IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

HAROLD HOLTSHOUSER and KATHY HOLTSHOUSER, Plaintiffs, vs. UNITED STATES OF AMERICA, Defendant.	)	CV 11-114-BLG-RFC **FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER**

This matter came before the Court for trial without a jury on April 22 through 24, 2013. Plaintiffs Harold and Kathy Holtshouser were represented by Daniel B. Bidegaray. Defendant United States of America was represented by Assistant United States Attorney, Timothy J. Cavan.[1]

Witnesses were sworn and testified, and certain exhibits were offered and received into evidence. From the evidence presented, the Court makes the following:

[1]Due to short time period between the finality of trial and my retirement on May 3, 2013, a transcript of the trial was not complete or available and specific references to the trial transcript are not included in this order.

I. FINDINGS OF FACT

1. This is a negligence action brought by the plaintiffs pursuant to the Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671, *et seq*. (Dkt. 1). Plaintiffs seek to recover damages from the United States based on medication filled and dispensed to Harold Holtshouser (Holtshouser) by the Department of Veterans Affairs (VA). Id.

2. Plaintiffs allege that the VA pharmacy negligently filled and dispensed prescriptions for a drug known as Metoclopramide, which caused an abnormal movement disorder, tardive dyskinesia. Plaintiffs also allege that it aggravated Holtshouser's Parkinson's symptoms. (Final Pretrial Order (FPTO) Nature of Action).

3. At the time this action was filed, Plaintiffs were residents of the State of Montana, and lived in the City of Livingston, Park County, Montana. (Dkt. 1, p. 2).

4. Plaintiffs Harold and Kathy Holtshouser submitted an administrative tort claim with the VA on May 11, 2010. The claim form listed both Harold and Kathy Holtshouser as claimants. The Court determined that the administrative tort claim form was sufficient for both claimants.

5. Harold Holtshouser was born on February 9, 1922. (FPTO, Agreed Fact (b)). He is a veteran of the U.S. Navy, and is eligible for VA healthcare benefits. Holtshouser obtained his primary medical care from the VA at the VA Bozeman Community Based Outpatient Clinic and the VA Medical Center in Fort Harrison, Montana.

6. During the time period from 2001 through 2008, Holtshouser received his primary medical care at a VA community outpatient clinic in Bozeman. His primary care provider during that period was a nurse practitioner, Shaunna Kersten.

7. The VA pharmacy filled prescriptions and dispensed Metoclopramide to Holtshouser at various times between May 15, 2001 and May 20, 2008.

8. Holtshouser suffered from a number of complicated medical conditions. Since 1975, he has had a 100% VA disability for chronic anxiety and depression. (Ex. 74, p. 34, Bates #255[2]). Also, in addition to regularly being treated for a multitude of acute medical problems, he also suffered from a number of other chronic medical conditions, including Type II diabetes, hyperlipidemia, coronary artery disease with a history of myocardial infarction and angina, chronic

[2]Unless otherwise noted, the page number of the exhibit precedes the bates-numbered page in citation to the exhibits.

low back pain with three prior lumbar surgeries, history of cor pulmonale, degenerative arthritis, mild dimentia, severe diabetic neuropathy, renal insufficiency, gastroeophageal reflux disease with diabetic gastroparesis, hypothyroidism, spinal stenosis, and a history of asbestosis. (Ex. 74, p. 95, #316).

9. Holtshouser also required many medications for his health problems, and was generally taking more than 20 medications on a daily basis during that time period. (See e.g., Ex. 74, p. 1017-18, #1238-39).

10. Prior to 2001, Holtshouser had a 20-25 year history of acid reflux symptoms. (Ex. 74, p. 854, #1075; p. 889, #1110). In 2001, however, his reflux symptoms became particularly severe. In fact, from April 2001 until October 2001, Holtshouser received and/or sought medical care from the VA or private health care providers for his reflux symptoms on 16 occasions. (Ex. 62, p. 1-9; Ex. 74, p. 849-895, #1070-1116).

