

**THE ARIZONA STATE BOARD OF PHARMACY
HELD A REGULAR MEETING MARCH 17 & 18, 2004
GLENDALE, ARIZONA**

The following Board Members and staff were present: President Dennis McAllister, Vice President Linda McCoy, Paul Draugalis, Charles Dutcher, William E. Jones, Daniel Ketcherside, and Bryan Tippett. Compliance Officers Rich Cieslinski, Larry Dick, Ed Hunter, Mitzi Wilson, and Dean Wright, Drug Inspector Tammy McPherson, Deputy Director Cheryl Frush, Executive Director Hal Wand, and Assistant Attorney General Roberto Pulver.

President McAllister convened the meeting at 9:00 A.M. and welcomed the audience to the meeting. Ms. Frush explained that law continuing education would be offered for attendance at the meeting.

AGENDA ITEM I - Introduction of New Board Member and Oath of Office
President McAllister introduced the newly appointed Board Member, Dr. Bryan Tippett. Dr. Tippett was appointed to replace public member, Gene Drake, who resigned due to illness. Dr. Tippett is currently Dean of Instruction at Estrella Mountain Community College in Arizona. Previously he was Senior Associate Dean of Instruction for mathematics, science, and physical education at Mesa Community College. Dr. Tippett earned a bachelor's degree from Gannon University, a master's degree from Duquesne University and a doctorate from the University of Sarasota.

President McAllister administered the Oath of Office to Dr. Tippett to allow Dr. Tippett to assume the duties of a voting member of the Board.

AGENDA ITEM II - Approval of Minutes
Following a review of the minutes and an opportunity for questions and on motion by Mr. Ketcherside and Mr. Dutcher the minutes of the Regular meeting and Executive Session held on January 14, 2004 were unanimously approved by the Board Members.

AGENDA ITEM III - Permits/Licenses
President McAllister noted that all permits were in order for resident pharmacies and stated that representatives were present from Arizona Orthopedic Surgical Hospital and Factor Sales, Inc. to answer questions from Board Members.

Arizona Orthopedic Surgical Hospital

Regional Director Robert Thurnberg, CEO Robert Conaway, and Consultant Pharmacist Cheryl Shafer were present to answer questions from Board Members.

President McAllister stated that the hospital is requesting two waivers. One waiver was for a reduction in the number of hours that pharmacy services would be provided and the other waiver was for the size of the pharmacy.

President McAllister asked Ms. Frush to further explain the waiver requests. Ms. Frush stated that pharmacy services shall be provided for a minimum of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee. (R4-23-653 (B)). Ms. Frush stated that the current minimum area of a hospital pharmacy is not less than 500 square feet (R-23-655 (B)).

She stated that the applicants had designed the hospital pharmacy in 2002. In 2002, the square footage of the pharmacy was calculated using the number of beds with a minimum square footage of 220 square feet. The rules were changed and after January 31, 2003 any new hospital permit issued or remodeled hospital pharmacy shall provide a minimum area of 500 square feet.

President McAllister opened the discussion by asking the representatives to discuss the waiver requests. Mr. Conaway opened the discussion by explaining that Arizona Orthopedic Surgical Hospital will be licensed by the State as a Specialty Hospital. The hospital will specialize in Joint Replacement Surgery. The hospital will begin with 16 inpatient beds and will have a maximum capacity of 24 beds. The hospital is anticipating a low inpatient volume. Most patients will have day surgery and be released.

In addressing the hours, Mr. Conaway anticipates a pharmacist will be needed for approximately twenty hours a week. He stated after the pharmacy is closed, an agreement has been made with Chandler Regional Hospital for backup and on call services.

In addressing the space requirements, Mr. Conaway stated that they have dedicated 415 to 420 square feet to this pharmacy. He stated that the hospital is not a typical hospital. He stated that the hospital would have six operating rooms. The pharmacy would be responsible for providing necessary medications to these six operating rooms.

President McAllister asked Ms. Shafer to explain her role as the consultant pharmacist to the hospital. Ms. Shafer explained that she is the Pharmacist-In-Charge at Chandler Regional Hospital. She stated that a pharmacist would be hired to work twenty hours per week at the surgical hospital. The pharmacist will work Monday through Friday during the morning hours when most of the surgeries are scheduled. If the pharmacist wants to work forty hours per week, the pharmacist can work an additional twenty hours at Chandler Regional

Hospital. Chandler Regional Hospital will provide all on call pharmacy services for the surgical hospital.

President McAllister asked Ms. Shafer if she felt that the request that the hospital is proposing for a waiver would satisfy the needs for safe pharmacy practice. Ms. Shafer replied that she feels it will at this point in time. She stated as the organization increases in volume, they would need to adjust accordingly.

Mr. Wand asked if there would be any emergency room or outpatient dispensing. Mr. Conaway replied that they would not have an emergency room since they are licensed as a specialty hospital and they will not be doing any outpatient dispensing.

Mr. Dutcher asked about the floor plans for the hospital pharmacy. Mr. Dutcher asked if the pharmacy would occupy multiple rooms. Mr. Thurnberg stated that one room would be used as an IV room and the other area would be used for the pharmacy.

Ms. McCoy asked if the pharmacist would be involved in the Operating Room suites in terms of controlled substances and other medications. Ms. Shafer replied that the pharmacist would be involved with the operating rooms.

Ms. McCoy asked if the pharmacists would work morning hours. Ms. Shafer replied that they would be working the morning hours.

Mr. Jones asked if only one pharmacist would be working in the pharmacy and if there would be any technician help for the pharmacist. Ms. Shafer replied at this time they are only anticipating that one pharmacist would be required to handle the workload. They will evaluate the volume before adding a technician.

Mr. Jones asked Ms. Shafer how many hours a day will the pharmacist work. Ms. Shafer replied that the pharmacist will work approximately four hours a day, Monday through Friday.

Mr. Jones asked Ms. Shafer to describe the pharmacist's duties. Ms. Shafer replied that the pharmacist's duties would include the following: ensure that the medications were ordered appropriately, dispensed appropriately, the medications were stocked, monitor the narcotics, and conduct a daily narcotic count.

Mr. Jones asked if the filling would be done using an automated system or medication carts. Ms. Shafer replied that medication carts would be used for inpatients and would be exchanged on a daily basis.

Mr. McAllister questioned if the main services provided by the hospital would be day surgeries with a few inpatients. Mr. Conaway stated initially most services would be outpatient services. As services expand, he stated that they will need to expand both pharmacist and technician hours. Mr. Conaway stated that they do not anticipate any substantial inpatient population during May or June.

Mr. McAllister asked what is the anticipated daily load of surgical cases. Mr. Conaway stated initially upon opening the hospital, they would not be Medicare certified. Mr. Conaway stated that for the first four to six weeks, they anticipate 10 to 12 cases daily. After Medicare certification, he stated that the surgical load would increase on a regular basis. Within six months, they will be up to full-time patient pharmacy perspective. The operating room plan initially is to have an anesthesia lock-box exchanged on a daily basis.

Mr. Dutcher asked Mr. Conaway if he knew at what point in time that the pharmacy space and hours will not be sufficient and what the process will be for expanding the pharmacy. Mr. Conaway replied that the hours will be the only issue and the hours will expand. Mr. Conaway stated that he feels that they have adequate floor space even when they reach the maximum capacity of 24 beds.

Ms. McCoy asked if Chandler Regional Hospital is in close proximity to the Surgical Hospital since they will be providing emergency services. Ms. Shafer replied that they are about three miles away.

Mr. McAllister summarized by asking the representatives if they are asking for a temporary waiver for the hours for providing pharmacy services and a permanent waiver for the pharmacy space requirement. Mr. Conaway replied that is correct.

Mr. Dutcher questioned if there was enough room for expansion. Mr. Wand stated that the square footage is double the square footage of the old minimum size. Mr. Wand stated that the applicant was caught in the middle when the rules changed.

Mr. Jones suggested a temporary waiver for the hours for a one-year period and then re-evaluate the situation in six months. Mr. Conaway stated he felt a temporary waiver of the hours would be fair and would be willing to return for a follow-up at whatever interval the Board determined.

On motion by Mr. Jones and Ms. McCoy, the Board unanimously voted to grant to Arizona Orthopedic Surgical Hospital a temporary waiver of R4-23-653 (B), which requires that pharmacy services shall be provided for a minimum of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee. The hospital will provide a report to the Board in six months concerning the pharmacist's hours and duties. The waiver will be good for one year and at that time the Board will re-evaluate the waiver request.

On motion by Mr. Jones and Mr. Draugalis, the Board voted unanimously to grant to Arizona Orthopedic Surgical Hospital a permanent waiver of R4-23-655 (B), which requires a minimum of 500 square feet for a hospital pharmacy. The waiver is permanent until a compliance officer deems that it is an unsafe practice area.

Factor Sales, Inc.

Administrative Assistant Gloria Cavazos and financial manager Raul Aquillera were present to address questions from the Board Members.

Mr. McAllister asked the representatives to explain their business since Factor Sales, Inc. did not sound like the name of a pharmacy.

Ms. Cavazos explained that Factor Sales, Inc. is an umbrella for a group of twelve grocery stores. She explained that Factor Sales, Inc is involved in mainly grocery sales. She explained that they would like to open a pharmacy in one of their stores.

Mr. McAllister asked if they planned on opening only one pharmacy. Ms. Cavazos replied yes and explained that they are anticipating opening a store in their San Luis grocery store. She explained that they have walk-in clinics in San Luis, but there are no actual pharmacies. Ms. Cavazos stated that the residents need to go to Yuma, which is almost 16 miles from Yuma.

Mr. McAllister asked if they had selected a pharmacist for the store. Ms. Cavazos stated that they had not hired a pharmacist yet. She stated that they had submitted the paper work within the last 2 weeks to be approved at this Board meeting.

Mr. Wand reminded Ms. Cavazos that the floor plan is only 350 square feet, which would allow them to have three people working in the pharmacy at any time. Mr. Wand pointed out that since they are close to the Mexican border, that

they can only sell U.S. FDA-approved medications. Ms. Cavazos stated that she understands the requirements.

At the conclusion of questions from the Board Members and on motion by Mr. Dutcher and Mr. Jones, the Board unanimously approved the resident permits listed below with the address changes to Target Pharmacy T-1863 and Target Pharmacy T-1439. All approvals are subject to final inspection by a Board Compliance officer where appropriate.

RESIDENT (in Arizona)

**Target Pharmacy T-1863 Target Corporation
9615 E. Old Spanish Trail
Tucson, AZ 85748**

**Walgreens #06880 Walgreen Arizona Drug Co.
2431 S. Higley Rd.
Gilbert, AZ 85297**

**El Dorado Hospital Northeast Hospital Corporation
1400 N. Wilmot Rd.
Tucson, AZ 85712 (O)**

**Fry's Food & Drug #81 Smiths Food & Drug Centers, Inc.
24th St/Baseline
Phoenix, AZ**

**Fry's Food & Drug #87 Smiths Food & Drug Centers, Inc.
51st Ave./Baseline
Phoenix, AZ**

**Fry's Food & Drug #90 Smiths Food & Drug Centers, Inc.
10249 E. Rita Rd.
Tucson, AZ 85747**

**Bashas' United Drug #28 Bashas' Inc.
160 Coffee Pot Dr.
Sedona, AZ 86336**

**Eckerd Drugs #5343 Eckerd Corporation
1209 E. Bell Rd.
Phoenix, AZ 85022**

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**Bashas' United Drug #57
1761 E. Highway 69
Prescott, AZ 86301**

Bashas' Inc.

