TESTIMONY OF

THOMAS G. ZIESER

PRESIDENT AND CHIEF EXECUTIVE OFFICER OF JACE SYSTEMS

BEFORE THE

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

SUBCOMMITTEE ON GOVERNMENT ORGANIZATION, EFFICIENCY AND FINANCIAL MANAGEMENT

SEPTEMBER 19, 2012

Thank you Mr. Chairman for this opportunity to testify before the committee regarding the effectiveness of Trade Adjustment Assistance for Firms (TAAF). Since 1999 I have been the President and Chief Executive Officer of JACE Systems. JACE Systems is medical device manufacturer and medical services provider located in Cherry Hill, New Jersey approximately 8 miles East of Center City Philadelphia. Our products are used by patients recovering from orthopedic surgery to their joints. The company manufactures devices that exercise the patients affected joint in a passive manner immediately following their surgery. This is commonly referred to as Continuous Passive Motion (CPM) therapy and the devices used in CPM therapy are identified as CPM machines. The most common application is after surgery of the knee, usually total knee replacement (TKR) or sports injuries like Anterior Cruciate Ligament (ACL) repair. Other applications for our products include the hand, wrist and toe. Surgery to the hand and wrist are usually the result of trauma and injuries in the work place. These products are particularly helpful for complex injuries that involve bone, soft tissue and nerve damage. The devices are used to prevent the formation of scar tissue and adhesions, reduce swelling and edema and reduce the need for pain medications.

The company also manufactures a neuro muscular electro stimulation device (NMES), JACE TriStim, that is used to reduce pain and swelling and also retrain damaged muscles, soft tissue and nerves. When the knee CPM is at the end range of motion (ROM) the CPM pauses and the TriStim stimulates the muscles thru a small electrical current via attached skin electrodes. The net result is the flexion and extension of the joint, combining with electro therapy hasten the rehabilitation of the affected joint. Patients return to work and resume daily activities as result of our CPM therapy.

The company has been in business since 1990. Our products are used throughout the United States and are also exported to Europe and Japan. The company is an FDA licensed medical device manufacturer with ISO 9001 and ISO 13485 certifications. The company is also recognized by Japan as a foreign medical device manufacturer. The K 100-A knee CPM is also recognized by the European Union (EU) to display the CE Mark on our product.

My business experiences includes an undergraduate Bachelor of Science Degree from Northland College in Biology and Masters Degree of Business Administration from Seton Hall University. My entire career has been in health care. I have held positions with companies that include Baxter International, Haemonetics, Nations Health Care and Fresenius USA. Positions held range from Professional Sales Representive, Product Manager, International Sales Director, International Business Development Manager, Vice President and General Manager.

JACE Systems competes in the highly regulated medical device industry. Over the last several years the demands and complexity of foreign regulations have had significant impact on our manufacturing operations and opportunity. Our flagship product, the K 100-A knee CPM machine was introduced in 1994. It is electrically powered and controlled by a sophisticated hand controller that is micro processor controlled thru a soft push button panel and viewed on a Liquid Crystal Display (LCD). There is also an interface on the controller for the TriStim that is often used to retrain and exercise muscles affected by the patient's surgery or trauma. Prior to the formation of the EU, most countries accepted the US FDA 510K product registration as proof of acceptance and the Under Writers Laboratory (U/L) seal for electrical safety. The Medical Device Directive (MDD) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, is intended to harmonize the laws relating to medical devices within the European Union. The MD Directive is a 'New Approach' Directive and consequently in order for a manufacturer to legally place a medical device on the European market the requirements of the MD Directive have to be met. Manufacturers' products meeting 'harmonised standards' have a presumption of conformity to the Directive. Products conforming with the MD Directive must have a CE mark applied. The Directive was most recently reviewed and amended by the 2007/47/EC and a number of changes were made. Compliance with the revised directive became mandatory on March 21, 2010.[1] The MDD included products currently distributed in the EU, consequently, there was no "grandfathering" for our products. JACE Systems medical devices had to be re-tested to the new "harmonized" standard and certified with the CE Mark. We were essentially excluded from selling new product in the EU. Our dwindling sales efforts were only for replacement parts for the existing fleet of machines in the EU. Our EU sales were managed by an independent sister company in Germany, JACE Systems Gmbh.

