



Science
Science



ur Vision:

To combine vision and inspiration with the best science possible to empower healthcare providers with the information and diagnostic tools to practice the cutting-edge medicine of the new millennium in healing.

- **Functional assessment exceeding the highest standards in the industry.**
- **Aggressive research and development to create the finest instruments available.**
- **Education about the emerging therapeutic paradigm.**
- **Information and knowledge for the medical breakthroughs of the future.**

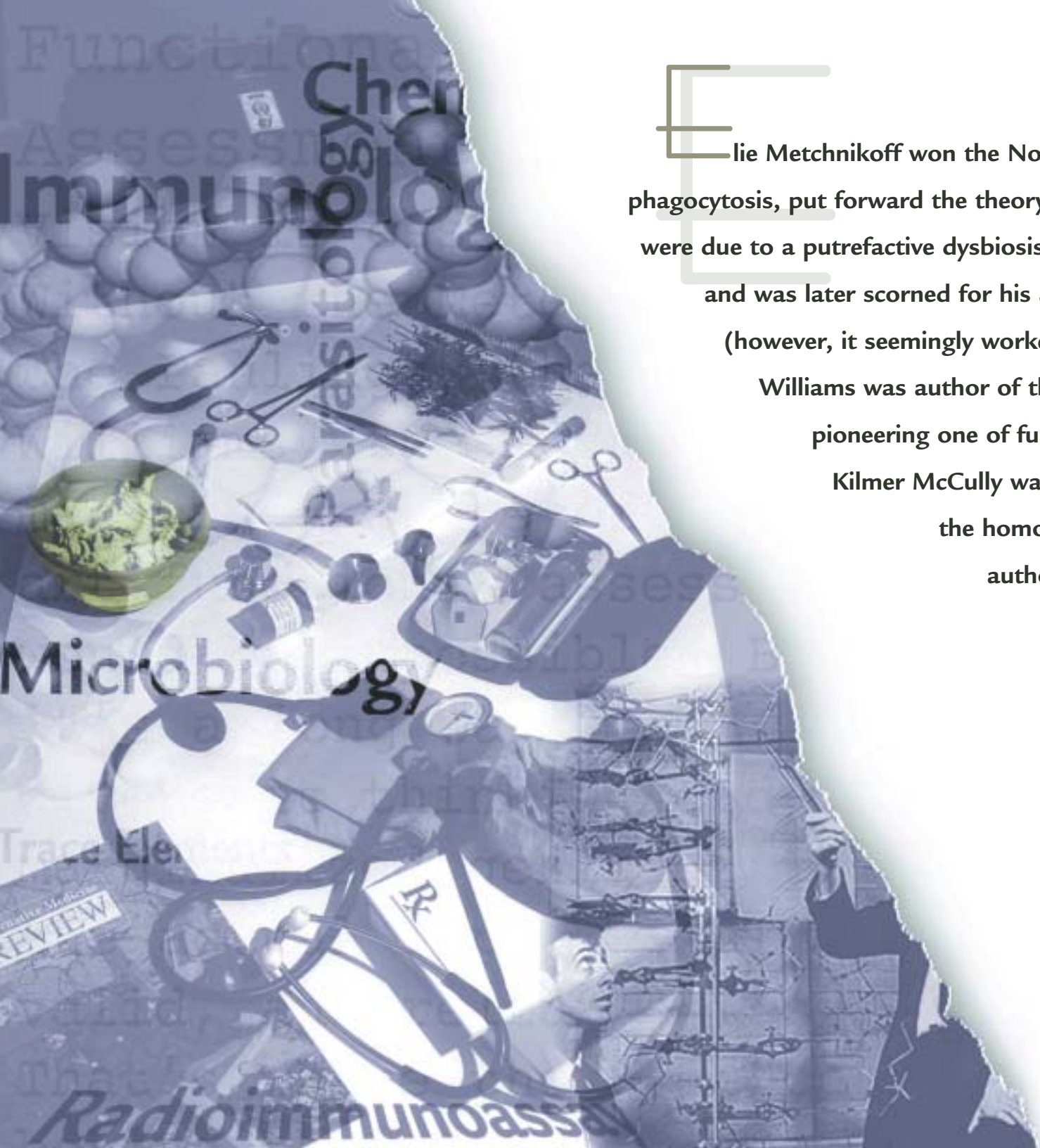




Emerging Paradigm
New Feedback Loop
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Science Science

Vision. Vision



Elie Metchnikoff won the Nobel Prize in 1908 for his work on phagocytosis, put forward the theory that most degenerative diseases were due to a putrefactive dysbiosis. Linus Pauling also won a Nobel and was later scorned for his advocacy of megavitamin therapy (however, it seemingly worked for him--he died at 93). Roger Williams was author of the classic *Biochemical Individuality*, pioneering one of functional medicine's key concepts. Kilmer McCully was the much-maligned advocate of the homocysteine theory in the 1960s and author of *The Homocysteine Revolution*.

