Dr. Howard McLeod Leads Personalized Medicine



TEAMED UP with Personalized Medicine: Clinical Group Offers Cancer Genomics Expertise

By Randolph Fillmore

It has been a circuitous and somewhat unusual professional route for a man with a doctorate in pharmacology, but after an educational and professional career bounding from Seattle to Philadelphia to Memphis to Glasgow, Scotland, to St. Louis and to Chapel Hill, **Howard McLeod, Pharm.D.**, finally landed in Tampa at Moffitt in September 2013.

Dr. McLeod's presence here has been a win-win-win situation. At Moffitt, he serves as medical director of the DeBartolo Family Personalized Medicine Institute, and he is a senior member in Moffitt's **Department of Cancer Epidemiology**. Being at Moffitt is a winning situation for him because he has a place to bring his diverse experience and interests to the job. It's a win for Moffitt because the promises of personalized medicine have taken a great leap forward, and it's a definite win for patients who will continue to have more and better treatment options.

"What I love most about Moffitt," says Dr. McLeod, "is that everyone here knows why they are here — no matter what their job or title, they all know they are here to help cancer patients. That is unique."

An apt perspective. From his office window, he can see most of the Moffitt campus, including a newer research building, the hospital section, an outpatient clinic, and a driveway leading to valet parking with the daily flow of hopeful patients.

Dr. McLeod, and what he is doing, is also unique. Many who have earned a Pharm.D. go on to acquire positions in retail pharmacies, while others work in clinical pharmacology in hospitals. Dr. McLeod, however, is using his pharmacology training in broad, innovative ways. It was the uniqueness, breadth and depth of his experience in

research and clinical pharmacology — as well as experience that included both pharmacological knowledge and time spent supervising large clinical trials — that brought him to Tampa to help further Moffitt's goal to "get the right drug, to the right patient, at the right time."

To arrive at this point, Dr. McLeod credits Moffitt's uniqueness in having both clinical expertise and basic science expertise "under one roof" and the success of the Total Cancer Care® protocol that, among its other successes, has established an enormous tissue bank of tumor samples, donated by patients, that can be used to match an individual's tumor genetics to the newest, most promising genetically targeted treatments.

Another giant step toward personalizing cancer treatment since Dr. McLeod's arrival at Moffitt has come with the establishment of Moffitt's Clinical Genomics Action Committee (CGAC), which Dr. McLeod leads with Dr. Christine Walko and Dr. Jamie Teer. The CGAC members include medical oncologists, surgeons, pathologists, basic scientists, genetic counselors and even financial administrators who participate to further the personalization of cancer care — one patient at a time.



The DeBartolo Personalized Medicine Institute team

The CGAC is not unlike the traditional tumor board in which a team of surgeons, medical oncologists, radiation oncologists, pathologists and other specialists meet regularly to discuss the comprehensive care of patients with specific types of cancer. But the CGAC takes things a few steps further.

"The committee implements cancer genomics and other individualized treatments by providing a multidisciplinary assessment of advanced diagnostic strategies and complex clinical results," Dr. McLeod explains. "We meet to discuss individualized care for patients diagnosed with all types of cancer, and working together we reach agreement on the best possible treatments for each patient, based on a variety of scientific assessment data."

He's passionate about his work. Despite all the hats he wears, when you sit down to talk with Dr. McLeod, he is very much "in the moment," focused on the conversation at hand.

In addition to offering the patient the best and most advanced personalized treatment available, the CGAC has a new goal: to assess the benefit and risk to that patient for a given treatment. This means hitting what Dr. McLeod calls "the sweet spot." His team is using genetic and other scientific testing to determine how the patient may respond, with an eye toward avoiding toxicities that could cause new and unnecessary illnesses, while simultaneously avoiding the costly management of adverse treatment effects.

The CGAC is set up to review tumor molecular information generated for every case at Moffitt. Also being set up under Dr. McLeod's leadership is a personalized medicine consulting service that will offer genomic expertise to physicians across the country. Moffitt is expanding its efforts with the aim of becoming one of the first cancer centers in the world to pre-test patients for genomics.

To reach these goals, Dr. McLeod is pulling from his toolbox, put together over many years of diverse experiences. An especially formative experience for Dr. McLeod came during his eight-year stint in the 1990s in Scotland at the University of Glasgow and the University of Aberdeen. There he was able to deploy and employ his training in pharmacology and add a large dose of the clinical and research experience. The total of his talents put him in a unique position in terms of the "hats" he could wear working within the United Kingdom's National Health Service system. Among other responsibilities, he ran clinical trials with large numbers of patients.

"The UK's National Health System does not allow all drugs to be prescribed for patients, so about the only way patients with cancer could get new and experimental drugs was to be on a clinical trial," he explains. "In the U.S., about 10 percent of cancer patients are on clinical trials. That is not the case elsewhere. For example, during my time at the University of Aberdeen, about 80 percent of the cancer patients were on clinical trials."

Having large numbers of patients on clinical trials, all in one place and with plenty of data to analyze, was a unique and formative experience, he says. Clinical trials are essential in the search for new and better treatments.

At Moffitt, he is able to merge his vast experience with resources and new technologies that have sped up the analysis of genetic and molecular data on patients, giving clinicians the kind of personalized information on patients not available just a few years ago. This information, both genetic and molecular, helps clinicians decide which patient should be on which clinical trial or treatment, as well as helping patients avoid serious side effects and the possibility of drug resistance.

"Moffitt's Precision Molecular Diagnostics Laboratory has been a game changer," says Dr. McLeod. The laboratory is directed by Anthony Magliocco, M.D., who also chairs Moffitt's Anatomic Pathology Department. "The lab provides us with fast turnaround when we need genetic and molecular data on a patient's tumor for procedures such as bone marrow transplants, for which there may be a very limited time window when a patient's white blood cells are at specific levels. Bone marrow transplants are high-stakes endeavors, and we need data on each candidate very quickly. And we have the advantages of this in-house specialized lab that can quickly carry out molecular analysis, work that is often not performed in a routine clinical laboratory."

Another technological advantage for Moffitt and for patients, says Dr. McLeod, is the research on patient tumor proteins carried out at Moffitt's Proteomics Core facility, headed by John Koomen, Ph.D. There, biomedical analysis goes beyond data about a patient's genetic makeup to information about how specific proteins, the workhorses of the genetic blueprint, function in tumor cells.

The power of Moffitt, says Dr. McLeod, is that basic scientists and clinicians together are using the most modern technology to glean genetic and molecular data on a patient's tumor and applying those findings to deliver the best possible individualized treatment to each patient.

"Everyone here is on the same page," he says.

The DeBartolo Personalized Medicine Institute was established to revolutionize the discovery, delivery and effectiveness of cancer care on an international scale. Providing oversight for Moffitt Cancer Center's Total Cancer Care® Study, the institute seeks to create and share targeted treatments that will improve outcomes, cure disease, extend survivorship and improve quality of life for patients regardless of where they live. The institute is supported by a generous donation from the DeBartolo family.

An internationally recognized expert in how genetic makeup affects an individual's response to cancer treatment, Dr. McLeod is the founding medical director of the DeBartolo Personalized Medicine Institute and senior member in the Department of Cancer Epidemiology. Dr. McLeod is also Moffitt's first cancer research endowed chair, as established by the Florida Legislature. He has been principal investigator for more than \$16 million in grants and co-investigator for more than \$80 million in grants from the National Institutes of Health. He has also authored more than 480 peer-reviewed papers on pharmacogenomics, applied therapeutics and clinical pharmacology.