PHYSICIANS for PROVENGE

February 4, 2008

The Honorable John Dingell
Chairman
Committee on Energy and Commerce
2125 Rayburn HOB
Washington, DC 20515

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
2322-A Rayburn HOB
Washington, DC 20515

The Honorable Frank Pallone
Chairman
Subcommittee on Health
Committee on Energy and Commerce
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Washington, DC 20515

The Honorable Nathan Deal
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
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The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
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Washington, DC 20515

The Honorable John Shimkus
Ranking Member
Subcommittee on Oversight & Investigations
Committee on Energy and Commerce
2322-A Rayburn HOB
Washington, DC 20515

Dear Chairman Dingell and Ranking Member Barton, Subcommittee Chairman Pallone and Ranking Member Deal, and Chairman Stupak and Ranking Member Shimkus:

We, *Physicians for Provenge,* are writing to urge you to honor the request of Congressmen Michaud, Burton, and Ryan. We concur with the Congressmen's statement "the FDA should not be appointing scientists leading the testing of a rival drug for another firm onto an advisory committee evaluating Provenge." An editorial in the peer-reviewed journal *Nature Biotechnology* put it this way, "In the real world, in a scientifically assessable way" this prostate cancer therapy Provenge shows real benefits and has real value, with minimal side effects. Prostate cancer patients, their physicians, and the rest of America benefit by getting serious answers to the significant questions in the Congressmen's letter and this *Nature Biotechnology* editorial.

On March 29, 2007, a multidisciplinary FDA advisory panel of immunologists, oncologists, statisticians, urologists, patients advocates, and other invitees reviewed Provenge, and decided unanimously that it was safe (17-0), and possessed substantial evidence of efficacy (13-4). On May 9, 2007, the FDA did something it has historically never done before in reviewing a therapy for a terminal patient group:

overruled its own panel of experts and delayed approval of Provenge pending results from an ongoing phase 3 trial, which may not be available until 2010. Since the FDA's decision, MORE THAN 22,000 AMERICAN MEN HAVE DIED at a rate of 82 men/day.

Clearly, many physicians believe Provenge works. Please consider why our colleagues and we KNOW that Provenge works and why tens of thousands of men with late stage prostate cancer should be given access to it. The Provenge results mentioned below are far stronger than might be suggested by a cursory read of the news. Provenge has shown activity and efficacy in every one of the six trials where it has been studied including three phase three trials. The FDA looked at the phase three trial that showed the median (midpoint) survival benefit was 4.5 months but the mean (average) survival benefit was much better: 34% of all men receiving Provenge were alive after three years compared to 11% of those who did not.

Unfortunately, two physicians, the same two listed in the Congressmen's letter, who specialize in chemotherapy and had egregious conflicts of interest, led a very public and visceral campaign against Provenge. However, Provenge is a vaccine, not chemotherapy, and these physicians are not experts in vaccines/immunology. For example, while it is true the Provenge study narrowly failed on its primary objective of Time To Progression, it has since been accepted within the medical community that Time To Progression measurements require adjustments for the ramping up of the patient's immune system, as in any vaccine. Moreover, that these adjustments would most certainly have resulted in the study's success for Time To Progression, as well as for the critically important survival and quality of life issues. The multidisciplinary experts consulted by the FDA, pointed this out. This is why Provenge was recommended for approval while an ongoing study is continued. Additionally, it should be noted that the FDA has in the past approved drugs that have failed in the primary goal of their designed studies but retrospectively demonstrated improved survival (e.g. carvedilol for heart failure). Provenge is not a "me- too" drug for which numerous alternatives exist such as for cholesterol, diabetes or hypertension. These men are dying with very little hope, many refusing chemotherapy because of the severe side effects coupled with a poor survival benefit. Why did the FDA not extend the same compassion to dying patients as they extend to patients living with chronic diseases?

Anyone following the FDA knows the FDA has been approving "me-too" drugs with serious side effects for chronic illnesses for years. This while preventing access of potentially lifesaving medicines to dying patients and their physicians. A common but inaccurate response to this is that a medicine like Provenge is currently available thru compassionate use programs. Unfortunately, most of these small drug companies that develop these innovative therapies are too cash-poor to participate in this program. Consequently, this unyielding approach by the FDA has already led to higher research costs, delays in the War on Cancer, and ultimately higher healthcare costs. The FDA should be carefully assessing risk versus reward for the treatment of terminally ill patients, rather than "gate keeping" based on outdated statistics, reducing short-term health care costs or backroom shenanigans. In addition, lest we forget, chemotherapy is the only medicine approved in the last 45 years to treat terminal prostate cancer.

The FDA's expert panel said Provenge was safe and it works. Our collective medical training has been lengthy and thorough. In addition, we have all learned to consider what is in the BEST interest of our patients and their families. All we ask of you is the same! Chairman Dingell, in the name of good science, patient benefit, and physicians looking for new and better options for their patients, please conduct these hearings.

Very Respectfully,

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Please note that the physicians who have signed this letter represent broad diversity geographically, politically and of medical specialties. We are, however, ***strongly united*** *in our desire to shine the light of truth and decency on the matter of Provenge.*