**El Rio Broadway Phcy.
1101 E. Broadway
Tucson, AZ 85719**

El Rio Santa Cruz Neighborhood Health

**Arizona Orthopedic
Surgical Hospital
2905 W. Warner Rd.
Chandler, AZ 85224**

Orthopedic & Surgical Specialty Co.,LLC.

**Wal-Mart #10-5124
5605 W. Northern Ave.
Glendale, AZ 85301**

Wal-Mart Stores, Inc.

**Eckerd Drugs #5324
4365 N. Oracle Rd.
Tucson, AZ 85705**

Eckerd Corporation

**Safeway #2699
13828 W. Waddell
Surprise, AZ 85379**

Safeway, Inc.

**Target #T-1439
3699 E. Broadway Blvd.
Tucson, AZ 85716**

Target Corporation

**Target #T-1429
1230 S. Longmore Ave.
Mesa, AZ 85202**

Target Corporation

**Walgreens #07784
2640 W. Glendale Ave.
Phoenix, AZ 85051**

Walgreens Arizona Drug Co.

**Medicap Pharmacy
1930 Juan Sanchez Blvd.
San Luis, AZ 85349**

San Luis Health, Inc.

**Southern Desert
123 E. Merritt Rd. #200
Prescott, AZ 86301**

LCPS Acquisition, LLC (O)

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Village Southern LCPS Acquisition, LLC (O)
Desert Pharmacy
10800 N. 115th Ave.
Youngtown, AZ 85363

Southern Desert LCPS Acquisition, LLC (O)
Pharmacy-Prescott
123 E. Merritt Rd. #100
Prescott, AZ 86301

Southern Desert Lobos Acquisition of Arizona, Inc. (O)
6250 E. Grant Rd. #387
Tucson, AZ 85712

Southern Desert Care LCPS Acquisition, LLC (O)
Center Pharmacy
1833 W. Main St. #120
Mesa, AZ 85201

Factor Sales, Inc. Factor Sales, Inc.
656 San Luis Plaza Dr.
San Luis, AZ 85349

Change of Ownership - (O)

President McAllister opened the discussion on non-resident permits. Mr. Wand indicated that non-resident applicants are not requested to appear before the Board. Mr. Wand stated that a Board Member had concerns about several non-resident permits.

Mr. Dutcher stated that he was concerned about the applications submitted by Ken Drugs #002, Ken Drugs #003, and Ken Drugs #004. Mr. Dutcher stated that he had a patient, whose spouse was receiving large quantities of narcotic drugs from a Ken Drugs in Florida. It was an Internet pharmacy and they were receiving prescriptions that were written by a doctor connected with the Internet site. He felt that the Board might want to take a closer look at their applications.

Mr. Wand stated in Arizona it would be illegal for an Arizona doctor to prescribe medications using an Internet survey. Arizona statutes require that a practitioner examines the patient or has a medical history with the patient before they prescribe medications. He stated unfortunately Florida does not

have the same regulations. He stated that there have been case laws that state in Florida the doctor does not need to examine the patient or have a prior patient-doctor relationship. Mr. Wand stated that if a Florida doctor wrote a prescription using an Internet survey that prescription would be legal. Mr. Wand offered to send the case to everyone. Mr. Wand stated that the Board would be approving a practice that is not legal in Arizona but is legal in Florida.

Mr. McAllister stated that he feels that we have the same issues with the large mail order facilities because in some states, it is illegal for a physician's assistant to issue prescriptions. Mr. McAllister stated that he feels that we do not have a valid reason to deny the permits in this case.

Mr. Wand stated that as an option the Board could table the applications and ask the applicant to appear at the next Board meeting.

Mr. Dutcher asked what are the applicants requesting when they apply for a non-resident permit. Mr. Wand stated that they are requesting to ship or deliver prescriptions to Arizona residents which is required by R4-23-607 (A)(1) which states that a person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, non-prescription drug, precursor chemical, or regulated chemical into Arizona without: (1) a current Board issued non-resident pharmacy permit.... Mr. Wand stated that the pharmacies are complying with this requirement. Mr. Wand stated that if a complaint were filed, the Board would need to determine if it was legal to fill the prescription without an exam in that state. Mr. McAllister suggested that the Board should watch for complaints or controlled substance violations from these applicants.

At the conclusion of discussion by the Board Members and on motion by Ms. McCoy and Mr. Jones, the Board unanimously approved the non-resident permits listed below.

NON-RESIDENT (out of state)

**Infusion Specialties, Inc.
9601 Katy Freeway, Ste. #480
Houston, TX 77024**

Option Care Enterprises, Inc.

**The Compounding Shop
4000 Park St. N
St. Petersburg, FL 33709**

The Compounding Shop, Inc.

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**Jen-Mar Pharmacy Services
7901 N. Armenia Ave, Ste. D
Tampa FL 33604**

Jen-Mar Pharmacy Services, Inc.

**The Drug Shoppe
4006 N. Armenia Ave.
Tampa, FL 33607**

The Drug Shoppe, Inc.

**MailRx
1410 N. 12th St.
Murray, KY 42071**

Healthcare Plus, PLLC.

**Vitality Home Infusion Svcs.
10 Powerhouse Rd.
Roselyn Heights, NY 11577**

Vitality Home Infusion Services, Inc.

**College Pharmacy
3505 Austin Bluffs Pkwy.
Ste. #101
Colorado Springs, CO 80918**

College Pharmacy, Inc.

**Applied Phcy Sciences LLC
2851 N. Tenya Way #202
Las Vegas, NV 89128**

Applied Pharmacy Services, LLC

**Ken Drugs #004
2942 W. Columbus Ave.
Ste. #109
Tampa FL 33607**

Ken Drugs, Inc.

**Ken Drugs #003
4730 N. Habana Ave.
Ste, #103
Tampa, FL 33614**

Ken Drugs, Inc.

**Ken Drugs #002
2220 E. Irio Bronson Hwy.
#104B
Kissimmee, FL 34744**

Ken Drugs, Inc.

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**Integrated HMO Pharmacy Pharmaceutical Technologies, Inc.
14301 First National Bank Pkwy.
Ste. #200
Omaha, NE 68154**

**Nelson Laboratories National Laboratories Limited Partnership
4001 N. Lewis Ave.
Sioux Falls, SD 57104**

**Todays Meds Pharmacom LLC
3500 N. Miami Ave.
Miami, FL 33127**

**Frontier Pharmacies Frontier Pharmacies, Inc.
12260 SW 53rd St. Ste 601B
Cooper City FL 33330**

**Caremark, Inc. Caremark, Inc.
19102 Northcreek Pkwy., Ste.#110
Bothell, WA 98011**

**Integrity Healthcare Services Integrity Healthcare Services, Inc.
11403 Bluegrass Pkwy, Ste. #400
Louisville, KY 40299**

**Integrity Healthcare Services Integrity Healthcare Services, Inc.
11403 Bluegrass Pkwy, Ste. #400
Louisville, KY 40299**

**Medco Health Solutions Medco Health Solutions of Parsippany, LLC
100 Parsons Pond Dr, A1-3
Franklin Lakes, NJ 07417**

Wholesale Permits

President McAllister indicated that there were two applicants for wholesale permits. Mr. Wand indicated that resident wholesale applicants are asked to appear before the Board. He explained the wholesale orientation sheet to the Board Members. He explained that Ms. Frush sends the sheet to applicants and answers any questions that they may have concerning the wholesale rules. The applicant is required to sign the orientation sheet and return the sheet to the Board Office prior to the meeting. Mr. Wand stated that the new NABP model

rules for wholesalers address issues such as counterfeit drugs. Mr. Wand stated that historically the Board has requested that wholesalers appear before the Board because the applicants are not usually pharmacists. By appearing before the Board, it allows the Board Members and the applicant to discuss their business.

Oasis Dairy Equipment and Supply

Oasis Dairy was represented by manager, James Lopez. President McAllister noted that Mr. Lopez had signed the orientation form and asked Mr. Lopez to describe their wholesale business.

Mr. Lopez stated that they would wholesale animal health pharmaceuticals. The business was purchased from Lextron and all employees did work for Lextron and are adhering to the policies and procedures established by Lextron.

Mr. Wand stated that the previous company had veterinarians on staff and asked if the current company will have veterinarians on staff. Mr. Lopez replied that they will not have veterinarians on staff. Mr. Wand asked Mr. Lopez if he had any questions for the Board. Mr. Lopez replied that he did not have any questions because they are familiar with the rules.

Mr. Dutcher asked Mr. Lopez about their customer base. Mr. Lopez replied that they sell to dairy owners and veterinarians. Mr. Lopez stated that non-prescription drugs would be sold to feed stores. Mr. Wand reminded Mr. Lopez to be sure that they have a copy of the non-prescription retailer's license on file when they sell to feed stores. He told Mr. Lopez that if they do not have a non-prescription retail permit to refer the individuals to the Board office, so that they may obtain a permit.

Meds Direct, Inc.

Meds Direct was represented by President Noah Salcedo and Operations Manager, Louis Arango.

President McAllister asked Mr. Salcedo to describe their wholesale business. Mr. Salcedo stated that they would be wholesaling pharmaceuticals to the physician market.

Mr. McAllister asked if they have any wholesale experience. Mr. Salcedo stated that he has eight years of experience. He is currently employed by a company in California that is a manufacturer/repacker. Mr. Wand reminded Mr. Salcedo that the wholesale license would not allow him to repackage medications. Mr.

hospital directors. There will be two meetings held in the afternoon for anyone who is not a district manager or hospital director. Mr. Wand passed out a copy of the application to Board Members. The application asks pertinent questions to see if the applicant has any convictions in other states. Mr. Wand explained the fee charts for the Board Members. If a technician applies in May, the technician will pay \$12.50 for their license that will expire on October 31, 2004. The pharmacy technician trainee will pay a one-time fee of \$25.00 that will be good for two years. All licensees will pay a \$10.00 wall certificate fee.

Beginning in October, the technicians will renew their licenses on the odd-even schedule. Renewals will be sent in the mail. If a technician does not change their address with the Board, their renewal may be returned to the Board Office. Mr. Wand stated that the Board is not required to notify licensees but as a courtesy all licensees are sent renewal letters. Renewal letters will be sent out in September.

Mr. Wand indicated that he and Ms. Frush would be formalizing the job descriptions in the office.

Mr. Wand indicated the follow-up financial audit was a success. He stated that all concerns from the initial audit were addressed and corrective actions were taken. During the follow-up audit, the auditors found a few new concerns. The new concerns have already been addressed and should not be a problem on the next audit. President McAllister commended Mr. Wand for correcting the financial issues on the audit in a six month time period, since these problems had existed for years.

Mr. Wand indicated that on February 25, 2004 he sent a letter to Attorney General Terry Goddard concerning the shipping of Accutane to Arizona residents from Canadian pharmacies. The concern is that the FDA requires strict record keeping for these restricted drugs. To this date, Mr. Wand has not received a reply from Mr. Goddard.

Deputy Director Report

Deputy Director Frush called the Board's attention to the Compliance Officers Activity Report in the meeting book for January and February. Currently, the Compliance Staff is ahead of the number of inspections that were completed at this time last year.

Ms. Frush took the opportunity to introduce the new Drug Inspector, Tammy McPherson. Ms. McPherson started on February 16, 2004 and trained in Tucson

with Mr. Hunter. Ms. McPherson will be responsible for inspecting non-prescription outlets and wholesalers.

