

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN**

HEATHER SIMCAKOSKI,)
PERSONALLY AND AS SPECIAL)
ADMINISTRATOR OF THE ESTATE)
OF JASON SIMCAKOSKI, AND)
ANAYA SIMCAKOSKI,)

Plaintiffs,)

v.)

UNITED STATES OF AMERICA,)

Defendant.)

Civil Action No.: 16-CV-591

AMENDED COMPLAINT

JURISDICTION AND VENUE

1. The plaintiffs bring this medical malpractice and wrongful death action against defendant United States of America under the Federal Tort Claims Act, 28 U.S.C.A. § 1346(b).

2. This court has jurisdiction over the subject matter of this complaint pursuant to 28 U.S.C.A. §§ 1331 and 1346(b).

3. On September 3, 2015, plaintiffs submitted an Administrative Tort Claim (“the tort claim”) to the United States Department of Veterans Affairs (“the VA”).

4. Representatives of the VA repeatedly assured the plaintiffs that the VA intended to take full responsibility for the death of Jason Simcakoski. VA officials repeatedly told the plaintiffs that the tort claim would be carefully evaluated and taken seriously. Yet, nearly one year after the tort claim was filed, no meaningful response has been forthcoming.

5. Last August, the Tomah VA facility's Acting Director, John Rohrer, said at a news conference, "We accept responsibility for any action or inaction that contributed to this man's death." The VA has failed to follow its words with deeds.

6. Nearly a year having elapsed since the submission of the claim to the VA, and no meaningful response having been received, the claim has been denied. The plaintiffs have therefore exhausted all available administrative remedies.

7. Venue is properly in this district court under 28 U.S.C.A. § 1402(b) as the acts that are the subject matter of this complaint occurred within the Western District, in Monroe and Portage Counties, Wisconsin.

8. At all times material hereto, David Houlihan, M.D., Ronda Davis, M.D., and any and all other VA employees, executives, administrators, agents and apparent agents involved in the negligent acts and omissions alleged herein, were acting within the scope and course of their employment with the VA and, as such, defendant United States of America is the appropriate defendant pursuant to the Federal Tort Claims Act.

9. At all times material to this complaint, Dr. Houlihan, Dr. Davis, the pharmacists, nurses, health care providers, and the other agents and apparent agents involved in the negligent acts and omissions alleged herein were health care providers as defined by Chapter 655 of the Wisconsin Statutes.

PARTIES

10. Plaintiff, Heather Simcakoski, is an adult resident of the State of Wisconsin and the Special Administrator of the Estate of Jason Simcakoski. Plaintiff Heather Simcakoski resides at 1301 West River Road, Stevens Point, Wisconsin 54481.

11. Heather Simcakoski was appointed Special Administrator of the Estate of

Jason Simcakoski by order of the Portage County Circuit Court on September 11, 2015, with the powers normally given to a fully appointed Personal Representative.

12. Anaya Simcakoski is the minor child of Heather and Jason Simcakoski residing at 1301 West River Road, Stevens Point, Wisconsin 54481.

13. Heather Simcakoski, Anaya Simcakoski and Jason Simcakoski at all times material hereto were citizens of the United States.

14. Jason Simcakoski was a United States Marine, honorably discharged on February 23, 2002.

FACTUAL ALLEGATIONS

15. Jason Simcakoski (“Jason”) was a patient of the VA health care facilities from 2006 through 2014 for a variety of health care conditions including mental health related issues.

16. On August 10, 2014, Jason was admitted to the Tomah VA Acute Psychiatric Unit.

17. On August 14, 2014, Jason was transferred to the Short Stay Mental Health Recovery Unit in the Tomah VA’s Community Living Center. He continued receiving treatment there until the time of his death.

18. On August 28, 2014, Jason met with Rhonda Davis, M.D. and a social worker. At that meeting, Dr. Davis recommended starting Jason on a prescription of Suboxone, which is a combination of the active ingredients Buprenorphine and Naloxone. Dr. Davis consulted with David Houlihan, M.D., who agreed with starting Suboxone at a dosage of 8 mg Buprenorphine/2 mg Naloxone two times daily, the maximum recommended dose for day one of a Suboxone prescription.

