Newsletter

Prostate Cancer 101, Inc.

http://prostatecancer101.org

September, 2010

The Prostate Cancer Information and Support Group of the Mid-Hudson

Whole-body MRI Not Necessary to Detect Bone Metastasis of Prostate Cancer

by Sarah Guy | MedwireNews.com | 08.05.2010

Axial skeleton (AS) magnetic resonance imaging (MRI) is as useful at detecting bone metastasis in prostate cancer patients compared with whole-body (WB) imaging, report Belgian researchers.

MRI has recently been shown to be superior in specificity and sensitivity to bone scintigraphy, the standard algorithm used to survey skeletal metastases, says the team.

Furthermore, advances in MRI technology have led to WB scanning, which has been reported to be superior to AS scanning for bone lesion detection in multiple myeloma patients.

"[Prostate cancer] patients with bone metastases are not eligible for local treatment," write Frederic Lecouvet and colleagues from the Université Catholique de Louvain.

They add: "Hence, early detection of bone metastases is critical for treatment planning."

To compare WB- and AS-MRI, the researchers performed both scans on 60 prostate cancer patients considered to be at high risk for bone metastasis (e.g., Gleason score =8, prostate-specific antigen level =20 ng/ml).

Two independent radiologists categorized scans as negative or positive for bone metastasis, and used the Response Evaluation Criteria in Solid Tumors (RECIST) to evaluate the metastatic status of the patient.

Using both WB-MRI and AS-MRI results, both radiologists considered 30 patients to be positive for bone metastasis and 31 to be negative.

The researchers highlight that neither radiologist missed a bone metastasis diagnosis using AS-MRI results because of lesions in the "peripheral" skeleton, out of the field of view of AS-MRI.

The numbers of measurable lesions identified by WB- and AS-MRI were not significantly different, at 134 versus 124. Again, notably, all peripheral lesions were found in ten patients who were considered positive for bone metastasis on the basis of their AS-MRI results, regardless of their WB-MRI results.

In addition, there was almost perfect 'inter-' and 'intra-observer' agreement between the radiologists in assessing bone metastatic status, with 57 out of 60 patients receiving the same positive or negative diagnosis from each, after both WB- and AS-MRI.

Finally, analysis according to RECIST showed strong agreement between both radiologists for lesion count, and only limited differences between both approaches for RECIST quantification.

"AS-MRI could be a sufficient and reproducible approach to determine the presence/absence of metastases and to quantify the number and RECIST burden," conclude Lecouvet et al.

Source: Zero – The project to End Prostate Cancer

The Long-term Survival of Patients with Metastatic Prostate Cancer

ProstateCancerInfoLink.net | 07.08.2010

In the late 1980s and early 1990s it was generally considered that men diagnosed with metastatic (but still hormone sensitive) prostate cancer had an estimated survival of 18 to 36 months from the time of diagnosis — including their time on treatment with hormonal therapy.

And prior to 2003, there was no known treatment that had any meaningful effect on the survival of men who had a rising PSA after they had started on hormonal therapy.

Many specialists in the treatment of advanced prostate cancer (and at least some of their patients) are convinced that the overall survival of men with metastatic prostate cancer is much longer today than it was in the early 1990s. We have been told that the median survival of a man diagnosed with metastatic prostate cancer today may be as much as 5 to 6 years, but actual data to support this belief are very hard to come by.

It does need to be recognized in this discussion that most men today are not being initially diagnosed with extensive, metastatic prostate cancer that is widespread in the boney tissues.

Rather, the majority of men with metastatic disease today are men who have progressed through various stages (including micrometastatic stages) until their doctor can say, "Yes, there is a clear signal of metastasis on your bone scan." In other words, they are commonly being diagnosed with an early form of metastaic disease because we have "stage-shifted" the development of prostate cancer as a consequence of earlier diagnosis and earlier treatment.

There have now been several publications from clinical studies providing information on the survival of patients who have ceased to respond to standard, traditional forms of hormone therapy (e.g., an LHRH agonist alone, orchiectomy alone, or some forms of hormonal combination).

