the communication is not current, someone will make it up for you**

“Social Media” in a nutshell Donut

- 
- Twitter  I'm eating a #donut
 - Facebook  I like donuts
 -  This is where I eat donuts
 - Instagram  This is a vintage photo of my donut
 - YouTube  Here I am eating my donut
 - LinkedIn  My skills include eating donuts
 - Pinterest  Here's a recipe for making donuts
 - Last FM  Now listening to “Donuts”
 - Google+  I've joined a circle of donut-eating enthusiasts

Is there a Statewide Social Media policy?

- IT Policy Letter 10-02 can be found at:
http://www.cio.ca.gov/Government/IT_Policy/pdf/ITPL_10-02_Social_Media.pdf.
- The Social Media Standard (SIMM 66B) can be found at:
http://www.cio.ca.gov/Government/IT_Policy/pdf/SIMM_66B.pdf

IT Policy Letter 10-02

POLICY

Agency heads shall:



- Maximize the use of the government sections of social media sites.



- Ensure that managers and users with access to social media sites are trained regarding their roles and responsibilities



- Assign the responsibility for management and monitoring of social media sites to the individual or entity responsible and authorized for outward-facing communications for the agency.



- The responsible individual or entity shall ensure compliance with the agency management requirements and the Social Media Standards included in SIMM Section 66B.

New or expanded use of social media by state agencies shall immediately comply with this policy. Agencies that have already established the use of social media but do not meet the requirements of this ITPL are required to comply by July 1, 2010.

Social Media Standard – SIMM 66B

2.0 GENERAL AGENCY MANAGEMENT REQUIREMENTS

Prior to authorizing and enabling Internet access to Social Media web sites, agency management shall conduct a formal risk assessment of the proposed connections utilizing agency Risk Management processes. The assessment shall, at a minimum, include the analysis of the risks (including risk mitigation strategies) involved in providing Users access to Social Media web sites including:

1. Employee productivity;
2. Network bandwidth requirements and impacts;
3. Reputational risk to personnel, the agency, and the State;
4. Potential avenue for exposure or leakage of sensitive or protected information such as copyrighted material, intellectual property, personally identifying information, etc; and
5. Potential avenue for malware introduction into the organization's IT environment.
6. The potential use of "other than government" sections of Social Media web sites.

State agencies shall document this risk analysis and retain it for a minimum of two years.

Social Media Standard – SIMM 66B

3.1 AGENCY IT ADMINISTRATOR REQUIREMENTS

Agency IT Administrators shall:

- ➔ 1. Limit Internet access Social Media web sites according to the agency's acceptable use policy, while allowing authorized Users to reach content necessary to fulfill the business requirements. Limitations may include:
 2. Enable technical risk mitigation controls to the extent possible. These controls may include:
 - ➔ a. Filtering and monitoring of all Social Media web site content posted and/or viewed.
 - b. Scanning any and all files exchanged with the Social Media web sites.

Social Media Standard – SUMM 66B

4.1 USER REQUIREMENTS

- Users shall connect to, and exchange information with, only those Social Media web sites that have been authorized by agency management in accordance with the requirements within this and other agency and State policies.
- Users shall minimize their use of “other than government” sections of the Social Media web sites.
- ➔ Users shall not post or release proprietary, confidential, sensitive, personally identifiable information (PII), or other state government Intellectual Property on Social Media web sites.
- ➔ Users who connect to Social Media web sites through State information assets, who speak officially on behalf of the state agency or the State, or who may be perceived as speaking on behalf of an agency or the State, are subject to all agency and State requirements addressing prohibited or inappropriate behavior in the workplace, including acceptable use policies, user agreements, sexual harassment policies, etc.

Social Media Standard – SIMM 66B

- ➔ Users shall not speak in Social Media web sites or other on-line forums on behalf of an agency, unless specifically authorized by the agency head or the agency's Public Information Office. Users may not speak on behalf of the State unless specifically authorized by the Governor.
- ➔ Users who are authorized to speak on behalf of the agency or State shall identify themselves by: 1) Full Name; 2) Title; 3) Agency; and 4) Contact Information, when posting or exchanging information on Social Media forums, and shall address issues only within the scope of their specific authorization.
- ➔ Users who are not authorized to speak on behalf of the agency or State shall clarify that the information is being presented on their own behalf and that it does not represent the position of the State or an agency.

Social Media Standard – SIMM 66B

- Users shall not utilize tools or techniques to spoof, masquerade, or assume any identity or credentials except for legitimate law enforcement purposes, or for other legitimate State purposes as defined in agency policy.
- Users shall avoid mixing their professional information with their personal information.
- Users shall not use their work password on Social Media web sites.

Does the Statewide Social Media policy ban Social Media sites for state agencies?

- Encourages using this powerful tool
- ~~Many~~ **MOST** agencies already use social media
- Consider Risks

Does the Social Media policy require that state agencies must use social networking sites?

- Not required
- Generally operated by public information officer, external affairs, etc.

Is the policy a step toward shutting down access for state employees who want to use Facebook, YouTube, and Twitter at work?

- Policy is intended as a guide for state agencies
- Department's executive management shall determine what staff should have access to social media sites.

Since the Governor uses Twitter in various ways, why are state employees not allowed to use Twitter and Facebook however they want?

- Individual departments determine access to social media sites while at work.
- Must comply with the Statewide Social Media policy.
- State agencies are responsible staff's activities, i.e. security, productivity, etc.

Can state employees post information
on Social Media websites on behalf of
the State?

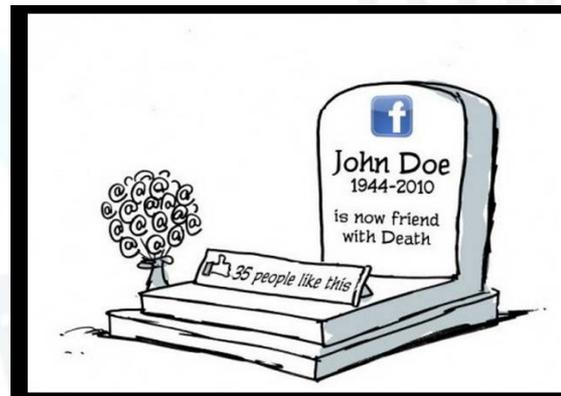
NO*

- Utilize your legal Department (make it their fault!)

