[Cite as *Ellahi v. Ohio Dept. of Mental Retardation & Dev. Disabilities,* 2012-Ohio-1243.]

Court of Claims of Ohio
The Ohio Judicial Center
65 South Front Street, Third Floor
Columbus, OH 43215
614.387.9800 or 1.800.824.8263
www.cco.state.oh.us

FRANKIE ELLAHI, Admx.

Plaintiff

v.

OHIO DEPARTMENT OF MENTAL RETARDATION AND DEVELOPMENTAL DISABILITIES

Defendant

Case No. 2009-08268

Judge Joseph T. Clark

DECISION

{¶1} Plaintiff, Frankie Ellahi, administrator of the estate of Michael Hornung, brought this action alleging wrongful death and medical negligence. The case was tried to the court on the issues of both liability and damages.

{¶2} Plaintiff's decedent[1] was a resident at the Montgomery Developmental Center (MDC) from September 23, 2002 until his death on October 17, 2008. Defendant owns and operates MDC, a facility that provides residential care and treatment for the mentally disabled.

{¶3} Michael was born in 1983 to parents who were mentally retarded. Tests showed that Michael had an IQ of 40, meaning that he was substantially mentally retarded as well. Plaintiff, Michael's grandmother, was granted custody of Michael and raised him until he was 18 years old. In addition to mental retardation, Michael suffered from behavioral disorders which caused him to act aggressively at times. At

[1]Michael Hornung shall be referred to as "Michael" throughout this decision.

approximately age 18, Michael was placed in a supported living program through the Butler County Board of Mental Retardation and Developmental Disabilities (MRDD). During the time that Michael was residing in a group home, he was sexually abused by a home health aide. Michael was traumatized by the abuse: he became more aggressive and began harming himself which led to his hospitalization on several occasions. In 2002, Michael was placed at MDC.

{¶4} Michael continued to exhibit signs of aggression at MDC, striking out both at staff and at other residents. Michael also tried to escape from MDC on multiple occasions. Beginning in 2003, Michael began treating with Dr. Sanders, the staff psychiatrist at MDC.[2] Dr. Sanders examined each patient at MDC at least once per year. Dr. Sanders also conducted quarterly medication reviews with MDC staff during which time each patient's medication regimen was evaluated. MDC patients did not attend the medication reviews.

{¶5} Dr. Sanders was Michael's psychiatrist at MDC from 2003 to 2008. During that time, Dr. Sanders diagnosed Michael with moderate mental retardation, disruptive behavior disorder, and "rule out post traumatic stress disorder." Dr. Sanders prescribed olanzapine, also known as Zyprexa, a drug which is FDA-approved to treat schizophrenia and other psychotic disorders. The FDA-recommended dosage of olanzapine is 20 milligrams per day.

{¶6} As of October 17, 2008, Dr. Sanders had prescribed the following psychiatric medication to treat Michael's condition: 40 milligrams of olanzapine, 20 milligrams of Haldol, and 1500 milligrams of Depakote per day.

{¶7} On the morning of October 17, 2008, Michael was found unresponsive in his bed. CPR was initiated but was not successful. An autopsy was performed by the

[2]The parties stipulate that Dr. Sanders was an employee of defendant as those terms are used in R.C. 2743.02 and 109.36(A)(1)(b).

Montgomery County Coroner's office. The cause of death was stated as: "gastric material aspiration due to olanzapine intoxication."

{¶8} Plaintiff asserts that defendant was negligent when it prescribed olanzapine in a manner that was "off-label," meaning that it was prescribed in a dosage that exceeded the FDA recommend dosage, and that olanzapine was not specifically recommended to treat Michael's condition. Plaintiff further asserts that defendant was negligent when Dr. Sanders failed to develop a proper care plan for Michael to prevent olanzapine intoxication, including the failure to monitor Michael for signs of such intoxication. Plaintiff also asserts that defendant's nursing staff was negligent when it failed to perform 15-minute bed checks on Michael as required per its own policy.

{¶9} Defendant admits that its staff failed to "bed check" Michael on the morning of October 17, 2008, from 12:00 a.m. to 2:00 a.m. However, defendant contends that neither the administration of olanzapine to Michael nor its failure to check on him for two hours proximately caused his death.

{¶10} "To maintain a wrongful death action on a theory of negligence, a plaintiff must show (1) the existence of a duty owing to plaintiff's decedent, (2) a breach of that duty, and (3) proximate causation between the breach of duty and the death." *Littleton v. Good Samaritan Hosp. & Health Ctr.*, 39 Ohio St.3d 86, 92 (1988), citing *Bennison v. Stillpass Transit Co.*, 5 Ohio St.2d 122 (1966), paragraph one of the syllabus.