In recent years, the earlier terms "hormone refractory prostate cancer" (HRPC) and "androgen independent prostate cancer' (AIPC) have, in fact been replaced by the term "castration-resistant prostate cancer" (CRPC). A significant

subset of these men are defined as having metastatic CRPC (mCRPC), meaning that they have evident metastasis on a bone scan or a CT scan, and that they have failed at least two forms of hormonal therapy (customarily an LHRH agonist and an antiandrogen and withdrawal of the antiandrogen).

The first drug combination to show any impact on the treatment of men with mCRPC was docetaxel + predisone. In the so-called TAX 327 study, according to long-term survival data published by Berthold et al. in 2008:

•For men receiving docetaxel + prednisone every 3 weeks, the median survival was 19.2 months, with a range from 17.5 to 21.3 months.
•For men receiving docetaxel + prednisone once every week, the median survival was 17.8 months, with a range from 16.2 to 19.2 months.
•For men treated with mitoxantrone + prednisone, the median survival was 16.3 months, with a range from 14.3 to 17.3 months.

(Remember that the combination of mitoxantrone + prednisone had shown no impact on patients survival in earlier trials; its only affects were on pain and quality of life.)

In April 2009, the results of the IMPACT trial in men with minimally symptomatic mCRPC were announced. According to the product prescribing information for sipuleucel-T (Provenge):

•For men receiving three doses of sipuleucel-T, the median survival was 25.8 months, with a range of 22.8 to 27.7 months.
•For men receiving three doses of a placebo (a "dummy" injection), the median survival was 21.7 months, with a range of 17.7 to 23.8 months.

It is important to note that these patients had generally less advanced disease than the men in the TAX 327 trial, which is reflected in the fact that the men in the placebo arm of the IMPACT trial had a median survival 5.4 months longer than the men in the mitoxantrone + prednisone arm of the TAX 327 study. On the other hand, the patients enrolled in the IMPACT study could already have been treated with docetaxel.

At the Genitourinary Oncology meeting in San Francisco, earlier this year, data were presented showing that cabazitaxel (Jevtana) + prednisone was able to extend (by 2.4 months) the survival of men with mCRPC who had a rising PSA after treatment with docetaxel + prednisone compared to a placebo (a sugar pill) + prednisone.

According to the cabazitaxel prescribing information:

•For men receiving cabazitaxel + prednisone, the median survival was 15.1 months, with a range of 14.1 to 16.3 months.
•For men receiving a placebo + prednisone, the median survival was 12.7 months, with a range of 11.6 to 13.7 months.

So we know that docetaxel + prednisone given every 3 weeks can extend median patient survival by 2.9 months compared to mitoxantrone + prednisone, and we know that cabazitaxel + prednisone can extend median patient survival by another 2.4 months for patients who have a rising PSA after treatment with docetaxel + prednisone, giving us a total theoretical median survival benefit of 5.3 months or a median survival of about 21.6 months after initiation of treatment with docetaxel.

Interestingly, a small (non-randomized) study just published by Shamash et al. suggests that a regimen as simple as diethylstilbestrol (DES) + dexamethasone has a significant impact on the survival of men with CRPC:

•For men treated with DES + dexamethasone, median overall survival was 18.3 months, with a range of 15.4 to 23.3 months.

However, there are other things that we really do not know:

•We don't really know whether hormone therapy still provides only 3 years of survival from the time of first diagnosis of metastatic disease — because most men today start to receive hormone therapy long before there are clear signs of metastasis (and there are at least some data — e.g., the Messing et al. data from ECOG 3886 – that suggest that early use of hormonal therapy may be able to significantly extend survival).

•We don't really know whether the use of various types of intermittent hormonal therapy might affect overall survival in men with metastatic disease; some would certainly argue that the use of 5a-reductase inhibitors (5-ARIs) as "bridging" therapy in between sessions of standard hormone therapy impacts disease progression and potentially impacts survival — but we don't have "proof" in the form of data from a well-conducted, randomized clinical trial.

•We have no idea whatsoever of the potential overall survival of men with minimally symptomatic mCRPC who are treated sequentially with sipuleucel-T, then docetaxel, then cabazitaxel. Is their median overall survival > 25.8 months?