*Unless specifically authorized by an appropriate authority within their department. A state employee who is authorized to speak on behalf of an agency, department, or the state must identify him or herself by name, title, agency or department, contact information, and should only address those issues within the scope of the specific authorization. (See SIMM Section 66B, Section 4.0, USER REQUIREMENTS, numbers 5 and 6.)

Can state employees post information on Social Media websites on their own behalf during their own non-work hours?

Yes... but... Be Careful!



The Social Snap



Can state employees communicate with each other about the terms and conditions of their employment through Social Media sites?

Yes! (As long as it's about the work!)

What kind of information should not be posted on Social Media websites?

- No confidential information, such as...
 - Internal Reports
 - Policies & Procedures
 - Materials considered intellectual property
 - Attorney-client communications

What are examples of inappropriate postings that may violate employer policies, whether posted at work or on an employee's own time?

BEFORE YOU



think

t=is it true?

h=is it helpful?

i=is it inspiring?

n=is it necessary?

k=is it kind?

Can state employees be disciplined for their postings?

YES!

I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again
I will not do dumb things with technology ever again



Are there only certain social media sites that state agencies are allowed to use?

- Nope
- Make sure it's safe
- See Social Media Standard

Where do we Begin?

Create a Use Case

Identify

- Target audience
 - Tools may differ by demographic
 - Millennials vs. Boomers
- Message/information
 - Current & Relevant
- Authorized person to respond/monitor

Social Media Policy

PLAN

- Do you have a Social Media Policy
 - Current/relevant
 - Review with legal
- If you don't, contact another department
 - Don't reinvent the wheel

Review Trending Tools

REVIEW

- Industry is constantly evolving
 - Keep it current
- Private industry invests \$\$ in analytics
 - Analyzing trends/patterns
 - Targeting focus groups/demographics

Articles about government using social media:

[10 Ways Local Government Can Use Social Media](#)

WHY USE SOCIAL MEDIA?



Real-time, two-way conversations

between Government and the Public



Gives everyone a voice

until recently, communication with any government body was limited to phone, mail, or in person and none guaranteed a response



Transparency

quick responses to issues, problems, and public questions



Efficiency

getting the word out on important programs and policies quickly and effectively

Articles about government using social media:



CIVICPLUS™ HELPING COMMUNITIES ENGAGE & INTERACT

[Request A Demo](#)
Personalize your experience

[Request A Quote](#)
Meet our eGov experts

CivicPlus Blog

10 Ways Local Government Can Use Social Media

Posted by [Michael Wolfe](#)

Jan 29, 2014 10:23:00 PM

[Tweet](#) 18 [Share](#) 8 [Like](#) [Share](#) 23 [g+](#) 3

For municipalities, having an active social media presence with relevant content posted regularly can help boost your fans and followers. But sometimes finding content and keeping social media channels active can be a challenge. If you manage a local government Facebook, Twitter or other social media account and are looking for some content ideas, this article is for you.

I have browsed dozens of official local government profiles, pages, timelines and Twitter feeds to collect and share ideas on how municipalities across the country use social media to inform, engage and interact with their citizens. Read through these 10 examples and see if it sparks some ideas for you. Have one I missed? Share it below!

Crime Prevention and Police Assistance

Police departments are posting crime prevention tips, time sensitive information such as Amber alerts

Subscribe to Email Updates

Email

Notification Frequency

Instant

[Subscribe](#)

Recent Posts

[Does Your State Have an Open Meeting Law?](#)
[E-government ROI: The numbers are hard to ignore.](#)

[What happens when citizens invest in communities? I Do It Locally](#)

[Employee Performance Management - A Webinar Invite](#)

[Ready to take the CivicLink Challenge?](#)

Resources Available

- State Information Officers Council (SiOC)
Collaboration/Sharing
 - Social Media Policy
 - Lessons learned
 - Implementation & ongoing support

California Mobile

- Mobile Gallery
 - Mobile apps
 - YouTube videos
 - Suggestions, ideas, feedback
 - Ratings/Reviews

*Monitored by Enterprise Solutions

Wrap-up

- Identify
 - Audience
 - Message
 - Authority to post
- Plan
 - Social Media Policy
 - Current

Wrap-up

- Review
 - Keep information/message current (monitor)
 - If it's not working...

CHANGE IT

*Thank you!
Questions?*

Scott Paterson

Scott.Paterson@state.ca.gov

Attachment 4

Discussion of Patient Centered Label from October Board Meeting

1. Should Purpose or Condition Be a General Requirement for Labels?

Chair Hackworth reported that the addition of this component as a required element to the label has been discussed periodically for years.

Chair Hackworth stated that committee members, especially those who have cared for an elderly parent, concurred that it is important to have purpose on the label; however, prescribers are not required to include it and may choose not to because of off-label use of medications.

Chair Hackworth noted that the committee also discussed whether or not a pharmacist could include purpose on the label, even though the prescriber didn't include it, if the patient requests it. This question was referred to legal counsel. It was also discussed that pharmacists should ask patients the purpose of the medication because that could prevent a medication error and the inclusion of purpose will be a new requirement for e-prescriptions.

Chair Hackworth concluded that the committee asked that draft language be presented at the next board meeting to determine whether there should be regulation/legislation and to see if there is support to proceed. As requested the draft language is below.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, ~~if requested by the patient or patients.~~ unless the patient requests that this information not be added to the prescription.

Mr. Brooks asked what would happen if the drug was prescribed for HIV. Ms. Hackworth replied that the patient could "opt-out." Mr. Brooks expressed his concern that a patient might not be aware that they have the right to opt-out.

Ms. Veale asked if a pharmacist would need to call the doctor if the purpose was not written on the prescription. Ms. Herold responded that the pharmacist could.

Mr. Santiago commented that if it was not provided by the doctor, the pharmacist would need to call the prescriber or talk to the patient to determine the purpose. Ms. Veale expressed her concern that requiring a pharmacist to call the doctor each time they receive a prescription will cause a significant delay in dispensing medication to patients.