Ms. Frush directed the Board's attention to the complaint review in the meeting book. At the January meeting, the Board Members asked Ms. Frush if a summary of the complaints for 2003 could be prepared for their review. Ms. Frush stated that she prepared a summary of the complaints for the Board Members to review. The complaints were classified by pharmacy, the type of error, and the action taken by the Board. The complaints were also classified by the type of error and the number of occurrences. Ms. Frush pointed out to the Board Members that the most common error was that the wrong drug was dispensed. The next common error was the wrong strength of medication was dispensed. The next largest complaint that the Board received was drug shortages. Ms. Frush pointed out that in most cases of drug shortage, the Board chose to take No Further Action since the evidence was usually inconclusive. Ms. Frush also stated that she classified the complaints by the action taken. She stated that the Board had taken No Further Action in 45 cases, held 34 conferences, had issued 10 consents, had sent 36 warning letters, and had 3 cases withdrawn. President McAllister told Ms. Frush that this is excellent data. Mr. McAllister stated that this a case based study and does give the Board a basis for the types of complaints that are received and the resolutions.

APA Report

**The APA was represented by Kathy Boyle. She presented the Board Members with a list of bills that the APA Legislative committee is tracking. Ms. Boyle stated that they are tracking the following bills:
SB1007 - Board of Pharmacy Continuation -Passed**

HB2196 - Pharmacist Technician Licensure - Requires a Pharmacy Technician to maintain their Board approved certification to maintain licensure in the state. The bill passed the House and will be heard in the Senate on March 18, 2004,

HB2001 - Canadian Prescription Drugs - Died in Senate

HB2555 - Prescription drug pricing - Bill never received a hearing due to opposition

Ms. Boyle stated that the dental hygienists withdrew their request to independently prescribe Fluoride and therapeutic mouthwashes to patients.

Ms. Boyle stated that the naturopaths would need to complete their training by the end of the year in order to continue prescribing medications. It has not been decided how the pharmacies will be notified of the naturopathic doctor's prescribing authority.

Ms. Boyle stated that the APA would be hosting a Diabetes CE program worth 24 CE units. It is in collaboration with the University of Arizona and Midwestern University.

Ms. Boyle stated the convention would be held on June 24-27, 2004 at the Westin-Kierland Convention Center in Scottsdale. The theme this year is "Are You Prepared". Friday will be devoted to the Bioterrorism Emergency Preparedness tract. Police Officer, Jason Schechterle, will be the keynote speaker on Saturday morning. On Thursday, the Board of Pharmacy will hold their meeting. Also, an immunization training program worth 16-½ credits will be held on Thursday.

AGENDA ITEM V - Proposed Rules

Immunization Rules

Compliance Officer/Rules Writer Dean Wright began by reviewing the Immunization Rules. In response to a request by Assistant Attorney General Roberto Pulver, Mr. Wright contacted the South Dakota Board of Pharmacy regarding their experiences with pharmacist administered immunizations. Mr. Wright stated that the South Dakota Board has certified 35 pharmacists to administer immunizations. The certification course consists of 16 hours of didactic online education and 4 hours of hands-on training in inoculation technique. The program also requires a current CPR certificate. When asked about adverse events, Mr. Wright stated that he was told that the pharmacists have administered 10,000 immunizations without a single adverse event. Mr. Wright was told that South Dakota statutes allow a certified pharmacist to administer all adult immunizations and allows the administration of epinephrine in emergencies. These immunizations are not based on a prescription, but rather are based on the pharmacist's scope of practice as defined in statute.

Mr. Wand mentioned that Mr. Wright stated that the South Dakota pharmacists had statutory authority. Mr. Wand stated that in Arizona the pharmacists do have statutory authority to administer immunizations, but our statute is different and requires the pharmacist to have a prescription to administer the immunization. Mr. Wright stated that the pharmacists in South Dakota do need to notify the patient's physician that an immunization was administered.

Mr. Wright then addressed the changes to the rules. He stated that he has added smallpox and meningococcal vaccine to the list of immunizations that can be administered by a pharmacist.

He added language that will allow a pharmacist to administer epinephrine in case of an emergency. Mr. Wright stated that he changed the definition to read Pharmacist Administered Immunization Training Program.

Mr. Wand stated that for the audience's benefit he wanted to let them know that we do have authority to give immunizations by prescription and the use of epinephrine by prescription. Mr. Wand stated that in order to give immunizations without a prescription we would need to go through the sunrise process, which would result in a statutory change to the scope of practice. Mr. Wand stated that the Board's strategy was to start the process now and then at a later time follow-up with the sunrise review to change the scope of practice. Mr. Wand stated that Mr. Wright stated in South Dakota they had difficulty getting the doctors to meet with the pharmacists to set up the certification requirements. Mr. Wand stated that starting in August the Board would be able to begin working on the process that will change the scope of practice to allow immunizations without a prescription. This process could take up to 24 months to complete.

Mr. Draugalis asked if it is a requirement that the patient obtain a prescription for both the flu vaccine and epinephrine. Mr. Wand stated that the pharmacist could call the physician for a prescription for the epinephrine. Mr. Wand stated that the pharmacist could have one prescription with both drugs or could have two separate prescriptions. Mr. Draugalis stated that it might become an issue when the pharmacist tells the patient that they may need an epinephrine prescription in case of an emergency. Mr. Wand stated unfortunately at this point a prescription is required for the epinephrine. Mr. Wand stated that from a liability standpoint he feels that the pharmacist would want to have a prescription for epinephrine. Mr. Draugalis stated that he still feels that it will be a difficult sale to the public.

Mr. Wand asked the Board Members to advise him and Mr. Wright if they would like to pursue the immunization rules since we do have the authority to give immunizations pursuant to a prescription or wait and make a statutory change.

Mr. Jones asked if a pharmacy wanted to provide a flu clinic at their pharmacy, how could a pharmacy offer a clinic without each individual presenting prescriptions. Mr. Wright stated a prescriber would need to be on site to issue prescriptions. Mr. Jones felt that if you did not have an epinephrine prescription

and were trying to call for the prescription at that time it would be too late.

Mr. Dutcher stated that he does not see much success for pharmacists getting involved in the program, as it is now set-up. Mr. Dutcher stated that if we go through this process, it will make it easier in the future to go through the sunrise process with other medical practitioners. He stated that the other practitioners would realize that we have statutory authority and we can share our experiences with the process. Mr. Dutcher stated that he feels it would help us transition from what we have now which is nothing to a full immunization program. He feels this program will be a benefit in the transition process.

The Board gave Mr. Wright approval to proceed with the rulemaking.

Security/Correctional/Mail Order

Mr. Wright informed the Board that the staff has identified changes for Sections R4-23-610, 672, and 673. The proposed rules will replace the term "certified pharmacy technician" with the term "pharmacy technician trainee" where appropriate. Changes have been made in R4-23-610 concerning the policies and procedures.

The Board gave Mr. Wright approval to proceed with rulemaking.

Pharmacist/Intern Licensure

Mr. Wright explained that the definition for "AZPLEX" would be removed from R4-23-110 because it is no longer used. Mr. Wright stated the definition for "MPJE" would be amended to clarify its use. Mr. Wright indicated that AZPLEX would be replaced with the term MPJE. Mr. Wright stated that the definition for "delinquent license" would be amended to include the terms pharmacy intern, graduate intern, and pharmacy technician.

The Board gave Mr. Wright the approval to proceed with the rulemaking.

Substantive Policy Statement - Prescription Faxing Policy Statement

Mr. Wright explained that last year Senate Bill 1301 made changes to the definition of "prescription order" in A.R.S. §32-1901. Mr. Wright stated that he revised SPO2, the Board's prescription faxing policy statement to reflect the changes. On motion by Mr. Jones and Mr. Ketcherside, the Board unanimously agreed to approve SP02, the Board's Prescription Faxing Statement.

Mr. Wand asked Mr. Wright if he had a hearing on March 22, 2004 and if he would make an announcement. Mr. Wright stated there will be a public hearing held on March 22, 2004 for the Compounding and Sterile Product rules. The sections include R4-23-410 and R4-23-670.

A brief recess was called and President McAllister reconvened the meeting.

AGENDA ITEM VI - Special Requests

#1 Carol Petersen

Carol Petersen appeared on her own behalf to request permission to pursue licensure by reciprocity from her active Wisconsin license. Wallace Simons was also present to help clarify issues resulting in the reprimand of Ms. Petersen.

President McAllister opened the discussion by asking Ms. Petersen what was the nature of her request. Ms. Petersen replied that her request was to obtain a license to practice pharmacy in the state of Arizona. Mr. McAllister asked Ms. Petersen if she had applied for reciprocity and she replied she had. Mr. McAllister asked why she was appearing before the Board. Ms. Petersen replied that she was notified by the Board to appear.

Mr. McAllister asked if there had been any disciplinary action taken against her Wisconsin license. Ms. Petersen replied yes. Mr. McAllister asked her to describe the disciplinary action. Ms. Petersen stated that it is difficult to explain. Ms. Petersen indicated that the issues stem from the FDA regulation of compounding. Ms. Petersen stated that they have been in litigation in Wisconsin since 1993 and the case is now in the appellate court.

Mr. Wand stated that according to the Board Order Ms. Peterson was ordered to make phone calls to patients and instead decided to send postcards to the patients. Mr. Wand stated the Wisconsin Board saw this as a violation of the order. Ms. Petersen stated that the prosecuting attorney presented this as a flagrant affront to the Board's authority. The pharmacy's policy was to make a phone call to every patient that they mailed a prescription. The pharmacy also served as a central fill pharmacy in some cases and before the signing the stipulation agreement the pharmacy did not make calls to the patients when the prescription was sent to another pharmacy. When the stipulation was signed, Ms. Petersen stated that they did not think it was an issue. The calls were made and if they were unable to reach the patient a postcard was sent. Ms. Petersen stated being naive on her part, she decided sending a postcard would be fine and would eliminate any confusion for the patient. Ms. Petersen stated

that the Board considered this an affront because the stipulation specified that a phone call was to be made to the patient.

Mr. Simons stated that this is an ongoing case. He stated that the Board or Prosecutor made this into a total erroneous situation by posting and publishing this into record, so legally Ms. Petersen has never been reprimanded. Mr. Simons stated that the announcement and the presentation in the pharmacy journals must be illegal because they did not sign an agreement, they did not agree to a fine, and they did not sign a stipulation that stated that they agreed to the settlement. Mr. Simons concluded because they did not sign an agreement, in reality Ms. Petersen has never received a reprimand and the case is still being decided in the courts.

Mr. Wand asked Ms. Petersen and Mr. Simons what was the original reprimand for against Ms. Petersen. Mr. Simons replied the original reprimand was because Ms. Petersen chose to switch from making phone calls to sending postcards.

Mr. Wand asked Ms. Petersen about the original agreement. Ms. Petersen stated that the issues were with the Wisconsin Board and the compliance guidelines for compounding issued by the FDA. Ms. Petersen stated that subsequently the FDA guidelines were withdrawn and replaced by the Modernization Act and then the Federal Court discounted the Modernization Act. She stated that Wisconsin is still actively pursuing the compounding standards against them and their pharmacy.

Mr. Wand summarized by stating that Ms. Petersen signed an agreement because compounding was considered to be manufacturing by Wisconsin. The FDA has repealed the rules that Wisconsin was following at the time. There was an agreement and that was published and that was legal. Mr. Simons stated that they were never proven to be a manufacturer. Mr. Wand asked if they signed a statement stating that they agree with or deny the following conditions. Mr. Simons said by the time the case was done, that issue was stricken. Mr. Simons stated that they signed the agreement to end the long battle and it had nothing to do with the original case. Mr. Simons stated that the attorney added additional charges hoping one would stick. Mr. Wand stated that there was a stipulated agreement that Ms. Petersen signed and that is what is recorded by the NABP clearing house and that is why Ms. Petersen is here today because she did have disciplinary action taken against her license.

Mr. Wand asked if the telephone versus postcard issue was erroneously published. Mr. Simons replied yes. Mr. Simons stated that the first case had

nothing to do with Ms. Petersen.

