



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

January 2009 "Error Prevention: Shared Responsibility for Pharmacists & Technicians" 707-000-09-001-H03-P

31st Year



This Month:
"Pharmacy Law 2009"

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HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

"ERROR PREVENTION." This is a topic that we discuss regularly--because it is so important. This lesson supplements our 2008 lesson when we covered the topic in detail. We are presently adding to that consideration because Congress is considering specific legislation regarding technicians, and their role in pharmacy errors. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-09-001-H03-P. Pharmacists completing this lesson by January 31, 2012 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the responsibilities of pharmacists & technicians to address the problem of pharmacy errors.
2. Discuss the facts & implications of the Shinn Case.
3. Describe how Boards of Pharmacy can react to a complaint of a pharmacy error.
4. List the components of the proposed federal legislation known as Emily's Act.
5. Discuss the advantages & disadvantages of increased legal requirements for pharmacy technicians.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.

BACKGROUND

Pharmacists and pharmacy technicians work together to process prescriptions accurately. Because pharmacists and technicians are humans, and because all humans make mistakes, there will inevitably be errors that occur in the processing of prescriptions. To err is human. The normality of human error in pharmacy does not lessen the impact of error when a patient is harmed by a wrong drug, wrong strength, or wrong directions. Emotions such as fear, despair, and anger following human errors are as inevitable as are the errors themselves. Patients or their survivors want to know what went wrong and who is to blame. Pharmacists and pharmacy technicians are full of remorse and shame. The purpose of discussing pharmacy errors is to determine what can be done to prevent them and how to respond to them after they occur.

In this lesson we will review a recent case brought before the Nevada Board of Pharmacy in which several pharmacists were disciplined after a tragic error that was caused by a breakdown in the pharmacy system. Pharmacists and a pharmacy technician shared in the responsibility for this error, although only the pharmacists were disciplined by the Board of Pharmacy. We will also review proposed federal legislation that, if passed, would enhance the professionalism of pharmacy technicians and reduce supervising pharmacist responsibility when a pharmacy technician makes an error. The legislation could change the system so that pharmacists are no longer solely responsible for an error that occurs due to the negligence of both pharmacists and pharmacy technicians.

RESPONSIBILITY OF THE PHARMACIST

Under the traditional view of legal responsibility in pharmacy, the culprit for pharmacy error has almost invariably been the pharmacist who was on duty at the time the error occurred. This tradition has made good sense for the many years during which pharmacists took charge as the "captain of the ship" with a mentality of "the buck stops here" when things did not go well in the dispensing area. Pharmacy technicians have been relatively immune to error. Those mistakes that pharmacy technicians have made have been ascribed to the supervising pharmacist, based on the assumption that the pharmacist had the opportunity to appropriately supervise the technician to avoid errors and that the pharmacist had the additional opportunity to check work done by the technician to discover and correct errors. According to the traditional view, if a pharmacy technician makes an error, that error is the responsibility of the supervising pharmacist.

The traditional view of pharmacist responsibility for technician error makes less sense today, because pharmacy practice systems are so complex that one person cannot possibly assure the accuracy of all participants in system activities. Consider the order of the Nevada Board of Pharmacy in the Shinn case as described below. As you read this case, focus on the errors in the system and the role of the pharmacy technician in the commission of them. This is a public document and it is provided to you without removing the names of individuals involved. The purpose of using this case study is to learn from it and to prevent similar incidents from occurring in the future. During your assessment of the case, ask yourself what errors occurred that led to the death of the patient, and what system improvements might be implemented to reduce the likelihood of errors of this type.

THE SHINN CASE

BEFORE THE NEVADA STATE BOARD OF PHARMACY, NEVADA STATE BOARD OF PHARMACY, Petitioner, FINDINGS OF FACT, v. CONCLUSIONS OF LAW, AND ORDER, PAMELA S. GOFF, R.Ph., Certificate of Registration No: 15083, Case Number 06-069A-RPH-S, NAZANIN REZVAN, R.Ph., Certificate of Registration No: 16715, Case Number 06-069B-RPH-S, JACKSON YU, R.Ph., Certificate of Registration No: 15169, Case Number 06-069C-RPH-S, ASIA I. CORNELIUS, P.T., Certificate of Registration No: PT04626, Case Number 06-069-PT-S, SUMMERLIN HOSPITAL MEDICAL CENTER PHARMACY, Certificate of Registration No: IA02194, Case Number 06-069-IA-S Respondents. _____/

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on July 25, 2007, in Las Vegas, Nevada. The Board was represented by Louis Ling, General Counsel to the Board. Respondent Pamela Goff was repre-