{¶11} In order to establish medical malpractice, it must be shown by a preponderance of evidence that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under like or similar conditions and circumstances, and that the injury complained of was the direct and proximate result of such doing or failing to

do some one or more of such particular things. *Bruni v. Tatsumi*, 46 Ohio St.2d 127 (1976), paragraph one of the syllabus.

{¶12} It is well-established that "[t]he coroner's factual determinations concerning the manner, mode and cause of death, as expressed in the coroner's report and the death certificate, create a nonbinding rebuttable presumption concerning such facts in the absence of competent, credible evidence to the contrary. (R.C. 313.19, construed.)" *Vargo v. Travelers Ins. Co.*, 34 Ohio St.3d 27 (1987), paragraph one of the syllabus.

{¶13} Kent Harshbarger, M.D., J.D., deputy coroner for Montgomery County, testified that he performed the autopsy on Michael and opined that the cause of death was gastric material aspiration due to olanzapine intoxication. Dr. Harshbarger explained that normally, if an individual vomits in his sleep, he wakes up. However, Dr. Harshbarger opined that Michael did not wake up because the sedating effect of the medication that he was taking prevented him from doing so. Thus, Michael aspirated gastric material into his lungs and then died. Dr. Harshbarger explained that when he performed the autopsy, he obtained blood samples from both the femoral artery and the liver, and that the samples showed that Michael had a "toxic" level of olanzapine in his bloodstream. Dr. Harshbarger also stated that plaintiff may have suffered a seizure before his death, but that there was no way to state with certainty from an autopsy whether a seizure occurred.

{¶14} On cross-examination, Dr. Harshbarger testified that he does not prescribe medications in his practice; that this case was the first time that he had cited olanzapine intoxication as a cause of death; and that he had to consult medical literature to make a finding that the level of olanzapine found in Michael's bloodstream was toxic. Dr. Harshbarger noted that in his search of the literature, he found that some individuals who had much higher levels of olanzapine in their blood than Michael did had survived. However, Dr. Harshbarger also stated that the level of olanzapine in Michael's bloodstream was hundreds of times higher than therapeutic levels.

{¶15} Plaintiff testified that she visited Michael one time at MDC during his 6 years of residency there, and that she did not visit him more frequently due to her ill health and inability to afford transportation to and from MDC. According to plaintiff, she did, however, speak to Michael two to three times per week over the telephone. Plaintiff testified that at times during her telephone conversations with Michael she felt that he was "over-medicated" because he mumbled his words.

{¶16} Robin Lindsly and Rae Jean Williams, both of whom were aunts of Michael, testified that they also spoke to Michael on occasion when plaintiff called him. Williams also testified that at times Michael sounded "groggy" to her.

{¶17} Debra Leger testified that she worked the 2:15 to 10:45 p.m. shift 5 days per week as a Therapeutic Program Worker (TPW) at MDC, that she was Michael's primary care giver, and that Michael was like "family" to her. Leger described Michael as higher functioning than some of the other residents, that he liked music, that he liked to help with cleaning and other chores, that he got along well with the other residents and that he liked the staff. Leger acknowledged that Michael had impulsive behavior and would sometimes hit people. Leger stated that she never witnessed Michael being "overly tired" unless he was ill. According to Leger, during the week before Michael's death, he was his normal, "happy-go-lucky" self. Leger described the evening of Michael's death as follows: that he helped with dinner, then took a shower, then at approximately 7 or 7:30 p.m. he went to his room to listen to music. Leger stated that she checked on him at 10:15 p.m. before she left for home and that he was sleeping at that time. Leger stated that when she was informed of Michael's death the following day, she was "shocked."

{¶18} Stephanie Johnson testified that she had been a TPW at MDC since 2005; that Michael was more independent than other residents; that during the week before he died, Michael was in a happy mood; and that during her last check of his room before

she left work on October 17, 2008, Michael was in his bed masturbating. Johnson stated that when she learned that Michael had died she was "dumbfounded."

{¶19} Richard Sanders, M.D., testified that he has been both licensed to practice medicine in Ohio and board-certified in general psychiatry since 1994. Dr. Sanders explained that MDC cares for patients with an IQ of less than 50 who have behavior problems that make them unmanageable in other places. Per his contract, Dr. Sanders worked at MDC approximately two days per week. Dr. Sanders explained that the TPWs work directly with the residents, and that they make direct, anecdotal observations that are recorded on a shift summary basis. Dr. Sanders noted that MDC also employs nurses and a full-time primary care physician.

