Finding Hidden Cancer Cells: FDA Approval of New Imaging Tool Could Transform Treatment Decisions for Advanced Prostate Cancer

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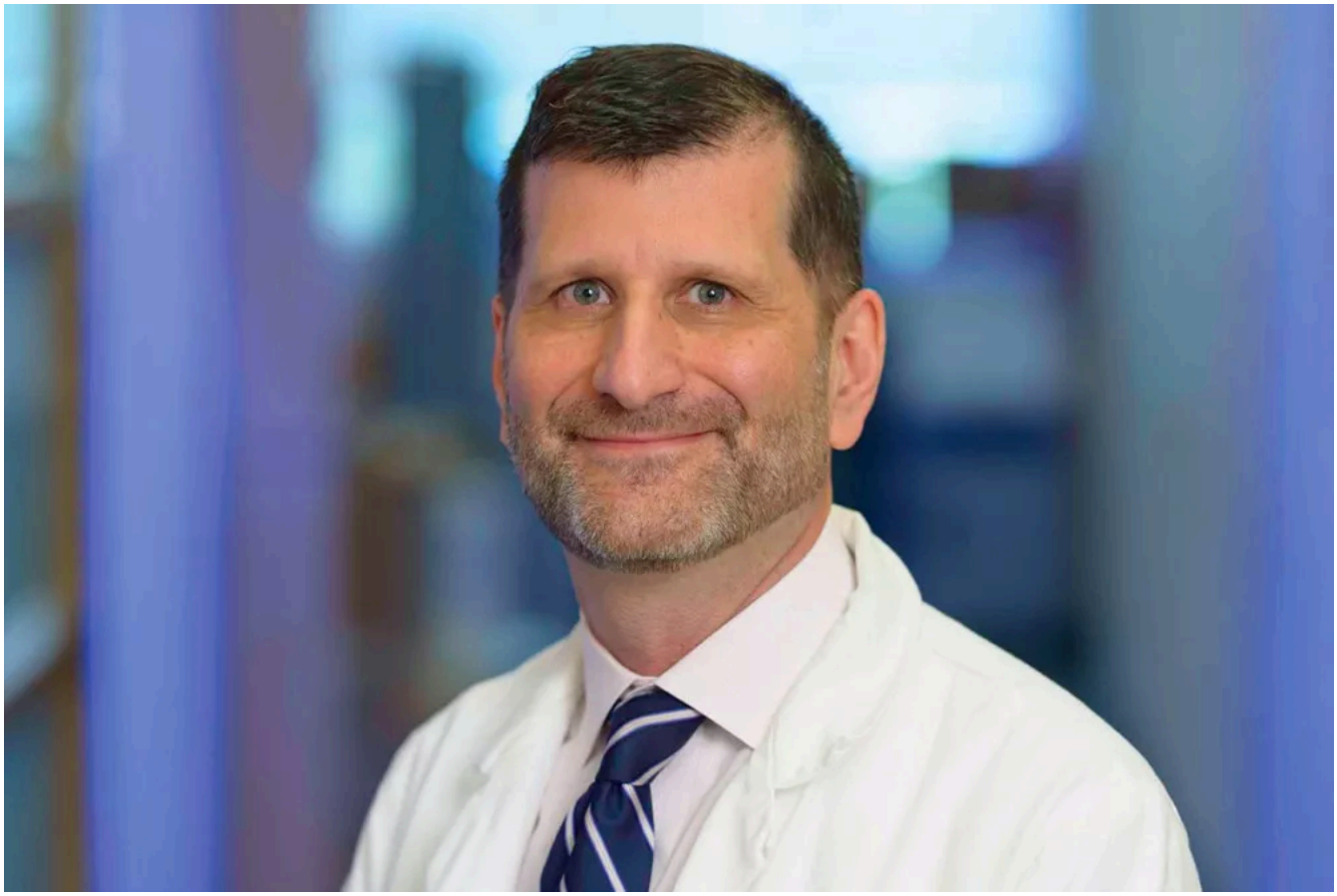

Medical oncologist Michael Morris says the new imaging tool can track the location of prostate cancer cells with unprecedented accuracy.

Prostate cancer diagnosis and treatment took a major step forward today as the US Food and Drug Administration approved an imaging technology that enables doctors to pinpoint the location of prostate cancer cells that would otherwise be hidden in the body. This new technology is especially helpful to track and treat prostate cancer that has spread.

"This is the biggest diagnostic advance for prostate cancer since the 1980s, when the PSA [prostate-specific antigen] test was introduced," says Memorial Sloan Kettering medical oncologist Michael Morris. Prostate cancer is the second leading cause of cancer death in men and kills 34,000 Americans every year.