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January 2009

sented by Robert Graham and Rob Graham & Associates, Respondent Nazanin Rezvan was represented by John Bailey and Bailey and Merrill, Respondent Jackson Yu was represented by Mr. Bailey and by Wendy Cozal, Respondent Asia Cornelius was represented by Mr. Bailey, and Respondent Summerlin Hospital Medical Center Pharmacy (Summerlin Pharmacy) was represented by Michael Prangle and Kenneth Webster and Hall, Prangle & Schoonveld, LLC. Based on the presentations of the parties and the public records in the possession and control of the Board, the Board issued the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. At hearing, Board Staff presented the testimony of Pamela Goff, Nazanin Rezvan, Asia Cornelius, Jackson Yu, Gretta Woodington, and Kathleen Shinn. The parties stipulated to the entry of five exhibits, four proffered by Board Staff and one proffered by Summerlin. Based on the testimony and evidence presented to the Board, the presentations of the parties, and the public records in the possession and control of the Board, the Board finds the following to be the facts in this matter.
2. On October 19, 2006, Alyssa Shinn was born to Mr. and Mrs. Shinn at Summerlin Hospital. Alyssa Shinn was born prematurely, weighing slightly over one pound at birth, and was placed in the Neonatal Intensive Care Unit (NICU) at Summerlin Hospital. Alyssa Shinn was under the care and treatment of Dr. Zenteno.
3. As part of Alyssa Shinn's care, Dr. Zenteno had ordered that Alyssa Shinn receive total parenteral nutrition (TPN), and those TPN orders were compounded by Summerlin Pharmacy. Per Summerlin Pharmacy's policies and procedures, compounded orders such as TPN orders were to be received by the Summerlin Pharmacy by 5:00 p.m. each night.
4. On November 8, 2006, Dr. Zenteno created a written order for TPN for Alyssa Shinn. The written order showed that Dr. Zenteno created the order at 4:30 p.m., but the order was not scanned into the computer system and received by the pharmacy until after 5:00 p.m. One of the components included in the TPN order for Alyssa Shinn was zinc, written by Dr. Zenteno for the concentration of 330 mcg/100 ml.
5. At 7:44 p.m., Ms. Goff processed the TPN order for Alyssa Shinn into the pharmacy's computer system. Because Dr. Zenteno's order for the zinc was written in quantity per volume rather than in quantity per patient weight, and because Summerlin Pharmacy's automated TPN compounding device (known as a BAXA device) was set up for orders to be placed in quantity per weight, Ms. Goff calculated the total volume for the bag that would contain the finished TPN, and then performed a calculation to convert Dr. Zenteno's zinc order as appropriate for the total volume of the bag. Ms. Goff performed this first calculation correctly, but because there had been concerns raised by the nursing staff regarding the quantity per volume calculations appearing on TPN labels, Ms. Goff recalculated the zinc order to convert it from mcgs/deciliters to mcgs/kilograms. In recalculating the zinc order, Ms. Goff selected "mg." for the quantity rather than "mcg." as ordered, thus resulting in a final quantity of zinc of 330 **mg** per 100 ml. rather than 330 **mcg** per 100 ml. Thus, when Ms. Goff printed the two label sets for the preparation of Alyssa Shinn's TPN order per Summerlin Hospital's policies and procedures, the labels contained an incorrect dose of zinc that was one thousand times more than ordered.
6. After creating the two label sets, Ms. Goff presented the label sets to Ms. Rezvan for Ms. Rezvan's double-checking of the accuracy of the data entered by Ms. Goff that was contained on the label sets. Such double-checking is required by Summerlin Pharmacy's policy and procedure for TPNs. Ms. Rezvan received Alyssa Shinn's TPN order, but, in violation of Summerlin Pharmacy's policy, did not place her initial on the label sets. Ms. Rezvan failed to catch the error Ms. Goff had committed regarding Alyssa Shinn's TPN order. At hearing, Ms. Rezvan explained that she simply did not notice the "mg." instead of the "mcg." that should have been on the zinc component of the order. After completing her check of the order, per Summerlin Pharmacy's procedure, Ms. Rezvan forwarded the label sets to the compounding room so that the order could be filled.
7. Ms. Cornelius was the pharmaceutical technician who performed the compounding on November 8, 2006. Ms. Cornelius was asked to compound a few products November 8, 2006 because the usual compounding pharmaceutical technician was unavailable that night.
8. Ms. Cornelius' testimony and the testimony of the pharmacists who worked with her or who supervised her showed that Ms. Cornelius was poorly trained regarding the compounding of products using the BAXA device. Several of the pharmacists who worked with Ms. Cornelius gave specific instances where Ms. Cornelius made errors in filling prescription orders. According to Ms. Cornelius, her training consisted of watching another technician use the BAXA device for about one week. Ms. Cornelius explained that prior to compounding Alyssa Shinn's TPN, she had

