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HEALTH BUSINESS - BRIEFING

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Group slams FDA for Provenge delay

NEW YORK, May 23 (UPI) -- A patient advocacy group Wednesday vowed to fight a decision by U.S. regulators to delay approval of prostate cancer vaccine Provenge.

The Food and Drug Administration said it would push back approval of the novel vaccine until 2010 to gather additional data on the novel vaccine, despite the fact that members of one of its advisory panels largely supported the product's approval.

"We believe that the FDA's decision to delay approving a safe, effective treatment for prostate cancer patients is inhumane," said Thomas Farrington, charter member of the coalition ProvengeNow, made up of patient groups including Us TOO! International, the Prostate Health Education Network and the Prostate Cancer Research Institute. "Furthermore, we are saddened and concerned the FDA has blatantly ignored not only its own advisory panel of experts, but the voices of the patients. We urge them to approve Provenge immediately to give patients this treatment option."

ProvengeNow said it would urge members of Congress to pressure the FDA to revisit its decision.

The coalition noted that men with advanced, hormone-refractory prostate cancer currently have only chemotherapy as a treatment option, yet a recent survey shows more than half of men with the disease are unwilling to undergo chemotherapy, which can cause debilitating side effects.

The coalition's action is another example of the sometimes no-win tug of war in which the FDA finds itself. As it faces heat from lawmakers and other groups to increase its scrutiny of new drugs before they are approved for market, patient advocacy groups charge that the agency is not approving new treatments at a fast-enough pace.