## COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BEFORE THE STATE BOARD OF MEDICINE

Commonwealth of Pennsylvania

Bureau of Professional and

Occupational Affairs

STANDARD OF CARE CASE

¥5.

Docket No./490 -49-06 File No. 05-49-07744

Roy Eugene Kerry, M.D.,

Respondent

## ORDER TO SHOW CAUSE

, 2006, Roy Eugene Kerry, M.D., (Respondent) is AND NOW, this day of hereby ORDERED TO SHOW CAUSE why the State Board of Medicine (Board), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's license, certificate, registration or permit, or impose a civil penalty. This action is brought pursuant to the Medical Care Availability and Reduction of Error (MCARE) Act, Act of March 20, 2002, P.L. 154, No. 13, 40 P.S. §§1303.101-1303.910 and the Medical Practice Act of December 20, 1985, P.L. 457, No. 112, as amended, (Act), 63 P.S. §422.1 et seq., and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§501-508, 701-704, 63 P.S. §§2201-2207; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date of this Order stated above, in accordance with 1 Pa. Code §35.37.

## **FACTUAL ALLEGATIONS**

- 1. Respondent holds a license to practice medicine in the Commonwealth of Pennsylvania, License No. MD-008220E.
  - 2. Respondent is 68 years old.
- 3. Respondent's license is active through December 31, 2006, and may be renewed thereafter upon the filing of the appropriate documentation and payment of the necessary fees.
- 4. At all times pertinent to the Factual Allegations, Respondent held a license to practice medicine in the Commonwealth of Pennsylvania.
- 5. Respondent's last known address on file with the Board is 17 Sixth Avenue, Greenville, PA 16125.

#### COUNT ONE

- 6. Paragraphs 1 through 5 are incorporated by reference.
- 7. On July 22, 2005, Abu Bakar Tariq Nadama, a child, (hereafter referred to as Tariq) came under the care of Respondent.
  - 8. Respondent is not a pediatrician.
- 9. Respondent treated Tariq from the Offices of the "Advanced Integrative Medicine Center" in Pennsylvania.
  - 10. These offices are located in Greenville and Portersville.
- 11. Advanced Integrative Medicine Center (hereafter "AIM") advertises itself to the public.
- 12. AIM claims in its advertisement that "along with providing chelation therapy...the
  Center also provides...the latest modalities in diagnosing and treating illness."
  - 13. Tariq was a 5-year-old boy during the course of treatment prescribed by Respondent.

- 14. Tario died on August 23, 2005.
- 15. The medical chart of Tariq, maintained by Respondent, contains a notation that reads "current complaint".
- 16. The current complaint notation reads "wants to have iv...edta injection...an iv push.mother states Tariq is autistic due to immunization shots he was a normal pregnancy...1st shots were given the day he was born...no sx noted until age 18 mo...has had 12 other inoculation bu time he was 18 mo old/..."
- 17. The medical chart of Tariq, maintained by Respondent, contains a notation entitled "constitutional".
  - 18. The entry for constitutional reads that Tariq is a "very energetic child...."
- 19. The medical chart of Tariq maintained by Respondent contains a notation entitled neurological.
  - 20. The entry for neurological reads that Tariq is a "Happy child"..."
- 21. The July 22, 2005 entry in Tariq's medical chart reads, "We don't have the entire record at all. Mother left her entire volume of his records home. But we have been in communication with Dr. Usman regarding EDTA therapy. He apparently has a very high aluminum and has not been responding to other types of therapies and therefore she is recommending EDTA, which we do on a routine basis with adults. We therefore checked him to it...But on testing for the deficiency indicator we find him only indicating the need for EDTA at the present time. Therefore we agree with Dr. Usman's recommendation to proceed with the treatment. She recommends 50mg per kilo. He is 42 pounds today. So we'll treat him as a 20-kilo child and give 1 gram of EDTA. We diluted it 1:1 with saline. Started the IV with saline. After a good blood flow in the right antecubital fossa with 3 other assistants and mother controlling him

and the papoose board. Had a good IV return flow. We then introduced the EDTA. Checked return flows frequently during administration. Gave the IV over approx. 5 minutes. Then rinsed with saline. He had no difficulty toleration it. No infiltration occurred. We'll have mother collect the urine for 12 hours. The most important are the first 6 hours for toxic and essential minerals. When we get that report back we'll proceed with further injections as indicated on approx. a weekly basis. Recheck the levels in 4-6 IV's depending on his response...Intial Impression: Autistic Syndrome, Heavy Metal Toxicity, Candidiasis, Multiple Food Allergies...Roy E. Kerry, M.D."