compounded fewer than 20 other products using the BAXA device. Ms. Cornelius testified that she had not replenished a syringe on the BAXA device before the night of November 8, 2006, and she was so poorly trained and unknowledgeable that she did not sense or understand that anything was wrong with Alyssa Shinn's TPN processing even though she replenished the zinc syringe numerous times. At hearing, Ms. Cornelius' testimony created the impression that she was sincere in her ignorance, but that her ignorance was profound. The testimony also showed that Summerlin Pharmacy had been told by its staff about concerns with Ms. Cornelius' competence and ignorance, but, nonetheless, Ms. Cornelius was allowed to compound TPNs by Summerlin Pharmacy.

9. When Ms. Cornelius compounded Alyssa Shinn's TPN, she was required because of the total calculated volume to use a 500 ml. bag rather than the 250 ml. bag that was usual for neonatal patients. Ms. Cornelius replenished the zinc supply in the BAXA device eleven times in the course of making Alyssa Shinn's TPN, accounting for 45-48 vials of zinc. Even though such a quantity of zinc was unprecedented to Ms. Cornelius, she did not speak of her knowledge or concerns regarding the zinc to any pharmacist on duty on the evening of November 8, 2006. As part of preparing Alyssa Shinn's TPN order, Ms. Cornelius manually added two ingredients beyond those that were placed in the bag by the BAXA device. Per Summerlin Pharmacy policy and procedure, when Ms. Cornelius completed the compounding of Alyssa Shinn's TPN order, she presented the bag on which one of the two label sets had been placed, the duplicate label set, and the vials and syringes for the two manually-added ingredients to Mr. Yu for his verification. At hearing, Ms. Cornelius explained that she did not tell Mr. Yu or any other pharmacist about the huge quantity of zinc she had added to Alyssa Shinn's TPN because she did not know or think there was anything wrong with what she had done.

10. Mr. Yu verified Alyssa Shinn's TPN order presented to him by Ms. Cornelius. At the time, Summerlin Pharmacy's policy and procedure required the verifying pharmacist to verify only the vials and syringes of the manually added ingredients, but did not require the verifying pharmacist to compare the completed TPN product with the order to verify whether the completed TPN product was compliant with the order. When Mr. Yu verified Alyssa Shinn's TPN order as filled by Ms. Cornelius, he performed the verification according to Summerlin Pharmacy's policy and procedure, thus performing a verification limited to verifying the vials and syringes of the manually added ingredients. Because Ms. Cornelius did not inform Mr. Yu of the unusual quantity of zinc she had used, and because the zinc was not manually added but added to the bag by the BAXA device, and because Mr. Yu performed only the limited verification required of him by Summerlin Pharmacy, Mr. Yu did not catch that Alyssa Shinn's TPN bag contained a one thousand times overdose of zinc.

11. At hearing, Mr. Yu explained that he followed Summerlin Pharmacy's policy and procedure rigidly and that he looked only at Alyssa Shinn's identifying information at the top of the BAXA printout and at the manual additive information on the bottom of the printout and that he did not look at any of the ingredient information in the middle of the printout. Mr. Yu admitted that there were several clues that something about Alyssa Shinn's order were wrong, including the large size of the IV bag and the clear statement on the printout – had he read it – that the bag contained 481.80 mls. of zinc in a bag that contained a total of 580 mls. In close questioning from several Board members, Mr. Yu revealed that his "verification" was really cursory, since he admitted that he did not seek out any information beyond the BAXA printout, which did not include Alyssa Shinn's weight, and that he examined even the three manual additives that he did look at closely he would have seen that even they were not calculated properly. Nonetheless, throughout his testimony, Mr. Yu insisted that he bore no responsibility for the error regarding Alyssa Shinn's TPN because he had followed Summerlin Pharmacy's policy and procedure, even though his verification failed to catch the calculation errors on the few items he admits he did check, namely the manual additives.

12. After verifying Alyssa Shinn's TPN bag, Mr. Yu gave it back to Ms. Cornelius for her to manually add the manual additives. Ms. Cornelius made the manual additions to Alyssa Shinn's TPN bag and sent it to the NICU for administration to Alyssa Shinn.

13. At approximately 3:00 a.m. on November 9, 2006, nursing staff at the NICU began administration of the TPN bag that contained the zinc overdose.

