



# PROSTATE CANCER *HOT SHEET*

**Us Too! INTERNATIONAL**

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## **A RANDOMIZED PHASE II STUDY OF A PSA-BASED VACCINE IN PATIENTS WITH LOCALIZED PROSTATE CANCER RECEIVING STANDARD RADIOTHERAPY**

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Prostate cancer is the most common cancer and the second most common cause of cancer death among men in the United States. Its incidence is directly correlated with age, and as the population ages, we are likely to continue to see more cases. Most men with this disease have organ-confined disease which can be treated with curative intent with either surgery or radiation treatments. Unfortunately, up to 1/3 of patients have recurrent cancer within 5-years. Once this disease spreads, it cannot be cured. Patients who develop recurrent disease may be treated with androgen deprivation strategies, however within 1-2 years, most patients will develop androgen independent prostate cancer (AIPC). While chemotherapy has been shown to have palliative benefit in this situation, there is no evidence of prolonged survival. Given the sheer numbers of patients with this disease, the frequency of failure of primary therapy, and its inexorable progression to AIPC for which can be very debilitating and for which no life prolonging therapy exists, there clearly is a need for improved curative treatment strategies for localized prostate cancer.

One potential treatment for prostate cancer is immunotherapy. By training the body's own immune system to fight the cancer, one should be able to overcome the "tolerance" of the immune system thought to be induced by the tumor cells. The use of proteins associated with cancer cells (tumor associated antigens), such as PSA, as immunogens has made it possible to specifically target prostate

cells. PSA itself does not cause a strong immune response, so it is vital to give it in such a way as to produce a strong inflammatory response. There are several ways to do this, but perhaps one of the most promising is the use of a viral "vector" to take the gene for PSA into the cell. Vaccinia is a virus that has been given to over 1 billion people worldwide in the successful eradication of smallpox thus we have very good data on the safety of this virus. This virus also has the capacity to accept a large amount of DNA that it can express when it infects cells. We have developed a virus that expresses PSA and can infect a large range of human cells and produce the PSA in an inflammatory environment. Antigen presenting cells are drawn to the area by the infection and take up the PSA, processing it to present to and activate PSA-specific T-cells. These T-cells can then circulate to areas where there is tumor and kill it. In a clinical trial designed to look at the safety of this vaccine, there were only minimal side effects such as redness at the site of injection. We also found that we could at least double the number of T-cells that recognized and were activated by PSA in 5 of 7 patients tested.

Further work in the lab has shown us that we can increase the immune response even more using three strategies. One way is by adding another gene to the vaccinia virus. This gene is for a protein (B7.1) needed to ensure that the T-cells are sufficiently activated by the antigen presenting cells. This causes a several-fold increase in the number of activated T-cells. We also found that when giving multiple injections with a vaccinia vector, that the immune response to the PSA plateaued. This was because the immune response directed at vaccinia was so great

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## **BILL DEHN HONORED BY Us Too! CHAPTER - PROSTATE FORUM**

**By Murray Corwin**

On March 27<sup>th</sup> we managed to surprise Bill Dehn to some extent with the number of people who came to demonstrate their affection and respect for all the accomplishments in the world of Prostate Cancer. Attendees were about 125 and included Dr. & Mrs. Israel Barken from San Diego, Dr. Tom Ahlering, head of Urology at UCI and Aubrey Pilgrim, who gave up attending his own group's meeting the very same night. Even Sophie Chen, developer of PC-Spes was there from New York. Other members spoke and Bill has a collection of notes and letters from the many others (including *Us Too!* CEO John Page) who couldn't be there.

If there are those of you out there who would still care to send a note, I will collect them and compile them with the others whenever I receive them. My E-mail is MURRAYCORW@AOL.COM.

It was a sensational event with much choking up and some tears of joy. Bill Dehn is a treasure and we were able to recognize that publicly in a significant way

For those of you who may not be familiar with the extent to which Bill has been involved in fighting this disease, here is a brief synopsis of his PCa activity.