19. Dr. Davis prescribed Suboxone to “alleviate Jason’s chronic pain and potentially decrease his overall level of anxiety without having the potential for addiction as had been a problem for him previously.” This is an off-label use of Suboxone.

20. Dr. Davis and Dr. Houlihan never informed Jason that they were prescribing Suboxone for an off-label use. Nor was Jason informed of the risks of initiating Suboxone treatment in any respect.

21. Suboxone is FDA-approved to treat patients with opioid dependence. Jason Simcakoski was not, at the time of this prescription, dependent on opioids.

22. Dr. Davis was not authorized to prescribe Suboxone to patients.

23. At the time Suboxone was ordered, given the other drugs Jason was receiving, the dispensing pharmacist should have warned the prescribing physician that the Suboxone prescription, together with the other drugs Jason was prescribed, results in a series of potentially fatal drug interactions.

24. At the time the Suboxone was ordered, given the other drugs Jason was receiving, the dispensing pharmacist should have refused to fill the Suboxone prescription or taken other steps to protect Jason from the drug interactions.

25. The recommended initiating dose of Suboxone should not exceed Buprenorphine 8 mg/Naloxone 2 mg for the first day.

26. Jason Simcakoski was given three doses of Buprenorphine 8 mg/Naloxone 2 mg within a 24-hour period, 300% of the maximum allowed initial dosage.

27. At the time the Suboxone was prescribed and administered to Jason, no adjustments were made to the other drugs prescribed to him at that time. The drugs administered to Jason from August 29 through August 30 are set forth in Exhibit 1, attached

hereto and incorporated by reference herein.

28. At approximately 8:30 a.m. on August 30, 2014, Jason's family visited him. Jason's father, Marv Simcakoski spoke with Jason. Marv was concerned because Jason was so sedated he could barely speak. Marv reported Jason's condition to the nurse on duty. The nurse told Marv that Jason would be alright in a few hours. She was wrong. This would be the last time anyone in Jason's family saw him alive.

29. At approximately 1:10 p.m., Jason was observed by a VA nursing staff member to be asleep and snoring, lying on his side and facing the door of his room. Jason had not gotten up for lunch. He had not taken his noon medications.

30. At approximately 2:45 p.m., August 30, 2014, a nursing staff member found Jason unresponsive.

31. Cardiopulmonary resuscitation was not initiated for approximately 10 minutes after Jason was found unresponsive, only beginning at 2:55 p.m.

32. Defibrillation was not commenced for approximately 24 minutes after Jason Simcakoski was found unresponsive.

33. Emergency responders did not arrive until approximately 20 minutes after Jason was found unresponsive.

34. Resuscitation efforts were unsuccessful and Jason was pronounced dead at 3:39 p.m.

35. The Monroe County Medical Examiner determined that Jason's cause of death was mixed drug toxicity.

36. A subsequent Office of Inspector General report found that the additive respiratory depressant effects of Buprenorphine and its metabolite NorBuprenorphine,

together with Diazepam and its metabolites as prescribed to Jason Simcakoski were the plausible cause of his death.

37. The Inspector General's report found no evidence that written informed consent for the Suboxone treatment was obtained from Jason Simcakoski.

38. According to the Inspector General's report both physicians involved in the prescription of Suboxone acknowledged that they failed to discuss the risks inherent in the treatment with Jason.

39. The Inspector General found that after Jason was found unresponsive, delays occurred in the initiation of CPR, calling for emergency medical assistance, and in applying defibrillator pads.

40. The Inspector General's report noted that the Tomah VA lacked medications useful in emergencies to reverse effects of drug overdose (such as Naloxone and Flumazenil) at the time of Jason's death.

41. Jason's death followed years of attempts by Jason and his family to obtain proper mental health care for Jason from the VA. Among Jason's mental health afflictions were bipolar disorder, depression and substance abuse.

42. The VA failed to diagnose and treat Jason's underlying bipolar illness which led to years of periodic psychotic mania, racing thoughts, sleeplessness, delusions and vivid, violent fantasies.

43. Jason's depression was never adequately addressed by the VA, leaving him in states of torpor, hopelessness and worthlessness.

44. Had Jason been properly diagnosed for his bipolar disorder and depression he could have been treated with mood stabilizers and anti-depressants, allowing him to lead

a normal and productive life.