Functional Assessment

Vision is essential. Without the Metchnikoffs, the Paulings, the Williams, the McCullys of medicine, state of the art functional assessment would be impossible. But it's a long way from the divergent thinking and marginalized geniuses to the actual reproducible, valid, and reliable test. That's where the science behind the vision comes in.

At Great Smokies that process involves a number of highly qualified professionals in several areas, but the end-product, the innovative test conducted

according to the strictest quality control standards, depends on the human resources led by Laboratory Director Dennis Freer, Ph.D., Assistant Laboratory Director James Rudrick, Ph.D., and Quality Control Officer

Leslie Hart, M.T., B.S. Together the lab management group directs the work of nearly one hundred technicians in seven laboratories.

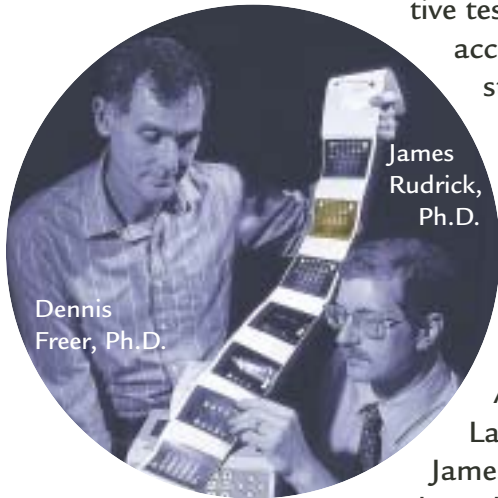
The individual labs--Parasitology, Microbiology, Chemistry, Immunology, Radioimmunoassay, and Trace Elements--all meet the highest standards in the industry. Our certifications include CLIA

(Clinical Laboratory Improvement Act), Medicare/Medicaid, individual states (including the rigorous standards of New York), and the College of American Pathologists--the most prestigious certifying body of all. To keep our certifications, Great Smokies' labs must pass regular proficiency testing involving split samples sent to several labs as a standard for comparing our results.

Along with our cutting edge technology, we also have one of the few laboratories in the United States doing clinical testing for trace elements in a "clean room." Whether we're performing manual examination for parasites and yeast or sophisticated molecular analysis of amino acids, fatty acids, or C-reactive protein, our technicians have the best equipment available and quality assurance protocols designed with redundancies to ensure the integrity of results. As an example of the rigor of these protocols, consider what happens before results of the Essential and Metabolic Fatty Acid Analysis are released:

Two quality control samples are similarly analyzed with each batch of samples, and if the QC percentages meet stringent criteria for reproducibility, the patient data is released for reporting.