Mr. McAllister noted that an order exists that is signed by the Chairman of the Wisconsin Board for a reprimand. Mr. Simons stated that they never signed the document. Assistant Attorney General Mr. Pulver stated that several issues were stricken from the order. Mr. Pulver told Mr. Simons and Ms. Petersen when the Board gives an order of reprimand that their signatures are not required because they are a licensing board.

Mr. McAllister stated that Arizona has new compounding rules going into effect and the Board is seriously looking at compounding procedures and business practices that may endanger the public. Ms. Petersen stated that no patient injury had occurred by sending out the postcards. She stated that their pharmacy ensures that information is available to the public. Ms. Petersen stated that the pharmacy's work record speaks for itself. Mr. McAllister stated that the Board is focusing on compounders because this is one place where the public is defenseless because the patient cannot identify the medication. Mr. McAllister stated the Board would also be looking at pharmacies that are skirting the issues of manufacturing versus compounding by changing the dosage slightly.

Mr. Jones asked for a point of clarification of why Ms. Petersen appeared before the Board. Mr. Wand replied that Ms. Petersen was reprimanded because she sent postcards to patients instead of making phone calls as stated in the agreement. Mr. Pulver stated that Ms. Petersen was not willing as a licensee to follow the Board's order.

Ms. Petersen stated that she did not realize that it was going to be a problem when she chose to send the postcards. Ms. Petersen stated that by sending the postcards she thought it was in the spirit of the law. Mr. Pulver told Ms. Petersen as an attorney he would recommend following the letter of the law and not the spirit of the law. Mr. Wand told Ms. Petersen and Mr. Simons that if they ever have any questions to please call the Board Office. Ms. Petersen stated that they were not able to talk to the Wisconsin Board. Mr. Wand stated that it is difficult to deal with consolidated boards. Mr. Wand stated that this is an issue in Arizona because there are always discussions of consolidating boards to save money. Mr. Wand stated that he has written numerous letters to the Governor opposing the consolidation of boards. Mr. Wand told the audience that if Board consolidation becomes an issue he hopes that they will attend a hearing because it will decrease services to them as pharmacists and increase costs instead of decreasing costs as anticipated.

On motion by Mr. Draugalis and Mr. Ketcherside, the Board unanimously agreed to allow Ms. Petersen to proceed with reciprocity.

#2 Women's International Pharmacy - Request Withdrawn

#3 Tewabech Rensing-Minelek

Tewabech Rensing-Minelek appeared with legal counsel Roger Morris to request a waiver of A.R.S. §32-1922 (D) and (E) involving the preliminary equivalency exam.

President McAllister asked Ms. Rensing about the nature of her request. Mr. Morris stated that Ms. Rensing grew up in Ethiopia and attended pharmacy school in Germany. She graduated from Martin Luther University in Germany. She received a temporary pharmacist license because she did not qualify for a permanent license due to citizenship requirements. Ms. Rensing was married and moved to the United States. She is currently residing in Arizona with her husband. Ms. Rensing is requesting to take an exam that is equivalent to the FPGE. Ms. Rensing is unable to qualify to take the FPGE exam. NABP requires that an applicant provide proof of licensure to practice pharmacy and/or a certificate of full registration in the country or jurisdiction where the candidate earned a pharmacy degree. Each license must be unrestricted and certified by the appropriate government official of the jurisdiction issuing the license. Mr. Morris stated that Arizona Statute 32-1922 (D) states that if an applicant for licensure is a graduate of a pharmacy degree program at a school or college of pharmacy that was not recognized by the board at the time of the person's graduation, the applicant shall pass a preliminary equivalency examination approved by the board in order to qualify to take the examinations prescribed in subsection A of this section. Mr. Morris stated that Arizona Statute 32-1922 (E) states that the preliminary equivalency examination required pursuant to subsection D of this section shall cover proficiency in English and academic areas the board deems essential to a satisfactory pharmacy curriculum. Mr. Morris stated Ms. Rensing is requesting to take an alternative exam to the FPGE examination. Mr. Morris said Ms. Rensing is willing to pay the cost of taking an alternative exam.

President McAllister stated that the FPGE is supported by most Boards of Pharmacy due to the complex nature of foreign pharmacy education and licensing issues. These issues are difficult to track, difficult to audit, and difficult to show authenticity of records. NABP has assumed this role. The Board supports this program because we do not have the resources or the knowledge to do this type of documentation. President McAllister stated that he

has talked to NABP about this issue and was told that they receive many fraudulent applications. He was told that a country that issues a permanent license would do a broader background check on the applicants. Mr. McAllister stated that Ms. Rensing finds herself in a unique situation due to the citizenship requirements to obtain a German license. The question before the Board is the authenticity of her records, her educational program, and her experiential training. Mr. McAllister stated that North Carolina recently approved a similar request and they received numerous requests which complicated the work of the office staff.

Mr. Jones asked Mr. Pulver if we could offer an alternative exam. Mr. Pulver said Mr. Morris is correct and that the Board could approve an alternative exam. Mr. Pulver stated that the question is can the Board find an exam that will give the same results since the FPGE is a psychometrically sound exam.

Mr. Jones asked if Mr. Morris had any suggestions for an alternative test. Mr. Morris stated that an English professor at the college could test Ms. Rensing on English proficiency. Mr. Morris stated that they could contract with one of the professors at the one of the pharmacy schools to test Ms. Rensing on the basics of pharmacy practice. Mr. Morris stated that Ms. Rensing is willing to pay the costs.

Mr. Jones asked Ms. Rensing if she was willing to pay the costs that the Board may incur. Ms. Rensing stated that she is willing to pay any costs associated with the examination.

Mr. Ketcherside asked Mr. Pulver what kind of precedent would we be setting if we allow Ms. Rensing to take an alternative exam. Mr. Pulver stated that if you allow this individual to take the exam it does not mean that you have to do this for other individuals, but it will give rise to others making similar requests. Mr. Pulver stated that there is nothing in our rules that prohibit a person from writing to the Board for a similar request. Mr. Pulver stated that the Board could state that this is a unique occurrence and the Board will not consider any other requests, but this will not prevent others from making the same request.

Mr. Morris stated that Ms. Rensing is an Arizona resident and has worked as a technician in Arizona pharmacies the last four years.

Mr. Ketcherside expressed concerns that we should make strong stipulations about the uniqueness of this situation and the costs involved with the testing. The Board does not have the resources to research cases on an individual basis.

Mr. Pulver stated that there is another possibility. Mr. Pulver stated that the candidate could possibly get another degree in the United States, such as an advanced pharmacy degree. Ms. Rensing replied that it is unfair processing by the NABP. She stated that the NABP is not looking at the uniqueness of the case. She stated that she should not be required to go back to school to study the same thing that she has studied before and she has spent more than five years in school. She stated the only thing preventing her from taking the exam is her citizenship requirements. Mr. McAllister stated that is only an option Mr. Pulver suggested.

Mr. Wand stated that NABP did not make any decision different in this case than they have done in any other case. It is a requirement that a license is obtained in the same state or jurisdiction from which a candidate graduates when the candidate graduates from a non-approved college of pharmacy. NABP did not handle this case any differently.

Mr. McAllister asked Ms. Rensing to describe her pharmacy curriculum, in terms of years, at Martin Luther University. Ms. Rensing replied it was five years. Mr. McAllister asked if she did an internship. She replied that she did an internship. Mr. McAllister asked how long was the internship. She said she did a one-year internship in a retail setting and worked in research until her degree was completed. Mr. McAllister stated that there is no equivalent exam that we could produce since programs here are PharmD programs. Mr. McAllister stated that Texas Tech has a final exam to test graduates prior to taking their boards. The issue is the program is a PharmD program. Mr. McAllister agreed with Mr. Ketcherside that if we make an exception, we will not be able to handle the additional workload with the number of foreign pharmacists that may want to move to Arizona.

Mr. Wand stated that part of the FPGE is a written and oral English exam. Mr. Wand stated that if the Board approves an alternative exam that it should closely match the FPGE exam.

Ms. McCoy asked Ms. Rensing if she obtained a temporary pharmacy license in Germany and did she practice in Germany. Ms. Rensing replied that she did not practice in Germany.

Mr. Draugalis asked if it was a temporary pharmacist license. Ms. Rensing replied it was a pharmacist license.

Ms. McCoy asked if the temporary license could be renewed indefinitely. Ms. Rensing replied if she stayed in Germany.

Mr. Jones stated it is understandable why NABP would take a strong stand on the issues. Mr. Jones said the real problem is how do we ensure we have an equivalent exam. Mr. Jones said we should have an equivalent exam and be sure that the exam does not just consist of someone speaking into a tape recorder.

Mr. Wand stated that he agreed with Mr. Jones that the final filter is still the NAPLEX exam. Mr. Wand stated that one other purpose of the FPGE is to screen candidates that may not pass the NAPLEX exam.

Ms. McCoy asked if other graduates of this university were approved by NABP. Mr. Morris stated that other graduates have been approved from this school and the main issue is her citizenship that prohibits her from obtaining a permanent license.

Mr. Wand asked Mr. McAllister if he knew when the Bachelors program will end. Mr. McAllister stated within the next 2 years all U.S. schools would only offer the PharmD program. He stated that we might also face an issue with Canadian pharmacists moving to the U.S. because they will be graduating from a five- year bachelor degree program.

Mr. McAllister stated that the Minnesota Board is offering a Comprehensive Intern Exam. Mr. McAllister suggested that Mr. Morris and Ms. Rensing do some research before the next Board meeting and make a proposal at the next board meeting.

Mr. McAllister stated that this is our intention only for this individual. Mr. Morris asked the request be tabled to the next meeting and they will return with a proposal.

AGENDA ITEM VII - Complaint Review

The Consumer Complaint Review committee met prior to the Board Meeting to review 14 complaints in preparation for making recommendations to the Board for final resolution. Members McCoy and Ketcherside served as the review committee. Ms. McCoy provided a summary of each complaint and provided the committee's recommendations to the Board. Board members were encouraged to ask questions. The following summary represents the final decision of the Board in each complaint:

**State of Arizona
Board of Pharmacy**

**Board Meeting
March 17-18, 2004**

- Complaint # 2742 - No Further Action**
- Complaint # 2743 - Conference**
- Complaint # 2744 - Letter - Stress Counseling**
- Complaint # 2746 - Conference**
- Complaint # 2747 - No Further Action - Commendation Letter to RPh**
- Complaint # 2748 - Letter to Pharmacist and Supervisor**
- Complaint # 2749 - Conference**
- Complaint # 2750 - No Further Action**
- Complaint # 2751 - Letter**
- Complaint # 2752 - No Further Action**
- Complaint # 2753 - Letter**
- Complaint # 2754 - Letter**
- Complaint # 2755 - Conference**
- Complaint # 2760 - Add additional fine to consent**

The Board decided that Mr. Dutcher and Mr. Tippett would serve as the complaint review committee for this year.

The meeting was recessed for lunch at 12:15. P.M.

President McAllister reconvened the meeting at 1:15 P.M. President McAllister presented Mr. Jones with a gift from the Board for his service to the Board for the last 5 years. Mr. Jones stated that it was pleasure to serve as a Board Member. Mr. Jones stated that he would continue to support the Board in the future.

AGENDA ITEM VIII - Conferences

COMPLAINT #2716

Pharmacist Phillip Milatovich , Supervisor John Kasper, and Regional Pharmacy Supervisor Jason Reiser were present relevant to a consumer complaint. Compliance Officer Larry Dick was requested to describe the findings of his investigation. President McAllister asked Mr. Milatovich to describe the events leading to this discussion. Mr. Milatovich replied that he does not remember the circumstances. He stated that a wrong drug was given to an infant. He stated that it was an error on his part. He stated that he does not remember talking to the mother. He stated the important thing to remember is that a mistake was made. He did recall that the Clotrimazole note was in his handwriting and was given to the patient. He stated that he apologized to the mother. He stated that he had developed a plan of action. He talked to all his pharmacists and technicians to put all OTC medications in the computer to have a hard copy available.

