



VIRGINIA PROSTATE CENTER **Newsletter**

A PROGRAM OF EASTERN VIRGINIA MEDICAL SCHOOL

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A Letter of Grateful Appreciation

Dear VPC Supporter:

This issue of the Newsletter is dedicated to all the individuals, organizations and businesses that have helped to make the Virginia Prostate Center a center of excellence for education, research and patient care in Hampton Roads. The Program and Scientific Directors, faculty and staff of the Eastern Virginia Medical School's VPC are indebted to the gifts that have made the VPC one of the premier cancer programs in the country and abroad. We send our most heartfelt thanks to all our supporters.

Sincerely,

*Paul F. Schellhammer,
M.D. Program Director*

*George L. Wright, Jr.,
Ph.D. Scientific Director*

THE COST OF RESEARCH: How Has Your Gift Been Spent?

George L. Wright, Jr. and Paul F. Schellhammer

People, organizations and businesses give considerable sums of money to charitable organizations every year, and without such funds many organizations/programs would not be able to provide needed public services. How often have you questioned or perhaps wondered how your generous contribution has been spent? Is it really making a difference? This article will focus on how your gifts to the VPC have been used to support the development of this national and international respected cancer research program.

Since its inception in 1992, the VPC (formally the Center for Urological Oncology) has been dedicated to fostering excellence in research, in education, and in the care of patients suffering from prostate, bladder, kidney and testicular cancer. We all know how very expensive medical care can be, especially for patients with cancer who often require multiple courses of treatment. There are many facets responsible for the high cost of health care, including the cost of training healthcare providers, cost of expensive state-of-the-art medical equipment and facilities, and the cost of drugs. But what about the cost of scientific research? The research cost for developing a new medical instrument or drug is a major contributor to the cost of healthcare. You have undoubtedly heard or read that it now requires hundreds of millions of dollars and 10 to 20 years of research and development to bring a prescription drug to market. Modern state-of-the-art research equipment can now cost as much or more than a million dollars! As science uncovers the mysteries of cancer biology, new and exciting discoveries are made that

require more sophisticated research and instrumentation to validate the clinical potential of the new discoveries. Thus a costly spiral develops whereby the instrumentation purchased today usually must be replaced at five year intervals with the next more refined generation of the instrument. And to reach research goals and stay competitive for federal funds, by necessity one must find a way to purchase the new generation instrument with its better "bells and whistles" (and at a higher price). This is true for all research institutions and programs. Thus if the VPC is to reach its goals of developing better diagnostics and therapeutics, it has to, by necessity, invest in the continued building of a strong research infrastructure that includes state-of-the-art equipment, highly qualified and trained personnel, adequate laboratory space, and effective support services.

Faculty Recruitment. Eastern Virginia Medical School provides laboratory space, full salary for key VPC faculty/scientists, and provides support services that include grant management, biosafety, and institutional review board. What is sometimes difficult for EVMS to fund from core dollars are incentive or "start-up packages." Faculty recruitment typically requires substantial start-up packages, generally in the range of \$300,000 - \$750,000 depending on the level and type of expertise. Although competition among institutions to attract the brightest young scientists is clearly a positive feature of the U.S. system, the sums now on the table are often back-breaking. The process is somewhat analogous to a signing bonus given to a professional athlete in an effort to get that player

THE COST OF RESEARCH: How Has Your Gift Been Spent? *continued*

to sign with your team. However, such funds are absolutely essential when recruiting highly qualified and trained faculty-scientists. Although a portion of these funds might incorporate a portion of the scientists' salary, most of the funds are used to assist the new faculty member in establishing their laboratory, pay for laboratory technicians and fellows, research supplies, and minor research equipment needs, with the funds usually being distributed over a 2-3 year period. We were very fortunate to receive a timely and substantial gift that was used as the start-up package in the successful recruitment of Dr. O. John Semmes, an outstanding protein biochemist/molecular biologist who is leading our proteomic efforts in the development of diagnostics for the early detection of prostate cancer (Dr. Semmes was featured in the *VPC Summer 2001 Issue, Vol. 6, No. 1*). The VPC was also instrumental in assisting with the recruitment of Dr. Jose Diaz, a Cancer and Molecular Pathologist, and a key member of the research team who is responsible for procurement and evaluation of surgical tissues specimens used in the search for diagnostic and therapeutic biomarkers (*Spring 2002 Issue, Vol. 7, No. 1*).