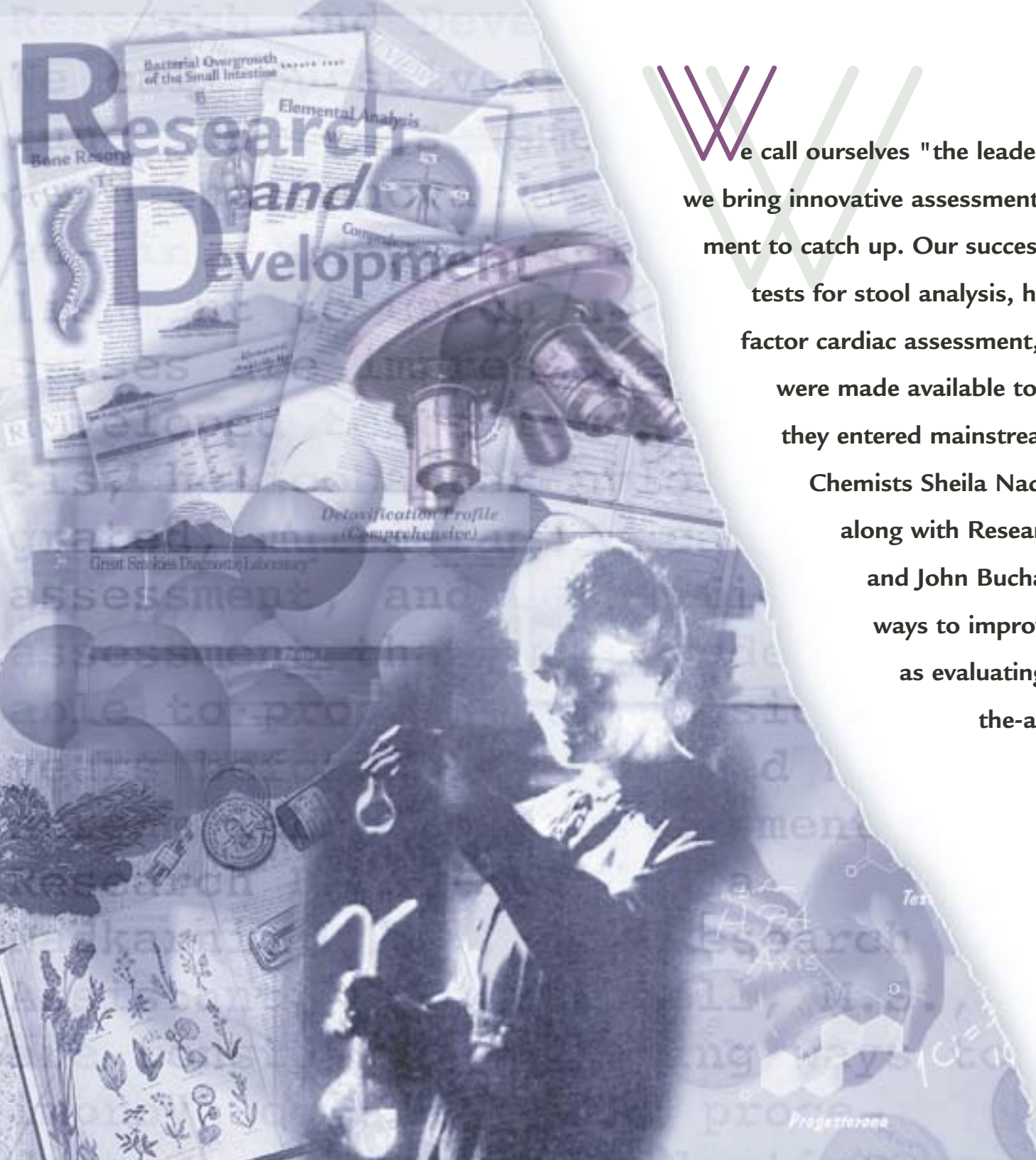
Only when Great Smokies is convinced it can stand behind test results are those results released to our clients to use in the treatment of their patients.



James
Rudrick,
Ph.D.

Dennis
Freer, Ph.D.

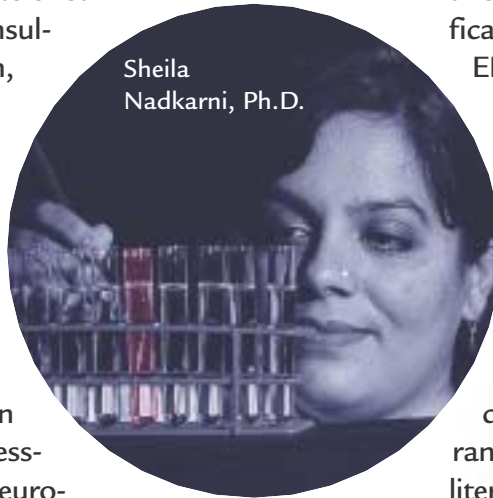




We call ourselves "the leader in functional assessment" because we bring innovative assessments on-line and wait for the establishment to catch up. Our successes are impressive: we've developed tests for stool analysis, helicobacter pylori, integrated, multi-factor cardiac assessment, and detoxification assessment that were made available to progressive physicians years before they entered mainstream laboratory assessment. Research Chemists Sheila Nadkarni, Ph.D., and Sooja Lee, Ph.D., along with Research Associates Gleta Carswell, M.S., and John Buchanan, M.S., are constantly exploring ways to improve our tests and procedures, as well as evaluating ways to move promising, state-of-the-art science from the Ivy Tower to the world of doctors and patients.

Research and Development

Doctors Sheila Nadkarni and Sooja Lee also work on an ad hoc basis with some of the best minds in biochemistry and laboratory science to develop new assessments and sophisticated existing ones. Currently, our consultants include: Jon Pangborn, Ph.D., a pioneer in amino acid and trace element analysis; Lindsay Hofman, Ph.D., a highly regarded endocrinologist who perfected assessments of hormone levels in saliva samples; and Sidney M. Baker, M.D., the well-known authority in biomedical assessments for psychiatric and neurological conditions.



Sheila
Nadkarni, Ph.D.