As co-founder of the Prostate Forum in Fullerton, California, William (Bill) Dehn has become one of this nation's significant contributors and an effective activist in the arena of Prostate Cancer, highly respected in the medical community as well as a leader among activists.

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## CLINICAL TRIALS

SOURCE: Nat'l Institutes of Health  
www.ClinicalTrials.gov

Choosing to participate in a clinical trial is an important personal decision. The following frequently asked questions will provide you with detailed information about clinical trials. In addition, it is often helpful to talk to your health care provider, family members, or friends about deciding to join a trial. After you have identified some trial options, the next step is to contact the study research staff and ask questions about specific trials.

### What is a clinical trial?

A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Ideas for clinical trials usually come from

researchers. Once researchers test new therapies or procedures in the laboratory and get promising results, they begin planning Phase I clinical trials. New therapies are tested on people only after laboratory and animal studies show promising results.

### What is a protocol?

All clinical trials are based on a set of rules called a protocol. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

### What are clinical trial phases?

Clinical trials of experimental drugs proceed through four phases:

- In Phase I clinical trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In Phase II clinical trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- In Phase III studies, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- Phase IV studies are done after the drug or treatment has been marketed. These studies continue testing the study drug or treatment to collect information about their effect in various populations and any side effects associated with long-term use.

### What protections are there for people who participate in clinical trials?

The government has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits.

An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support bio-

medical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

### What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before you decide whether or not to participate. These facts include:

- Why the research is being done.
- What the researchers want to accomplish.
- What will be done during the trial and for how long.
- What risks are involved in the trial.
- What benefits can be expected from the trial.
- What other treatments are available.
- The fact that you have the right to leave the trial at any time.

If you are considering joining a clinical trial, the research staff will give you informed consent documents that include the details about the study. If English is not your native language, you can ask for the consent documents in languages other than English. Since joining a clinical trial is an important decision, you should ask the research team any questions you may have about the study and the consent forms before you make a decision.

It is also a good idea to take the consent documents home and discuss them with family members or friends. Talking about your options can help you to feel comfortable with your decision. If you decide to join the clinical trial, be sure to ask for a copy of the informed consent documents so you can review them at any time.

Remember informed consent is more than signing a form. It is a process that continues through the study. You should feel free to ask the research team questions before, during, and after the study. Informed consent continues as long as you are in the study.

### Who can participate in a clinical trial?

All clinical trials have guidelines about who can get into the program. Guidelines are based on such factors as age, type of disease, medical history, and current medical condition. Before you join a clinical trial, you must qualify for the study. Some research studies seek volunteers with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Healthy volunteers participate in Phase I trials, vaccine studies, and trials on research on preventive care for children or adults.

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The factors that allow you to participate in a clinical trial are called inclusion criteria and the factors that keep you from participating are called exclusion criteria. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

#### Who sponsors clinical trials?

Clinical trials are sponsored by government agencies: such as the National Institutes of Health (NIH); pharmaceutical companies; individual physician-investigators; health care institutions such as health maintenance organizations (HMOs); and organizations that develop medical devices or equipment. Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

#### What happens during a clinical trial?

The clinical trial process depends on the kind of trial you participate in. The team will include doctors and nurses as well as social workers and other health care professionals. They will check your health at the beginning of the trial, give you specific instructions for participating in the trial, monitor you carefully during the trial, and stay in touch with you after the study.

Some clinical trials involve more tests and doctor visits than you would normally have for your illness or condition. For all types of trials, you will work with a research team. Your participation will be most successful if you follow the protocol carefully and stay in contact with the research staff. Some terms that will help you understand what happens in a trial are defined below.

#### What is a placebo?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.

#### What is a control or control group?

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

#### What is a blinded or masked study?

A blinded or masked study is one in which participants do not know whether they are in the experimental or control group in a research study. Those in the experimental group get the medications or treatments being tested, while those in the control group get a standard treatment or no treatment.