Research Technicians and Fellows. The VPC also has used private gifts to fund, on a limited basis (usually no more than 3 years), the salary of research technicians and fellows (Fellows are Ph.D. or M.D.'s who provide a service to the research programs while *receiving scientific training*). Although initial salaries are paid from VPC funds, fellows are expected to submit fellowship/grant proposals to outside agencies to relieve salary support initially provided from VPC funds. The success and benefits of this program is illustrated by two of our recent fellows Bao-Ling Adam, Ph.D. and Antonia Vlahou, Ph.D. Both were successful in receiving prestigious fellowship awards from the National Cancer Institute (BLA) and the American Foundation for Urological Diseases (AFUD) (AV). Furthermore, after completing their fellowships, they accepted Research Assistant Professor faculty positions in the VPC, and have been

valuable members of our research team in the development of novel approaches for identifying diagnostic and prognostic biomarkers. As research faculty members, they are required to seek extramural grants to support their salary and a good portion of their research program, with the ultimate goal of becoming independent investigators. Both Drs. Adam and Vlahou successfully met this goal as well, each receiving extramural grant funding to support their research activities. Another research fellow of note is John Davis, M.D., also a recipient of an AFUD fellowship, who received his residency and training in Urology at EVMS. After completing clinical fellowships at MD Anderson Cancer Center and Charter Hospital, Berlin, Dr. Davis returned to Norfolk and joined the Devine Tidewater Urology (See *VPC Newsletter Spring 2003, Vol. 8, No. 1*) and clinical faculty of EVMS. We are indeed very fortunate to have this outstanding young physician join Drs. Paul Schellhammer, Donald Lynch, Jr., and Robert Given, as the physician team supporting the translational research programs of the VPC.

Biorepository. Perhaps the most significant and key program supported by the VPC is the Center's biorepository. It is in the Biorepository (sometimes referred to as the tissue bank) where all the surgical tissue specimens, and body fluid samples (i.e., blood serum and plasma, urine, seminal plasma, prostatic fluid) are stored for research studies. Once specimens are procured, they are processed, carefully labeled, and stored in the Biorepository until such time when they are needed for a research study. The process of procurement, processing, and storage require a full-time team of four individuals; the Biorepository Manager and Assistant Manager, the Clinical Coordinator, and Database Manager. Over 10,000 specimens are currently stored in multiple ultra-low freezers. It is critical that each specimen be carefully linked to a patients' clinical history, otherwise the specimen will not provide useful information in a research study. Government regulations must also be strictly adhered

to, to protect the identity and personal information of the patient donor. This begins by first obtaining approval to conduct a clinical study from the Institutional Review Board and then obtaining informed consent from each patient/donor before specimens can be obtained. Having a well managed biorepository has had a significant impact on the VPC scientists ability to obtain federal, foundation, and industrial contracts/grants. Abbott laboratory, with whom the VPC has conducted several clinical studies, has stated "that the VPC biorepository is one of the top five such programs in the U.S."

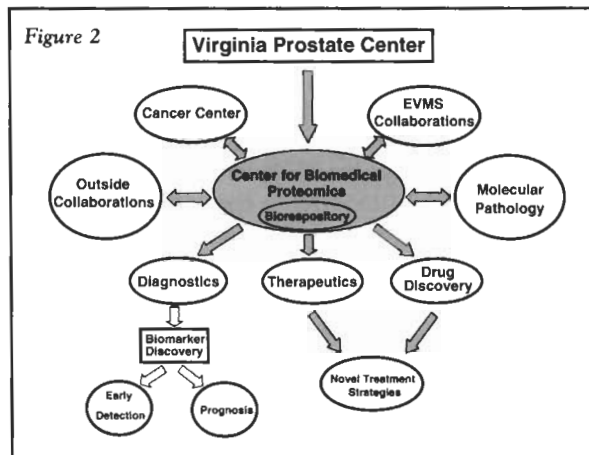
Provision of Grants and Assisting Other Research Programs. VPC funds have been used, on a limited basis, to provide small grants (usually not more than \$10,000) for investigators to conduct pilot experiments. The goal of these pilot studies is to obtain sufficient research data to prepare a competitive grant application to outside agencies. A grant awarded to Dr. Richard Ciavarra, a cellular immunologist, has supported his studies on developing novel immunotherapeutic strategies for treating prostate cancer. Based on results of this pilot study, several grant applications to outside agencies are currently pending. The expertise and infrastructure available in the VPC has also been instrumental in funding other cancer programs such as the breast cancer program headed by Drs. Christine Laronga, a surgical oncologist, and Richard Drake, a protein biochemist and molecular biologist; the head and neck cancer program lead by Drs. Trad Wadsworth, a surgical oncologist and Dr. Drake; an ovarian cancer study (Dr. Vlahou), and a leukemia study by Dr. Semmes and Ali Haoudi (a molecular biologist). Other studies in colon, lung, and pancreatic cancers are in the planning stages. The major focus of these later cancer studies follow in the footsteps of the VPC's prostate proteomic program in developing approaches for the early detection/diagnosis of cancer. The VPC supported studies have resulted in obtaining three extramural grants and several scientific publications (see list of publications).