Great Smokies' laboratory professionals actively participate in professional development organizations. Research Department staff, in addition, coordinates projects with university-based researchers around the country and disseminates information in professional journals. Our collaborators have included medical researchers at the University of Virginia, Albert Einstein School of Medicine, Robert Wood Johnson Foundation, and Johns Hopkins University. Great Smokies regularly donates laboratory services to practitioners and researchers in an effort to improve service delivery to patients.

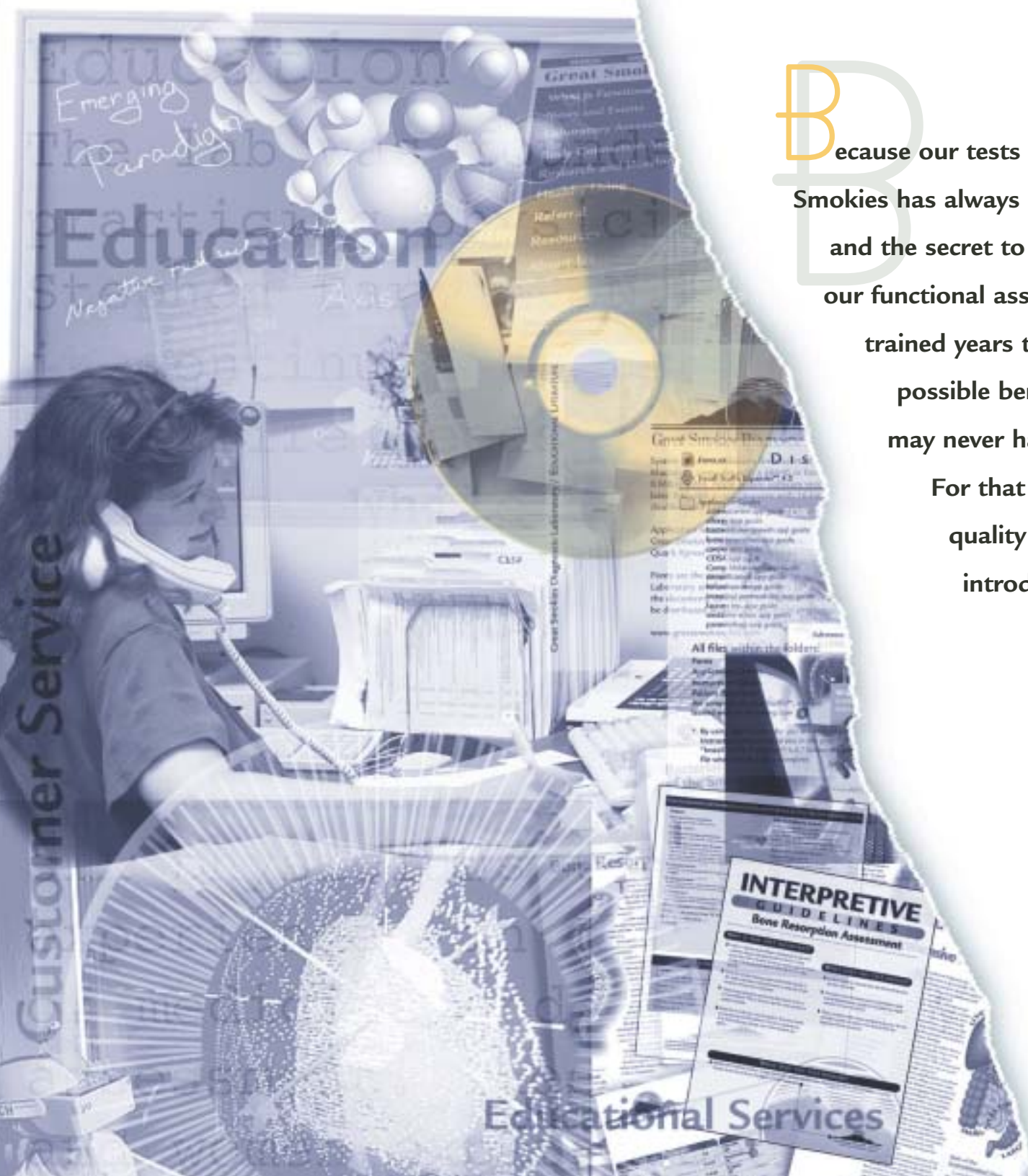
Under the overall guidance of Laboratory Director Dennis Freer, Ph.D., Research and Development

chemists continue to develop Enzyme Immunoassay (EIA) testing for more of the protozoans we analyze in our Comprehensive Parasitology Assessment. R & D in this area has already dramatically improved the identification rate for the four parasites now detected by EIA as well as microscope examination. As R & D develops EIA for additional parasites, the once "hidden" traces of parasite organisms will be detected--helping more physicians pinpoint the causes of illness and more patients recover from the effects infection.