#### What is a double-blind or double-masked study?

A double-blind or double-masked study is one in which neither the participants nor the study staff know which participants are receiving the experimental treatment and which ones are getting either a standard treatment or a placebo. These studies are performed so neither the patients' nor the doctors' expectations about the experimental drug can influence the outcome.

#### What are side effects and adverse reactions?

Side effects are any undesired actions or effects of drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

#### What are the benefits and risks associated with clinical trials?

There are both benefits and risks associated with clinical trials. By participating in a clinical trial, you can:

- Take an active role in your own health care.
- Gain access to new treatments that are not available to the public.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

#### *Clinical trials have risks:*

- There may be side effects or adverse reactions to medications or treatments.
- The treatment may not be effective for you.
- The protocol may require a lot of your time for trips to the study site, treatments, hospital stays, or complex dosage requirements.

#### What should I know before I join a clinical trial?

You should know as much as possible about the research study. It is important for you to feel very comfortable asking questions and the staff should answer them in a way you can understand. A list of sample questions appears below.

#### How should I prepare for the meeting with the research coordinator or doctor?

- Plan ahead and write down the questions you want to ask.
- Ask a friend or relative to come with you for support and to hear the responses to your questions.
- Bring a tape recorder so you can replay the discussion after you get home.

#### What questions should I ask?

Some questions you might ask about the research include:

- Why is this research being done?
- What is the purpose of the study?
- Who is sponsoring the study?
- Who has reviewed and approved this study?
- Why does the research team think the treatment, drug, or medical device will work?

Some questions about your participation in the study include:

- Where is the study site?
- What kinds of therapies, procedures, and/or tests will I have during the trial?
- Will they hurt? If so, for how long?
- How will the tests in the study compare to tests I would have outside the study?
- How long will the study last?
- How often will I have to go to the study site?
- Who will provide my medical care after the study ends?
- Will I be able to take my regular medications during the trial?
- What medications, procedures, or treatments must I avoid while in the study?
- What are my responsibilities during the study?
- Will I have to be in the hospital during the study?
- Will the study researchers work with my doctor while I am in the study?
- Can anyone find out that I am participating in a study?
- Can I talk to other people in the study?
- Will I be able to find out the results of the trial?

Questions about risks and benefits include:

- How do the possible risks and benefits of the study compare with approved treatments for me?
- What are the possible immediate and long-term side effects?

Other questions include:

- What other treatment options do I have?
- Will I have to pay anything to participate in the study?
- What are the charges likely to be?
- Is my insurance likely to cover those expenses?

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**SCIENTIFIC JOURNAL  
REVIEW - April 2001**

The following prostate cancer related articles have appeared in well-known scientific journals. Abstracts only have been posted at the *Us Too!* website (www.ustoo.org). *Us Too!* cannot provide copies of the complete article.

**TO OBTAIN A COPY OF THE ARTICLE:** take the citation to your local public or hospital library. The librarian can assist you in obtaining a copy of the article from their collection or from interlibrary loan.

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**PROSTATE CANCER NEWS YOU CAN USE**

Us Too! publishes a FREE daily e-mail based news service which provides updates on the latest prostate cancer related news. Archives (with a brief summary of the article) are available for one year. To subscribe or link to the archives simply visit: [www.ustoo.org](http://www.ustoo.org)

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**WHAT YOU EAT CAN AFFECT SEX HORMONES: TESTOSTERONE LEVEL DROPS AFTER LOW-FAT MEAL, MAY PROTECT AGAINST CANCER**

(WebMD Medical News - May 17, 2001)  
(Us Too! PCa News archive - May 23)  
Watching how much and what kind of fat you eat may have an unexpected benefit, according to a report in the May issue of Metabolism. Meals low in fat may actually decrease levels of testosterone, a male sex hormone that may increase risk of prostate cancer.  
[my.webmd.com/content/article/1728.79950](http://my.webmd.com/content/article/1728.79950)

