

REGIONAL LABORATORY AWARD

Awardee's Name: Naval Medical Research Center (CAPT Richard B. Oberst, Dr. Charles Schlagel, Mr. Joseph K. Hemby, Jr., Mr. Phil Ketner, and Dr. Adam McKee)

Nomination Submitted by: Nancy Groves, Department of Navy FLC Agency Representative, phone: 703-696-5991

The Naval Medical Research Center (NMRC) in Silver Spring, Maryland executes an exemplary Technology Transfer Program on behalf of naval biomedical research laboratories and medical centers located around the globe. The leadership and initiative of five key individuals; CAPT Richard B. Oberst, Dr. Charles Schlagel, Mr. Joseph K. Hemby, Jr., Mr. Phil Ketner, and Dr. Adam McKee form the basis for this most successful program.

CAPT Richard Oberst serves as the Commanding Officer, Naval Medical Research Center - the Navy's largest biomedical research laboratory. He directs over 500 personnel worldwide, with reporting laboratories in the United States, Indonesia, Cambodia, Egypt, Ghana, and Peru. These laboratories are involved in the conduct of research, development, tests, evaluations and disease surveillance to enhance the health, safety, performance and medical readiness of Navy and Marine Corps personnel deployed throughout the world.

Recognizing the value of Cooperative Research and Development Agreements (CRADAs) to gain access to the latest state of the art technology for his research team and the need for patent license agreements to commercialize their products, CAPT Oberst and his predecessors have expanded the Intellectual Property/technology transfer offices and created an Intellectual Property Committee to evaluate each invention submitted by the ten biomedical research labs and the three major medical centers. The office began with one person filling the rolls of both patent attorney and ORTA. Today, there are six individuals, including Dr. Adam McKee, Head of the Research Support Directorate and Chairman of the Intellectual Property Committee; Dr. Schlagel, ORTA and Director of the Office of Technology Transfer; Ms. Roxanne Charles, a licensing specialist (just hired in August 2004); Mr. Joseph K. Hemby and Mr. Phil Ketner, patent counsels; and Lawana Brady, a paralegal. CAPT Oberst has empowered this team to develop and implement streamlined technology transfer processes. At the same time, CAPT Oberst shares his knowledgeable team with sister Navy biomedical research laboratory, the Naval Health Research Center (NHRC) in San Diego, CA and NHRC's four subordinate labs in addition to the major Naval Medical Centers in San Diego, CA; Bethesda, MD; and Portsmouth, VA to ensure they reap the rewards of collaborations with academia and the private sector.

Through Dr. McKee's active leadership and innovations, the NRMC technology transfer team has been responsible for a dramatic increase in technology transfer partnerships with industry, and a resulting improvement of the Navy medical system's ability to

accomplish its mission. An outstanding example is the development of a standardized CRADA for industry-sponsored clinical trials with the Navy. The previous *ad hoc* practice was outside of approved technology transfer means and caused uncertainty and risk for both the Navy and industry. To address this major shortcoming, Dr. Schlagel and Mr. Hemby created, and CAPT Oberst endorsed, a Standard Navy Clinical Trial CRADA which was approved by ONR for general use in 2003. Use of this CRADA has resulted in an increase from a cumulative total of two non-reimbursable CRADAs prior to 2003 to 28 signed Clinical Trial CRADAs generating over \$750,000 for the medical centers. These partnerships provide vital exposure and experience for Navy doctors and clinical staff to emerging medications and equipment, as well as a structured and talented medical research staff to conduct trials on behalf of our American industries.

Promoting technology transfer and providing training is an integral role for all technology transfer offices, but additionally crucial for an organization as globally dispersed as the Naval Medical Research Center. CAPT Oberst frequently sends his technology transfer team to visit the thirteen medical facilities, conducting training workshops for both technology transfer personnel as well as medical researchers. Workshops focus on intellectual property basics as well as the various technology transfer mechanisms. These workshops have played a major role in increasing the number of invention disclosures from the Navy's medical laboratories, with a resultant dramatic increase in patenting activity.

Mr. Hemby and Mr. Ketner's case-load is extensive, with 67 issued patents as well as another 95 pending patent applications. These innovations are marketed through Executive Summary Sheets and active coordination with TechLink, a Department of Defense technology transfer partnership intermediary. In addition, Dr. Schlagel encourages inventors to promote their innovations through publishing technical papers and attending industry conferences and instructs them to be aware of potential collaboration and licensing opportunities. For example, in the past four years, one Directorate published over 190 peer-reviewed articles and presented over 400 papers at conferences. These publications and presentations generate many leads for CRADAs, licenses, and other partnerships. In the past three years, the NMRC technology transfer team has been directly involved in the establishment of over 250 CRADAs, which have generated more than \$5,000,000 for the medical laboratories and in the negotiation and monitoring of more than 20 patent license agreements.

Dr. Schlagel not only teaches his inventors the tools of successful outreach at conferences, he practices the techniques himself. As an active member of the Licensing Executives Society, he attends its meetings, which are well attended by the pharmaceutical and biomedical industries and are important venues for making these industries aware of partnering opportunities with the Navy medical system.

One of the best examples of NMRC's success involves the transfer of novel Navy technology that helps prevent and treat acute noise-induced hearing loss. Mr. Ketner secured appropriate patent protection and Dr. Schlagel negotiated an exclusive license with American BioHealth Group (ABG), formed for the sole purpose of commercializing

the Navy technology. The license was finalized in February 2002 and by December 2003, ABG successfully launched an over-the-counter nutraceutical called *The Hearing Pill*TM. Dr. Schlagel further assisted the company by negotiating a clinical trials agreement between ABG and the Navy, which was signed in January 2004. *The Hearing Pill* has the potential to help prevent or reverse noise-induced hearing loss in 30 million Americans who suffer from reduced hearing capacity. In addition to the huge commercial market, this technology addresses a major military need: the DoD spends an estimated \$1.5 billion per year treating noise-induced hearing loss from weapons fire, aircraft, and other loud noises. The requirement for this product is particularly evident today as ABG reports sending *The Hearing Pill* to IRAQ, at the request of one of the military field doctors, with positive feedback on the Pill's benefit to troops experiencing blast injury.

The Naval Medical Research Center is a commendable example of a federal laboratory that both captures and provides enormous benefits through technology transfer. The vision for collaboration was established by CAPT Richard B. Oberst, led by Dr. Adam McKee, implemented by the ORTA, Dr. Charles Schlagel and Patent Counsels Joseph K. Hemby and Phil Ketner, and practiced by nearly every member of the research staff.