How Has Your Gift Been Spent? *continued*

Research Equipment and Pioneering New Technology: Once patient specimens are available and a research team has been assembled that include outstanding clinicians and basic scientists, the second most important infrastructural need is having the appropriate research equipment to conduct “translational” research. What makes the VPC research program unique is its focus on translational research where scientists and physicians work together in close collaboration so that information discovered in the laboratory is made instantly available to physicians and vice versa: knowledge gained in the doctor’s office is made available to scientists working in the laboratory. By taking this approach, the VPC has made significant progress in answering some of the toughest questions concerning early detection and better treatment of prostate and other cancers. Key to its recent progress was the realization that not all cancers derived from the same organ, such as the prostate, were identical. This is due to the fact that the genetic makeup of each individual is different, and because of these genetic differences, no two prostate or breast cancers are alike. Once this was realized, it was highly unlikely that a single biomarker like PSA was going or should be expected to be accurate in detecting all prostate cancers. The poor specificity of PSA supports these facts. VPC scientists’ reasoned that what would be needed to improve early detection was a way to identify all the molecular differences associated with all prostate cancers that differentiate prostate cancers from healthy men. To achieve this goal, the VPC would require a novel way of simultaneously discovering all changes associated with cancers that are not found in normal tissues. With the

help of gifts to the VPC for the purchase of two new state-of-the-art instruments, the SELDI ProteinChip® mass spectrometer (\$150,000) and the Laser Capture Microdissection Microscope (\$80,000), the VPC scientist initiated studies towards achieving this goal. Furthermore, without the availability of these two key instruments, the VPC would not have been successful in obtaining a \$3,000,000 grant from the National Cancer Institute Early Detection Research Network and a \$800,000 grant from the Department of Defense. The VPC also provided a \$100,000 matching fund that was instrumental in obtaining a \$200,000 NCI grant for the purchase of an instrument (\$300,000) which is being used to identify and characterize potential protein biomarkers detected by SELDI.

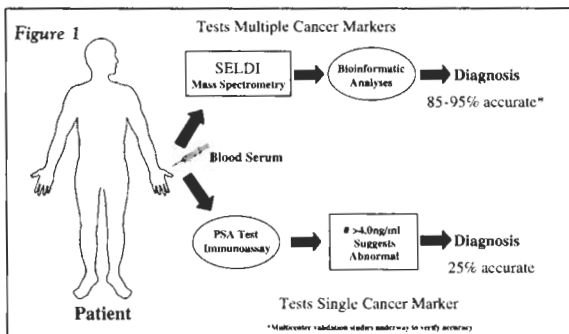
VPC scientists are regarded as pioneers and leaders worldwide in the development and application of SELDI protein profiling as a potential novel approach for the early detection of cancer. Since this research has been described in previous Newsletters and local and national media, it won’t be detailed here, other than to say that the SELDI technique shows considerable promise as an accurate clinical assay for early detection of prostate and other cancers. Fig.1 illustrates the comparative accuracy of SELDI vs. PSA, the current gold standard for the diagnosis of prostate cancer. Because of our groundbreaking research, research investigators at highly regarded institutions have asked to collaborate with VPC scientists. Collaborations have been established with Johns Hopkins University; University of Pittsburg Cancer Center; the Center for Prostate Disease Research at the Uniformed Services University of the Health Sciences; University of Alabama; Fred Hutchinson Cancer Institute; University of Texas Southwestern; and the National Cancer Institute



(Frederick campus). The VPC also has a collaborative agreement with Ciphergen Biosystems, Inc., the manufacturer of the SELDI instrument; and is in the process of negotiating with other potential industrial partners. To continue further our pioneering efforts and maintain our competitive stature in securing extramural grant funding, additional equipment and personnel will be essential. The VPC wishes to purchase two state-of-the-art mass spectral instruments that will give us more flexibility and accuracy in identifying and characterizing diagnostic and therapeutic markers. The combined cost of these two instruments will be close to \$1,000,000; again illustrating the high cost of scientific research.