11. In April 2001, he reported to the VA that he felt burning from his mouth to his stomach. (Ex. 74, p. 850, #1071). By May 3, 2001, he complained that his acid reflux symptoms had become "really bad." (Ex. 74, p. 853, #1074). He was nauseous, and had acid burning up to his throat and burning his lips. (Ex. 74, p. 854, #1075). Consequently, a esophagogastroduodenoscopy (EGD) was ordered to evaluate his upper gastrointestinal tract, which was scheduled with the

VA surgical department on May 11, 2001. Nevertheless, he returned to the VA on May 8, 2001, and reported that he had constant burning and acid coming up into his mouth and burning his lips, and he felt he could not "take it" until his appointment. (Ex. 74, p. 863, #1084).

12. Holtshouser's EGD was performed on May 11, 2001, which did not reveal the cause of his symptoms. (Ex. 74, p. 868, #1089). Since first line therapies for acid reflux, such as H2 Blockers and PPI inhibitors, had not been effective in relieving his condition, the VA surgeon recommended that Holtshouser be put on Carafate and Reglan. (Ex. 74, p. 868, #1089). Reglan is the brand name for Metoclopramide, which is the medication at issue in this case. VA pharmacy records indicate that a prescription for Metoclopramide was issued by VA surgeon Michael Evans on May 15, 2001. (Ex. 74, p. 3610, #3835). The prescription was for 10mg, one tablet four times a day before meals and at bedtime. (Ex. 74, p. 4093, #5898).

13. It appears that Holtshouser did not immediately start the medication, and his severe reflux symptoms persisted. On May 17, 2001, he presented to the emergency room at the Livingston Memorial Hospital with complaints of continuing upper abdominal distress. (Ex. 67, p. 91). The emergency room physician noted that Holtshouser had not been on Reglan. Therefore, he also

prescribed Reglan, 10mg before meals and at bedtime, and directed him to followup at the VA. (Ex. 67, p. 91).

14. When Holtshouser's severe reflux symptoms did not resolve (Ex. 74, p. 885-891, #1106-1112), he was referred by the VA to a private gastroenterologist, Timothy Johnson, M.D. Holtshouser saw Dr. Johnson on July 12, 2001, and advised Dr. Johnson that he had experienced some improvement on Metoclopramide. (Ex. 62, p. 9). Dr. Johnson, therefore, continued to prescribe Metoclopramide. (Ex. 62, p. 8). Dr. Johnson also performed a repeat EGD and colonoscopy on September 5, 2001, which was again largely unremarkable. (Ex. 62, p. 5-6).

15. While Dr. Johnson ultimately discontinued Holtshouser's Metoclopramide prescription, he also concluded that diabetic gastroparesis was contributing significantly to his reflux and regurgitation symptoms. (Ex. 62, p. 2, 7, 8). When he was unable to manage his symptoms from the condition, however, Dr. Johnson simply referred Holtshouser back to his primary care provider at the VA on September 21, 2001. (Ex. 62, p. 2).

16. Holtshouser was seen back at the VA by NP Kersten on October 2, 2002. He reported that his reflux symptoms were actually worse overall. He could not find anything to eat, he experienced burning all of the time, and had

developed a hoarse voice. Like Dr. Johnson, NP Kersten believed that his symptoms were related to diabetic gastroparesis. (Ex. 74, p. 896, #1117). It is undisputed that Metoclopramide was an appropriate medication to treat diabetic gastroparesis and/or gastroesophageal reflux disease (GERD) in the time period from 2001 through 2008.

17. Due to the severity of Holtshouser's reflux complaints, and NP Kersten's conclusion that his symptoms were the result of diabetic gastroparesis, she continued Holtshouser's prescription for Metoclopramide. (Ex. 74, p. 895-96, #1116-17). The medication was ultimately effective in relieving Holtshouser's reflux symptoms. Holtshouser spent the winter of 2001 in Arizona, and did not complain of any reflux symptoms during his several visits to the VA in Prescott, Arizona. (Ex. 74, p. 3759-82, #5488-5511). He returned to the VA clinic in Bozeman on March 21, 2002, and reported at that time that his reflux symptoms were stable. (Ex. 74, p. 902, #1123).