•We don't even know the optimal timing of chemotherapy with docetaxel + prednisone in a man with a rising PSA after treatment with sipuleucel-T.

Does that have to be based on some other signal of disease progression? We do know that treatment with sipuleucel-T has no significant impact on time to disease progression (as opposed to overall survival).

And all of this comes while we are investigating the clinical effects of a host of new products (abiraterone acetate, ipilimumab, dasatinib, MDV 3100, etc.) that might get used before, after, or in conjunction with the treatments that are already available.

From the viewpoint of drug developers, the overall survival of patients with late stage prostate cancer is not of the highest priority. Their highest priorities are: (a) demonstrating that their [new] drug does something better than the current standard and (b) optimizing belief that their product(s) represent some new and better standard.

The most recent example of this is seen with cabazitaxel. The primary goal of the developer was to show that cabazitaxel therapy could extend the survival of patients with mCRPC when the patients were no longer responding to docetaxel (the standard of care of first-line treatment of mCRPC) so that it became the new "standard" for the treatment of patients who ceased responding to docetaxel-based chemotherapy.

From the viewpoint of a patient, however (and we hope from the viewpoint of his doctor too), the key question is shortly going to become, "What is the sequence of treatments that will optimize the survival of a patient with a rising PSA after first- and second-line treatments and who can be assumed to have micrometastatic prostate cancer?"

Such men can already live for 15+ years with their cancer, but that isn't true for all men with micrometastatic disease. There are others who are at risk for a much earlier demise because they have especially aggressive, andogen-resistant forms of prostate cancer.

The prostate cancer community needs to come together to work out how best to answer the above question — and it isn't going to be easily or quickly resolved.

Source: Zero – The Project to End Prostate Cancer http://www.zerocancer.org

Key Pathway in End-Stage Prostate Cancer Tumor Progression Blocked

ScienceDaily | 07.21.2010

Prostate cancer advances when tumors become resistant to hormone therapy, which is the standard treatment for patients, and begin producing their own androgens.

Researchers at UT Southwestern Medical Center have found that blocking one of the enzymatic steps that allow the tumor to produce androgens could be the key in halting a tumor's growth.

The findings, appearing online and in the August issue of Endocrinology, suggest that this step might one day provide a new avenue of therapy for patients with end-stage prostate cancer. Health care experts estimate that more than 2 million men in the U.S. have prostate cancer, with more than 27,000 deaths related to the disease in 2009.

"We were able to block the androgen response, which is a central pathway for tumor progression," said Dr. Nima Sharifi, assistant professor of internal medicine and the study's senior author.

End-stage prostate tumors typically are treated with hormones that suppress the levels of the androgens, or male hormones like testosterone, that cause prostate cancer cells to grow. Eventually, however, the tumors become resistant to this therapy and resume their growth.

Using prostate cancer cell lines, Dr. Sharifi and his colleagues found that the hormone dehydroepiandrosterone (DHEA) is converted by the tumors into androgens. By blocking the enzyme 3ß-hydroxysteroid dehydrogenase (3ßHSD), which is responsible for the first enzymatic step that is required to convert DHEA to androgens, researchers were able to shut down the tumors' lifeline.

"Enzymes in general can make great drug targets, so this process conceivably could be targeted for the development of new treatments for end-stage prostate cancer, which has limited therapeutic options right now," said Dr. Sharifi, an investigator in UT Southwestern's Harold C. Simmons Comprehensive Cancer Center.

"The goal would be to develop a drug that targets that enzyme to be used for the advanced, incurable stage."

No standard treatments currently target this enzyme, but there is proven clinical evidence that this pathway is central to driving tumor progression.

Source: ZERO – The Project to End Prostate Cancer http://www.zerocancer.org

"The final test of a leader is that he leaves behind in other men the conviction and the will to carry on."

Walter Lippman

"Being powerful is like being a lady. If you have to tell people you are, you aren't."