Center for Biomedical Proteomics. Based on the success of the VPC SELDI proteomics program in prostate and other cancers, and the requests for assistance and collaboration by investigators within and outside EVMS, the VPC Center for Biomedical Proteomics was established in 2002. The purpose of this facility is to assist research investigators with proteomic needs such as purification and identification of proteins detected/discovered by SELDI and other proteomic methodologies. The Director is Dr. Semmes and the Associate Director is Dr. Drake. Figure 2 illustrates how the Center for Biomedical Proteomics supports the VPC translational research programs and provides services to other programs.

A Community Service. The VPC cancer proteomic programs have initiated a great deal of excitement in the



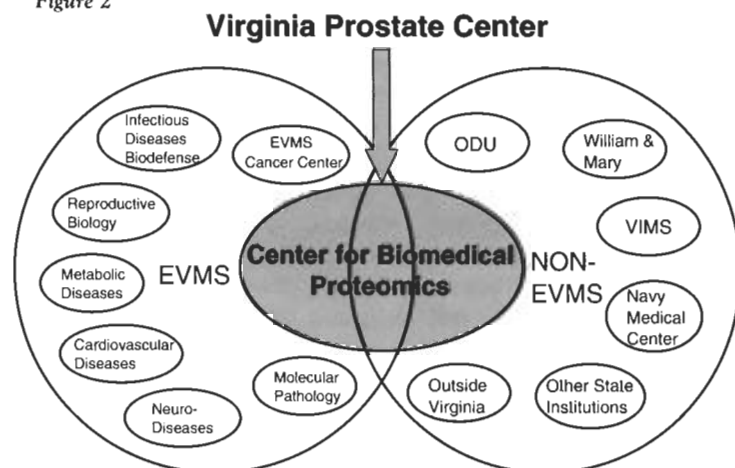
How Has Your Gift Been Spent? *continued*

Hampton Roads community by showing how proteomic applications have the potential to enhance scientific knowledge in many biomedical endeavors. One area of vital national interest that can benefit from proteomic research is in the development of biodefense systems, such as development of rapid detection assays and vaccines. The proteomic expertise and programs of the VPC, coupled with the application of genetic tools, has spawned the establishment of the EVMS Scientific Center for Biodefense earlier this year. A further collaboration with the Virginia Institute of Marine Sciences has recently been initiated to apply proteomics for development of new and rapid diagnosis of environmental factors that threaten human health in our waterways and the Chesapeake Bay. Figure 3 illustrates important interrelationships that the VPC's Center for Biomedical Proteomics can have with various EVMS biomedical

programs and investigators at other institutions in Hampton Roads and beyond.

We sincerely trust that this brief overview has clearly presented how your gifts have been used to support the research, education, and patient care programs of the Virginia Prostate Center. The VPC scientists and physicians have and will continue to make significant contributions to the healthcare of the citizens of Hampton Roads. We are proud of our accomplishments and your continued support of this nationally and internationally recognized and respected

Figure 2



cancer program. Together we will strive to meet the goal voiced by the current director of the NCI – “to markedly reduce and hopefully eliminate cancer-related suffering and death by the year 2015.”