18. Holtshouser's reflux symptoms remained stable during the periods he was on Metoclopramide for the next 6 years. His first prescription expired on May 9, 2002, and he was thereafter off the medication for one year, from May 2002 until May 2003. (Ex. 74, p. 3610, #3835). By May 2003, however, Holtshouser contacted the VA and again complained of "really bad acid reflux" to the extent

that it was again burning his lips. (Ex. 74, p. 980, #1201). It was noted that the surgical department had previously recommended Carafate and Reglan for the condition. (Ex. 74, p. 980, #1201). NP Kersten recommended that these medications be renewed on a trial basis for one month. (Ex. 74, p. 982, #1203). Holtshouser's reflux was to be evaluated in a followup appointment in two weeks. (Ex. 74, p. 982, #1203).

19. Holtshouser returned for a followup on June 12, 2003, and reported that his reflux was better. (Ex. 74, p. 986, #1207). He was thereafter left on the medication until December 2004, during which time he had minimal complaints of acid reflux. (Ex. 74, p. 986-1165, #1207-1386).

20. Holtshouser was again off of the medication for approximately two years from December 2004 to November 2006. (Ex. 74, p. 3610, #3835). The medication was restarted in November 2006. While the circumstances of the second renewal are not clear from the record, NP Kersten testified that it was necessarily at the request of the patient. That is, in order for a medication to be renewed, there must be a request by the patient. (Kersten Dep. 174:2-29). Thereafter, Holtshouser's reflux remained under good control, without significant complaints.

21. In all, Holtshouser was prescribed the medication during three different periods from 2001 to 2008: May 2001 to June 2002; May 2003 to January 2005; and November 2006 to May 2008. (Ex. 74, p. 3610, #3835; p. 4093-4105, #5898-5910).

22. All of the Metoclopramide prescriptions were accurately filled and dispensed by the VA pharmacy, according to the prescriptions issued by VA health care providers licensed to prescribe the medication. (Testimony of Lori Fitzgerald).

23. The VA pharmacy is largely a mail-out operation. There is a pharmacy located at the Fort Harrison VA Medical Center, but it only dispenses medications for inpatient use at the medical center, or for veterans who obtain their prescriptions on-site. Prescriptions for all other VA patients around the state are mailed to the patient. (Testimony of Lori Fitzgerald).

24. Once a prescription is issued by a physician, it is entered into the VA electronic system. A VA pharmacist will review the prescription and request that it be filled at a centralized VA dispensary in Kansas. The medication is then mailed by the dispensary to the patient's residence. (Testimony of Lori Fitzgerald).

25. Package inserts, containing consumer medical information for use, warnings, and side effects were dispensed with each new Metoclopramide prescription, and with each prescription renewal. The information contained in the package inserts from October 2003 through October 2008 was introduced into evidence as Exhibits 77-82. That information was updated periodically, but the inserts consistently advised patients that they should immediately notify their doctor if they experienced any "involuntary movements of the eyes/face/limbs, muscle spasms, trembling of hands," and that symptoms of overdose includes "unusual movement of eyes, face, or limbs." In addition, beginning in at least in 2006, warnings were added for elderly patients, advising that they may be more sensitive to "the effects of the drug, especially . . . uncontrollable movements of the mouth/face/hands."

26. In May 2008, VA health care providers concluded that Holtshouser was exhibiting signs and symptoms of Parkinson's disease. He was, therefore, taken off of Metoclopramide, pending his evaluation by a neurologist. (Kersten Dep. 180:21-181:8).

27. The medical record does not reveal that Holtshouser exhibited a movement disorder prior to the time the Metoclopramide was discontinued. Even

upon his referral to a neurologist for an evaluation in May 2008, no movement disorder was observed.