- 22. Respondent performed chelation therapy on Tariq on July 22, 2005.
- 23. Tariq received the chelation in a five to ten minute intravenous "push" (hereafter referred to as "IV push").
- 24. An IV push is when all of the medication is placed into the patient's intravenous line at once.
  - 25. The IV push facilitates fast delivery of drugs into the body of the patient.
  - 26. The chelating agents used by Respondent bind with heavy metals such as lead.
- 27. These agents mobilize metals in the body and enhance urinary excretion of metals thus decreasing the levels of these metals in the body of the patient.
- 28. Respondent used a form of Ethylene diamine tetraacetic acid (hereafter referred to as EDTA), in chelating Tariq.
- 29. As a drug used in intravenous or chelation therapy, EDTA is sold in two separate formulas.
  - 30. One formula is sold as Edetate Disodium (hereafter referred to as Disodium EDTA).
  - 31. Tariq received chelation therapy on three occasions as ordered by Respondent.

- 32. Respondent prescribed or ordered Disodium EDTA to chelate Tariq.
- 33. A typical insert from the drug manufacturer of the drug Endrate is attached hereto and incorporated by reference as Exhibit 1.
- 34. Diosodium EDTA is a sterile solution of the disodium salt of the synthetic chemical, ethylenediamine tetraacetic acid (EDTA), and water for injection.
- 35. Disodium EDTA injections are indicated in selected patients for the emergency treatment of hypercalcemia and in control of ventricular arrhythmias associated with digitalis toxicity.
- 36. Disodium EDTA increases excretion of heavy metals and, importantly, minerals, such as calcium.
  - 37. Tariq was not diagnosed with hypercalcemia.
  - 38. Tariq was not diagnosed with digitalis toxicity.
- 39. The second formula of EDTA is Edetate Calcium Disodium (hereafter referred to as CaNa2EDTA).
- 40. CaNa2EDTA is Edetate Disodium with added calcium to counter the risks associated with Disodium EDTA.
- 41. CaNa2EDTA is indicated for the reduction of blood levels and depot stores of lead in order to treat lead poisoning (acute and chronic) and lead encephalopathy in both pediatric populations and adults.
  - 42. Respondent never treated Tariq with CaNa2EDTA.
- 43. A physician who previously treated Tariq, recommended treatment with CaNa2EDTA as recently as June 2005.
  - 44. Respondent obtained a "post provocative" urine sample from Tariq on July 22,2005.

- 45. A "post provocative" sample is a urine sample taken after the patient has been subject to drug therapy or chelation.
- 46. The laboratory report of this sample was completed on July 29, 2005 and sent to Respondent.
- 47. This laboratory report listed Tariq's lead level as "elevated" but not in the" very elevated" reference range.
- 48. It should be noted that this laboratory report has a notation in bold print that reads "Reference ranges are representative of a healthy population under non-challenge or non-provoked conditions."
  - 49. Tariq had a minimal elevation of his lead level.
- 50. The result of Tariq's urine test also revealed a marked depletion in the iron present in Tariq's body.
- 51. Controlled studies have shown a correlation between learning problems and low iron levels in children.
- 52. Respondent subjected Tariq to a second round of Disodium EDTA chelation on August 10, 2005.
- 53. In Tariq's medical chart, for the date August 10, 2005, Respondent writes, "The last IV EDTA produced 15mcg of lead level per gram of Creatinine. We really expected a higher output. Recommend repeating the IV again. Use the 1 gram of EDTA...on the next IV we'll do another collection...IV given in the right antecubital fossa with no difficulty over about a 5-minute span. He gets a little sleepy afterwards and then he recovers in about 5 minutes. Recheck in 2 weeks."
  - 54. Theresa Bicker, a medical assistant employed by Respondent, stated she

administered the Disodium EDTA on the second treatment on August 10, 2005.