Recent Publications (2001-2003)*

1. *Vlahou, A., Schellhammer, P.F., Mendrinos, S., Patel, K., Kondylis, F.I., Gong, L., Nasim, S., and Wright, Jr., G.L.* Development of a novel proteomic approach for the detection of transitional cell carcinoma of the bladder in urine. *Am. J. Pathol.* 158 (4), 1491-1501, 2001.
2. *Vermia, M., Wright, Jr., G.L., Hanash, S.M., Gopal-Srivastava, R., and Srivastava, S.* Proteomic approaches within the NCI early detection research network for the discovery and identification of cancer biomarkers. *Ann NY Acad Sci.* 945:103-115, 2001.
3. *Srinivas, P.R., Srivastava, S., Hanash, S., and Wright, Jr., G.L.* Proteomics in early detection of cancer. *Clin. Chem.* 47:1901-1911, 2001.
4. *Adam, B-L., Vlahou, A., Semmes, O.J., and Wright, Jr., G.L.* Proteomic approaches to biomarker discovery in prostate and bladder cancers. *Proteomics* 10:1264-1270, 2001.
5. *Xiao, Z., Adam, B-L., Cazares, L.H., Clements, M.A., Davis, J.W., Schellhammer, P.F., Dalmasso, E., and Wright, Jr., G.L.* Quantitation of serum prostate-specific membrane antigen by a novel protein biochip immunoassay discriminates benign from malignant prostate disease. *Cancer Res.* 61: 6029-6033, 2001.
6. *Adam, B-L., Qu, Y., Davis, J.W., Ward, M.D., Clements, M.A., Cazares, L.H., Semmes, O.J., Schellhammer, P.F., Yasui, Y., Feng, Z., and Wright, Jr., G.L.* Serum protein fingerprinting coupled with a pattern-matching algorithm distinguishes prostate cancer from benign prostate hyperplasia and healthy men. *Cancer Res.* 62: 3609-3614, 2002.
7. *Qu, Y., Adam, B-L., Yasui, Y., Ward, M.D., Cazares, L.H., Schellhammer, P.F., Feng, Z., Semmes, O.J., and Wright, Jr., G.L.* Boosted decision tree analysis of SELDI mass spectral serum profiles discriminates prostate cancer from non-cancer patients. *Clin. Chem.* 48:1835-1843, 2002.
8. *Cazares, L.H., Adam, B-L., Ward, M.D., Nasim, S., Schellhammer, P.F., Semmes, O.J., and Wright, Jr., G.L.* Normal, benign, pre-neoplastic, and malignant prostate cells have distinct protein expression profiles resolved by SELDI mass spectrometry. *Clin. Cancer Res.* 8:251-2552, 2002.
9. *Wright, Jr., G.L.* SELDI proteinchip mass spectrometry: A platform for biomarker discovery and cancer diagnosis. *Expert Rev. Mol. Diagn.* 2:549-563, 2002.
10. *Qu, Y., Adam, B-L., Thornquist, M., Potter, J., Yasui, Y., Davis, J., Schellhammer, P.F., Cazares, L., Clements, M.A., Dalmasso, E.A., and Wright, Jr., G.L., and Feng, Z.* Data reduction using discrete wavelet transform in discriminant analysis with very high dimension. *Biometrics* 59:141-151, 2003.
11. *Yasui, Y., Pepe, M., Thompson, M.L., Adam, B-L., Wright, Jr., G.L., Qu, Y., Potter, J.D., Winget, M., Thornquist, M., and Feng, Z.* A data-analytic strategy for protein biomarker discovery: profiling of high-dimensional proteomic data for cancer detection. *Biostatistics* 4:449-463, 2003.
12. *Meighan, M.A., Dickerson, M.T., Glinskii, O., Vladislav, V.G., Wright, Jr., G.L., and Deutscher, S.L.* Recombinant glutamate carboxypeptidase II (Prostate specific membrane antigen - PSMA): Cellular localization and bioactivity analyses. *J. Protein Chem.* 22:317-326, 2003.
13. *Wadsworth, J. T., Somers, K.D., Stack, B.C., Jr., Cazares, L., Malik, G., Adam, B-L., Wright, G.L., Jr., and Semmes, O.J.* Identification of head and neck cancer patients using serum protein profiles. *Arch. Otolaryngology Head & Neck Surgery (In Press)*
14. *Vlahou, A., Laronga, C., Wilson, L., Gregory, B.S., Fournier, K., McGaughey, D., Perry, R.R., Wright, G.L., Jr., and Semmes, O.J.* A novel approach towards development of a rapid blood test for breast cancer. *Clin. Breast. Cancer (In Press)*
15. *Ciavarra, R.P., Holterman, D.A., Brown, R.R., Mangiotti, P., Yousefieh, N., Wright, G.L., Jr., Schellhammer, P.F., and Somers, K.D.* Prostate tumor microenvironment alters immune cells and prevents long-term survival in an orthotopic mouse model following ft3-ligand/CD40-ligand immunotherapy. *J. Immunol. Transplan. (In Press)*
16. *Somers, K.D., Brown, R.R., Holterman, D.A., Yousefieh, N., Margiotta, A., Glass, W.F., Wright, G.L., Jr., Schellhammer, P.F., Qian, J., and Ciavarra, R.P.* Orthotopic treatment model of prostate cancer and metastasis in the immunocompetent mouse: Efficacy of FLT3 ligand immunotherapy. *In. J. Cancer (In Press)*

*VPC members are identified by the names in *bold italics*.

Gifts

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Men age 40 and older who have a diagnosis of prostate disease (prostatitis, benign prostate hyperplasia or prostate cancer), and men who do not have prostate disease are needed to donate body fluids for the SELDI Biomarker study. A compensation for the donation will be provided.

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