Margaret Thatcher

The Great Prostate Cancer Challenge October 24 – Walkway Over the Hudson

Zero – The Project to End Prostate Cancer and Hudson Valley Urology of Kingston and Poughkeepsie (Premier Medical Group) have united to announce the inaugural of the Great Prostate Cancer Challenge. Other cities across the country will be having similar events this fall.

Many of you know Dr. Paul Pietrow, Dr. Naeem Rahman and Dr. Jose Sotolongo of HVU in Kingston and are happy to have them as your urologists. Here's a chance to help them reach out to others. A "Zero" mobile unit will be onsite offering cost free prostate screenings.

Our local event across the new and beautiful Walkway Across the Hudson will occur on October 24, rain or shine from the **Ulster County** side (Highland). Registration will be between 9:00 and 9:45 am with the actual walk between 10:00 and 11:00 am. We encourage you to get your sons, daughters and grandchildren to form teams to help raise funds for the Dyson Center for Cancer Care at Vassar Medical Center and the Eileen Hickey Center at St. Francis as well as to help raise awareness about prostate cancer. Registration is $15 or $25 for a family of four with T-shirts and goodie bags. Awards will be given to those who raise $100, $500 and $1000.

Come on, fellas – let's wake up men about prostate cancer the way the women have about breast cancer! We're being left in the dust by not being pro-active. Sure, a guy doesn't talk about his private parts, unless it's in the course of a locker room joke. Well, you all know, prostate cancer is no joke, so stand up like the great men you are and be counted in the fight. It's time to help those who don't even know they may need it yet.

Contact: Sinikka Sherwood at
845 437-3803
or
ssherwood@hvubest.com
And you can call or email Arlene Ryan or Diane Sutkowski of PCa101.Just look at your back page for the numbers.

We'd love to see a big turnout of our members and their families.

Thank you all for your Contributions

Kenneth Gelhaus
David Lustig
Earl Prochaska
Kevin Reynolds

Prostate Cancer 101 is a 501 (c) (3) IRS approved non-profit organization.

Your tax deductible donations should be mailed to:

Prostate Cancer 101
c/o Diane Sutkowski, Treasurer
8 Alcazar Avenue
Kingston NY 12401-4302

New Prostate Cancer Tests on the Horizon

www.ohsu.edu | 07.26.2010

Two new prostate cancer tests in development may offer added clues about which cancers require early treatment and which can be left for "watchful waiting," researchers reported at the recent annual meeting of the American Urological Association.

The tests can check for increased levels of genetic material. One test looks for the DNA of which genes are made, while the other test looks for the RNA that carries the messages from those genes. They show promise for cutting down on the number of biopsies now taken from men suspected of having prostate cancer.

Both tests appear to add certainty to the suspicion of prostate cancer provided by the most widely used test for prostate cancer, the prostate-specific antigen (PSA) blood screen.

Testing for Prostate Cancer with Genes

PSA testing is often used to screen men for prostate cancer. A high blood level reading of PSA is often followed by a biopsy, or tissue sample, to detect cancer cells.

Dr. Rakesh Singal, at the University of Miami, presented one of the reports at the meeting. He says about one of three patients is likely to have a positive biopsy.

"We wanted to come up with a test that tells us which patients are likely to have positive biopsies," he says. "This may help spare men unnecessary procedures and worry."

The test Dr. Singal described looks at blood levels of specific DNA. Prostate cancer can increase those levels because malignant cells grow abnormally fast and cause the death of other cells.

The study included 252 men referred for prostate biopsies because of abnormal PSA test readings. Dr. Singal's team found that high levels of the target DNA were linked closely with the presence of a cancer.

"What we think will probably happen in the future is that those men who have high PSA levels will have this test," says Dr. Singal. "If the DNA levels are high they will have biopsies; if low, they can be observed periodically."

But for that to happen, the results of this study have to be confirmed, he explains.

Biomarkers Help Find Cancers

The other test, described by Dr. E. David Crawford, at the University of Colorado, is targeted to elevated levels of PCA3 "messenger RNA" in urine. Again, elevated levels of this genetic material are associated with the presence of a tumor.

According to Dr. Crawford, about a million biopsies are done in the U.S. each year because of suspected prostate cancer. "Anything you can do to cut down the large number of biopsies has innumerable advantages," he says.

