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Q&A: Prostate Cancer Vaccine

BY LEN LICHTENFELD, MD

Q: Why is Provenge still not available for terminally ill prostate cancer patients?

A: When the Food and Drug Administration withheld approval in May on a cancer vaccine for treating advanced prostate cancer, it highlighted once again the question of whether terminally ill patients should have access to medications that may be effective, but have not yet met the usual criteria for approval. The vaccine, Provenge (sipuleucel-T), is designed to treat advanced prostate cancer that is no longer responsive to hormonal therapy.

In a nutshell, a clinical trial intended to demonstrate Provenge's usefulness in the treatment of advanced prostate cancer did not meet its goal of prolonging the time to tumor progression. Subsequently, on an unplanned re-analysis, Dendreon, maker of the vaccine, concluded there was some information in that "failed" trial that suggested the vaccine may have actually increased the lifespan of the men who received the vaccine.

Results of the clinical trial were presented to an FDA advisory committee in March, which voted to recommend approval of the vaccine, 13 to 4. Advisory committee members who voted against recommending approval contend the vaccine had not met the FDA standards for approval.

So now, the FDA awaits results from an ongoing, more definitive clinical trial that will hopefully determine if the vaccine improves the survival of men with advanced prostate cancer. Interim results of the trial will be available in 2008, with final results in 2010.

But prostate cancer advocates were outraged at the FDA's decision, saying many advanced prostate cancer patients can't wait that long, and questioned why the agency would prevent terminally ill patients from receiving a vaccine when many of them have no other treatment alternatives. Advocates have approached Congress and the FDA, asking them to reverse the decision, but to date, they have not.

The issue of providing drugs that have not yet adequately demonstrated safety and efficacy is controversial, and contention will likely continue for some time, but there are other methods for getting nonapproved drugs. In some cases, a drug

that has cleared most of the hurdles in proving effectiveness in treating a particular cancer can be made available to patients directly through the drug company in a process called compassionate use. Patients can also ask their physicians about participating in a clinical trial, where many new drugs are evaluated for cancer treatment.

The question of access to investigational drugs is an important one, and one that is currently being debated in multiple forums. When it comes to drug (or vaccine) approval, we must have the best evidence possible that the drug is effective as well as a valid understanding of its risks.

Len Lichtenfeld, MD, is deputy medical officer for the American Cancer Society.