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**IMMUNOTHERAPY MAY PROVE POTENT WEAPON AGAINST ADVANCED PCA**

(AScribe Newswire - May 21, 2001)  
(Us Too! PCa News archive - May 22)  
Researchers at UCLA's Jonsson Cancer Center have shown for the first time that immunotherapy delivered via gene therapy may prove to be a potent weapon in the fight against locally advanced prostate cancer, according to an article published in the peer-reviewed journal Human Gene Therapy. For info on the clinical trial: 888-798-0719  
<http://www.cancer.mednet.ucla.edu>

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**LATERALLY DIRECTED BIOPSY IMPROVES PCA DETECTION**

(FaxWatch Inc. - May 21, 2001)  
(Us Too! PCa News archive - May 22)  
Biopsy cores collected from the base and apex provide the most valuable information for the detection of prostate cancer, a new study indicated. Prostate cancer is most likely to be identified laterally rather than

in the mid sagittal sections of the prostate. Also, a combination of at least 8 and probably 10 biopsies are needed to accurately diagnose PCa in a majority of patients.  
<http://www.faxwatch.com>

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**DRUG BENEFITS GENEROUS FOR VETERANS**

(COX News Service - May 21, 2001)  
(Us Too! PCa News archive - May 22)  
All veterans who were honorably discharged are eligible for health benefits through the VA. Vets who were prisoners-of-war and those with at least 50 percent service-connected disabilities can qualify for free prescription drugs. Vets who make less than \$12,000 a year can have the co-payments waived. For more information about registering with the VA health system, call 1-800-972-8262

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**BORON MAY CUT PCA RISK**

(HealthScout.com - May 16, 2001)  
(Us Too! PCa News archive - May 17)  
Science News reports that researchers at the University of California at Los Angeles recently discovered that men who consume the lowest amounts of boron in their diets have the highest rates of prostate cancer. Large amounts of boron can be toxic, so health officials advise against taking boron supplements. The best and safest sources come from plants such as green leafy vegetables, legumes, grains, nuts, wine, beer and cider, and non-citrus fruits, including grapes, raisins and apples.  
[www.sciencenews.org/20010414/fob1.asp](http://www.sciencenews.org/20010414/fob1.asp)

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**PROSTATE TREATMENT MIGHT INCREASE ALZHEIMER'S RISK**

(Lexington Herald-Leader - May 15, 2001)  
(Us Too! PCa News archive - May 16)  
The standard treatment for prostate cancer drugs to lower testosterone might double the levels of circulating amyloid, the sticky substance that has been implicated as a cause of Alzheimer's disease, according to a new study. While it's too early to tell whether the men are at increased risk for the mind-robbing disease, scientists caution that animal and human studies suggest that they might be. Dr. Sam Gandy, a professor of psychiatry and cell biology at New York University School of Medicine and lead author of a letter published in the May 2 Journal of the American Medical Association, said they will continue to study whether the amyloid levels stay high and trigger symptoms of cognitive decline.

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**MATRITECH MOVING ON PCA TESTS**

(SmallCapCenter.com - May 04, 2001)  
(Us Too! PCa News archive - May 07)  
At the American Association for Clinical Chemistry's 33rd Oak Ridge Conference

in Seattle, data from its ongoing study of its proprietary blood test now under development for men with prostate cancer or those at risk of developing it. The Matritech researchers, in collaboration with scientists at the Johns Hopkins Hospital, zapped the blood with a novel mass spectroscopy technique and pulled out a nuclear matrix protein (NMP) that seemingly only occurs when PCa is present. Even more important, the test flagged what standard PSA tests missed. Because PSA is not cancer-specific, it sometimes produces false-negative or false-positive results. In commenting upon the results, Dr. Alan Partin, the Bernard L. Schwartz Distinguished Professor of Urology at the James Buchanan Brady Institute of the Johns Hopkins Hospital, said mass spectroscopy "has a promising future" when sleuthing down the markers for PCa and other tumors.