Ms. Sodergren commented the proposed language only changes Business and Professions Code 4040, which talks about the requirements for writing the prescription. According to Business and Professions Code 4076, a pharmacist only has to include the purpose if it is included on the prescription. Ms. Sodergren concluded that in her opinion, a pharmacist would not have to call a prescriber if they did not include the purpose on the prescription. Dr. Gutierrez and Ms. Veale disagreed.

Ms. Veale commented that she agrees that purpose should be on the label, however, she does not want pharmacists to have to become the police for how doctors write prescriptions.

The board asked that this item be sent back to the committee for additional discussion.

Mr. Brooks again expressed his concern that patients have to opt-out.

Doug Hillblom commented that a doctor is not required to provide the diagnosis for electronic prescriptions.

The board recessed for a break at 11:48 a.m. and returned at 11:58 a.m. Note: Mr. Brooks returned at 12:03 p.m.

2. Should the Existing Requirements for “Added Emphasis” in the Patient-Centered Area of the Prescription Label Be Modified?

Chair Hackworth reported that at the January 2014 committee meeting, there was no committee or public discussion on this item. It was again included on the September committee agenda to ensure the committee had no interest in modifications to this element. Chair Hackworth concluded that the committee decided that this element should be left as is.

There was no comment from the board or from the public.

a. Translations on Labels

Chair Hackworth reported that the committee discussed the two questions below at their September meeting.

1. Translated Directions for Use Are Available on the Board’s Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
2. Should There Be a Specific Requirement for Labels to Be Translated? If So, What Components Are Needed (e.g., Also printed in English, Only Directions, and Exemption from Liability for Translation Errors)?

Chair Hackworth explained that the committee agreed that patients benefit when translated instructions are provided in their native language; however, there are liability issues for pharmacists when they cannot read or write the language on the label or in ancillary information.

Chair Hackworth reported that the committee discussed that requiring translations could first begin by requiring the use of the vetted instructions on the board’s website, which appear in

English and five different languages; and then addressing the issue of liability through legislation.

There was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescription.

Ms. Herold provided the board with draft language to consider, it was noted that the language specifically took the liability off the pharmacist if they used the translations provided on the board's website.

President Weisser asked if the patient centered label requirements apply to mail orders. Ms. Herold responded that all prescriptions coming into California, including mail order, must use the patient-centered format.

Mr. Brooks asked if the translated languages would fit on the label in 12 point font.

Dr. Wong commented that requiring translations will be difficult for many pharmacies and will negatively affect the workflow. Dr. Wong expressed his opinion that requiring translations would be over-regulation and encouraged the board to allow the market to dictate the need.

Dr. Wong asked if the board had data on the number of people requesting translation services. Ms. Herold responded that when the board conducted a survey two years ago, approximately 70 percent of the pharmacies indicated they had a system to provide translations. Ms. Herold noted that staff does not have any data on the demand for translations.

Mr. Brooks asked if there are any problems for law enforcement or emergency medical workers when they arrive at a scene and the medication labels are not in English. Gregory Murphy, board member and peace officer, stated that not having a label in English would prolong an investigation, as the officer on the scene would have to contact someone to translate the label. Ms. Herold stated that she would discuss this with law enforcement and emergency personnel. Dr. Gutierrez commented that the requirement is for the label to be in both English and the translated language, so this shouldn't be a problem.

Ms. Herold explained that the intent is to have pharmacists use the standardized directions for use which are on the board's website and are translated into five languages. She briefly explained how a pharmacist would use the translations on the web site and noted that translations would only be required for *standard* directions for use.

Mr. Brooks asked if the translations on the board's web site are accurate. Ms. Herold responded that the California Endowment vetted the translations; however, the board has found that no one is using the translations.

Ms. Veale asked if a pharmacist would have to translate the disease state. Ms. Herold responded that the pharmacist would not be required to translate the disease state, only the standard directions for use.

Ms. Herold stated that the goal of the proposed language is not to provide translations for every language and for every possible type of prescription with complicated directions for use. The goal is to provide translations for the 90 percent of medications that are dispensed with standard directions for use in the five languages spoken by the majority of Californians.

Ms. Herold stated that 40 percent of patients cannot read their prescriptions and this poses a real threat to their health.

Desiree Kellogg commented that the proposed language states that a pharmacist would not be held liable for providing an incorrect translation as long as they used the translations provided on the board's web site and were not grossly negligent.

Dr. Gutierrez commented that there may be an issue for some pharmacies providing translations due to their IT system capability.

Dr. Wong expressed his concern for the space available on the label and again stated that the market should determine what translations a pharmacy offers.

Mr. Law agreed that the board should not mandate translations and noted that some of the translations on the board's Chinese poster are incorrect.

Dr. Gutierrez asked if the board does not address the issue of translations if it will be taken over by the legislature. President Weisser responded that if the board does not address it, another entity will.

Note: Mr. Brooks left the meeting at 12:24 p.m.

Ms. Veale asked if the committee could discuss this item further, specifically regarding the issue of the translations fitting on the label. She also asked the committee to consider allowing a pharmacy to have their own translation system in place rather than being required to use the board's web site.

Mr. Law asked the committee to determine if there is really a need for the board to mandate translations. Mr. Lippe commented that the board has heard multiple times from the public that translations are needed.

Ms. Veale commented that the board should consider encouraging the use of the translations on the board's web site, rather than mandating it. Ms. Butler agreed that the board should encourage rather than mandate the use of translations.

Ms. Herold commented that pharmacies are not currently using the web site translations because they are worried about liability.

President Weisser asked the board members with expertise in this area to attend the next committee meeting to offer input. He also asked that members of the public attend the next committee to provide input.

Carrie Sanders, from the California Pan-Ethnic Health Network, commented that their organization is willing to work with the board on developing language. Ms. Sanders expressed frustration with the board's comments that there is not a need for translations as there has been data provided showing that there is a need. She also commented that if the board does not address this issue there will be attempts by other organizations to do so.

President Weisser asked Ms. Sanders to attend the next committee meeting to provide additional input.

A pharmacist agreed with Dr. Wong that translations should not be mandated.