- 55. The Respondent ordered this second treatment.
- 56. Respondent was in attendance during the August 10, 2005 round of Disodium EDTA chelation.
- 57. The August 10, 2005 chelation treatment was administered by a five to ten minute IV push.
- 58. On August 23, 2005, a third and final round of Disodium EDTA chelation therapy was administered to Tariq.
  - 59. Theresa Bicker administered the IV Disodium EDTA to Tariq.
- 60. Bicker requested Doctor Mark Lewis, D.O., to come to the treatment room to help restrain Tariq for the IV push of Disodium EDTA.
  - 61. Respondent was not present when Tariq received chelation on August 23, 2005.
  - 62. Theresa Bicker administered the Disodium EDTA pursuant to Respondent's orders.
- 63. Tariq's medical chart for August 23,2005 reads "TV push ordered per Dr. Kerry and his protocol....prior to procedure patient was alert and oriented. No acute distress. Mother was present in room...."
  - 64. During the IV push, Tariq's mother, Marwa Nadama said that something was wrong.
  - 65. Doctor Lewis took Tariq's vitals and then Tariq went limp.
  - 66. Bicker called 911 and helped with CPR while the ambulance was en route.
  - 67. Tariq was taken by ambulance to Butler Memorial Hospital.
  - 68. On August 23, 2005, at Butler Memorial Hospital, Tariq was pronounced dead.
- 69. Respondent spoke to Professional Conduct Investigator of the Bureau of Enforcement and Investigation concerning his treatment of Tariq.

- 70. Respondent admitted that EDTA is "pretty rare to use on children".
- 71. Respondent admitted to using Disodium EDTA to chelate Tariq.
- 72. Respondent stated to Investigator Reiser that Disodium EDTA is the only formula of EDTA he stocks in his office.
- 73. Respondent admits that CaNa2EDTA is available but that he has never used this agent.
- 74. Respondent admits that he used the IV push because he did not believe that Tariq would be able to remain still and tolerate the one and ½ hours it takes to have the IV drip complete and therefore he administered the drug via IV push.
  - 75. An Autopsy was performed on Tariq's body.
- 76. The opinion of the Chief Forensic Pathologist is that "Abu Bakar Tariq Nadama, a 5 year old African-American male, died as a result of diffuse, acute cerebral hypoxic-ischemic injury, secondary to diffuse subendocardial myocardial necrosis. Myocardial necrosis is a result of hypocalcemia due to administration of EDTA."
- 77. Disodium EDTA carries the risk of upsetting the electrolyte balance of the blood in that it removes calcium, magnesium, zinc and other trace metals and causes potassium excretion.
  - 78. This effect has the potential to cause cardiac arrhythmias, seizures and death.
- 79. Disodium EDTA carries a warning for the health care professional using the drug on a patient.
- 80. This warning reads "rapid intravenous infusion or attainment of high serum concentration of edentate disodium may cause a precipitous drop in the serum calcium level and may result in fatality. Toxicity appears dependent upon both total dosage and speed of administration...the rate of administration and dosage should not exceed that indicated in Dosage

and Administration."

- S1. The Dosage and Administration instructions for administering Disodium EDTA to children reads, "The intravenous infusion should be regulated so that three or more hours are required for completion and the cardiac reserve of the patient is not exceeded."
- Based upon the foregoing Factual Allegations, the Board is authorized to suspend revoke, or otherwise restrict Respondent's license or impose a civil penalty under 63 P.S. § 422.41(8), 49 Pa Code Section 16.61(a)(6) in that Respondent engaged in unprofessional conduct in that he practiced medicine with negligence on repeated occasions when Respondent, did any or all of the following acts, administered and/or prescribed and/or ordered the administration of Disodium EDTA to Tariq in an IV push despite the warnings that 1) this method of administration of the drug can be lethal to the patient and 2) the drug used was the incorrect formula of EDTA in that it did not contain calcium.