28. Holtshouser was referred to VA neurologist, Wynde Cheek, D.O. Dr. Cheek saw Holtshouser on May 28, 2008. She did a complete neurologic examination, including an evaluation of his tongue during her cranial examination. (Deposition of Wynde Cheek, M.D. (Cheek Dep.) 16:23-17:10; 52:5-53:13). She spent approximately one hour with Holtshouser, and did not see any abnormal movement of his mouth or tongue. Id.

29. Holtshouser returned to see Dr. Cheek on August 4, 2008. She again did a complete neurologic exam, and examined his tongue during her cranial examination. She again did not notice any abnormal movements of his tongue or mouth (Cheek Dep., p. 17:1-4).

30. In November 2008, seven months after he had been taken off Metoclopramide, NP Kersten began noting movements of Holtshouser's mouth and tongue in conjunction with dental work. The first entry in the VA record relative to movements of his tongue was on a November 14, 2008. (Ex. 74, p. 1470, #1691). On that visit, NP Kersten noted that Holtshouser had received new dentures about a year ago, and has had mouth problems ever since. She also noted

that he fidgets with his tongue and cheek, and consequently has sore mouth/tongue/gums and bleeding. (Ex. 74, p. 1470, #1691).

31. On January 8, 2009, NP Kersten again noted that Holtshouser's tongue was constantly moving over his gums and dentures, with gum swelling noted. (Ex. 74, p. 1476, #1697). Kersten again noted tongue movements during an examination on January 26, 2009, and referred Holtshouser to Dr. Cheek for a neurological consult to evaluate his mouth movements. (Ex. 74, p. 1510, #1731).

32. Holtshouser returned to see Dr. Cheek on February 18, 2009. (Ex. 74, p. 1512, #1733). He reported that he had been experiencing pain on the bottom dentures which had started after the placement of pegs to retain his dentures. (Ex. 74, p. 1512, #1733). He felt as though placing pressure on the bottom teeth with his tongue helped with the pain. (Ex. 74, p. 1512, #1733). Even at this time, Cheek did not think these were abnormal tongue movements, because Holtshouser was adamant that they were not involuntary, and he was only doing it secondary to pain from the dental work. (Cheek Dep. 22:16-25).

33. Ultimately, Holtshouser's VA providers determined that he had likely developed tardive dyskinesia (TD). TD is a condition characterized by repetitive, involuntary body movements, which often involves the tongue and/or mouth. The condition is treatable, and is, at times, reversible. (Testimony of Matthew

Brodsky, M.D.). In Holtshouser's case, some medications have been effective in reducing his tongue and mouth movements, but none have been effective in eliminating his symptoms.

34. Holtshouser did exhibit certain symptoms that could be consistent with Parkinson's disease prior to May 2008. For example, a shuffling gait and possible Parkinson's disease was mentioned in the VA record in a urology consult note in May 2006 (Ex. 74, p. 1249, #1470), and a nurse's triage note in July 2006. (Ex. 74, p. 1265, #1486).

35. Holtshouser's most prominent Parkinson's feature was an abnormal gait. (Cheek Dep. 147:18-148:3). He also had chronic low back problems with lumbar stenosis, and three prior back surgeries. (Cheek Dep. 149:20-150:14) He also had "severe, severe sensory peripheral neuropathy," which causes gait abnormalities. (Cheek Dep. 68:4-9; 149:13-19). It was, therefore, difficult to determine whether Holtshouser had Parkinson's symptoms, or was exhibiting symptoms of age associated with his many co-morbid conditions. In fact, a movement disorder specialist who examined Holtshouser in 2010 still did not believe he was "Parkinsonian," and was of the opinion that his gait abnormality was likely the result of vascular disease as opposed to Parkinson's disease. (Ex. 74, p. 3737-38, #5466-67).