45. For the last years of his life, Jason and his family repeatedly sought help from the VA for competent diagnosis and treatment of his substance abuse problem.

46. Jason's family repeatedly questioned whether Jason was receiving competent mental health care from the VA, particularly the large amounts of medication Jason was prescribed and how it was administered. These concerns were ignored or dismissed.

47. Rather than take constructive steps to diagnose and treat Jason's substance abuse problem, VA providers allowed him to influence his choice and level of drugs, to have access to drugs of abuse, to consume a month's supply in a week or two and to struggle with his family members over control of medication at home.

48. The VA, at times, would even send opioids and other drugs to Jason's home through the mail, allowing him to have access to large amounts of opioids even though he had a known opioid abuse problem.

49. The VA allowed an atmosphere of fear and intimidation to prevail at its Tomah Medical Center, causing medical professionals to be unwilling or unable to question the orders of Dr. Houlihan, despite the fact that many of Dr. Houlihan's orders were contrary to the applicable standard of care.

50. In a recent deposition, current VA employee and whistleblower, Noelle Johnson, PharmD, BCACP, testified regarding the drug combination prescribed and dispensed to Jason Simcakoski. Dr. Johnson said, "In my clinical opinion as a pain pharmacist, I would say that, yes, they should not have been prescribed in the dosages in which they were. Not the full regimen, but particular parts of the combination, and they should not have been dispensed as a pharmacist."

51. Dr. Johnson further testified that the medication combination prescribed and dispensed to Jason Simcakoski did not follow evidence-based guidelines or the standard of care.

52. Dr. Johnson also testified that systemic problems led to the over prescription of medications to Jason Simcakoski, including VAMC pharmacists' fear that if they questioned Dr. Houlihan's orders, they would be in trouble, lose their jobs or suffer retaliation, and were thus afraid to question or stop the combination of drugs prescribed to Jason Simcakoski.

53. Dr. Johnson said, "I believe any pharmacist that you talk to knows the risks of these medications. These are not hard medications." According to Dr. Johnson, the Tomah VAMC pharmacists allowed the lethal drug combination to be dispensed to Jason Simcakoski because they were "fearful to stand up and say no."

54. The VA was aware of the climate of fear prevailing at the Tomah VAMC described herein because it was reported by numerous VA employees, including Dr. Johnson herself, to various officials at the VA and to others in the government on numerous occasions. The VA failed to act on these reports and failed to remedy the climate of fear.

COUNT I

55. Defendant United States of America, through its agents, employees and apparent agents failed to exercise the appropriate degree of care, skill and judgment in at least the following respects:

- a. Prescribing Suboxone and other CNS depressants to Jason Simcakoski and failing to monitor, observe, supervise, and react to the effects of the drugs Mr. Simcakoski was prescribed to ensure his

- safety;
- b. Prescribing Suboxone for an off-label use without accounting for the CNS depressive effects of Suboxone in combination with the other drugs Jason had been prescribed;
 - c. Failing to appropriately account for and respond to the known drug interactions existing between the drugs Jason was prescribed;
 - d. Failing to obtain informed consent from Jason Simcakoski for the use of Suboxone, particularly for an off-label use in combination with other CNS depressants;
 - e. Failing to appropriately account for and respond to the known drug interactions existing between the drugs Jason was prescribed at the time of his death;
 - f. Failing to provide adequate emergency care for Jason Simcakoski when he was found unresponsive, including failing to take timely and adequate steps to save his life and reverse the effects of the drugs he had been given;
 - g. Failing to adequately diagnose and treat Jason's bipolar disorder, depression and substance abuse problems; and
 - h. Dispensing the Suboxone in a lethal combination with other drugs to Jason Simcakoski through its pharmacy, despite the numerous and severe drug interactions resulting from the combination of drugs prescribed to Jason Simcakoski;
 - i. Failing to address the numerous and severe drug interactions resulting

from the combination of drugs prescribed to Jason Simcakoski; and

j. In other respects not specifically enumerated here.

COUNT II

56. The plaintiffs reallege and incorporate paragraphs 1 through 55 of their complaint as if set forth in full.

57. The mission of the VA “Was born from the immortal words of Abraham Lincoln’s second inaugural address. The Veterans Health Administration embodies the promise of a grateful nation in the form of the quality health care that veterans have earned through their service and sacrifices.”