The new technology (called piflufolastat F 18 or PYLARIFY®) consists of a radioactive targeting molecule which, upon injection, selectively seeks out and attaches to a protein on the cancer cells' surface. The protein, called prostate-specific membrane antigen (PSMA), is not found on most normal cells. When the radioactive tracer binds to the prostate cancer cells, they show up as bright spots on a PET scanner.

Dr. Morris played a leading role in two phase III clinical trials testing a particular imaging tracer that is easy to manufacture and can be used at all institutions. MSK radiologist Hebert Alberto Vargas and interventional radiologist Jeremy Durack were key

collaborators in the development and testing of the tracer. Today's approval is the first for a tracer that can have national, widespread use.

A similar tracer was fully FDA-approved in December 2020, but only for use at two institutions. Similarly, the Molecular Imaging and Therapy Service at MSK has been offering PSMA imaging with a slightly different tracer for the past three years under an FDA-approved investigational new drug (IND) application, benefiting more than a thousand patients thus far.

"Imaging has been the Achilles heel of prostate cancer because the disease is hard to detect after it has spread," Dr. Morris says. "Now we can be much more confident that we are correctly identifying the location of the disease to make an accurate treatment plan."

> **"The benefits this advance will bring to men with this common disease cannot be overstated."**

Michael J. Morris
medical oncologist

Pinpointing Cancer's Return

Kevin Taylor has benefited greatly from the new imaging. A 65-year-old textile designer living in New York City's Financial District with his wife and two teenage boys, he has been under the care of Dr. Morris for a decade. After being diagnosed with prostate cancer in 2010, he had his prostate removed at another New York City hospital and came to MSK in the spring of 2011 when his disease relapsed.

Over the next eight years, his cancer came back twice. It was temporarily held at bay with different treatments — including radiation and a clinical trial testing an experimental vaccine — only to rear its head again.

After conventional imaging scans had shown that Kevin had no disease, Dr. Morris asked if he was willing to enroll in a clinical trial, called OSPREY, which was testing PSMA PET imaging. Participation held virtually no risk and might benefit him.

"I had already been in one trial and was glad to try another," Kevin says. "I thought even if it didn't help me, it might help somebody else down the road."

Several weeks after the conventional imaging found no disease, he had a PSMA PET scan that produced a worrisome result: Prostate cancer was detected in lymph nodes in Kevin's pelvis. But the precision of the imaging –- showing that the cancer had spread to the nodes but nowhere else –- allowed Dr. Morris to concentrate treatment on those specific sites.

Kevin received radiation targeted to those nodes along with hormone therapy, completing his treatment in late April 2020. As a result of the radiation and hormone therapy, Kevin's PSA dropped to zero and has remained so for more than a year. He has needed no further therapy.

"We were able to take a family trip to India ten days after I received my last radiation treatment," Kevin says. "My two boys were very young when I was diagnosed, and it has been very gratifying for me to be around for them."

Just ten days after his final radiation treatment, Kevin Taylor enjoyed a vacation in India with his wife and two boys.

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A Clearer Picture

Kevin's experience illustrates the striking advantages of the new imaging technology. Traditionally, doctors knew prostate cancer had returned after initial therapy if a patient's PSA levels began to rise. Knowing where the disease was located was usually not feasible, especially when the PSA levels were low. And if the cancer had spread to the lymph nodes, the only way to tell was when the nodes swelled up, after the cancer had already been there a while.

The OSPREY trial proved the imaging method to be very accurate. It identified the location of cells that were highly likely to be prostate cancer –- more than 80% in some cases and more than 90% in others. Results of the trial, published in the *Journal of Urology*, were partly responsible for the FDA approval.

"With PSMA PET, we can now detect the cancer cells directly and much earlier than we could with standard CT or PET scans," Dr. Morris says. "For newly diagnosed men with high-risk disease who were preparing to undergo surgery or radiation, we had to wonder whether there was disease outside of the prostate that we couldn't identify. For men like Kevin whose prostate cancer relapsed, we often did not know where the cancer was and had to decide on a treatment plan without this knowledge."

Today, Kevin remains active with his family –- shepherding his younger son to soccer games six times a week. He enjoys cooking, listening to music and is looking forward to resuming travel for leisure. After 40 years in New York, he and his wife are even contemplating moving the family back to his native England.

"My main fear is not being able to access MSK for my checkups and treatments," he says. "I have 100% trust in Dr. Morris and wouldn't go to anyone else –- my only regret about this whole experience is that I didn't go to him first when I was diagnosed."

For Dr. Morris, knowing the FDA approval will benefit people across the entire spectrum of this stubborn disease is especially gratifying.

"I have been involved in the PSMA research since the end of my fellowship at MSK in the late 1990s, and it's amazing to see it all come to fruition this year," Dr. Morris says. "The benefit this advance will bring to men with this common disease cannot be overstated."

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