

July 2010

News



# Arizona State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Board Member/Board Staff Changes**

The March 2010 Arizona State Board of Pharmacy meeting was Board President Dr Ridge Smidt's last meeting. His leadership and insight were very much appreciated during his five-year term on the Board. Time seems to fly by; it seems just like yesterday that Dr Smidt was chairing task forces for the Board and helping to prepare the Board budget for fiscal years 2009 and 2010. Thank you Dr Smidt for your years of dedicated service to the Board and to the citizens of Arizona.

Dr Zina Berry was elected the new president of the Board at the meeting and Steve Haiber was elected vice president.

Governor Jan Brewer appointed Dr James W. Foy to the Board to fill the member position vacated by Dr Smidt. Dr Foy's term is for five years and is currently slated to expire on January 19, 2015. Dr Foy received his PharmD from the University of Illinois and also obtained a master of business administration with an emphasis in health care. Dr Foy is very familiar with pharmacy practice in the state of Arizona and has had operational responsibilities for pharmacies in Arizona from Flagstaff in the north to Sierra Vista in the south and from Yuma in the west to Apache Junction in the east-central areas of the state. He also served on the Task Force for Medication Errors with the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy and has been employed in community pharmacy since 1983. Jim is currently a district manager for CVS pharmacy in Arizona.

Dr Paul Sypherd resigned after five years with the Board as a public (non-pharmacist) member following a notable career in microbiology and academia, most notably as provost for the University of Arizona. The Board and staff will miss Dr Sypherd's calm demeanor and insightful summaries of topics before the Board. He was always able to "translate" or reduce complicated issues to terms that the public could understand. Thank you for your service Dr Sypherd.

Governor Brewer appointed Kyra Locnikar to succeed Dr Sypherd as a public member. Ms Locnikar is a graduate of Arizona State University with a bachelor's degree in psychology. She also has a master's degree in clinical psychology from the Arizona School of Professional Psychology and is a doctoral candidate at Argosy University. Ms Locnikar recently served on the Arizona Board of Cosmetology and has extensive experience in dermatologic medical sales. She is currently an aesthetician and is president of ESTETx LLC. Her term on the Board will expire on January 19, 2015, as well.

Tom Petersen, RPh, has accepted the Board compliance officer position that is based in Tucson, AZ. Tom is an alumnus of the University of Arizona College of Pharmacy and has been a licensed pharmacist in Arizona for over 33 years. His career in community pharmacy includes owning a pharmacy in Tucson for 10 years. Tom has been working in

correctional pharmacy for the last few years and will begin training for his new position in Phoenix, AZ, and Tucson in late June.

Congratulations to our two new Board members and our new compliance officer. Please plan on meeting them at the July 15, 2010 Board meeting at the Board office. They will be busy "learning the ropes" but I am sure they will have time to converse with you if you have the time to introduce yourself.

## **Authorization for Changes to CII Prescriptions**

As of June 7, 2010, Drug Enforcement Administration (DEA) advises that pharmacists should adhere to state regulations or policy regarding changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber. DEA recognizes that there may be confusion regarding federal regulations on this matter, as DEA published in the *Federal Register* on November 19, 2007, the Final Rule titled Issuance of Multiple Prescriptions for Schedule II Controlled Substances, which contained instructions that conflict with prior DEA policy. Specifically, the more recent final rule states in its preamble that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally," while prior DEA policy permitted the same changes a pharmacist may make to Schedule III-V controlled substance prescriptions after oral consultation with the prescriber. DEA plans to resolve the issue through future rulemaking. The current, applicable Arizona statute is reprinted below:

ARS §36-2525(A) – "If authorized verbally by the prescriber, the pharmacist may make changes to correct errors or omissions made by the prescriber on the following parts of a written Schedule II controlled substance prescription order:

1. The date issued.
2. The strength, dosage form or quantity of drug.
3. The directions for its use.

B. The pharmacist must document on the original prescription order the changes that were made pursuant to the verbal authorization and record the time and date the authorization was granted."

## **Reminder – Arizona Optometrist Prescribing Authority**

Optometrists in Arizona holding a Pharmaceutical Agent (PA) certificate (currently 88.9% of all optometrists) are authorized to prescribe, administer, or dispense topical diagnostic, topical therapeutic, and oral pharmaceutical agents; "pharmaceutical" or "pharmaceutical agent" means a prescription or nonprescription substance or a Schedule III controlled substance used for examination, diagnosis, or treatment of conditions of the human eye and its adnexa. Additionally, optometrists in

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## FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at [www.fda.gov/Drugs/Resources/ForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm](http://www.fda.gov/Drugs/Resources/ForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm).

## DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

## Confirmation Bias



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see [www.ismp.org/Tools/confuseddrugnames.pdf](http://www.ismp.org/Tools/confuseddrugnames.pdf) for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when *Norvase*® is entered into the computer, a formulary note screen appears, alerting the pharmacist that *Norvasc* often looks like *Navane*® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

## FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at [www.fda.gov/AboutFDA/WhatWeDo/track/default.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/default.htm). FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at [www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm), Center FDA-TRACK Program Areas available at [www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm).



*AboutFDA/WhatWeDo/track/ucm195008.htm*, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to [FDATRACK@fda.hhs.gov](mailto:FDATRACK@fda.hhs.gov).