14. On November 9, 2006 at approximately 6:00 a.m., Ms. Cornelius was going off shift and Rebecca Weiss, a lead pharmaceutical technician, was coming on shift. In the course of discussing the previous evenings work, Ms. Cornelius related to Ms. Weiss the unusual preparation of Alyssa Shinn's TPN order because Ms. Cornelius had had to replenish the zinc in the BAXA machine numerous times to create the TPN bag. Ms. Weiss immediately rechecked Alyssa Shinn's order and discovered the zinc overdosing, and thereafter she took her concerns to Mr. Yu's attention. At approximately 6:15 a.m. on November 9, 2006, Mr. Yu contacted the NICU and ordered that Alyssa Shinn's TPN be immediately discontinued, which it was. Mr. Yu thereafter contacted the managing pharmacist for Summerlin Pharmacy, Gretta Woodington, and the poison

control center and began internet research to determine whether there was an antidote for a zinc overdose. The possible antidote was determined to be EDTA. Some time after 8:00 a.m., when Mr. Yu went off shift and left Summerlin Pharmacy, a compounded order for EDTA was received from a private retail pharmacy and was administered to Alyssa Shinn.

15. Unfortunately, the EDTA did not reverse Alyssa Shinn's overdose. At approximately 4:20 p.m. on November 9, 2006, Alyssa Shinn was declared dead. The Clark County Coroner ruled that the cause of Alyssa Shinn's death was zinc intoxication.

16. At hearing, Ms. Woodington testified that she took over in July 2006 as the seventh managing pharmacist in approximately four years as a result of being hired as a consultant when Summerlin Hospital made the transition from a contract operator of the pharmacy to Summerlin retaking management of the pharmacy. Ms. Woodington testified that she had been reviewing and changing all of the pharmacy's operations and that, unfortunately, review and changes to the TPN compounding process had not yet made it to her attention by November 8 2006 because of other issues she had been reviewing and dealing with. Ms. Woodington testified that the day after Alyssa Shinn's death, November 10, 2006, she conducted a root-cause analysis regarding the error. As a result of the error, she instituted several changes in policy. One change was to add "hard stops" and "medium stops" into the BAXA devices computer programming. A "hard stop" would not allow pharmacy personnel to go forward with the compounding because the amount of a component was too high. A "medium stop" would require pharmacist review and intervention before the order could be further processed because the amount of a component had crossed a threshold indicating that the amount should be questioned. Ms. Woodington also changed the policy regarding TPNs to require that trace minerals be manually added and no longer included in the BAXA compounding. Ms. Woodington also changed Summerlin Pharmacy's policy and procedure regarding the final verification of a TPN by a pharmacist so that the pharmacist is now required to review the entire order and compare the order with the printout and label from the BAXA device. Finally, Ms. Woodington explained that Summerlin Hospital changed the Neonatal TPN Order form so that all of the routine components of a neonatal TPN were required to be written consistently with the templates contained in the BAXA device so that all physicians ordering neonatal TPNs must now write the orders in a way that no recalculation by pharmacy or nursing staff will be required.

17. Ms. Shinn told the Board that she is a practicing nurse of many years' experience, so she understood medically what had happened with her throughout her and her husband's attempts to conceive, the complications with her pregnancy, and Alyssa's medical condition. Ms. Shinn testified that she and Richard had determined to start a family and that their first pregnancy terminated by miscarriage. Ms. Shinn explained that Alyssa was conceived as the result of a lengthy and costly process of in vitro fertilization and that her pregnancy was difficult and complicated. Alyssa was born prematurely by caesarian section because of medical complications that threatened Ms. Shinn's and Alyssa's life. When Alyssa was born, she was one pound, four ounces. Ms. Shinn explained that up to November 8, 2007, Alyssa was progressing well. Alyssa was able to breathe without a respirator, had just begun consuming some milk provided by Ms. Shinn, and had gained almost three-fourths of a pound. Thus, according to Ms. Shinn, up until the zinc overdose, all signs regarding Alyssa seemed to be positive.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter because Respondents Goff, Rezvan, and Yu are pharmacists licensed by the Board, Respondent Cornelius is a pharmaceutical technician registered with the Board, and Summerlin Pharmacy is a pharmacy licensed with the Board.

2. In entering the amount of zinc for Alyssa Shinn's TPN order incorrectly by entering the order for milligrams instead of micrograms, Ms. Goff violated NRS 639.210(4) and NAC 639.945(1)(i).

3. In failing to catch the one thousand times overdosing of zinc on the label prepared by Ms. Goff for Alyssa Shinn's TPN order when verifying the accuracy of Ms. Goff's data entry regarding the order, Ms. Rezvan violated NRS 639.210(4) and NAC 639.945(1)(i).