In the study, nearly 2,000 men with elevated PSA levels or abnormal results on a digital rectal examination (which measures prostate enlargement) also underwent PCA3 urine tests followed by biopsies.

The PCA3 readings were significantly higher in those men whose biopsies turned out positive for cancer, the team found.

In addition, "PCA3 level reflects the aggressiveness of cancer," says Dr. Crawford. The test could be used to single out prostate cancers requiring immediate surgery or radiation treatment.

Further studies are needed to determine whether PCA3 testing could serve that purpose, he says.

In the meantime, says Dr. Crawford, the immediate effect of the new study results is to help develop "a new paradigm" for early detection of cancer, in which PCA3 testing would go along with PSA testing and digital rectal examinations.

That combination could reduce the need for biopsies, which are expensive, cause discomfort, and are associated with a risk of infection, he says.

Always consult your physician for more information.

Testing for Prostate Cancer
Diagnosing prostate cancer is often a multi-step process. In addition to a complete medical history and physical examination, diagnostic procedures for prostate cancer may include the following:

DRE (digital rectal examinations) - usually conducted annually for men over the age of 50.

PSA (prostate-specific antigen) and PAP (prostatic acid phosphatase) - these blood tests are usually conducted annually for men over the age of 50. Men in high-risk groups, such as African-Americans, or those with a strong family history of prostate cancer, should consult their physicians about being tested at age 45.

If the DRE or PSA are unusual, other evaluation tools may include:

Transrectal ultrasound (TRUS) - a test using sound wave echoes to create an image of the prostate gland to visually inspect for abnormal conditions such as gland enlargement, nodules, penetration of tumor through capsule of the gland, and/or invasion of seminal vesicles.

Computed tomography scan (also called a CT or CAT scan) - a diagnostic imaging procedure that uses a combination of x-rays and computer technology to produce cross-sectional images (often called slices), both horizontally and vertically, of the body.

Magnetic resonance imaging (MRI) - a diagnostic procedure that uses a combination of large magnets, radiofrequencies, and a computer to produce detailed images of organs and structures within the body.

Radionuclide bone scan - a nuclear imaging method that helps to show whether the cancer has spread from the prostate gland to the bones.

Lymph node and/or prostate biopsy - a procedure in which tissue samples are removed (with a needle or during surgery) from the body for examination under a microscope to determine if cancer or other abnormal cells are present.

Source: Zero – The Project to End Prostate Cancer http://www.zerocancer.org

"Anything done for another is done for oneself."

Pope John Paul II

"We make a living by what we get; we make a life by what we give."

Winston Churchill

FDA Objects to Dendreon Promotions for Provenge

Reuters | 08.06.2010

Dendreon Corp. exaggerated the benefits of its novel prostate cancer vaccine and downplayed risks in some sales materials for the product, U.S. regulators said in a letter released on Friday.

"These promotional materials are false or misleading because they omit and minimize the risks and overstate the efficacy of Provenge," the U.S. Food and Drug Administration said in a letter to the company.

Some of Dendreon's promotions included a chart that "does not provide sufficient contextual information for the presented survival rate estimates to convey the limitations of" the company's main study, the FDA said.

The materials also left out some information about sterility testing, the agency said.

The FDA asked Dendreon to immediately stop using the promotions and any others with similar claims.

Dendreon spokeswoman Katherine Stueland said the company "has spoken with the FDA and intends to comply with the request."

The FDA approved Provenge in April for treating advanced prostate cancer.

Unlike traditional vaccines that prevent a disease, Provenge treats prostate cancer by stimulating the body's own immune system to attack malignant cells. It is produced by taking cells from a patient's tumor and incorporating them into a vaccine that is injected back into the patient.

Dendreon shares fell slightly after the FDA letter was released, but recovered to close 1.5 percent higher at $39.05 on Nasdaq.