Attachment 5

Board of Pharmacy Media Activity

Sept. 18 – Dec. 5, 2014

Patient Centered Labels and Label Translations

9/18 & 10/30 Sammie Carriola, *Sacramento Bee*

Sep – Oct. Sonya Collins, *Pharmacy Today*

Disciplinary Case against RSF Pharmaceuticals

Ongoing: Aaron Gordon, *Vice.com*

Medication Errors

12/3/14 Brian Heap, *KCRA 3, Sacramento*

Disciplinary Cases

12/1/14 David Lazarus, *L.A. Times*

Ongoing: Donna Evans, *Downtown News, Los Angeles*

10/30/14: S. Branson, *KCBS, Los Angeles*

10/28/14 Chad Terhune, *L.A. Times*

9/24/14: Jeff Gottlieb, *L.A. Times*

Senior Care Facilities

10/21/14: Marjie Lundstrom, *Sacramento Bee*

Board Position on Tobacco

11/14: KFBK, *Sacramento*

Supreme Court Considers if State Boards Limit Competition

10/15/14: David Savage, *L.A. Times*

Opioid Painkiller Abuse

9/24/14: Lissette Rodriguez, *KCRA 3, Sacramento*

Attachment 6

Chantix, Suicide, and the Point of Prescription Drug Warnings

<http://phenomena.nationalgeographic.com/2014/10/28/chantix-suicide-and-the-point-of-prescription-drug-warnings/>

by Virginia Hughes

Quick poll: Think back to the last time you bought a prescription medication. Did you read any of the information about the drug printed on the papers inside the box? And if you did read it, did that stop you from taking the drug?

I can't recall a time when I read any of that fine print, despite the fact that I'm fascinated by medicine and often write about it. I got thinking about the potency (or impotence) of these warnings this week while reading about a controversy surrounding Chantix, a drug that helps people quit smoking.

Chantix (Pfizer's branded name for [varenicline](#)) works by stimulating nicotine receptors in the brain, thus curbing cravings for cigs. The Food and Drug Administration (FDA) approved the drug in 2006. Since then, a small percentage of people who take Chantix have reported neurological side effects, and serious ones: depression, psychosis, erratic behavior, even "feeling like a zombie." The drug has been linked to [more than 500 suicides, 1,800 attempted suicides](#), and the bizarre [death of an American musician](#). Here are a few anecdotal reports about the drug from a [Reddit thread](#):

Chantix was the most miserable drug I have ever taken...severe GI distress, depression, paranoia, crazy and vivid dreams, etc. BUT, it got me off cigarettes after everything else I tried had failed...As I knew that it really XXXXX with you I prepped by temporarily getting rid of the guns and having my brother check up on me daily...What keeps me from going back to smoking is knowing that one day I'll want to quit again, and I NEVER want to experience Chantix again!!!

I'm convinced Chantix played a part in my divorce. My ex gave up smoking, her Pepsi habit, as well as marriage.

My mother was on it (and successfully quit smoking using it) and she had some outrageous paranoia. She would accuse us of conspiring against her, making her sick, not loving her, lying to her, stealing things (that she misplaced), turning the dog against her, trying to poison her and sabotaging her car...she smoked for 40 years and failed at quitting hundreds of times. Chantix did the trick somehow but made her nuts.

Yikes! Reading stories like that might scare me enough to think twice about the drug. But would the information in the package insert?

That insert has been the focus of the recent hoopla about Chantix. In 2009, the FDA decided that the Chantix insert needed a "black box warning" about the risk of neurological side effects (so named because this text is outlined with a black border). Here's part of that warning:

Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are

not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior while taking CHANTIX or shortly after discontinuing CHANTIX.

The black box is the FDA's most severe safety warning. Pfizer fought it tooth and nail, citing several studies showing that Chantix is not associated with a higher risk of psychiatric problems. (If you want to read more about these studies and counter arguments from the FDA advisory panel, check out this excellent piece by John Gever at [MedPage Today](#).) Earlier this month, the FDA confirmed that the warning would stay, and in fact suggested that it have even stronger language.

But... why so much fuss over these warnings, anyway? Does anyone actually read them?

There doesn't seem to be a lot of research on that question, though the data that does exist suggests that some patients are more conscientious than I am. One [report](#) I stumbled on, surveying 1,500 patients from a community pharmacy in Germany in 2001, found that 80 percent always read the inserts. A 2007 study looked at 200 patients in Israel who were prescribed antibiotics, analgesics or antihypertensives. It found that [just over half](#) of participants read the inserts. And a 2009 study in Denmark found that 79 percent of patients ["always or often" read them](#). On the other hand, a 2006 report of American consumers reported that [just 23 percent](#) looked at this info.

Even if patients are interested in reading those materials, they might not understand the information. [A 2011 study](#) asked 52 adults with a high-school education or less to read the package insert and similar materials describing an antidepressant medication. Afterwards, less than 20 percent could name the rare-but-dangerous side effect of the drug. A [report from the Institute of Medicine](#) similarly concluded that drug labeling is a big part of why patients often use drugs incorrectly.

Studies like those have led some researchers to propose ways to make labels [more useful to patients](#). But the reason Pfizer was so concerned with the black box warning for Chantix has little to do with consumer behavior. The company was worried because of the warning's potential influence on doctors and their prescribing habits.

There aren't many studies looking closely at the correlations between black-box labeling and prescribing patterns. But there are two notable examples that seem to suggest that the warnings have teeth. Remember the Vioxx controversy? Vioxx was a hugely popular anti-inflammatory drug that was pulled from the market in 2004 because of its risk of heart disease and stroke. After that, the FDA reacted by issuing black-box warnings for several similar drugs, leading to [a "rapid decline" in prescriptions](#).

The other example comes from the link between antidepressants and suicide in children and adolescents. In March 2004 an FDA advisory committee reported on this link, **and several months later it issued a black-box warning on all antidepressants. By June 2005 prescriptions for children and adolescents had [dropped 20 percent](#).**

To sum up, I was wrong: prescription warning labels, though flawed, actually matter to many patients, doctors and pharmaceutical companies.

As for Chantix... if you're thinking of trying the drug to quit smoking, you might want to wait until results come back from a [prospective clinical trial](#) slated to end next year.