4. In failing to verify the correctness of the entirety of Alyssa Shinn's TPN order as prepared by and presented to him by Ms. Cornelius, especially where the label and bag size would have reasonably indicated that the order might be incorrect, Mr. Yu violated NRS 639.210(4) and NAC 639.245(1)(b) and (c), 639.252(1), 639.467(3), 639.475(2)(d), and 639.945(1)(i).

5. In establishing and enforcing the policies and procedures and in owning and operating the pharmacy in which all of the above factual allegations and legal violations occurred, Summerlin Pharmacy violated NRS 639.210(4) and NAC 639.945(1)(i).

6. The Third Cause of Action is dismissed.

ORDER

Based upon the foregoing, the Board hereby orders the following regarding the Respondents in this matter:

1. Ms. Goff shall pay a fine of \$5,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.
2. Ms. Rezvan shall pay a fine of \$2,500.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.
3. Mr. Yu shall pay a fine of \$2,500.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.
4. Summerlin Pharmacy shall pay a fine of \$10,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.
5. Summerlin Pharmacy shall pay the Board's costs and attorney's fees of \$12,467.38 and the Board's administrative fee of \$295.00, for a total of \$12,762.38 by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" to be received by the Board's Reno office within 90 days of the effective date of this Order.
6. The licenses of Ms. Rezvan and Mr. Yu shall each be suspended for 30 days commencing August 22, 2007 and ending September 21, 2007. During the period of suspension, neither Ms. Rezvan nor Mr. Yu may work in any capacity in any business or facility licensed or registered by this Board.
7. Ms. Goff, Ms. Rezvan, and Mr. Yu shall each participate in the Your Success Rx pharmacist's remedial program (hereinafter "the program") according to the terms and conditions imposed by the program. Each shall contact the program within ten days of the effective date of this Order to arrange for her or his participation in the program.
 - a. Each pharmacist shall cooperate fully and genuinely with the needs, demands, and requirements of the program.
 - b. Each pharmacist shall inform and assure that her or his employing pharmacy is made aware of his participation in the program and that her or his employing pharmacy accommodates the program's needs regarding her or his time needed to participate in the program and the program's potential need to be present in the employing pharmacy.
 - c. Each pharmacist shall pay the costs of her or his participation in the program. After receiving an invoice from Your Success Rx, Board Staff shall pay the invoice and shall inform the pharmacist of the amount due for the invoice, which the pharmacist shall pay to the Board by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" within 30 days of being notified by Board Staff of the amount due.
 - d. When each pharmacist has completed the program, the program shall submit to Board Staff a final report regarding each's participation in the program. Board Staff may set an item on the Board's subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board's agenda, the pharmacist may be required by Board Staff to be present for the Board's discussion, which may be held in open or closed session at the discretion of the Board.
 - e. Mr. Yu shall complete 10 hours of continuing education specifically addressed to parenteral nutrition or error prevention. The hours of continuing education shall be completed before Mr. Yu renews his pharmacist's license and shall be in addition to the continuing education hours required for renewal of his license.
8. Ms. Goff's pharmacist's license shall be on probation for a period of one year from the effective date of this Order, during which probation she shall comply with all laws related to the practice of pharmacy, whether state or federal and whether statutory or regulatory.
9. Summerlin Pharmacy shall participate in the Your Success Rx pharmacist's remedial program (hereinafter "the program") according to the terms and conditions imposed by the program. Summerlin Pharmacy shall contact the program within ten days of the effective date of this Order to arrange for its participation in the program.
 - a. The purpose of the program's involvement with Summerlin Pharmacy is to review the pharmacy's policies and procedures, working conditions, staffing, and actual operations so that the program can assess and analyze the present operations, make findings regarding

the quality of the present operations, and make recommendations regarding the present operation to improve its safety and service in the public interest.

b. Summerlin Pharmacy and all of its personnel shall cooperate fully and genuinely with the needs, demands, and requirements of the program. Summerlin Pharmacy shall make available to the program any documents, access to personnel, or use of the facilities as the program deems necessary to complete the program's work under this Order.

c. Summerlin Pharmacy shall assure that its personnel are made aware of its participation in the program and that it and its personnel accommodate the program's needs regarding the time needed to participate in the program and the program's potential need to be present in the employing pharmacy.

d. Summerlin Pharmacy shall pay the costs of its participation in the program. After receiving an invoice from Your Success Rx, Board Staff shall pay the invoice and shall inform Summerlin Pharmacy of the amount due for the invoice, which Summerlin Pharmacy shall pay to the Board by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" within 30 days of being notified by Board Staff of the amount due.

