

# Business & Innovation

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## Prostate therapy's delay sets off a fight

### Drug's believers pressure regulators

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WASHINGTON — When federal regulators delayed approving a promising new prostate cancer therapy, patients and the drug's advocates reacted with more than disappointment.

They took a page from the playbook of AIDS activists and took to the streets and to the Internet, mounting an unusually intense lobbying campaign to pressure the Food and Drug Administration to reverse its stance on Provenge, the experimental cancer drug.

Provenge's advocates are working with lawmakers in Congress to attach an amendment to a funding bill that would make it easier for patients to get access to promising experimental drugs. They've held rallies in Chicago and at the Capitol. A few met with the FDA commissioner, who is one of the nation's top prostate cancer researchers and a prostate cancer survivor.

An op-ed piece that ran in *The Wall Street Journal*, written by a scientist who advocates for greater patient access to drugs prior to FDA approval, decried the day the FDA made its Provenge decision, calling it Black Wednesday.

Blogs and websites are uniting disappointed cancer patients and disillusioned investors who put money on Seattle-based Dendreon Corp.'s Provenge, believing it could rally the body's immune system to combat cancer.

Some, however, question whether some Provenge advocates are too aggressive. Some patient advocates say the FDA should be guided only by science.

"Do people in this country really want drugs to be approved by riot?" asked Ab-

bey Meyers, president of the National Organization for Rare Disorders. "Every other patient organization is going to go down there and have a March on Washington and use political pressure to get their drug approved. That's not what the American people want."

On one investors' site, InvestorVillage, commenters questioned the motives of FDA advisers who opposed Provenge's approval during an advisory meeting and in correspondence to the FDA.

On the MySpace page of one angry Dendreon investor, titled Approve Provenge Now, Mozart's Requiem plays in honor of men who are dying, while images of scientists who slowed or opposed Provenge's approval flash on screen.

Ray Vestal, the Dendreon shareholder to whom the MySpace page belongs, said he does not see a direct tie between his page or other Provenge websites and threatening e-mails that scientists who have been skeptical of the drug reported receiving.

"These are intelligent people asking why," Vestal said of the people posting the Provenge-related messages he has read. "These don't seem to be radical people who seem to have some hostile agenda."

Still, the tactics of a few Provenge advocates are dividing patient advocates. The push for speedier Provenge approval comes as the FDA faces heightened scrutiny for its handling of such therapies as the diabetes drug Avandia and the painkiller Vioxx, both linked to heart attacks years after approval.

Dr. Howard I. Scher, a Memorial Sloan-Kettering Cancer Center researcher whose image is featured on Vestal's MySpace page and who was pilloried on the InvestorVillage website, received additional security during a recent cancer conference after receiving e-mails from Provenge supporters that he considered threatening.

Paul Goldberg, editor of *The Cancer Letter*, a weekly newsletter that reprinted letters from Scher and other Provenge skeptics, received a spate of irate e-mail messages, including one that said: "I hope the entire male staff at the Cancer Letter is diagnosed with Prostate Cancer."

Another Provenge supporter told him about her idea to create "hit squads," people assigned to chat up FDA advisers during meeting breaks, Goldberg said.

"The idea of a 'hit squad' is really unpleasant," he said. "The idea of a committee member getting threats, being approached on the way to the restroom, at coffee breaks — this is about science.

"Or it should be about science. That's how patient interests are protected."

And Adam Feuerstein, a senior writer for *TheStreet.com*, received at least 100 e-mails, some of them anti-Semitic, after writing about Provenge and suggesting that investors "ditch Dendreon" stock.

Why is one stalled drug approval inciting such passions?

Thomas A. Farrington, a Boston prostate cancer survivor whose father and both grandfathers succumbed to the disease, says patients' passion is driven by the "ugly" disease and the tantalizing promise of Provenge.

Prostate cancer is the second-most-common cancer among US men, surpassed in prevalence only by lung cancer. This year, 218,890 American men will be newly diagnosed with prostate cancer, according to the National Institutes of Health, and 27,050 will die.

African-American men face disproportionately higher death rates. Men who survive prostate cancer may face "chemical castration" from the treatment, Farrington said. Provenge appears to be "a treatment that allowed men to retain their quality of life without the side effects of chemotherapy. There was tremendous hope."

Farrington created a different website, *ProvengeNow.org*, and is working with sympathetic members of the House of Representatives to amend an FDA bill to speed patients' access to Provenge.

Dendreon is among the drug industry sponsors that have provided funding for a patient advocacy group that Farrington founded.

Farrington doubts the "unfortunate" e-mails were sent by cancer patients.

"Terminally ill men . . . are no threat to them. They're not going to get out of their beds to threaten two doctors," he said.

But others say the fact that the Web was the crucible for Provenge-related advocacy made such clashes inevitable.

Online communities can be rough-and-tumble places populated by people known only by screen names, inspiring freedom and recklessness, said the *TheStreet.com*'s Feuerstein.

"You get a lot of hate mail," he said. "It just rolls off my back."