Fears Rise of Medication Misuse by the Elderly

With the Senior Population Growing, Experts on Addiction and Geriatric Care Raise the Alarm

By
Barbara Sadick
Sept. 14, 2014 4:00 p.m. ET

Prescription-drug abuse and misuse by seniors doesn't get much attention. But with the senior population steadily growing, it's getting harder to ignore.

Many seniors develop addictions to prescription drugs. Others are taking medication that is having little effect or unintentional effects, either because they are taking it for too long, they were prescribed too big a dose, or it is reacting badly with other medications.

The misuse of medications "is a rising problem in seniors as the baby-boom generation ages," says David Oslin, professor of psychiatry at the University of Pennsylvania's Perelman School of Medicine.

Exactly how much of a problem is unclear, because there isn't much data available. But it's enough of a concern that experts in addictions and geriatric care are trying to raise awareness of the issue.

Addiction and Carelessness

For starters: "The use and availability of highly addictive medications continues to rise, with very little recognition of the problem," says Dr. Oslin.

It isn't just that doctors sometimes don't recognize addiction in their patients. Physicians also sometimes fail to recognize the *potential* for addiction, says James Huysman, a psychologist and a senior clinical consultant at the Hanley Center, a drug-treatment center in West Palm Beach, Fla.

"Physicians who work in a fee-for-service system and are traditionally paid by procedure are pressed for time, and too often write prescriptions in the interest of time management without knowing the necessary behavioral health background of a patient," says Dr. Huysman. That may lead to potentially addictive drugs being prescribed for people who have a history of addiction or who have a high risk for addiction.

Opiates and antianxiety medications are of particular concern, not just for their addictive potential but also because of the dangers that arise when patients simply remain on these medications for too long. Prolonged use of psychoactive medications such as these has been associated with cognitive decline and depression, according to the Substance Abuse and Mental Health Services Association, an agency of the U.S. Department of Health and Human Services.

An Increasing Problem for Seniors

■ The percentage of older adults who **misuse prescription medications is estimated to increase 100%** to 2.7 million (2.4%) in 2020 from 911,000 (1.2%) in 2001.

■ From 2004 to 2008, there was a **121% increase in emergency room visits** involving prescription medication misuse by older Americans.

■ One study found that up to **11% of women older than 60** misuse prescription medications.

■ Combined **misuse of alcohol and medication** has been estimated to **affect up to 19%** of older Americans.

Sources: Administration on Aging; Substance Abuse and Mental Health Services Administration; Annals of Epidemiology, (forecast of misuse); Center for Behavioral Health Statistics and Quality, DAWN Report (emergency room visits); American Journal of Geriatric Pharmacotherapy (misuse among women); Annals of Pharmacotherapy, National Institute on Alcohol Abuse and Alcoholism (alcohol and medication)

The Wall Street Journal

Excessive sedation, low respiratory rates, attention impairment, vision problems and loss of motivation are some of the side effects common in seniors, according to the agency. Confusion, falls and broken bones can result. Patients may have difficulty carrying out the routine activities of daily living and lose interest in personal hygiene and grooming, and in family and friends.

The agency says a doctor's failure to monitor a patient's reactions to medications or schedule follow-up appointments should be cause for concern.

The dangers of unintended effects aren't limited to psychoactive drugs. Older men and women frequently are in pain and suffer from multiple chronic conditions such as arthritis, hypertension, anxiety and an inability to sleep. As a result, they are often prescribed a regime of different medicines, and the mix has

the potential to interact badly. In addition, as people age, the body is slower to metabolize medications, so a dosage appropriate for a younger adult may be too much for an older person.

Taking Action

Experts in senior care are working to raise awareness of the problem among patients and health-care providers. Dr. Huysman gives seminars and speeches to health-care groups around the country on the perils of inappropriate prescribing practices for older patients, and he advises health-care workers on how to recognize the signs of addiction and how to integrate addiction services into medical clinics.

The American Geriatrics Society, meanwhile, is updating its Beers Criteria for determining what medications are potentially inappropriate for seniors, with the aim of helping health-care providers make better decisions.

Others are focusing on getting patients to stop taking drugs that aren't effective. In one such program, the University of Pennsylvania has joined with a state pharmacy-assistance program aimed at the elderly in an effort to improve results for older patients who have been prescribed antidepressants, antipsychotics and antianxiety medications by nonpsychiatrists. Researchers conduct regular follow-up calls to check whether prescribed medications are being taken properly and whether they're effective.

In its sixth year, the program has worked with more than 2,000 older patients in Pennsylvania. Data are still being compiled and analyzed, but preliminary findings show improvement in symptoms of depression and better overall emotional well-being in program participants.

Dr. Oslin, the Penn professor, who is the lead investigator in the program, says drugs often are misused simply because patients keep taking them long after they stopped being effective, while the underlying health problem—such as depression or obesity—goes untreated.

"Unfortunately," says Dr. Oslin, "it's much easier to take a pill than to exercise or routinely train health-care workers to properly treat the pain, anxiety, and insomnia often experienced by older adults."

Ms. Sadick is a writer in New York. She can be reached at reports@wsj.com.



2014 U.S. Pharmacy Study

The Challenge

Pharmacy customers are confronting trends such as industry consolidations, mandatory mail-order programs, and new forms of receiving service at the point-of-sale. How do pharmacy customers rate their experiences with these evolving drug distribution channels in the U.S.? How does the pharmacist impact satisfaction and sales? In what situations are cost, convenience, or customer service the most influential concerns?