## **Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications**

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News\_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

## **California PMP Data Shows Frequency of Doctor Shopping**

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26<sup>th</sup> Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

## **Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns**

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor<sup>®</sup> (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

## **New OxyContin Formulation to Help Prevent Abuse of the Drug**

FDA has approved a new formulation of the controlled-release drug OxyContin<sup>®</sup> which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at

preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

## **Use of e-Prescribing Grows Dramatically**

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

## **Study Shows e-Prescribing Reduces Prescriber Errors**

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5% to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at [http://weill.cornell.edu/news/releases/wcmc/wcmc\\_2010/02\\_26\\_10.shtml](http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml).

## **Counterfeit Drug Investigation Leads to Two Arrests**

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

Arizona holding a Topical Pharmaceutical Agent (TPA) certificate are authorized to prescribe, administer, or dispense topical diagnostic and topical therapeutic pharmaceutical agents only. The Arizona State Board of Optometry maintains a list of the prescribing authority (PA or TPA) at the following link: [www.optometry.az.gov/directory.asp](http://www.optometry.az.gov/directory.asp).

Optometrists are not required to possess a DEA number when prescribing non-controlled substance drugs and therefore many do not possess a DEA registration. The absence of a DEA registration number on a non-controlled substance prescription written by an authorized optometrist does not mean that prescriptions written by optometrists are to be disregarded or declared invalid even though it creates some reimbursement issues for the pharmacist. Pharmacists using their professional judgment should dispense valid prescriptions presented to them in order to meet patient's therapeutic requirements. The staff at the Board of Optometry welcomes the opportunity to discuss issues and questions pharmacists may have regarding prescriptions written by Arizona optometrists. Please feel free to contact Margaret Whelan, executive director, at 602/542-8155, any time or visit their Web site, [www.optometry.az.gov](http://www.optometry.az.gov), to verify an optometrist's prescribing authority.

### **Disciplinary Actions**

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

#### **Pharmacists**

**Allen, Casey (S014694)** – \$2,000 civil penalty paid within 90 days and three years probation. No pharmacist-in-charge (PIC) or preceptor while on probation. Effective May 12, 2010.

**Baron, Martin (S003388)** – Revoked. Effective March 22, 2010.

**Cluff, Greg (S010248)** – Probation until further notice. No PIC or preceptor while on probation. Sign new five-year Pharmacists Assisting Pharmacists of Arizona (PAPA) contract and perform 400 hours of community service. Effective May 12, 2010.

**Cutter [Wickenhauser], Lori (S012731)** – Probation terminated. Effective May 12, 2010.

**Davis, Evan (S010537)** – Probation terminated. Effective May 12, 2010.

**Dayton, Thomas (S011256)** – Suspension terminated. Probation imposed. Effective May 12, 2010.

**Denick, Kevin (S008392)** – Consent amended: Remove condition requiring him to work under the supervision of another pharmacist. Effective June 1, 2010.

**Dykstra, Jason (S015524)** – \$500 civil penalty and eight hours additional continuing education (CE) within 90 days. Effective May 12, 2010.

**Goebig, Thomas (S013463)** – Suspension terminated. Probation imposed. Effective May 12, 2010.

**Kaizer, Arleen (S006122)** – Probation terminated. Effective March 17, 2010.

**Kilaru, Jayaram (S009171)** – \$1,000 civil penalty paid within 90 days. Effective May 12, 2010.

**Kisakye, Kisa (S014292)** – \$1,000 civil penalty due within 90 days. Effective March 22, 2010.

**Lucas, Patrick (S015020)** – Revoked. Effective May 19, 2010.

**Malladi, Venkateswara (S012355)** – Probation terminated. Effective May 12, 2010.

**Mekhael, Paul (S017646)** – \$100 civil penalty due within 90 days and 10 hours of additional CE within six months. Effective March 22, 2010.

**Olsen, Maren (S016682)** – \$1,000 civil penalty and eight hours additional CE due within 90 days. Effective May 12, 2010.

**Roberts, Scott (S008515)** – \$1,000 civil penalty, retake Multistate Pharmacy Jurisprudence Examination® and three hours of additional CE, all due within 90 days. Effective May 12, 2010.

**Rothschild, Jacqueline (S013570)** – Five-year probation. No PIC or preceptor while on probation. Effective May 3, 2010.

**Tybor, Brian (S016773)** – Revoked. Effective March 22, 2010.

#### **Technicians**

**Acedo, Teri (T000003)** – License reinstated with five-year probation. Five-year PAPA contract and perform 400 hours of community service. Effective May 12, 2010.

**Rocha, Angel (T016771)** – Six-month suspension, followed by three years probation. Effective March 22, 2010.

#### **Arizona Medical Board (MD)**

**Chirban, Angelo L. (MD 27055)** – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective June 10, 2010.

**Higuera, Jose A. (MD 12358)** – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective May 27, 2010.

**Jackson, Teresa L. (MD 32627)** – Non-disciplinary – *Interim Consent Agreement for Practice Limitation* – Physician's practice is limited in that she shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective May 12, 2010.

**Miller, Ian D. (MD 9249)** – Non-disciplinary – *Interim Consent Agreement for Practice Limitation* – Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective June 8, 2010.

**Scott, Michael E. (MD 14234)** – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective May 18, 2010.

**Sora, Raul Juan Rodriguez (MD 21047)** – Non-disciplinary – *Interim Consent Agreement for Practice Limitation* – Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective June 7, 2010.