Consequently without the CE Mark, our sales declined in 2004 and 2005 and caused decreased profitability. JACE Systems was forced to reduce overhead and lay off employees. I was discussing our predicament with the US Commercial Service Trenton, NJ office and they recommended I contact the Mid Atlantic Trade Act Assistance Center (MATAAC) to discuss our situation. I applied for a grant and submitted the necessary documentation and paperwork. In February 2008, JACE Systems was approved for a matching grant of $73,000.00 That is, for every dollar JACE invests in a MATAAC approved project, MATAAC will match it dollar for dollar.

In April 2008, our grant was funded and the Project work began to bring our flagship product, the K 100-A to CE Mark status. The electrical safety testing and electronics emissions testing (EMC) was completed at BEC Laboratories in Pottstown, PA at a cost of $15,370 and $6,750 respectively. The ISO Registrations and Quality Management

Systems (QMS) requirements were completed by the Enterprise Strategy Group at a cost of $24,000. After the tests were completed, additional engineering and design requirements had to be achieved. Nelson Design Services in Willow Grove, PA reviewed our circuit board layout for compliance to the new standard at a cost of $17,060.00. None of these projects could have been done in the short time frame without the MATAAC matching grant assistance program.

Since acquiring CE Mark and ISO Registrations we have seen our sales to Germany increase to $ 177,318.00 in 2011 from a low $ 76,000 in 2007. In addition we have hired 1 new employee in 2010. The real impact of the assistance however, is not just seen at JACE Systems and the test laboratories and design services companies we contracted with to get us CE Ready. JACE Systems is an assembly operation. We purchase parts and assemblies from many companies in our area and thru out the USA. MATAAC grant assistance helped JACE design new tools and first articles that reduced cost, improved design and made us more efficient. For example, C&K Plastics, Metuchen, NJ re-designed our tools that vacuum formed the plastic pieces for the K 100-A knee CPM at a cost $9,970. The new design reduces waste and evens out our parts inventory imbalances. Kaiser Medical Inc, Southampton, NJ designed a new anatomical hinge movement for the K-100-A for $10,000 that reduced cost and increased flexion end Range Of Motion (ROM) from 120º to 130º. Pittsfield Plastics Engineering, Pittsfield, MA created first articles at a price of $30,000 for injection molded plastic parts that reduced our unit cost and increased assembly efficiency. JACE Systems is the export engine for the many companies that do not export at all. JACE Systems is the tip of the spear in all of our export efforts.

The MATAAC Grant assistance has not only helped the companies listed previously. The MATAAC Grant assistance also has trickle down effect that aids in the sales growth and development of many other small companies in the past year. To name a few, Cardinal Precision Co., Oreland, PA received no grant assistance but they fabricated the metal parts that are the product of the MATAAC funded Kaiser Medical anatomical hinge project that netted Cardinal sales of $27,258. Another example is Youngtron, Hatfield PA. Youngtron had no direct MATAAC Grant assistance but they are now supplying the redesigned circuit boards and electronic layouts that make us compliant to the CE Requirement that netted sales of $9,287. Maven Medical Manufacturing, St. Petersburg, FL supplies the synthetic lamb wool soft good that supports the patient’s limb while it is in the CPM machine netted sales of $77,648. In addition to helping small companies grow, JACE made significant purchases from large companies as well. Merkle Korff Corporation, Elk Grove Village, IL sold JACE $23,999 worth of electric motors and Thomson Linear Motion, Radford, VA sold JACE $30,672 worth of precision ball screws in 2011.

