

## **Unique Combination of Critical Vitamins, Minerals and Antioxidants Shown to Reverse the Affects of Diabetic Neuropathy According to New Study**

### **Condition Caused By Diabetes Affects Millions Nationally; Study Reveals Significant Reductions in Patients' Complications and Overall Pain**

GRAND RAPIDS, Mich., Sept. 10 /PRNewswire/ -- Mark L. Gostine, M.D., founder of Michigan Pain Consultants, PC, one of the nation's leading full-service pain management practices, and Lawrence Pawl, M.D., a recognized oncologist, today released the results of a new study revealing that the under consumption of micro-nutrients -- essential vitamins, minerals and antioxidants -- can accelerate pain and other complications associated with diabetic neuropathy, a peripheral nerve disorder caused by diabetes. Of the 20.8 million reported diabetics in the country, an estimated 70 percent, or 14.6 million, have or will develop some form of diabetic neuropathy.

"While the over consumption of macro-nutrients, such as carbohydrates and fats, is recognized as a root cause of type 2 diabetes, we set out to determine if the under consumption of select micro-nutrients might be the cause of diabetic complications such as neuropathy," said Gostine. "What we found is that restoring a group of five dietary vitamins and minerals was very effective in alleviating a number of key symptoms, including burning, numbness and overall pain."

During the six-month long study, patients were asked to rate eight parameters using a modification of the Wong-Baker FACES Pain Rating Scale where pain is rated on a scale from 1 to 10. The patients who participated in the study reported an average rating of 6.59 for "burning pain in hands and feet" before taking the combination of micro-nutrients and a 2.44 rating after 12 weeks, a 63 percent decrease. In addition, patients reported an average rating of 6.54 for "overall pain" before taking the combination of micro-nutrients and a 2.85 rating after 12 weeks, representing a 56 percent decrease.

"Our goal with this study was to better understand how to more effectively manage pain and other complications associated with diabetic neuropathy," added Gostine. "It's not just that people are eating too much bad food; it's that they are eating too little of high quality foods. In other words, it's not what you eat; it's what you don't eat that hurts you."

#### Prevalence of Diabetes

According to the National Diabetes Information Clearinghouse (NDIC), 20.8 million people in the United States have diabetes, approximately 7 percent of the population. There are 10.3 million people aged 60 years or older, or 20.9 percent of all people in this age group, that have diabetes.

Diabetes was the sixth leading cause of death in the United States in 2002. In addition, 1.5 million new cases of diabetes were diagnosed in people aged 20 years or older in 2005.

#### About the Study Population

Patients enrolled in the study were selected from a practice of podiatrists specializing in surgical and non-surgical care of the feet and ankles. The nature of their practice results in a large population of patients suffering from complications of the diabetic foot including ulcers, infections, calluses and neuropathy.

Patients complaining of symptoms of neuropathy, despite maximal medical therapy, were entered in the study to investigate the use of nutritional supplements for controlling their pain. Thirty patients were enrolled and 28 completed the study over a six-month period extending from November 2006 through May 2007 with 12 men and 16 women participating. The average age was 68 with a range from 48 to 94. Most patients had comorbid conditions including hypertension, obesity and hyperlipidemia.

## Secondary Research Critical to Study

The foundation of the study was shaped by extensive data mining of the PubMed database established by the National Institute of Health and National Library of Medicine which catalogues thousands of journals and millions of articles in the field of medicine. Based on this effort, five nutritional supplements -- N-acetyl-cysteine (NAC), alpha-lipoic-acid (ALA), L-carnitine (LCA), vitamin C and selenium -- were selected and provided to patients over a three-month period. Baseline status was assessed using a modification of the Wong-Baker FACES Pain Rating Scale (rating scale from 1 to 10). The following eight parameters were judged:

- Burning pain
- Numbness
- Overall pain
- Perceived level of impairment of function
- Perceived level of impairment of concentration
- Perceived level of impairment of thought clarity
- Perceived level of impairment of alertness
- Perceived level of impairment of energy

The last four parameters were secondary endpoints that were assessed because an earlier pilot investigation indicated this group of nutritional supplements had a beneficial effect on mental function. Patients were followed for three months with ratings at initiation and every four weeks thereafter.

## Results

	initiation	four weeks	eight weeks	twelve weeks	% change 4 weeks	% change 8 weeks	% change 12 weeks
Burning	6.59	4.71	3.06	2.44	-29 %	-54 %	-63 %
Numbness	7.41	6.21	5.16	4.37	-16 %	-30 %	-41 %
Overall Pain	6.54	4.98	3.67	2.85	-24 %	-44 %	-56 %
Impairment Of Function	4.3	3.93	2.96	2.76	-9 %	-31 %	-36 %
Impairment Concentration	3.11	2.91	2.33	2.26	-6 %	-25 %	-27 %
Impairment Clarity	2.18	2	1.78	1.74	-8 %	-18 %	-20 %
Impairment Alertness	2.39	2.2	1.69	1.52	-8 %	-30 %	-36 %
Impairment Energy	4.89	4.29	3.61	3.33	-12 %	-26 %	-32 %

"It is interesting to note from the results that every parameter improved at every four-week assessment during the study which suggests that if we were to follow the patients over a longer period of time, we would likely see further improvement," said Gostine. "At the end of the day, the study supports the original hypothesis that we set out to examine -- that there are health benefits for diabetics who include these key nutrients in their diet while continuing to watch their calories."

## About the Research Team

Dr. Gostine is a University of Michigan trained anesthesiologist and board certified in anesthesia with a fellowship in pain management. He has practiced pain management full time since 1984 and has treated over 15,000 individual patients for pain complaints for over 25 years. He is a founding member of the Michigan Pain Society and served as a consultant to Hospice of West Michigan where he helped develop pain management protocols for cancer.

Dr. Gostine is also co-founder of Grand Rapids based Michigan Pain Consultants, PC, one of the nation's leading full-service pain management practices specializing in the diagnosis, treatment and relief of chronic and acute pain syndromes. The practice operates six full-service, community-based pain management centers throughout Western Michigan.

Dr. Pawl graduated from Wayne State University Medical School in Detroit. He has had a medical oncology practice in Grand Rapids, MI, for over 25 years, administering chemotherapy and dealing with its side effects including chemotherapy induced neuropathy. He also has a satellite clinic in Big Rapids, 60 miles north of Grand Rapids. While serving as the Medical Director of Hospice of West Michigan for 14 years, he worked with Dr. Gostine. Dr. Pawl is currently a co-investigator in several local and national cancer research groups.

With their vast experience in treating neuropathy through their respective medical specialties, Dr. Gostine and Dr. Pawl co-founded Neuropathy Solutions, an organization dedicated to providing natural solutions for the treatment of peripheral neuropathy including neuropathy secondary to diabetic origin and toxicity secondary to chemotherapy.