36. Dr. Cheek eventually concluded Holtshouser fulfilled the criteria for Parkinson's disease after an exam on May 28, 2008. She noted that he had a gait abnormality and decreased facial expression. She also noted a very subtle tremor of his right-hand, which consisted of two slight movements of his right hand in a one-hour period. (Cheek Dep., 51:9-22). The movements were so minor that family, friends, or other physicians not focused on the symptom would not have noticed it. (Cheek Dep., 51:12-18). She characterized his overall Parkinson's symptoms as mild. (Cheek Dep. 154:21-155:2). She prescribed Ropinirole to hopefully improve his ambulation and mobility and thereafter noted a very good response to it. (Ex 74, p. 1448, #1669).

37. One of Holtshouser's primary complaints in recent years has been ongoing oral pain. His medical records illustrate, however, that Holtshouser has a long history of oral pain and discomfort from dental/denture issues, particularly with his lower jaw.

38. In 2000, he reported that he had not worn a lower denture for some time, stating that his lower denture "never fit right and I threw it away." (Ex. 74, p. 188, #409; p. 393, #614). The lower denture was replaced by the VA in 2000. In August 2002, however, he had to have his dentures adjusted. (Ex. 74, p. 927, #1148). By February 2003, he reported that the bottom denture worked "terrible"

and "they hurt." (Ex. 61, p. 9). In 2006, he reported that his dentures fit "pretty good, but always hurt." (Ex. 61, p. 1). His dental records at this time also document that some of his dentures had not been worn for a long time. (Ex. 61, p. 1).

39. In May 2007, he had mini implants placed in his lower jaw to permit the attachment of different dentures. (Ex. 61, p. 5). This procedure marks the onset of ongoing pain and discomfort in his lower jaw which continues to this date. On August 21, 2007, he reported that he was "still having troubles w/lower teeth implants." (Ex. 74, p. 1310, #1531). On June 9, 2008, it was reported that his dentures were not fitting due to swelling of the gums and there was a concern of infection. (Ex. 74, p. 1424, #1645). He again returned to the VA clinic on July 28, 2008 with concerns of mouth pain. (Ex. 74, p. 1447, #1668).

40. Holtshouser was also seen by a VA dentist at Fort Harrison on March 13, 2008 for problems with his lower denture. (Ex. 74, p. 1342, #1563). He thereafter had his dentures readjusted by the VA on August 27, September 3, September 15, September 25, October 8, and November 4, 2008. (Ex. 74, p. 1453-55, #1674-76; p. 1457, #1678; p. 1465, #1686; p. 1468, #1689). It was also reported on October 10, 2008, that his oral pain led to the increased use of narcotics to treat the pain.

41. All of this dental work, and all of this oral pain and discomfort, occurred prior to the onset of any involuntary, abnormal movements of his tongue or mouth. In short, his oral pain had persisted for almost a decade prior to the onset of his TD.

STANDARD OF CARE

42. The plaintiffs allege that the VA pharmacy violated the standard of care for pharmacists in filling prescriptions for Metoclopramide in excess of the manufacturer's recommendation for duration of treatment, without warning the plaintiffs or contacting Holtshouser's treating provider. (FPTO, Section V). The plaintiffs also maintain that, given Holtshouser's renal impairment, the dosage of the drug was excessive. (FPTO, Section V).

43. Pharmaceutical manufacturers create labels for the use of their products, which include recommendations for the medication's indication and use, dosage and administration, contraindications, adverse reactions and warnings. These labels are approved by the FDA, and are collected and published in the Physician's Desk Reference (PDR).

44. When Holtshouser was first prescribed Metoclopramide in 2001, the manufacturer recommended the medication for the treatment of GERD as well as diabetic gastroparesis. Under "Indications and Usage," the label provided:

> **Symptomatic Gastroesphageal Reflux**
> Reglan Tablets and syrup are indicated as short-term (4-12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy.
>
> **Diabetic Gastroparesis (Diabetic Gastric Stasis)**
> Reglan . . . is indicated for relief of symptoms associated with acute and recurrent diabetic gastric stasis. The unusual manifestations of delayed gastric emptying (e.g., nausea, vomiting, heartburn, persistent fullness after meals, and anorexia) appear to respond to reglan within different time intervals. Significant relief of nausea occurs early and continues to improve over a three-week period. Relief of vomiting and anorexia may precede the relief of abdominal fullness by one week or more.