He instituted a plan that they will ensure that they have open communication between the pharmacist, the doctor, and the patient. He stated that it is the responsibility of the pharmacist to dispense the right medication. He stated that it was not his intention to hurt anybody.

Mr. McAllister asked Mr. Dick if the doctor called in Clotrimazole 1% solution. Mr. Dick stated that the office manager indicated that the Nystatin Oral Suspension was called in on 9/4/2004 and was to be used for Thrush. The office manager stated that they phoned in a prescription on 9/25/2004 for Clotrimazole 1% solution to be used topically. Mr. Dick stated that they did not have a record at the doctor's office of who phoned the prescription to the pharmacy. Mr. Reiser stated that the doctor's notes are confusing and he does not believe that Mr. Milatovich gave Clotrimazole instead of Nystatin Suspension.

President McAllister asked Mr. Milatovich about the changes. Mr. Milatovich stated that they should have called the doctor to clarify the medication. He stated that obviously there is no hard copy for this prescription. He now enters OTC products as prescriptions when phoned by the physician and this will alleviate any problems if someone questions what was phoned to the pharmacy. Mr. Milatovich stated that it is very important to talk to the patient and the physician. He stated that no matter how busy the pharmacy is it is necessary to clarify the prescription so that the patient gets the correct medication.

Mr. McAllister asked Mr. Milatovich about talking to the patient. He told Mr. Milatovich if he talked to the patient and asked what why the medication was being used, he might not have made this mistake. Mr. McAllister reminded Mr. Milatovich that it is important to talk to the patient. He stated that he does not remember discussing the medication with the patient. Mr. McAllister stated that the mother might have misunderstood that the medication was supposed to be used for the skin folds. He told Mr. Milatovich that he has a higher responsibility to talk to patients about their OTC medications. Mr. Milatovich stated that he knows a mistake was made and improper communication took place between the pharmacist and the patient. Mr. McAllister told Mr. Milatovich that another individual signed a consent form for giving a patient an OTC product instead of the prescribed prescription medication, and he also did not listen to the patient.

Mr. Draugalis stated that he agreed with Mr. McAllister in that the pharmacist must talk to the patient. Mr. Draugalis stated that it would have been more important in this case to listen to the patient. Mr. Draugalis stated when the patient told you that this is wrong, an alarm should have went off. Mr. Draugalis stated that he did not listen to the patient and he should add listening to his list of corrective actions. Mr. Milatovich agreed with that statement.

Mr. Jones asked Mr. Milatovich about the change to keep hard copies of all OTC prescriptions.

Mr. Jones asked Mr. Milatovich if the prescription for the Clotrimazole was phoned to the pharmacy. Mr. Milatovich replied that there was no hard copy. Mr. Milatovich stated that it was phoned in and was not entered into the computer.

Mr. Jones asked if the doctor phoned in Clotrimazole. Mr. Milatovich replied that the doctor's office did phone in Clotrimazole. Mr. Jones asked how it was misinterpreted where the medication was to be applied. Mr. Milatovich stated that it was his handwriting and not knowing that it was for internal use he gave her the product. Mr. Jones stated that he wrote on the note to use on each side of the mouth and if he knew the product was for external use why did he give it to the patient. Mr. Milatovich stated that it was an error and he missed it. Mr. Jones replied that this is a pretty big miss. Mr. Jones replied that the pharmacist's job is to protect the patient. Mr. Jones stated that he could not imagine how someone could take an antifungal medicine used for the feet and write out instructions to use in the mouth. Mr. Milatovich stated that it was a mistake. He stated that he does not recall talking to the patient and he dispensed the wrong medication.

Mr. Dutcher asked Mr. Milatovich how he could make such a blunder in modality.

Mr. Milatovich stated he wrote it down and it was the wrong modality. Mr. Milatovich stated that if there are any questions in their minds they are to stop what they are doing and call the physician. Mr. Dutcher asked Mr. Milatovich if there were no red flags. Mr. Milatovich replied No.

Ms. McCoy wanted to know if Mr. Milatovich spoke with the patient or did someone else speak with the patient. Mr. Milatovich replied he did not know. Mr. Dick stated that the patient came to the store and identified Mr. Milatovich as the person she spoke with at the pharmacy. Mr. Dick stated that Mr. Milatovich identified the note as being written by him. Mr. Milatovich stated that the patient did talk to one of his technicians. Mr. Milatovich stated that he apologized to the patient.

Ms. McCoy stated that she is concerned that when the mother asked him about using the external solution in the baby's mouth that he ignored the big red flag. Mr. Milatovich stated that he does not recall the mother asking anything about the child's feet.

Mr. McAllister asked Mr. Milatovich if he had enough help. Mr. Milatovich replied that he was the only pharmacist and had probably 2 technicians. Mr. McAllister asked him again if he had enough help. Mr. Milatovich replied does a pharmacist ever have enough help. Mr. Milatovich stated that you can run into third party problems, you can run into a lot of problems with mandatory counseling, and all these other things put on pharmacists. Mr. Milatovich stated that he did have technician help.

Mr. McAllister reminded Mr. Milatovich that counseling is required and is not a problem. If he had counseled his patient he would not be here today. He told Mr. Milatovich that he needs to recalibrate the way that he talks to his patients.

Mr. Jones asked if he could make a motion to recommend continuing education. Mr. Wand stated that Mr. Jones could make the recommendation voluntarily or could make a motion to go to a hearing that would require him to do CE. Mr. Jones stated that students coming out of pharmacy school know that Clotrimazole solution is not used orally. Mr. Jones stated that he feels that CE units are appropriate and to prove to the Board that Mr. Milatovich is competent in pediatric dosing and counseling patients. Mr. Milatovich stated that he is not against doing the CE units. Mr. Wand stated that the consent orders require 8 ACPE -approved units in error prevention or patient counseling. Mr. Jones stated that Mr. Milatovich should submit 8 hours voluntarily to the Board in either of those areas. Mr. Milatovich stated that he would do the 8 hours.

Mr. Ketcherside asked if he would need to submit the documentation to the Board. Mr. McAllister stated that he would be smart to submit the documentation, since he is not under a Board order. Mr. Reiser assured the Board that Mr. Milatovich will submit the documentation. Ms. McCoy told Mr. Milatovich not to just do the CE but to incorporate it into his practice.

COMPLAINT #2726

President McAllister called Pharmacist Warren Herzog and Supervisor Visockis forward to address the Board about the Consumer Complaint. Compliance Officer Ed Hunter was present to report the findings of his investigation. President McAllister asked Mr. Herzog to discuss the events leading up to this complaint. Mr. Herzog replied that patient received Toprol XL 200 mg instead of Tegretol XR 200mg. Mr. Herzog stated that the technician filled the prescription and when he checked the prescription he did not catch the error. He said that he was sorry for the error and apologized to the patient. He stated that the Toprol and Tegretol bottles look alike and both medications were the same strength. Mr. Herzog stated that they have now instituted a double check process. Every prescription that leaves the pharmacy will be taken out of the bag, the directions will be reviewed, the use of the prescription, and ask the patient if they have any questions. If it is a caregiver picking up the prescription, they will be told that the patient can call the pharmacy or come back to speak with the pharmacist at anytime.

Mr. McAllister asked if the technician leaves the stock bottle with the filled prescription. Mr. Herzog stated that the bottle is left for the pharmacist to check the prescription.

Mr. Dutcher asked Mr. Herzog if the patient was counseled because the patient stated that she was not counseled. Mr. Herzog said that patients receiving refills were not counseled. Mr. Herzog stated that he counsels all patients on new prescriptions. Mr. Herzog states that now they are counseling on refills.

Ms. McCoy asked if the stock bottles are stored in close proximity to each other. Mr. Herzog stated that they were not. Ms. McCoy asked if alert stickers were put on the bottles and would recommend that they be marked in some way. Mr. Herzog stated that they might try to make the print larger on the bottle.

Mr. Visockis addressed the Board. He stated that they are making other changes. He stated that one of the issues that they are facing at this pharmacy is the aging population. He said that sometimes they need to assess the mental capability of the patients. He stated in this case they did not assess the mental

capability because the patient had taken the medication previously and still took the incorrect medication. He stated that Mr. Herzog spends more time with people being sure that they understand what he explained to them about their medications. He stated that they have also made a proposal for bar-coding that should help eliminate errors.

Ms. McCoy stated that there are articles with recommendations on error prevention. She stated that the very elderly are dependent on the pharmacist and she is glad that they are making efforts to be sure that the patients do understand what they were told about their medications. Mr. Visockis stated that more and more care givers are picking up prescriptions for elderly patients and that is another challenge. He stated that you cannot trust children in all cases.

President McAllister told Mr. Herzog and Mr. Visockis that they are taking steps in the right direction and to be careful.

COMPLAINT #2728 - Postponed until May Meeting

COMPLAINT #2735

President McAllister called Pharmacist Kathleen LaBranche forward to address a Consumer Complaint. Compliance Officer Mitzi Wilson was requested to describe the findings of her investigation.

President McAllister opened the discussion by asking Ms. LaBranche to discuss the complaint.

Ms. LaBranche stated that she would like to make a statement concerning events that lead up to this situation.

Ms. LaBranche stated that there is a retaliatory problem at the Safeway stores in the Flagstaff area. She stated that the pharmacy prefers to staple the dispensing bags shut with the receipt on the outside of the bag. She found it difficult to counsel in that manner and would rip the bags open. The Pharmacy Manager asked her to leave the bags stapled and use the receipt to counsel the patient. Ms. LaBranche stated that she did not like to counsel from the receipt because the receipt did not have the directions for the medication. Ms. LaBranche stated that she found misfilled prescriptions by opening the bags. She stated that the Pharmacy Manager did not like that she kept tearing the bags open and removed the staplers and extra bags from the register area.

She stated that the Pharmacy Manager then found other ways to harass her. She stated that the Pharmacy Manager called the Corporate Office when she did not wear dark enough shoes. Ms. LaBranche stated that the regional manager came in from Ashfork and presented her with a three page memo that stated if she did not wear black shoes again that she would have something permanent put in her file. Ms. LaBranche stated that these problems went on for several weeks and she was not on good terms with the Pharmacy Manager.

Ms. LaBranche stated that she did not leave the other pharmacy that she worked at in Flagstaff on good terms either. Ms. LaBranche stated that she had reported a medication error and had documented that the other pharmacist had dispensed a generic for the brand name product. She stated that the district manager came to the store and wanted her to deny that she took the phone call and tear up the documentation and she refused. She stated that she had just got married and asked to take a 3- week leave for a honeymoon. She stated the following week when her husband was in the store the technician took her license off the wall and put in her husband's shopping cart. She assumed that was the end of her career at this pharmacy.

President McAllister asked if she transferred prescriptions using a name other than her own. Ms. LaBranche stated that she did not know the technician's last name, so she could not have given a transfer using her name. Ms. LaBranche stated that she infers that there is some type of collusion between the two pharmacy chains. She stated that this sounds like a conspiracy because she stated that four other pharmacists were forced out of the chain during the same time period for similar circumstances. She feels that this is retaliation or retribution. She stated that she did not have any complaints concerning patient counseling.