The Solution

The *J.D. Power 2014 U.S. Pharmacy Study*SM provides both retail and mail-order pharmacy executives with the information necessary to achieve better business outcomes by improving customer satisfaction. One of the most effective and economical ways to optimize marketing practices and maximize pharmacy profits is to provide service experiences that exceed customers' expectations. While other studies compare products sold, this study provides a framework to help pharmacies define where and how customer service experiences are working best and where there is room for improvement. Specific customer satisfaction areas addressed in the study include:

- Experience with pharmacist and non-pharmacist staff
- Pharmacy location and environment
- Shopping behavior, cross-purchasing, and purchase experience
- Impact of new service models on satisfaction
- Experience with prescription ordering and pick-up/delivery in retail, as well as ordering via mail
- Loyalty and purchase behavior dynamics, including integrated delivery systems
- Out-of-pocket price sensitivity and perceived value of prescription drugs
- Demographics, disease state, and customer profiles

The Benefits

The study measures customer satisfaction with their pharmacy experience across major chain drug stores, mass merchandisers, supermarkets, and mail-order pharmacies. Study findings will allow you to:

- Determine critical factors that drive customer satisfaction with the retail and mail-order pharmacy experience
- Benchmark performance across key performance indicators
- Optimize the impact that pharmacists and non-pharmacist staff may have on the overall customer experience
- Compare performance of major pharmacy brands to provide retail and business-to-business customers with detailed information on which to base their retail, mail-order pharmacy, and PBM choices

J.D. Power Industry Solutions

J.D. Power's products and solutions help companies measure, understand, and improve the key performance metrics that drive growth and profitability. Since 1968, organizations around the world have relied on J.D. Power as a trusted advisor for:

- Deep expertise in the industries we serve
- Advanced research science to drive insights
- A proven success record for driving results

Through an unmatched 360° view of the customer, J.D. Power can identify the multiple drivers of customer experience, measure and understand their impacts, and help you drive business results by monitoring and improving performance.



J.D. Power's Offerings include:

Industry Benchmarking

J.D. Power's independent industry benchmarking research measures quality and customer satisfaction based on survey responses from millions of customers worldwide. The company has one of the largest, most comprehensive historical customer satisfaction databases in existence, which includes feedback on customers' shopping, buying, and ownership experiences for a variety of products and services.

Tracking

J.D. Power offers three tracking solutions that enable your company to measure quality and customer satisfaction in real time and compare the data against industry benchmarks to identify areas of improvement:

Acutrend™—Provides a 360° view of the customer experience in real time through a Web-based interface that allows for an analysis of every key performance measure against established industry benchmarks

Custom Tracking—Offers a customized research and customer satisfaction measurement and tracking on a proprietary basis utilizing a variety of data collection

methods, which are accessed via a user-specific data-reporting platform

Customer Community—With J.D. Power's online panel, tracking clients receive fast feedback from their customers, while building a database of comprehensive customer profiles over time.

Performance Improvement

J.D. Power offers comprehensive solutions for businesses looking to improve customer service, satisfaction and operational performance. The company derives its insights from industry-wide benchmarks known to drive the highest levels of satisfaction, and helps organizations make changes to improve business results.

Social Media Insights

Collect and evaluate consumer sentiment in its natural form—unprompted. J.D. Power's advanced social media intelligence solutions easily integrate into your company's existing research, surpassing the basic monitoring tools that many companies currently use.

Text Analytics

J.D. Power's state-of-the-art technology analyzes all of your company's unstructured text—gathered from any

source—and provides actionable solutions and analyses that enable rapid, effective responses to the continuously changing needs and opinions of consumers.

Digital Experience Evaluation Solutions

Gain an understanding of how consumers interact with your company's website, as well as whether it is meeting the needs of consumers and how it compares to competitors. J.D. Power experts work with you to re-engage consumers on your website and to implement continual improvement.

Mystery Shopping

J.D. Power's rigorous and comprehensive sales and service mystery shopping, observational audit, and compliance services can be customized to virtually any industry.

Consulting and Training

Develop competitive advantages by integrating Voice of the Customer data, benchmarking study findings, and J.D. Power's industry expertise into your company's strategic planning and operational activities.

Los Angeles cracking down on sale of illegal pharmaceuticals

LA cracking down on sale of illegal pharmaceuticals

Los Angeles city officials are cracking down on the illegal sale of pharmaceutical drugs.

<http://abc7.com/news/la-cracking-down-on-illegal-pharmaceutical-sales/335517/>

KABC

By Robert Holguin

Friday, October 03, 2014

LOS ANGELES (KABC) --

Los Angeles city officials are cracking down on the illegal sale of pharmaceutical drugs. Authorities aren't just targeting those who are selling the medications, they're also warning those who are buying them.

Thousands of illegal pharmaceutical products -- from fake steroids to phony pain relievers to bogus miracle cures -- were confiscated in Los Angeles in just the last week.

Erick Aguilar, who works for the Los Angeles County Department of Public Health, says these recent seizures are the result of a spike in the amount of illegal pharmaceuticals hitting the streets.

"We can't really explain why but we have seen it," said Aguilar.

City Attorney Mike Feuer held a news conference on Thursday, promising to crack down on people who sell the drugs.

"We have multiple pending cases now that we filed against those who would dispense illegal pharmaceuticals and we will be filing even more next week," said Feuer.

Typically, these counterfeit or bogus pills and compounds are sold in swap meets or in neighborhood stores. Authorities say the sellers target the Mexican immigrant community.

"The targets of these sales are among the most vulnerable people -- the people who often feel the least protected in our society," said Feuer.

Several people, who did not want to be interviewed on camera, told Eyewitness News they sometimes purchase pharmaceuticals or vitamins from swap meets in hopes of saving money. They said that without insurance, the underground pharmacies are often their only option.

"If you have an ailment that requires attention, see a legitimate physician," Feuer advised.

Investigators say the people who sell the bogus pills are not only breaking the law, they are putting people's lives at risk.

"In some cases, the ingredients contained in the so-called medications could themselves be dangerous to the person in any quantity," said Feuer.

Selling bogus or counterfeit pharmaceuticals that aren't controlled substances is a misdemeanor, which can result in jail time or fines.

9 Sure-Fire Prescription Drug Safety Tips That Work

http://www.automatedtrader.net/blogs/edrugssearch-_inc/150301/9-sure_fire-prescription-drug-safety-tips-that-work

from [eDrugSearch, Inc](#) : Cary Byrd - 20th May 2014

The opinions expressed by this blogger and those providing comments are theirs alone, this does not reflect the opinion of Automated Trader or any employee thereof. Automated Trader is not responsible for the accuracy of any of the information supplied by this article.



It is important to keep you and your loved ones safe when it comes to **prescription drugs**. There are some simple yet effective prescription drug safety tips that you can take to prevent complications and other problems that may arise. Learn how to protect your family and yourself from possible interactions, abuses, and other problems.