e. When the program has completed its work regarding Summerlin Pharmacy, the program shall submit to Board Staff a final report regarding its findings and recommendations. Board Staff shall set an item on the Board's subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board's agenda, appropriate and knowledgeable members of Summerlin Pharmacy or management for Summerlin Hospital may be required by Board Staff to be present for the Board's discussion, which may be held in open or closed session at the discretion of the Board. The Board retains its jurisdiction to order further action regarding Summerlin Pharmacy based upon the recommendations from the program, which additional action shall be part of the agenda item regarding the program's report to the Board.

f. One year from the program's completion of its report, the program shall revisit Summerlin Hospital under the same terms and conditions as are set out in this Order to assess and analyze whether the recommendations made in the report have been implemented and whether the pharmacy is operating safely and in the public interest. The program shall submit a report to the Board at the completion containing its findings and recommendations, if any. Board Staff shall set an item on the Board's subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board's agenda, appropriate and knowledgeable members of Summerlin Pharmacy or management for Summerlin Hospital may be required by Board Staff to be present for the Board's discussion, which may be held in open or closed session at the discretion of the Board. The Board retains its jurisdiction to order further action regarding Summerlin Pharmacy based upon the recommendations from the program, which additional action shall be part of the agenda item regarding the program's report to the Board.

g. The program may, in its discretion, employ such experts or consultants as it deems necessary to complete the evaluation, analysis, and reporting required of the program by this Order. Such costs of experts or consultants will be included as part of the program's invoice.

10. The failure by any pharmacist to comply with any term in this order shall result in the immediate suspension of her or his license and will also result in further discipline, up to and including revocation of the her or his license. The failure by Summerlin Pharmacy to comply with any term in this order shall result in a fine of \$1,000 per day for every day that it has failed to comply with the Order until the Order is fully complied with, up to a total fine not to exceed \$30,000, and will also result in further discipline, up to and including revocation of the its license.

Signed and effective this 9th day of August, 2007. J. David Wuest, J. David Wuest, President, Nevada State Board of Pharmacy.

LESSONS FROM THE SHINN CASE

The Shinn case is based on a relatively common pharmacy error; an overdose caused by the use of incorrect units of measure. The pharmacy system uses very similar designations to describe very different volumes of drug. The written appearance of "mcg" and "mg" are simply not different enough to alert pharmacists to a difference between an ordered drug and a prepared drug, and this distinction can mean the difference between the life and death of the patient. It is a setup for failure. Eventually, no matter how careful a pharmacist is, there will be a mistake of "mg" for "mcg" and a calculation will be made in error. Recognizing the inevitability of error in the system, it is essential to implement checks and balances that will detect and absorb errors when they occur so that patients do not

suffer as the result of errors.

In the Shinn case, the error was not detected by a checking pharmacist. A second checking pharmacist also failed to note the original error. An inexperienced technician could have thought twice about the large volume of a trace element being used, but the technician had no frame of reference within which to become concerned. Other errors that should be addressed to learn and improve from this case are the acceptance of a physician's order that had been written contrary to hospital policy (quantity per volume rather than quantity per weight) and undertaking to provide a service at a time when hospital policy had established that the service would not be available due to the lack of adequately trained personnel.

The fines assessed by the Board of Pharmacy and the suspensions/probations of the pharmacists will serve as notice to pharmacists in Nevada that the Board takes seriously its role as a public health protection agency. The training mandated for the pharmacists and for the pharmacy will give them the knowledge and skills necessary to modify their system so that errors of this kind can be detected and absorbed in the future. The lack of direct discipline of the pharmacy technician is standard in situations such as this one, because state boards of pharmacy often lack the ability to impose disciplinary action on pharmacy technicians. Pharmacists who supervise pharmacy technicians are generally held liable for the errors of technicians. That approach could change if proposed federal legislation directed toward pharmacy technicians is passed.

PROPOSED FEDERAL LEGISLATION TO PROFESSIONALIZE PHARMACY TECHNICIANS

Although not passed in the 2008 legislative session, momentum is gathering behind a piece of federal legislation that will be reintroduced in the new session and would provide economic incentives to states that adopt requirements for pharmacy technicians to enhance the ability and accountability of those who function in that role. This legislation is technically known as the "Pharmacy Technician Training and Registration Act of 2008." It is commonly referred to as "Emily's Act," because the catalyst for it is the death of 2-year-old Emily Jerry, following the administration of a last round of chemotherapy just to assure that her cancer was completely cured. Instead, the treatment killed her. A pharmacy technician at Rainbow Babies and Children's Hospital mixed Emily's chemotherapy drug with a saline solution 26 times above normal. The pharmacist on duty did not catch the error. Soon after getting the drug, Emily was on life support. She died three days later, on March 1, 2006. The purpose of the legislation is to reduce errors of this type.