Mr. McAllister asked Ms. Wilson if the receiving pharmacy was the store where Ms. LaBranche used to work. Ms. Wilson replied yes. Mr. McAllister asked Ms. Wilson if she saw the documentation on both transferred prescriptions with the other two names at the receiving store. Ms. Wilson replied that one prescription had the initials T.M. that was taken by a floater pharmacist and the other prescription had the name of the Pharmacy Manager where Ms. LaBranche worked and was taken by a staff pharmacist at that store. The pharmacist at the receiving store stated that when he took the transfer that she used the name of the Pharmacy Manager. The technician at the transferring store overheard Ms. LaBranche give the name of the Pharmacy Manager when she transferred the prescription. Ms. LaBranche stated that the technician that stated she overheard her use the Pharmacy Manager's name also stated that Ms. LaBranche's father had a prescription filled incorrectly at an Arizona pharmacy.

Ms. LaBranche stated that she feels that there is a problem of credibility with this technician.

Mr. McAllister told Ms. LaBranche that the evidence put before the Board seems fairly credible that she used the wrong names. He asked her if she denied that statement. She denied that she used a name that she did not know. Mr. McAllister asked if she knew the other name. She replied yes but she said that she would have no reason to use the name of the Pharmacy Manager to someone who knows her and the Pharmacy Manager. Ms. LaBranche stated that the Pharmacy Manager at her store fired the pharmacist at the receiving pharmacy.

Dr. Tippett asked if there would be any benefit to a pharmacist transferring under an assumed name in this type of situation unless they were trying to do something fraudulent or something they were trying to cover up.

Mr. Draugalis stated that the documentation states that Ms. LaBranche was fired from one store and did not want the other store to know she was working at the other store. Mr. Draugalis stated that seems to be the impetus to use someone else's name.

Ms. LaBranche stated that many patients followed her to the new store because they like the way she counseled.

Mr. Draugalis asked Ms. LaBranche if she denied doing the transfers. Ms. LaBranche replied yes.

Mr. Draugalis asked if she denied that fact that she did not want the one pharmacy to know that she was working at the other pharmacy. Ms. LaBranche replied no. She stated that Flagstaff is a small town and the stores share patient's back and forth. Mr. Draugalis stated that is not the question he asked. Ms. LaBranche stated that she would have no reason. Mr. Draugalis asked if there was a huge conspiracy going on here. Ms. LaBranche stated it is not huge but something is going on because someone used a name she did not know. Mr. Draugalis asked if it was a conspiracy because she was fired at one store and then was fired at another store. Ms. LaBranche said she cannot tell him what was going on and why they would transfer a prescription using false names and say she did it. Ms. LaBranche stated that she did not leave either company on good terms. Ms. LaBranche said she cannot give him a reason because she does not understand.

Mr. McAllister called Mr. Steve Lerch forward at his request to address the Board. Mr. Lerch is the Director of Pharmacy for Safeway. Ms. Sharon Richardson, the Regional Pharmacy Manager, also came forward.

Mr. Lerch stated that Ms. LaBranche was making unflattering remarks about the company and he would like to set the record straight. He stated that Safeway would never discourage show and tell counseling and as a matter of fact they support the show and tell method. He stated that Ms. LaBranche's portrayal of the pharmacy operation was not accurate. He stated that he is not sure what the other instances have to do with the transferring of the prescriptions. He also stated that the Pharmacy Manager that was working with Ms. LaBranche is one of the best operators in the chain.

Ms. Richardson addressed the Board. She also stated that the Pharmacy Manager at this store is very good. She also stated that the pharmacist at the other store was not fired. Ms. Richardson could not think of any type of retaliation that the Pharmacy Manager would want against Ms. LaBranche. The Pharmacy Manager told Ms. Richardson that she did not know what happened but she did not do these transfers. Ms. Richardson also stated that no one would tell her not to open the bag to counsel the patients since this is not their policy.

Mr. Jones asked Ms. Wilson if she asked the Pharmacy Manager about the transfers. Ms. Wilson replied yes. Mr. Jones asked whose name was in the Pharmacy computer as the transferring pharmacist. Ms. Wilson replied Kathleen Thompson (Ms. LaBranche's maiden name). Mr. Jones asked whose name was on the prescriptions at the receiving store. Ms. Wilson replied that the Pharmacy Manager's name was on one prescription and the technician's initials were on the other prescription. Mr. Jones asked Ms. Wilson if she spoke to the pharmacist that used just the initials and not the pharmacist's name. Ms. Wilson replied that he was a floater pharmacist for a temporary agency and she was not able to contact him. Ms. Wilson stated that she did speak to the other pharmacist that took the transfer where Ms. LaBranche gave the Pharmacy Manager's name. Ms. Wilson stated that he knew it was not the Pharmacy Manager because he had worked with the Pharmacy Manager at that store.

Ms. LaBranche stated that she was concerned about the counseling issues and sent e-mail memos to Mr. Lerch in October, November, and December.

President McAllister stated in his opinion the evidence is pretty strong that this did occur and instead of discussing this in a conference setting, he would entertain a motion to move to a hearing.

On motion by Mr. Jones and Mr. Ketcherside, the Board unanimously agreed to stop the discussion and move to a hearing.

COMPLAINT #2737

President McAllister called Pharmacist Richard Olness, Pharmacy Technician Joseph Swingle, and Supervisor Richard Wendling forward to address the Board concerning a Consumer complaint. Compliance Officer Mitzi Wilson gave an overview of her findings. President McAllister asked Mr. Olness to describe the events. Mr. Olness stated that he would like to apologize for the error. He stated that he is very happy and relieved that nothing happened to the individual that digested that medication. Mr. Olness stated that there have been no problems with the patient as a result of taking the medication. Mr. Olness stated that the size and the color of the two tablets are identical. He stated that he missed the ID marking on the tablet and he apologized.

Mr. McAllister stated that this was a Baker Cell misfill and asked if any other errors were caught before any other patients took the incorrect medicine. Mr. Wendling addressed the issue.

Mr. Wendling stated that a subsequent pharmacist doing verification identified that the bottle he was checking contained the wrong medication. The Baker Cell was shut down. Mr. Wendling stated that a report was generated and they had learned that three prescriptions were shipped. They proactively called the patients and asked them to review their medications. They found two prescriptions were correct and one prescription had been filled incorrectly and the patient had ingested the medication. This is the patient that filed the complaint. Mr. Wendling stated that the pharmacist contacted the patient, counseled the patient about the side effects of the wrong medication, and contacted the physician on behalf of the patient. They discussed with the physician any concerns that they may have and arranged for a doctor's visit for the patient. Mr. Wendling stated that the correct medication was shipped overnight to the patient to prevent any further disruption to their therapy. Mr. McAllister stated that he was impressed to see that kind of reaction.

Mr. Dutcher asked where the problems arise. Mr. Dutcher asked if the Baker Cell is verified by a pharmacist when it is filled. Mr. Wendling stated that the Baker Cell notifies a technician that the cell needs replenished. The bottle is to be scanned . If the technician does not have the correct bottle, the technician will be prompted to get the correct bottle. Also, a digital image of the tablet will appear on the screen. A pharmacist doing product verification found the error downstream.

Mr. Dutcher asked if the technician was certified and once we license technicians we will be taking action against the technician. Mr. Wendling stated

that the technician took his eye off the ball on one occasion. The entire department was retrained because patient safety was compromised. The staff was told that they need to follow the processes or subsequent disciplinary action will be taken. Mr. Wendling stated that the technician has great remorse for the error and has taken additional steps to ensure that an error like this does not occur again.

Mr. Jones asked if technicians fill the baker cells. Ms. Wilson stated that in most mail order facilities the technicians do fill the baker cells without a pharmacist check. Ms. McCoy stated that the bar code technology is the reason that we allow technicians to fill the baker cells without the additional check. Ms. McCoy asked if there was a way that they could review if the scanning process took place in every instance that a baker cell was filled. Mr. Wendling stated that they could generate a report showing scanning errors and that report could be printed on a daily basis.

Ms. McCoy stated that she did agree with Mr. McAllister that the follow-up was excellent.

President McAllister told the participants to fix the little problem in their system. He again stated that he was impressed with the follow-up.

COMPLAINT # 2739 - Postponed until May

COMPLAINT #2741

Pharmacist Kim Lewis and Supervisor Craig Yee were present relevant to a consumer complaint.

Compliance Officer Rich Cieslinski was requested to describe the findings of his investigation.

President McAllister asked Ms. Lewis to describe the events that lead up to this discussion.

Ms. Lewis stated that she dispensed Methotrexate 2.5 mg instead of Medroxyprogesterone 2.5 mg. Ms. Lewis apologized for the error and has spoken to the patient several times after the error. She stated that the patient has had additional prescriptions filled after the incident. Ms. Lewis stated that she checks the middle four numbers of the NDC number and documents the number on the back of the prescription. Ms. Lewis stated that she typed the prescription correctly and wrote down the numbers she wanted to see from the bottle. Mr.

McAllister asked if she typed and filled the prescription. Ms. Lewis stated that she did.

Mr. McAllister asked if the bottles were close to each other on the shelf. Ms. Lewis replied that they are no longer close to each other on the shelf. She said that the bottles have been moved and dog tagged. She said that this incident has made her think about the power that a pharmacist has to endanger a person's life.

Mr. Draugalis asked Ms. Lewis if she was the only pharmacist working that day. She replied that she was the only pharmacist. He asked her how many hours a day does she work. She replied that she works 10- hour days. She stated that she fills prescriptions for 8 and ½ hours daily. The pharmacy is closed for ½ hour for lunch. She stated that she comes in one hour before the pharmacy opens to retrieve voice mails.

Mr. Draugalis asked about the workflow. Ms. Lewis stated that the pharmacy chain has had several promotions that have increased the prescription volume. She stated that the drop off window is at one end and the counseling window is at the other end where the patient pays for their prescription. Mr. Draugalis asked Ms. Lewis where she is located in the workflow. She replied that she is in the middle. She stated that she checks the prescriptions and counsels the patients. Mr. Draugalis asked if she does any of the counting. She stated that she counts about 20% of the prescriptions. Ms. Lewis stated since this incident she asked Mr. Yee for additional help. She said that they do have additional pharmacist hours and the number of certified technicians has been increased from three to four. She stated that she now has a cashier to ring up the prescriptions, which allows her certified technician to help in the pharmacy.

Ms. Lewis stated that if a patient denies counseling, she still shows the patient the contents of the bottle. She said this ensures that she checks the prescription a second time before the prescription leaves the pharmacy.

President McAllister recessed the meeting for a short break. President McAllister reconvened the meeting after the break.

AGENDA ITEM IX - Consent Agreements

President McAllister asked Board Members if there were any questions or discussions concerning the Consent Agreements. Executive Director Wand indicated that the first three consents on the agenda have been resolved as Consent Agreements or stipulated orders that have been reviewed and approved

AGENDA ITEM XI - Legal Issues

Consolidation of Refills

President McAllister opened the discussion by stating that he wanted to address the topic of consolidation of refills. He stated that consolidation of refills is when a prescription is written for 30 tablets with 3 refills and the pharmacist dispenses the total quantity of 120 tablets at one time. He stated that this does not exceed the total quantity for which the prescription was written. He stated the first issue is that by dispensing more than the quantity the doctor prescribed (30 tablets) the prescription is misbranded. The second issue is that the quantity is increased due to economic reasons, such as third party copays. The third issue is did the doctor intend for the patient to receive all 120 tablets at once. The doctor may have written the prescription for 30 tablets to see if the patient is taking his medicine correctly or he may want the patient to return for a visit. It is also a problem if the patient takes all 120 tablets at once on purpose and dies. Mr. McAllister said he is concerned because the pharmacy is making the decision. The doctor and the patient are not involved in the decision and he is not sure if this is legal.