## **COUNT TWO**

- 84. Paragraphs 1 through 83 are incorporated by reference.
- 85. Based upon the foregoing Factual Allegations, the Board is authorized to suspend or revoke, or otherwise restrict Respondent's license or impose a civil penalty under 63 P.S. § 422.41(8) and 40 P.S. Section 1303.908 in that Respondent breached the standard of care in that he ordered IV push chelation therapy using the drug Disodium EDTA on a five year old patient. The above actions were done despite the fact, among others, that the drug used was the wrong type, the method of administration was inherently dangerous and the patient had a minimally elevated lead level. Due to these acts, Respondent departed from a quality standard of his profession.

## COUNT THREE

- 86. Paragraphs 1 through 85 are incorporated by reference.
- The Board is authorized to suspend or revoke, or otherwise restrict Respondent's license, or impose a civil penalty under 40 P.S. sections 1303.905 and 1303.908 in that Respondent was negligent in the care of Tariq because Respondent breached the standard of care when he did any or all of the following acts, 1) practiced medicine negligently by repeatedly ordering chelation by way of IV push of Tariq with the drug Disodium EDTA when there are specific warnings not to rapidly infuse a pediatric patient, 2) used Disodium EDTA to chelate Tariq for metal toxicity which should be treated with CaNa2EDTA instead, and 3) he treated his patient with EDTA when this type of EDTA it was not indicated in the first place.

#### **COUNT FOUR**

- 88. Paragraphs 1 through 87 are incorporated by reference.
- The Board is authorized to suspend or revoke, or otherwise restrict Respondent's license, or otherwise restrict Respondent's license or impose a civil penalty under 63 P.S. § 422.41(8) and 49 Pa Code Section 16.61(a) (3) in that Respondent engaged in unprofessional conduct in that he performed a medical act incompetently or performed a medical act which the physician knows or has reason to know that he is not competent to perform, in that Respondent did all or any of the following; used chelation therapy for a pediatric patient for heavy metal toxicity, did not use the correct drug and did not order administration of the drug in a manner which would ensure the safety of his patient.

#### COUNT FIVE

- 90. Paragraphs 1 through 89 are incorporated by reference.
- 91. The Board is authorized to suspend or revoke, or otherwise restrict Respondent's

license, or otherwise restrict Respondent's license or impose a civil penalty under 63 P.S. § 422.41(8) and 49 Pa Code Section 16.61(a) (3) in that Respondent engaged in unprofessional conduct in that he performed a medical act incompetently or performed a medical act which the physician knows or has reason to know that he is not competent to perform, in that Respondent did use Disodium EDTA to chelate Tariq for metal toxicity that should be treated with CaNa2EDTA.

### COUNT SIX

- 92. Paragraphs 1 through 92 are incorporated by reference.
- 93. The Board is authorized to suspend or revoke, or otherwise restrict Respondent's license, or otherwise restrict Respondent's license or impose a civil penalty under 63 P.S. § 422.41(8) and 49 Pa Code Section 16.61(a) (3) in that Respondent engaged in unprofessional conduct in that he performed a medical act incompetently or performed a medical act which the physician knows or has reason to know that he is not competent to perform, in that Respondent treated his patient with EDTA when this type of EDTA it was not indicated in the first place.

#### **PENALTIES**

If the Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's license, the Board may, in its discretion, impose one or more of the following penalties:

The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in

the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action which the Act authorizes the Board to impose.

The imposition of a civil penalty of up to ten thousand dollars (\$10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

#### **PROCEDURES**

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§501-508, 701-704; 63 P.S. §§2201-2207; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§31.1-35.251. RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE OF THIS ORDER. The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which he or she may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of this Order. IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THIS ORDER.

RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A

# HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in accordance with 1 Pa. Code §35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with:

Deanna S. Walton, Prothonotary Department of State 2601 North Third Street Harrisburg, PA 17110 717-772-2686

Also, you must send a separate copy of the Answer, and any other pleadings or documents, to the prosecuting attorney named below at:

P.O. BOX 2649 HARRISBURG, PA 17105-2649 Notices and petitions to intervene must be filed within thirty (30) days of the date of this Order, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

# BY ORDER:

DEPARTMENT OF STATE LEGAL OFFICE

Andrew E. Demarest
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P.O. Box 2649
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DATE: 9-8-06