As you read the proposed legislation, ask yourself whether the findings of the Congress are accurate based on your knowledge and experience. Also ask yourself whether the approach suggested by the legislation will achieve the objectives sought. Might it be possible to anticipate any unintended adverse consequences of the legislation?

EMILY'S ACT

110th Congress, 2nd Session, IN THE HOUSE OF REPRESENTATIVES, AS INTRODUCED IN THE HOUSE, H.R. 5491, 2008 H.R. 5491; 110 H.R. 5491.

SYNOPSIS

A bill to amend the Public Health Service Act to authorize grants to States to establish and implement programs for registering pharmaceutical technicians

DATE OF INTRODUCTION: February 26, 2008, **SPONSOR(S):** Sponsor and Cosponsors as of 02/26/2008, LaTourette, Steven C. (R-OH) – Sponsor, Lynch, Stephen (D-MA) – Cosponsor, Burton, Dan L. (R-IN) – Cosponsor, Porter, Jon (R-NV) – Cosponsor.

TEXT

HR 5491 IH, 110th CONGRESS, 2d Session, H. R. 5491.

To amend the Public Health Service Act to authorize grants to States to establish and implement programs for registering pharmaceutical technicians.

IN THE HOUSE OF REPRESENTATIVES

February 26, 2008

Mr. LATOURETTE (for himself, Mr. LYNCH, and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce.

A BILL

To amend the Public Health Service Act to authorize grants to States to establish and implement programs for registering pharmaceutical technicians.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Pharmacy Technician Training and Registration Act of 2008' or as '**Emily's Act**'.

SEC. 2. FINDINGS.

The Congress finds as follows:

- (1) Common pharmacy technician tasks include calling doctors to authorize prescription refills, putting medications into prescription containers, entering prescriptions into computers, typing drug labels, and, in many States, mixing drugs from raw materials, preparing intravenous solutions, and even preparing chemotherapy treatments.
- (2) There are few State and no Federal requirements for formal training or certification of pharmacy technicians, according to the Bureau of Labor Statistics (BLS).
- (3) Employment of pharmacy technicians is expected to grow much faster than the average rate for all occupations through 2014, because, according to the Bureau of Labor Statistics, as the population grows and ages demand for pharmaceuticals will increase dramatically.
- (4) About 7 out of 10 of pharmacy technician jobs are in retail pharmacies, grocery stores, department stores, or mass retailers, according to the Bureau of Labor Statistics.
- (5) About 2 out of 10 pharmacy technician jobs are in hospitals, according to the Bureau of Labor Statistics.
- (6) Millions of medication doses are dispensed annually at hospitals, and a February 2006 study on hospital dispensing errors by the Joint Commission Journal on Quality and Patient Safety found that pharmacists failed to detect more than 20 percent of all filling errors made by pharmacy technicians.
- (7) The MEDMARX Data Report released in January 2008 revealed that more than 1,400 commonly used drugs are involved in medication errors linked to drug names that look or sound alike. This study reviewed more than 26,000 records from 2003 to 2006. This result is nearly double the number of pairs that were identified in the previous report on this topic in 2004.
- (8) Since 1992, the Food and Drug Administration has received more than 20,000 voluntary reports of medication errors.

SEC. 3. STATE PHARMACEUTICAL TECHNICIAN REGISTRATION PROGRAMS.

Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

'Subpart XI—Pharmaceutical Technicians

'SEC. 340H. STATE PHARMACEUTICAL TECHNICIAN REGISTRATION PROGRAMS.

'(a) Grants.—The Secretary of Health and Human Services may make grants to States to establish and implement a pharmaceutical technician registration program described in subsection (b).

'(b) Registration Program Description.—A pharmaceutical technician registration program described in this subsection is a program under which—

'(1) the State prohibits an individual from performing the duties of a pharmaceutical technician in such State unless the individual is registered by the State Board of Pharmacy to perform such duties; and

'(2) as minimum requirements for such registration, the State requires the individual—

'(A) to have attained a secondary school diploma or its recognized equivalent;

'(B) to be certified by the Pharmacy Technician Certification Board; and

'(C) to have—

'(i) attained an associate's degree in pharmacy technology;

'(ii) completed a course of training for pharmaceutical technicians accredited by the American Society of Health-System Pharmacists; or

'(iii) graduated from a school of pharmacy recognized by the State Board of Pharmacy.

'(c) Annual Reporting on Pharmaceutical Technician Errors.—As a condition on the receipt of a grant under this section, a State shall agree to submit an annual report to the Secretary of Health and Human Services on pharmaceutical technician errors in the State.

'(d) Transitional Period for Practicing Technicians.—A State receiving a grant under this section may provide a transitional period for individu-

als who began practicing as pharmaceutical technicians before the date of the enactment of this section to comply with the requirements of the registration program under this section.