{¶20} With regard to medications, Dr. Sanders stated that when a patient arrives at MDC, he initially examines the list of medications that a patient is taking and begins a process of elimination to see whether the medications and their dosage levels are effective and appropriate. Dr. Sanders explained that he performs an annual psychiatric evaluation for each patient at least one time per year, during which time he observes the patient, interviews the patient if he is verbal, and talks to the direct care workers to obtain their impressions of the patient. Dr. Sanders testified that when Michael was admitted to MDC, he was taking a variety of medications including olanzapine, Haldol, and Depakote. Dr. Sanders tried to vary the dosages and types of medications for Michael, but he was eventually placed on tranquilizers to try to improve his behavior.

{¶21} Dr. Sanders explained that with MRDD patients, making a firm diagnosis of their condition is difficult. Dr. Sanders diagnosed Michael with "disruptive behavior disorder, unspecified." Dr. Sanders added that once a patient is diagnosed, a psychiatrist then tries to find medications to help with that disorder. When Michael arrived at MDC, he was taking 30 milligrams per day of olanzapine. From December 2003 to May 2007, Michael was prescribed 40 milligrams per day of olanzapine. In May 2007, Dr. Sanders lowered Michael's dosage of olanzapine to 20 milligrams per day

because Michael was suffering from tremor. Dr. Sanders explained that he had hoped to replace olanzapine with Seroquel, another anti-psychotic drug. However, after two and a half months, the tremor did not improve, and Michael broke his toe in a fit of rage. Dr. Sanders reasoned that a reduction in olanzapine resulted in more agitation, so he then prescribed olanzapine at 40 milligrams per day from July 2007 through October 2008.

{¶22} Dr. Sanders described "off-label" as prescribing medications for indications not specified in the Physicians' Desk Reference, which is approved by the FDA. Dr. Sanders stated that it is within the standard of care to prescribe drugs off-label when nothing else is working for the patient. Dr. Sanders added that there was no medication that was FDA approved to specifically treat aggression in a mentally retarded adult with disruptive behavior disorder.

{¶23} According to Dr. Sanders' notes, in 2007 during his annual exam, Michael was angry during his interview, asking questions such as "[w]ho are you and what are you doing?" In his 2008 interview, Dr. Sanders testified that Michael gave perfunctory responses to his questions, but Dr. Sanders added that he did not perceive Michael to be overly-tired or overly-medicated.

{¶24} On cross-examination, Dr. Sanders testified that 20 milligrams per day is the recommended dose of olanzapine; that side effects of olanzapine include drowsiness and sedation; that Haldol can also cause drowsiness and sedation; that Michael was on more than one anti-psychotic drug; and that Dr. Sanders was dissatisfied with the efficacy of Michael's medications.

{¶25} Plaintiff's expert, Robert P. Granacher, Jr., M.D., M.B.A., testified that he is board certified in general, geriatric, and forensic psychiatry, neuropsychiatry, and clinical psychopharmacology. Dr. Granacher stated that he prescribes anti-psychotic medication such as olanzapine and Haldol, and anti-epilepsy drugs such as Depakote.

{¶26} Dr. Granacher testified that in comparing Michael's annual exam from 2007 to 2008, Michael had become much "quieter." According to Dr. Granacher, Michael did not talk as much, was not as alert, and seemed more sedated and lethargic in 2008. Dr. Granacher's basis for this conclusion was that Dr. Sanders used the term "minimally responsive" when he described Michael in the 2008 evaluation.

{¶27} Dr. Granacher explained that olanzapine is prescribed to treat two types of psychosis: bipolar illness and schizophrenia. However, Michael was not diagnosed with either disorder. Dr. Granacher stated that the risk of aspiration increases with anti-psychotic drugs because they affect the ability to swallow and cough, and they also increase the risk of seizures.