1. Know the Source

Many people look to save money by using an **online pharmacy**. This can be a very safe way to save money on some common prescriptions - as long as the company is reputable. There are some unscrupulous sites known as "rogue" online pharmacies that will sell you counterfeit drugs. These are very dangerous, as most are made with toxic ingredients. Do your research and make sure you are purchasing from **safe and licensed online and mail-order pharmacies**.

2. Know the Purpose

It is important to know why you are taking the prescriptions your doctor has given you. Feel comfortable talking to your doctor and understanding the purpose of each drug. This is especially true for people who are taking multiple medications.

3. Communicate with Your Pharmacist

A pharmacist is very knowledgeable about medications and how they may interact with one another. If you are unsure about any of the interactions, side effects, or other aspects of the drugs, make sure you ask. Your pharmacist can also clear up any confusion or questions you may have about the drugs.

4. Make a List

Keep a list of your current medications and the dosages. Most doctors will request that you do this. Even things like eye drops or specialty lotions should be included. Make sure the list is kept up to date.

5. Know the Side Effects

Review each of the possible side effects listed on your medications. Most of the time, a reaction will occur when the prescription has just been started, but this is not always the case. Sometimes there will be a reaction after you have been taking the medication for awhile or when a new one is added. Understanding the side effects will help you know what to expect. If you experienced side effects that are not listed or that seem unusual, make sure you contact your doctor right away.

6. No Sharing

Never share your medication with others. While it might seem harmless to give your friend a pill if they are on the same prescription, this is not a good idea. Your doctor has given you that set amount of medication and expects you to take the full amount. Sharing is not only illegal, but it can also provide your doctor with inaccurate information about your dosages.

7. Out with the Old

Do not keep medications that are expired or no longer needed. Go through and clean out your cabinets to make sure any old medications are disposed of. While it used to be common practice to flush them, this is

no longer recommended. Check your community for medication collection and disposal days. Most cities and towns will now take this old medication from you and dispose of it safely and properly.

8. Guard Your Prescriptions

Prescription drug abuse is very common. If you have commonly abused drugs, such as pain killers or anti-anxiety medications, it is a good idea to keep them secure. Consider locking them up. Keep a count of how many pills are in each bottle so you will know if any are missing.

9. Communicate

Maintain a good relationship with your doctor. Talk to him or her about any concerns you have about your prescriptions. Never feel rushed or embarrassed when talking about your health. Your body and health are extremely important, so take whatever time you need in order to have all your questions and concerns addressed.

There are many ways to keep you and your family safe with prescription drugs. It is important to be knowledgeable about your medications and to understand how they can affect you. Follow these prescription drug safety tips and stay smart about your medication!

The post **[9 Sure-Fire Prescription Drug Safety Tips That Work](#)** appeared first on **[eDrugSearch Blog](#)**.

OTC Package Designs Can Contribute to Errors



Over-the-counter (OTC) medications and other products are not immune from being involved in medication errors. The packaging design of OTC products can increase the risk of confusion and error. Here are a couple examples of OTC products whose product designs have contributed to medication errors and accidental exposure in children.

In early 2013, 16 elementary school children were taken to local hospitals with a sudden illness. The children were 9- and 10-year olds who began vomiting after eating "mints" given to them by a classmate. It was later found that these "mints" were actually nicotine replacement lozenges, called NiQuitin Minis. NiQuitin is a product from the United Kingdom that is sold online. NiQuitin Minis are available in 1.5 mg and 4 mg flavored lozenges. Nicorette, which is marketed in the United States, has a similar product available in 2 mg and 4 mg lozenges. Compared to nicotine gum, NiQuitin Minis release their full dose of nicotine three times faster. These lozenges look very similar to candy breath mints such as Tic Tacs. Also, the size and shape of the container is similar to PEZ candy or breath mint dispensers. Fortunately, none of the children mentioned above were seriously hurt.

Melatonin is another OTC product designed and packaged similarly to breath mint film strips. Melatonin is a hormone that is involved in the management of sleep and wake cycles. It is available as an OTC dietary supplement promoted to help with jet lag and sleeplessness. A mother contacted us and shared that a child at her son's school gave what

NiQuitin Minis (United Kingdom) (left) and Nicorette, Lozenges (United States) (right) can be mistaken for mints and candy.

he thought were breath mint film strips to several children before it was recognized that the film strips actually contained melatonin. It is easy to see how people, especially children, can mistake medicated oral film strips for breath mints as the packaging looks similar and both advertised in various flavors.

SAFE PRACTICE RECOMMENDATIONS

It is critical that health care practitioners promote medication safety practices in the home and community. Listed below are some recommendations to provide to patients and caregivers to prevent children from accidental poisonings from nicotine-replacement products and other OTC products.

- Keep all prescription and OTC medications up and away and out of the reach of children.
- Secure purses and other bags that may contain prescription and OTC products. Be aware of products visitors may bring into the home; children are curious and may investigate visitors' bags.
- Don't refer to medications as candy.
- Avoid taking medications in front of children.
- Don't leave any medicine unattended, even while answering the door or phone.

► *Continued on page 63*

You
We

Your p
to mee
help y
Advan
soluti
busine
Whate

Learn
you w
cardi

Prescriptions Never Picked Up At Pharmacy A Cause For Concern

<http://www.nacds.org/Home/TabId/107/PostId/5179/Prescriptions-Never-Picked-Up-At-Pharmacy-A-Cause-For-Concern.aspx>
Medications left on the shelf are a major, largely unacknowledged problem in U.S. health care

Boston, Mass. - The U.S. health care system must address the problem of patients not picking up newly-prescribed medicines if national goals for improved health and reduced costs of medical care will be realized, according to a NEHI [white paper](#) issued today.

The paper, "[Ready for Pick Up: Reducing Primary Medication Non-Adherence – A New Prescription for Health Care Improvement](#)," outlines the problem of prescriptions for newly-initiated therapy that are not picked up for the first time and, thus, never taken, leading to the possibility of worse health and increased stress on the health care system.

The rate of primary non-adherence (PMN), that is, the percentage of first-time prescriptions abandoned by patients (and thus not picked up at pharmacies), can range as high as 30 percent among some classes of medication, according to recent research.

