

Delay in approving cancer vaccine sparks protest

Some allege racism influenced FDA decision

By Marie McCullough - The Philadelphia Inquirer
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Philadelphia — Having lost an uncle to prostate cancer and now, watching his father's losing battle, Ed Gorkes cannot understand why the government is keeping a breakthrough therapy in limbo.

The 51-year-old Horsham, Pa., businessman and other prostate cancer activists are outraged that the Food and Drug Administration last month demanded more proof that Provenge works, even though the agency's own advisory panel voted overwhelmingly for immediate approval.

The activists are petitioning Congress — and pressuring the FDA — to approve marketing of the promising prostate cancer “vaccine” while its manufacturer, Dendreon Corp., completes a 500-patient study.

After about 100 activists from 19 organizations rallied Monday in Washington, D.C., six of them met with FDA Commissioner Andrew von Eschenbach — himself a casualty of the disease.

Gorkes thinks it's clear the drug works.

“The advisory committee saw that, all the literature says it. It's not just desperate patients saying it,” Gorkes said.

The FDA's delay, the activists believe, could add years more to Provenge's long development odyssey.

“You're talking a minimum of two more years. Since prostate cancer kills 27,000 men a year, you're talking 54,000 deaths,” declared rally leader Thomas Farrington, founder of the Prostate Health Education Network, aimed at blacks and other men at high risk of the disease.

The FDA's unexpected conservatism also sent a shudder through the biotech start-ups that have more than a dozen cancer vaccines in the final phase of human testing. Seattle-based Dendreon, which saw its stock value soar with the advisory committee's recommendation and plummet with the FDA's postponement, was expected to pave the way for the novel technology.

“... (W)e are disappointed that this decision will cause a delay in the availability of Provenge for patients who suffer from advanced prostate cancer,” said Mitchell H. Gold, president and chief executive officer of Dendreon, in a statement after the FDA asked for more data.

Unlike conventional disease-preventing vaccines, the new ones work after cancer develops. Basically, the therapies unmask malignant cells, thus provoking a heightened immune attack. The immune system normally tolerates cancer cells because these renegades arise from the body’s own tissue.

“It’s very disappointing for all of us who work in cancer vaccine research,” said University of Pennsylvania microbiologist Yvone Paterson, founder of Advaxis Inc., which is testing a therapeutic cervical cancer vaccine. “We know that in order to get acceptance from the public and from investors, we need something in the clinic.”

Farrington and others who talked Monday with von Eschenbach could not be reached afterward for comment, but an FDA spokeswoman confirmed that they met. Dendreon did not return calls requesting comment.

Evaluating the effectiveness of experimental cancer vaccines has been a vexing challenge both for developers and regulators. Like any unproven cancer drug, immune-boosting vaccines must first be tested in patients who have exhausted all other treatments — even though such patients don’t have much immune function left to boost.

In a small study, the median survival of men treated with Provenge was 26 months, just 4.5 months more than patients receiving a placebo. A survival edge in a second small study could have been by chance. And Provenge did not achieve one of its primary goals of delaying disease progression.

Yet the 4.5-month survival benefit was almost double that of Taxotere, a treatment with tough side effects that is the only other option for advanced, progressing cancer.

The FDA’s expert advisory panel voted unanimously that Provenge is safe, but voted only 13 to 4 that it was effective.

Farrington, who testified before the Provenge advisory committee, also said the FDA turned its back on blacks. Partly because of genetics, they are 50 percent more likely to develop prostate cancer than white men and twice as likely to die from it.

“If there was a mortality rate in white men as high as that of African-Americans,” Farrington said, “there would be a push to approve Provenge.”