Sometimes the lines between QA and R & D blur, because one of our most important goals is to develop and update the most accurate reference ranges possible. Research in this area begins with the literature, but before any test comes on-line, Great Smokies evaluates published reference ranges with the test results from its own sample population and the process of testing sample populations continues on a regular basis.

More accurate and innovative testing is the goal of the research teams at Great Smokies. At present, the teams are working on exiting new assessments of genetic markers for aging, additional markers of cardiac health, a fecal mercury test, an organic acids profile, and an analysis of essential fatty acids in mother's milk. As the latest research uncovers more opportunities for precise assessments to help physicians extend the lives of their patients and improve the quality of those lives, Great Smokies' researchers will be looking for ways to bring important new tests on-line.





Because our tests are on the frontier of medicine, Great Smokies has always considered education its primary goal and the secret to successfully introducing physicians to our functional assessments. We can't expect physicians trained years to decades earlier to reap the greatest possible benefit from tests based on science they may never have encountered during their training. For that reason, we have gathered the highest quality human and educational resources to introduce physicians to the new functional/biochemical paradigm and to support them as they assess and treat their patients.

Education

The lab was founded by a practicing physician, Stephen Barrie, N.D., and it continues to address the real life needs of practitioners. While we need our specialized laboratory scientists to research and implement our testing, we also maintain a staff of six physicians trained and experienced in the practice of medicine and laboratory assessment. These are men and women experienced in the wide range of patients and conditions who can provide valuable assistance to doctors on the front line of medical practice.

In addition to providing personalized consultation for our clients, the Education Services professionals work closely with our consultants and our production writers, graphic artists, and media specialists to create a wide range of educational materials for physicians and patients. Printed resources include detailed and referenced application guides about the scientific basis and practical uses of the tests; interpretation guides to suggest strategies for interventions; colorful, patient- and physician-friendly test reports with detailed commentary on test results; and patient brochures to help patients understand why the physician has ordered the test.

Just as the world of communications is changing so are we. Great Smokies produces its own audio and video tapes for physicians on the go and animated A/V resources for our lecturers. We have recently redesigned and augmented our internet sites and are constantly exploring ways to make them even more user-friendly and interactive. To make distrib-



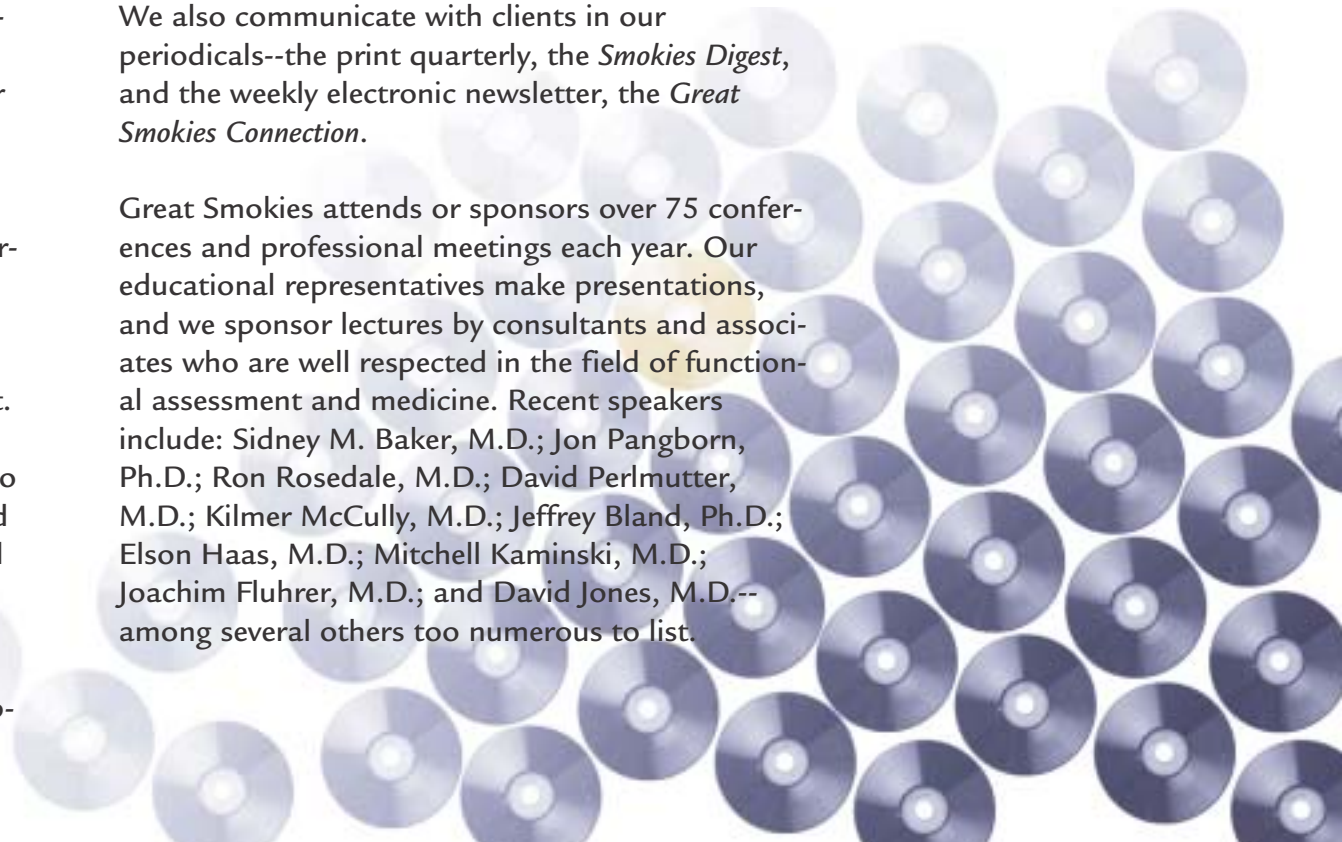
Allison
Levitt,
M.D.