"In recent years our health care system has begun to take action to improve patient medication adherence, and yet primary medication non-adherence – the failure to commence newly-initiated therapy – remains a major but largely unacknowledged problem," said Tom Hubbard, NEHI vice president of policy research, who authored the paper. "The good news is that potential strategies for reducing primary medication non-adherence are emerging as electronic prescribing (e-prescribing) becomes common. This paper is a call to accelerate action that will reduce the failure to pick-up newly initiated medication therapy."

A May 2014 working group convened by the National Association of Chain Drug Stores (NACDS) Foundation, the Pharmacy Quality Alliance (PQA), and NEHI framed the issues outlined in the paper. The paper addresses key issues in the adoption and utilization of a new pharmacy quality metric on primary medication non-adherence endorsed by the Pharmacy Quality Alliance in November 2013. Prior to the advent of e-prescribing, tracking PMN rates was not feasible.

"The PQA PMN measure introduces a consensus-based, scientifically tested, nationally endorsed metric to the market," noted Laura Cranston, PQA Executive Director. "This metric brings much-needed consistency in defining PMN, which will help us to identify, test, and compare results for PMN interventions across healthcare settings."

Current adherence policy focuses on patients who have received their therapies at least once – because these patients trigger payment claims processing that allows medication adherence to be tracked.

"Obviously this leaves out patients who never get their newly-prescribed therapy at all," Hubbard said. "Community pharmacies that receive e-prescriptions can now track primary medication non-adherence by comparing the e-prescriptions they receive to the records of the prescriptions that are actually picked up. This paper outlines the issues pharmacies face in using this data to create effective interventions with patients that will increase the first-fill of new prescriptions."

NEHI makes eight recommendations that stakeholders, from physicians and pharmacists to insurers and health plans, could do to understand and attack the problem, including pharmacist interventions with non-adherent patients.

High on the list: more dialogue among health care payers, the physician community and the pharmacy industry to establish common ground for action.

"Collaboration is key in the face of the challenges that result from patients not taking their medications as prescribed. And to that end, pharmacy works in close partnership with hospitals, physicians, nurses and other healthcare

providers in helping patients understand the importance of taking their medications as prescribed,” said Kathleen Jaeger, NACDS Foundation President. “We are pleased that NEHI has raised awareness of primary medication non-adherence – a critical public health gap.”

Said Hubbard: “As the late Surgeon General C. Everett Koop said, ‘Drugs don’t work in patients who don’t take them.’ He might have continued, ‘Drugs never work in patients who don’t take them for the very first time.’ ”

Translating prescription labels: California considers proposal

<https://www.pharmacist.com/translating-prescription-labels-california-considers-proposal>

November 03, 2014

Pharmacists concerned error in translation could lead to medication error

The Affordable Care Act has prompted shifts in health care delivery towards a more patient-centered approach. In California, one of the next such shifts could be prescription labels in the patient's native language. Forty-four percent of California residents speak a language other than English at home. The state's board of pharmacy is now considering a proposal to require that pharmacies provide prescription instructions in the dominant other languages.

Difficulty understanding medication instructions contributes to nonadherence and poor outcomes for patients, studies show. Translated labels could be the answer, but the proposal raises big questions for pharmacists.

"Some advocates feel strongly that they want other languages on the bottle, and others are concerned an error in translation can lead to a medication error," said Virginia Herold, Executive Officer of the California Board of Pharmacy.

In 2011, the California Board of Pharmacy redesigned prescription labels—increasing font size and dedicating 50% of labels to information intended for the patient—to make them more patient-centered. The board opted not to introduce translated labels at that time, instead requiring the availability of oral interpreter services at the pharmacy counter. Last July, the translation proposal was back on the table after a forum on further patient-focused label redesign.

The proposed legislation currently awaits review by the board of pharmacy. A committee met in late September to make a formal recommendation. The proposed statutory requirement currently awaits further work by a board committee before its review by the board of pharmacy in late January.

Pharmacists' concern

Pharmacists' main concern with translated labels has been how to ensure the accuracy of the translation and whether pharmacists would be responsible for adverse events associated with translated labels, although many pharmacies do provide translated directions on labels now.

"The first and foremost issue for pharmacists is, 'If I can't read what I'm putting on the label, I can't be certain that I've got the right directions for this patient,'" Herold said. "And that is an important and serious obligation of the pharmacist."

The California Board of Pharmacy's website already offers translations of the 21 most common medication instructions in Spanish, Chinese, Vietnamese, Korean, and Russian—the five languages after English most commonly spoken in California.

The board created 16 standardized medication instructions and translations of them for the 2011 label redesign. For example, "Take one pill twice daily" became "Take 1 pill in the morning and 1 pill at bedtime."

When the standardized language was created, a team of researchers had the instructions translated into the five languages and vetted them in communities where those languages are spoken. Pharmacists were not required to use the standardized language, but they were urged to whenever possible.

The committee recommendation on translated labels suggests that the board “empower pharmacists to use [those existing] translations,” Herold said, “which will perhaps mean a waiver of liability in the event someone makes an inadvertent mistake in transferring the information to the label.”

It remains to be seen whether legislation, if passed, would require translations in additional languages and translations of instructions other than the 16 medication instructions currently available on the board’s website.

It’s possible, said Herold, that legislation would require that English instructions appear somewhere on the label as well so that anybody that comes across the label understands how to take it.

Around the country

California would not be the first state to require translated prescription labels. New York passed the Safe Rx Act in 2012, which requires pharmacy chains of eight stores or more to provide oral interpretation at the pharmacy either in person or by phone and translated prescription labels in Chinese, Italian, Russian, or Spanish to non-English-speaking patients.

New York’s legislation ensures that pharmacies are not liable for third-party translation errors. While the mandate only requires labels in four languages, many pharmacies offer additional languages, said a spokesperson for the state board.

Meanwhile, pharmacies around the country, including in California, voluntarily offer prescription labels in the languages their patients speak. Walgreens has offered this service for nearly 15 years. Patients can get prescription instructions in 21 of the languages most commonly spoken in the United States.

“The single most important information patients have to refer to about how to take their medication is that label,” Herold said, “so you want it to be clear, you want it to be consistent, and you want people to be able to read it and understand it.”