58. The VA’s mission is “to care for him who shall have borne the battle, and for his widow and his orphan.”

59. The VA holds itself out as providing health care that “compares favorably to the best of the private sector.”

60. The VA, its administrators and executives have a duty, pursuant to the VA’s mission, covenant with veterans, statutory requirements, rules and the standard of care, to ensure the delivery of high quality health care to its patients at all times. Said officials have a duty to ensure provision of adequate staffing, funding, resources, policies and procedures necessary to the delivery of high quality health care to patients, including Jason Simcakoski.

61. The VA was negligent in failing to ensure provision of adequate staffing, funding, resources, policies and procedures necessary to deliver high quality health care to Jason Simcakoski.

62. The VA was further negligent in:

a. Failing to develop, promulgate and implement policies and

procedures to protect patients, including Jason Simcakoski from the negligent conduct complained of herein;

- b. Failing to ensure that the VA followed appropriate standards in hiring, training and supervising qualified staff to provide for the delivery of high quality health care to its patients, including plaintiff Jason Simcakoski;
- c. Failing to adequately supervise its employees, agents and apparent agents and enforce its policies and procedures;
- d. Failing to adequately train and supervise VA health care providers in responding to medical emergencies such as that suffered by Jason Simcakoski on August 30, 2014;
- e. Failing to provide adequate medical equipment including medicines to resuscitate patients suffering a medical emergency such as that experienced by Jason Simcakoski on August 30, 2014;
- f. Failing to ensure that those to whom it granted privileges, employment or permission to provide health care services to its patients were trained and competent to do so;
- g. Failing to maintain adequate staffing levels to monitor and provide health care, including emergency health care services to its patients including Jason Simcakoski;
- h. Allowing a climate of fear to develop at the Tomah VAMC deterring health care providers from disagreeing with or questioning the orders of Dr. Houlihan, including his order to dispense Suboxone in

combination with other drugs to Jason Simcakoski;

- i. Failing to have in place adequate supervision, policies, procedures and protocols to allow health care providers at the Tomah VAMC to provide medical care to patients in conformity with the standard of care without fear of retribution; and
- j. In other respects not specifically enumerated herein.

COUNT III

63. The plaintiffs reallege the allegations contained in paragraphs 1 through 62 of this complaint as if set forth in full herein.

64. By failing to inform Jason Simcakoski of the risks and benefits of the Suboxone prescription, particularly its off-label use and its use in combination with the other drugs which were prescribed to Jason Simcakoski, the VA was negligent in failing to inform Jason Simcakoski about the availability of reasonable alternate medical modes of treatment and about the risks and benefits of those alternate treatments.

65. As a direct and proximate result of the negligence as alleged in Counts I, II and III, Jason Simcakoski suffered physical and mental pain, anxiety, anguish, embarrassment, emotional distress, physical injuries and his own wrongful death.

66. As a further direct and proximate result of the negligence as alleged in Counts I, II and III, plaintiff Heather Simcakoski individually and as the Administrator of the Estate of Jason Simcakoski has suffered substantial mental and emotional pain and suffering, loss of consortium, society and companionship, economic damages including loss of support and loss of services and other economic and non-economic damages.

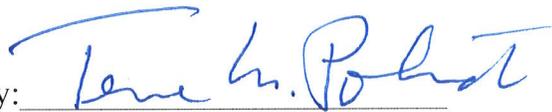
67. As a direct and proximate result of the negligence as alleged in Counts I, II and III, plaintiff Anaya Simcakoski has suffered the loss of society and companionship of her father, the loss of his support and other economic and non-economic damages.

WHEREFORE, the plaintiffs demand judgment against the defendants jointly and severally as follows:

- a. For a sum of money that will reasonably compensate the plaintiffs for damages sustained as the result of the negligence described herein, including economic and non-economic damages;
- b. For the costs, disbursements and expenses incurred by the plaintiffs in bringing this action and;
- c. For such other and further relief as this court may deem is just and equitable.

Dated this 22nd day of May, 2017

CLIFFORD & RAIHALA, S.C.

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