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**RESEARCHERS TO DETERMINE EFFECT OF NOMOGRAMS ON PATIENT DECISIONMAKING**

(FaxWatch Inc. - May 03, 2001)  
(Us Too! PCa News archive - May 04)  
Previous research had confirmed nomograms (a graphical representation of the relation between different quantities) for prostate cancer as accurate predictors of 5-year, recurrence-free probabilities. Now researchers at the Memorial Sloan-Kettering Cancer Center are tackling the question whether these predictions influence patient choices regarding treatment. Dr. Michael Kattan and associates will randomize newly diagnosed prostate cancer patients to assess their acceptance of nomograms and how much they are influenced by the predictions of recurrence-free survival. "Our goal is really to look at the hypothesis of whether patients truly benefit," Dr. Kattan said "I don't have hard data to prove that if you give a nomogram prediction to a patient that he definitely makes a better decision. That is what we'll test prospectively.

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**RESULTS INDICATE CHEMOTHERAPY COMBO PROMISING FOR LATE-STAGE PCA**

(PR Newswire - May 01, 2001)  
(Us Too! PCa News archive - May 02)  
The chemotherapy combination of docetaxel (Taxotere(R)) and estramustine phosphate (Emcyt(R)) plus low-dose hydrocortisone appears to be a promising treatment for men with an advanced form of prostate cancer, according to the results of a Phase II trial conducted by the Cancer and Leukemia Group B (CALGB) and published in the May 1st issue of Journal of Clinical Oncology. Diane Savarese, MD, Associate Professor of Medicine University of Massachusetts Memorial Medical Center in Worcester, and lead investigator of the study

## BILL DEHN HONORED

(continued from P. 1)

Bill was diagnosed with Prostate Cancer at an early stage and successfully treated in 1985. After researching medical journals at UCI Medical Library, Bill decided on radioactive seed implantation, then applied by open abdominal surgery. This technique has kept his prostate cancer under control to this day. In 1999, he underwent another successful cancer sur-



Bill Dehn windsurfing off the California coast - clearly does not fit the stereotype of a prostate cancer survivor!

gery for early stage colon cancer found through a routine colonoscopy. He did not allow any of these events to interfere with his quality of life, being an Elder in his church nor his interest in exercising regularly and competing as a senior windsurfer, beginning at age 62. Bill is able to research the medical literature and share his knowledge and experience with others, counseling callers from all over the country. Until recently, he spent most of his time researching and disseminating current information on prostate cancer.

However, about 5 months ago, Bill was diagnosed with Lou Gehrig's Disease (ALS) and has turned his attention to

researching the latest scientific information about this devastating disease. Now would be an ideal time to recognize and acknowledge Bill Dehn's many significant contributions in bringing information, education and hope to thousands of prostate cancer survivors and their families.

Among his many extraordinary, personal contributions are:

- Creation 9 years ago, as co-founder, of what is now the largest, independent Prostate Cancer Support group in the Southwest, and guiding it to become a respected, well educated survivor's resource with nearly 1000 members.
- Conceived and led a team to produce the first national Prostate Cancer Public Forum with renowned physicians presenting medical information to a lay audience, both in 1995 with 850 attendees and again in 1996 bringing in 1260 persons. These events have become the model for others to follow.
- Charter member of the National Prostate Cancer Coalition, bringing together in 1996 the many differing organizations in the Prostate Cancer world to a unity of purpose. Later, serving a term on their Board of Directors.
- Served as a member of Department of Defense scientific task forces to plan the future directions for scientific research into prostate cancer.
- Served as a member of the California Prostate Cancer Coalition Board to provide information to help guide the state's efforts at solving the prostate cancer problem.
- Invited to attend the significant CapCure annual retreat in year 2000, to review the scientific progress in prostate cancer over the prior year
- Awarded numerous times "Volunteer of the Year" and other special recognition by the American Cancer Society