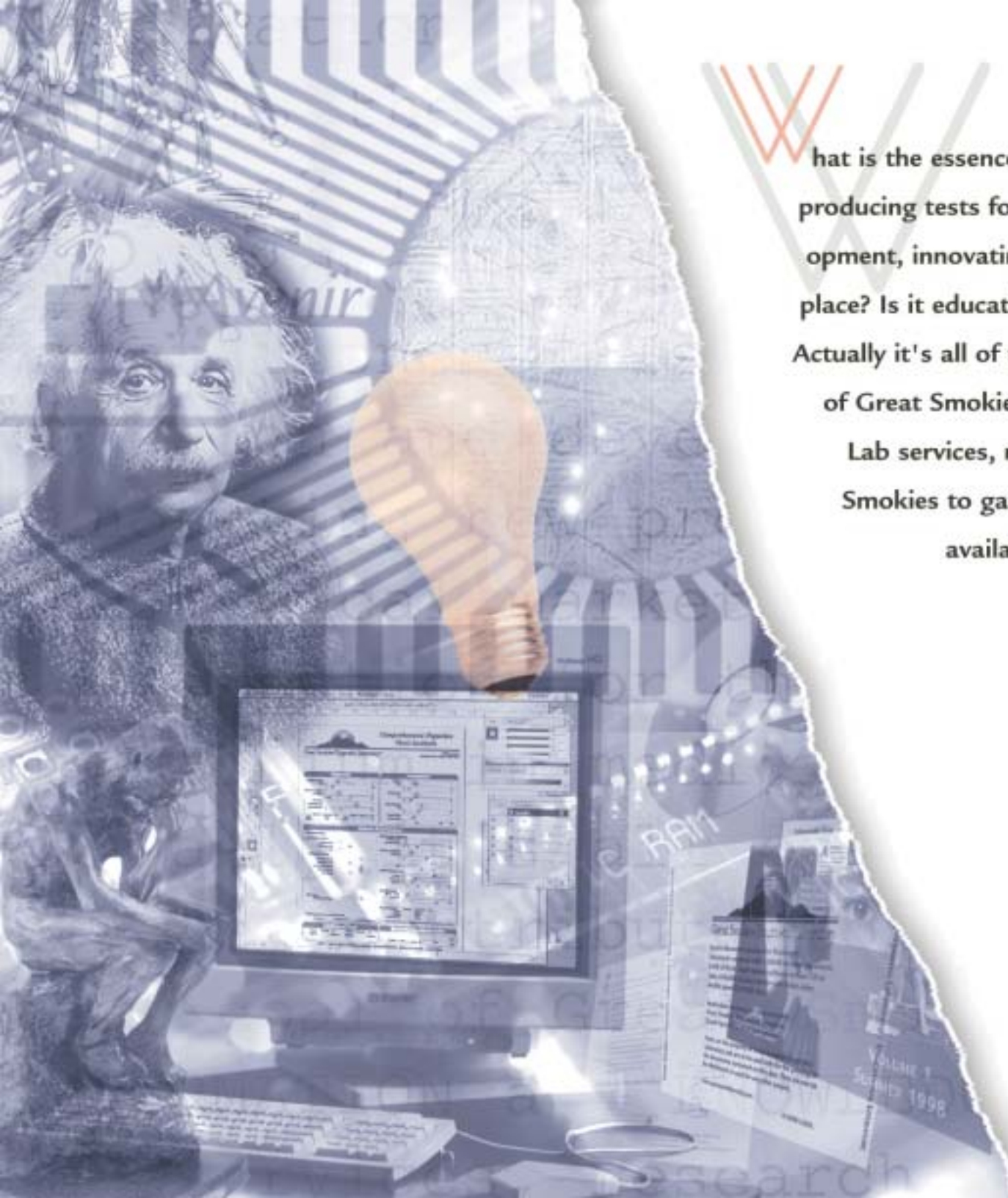
ution and translation of materials even easier for our distributors abroad, we are also involved in producing our materials on CD ROM for the most