{¶28} Dr. Granacher opined that one of three things happened to Michael: 1) that excess sedation which was caused by the medications that he was prescribed produced obstructive sleep apnea, resulting in the loss of Michael's airway; 2) that Michael's peptic ulcer disease was aggravated by the high doses of medication, which in turn caused him to vomit, aspirate his vomit and die of respiratory failure; or 3) that the drugs that he was prescribed caused a cardiac arrhythmia, which resulted in ventricular tachycardia, which led to Michael vomiting and then aspirating vomit into his lungs. In Dr. Granacher's opinion, Michael was too sedated to wake up when he vomited due to olanzapine intoxication. Dr. Granacher explained that medical literature states that a toxic blood level of olanzapine is above 160 nanograms per milliliter, and that the coroner found that Michael had 440 nanograms per milliliter in one area of his body and 280 nanograms per milliliter in another area. Dr. Granacher described the lethal blood level of olanzapine as between 240 and 5000 nanograms per milliliter.

{¶29} Dr. Granacher opined that Dr. Sanders' prescription of 40 milligrams of olanzapine, 20 milligrams of Haldol, and 1500 milligrams of Depakote per day was not within the standard of care. Dr. Granacher explained that it is within the standard of care to prescribe a drug off-label but that the dosage level of twice the recommended

dosage was not within the standard of care. Dr. Granacher further stated that Dr. Sanders did not meet the standard of care when he prescribed excessive doses of drugs in a medically incompetent patient. Dr. Granacher stated that it is "obvious" that the excessive dosage of medication caused Michael to be unable to protect his airway. Dr. Granacher further stated that the clinical signs of olanzapine intoxication were the variances in Michael's appearance between the 2007 annual review and the 2008 annual review. However, Dr. Granacher noted that an individual can be intoxicated from olanzapine without showing any signs or symptoms.

{¶30} Dr. Granacher stated that Dr. Sanders should have sent Michael for further medical testing, including seeing a sleep specialist. Dr. Granacher also stated that Dr. Sanders should have sent Michael's blood for testing to see if there were excessive levels of olanzapine. On cross-examination, Dr. Granacher stated that this was the first case in which he had testified regarding a death caused by olanzapine.

{¶31} Defendant's expert, Heath Jolliff, D.O., testified that he was board-certified in emergency medicine and medical toxicology. Dr. Jolliff is employed by the Adena Medical Center in Chillicothe, Ohio and by the Central Ohio Poison Center at Children's Hospital in Columbus, Ohio. Dr. Jolliff also maintains a full-time medical toxicology practice where he treats patients in various hospitals in Columbus. Dr. Jolliff stated that he prescribes medications such as olanzapine and Haldol.

{¶32} In regard to his work for this case, Dr. Jolliff stated that he performed a literature search regarding toxicity of olanzapine and found 51 articles about it worldwide. Dr. Jolliff stated that he found a case study of an individual who had died solely of olanzapine overdose and that the level of olanzapine in that individual's bloodstream was twice the level that was found in Michael's bloodstream.

{¶33} Dr. Jolliff opined that Michael did not die as the result of olanzapine toxicity. Dr. Jolliff stated that when a patient is suffering from toxicity from a drug, the patient will show an elevated level of that drug in the bloodstream as well as signs or symptoms of

impairment. Upon review of Michael's documented daily activities in the week before his death, Dr. Jolliff noted that the TPW notes did not show any evidence of lethargy or sedation. Dr. Jolliff also opined that Dr. Sanders' use of the off-label dosage of olanzapine was within the standard of care for a patient such as Michael. Dr. Jolliff noted that there have been studies with individuals who have been prescribed 80 milligrams of olanzapine per day, and that he has treated patients who had been prescribed higher daily doses of olanzapine than Michael had been prescribed. Dr. Jolliff further opined that olanzapine did not contribute to Michael's death but rather that the proximate cause of his death was gastric content aspiration. Dr. Jolliff also opined that the medical literature does not support the theory that olanzapine toxicity was a proximate cause of Michael's death. Dr. Jolliff explained that post-mortem levels of drugs in the bloodstream are always higher than ante-mortem levels. Dr. Jolliff opined that the high level of olanzapine that was identified in Michael's bloodstream was the result of post-mortem redistribution, which he described as a phenomenon whereby a medication that has been prescribed to a patient over a long period of time begins to store itself in areas of the body, and that upon death, those drugs "leak" into the bloodstream, resulting in a toxic medication level. Dr. Jolliff added that the administration of CPR can also increase the level of medication found in the bloodstream. Dr. Jolliff opined that the more probable explanation for Michael's death was that he suffered a seizure, which led to aspiration.

{¶34} On cross-examination, Dr. Jolliff stated that he was not qualified to opine on the psychiatric standard of care; his opinions relate solely to the cause of Michael's death. However, he added that he is qualified to testify as an expert with regard to drug dosing. Dr. Jolliff agreed that sedation can be a reason for not waking up once a person starts to vomit.