Mr. Wand stated that on law exams this practice is considered misbranding. Mr. Wand stated that when you sell a prescription drug you are required to sell the product in the original manufacturer's container with the package insert on it unless you have a prescription, which allows you to put the medication in your bottle and not attach the package insert except for certain classifications of products. Mr. Wand stated that when you get a prescription for 30 tablets with 6 refills that you have a prescription for 30 tablets and not a prescription for 210 tablets. When you dispense a prescription for 90 tablets, you have misbranded the medication.

Mr. Wand passed out the Brushwood article that explains how the misbranding law has evolved over the years.

Mr. Wand stated that if you review the drug therapy management rules, it states that no pharmacist may change or modify, implement or modify a prescription unless they are in a protocol approved by the physician and the Board approves the protocol. Mr. Wand stated that if you are changing a prescription you are in violation of that statute as well. There is also an enforcement issue concerning the patient who needs an additional refill to go on vacation.

Ms. McCoy states that she has concerns that the patient has no say in the matter. The patient is presented with a larger quantity of medication than they were supposed to receive. Ms. McCoy is concerned that on a new prescription if a patient receives 4 months worth of medication that the medicine may not agree with the patient and the medicine is wasted. She feels that the pharmacy does not have enough information about the patient and are arbitrarily making decisions that are not in the best interest of the patients.

Mr. Dutcher said it is an individual issue when the patient asks the pharmacist for an additional refill for vacation. Mr. Dutcher is concerned when a patient mails a prescription to the pharmacy and the pharmacy fills a 90-day supply and the patient forfeited the remaining quantity because there was not a 90-day supply remaining. Mr. Dutcher asked if we are looking for a policy change or a rule change. President McAllister stated that he feels the question in front of the Board at this time concerns if this practice is legal according to our statutes and rules.

Mr. Jones stated that patients are getting ripped off because they need to go back to their physicians to get new prescriptions when their original prescription had a remaining quantity. Mr. Jones said one solution would be for the physicians to write that the pharmacy may dispense the whole quantity which he feels would not happen. Mr. Jones said that he sees a lot of waste when a patient is sent a 90-day supply and the doctor changes the medication.

Mr. Wand stated that some states have passed rules stating that you cannot exceed the amount for which the prescription is written by using the refills. Mr. Wand stated that this still does not get around the misbranding issue. Mr. Wright stated that you could increase the quantity with the physician's approval.

Mr. Morris addressed the Board. Mr. Morris stated that he does not think anybody is saying the patient does not have a right in this process. Mr. Morris stated that nobody should be able to consolidate without patient consent. Mr. Morris stated that the authorization could be per prescription or in the patient's profile. Mr. Morris stated that by consolidating prescriptions the patient should never lose any remaining quantity of medication. Mr. Morris stated that the pharmacist should be communicating with the doctor appropriately. Mr. Morris stated that many doctors would consider this an intrusion call. Mr. Morris stated that a doctor might consider it a stupid question if he is pulled out of a patient's room to authorize the dispensing of 90 tablets when he gave the patient a prescription for 30 tablets with 6 refills. Mr. Morris stated that consolidation is for the benefit of the patient because they will pay less in copays. Mr. Morris stated that every call to a doctor's office costs \$6.00 and

wanted to know why we are adding that cost on to the prescription and intruding on the doctor's time. Mr. Morris stated that the Board stated that an exception might have to be made for a patient going on vacation. Mr. Morris feels that pharmacists using their professional judgment should make the decision to consolidate prescriptions. Mr. Morris stated that his staff called different Board offices and received different replies to the question if prescriptions can be consolidated. Mr. Morris stated that if the Board were going to prohibit this practice he would like to see a rule written.

Mr. Dutcher wants to know who is making the decision. He said will the pharmacist be making the decision or will corporate policy make the decision for the pharmacist. Mr. Dutcher said he is concerned about the patients that actually lose tablets because of the process.

Mr. Wand said it is an issue when we get complaints and we have received numerous complaints regarding this issue. Mr. Wand again stated that this is considered misbranding.

Ms. McCoy stated that the pharmacies involved in the complaints are not talking to the patients. The medication is automatically increased for the patient by the pharmacy. Ms. McCoy stated that she has an issue with someone in an office making a decision about patient care and the patient is not involved in the decision.

Mr. McAllister stated that if the Board receives a complaint and the patient was not involved in the decision then there would be an easy resolution that will result in disciplinary action. Mr. Dutcher asked who would be disciplined the pharmacist or the permit holder. Mr. McAllister stated that a pharmacist ultimately made the decision.

Mr. Pulver stated that R4-23- 402 (10) states that a pharmacist must check a prescription label to ensure that it communicates the prescriber's directions precisely. Mr. Pulver says that this rule could be strictly interpreted. Mr. Pulver stated that the rule could be changed or modified. He stated that we do have a rule and the language uses the term precisely.

Mr. Wand stated the Brushwood article stated that pharmacists could do refills only if the doctor writes refills. Mr. Wand stated that he feels that in most pharmacies the pharmacist is not talking to the patient when extra refills are given.

President McAllister stated that we are not ready to come to a conclusion today. He stated that many issues were brought to the table and we should continue to talk and watch our complaints.

Mr. Jones said the bottom line is to protect the patient's rights and we have an obligation to protect the consumer. Mr. Jones feels that if we dispense a larger quantity on an initial dispensing that there is a liability attached to that for the pharmacist.

Compounding

President McAllister opened the discussion by stating that in the book is the definition of compounding. It states that Compounding does not include the preparation of commercially available products from bulk compounds. Mr. McAllister stated that the patient is defenseless when a product is compounded. The patient is unable to identify the drug. Mr. McAllister stated that he has come across issues of profit motivated compounding by changing a commercially available product by a few milligrams in order to compound the product. Mr. McAllister stated that the Compliance Staff has been asked to note any examples of this during their inspections and bring the pharmacies up for citations.

Mr. Dutcher stated that he has had a patient show him a compounded prescription that was compounded for carisoprodol 700 mg. He stated that the product is available as a commercially available tablet of 350 mg. He stated he could not see anything wrong with the patient taking two tablets of the 350 mg to make 700 mg. Mr. Dutcher stated that the same physician has the pharmacy compound Oxycodone in various strengths such as 10 and 20 mg tablets. There is a commercially available tablet available in a 5 mg strength. Mr. Dutcher said that this might be profit motivated. He said the patients are receiving large quantities of medication.

Mr. Wand asked Mr. Dutcher if the carisoprodol 700 mg was time released. Mr. Dutcher replied it was not time released. Mr. McAllister said it would be impossible for a patient to get a one thousand time overdose in a commercially available product, yet a patient did get a one thousand time overdose in a compounded product. Mr. McAllister stated that there is definitely a risk issue.

Mr. Dutcher stated that does it mean that if the product is available in any commercial strength that it cannot be compounded. He would like to define what is meant by commercially available to assist the compliance staff and the Board if they get a complaint involving compounding issues.

Ms. McCoy stated that she has concerns and asked if we can go into the compounding pharmacies to determine what products are being compounded. She feels that if pharmacies are compounding products 2 mg over the commercially available product there is probably something else going on there and patients are at risk.

Mr. Jones stated that any Compliance Officer should be able to go into any compounding pharmacy and review their records and get a feel for what products are being compounded. Mr. Jones stated that compounding should provide a service and in communication with the physician, a pharmacist could compound a product that is not available in a particular strength or in a particular dosage form. Mr. Jones stated that making a product that skirts the issue might be profit motivated.

Ms. McCoy stated that she is not concerned about alternative dosage forms when a patient cannot take oral medications. She stated that this is a far cry from the pharmacy compounding a product that is off by a couple of milligrams. She stated that not many patients would have trouble with a commercially available product. She stated that there are no trials that show that the compounded product is better than the commercially available product.

Mr. Jones stated that from the Compliance Officers standpoint that we have made significant improvements in the quality of practice in the last 3 years. Initially, there were many pharmacies not maintaining compounding records. Mr. Jones stated that the Board needs to verify who is doing the compounding and who is checking the finished product.

Mr. Wand stated that there is a hearing scheduled for the compounding rules on March 22, 2004. If we make changes that are substantive, it will delay the rules. Mr. Wand stated as the definition states that if you make a 21 mg product and only a 20 mg product is commercially available then it is legal to make the 21 mg product. Mr. Dutcher asked about the double strength. Mr. Wand stated that it is not commercially available.

Mr. Pulver stated that part of the problem is that the physicians are writing for these strengths. Mr. Pulver stated the question to ask is if the product is being compounded because the physician is aware that the patient cannot take medication in the dosage form that is available commercially and an alternate dosage form is necessary.

President McAllister stated that this practice is not being stimulated by the physicians but are following recommendations from the pharmacy. Mr. McAllister stated that he is aware of an instance where a pharmacist stated that he could change the prescription a little bit and do something special for the patient. Ms. Wilson stated that it is often the way the pharmacies are marketing the product to the physician. She stated in Mr. Dutcher's case the pharmacy may be marketing the product to the physician by stating that they could make a strength where the patient only needs to take one tablet instead of two tablets at a time. Mr. McAllister stated that this goes against evidence based medicine. He stated that there may not be proof that it works better than the commercially available product.

Mr. Ketcherside asked about the 5% rule. Mr. Wand stated that when a pharmacist compounds a prescription he could dispense the prescription pursuant to a prescription for an individual patient. If he compounds a prescription to sell to a doctor's office for the doctor to administer that can only be 5% of his business. The reason being compounding should be patient specific. Mr. Ketcherside asked who governs this at this time. Mr. Wand stated that the Compliance officers note during their inspections if a pharmacy is going over the 5%. He stated that during an inspection it was noted that a pharmacy was doing about 40% of their business by selling medications to physicians and the pharmacy then applied for a wholesale permit and limited the compounding to patient specific prescriptions. Mr. Ketcherside asked about veterinary compounding. Mr. Wand stated that the FDA is looking at some of the issues with veterinary compounding. Mr. Ketcherside said that he feels that we should scrutinize what products are being compounded.

Mr. Wand stated that the compounding error that resulted in the consent order was available in a commercially available product. The patient may have had to take a combination of tablets to make the exact strength. Mr. Dutcher said do we need to clarify the definition for commercially available. Ms. McCoy asked if the definition could be changed to include the wording dosages for example if a patient could take 3 tablets to make a 15 mg dosage then a product should not be compounded. Mr. Draugalis suggested that we could use the term fraction or multiple of the commercially available product.

Mr. McAllister stated that the issue cannot be concluded today and we do not want to hold up the rule-making process. Mr. McAllister said to keep this on the forefront and watch for any complaint issues.

Mr. Wand stated that this is a statute and could only be changed on the statute level. He stated that rules explain the statute and a rule could be written. He stated any changes would hold up the current rule package. Mr. Wright stated that we could proceed with the current Compounding Rule package and start a new rule later.

Mr. Jones stated is there a need for competency testing. Mr. Jones asked if there would be credentialing for compounding pharmacies. Mr. Jones said there are also issues if these pharmacies have ethical business practices. Mr. McAllister replied that the model act is considering the credentialing of pharmacies and one of the areas is compounding.

Mr. McAllister asked Mr. Wright if he would try and work on some of the language for the next Board meeting.

Posting Size of Pharmacy

Mr. Dutcher asked if the size of the pharmacy could be posted for the ease of the Compliance Officers and the relief pharmacists in the store. He feels if the pharmacy size is posted then the pharmacist will know how many employees can work in the pharmacy. Mr. Wand was asked if this could be printed on the pharmacy license. He stated that it could be printed on the license and if the pharmacy was remodeled then it would need to be changed.