popular computer platforms.

We also communicate with clients in our periodicals--the print quarterly, the *Smokies Digest*, and the weekly electronic newsletter, the *Great Smokies Connection*.

Great Smokies attends or sponsors over 75 conferences and professional meetings each year. Our educational representatives make presentations, and we sponsor lectures by consultants and associates who are well respected in the field of functional assessment and medicine. Recent speakers include: Sidney M. Baker, M.D.; Jon Pangborn, Ph.D.; Ron Rosedale, M.D.; David Perlmutter, M.D.; Kilmer McCully, M.D.; Jeffrey Bland, Ph.D.; Elson Haas, M.D.; Mitchell Kaminski, M.D.; Joachim Fluhrer, M.D.; and David Jones, M.D.--among several others too numerous to list.





What is the essence of Great Smokies? Is it the laboratory, producing tests for practitioners? Is it research and development, innovating new products for the medical marketplace? Is it education for the new millennium in medicine? Actually it's all of these as they contribute to the real goal of Great Smokies--INFORMATION and KNOWLEDGE.

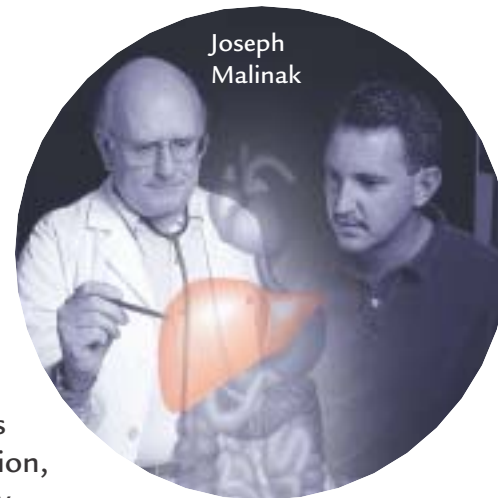
Lab services, research, and education all enable Great Smokies to gather and provide the information that is available nowhere else in quite the same way.

Information and Knowledge

Great Smokies is an information company working toward a merger with the greatest functional medicine think tank in the world--HealthComm, Inc., led by Jeffrey Bland, Ph.D. Dr. Bland's company performs a three-fold service for the medical community. It produces pharmacy-grade medical foods in an FDA-approved facility. It distributes print and electronic information for practitioners. It sponsors the non-profit Institute for Functional Medicine which offers a series of seminars each year granting Continued Education Credits for practitioners worldwide, and it supports clinical research through a program of fellowships.

Together Great Smokies and HealthComm will diversify horizontally to provide an exhaustive informational service for doctors and patients. As one company, we will gradually evolve from a laboratory services/medical foods manufacturing business (offering education as a support service) to a source of empowerment through information and knowledge products (while offering the tools to take full advantage of that information and knowledge). The synergy which will emerge from the union of these two companies will broaden the technical and human resources available to create the ground-breaking medical knowledge for the future.

As an information and knowledge company, success and growth will depend on the uniquely innovative nature of the methods we use to communicate as well as the quality of the matter we provide consumers and medical professionals of all kinds, all over the world.



Joseph
Malinak

It's a challenge that demands vision on the part of Great Smokies Diagnostic Laboratory. It means opening minds to new approaches to health and medicine. It requires hard work, relentless investigation, and a flexible, multi-disciplinary approach to the ground-breaking ideas of the future of medicine. But it also requires the hard science behind the vision, the testing of new concepts against the touchstone of practical healing and the rigors of the accepted scientific investigation. And, finally, it demands the creation of an information product to bridge effectively the conceptual gulf between the present and future--the ability to bring new knowledge and unfamiliar paradigms to physicians and patients.

It's a challenge Great Smokies continues to meet today and plans to meet into the exciting new millennium that approaches. More than ever before, medicine will need a sort of virtual university that blurs the artificial distinction of disciplines and is not bound by the old limits of time and place. A constantly unfolding, an ever redefining provider of knowledge and the power that comes with its mastery



Stephen Barrie, N.D., founded Great Smokies Diagnostic Laboratory in 1984 and has served as President since. He is recognized internationally as a leader in the development of innovative functional assessments.