45. The manufacturer's label also contained a number of warnings associated with the use of Metoclopramide, including the possibility of developing Parkinson-like symptoms and/or tardive dyskinesia.

> Parkinsonian-like symptoms have occurred, more commonly within the first 6 months after beginning treatment with metoclopramide, but occasionally after longer periods. These symptoms generally subside within 2-3 months following discontinuance of metoclopramide. Patients with preexisting Parkinson's disease should be given metoclopramide cautiously, if at all, since such patients experience exacerbation of parkinsonian symptoms when taking metoclopramide.

> **Tardive Dyskinesia**
> Tardive Dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, particularly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and total cumulative dose. Less commonly, the syndrome can develop after relatively brief treatment at low doses; in these cases, symptoms appear more likely to be reversible. . . .

46. As far as dosage administration, for symptoms of GERD, the manufacturer recommended 10 to 15 mg up to 30 minutes before meals and at bedtime. It also advised that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended."

47. For symptoms associated with diabetic gastroparesis, the manufacturer recommended "10 mg of metoclopramide 30 minutes before each meal and at bedtime for two to eight weeks, depending upon responses and the likelihood of continued well being upon drug discontinuation."

48. For patients with renal impairment, the label also provided:

> Since metoclopramide is excreted principally through the kidneys, in those patients whose creatinine clearance is below 40 mL/min, therapy should be initiated at approximately one-half the recommended dosage. Depending upon clinical efficacy and safety considerations, the dosage may be increased or decreased as appropriate.

49. In 2004, the manufacturer revised the language of its recommendation. Under "Indications and Usage" the manufacturer advised that "[t]he use of reglan tablets is recommended for adults only. Therapy should not exceed 12 weeks in duration."

50. For relief of symptoms associated with diabetic gastroparesis, it continued to recommend therapy for "two to eight weeks, depending upon response and the likelihood of continued well-being upon drug discontinuation."

51. In 2009, after Holtshouser's use of Metoclopramide had been discontinued, the FDA required the manufacturer to add a "black box warning" to its label. The warning highlighted that treatment with Metoclopramide can cause tardive dyskinesia, and recommended that treatment with Metoclopramide beyond 12 weeks should be avoided "in all but rare cases where the therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia."

52. All of the providers and experts in this case agree on two things with respect to the PDR. First, it is not used by medical practitioners in their practice. As Kluger noted, there are so many side effects listed in the PDR that it is not as helpful as looking at other literature.

53. Second, all of the medical providers, pharmacists, and experts in this case agreed that many medications – and possibly a majority of medications – are

prescribed "off label"; *i..e.*, contrary to the usage duration recommendations set forth in the manufacturer's label. In fact, some medications are prescribed more off label than they are according to the label. (Kluger Testimony).

54. As explained by the United States' pharmaceutical expert, Arthur Lipman, Parm.D., a manufacturer's label is not proscriptive, and does not prohibit use for a longer period, or in any other manner not described in the labeling. (Lipman Testimony). Labeling, including indications and duration of therapy, are limited to the clinical studies that the sponsor submits to the FDA to receive approval of a "New Drug Application." (Lipman Testimony). Once the drug is approved, however, a licensed prescriber can prescribe the drug for any use either within or outside of the label, if doing so, in the opinion of the prescriber, is in the best interests of the patient. (Lipman Testimony).

55. Plaintiffs called Sunny A. Linnebur, Pharm D. as a pharmaceutical expert at trial. Dr. Linnebur is an associate professor at the School of Pharmacy at the University of Colorado, and she testified that the VA pharmacists did not meet the appropriate standard of care in filling and dispensing Metoclopramide prescriptions to Holtshouser.

56. It was obvious from Dr. Linnebur's testimony that she was not aware of the standard of care required of pharmacists practicing their profession in

Montana, other than a general standard of care. Dr. Linnebur never practiced in Montana and has done no research about how pharmacy is practiced in the state of Montana. Dr. Linnebur contended that the VA has a higher standard of care due to the fact that they have "an integrated system" which allows the patients to have access to a higher level of care than the general public.