{¶35} The court allowed the record to be held open for plaintiff to submit the testimony of Stephen R. Payne, M.D., as a rebuttal witness with regard to whether

Michael had suffered a seizure shortly before his death.[3] Dr. Payne testified that he is a primary care internist who cares for adult patients. Dr. Payne opined that he did not believe that Michael suffered a seizure shortly before his death because there was no physical evidence, such as lacerations of the tongue from biting, consistent with a seizure. Dr. Payne further stated that Michael was also taking what he considered to be a therapeutic dose of anti-convulsant medication at the time of his death. Lastly, the very high level of olanzapine that was found in Michael's bloodstream and his liver during the autopsy caused Dr. Payne to believe that the chance of Michael suffering from a seizure that caused aspiration was unlikely.

{¶36} On cross-examination, Dr. Payne stated that any patient of his who has seizures is referred by him to a neurologist to treat seizures, and that he does not prescribe olanzapine, Haldol, or Depakote in his practice.

{¶37} Upon review of the evidence, the court finds that plaintiff has failed to prove that defendant breached the standard of care. Plaintiff's expert, Dr. Granacher, was not particularly persuasive to the court. Specifically, Dr. Granacher's testimony that Michael was lethargic, sedated, and minimally responsive in a general sense is not supported by the evidence. Although Dr. Sanders used the phrase "minimally responsive" to describe Michael's responses to his questions during his 2008 annual review, the court finds that Michael led an active life immediately prior to his death. Indeed, the court finds that the testimony of the TPWs, who interacted with Michael on a daily basis, was credible as to Michael's activity level prior to his death. The greater weight of the evidence shows that Michael was able to help perform chores and that he had been active in the days prior to his death, in stark contrast to Dr. Granacher's depiction of him as being sedated and showing objective signs of olanzapine intoxication.

[3]Upon review of the deposition of Dr. Payne, all objections contained therein are OVERRULED.

{¶38} Furthermore, the court finds that Dr. Sanders met the standard of care when he prescribed olanzapine "off-label." The court finds that Dr. Sanders evaluated Michael's medication regimen during quarterly reviews after carefully balancing the risk of his aggressive behavior and the side effects of the medications. The medical records show that Michael was prescribed a static dose of olanzapine, 40 milligrams per day, from July 2007 through October 2008, and that the 40 milligram dosage improved his violent behavior. The greater weight of the evidence shows that Michael tolerated olanzapine well and that he did not show objective signs or symptoms of olanzapine intoxication. It is difficult for the court to believe that the prescription of a static dose of olanzapine for approximately 15 months proximately caused Michael's death. The court finds that Dr. Jolliff's opinion that Michael's death was most likely caused by a seizure was more credible than Dr. Granacher's testimony regarding the cause of Michael's death. Moreover, the court finds that Dr. Payne's testimony was not particularly persuasive. Therefore, the court cannot find that either Dr. Sanders or any of defendant's other employees failed to meet the standard of care in this case.

{¶39} Defendant admits that its staff failed to "bed check" Michael on the evening of October 17, 2008 from 12:00 a.m. to 2:00 a.m., which was a violation of its policy to check on patients every 15 minutes. However, failure to comply with internal regulations in itself does not constitute negligence. *Williams v. Ohio Dept. of Rehab. & Corr.*, 67 Ohio Misc.2d 1, 3 (Ct. of Cl.1993). Plaintiff has not proven to the court that defendant's failure to check on Michael during that time period was a breach of the standard of care. The court further finds that defendant's failure to perform 15-minute bed checks was not a proximate cause of Michael's death. For the foregoing reasons, the court finds that plaintiff has failed to prove any of her claims by a preponderance of the evidence and, accordingly, judgment shall be rendered in favor of defendant.

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Defendant

Case No. 2009-08268

Judge Joseph T. Clark

JUDGMENT ENTRY

{¶40} This case was tried to the court on the issues of liability and damages. The court has considered the evidence and, for the reasons set forth in the decision filed concurrently herewith, judgment is rendered in favor of defendant. Court costs are assessed against plaintiff. The clerk shall serve upon all parties notice of this judgment and its date of entry upon the journal.

_____
JOSEPH T. CLARK
Judge

cc:

Eric A. Walker
Assistant Attorney General
150 East Gay Street, 18th Floor
Columbus, Ohio 43215-3130

Eric P. Allen
2200 Kroger Building
1014 Vine Street
Cincinnati, Ohio 45202

HTS/dms
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