Jeffrey Bland, Ph.D., is the Chief Executive Officer of HealthComm International and Director of the Institute for Functional Medicine in Gig Harbor, Washington. He has written extensively on health and nutrition and serves as a nutritional consultant for Great Smokies.

John Buchanan, M.S., Research Associate, is an experimental physical chemist currently engaged in instrumentation development for assays of toxic and nutritional elements. Prior to joining Great Smokies, he worked with laser emissions and inductively coupled plasma spectroscopy in academic and industrial labs.

Gleta Carswell, M.S., Research Associate, is a plant cell biologist engaged in ELISA (enzyme-linked immunosorbent assay) development for allergy assessments. She has 13 years experience in cell biology and molecular biology in an industrial laboratory.

Joseph Collins, N.D., has worked in both private and integrative group practices before joining the educational staff in 1996. Dr. Collins provides practical and technical support for practitioners. His special interest is assessment and management of endocrine function.

Michael Culp, N.D., worked as a family doctor in Seattle and taught nutritional biochemistry and other courses at Bastyr University prior to joining Great Smokies in 1998. His special interests are nutritional interventions and Essential and Metabolic Fatty Acids Analysis.

Dennis Freer, Ph.D., Laboratory Director, has 20 years experience as Clinical Chemistry Director in university and private hospitals, and private clinical laboratories. Dr. Freer holds a Laboratory Director License from the American Board of Bioanalysis and from New York State.

John Furlong, N.D., spent ten years in private practice and has taught anatomy and physiology. John Furlong joined the educational staff of Great Smokies in 1996 and provides practical and technical support for the physicians, especially in the areas of detoxification/oxidative stress, glucose and insulin tolerance, elemental analysis, and cardiac assessment.

Mary James, N.D., was in private practice for four years before becoming a nutritional consultant for a supplement manufacturer. With four years experience at Great Smokies, she is our senior laboratory physician and a popular speaker at conferences and special training sessions. She specializes in gastrointestinal, bone resorption, allergy, and amino acid assessment.

Mitchell Kaminski, M.D., is board certified in Nutrition and is Clinical Professor of Surgery at the Thorek Hospital Medical Center in Chicago. He serves as a consultant for oxidative stress with Great Smokies and is active in the field of anti-aging medicine.

Sooja Lee, Ph.D., Senior Research Associate, is a research biochemist for Great Smokies. She worked on the EIA (enzyme immunoassay) development for the Comprehensive Parasitology test and is involved in the ELISA development for allergy assessments.

Uta Levinson, M.S., formerly research associate, is now supervisor of the Chemistry Laboratory. She has been actively working toward improved plasma homocysteine and C-reactive protein assays.

Alison Levitt, M.D., is board certified in Family Practice. Her special interest is establishing integrative applications for functional assessment in conventional practices.

Joseph Malinak is Manager of the Educational Services Department. He has over fifteen years experience designing educational programs for software developers and specializes in the development of effective, state-of-the art training programs.

Sheila Nadkarni, Ph.D., Senior Research Associate, is a research biochemist for Great Smokies and supervisor of the radioimmunoassay laboratory. Her most recent project involved the development of assays for hormone assessment in saliva.

Jon Pangborn, Ph.D., serves as elemental and amino acid analysis clinical specialist and consultant for Great Smokies. Since 1981, he and his wife Chris have also operated Bionostics, Inc., a technical consulting. Dr. Pangborn is also Adjunct Professor of Nutritional Biochemistry, Union Institute (Cincinnati, OH).

James Rudrik, Ph.D., serves as Assistant Laboratory Director for Great Smokies. He has over seventeen years laboratory experience, and he holds a New York State director's license for Bacteriology, Parasitology, Mycology, Mycobacteriology, and Diagnostic Immunology.

Russel Sher, D.C., practiced integrative chiropractic and nutritional medicine for 12 years in the United States and his native South Africa. He is available for consultation on functional assessment and, specifically physiological dysfunction as a cause of pain and inflammation.

Bob L. Smith, Vice-President-Elemental Analysis, developed assessments of element and nutrient levels using hair, blood, and urine specimens. He is recognized as an authority on the effects of nutrition and toxic element exposure on human behavior, and he lectures worldwide on the topic.



Emerging Paradigm

Neurotrophic Factor Inhibitor

Testosterone

Cortisol

Bone Resorp

Elemental Analysis

Comprehens

Detoxificat (Complex)

Quantitative Diagnostic Laboratory