57. Dr. Linnebur frequently referred to a "physician description," an internal agency document, for a VA pharmacist in her testimony regarding what she believed was the standard of care for a VA pharmacist in Montana. However, this expert had no specific knowledge of how the VA pharmacies operate in Montana. Dr. Linnebur was not aware of a VA pharmacy outside of Fort Harrison where a veteran has personal contact with a pharmacist.

58. Much of Dr. Linnebur's testimony reflected her personal standard of care that had no concept of the reality of the operation of the VA system in Montana.

II. CONCLUSIONS OF LAW

1. Plaintiff, Harold and Kathy Holtshouser properly exhausted their administrative remedies under the FTCA by submitting an administrative tort claim with the VA on May 1, 2010, and thereafter filing their complaint in this Court within six months of the final denial of his administrative claim on July 7,

2011. This Court, therefore, has subject matter jurisdiction of Harold and Kathy Holtshouser's claims, pursuant to 28 U.S.C. § 1346(b)(1).

2. Venue is proper in the District of Montana, because the plaintiffs reside in the District of Montana. 28 U.S.C. § 1402(b). Further, venue is appropriate in the Billings Division, pursuant to L.R. 1.2(c)(1)(d) and 3.2(b)(1)(B), since the plaintiffs resided in Park County at the commencement of this action.

3. The burden of proof in a civil action is the same regardless of whether the finder of fact is a judge in a bench trial or a jury. *Cabrera v. Jakabovitz*, 24 F.3d 372, 380 (2d Cir. 1994), *cert denied*, 513 U.S. 876 (1994). That is, a plaintiff bears the burden of satisfying the finder of fact that he or she has proven every element of their claim by preponderance of the evidence. Preponderance of the evidence means such evidence as, when considered with that opposed to it, has more convincing force, and demonstrates that what is sought to be proved is more likely true than not true.

4. Under the FTCA, the United States is liable for torts committed by its agencies and employees in the same manner and to the same extent as a private individual under like circumstances, in accordance with the law of the place where the act or omission occurred. 28 U.S.C. § 2674. Applicable state law must be the

source of the claim for relief. *Trobetta v. United States*, 613 F. Supp. 169 (D. Mont. 1985).

5. Although the Montana Supreme Court has never addressed the issue, a clear majority of courts have found that a pharmacist has no duty to warn a patient, or to contact the prescribing health care provider regarding a prescription, unless the pharmacist has knowledge of a patient-specific risk associated with the medication. *See e.g., Klasch v. Walgreen Co.*, 264 P.3d 1155 (Nev. 2011). Courts have found that the duty to warn customers about potential side effects of medication falls with the physician, not the pharmacist. *See e.g., Allberry v. Parkmore Drug, Inc.*, 834 N.E.2d 199 (Ind. Ct. App. 2005).

6. The majority of jurisdictions have refused to apply any greater duty on pharmacists for a number of policy reasons. For example, the "[p]roper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition." *McGee v. Am. Home Prods. Corp*, 782 P.2d 1045, 1051 (Wash. 1989). It is the physician, not a pharmacist who has no relationship with the patient, "who can relate the propensities of the drug to the physical idiosyncrasies of the patient." *Id.* at 1050. A physician is also "in the best position to decide when to use and

how and when to inform his patient of the risks and benefits pertaining to drug therapy." *Id.* at 1050-51.

7. Imposing a duty on a pharmacist to intervene in a physician's drug therapy of a patient "would place the pharmacist between the physician – who knows the patient's physical condition – and the patient and could lead to harmful interference with the patient-physician relationship." *Allberry*, 834 N.E.2d at 202.

8. Moreover, the rule "prevents pharmacists from constantly second-guessing a prescribing doctor's judgment simply in order to avoid his or her own liability to the customer," . . . and would thus preserve "the pharmacists role as a conduit for dispensing much-needed prescription medication." *Klasch*, 264 P.3d at 1159.