Gaining the CE Mark has also helped JACE develop business in Turkey. Turkey signed a Customs Union agreement with the EU in 1995. The CE Mark enables us to sell to Turkey and more importantly, enables JACE to establish a beach head in that part of the world and distribute our products to the Middle East region, a rapidly growing market for Made in America Medical products. We have shipped 1 knee CPM to Turkey and it is being evaluated at a large private hospital group. I expect positive results after the trial

period is over in October 2012. JACE Systems also receives inquiries from the UAE, Saudi Arabia, Kuwait, Egypt and other countries in that area of the world. Because of language, cultural differences and time difference, it is difficult for a small company to establish business relationships in that part of the world. I sincerely believe that our partner in Turkey will help establish JACE systems in the Middle East.

The data and information gathered from the K 100-A testing was extremely helpful in establishing our presence in Mexico. Mexico does not require a CE Mark. They do however, require medical device manufacturer's registration and approval by the Mexico Health Authority to market and sell your product to hospitals and compete in public tenders. We identified a distributor in Mexico while participating in US Commercial Service Trade Winds the Americas business development mission. The distributor selected, Kuxtal DME, Mexico City, MX assisted us in getting our knee CPM approved and registered with the Mexico Health Authority. Much of the technical information and test data we completed for the CE Mark was also required by the Mexico Health Authority. Having this data readily available greatly accelerated having our product Registered with the Mexico Health Authority. Consequently, Kuxtal DME was successful in selling 5 knee CPM's in a Public Tender to Mexico Defense Department in June 2012. There are other tenders coming in the next few months and I feel he will be equally successful in our efforts to penetrate the Mexico market and also establish a beach head for Central and South America.

In conclusion, I want to thank the Committee members for allowing me to share my JACE Systems journey. I encourage you to support the TAAF and other programs, like Trade Winds the Americas offered by the US Commercial Service. They are a valuable resource for small companies like JACE to compete in the world and provide jobs for JACE employees and the many suppliers throughout USA. Thanks again for your time and attention today.

1. Wikipedia Medical Device Directive

Thomas Zieser
930 Pelican Drive Box 342
Lanoka Harbor, NJ 08734
(609)242-1384

Personal

A highly motivated, team-oriented management professional with more than 30 years experience in the medical industry including pharmaceuticals, disposable medical devices, capital equipment and health services.

Experience

JACE Systems, Cherry Hill, NJ
President, 1999 - Present
Specialty orthopedic rehabilitation equipment manufacturer and service provider. Our products are used to assist patients in their post operative rehabilitation following joint replacement surgery . Our products are sold in the USA, Europe, Japan and Mexico

Nations HealthCare, Alpharetta GA
Various Executive Positions 1996 - 1999
Executive management positions focused on non-hospital based specialized pharmacy products and services, oxygen therapy, nursing care and specialty therapies.

FreseniusUSA, Waltham MA
Oncology Business Development Manager, 1994 - 1996
USA division of Fresenius AG, Homburg Germany. Company is world's largest provider of kidney dialysis products. Oncology business development was focused on stem cell collection and protocol development at major cancer research centers in the USA

Haemeonetics Corporation, Braintree MA 1986-1994
Management positions with several divisions of the company 1986-1994
Haemonetics is a global leader for products serving the blood banking industry.

Baxter Healthcare, Deerfield, IL 1978-1983
Sales and Management positions with several divisions of the company
Positions included Asia Pacific Sales Manager for the Pacific for company's critical care and life support division. Business unit director responsible for domestic sales and off shore manufacturing facility, (Puerto Rico)

Education & Professional Memberships

Northland College, Ashland WI
B.S., Biology, 1970

Seton Hall University, South Orange
M.B.A., 1976

Member Industry Trade Advisory Committee (ITAC) 3
Chemicals, PhRMA, Health/Science Products and Services

Member District Export Council (DEC_
Philadelphia/South Jersey

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Thomas Zieser

---

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2009. Include the source and amount of each grant or contract. MATAAC Grant awarded February 2008

EMC Testing	$3,375.00
Data Migration	$1,900.00
Data Migration	$ 812.50
Bottom Cover	$2,725.00
Web Site Design	$2,600.00
Product Design	$1,897.50

---

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

Testifying for JACE Systems as President and CEO

---

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2009, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

None

I certify that the above information is true and correct.

Signature: Thomas Zieser Date: 9/12/2012