(e) Definitions.—In this section:

(1) The term ‘State Board of Pharmacy’ means the regulatory body empowered by the State to regulate the pharmaceutical practice, including granting registrations to and disciplining individuals and companies.

(2) The term ‘pharmacy technician’ means an individual who assists a pharmacist in the performance of his or her pharmacy-related duties.

(3) The term ‘secondary school’ has the meaning given to such term in section 9101 of the Elementary and Secondary Education Act of 1965.

(4) The term ‘Secretary’ means the Secretary of Health and Human Services.’.

SEC. 4. SENSE OF CONGRESS.

It is the sense of the Congress that State Boards of Pharmacy should strive to ensure—

(1) a ratio of 2 pharmaceutical technicians to each pharmacist in hospital settings; and

(2) a ratio of 3 pharmaceutical technicians to each pharmacist in other settings, including drug stores.

SIGNIFICANCE OF THE EMILY’S ACT PROPOSED LEGISLATION

There is no question that, if passed, Emily’s Act will improve the quality of pharmacy technicians and will reduce the exposure to liability of pharmacists for pharmacy technician errors. The Act sets the bar relatively high for the education of technicians, who would have to complete a program leading to an associate’s degree or complete a similar program with a designated professional organization or a recognized school of pharmacy. Requiring training at this level will undoubtedly increase the compensation necessary for pharmacy technicians. While there will be concerns expressed about the costs association with this increased compensation, those expressing concerns will have to explain why the reduction in errors does not justify the cost.

CONCLUSION

The problem of pharmacy errors is a complex one. No single solution will solve it. State boards of pharmacy will continue to find ways to punish those who err, and to require educational activities directed toward the implementation of error prevention systems. The United States Congress has taken an interest in the matter, and that interest can be expected to continue. Working together, pharmacists and pharmacy technicians will improve the systems in which they work to meet the responsibility they share for the provision of high quality pharmaceutical products and services.

TOPICS FOR 2009

Pharmacy Waste	Update on the HPV Vaccine
Herbals	Commonly Acquired MRSA
Cholesterol Management	Update: Chronic Fatigue Syndrome & Fibromyalgia
Current Status of Hormone Replacement Therapy	Review & Update on Immunizations
Contemporary Parkinson’s Therapy	

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe responsibilities of pharmacists & technicians regarding errors Yes No

Discuss the facts & implications of the Shinn Case Yes No

Describe how pharmacy boards can react to pharmacy errors Yes No

List components of the proposed federal legislation known as Emily's Act Yes No

Discuss advantages & disadvantages of increased legal requirements for technicians Yes No

2. Was the program independent & non-commercial Yes No

	Poor		Average			Excellent
	1	2	3	4	5	6 7

3. Relevance of topic

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Please Select the Most Correct Answer

1. Under the "captain of the ship" mentality, who has generally been considered responsible for an error in pharmacy?

- A. Supervising pharmacist
- B. Pharmacy technician
- C. The pharmacy
- D. Board of Pharmacy

2. In the Shinn Case, how much more drug than ordered was included in the compounded drug product?

- A. 2 times more
- B. 10 times more
- C. 100 times more
- D. 1,000 times more

3. How many vials of zinc did the pharmacy technician use in compounding the TPN for the patient in the Shinn Case?

- A. 3 – 5
- B. 7 – 10
- C. 22 – 25
- D. 45 – 48

4. In the Shinn Case, the pharmacist who was supposed to have checked the calculations stated that she did not notice "mg" rather than "mcg." This pharmacist also did not place her initials on the label sets.

- A. True
- B. False

5. Who was disciplined in the Shinn Case?

- A. Pharmacists only
- B. Pharmacists & pharmacy only
- C. Pharmacists & pharmacy technician only
- D. Pharmacy & pharmacy technician only

6. The hospital where the Shinn Case occurred has now changed procedures so that physician orders are written in a way that does not require pharmacy recalculation

- A. True
- B. False

7. According to Congressional findings in the proposed Emily's Act legislation, more than what percent of all prescription filling errors made by technicians are not detected by a pharmacist?

- A. 5 %
- B. 10%
- C. 15%
- D. 20%

8. According to the Bureau of Labor Statistics, about what percent of technician jobs are in retail pharmacies, grocery stores, department stores or mass retailers?

- A. 60%
- B. 70%
- C. 80%
- D. 90%

9. According to the proposed Emily's Act legislation, all technicians will eventually have to obtain an associate's degree in pharmacy technology.

- A. True
- B. False

10. According to the proposed Emily's Act legislation, state boards of pharmacy should strive to ensure a ratio of 2 technicians for each pharmacist in hospital settings.

- A. True
- B. False

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