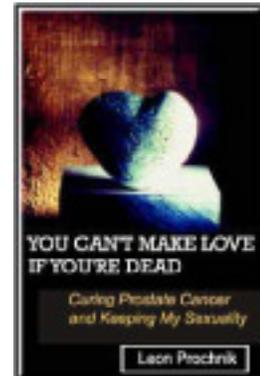
## YOU CAN'T MAKE LOVE IF YOU'RE DEAD . . .

PROSTATE CANCER . . . those two simple words have a way of hitting men like a strong blow to the groin.

Although some won't admit it, alot of men have found themselves having to grapple not only with the cancer, but with the physical and emotional side-effects of the treatment.

In the book "You Can't Make Love If You're Dead - Curing Prostate Cancer and Keeping My Sexuality" author Leon Prochnik takes you through his journey from asymptomatic diagnosis (with a PSA of 8.2 which rose to 10.1 four months later), to evaluation of alternative treatments and practitioners, through a search for the simple, magic cure (the wish for a "frigging pill that could fix it"), to the realization that prostate cancer will change your life but can only end it if you allow it to.

In an open and easy to read novelesque style, the author provides his personal insight into his discovery of what really "makes a man a man" - and what, in the end is really important. Throughout his journey he provides a first hand view of how he dealt with the fear and despair of his diagnosis and then the realization that his post-treatment life would be much different. This story of self-discovery and healing provides a satisfying, inspirational and sometimes humerous view of one man's walk through the valley of the shadow of death - a journey that so many survivors can certainly relate to.



For more information:

[www.protestory.com](http://www.protestory.com)

or

Leon Prochnik - c/o Ari Press  
501 South Orange Grove Ave  
Los Angeles, CA 90036

## JOURNAL CITATIONS

(continued from P. 6)

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## CLINICAL TRIALS

(continued from P. 3)

Should I continue working with my primary health care provider if I participate in a trial?

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but not extended or complete primary health care. In addition, by having your health care provider work with the research team, you can ensure that your other medications or treatments will not conflict with the clinical trial protocol.

Can I leave a clinical trial after it has begun?

Yes. You can leave a clinical trial at any time. If you plan to stop participating, let the research team know why you are leaving.

Will I be paid for participating in a trial?

Some clinical trials will pay you for joining the trial, while others will not. In some programs, researchers will reimburse you for expenses associated with participating in the research. Such expenses may include transportation costs, child care, meals, and accommodations.

**VISIT [www.UsToo.org](http://www.UsToo.org)**

**FOR LINKS TO CURRENT CLINICAL TRIALS!**

## PSA-BASED VACCINE

(continued from P. 1)

that it overwhelmed the response against the PSA in subsequent vaccinations. However, if we used a similar virus (fowlpox) that could infect but not replicate (so there would be few viral proteins), the immune response continued to increase after each vaccination. By using this strategy, after only 2 vaccinations we could increase the immune response by five-fold more than the vaccinia only vaccinations. Our third discovery was that by using both GM-CSF to draw in the antigen presenting cells to the vaccination site, and IL-2 to stimulate the T-cells after the vaccination, we could significantly increase the ability of mice to eradicate established tumors (6 of 10 vs. 0 of 10 without these cytokines).

The power of this approach is that it takes a vaccine with proven immunologic responses and adds 3 improved components, shown to significantly improve efficacy in the lab. By using this strategy with standard radiotherapy, we hope to show that we can induce an immune response to PSA. The significance of this vaccine strategy is that it may provide a safe, more effective treatment for localized prostate cancer.

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*Dr. Gulley presented this information at a recent meeting of the Us Too! Chapter at Walter Reed Army Medical Center.*

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