Mr. McAllister asked if the Compliance Staff has seen any violations. Mr. Wright stated that he had two violations last year. Mr. McAllister stated that it would be a nice newsletter item because the pharmacist should know the law. Mr. Dutcher stated that many pharmacists do not know the size of the pharmacy. Mr. McAllister stated that we should keep our eye on the situation since the technician rule has not been implemented yet.

AGENDA ITEM XII - Approval of ACPE Approved Colleges of Pharmacy

President McAllister opened the discussion by stating that the former American Council on Pharmaceutical Education is now the Accrediting Council on Pharmaceutical Education and has accredited the pharmacy school in Beirut, Lebanon. By our blanket process of approving all ACPE programs, Mr. McAllister stated that the Board would now be approving the school in Lebanon. Mr. McAllister stated that the council did accredit the school based on the same standards that they accredit all the U.S. schools. The school does teach in English and do have practice sites in retail and hospital areas.

Mr. McAllister asked the Board Members if they wanted to continue the blanket approval of all ACPE approved programs or consider the international programs separately.

Mr. Wand stated that the members have been provided with a list of schools. Mr. Wand stated that he was an observer at the University of Arizona during their accreditation process. It is a very comprehensive evaluation. He stated that professors, students, preceptors, and administrative office personnel are interviewed.

Mr. McAllister stated that it might open up new challenges when ACPE approves Canadian Colleges of Pharmacy. The Canadian colleges will not have a 6- year PharmD program.

Ms. McCoy stated that the accrediting body is probably more qualified to determine if the colleges are meeting the necessary standards than the Board members.

On motion by Ms. McCoy and Mr. Tippett, the Board unanimously agreed to accept the list of Accredited Colleges of Pharmacy

AGENDA ITEM XIII - Review of Patient Counseling Rules

President McAllister opened the discussion by asking the Board Members to look at R4-23-402(C) and (D) which state the requirements for oral consultation. Mr. McAllister stated that section C states that the pharmacist shall include the listed information when counseling and section D lists additional items that the pharmacist may provide during oral consultation. Mr. McAllister stated that the rule was written during a confrontational period between the Board and the practice areas to provide counseling. As a result, the rule is probably diluted. Mr. McAllister stated it is difficult for the Board to regulate in terms of errors and inspection issues.

Mr. McAllister asked the Board members to review the Nevada rules. The list is more extensive than the Arizona rules. Mr. McAllister stated that these are the items that the pharmacists should be talking about with their patients. Mr. McAllister suggested that the Board should update the counseling rules.

Mr. Jones agreed with Mr. McAllister that the counseling rules should be updated. Mr. Jones stated that the pharmacists that have appeared before the Board for conferences have not even provided their patients with the 4 basic requirements listed for oral consultation.

Mr. Jones stated that now that since there are no restrictions on the number of technicians, the pharmacist should be able to counsel the patient. Mr. McAllister stated that was the intent of changing the technician ratio.

Mr. Dutcher stated that the Nevada rules require the pharmacist to tell the patient about the intended use of the drug. Mr. Dutcher said that if the pharmacist told the intended use of the medication, he felt we would not have had as many conferences for misfilled prescriptions when the wrong drug was dispensed.

Mr. McAllister stated that NABP is working on resolutions to implement in the model act to require the intended use of the medication on the prescription. Mr. Dutcher asked if that would not require re-educating of the prescriber. Mr. McAllister said that the prescriber will be required to write the intended use on the prescription.

Mr. Dutcher asked President McAllister if this issue should go to Dean for rulewriting or should a task force be organized. Mr. McAllister said a task force including practice personnel would be good.

Ms. McCoy stated that in Arizona the rules state that only a pharmacist or an intern can take the refusal of counseling. She stated often the Board is told that the technician asked the patient if they wanted to be counseled. She stated that the Board needs to remind the pharmacists that counseling is not offered but is required. She stated that maybe we need look at the rule that states an individual can sign a waiver of consultation. Mr. McAllister stated the Nevada rules require that the pharmacist document whether or not consultation occurred. Mr. McAllister stated that this is a very good protection mechanism for the pharmacist when a consumer complaint is filed because the pharmacist has documented that he spoke with the patient.

President McAllister asked Ms. McCoy to chair the task force and asked Dr. Tippet to serve on the task force. Mr. McAllister stated if anyone from the practice community was interested in serving on the task force to contact Hal.

AGENDA ITEM XIV - Approval of NABP Resolutions

Mr. Wand explained that we have two resolutions for the NABP convention in Chicago. The first resolution is National Patient Safety Goals. The resolution hopes to instill and perpetuate the concepts of prohibited abbreviations, acronyms, and symbols in written communication between health care providers.

Mr. Wand stated that the second resolution is a recognition resolution. The Board is saddened by the serious illness of Eugene "Gene" Drake. The resolution recognizes Mr. Drake for his significant contributions to the Arizona Board of Pharmacy and NABP. The Board would like to commend Mr. Drake for his many years of service to the Arizona Board of Pharmacy.

On motion by Mr. Dutcher and Mr. Draugalis, the Board unanimously agreed to accept both resolutions.

AGENDA ITEM XV - Drug Therapy Management Protocol Approval/ Denial

President McAllister called on Ms. Frush to discuss the Drug Therapy Management Protocols that were reviewed by the committee. Ms Frush stated that the Drug Therapy Management Advisory Committee reviewed three proposals.

The committee made the following recommendations:

1. Heather Jaeger, Cigna	Anticoagulation Clinic	Approval
2. Kenton Brown, Cigna	Anticoagulation Clinic	Approval
3. Marissa Soto, El Rio	Diabetes , Hypertension Hypercholesterolemia	Approval upon clarification of protocol

Ms. Frush also stated that a committee member expressed concern about a pharmacist trying to manage a specific disease state and then branching out to manage a related comorbidity. The intent of the drug therapy management agreement is to manage the drug therapy and not manage the disease state. The concern was that ordering EKG, Chest X-rays, and Eye Exams are not in the scope of practice of the pharmacist. Board Members did agree that these are tests that are not in the scope of practice of the pharmacist. Ms. Frush stated that a statement could be added to the protocol template addressing the tests to be ordered by the pharmacist.

On motion by Mr. Jones and Ms. McCoy, the Board unanimously agreed to approve the Drug Therapy Management Proposals with the stipulation that Proposal Applicant #3 address the issues that the committee requested to be clarified.

CALL TO THE PUBLIC

President McAllister announced that interested parties have the opportunity at this time to address issues of concern to the Board, however the Board may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

Comments were made concerning the following issues:

1. It was recommended that non-resident pharmacies licensed in Arizona could be required to comply with our Arizona laws when our laws are stricter.

2. It was brought to the attention of the audience and Board that individual charged with a felony must report the felony to the Board.

3. It was recommended that the summary of the Complaint Review for 2003 be placed on the website for licensees to review.

4. It was stated that consolidated boards are impossible to deal with and often cannot answer your questions.

5. It was noted by a pharmacist at a compounding pharmacy that many animals' lives are saved by the medications that are compounded for people's pets.

There being no further business to come before the Board on motion by Ms. McCoy and Mr. Dutcher, the Board unanimously agreed to adjourn the meeting at 3:50 P.M.

President McAllister reconvened the meeting at 9:00 A.M. President McAllister stated that law continuing education would be offered for attendance at the meeting and to see a Compliance Officer at the conclusion of the meeting.

The following Board Members and staff were present: President Dennis McAllister, Vice President Linda McCoy, Charles Dutcher, William E. Jones, and Bryan Tippett. Compliance Officers Rich Cieslinski, Larry Dick, Ed Hunter, Mitzi Wilson, and Dean Wright, Drug Inspector Tammy McPherson, Deputy Director Cheryl Frush, Executive Director Hal Wand, and Assistant Attorney General Roberto Pulver.

AGENDA ITEM X - Hearings

President McAllister opened the administrative hearing. This is the time and place for consideration of the matter of the hearing to determine whether to revoke or suspend the License Number 11976, issued to Kristine M. Wells, Notice of Hearing No.2004-01-PHR.

Ms. Wells was not represented by counsel. President McAllister told Ms. Wells that she does have a right to have counsel present. The state was represented by Assistant Attorney General Roberto Pulver.

The licensee and the witness for the state were sworn in by President McAllister. Both sides waived the reading of the Notice of Hearing.

Opening statements were made by the counsel for the state and by the licensee. The hearing then proceeded.

The attorney for the state presented his evidence. At the conclusion of the State's presentation of evidence, the licensee presented her evidence.

After both sides presented their evidence, closing statements were made by the attorney for the state and by the licensee.

On motion by Mr. Jones and Ms. McCoy, a roll call vote was taken and all Board Members agreed unanimously to adopt the findings of fact.

On motion by Mr. Jones and Ms. McCoy, a roll call vote was taken and all Board Members agreed unanimously to adopt the conclusions of law.

On motion by Mr. Jones and Ms. McCoy, a roll call vote was taken and all Board Members agreed unanimously to revoke license number 11976 issued to Kristine

M. Wells and order Ms. Wells to pay all monies owed to PAPA.

On motion by Mr. Dutcher and Mr. Jones, a roll call vote was taken and all Board Members agreed to revoke the license immediately since a rehearing would be impracticable and she posed a threat to the public.

The Board Office will have copies of the transcript of the hearing prepared within 2 weeks.

President McAllister recessed for a short break. President McAllister reconvened the meeting after the break.

AGENDA ITEM XVI - NABP's Revised Model Rules for the Licensure of Wholesalers

President McAllister asked Mr. Wand to start the discussion. Mr. Wand stated that NABP has revised the Model Rules on the Licensure of Wholesale Distributors. He stated that NABP and the FDA partnered to develop rules that will combat the distribution of counterfeit drugs and they want to make sure that the U.S. medication distribution system is secure. He stated that this could be a topic for a future meeting. He stated that the Board might want to review our wholesale rules and change our rules to match the new rules in the Model Act.

President McAllister stated that these rules are very important to protect the drug supply. He stated that NABP is taking a lead role in developing the rules by meeting with wholesalers.

AGENDA ITEM XVII - DEA Proposed Rulemaking for Controlled Substance Surplus in LTCF

President McAllister asked Mr. Wand to address this issue. Mr. Wand stated that the DEA is proposing changes to its existing regulations to allow for pharmacy installation of automated dispensing systems at LTCFs. Automated dispensing machines will allow the dispensing of single dosage units and alleviate the problem of excess stocks and disposal. Board Members supported this proposed rulemaking change.

AGENDA ITEM XVIII - Discussion of Board Meeting Schedule for October 2004

President McAllister asked the Board Members if the October Board meeting could be rescheduled because the meeting conflicts with the NABP District

Meeting. After discussion, it was decided that the Board Meeting scheduled for October 27 and 28, 2004 would be moved to November 17 and 18, 2004.

AGENDA ITEM XIX - Approval of Travel & Registration Reimbursement for NABP Convention

President McAllister asked Mr. Wand to address this issue. Mr. Wand stated that the Board must approve the travel and registration reimbursement for the three representatives attending the NABP convention in Chicago. Mr. Wand stated that Linda McCoy will be attending as the voting delegate, Mr. Wand will be attending as the alternate delegate, and Mr. Draugalis will be attending as the past Board President. On motion by Mr. Jones and Mr. Dutcher, the Board unanimously agreed to approve the travel and registration reimbursement for the individuals selected to attend the NABP Convention in Chicago.

President McAllister stated that is the Centennial Meeting for NABP. He stated that this would be the first time that all fifty states will have members in attendance.

AGENDA ITEM XX - Call to the Public

President McAllister announced that interested parties have the opportunity at this time to address issues of concern to the Board, however the Board may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

There being no further business to come before the Board on motion by Mr. Dutcher and Ms. McCoy, the Board unanimously agreed to adjourn the meeting at 10:05 A.M.