

Tennessee Board of Pharmacy
Board Meeting
May 12, 2014

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
May 12, 2014

BOARD MEMBER PRESENT

Nina Smothers, D.Ph., Vice President
Charles Stephens, D.Ph.
R. Michael Dickenson, D.Ph.
Kevin Eidson, D.Ph.
Will Bunch, D.Ph.
Joyce McDaniel, Consumer Member

STAFF PRESENT

Reggie Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Jane Young, General Counsel
Terry Grinder, Pharmacist Investigator
Tommy Chrisp, Pharmacist Investigator
Sheila W. Bush, Administrative Manager
Michelle Long, Assistant Commissioner
Valerie Nagoshiner, Legislative Liaison

BOARD MEMBER ABSENT

Jason Kizer, D.Ph., President

STAFF PRESENT ELECTRONICALLY

Rebecca Moak, Pharmacist Investigator
Scott Denaburg, Pharmacist Investigator
Andrea Miller, Pharmacist Investigator

The Tennessee Board of Pharmacy convened on Monday, May 12, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 12:104 p.m.

Agreed Order

New England Compounding Center

Barry Cadden

Ms. Young presented to the board a proposed settlement agreement and order from New England Compounding Center and Barry Cadden. New England Compounding Center voluntarily surrendered their Tennessee pharmacy license on October 12, 2012 and Barry Cadden surrendered his Tennessee pharmacist license on October 20, 2012. The board along with the Division of Health Related Boards sought a civil penalty assessment pursuant to T.C.A. § 63-1-134(a) and T.C.A. § 63-10-305, as well as assessment of costs pursuant to T.C.A. § 63-1-144, pursuant to T.C.A. § 63-10-309, for asserted violations of Tenn. Comp. R. & Regs. No. 1140-01-.08, Tenn. Comp. R. & Regs. Nos. 1140-03-.08, 1140-03.03, 1140-03-.14(8), 1140-03-.14(14), 1140-03-.06 and 1140-01-07-.05. Ms. Young explained that the consent orders signed by New England Compounding Center and Barry Cadden surrendering their Tennessee licenses provided an opportunity to bring an action for imposition of civil penalties. New England Compounding Center has entered into a Chapter 11 bankruptcy on December 12, 2012. The Division has agreed to a five (5) million dollar settlement filed in the bankruptcy court and he claim is subordinate for purposes of distribution and voting to the claims of tort claimants and other general unsecured creditors of NECC. Dr. Bunch asked if this settlement will interfere with the victims claim. Ms. Young stated that it will not. Ms. McDaniel asked if the settlement included

cost accrued during the investigation. Ms. Young stated that the five (5) million dollar settlement represents all cost associated with this case. Dr. Eidson stated that he is concern that New England Compounding Center and Mr. Cadden did not admit fault. Mr. William West, Attorney for New England Compounding Center, stated that the language is standard and that when you do a settlement and have other cases pending it would be inappropriate for Mr. Cadden or the bankruptcy trustee to admit any liability. If they did it would affect a number of issues that they have going on such as insurance issues and the victim's financial recompense going forward in the bankruptcy court. Mr. West stated that if they board accepts the settlement then the other proceedings are dropped and the focus shifts to the individual claimant in the bankruptcy court. Dr. Eidson stated that there is nothing in the settlement order that states that unprofessional or unethical conduct and he is really concerned about it. He asked Ms. Young how this is protecting the public and is the board protecting the public with this settlement. Ms. Young stated that she thinks that it does protect the public and stated that the language in the order is in every order that they present. She stated that the order is making a statement in protecting the public and that Tennessee is the only state requesting a civil penalty. Dr. Dickenson stated that he would like a statement to be release that states the reasons why the board made the decision that was made and to move forward to give relief to the victims and their families. Ms. McDaniel asked if the department can release a statement listing the statement of facts in the settlement agreed order. Ms. Young stated that the department can issue a statement with all the charges listed along with the references to the laws that have been broken. After further discussion, Dr. Bunch made the motion to accept the proposed settlement and for the Department of Health to issue a press release Dr. Dickenson seconded the motion. The motion carried. Dr. Stephens abstained.

Rules

Ms. Young asked the board to authorize a rulemaking hearing for the emergency rules to become permanent rules. There have been no changes to the rules. Ms. Young explained that the emergency rules will expire on July 30, 2014. The rulemaking process requires that a rulemaking hearing take place at least 45 business days after the filing of the rules with the Secretary of State. The rules must first be approved by the Governor's Office. She stated that she has spoken with the Governor's office and has already sent the rules to the Governor's office for a quick turnaround. Once the rules have been approved by the Governor's office they will file them with the Secretary of State's office. If the rules are filed today a rulemaking hearing will be scheduled for July 7, 2014. After the rulemaking hearing the rules will be sent to the Attorney General's Office and once they have been approved and filed with the Secretary of State they will become effective 90 days thereafter. Ms. Young apologize to the board for the delay in requesting a rulemaking hearing causing a gap of roughly 2 months before the rules will be effective. Since the emergency rules had a fee increase that was used to hire additional pharmacy investigators the gap will effective the revenue for next fiscal year. After discussion, Dr. Eidson made the motion to authorize a rulemaking hearing with the rules as presented. Dr. Stephens seconded the motion. The motion carried.

The meeting adjourned at 1:00 p.m.

Tennessee Board of Pharmacy
Board Meeting
May 12, 2014

The minutes were approved and ratified as amended at the May 28-29, 2014 board meeting.