9. This Court finds that these are sound policy considerations, and that the Montana Supreme Court would join the majority of jurisdictions which have adopted the rule that pharmacists have no duty to warn patients of the generalized risks inherent in the prescriptions they fill. A pharmacist only has the duty to warn a patient, or to contact the patient's prescribing provider, if he/she has knowledge of a patient-specific risk that would render the prescription contraindicated for the particular patient. *Klasch*, 264 P.3d at 1160.

10. In the present case, Plaintiffs allege that the VA pharmacy failed to warn Holtshouser of the generalized risks associated with the medication. There is no evidence that the pharmacy had knowledge that Holtshouser had a condition that would render Metoclopramide uniquely hazardous to him. The VA pharmacy, therefore, had no duty to warn Holtshouser, or to contact his treating provider.

11. Even if the VA pharmacy had a greater duty to Holtshouser beyond appropriately screening, filling, and dispensing the Metoclopramide prescription, that duty is determined by the same standard of care analysis applied to other claims of professional negligence. The standard of care is controlled by state law; not federal law and/or VA declarations, job description duties, or regulations.

12. To establish a duty and breach in a medical negligence claim under Montana law, for example, a plaintiff must initially satisfy a two-part threshold obligation: (1) evidence must be presented to establish the standard of professional care in the type of case involved; and (2) it must be shown that the physician departed from this recognized standard in his/her treatment of the plaintiff. *See e.g., Gilkey v. Schweitzer*, 983 P.2d 869, 871 (Mont. 1999). Moreover, it must be established that the departure from the standard was the proximate cause of injury to the plaintiff. *Montana Deaconess Hospital v. Gratton*, 545 P.2d 670, 673 (Mont. 1976); *Falcon v. Cheung*, 848 P.2d 1050, 1055 (Mont. 1993).

13. Plaintiffs' pharmacy expert, Dr. Linnebur, did not apply an appropriate standard of care in this case. Dr. Linnebur testified that the VA pharmacy has an increased standard of care, because VA pharmacists are in a unique position of having access to the medical records of the patient, which are generally not available in a retail setting. Even with respect to "baseline" pharmacy standards, she opined that VA pharmacists are expected to perform at a higher level, because they are in a closed system where the patients receive both their medical care and medications in the same system. Therefore, her opinions in this case consist of what she believes constitutes the standard of care of a VA pharmacist in the VA system.

14. Under the FTCA, however, the United States has waived its sovereign immunity only and rendered itself liable only "in the same manner and to the same extent as a private individual under like circumstances." 28 U.S.C. § 2674. It is liable under the FTCA only "under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b).

15. Consequently, the United States is only liable in this case to the extent that a private pharmacist would be liable under Montana law. It is not held

to a higher standard. Its standard of care is the same as any privately owned pharmacy in the state – no greater, no less.

16. For these same reasons, Plaintiffs' reliance on internal VA policies, procedures, and guidelines to establish the standard of care is also misplaced. The source of liability under the FTCA must be state law, not federal laws or regulations. *See e.g. FDIC v. Meyer*, 510 U.S. 471, 478 (1994). A private pharmacist is obviously not liable under Montana law for failing to comply with VA policies and guidelines. That being the case, the United States has simply not rendered itself liable under the FTCA for alleged violations of those policies, procedures and guidelines.

17. The Court further finds that the VA did not violate the applicable standard of care in this case.

III. ORDER

Accordingly, IT IS HEREBY ORDERED, pursuant to Fed. R. Civ. P. 58, that the Clerk of Court enter judgment by separate document in favor of the defendant, United States of America, dismissing Plaintiffs' claims, with prejudice.

IT IS FURTHER ORDERED that the Clerk of Court shall notify the parties of the making of this order.

DATED this 1st day of May, 2013.

*/s/ Richard F. Cebull*_____
RICHARD F. CEBULL
SENIOR U.S. DISTRICT JUDGE