The FDA posted the letter here:

PROVENGE (sipuleucel-T) - Untitled Letter
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and
Research
1401 Rockville Pike
Rockville, MD 20852-1448

August 3, 2010

Helen Kim
Director of Regulatory Affairs
Dendreon Corporation
3005 First Avenue
Seattle, WA 98121

Re: PROVENGE® (sipuleucel-T)
BLA STN# 125197

Dear Ms. Kim:

The Office of Compliance and Biologics Quality (OCBQ) in the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) has reviewed an In Service Kit (P-A-04.10-007.00) (kit) and PROVENGE Detail Aid (P-A-04.10.009.00) (detail aid) for PROVENGE® (sipuleucel-T). Dendreon Corporation (Dendreon) submitted the kit and detail aid under cover of Form FDA 2253 on May 4 and May 27, 2010, respectively.

These promotional materials are false or misleading because they omit and minimize the risks and overstate the efficacy of PROVENGE. Therefore, this material misbrands PROVENGE under sections 502(a) and 201(n)

of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §352(a) and §321(n), and FDA implementing regulations, Cf. 21 CFR 202.1(e)(5)(iii) and (e)(6)(i).

Background

According to the FDA-approved prescribing information (PI), PROVENGE is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The Warnings and Precautions section of the PI includes, but is not limited to, the following risks for PROVENGE:

PROVENGE is released for infusion based on the microbial and sterility results from several tests: microbial contamination determination by Gram stain, endotoxin content, and in-process sterility with a 2-day incubation to determine absence of microbial growth. The final (7-day incubation) sterility test results are not available at the time of infusion. If the sterility results become positive for microbial contamination after PROVENGE has been approved for infusion, Dendreon will notify the treating physician. Dendreon will attempt to identify the microorganism, perform antibiotic sensitivity testing on recovered microorganisms, and communicate the results to the treating physician. Dendreon may request additional information from the physician in order to determine the source of contamination.

According to the Clinical Studies section of the PI, the effectiveness of PROVENGE was studied in 512 patients, "randomized in a 2:1 ratio to receive PROVENGE (n=341) or control (n=171)." This study "was a randomized, double-blind, placebo-controlled, multicenter trial in patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer." As shown in Table 2, the observed median survival time for patients randomized to the PROVENGE arm was 25.8 months and for patients randomized to placebo was 21.7 months. The Hazard Ratio was 0.775 (95% Confidence Interval: 0.614, 0.979). The study achieved a p-value of 0.032 based on a log-rank test (not prespecified).

Omission and Minimization of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of representations made with respect to consequences that may result from the use of the product as recommended or suggested by the materials.

Specifically, the kit presents a misleading product timeline on the slide entitled, "Is PROVENGE therapy approved for infusion?" The timeline includes "Test Results Complete" before the product arrives at the office, which is contrary to the Warnings and Precautions section of the PI which states that the final (7-day incubation) sterility test results are not available at the time of infusion. Furthermore, the kit omits the Warning and Precaution that the final sterility test results are not available at the time of infusion.

Overstatement of Efficacy

Promotional materials are misleading if they contain a representation or suggestion, not approved or permitted for use in the labeling, that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

Page seven of the professional detail aid includes a chart entitled, "Kaplan-Meier Survival Rate Estimates." This chart presents the percentage of patients alive at 12, 24, 36 and 48 months. This information is misleading because it does not provide sufficient contextual information for the presented survival rate estimates to convey the limitations of the study. For example, the chart does not include a measure of variability, such as the 95% confidence intervals, when presenting the survival rate estimates.

Conclusion and Requested Actions

For the reasons discussed above, your promotional material misbrands PROVENGE under sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §352(a) and §321(n), and FDA implementing regulations, Cf. 21 CFR 202.1(e)(5)(iii) and (e)(6)(i).

We request that Dendreon immediately cease the dissemination of these violative promotional materials for PROVENGE, as well as promotional materials with the same or similar representations. Please submit a written response within ten (10) business days of the date of this letter, stating whether you intend to comply with this request, listing all violative promotional materials for PROVENGE and explaining your plan for discontinuing use of such materials. Please direct your response to Lisa Stockbridge, PhD, Acting Branch Chief at the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Case Management, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. In all future correspondence regarding this matter, please refer to the BLA/STN number. We remind you that only written communications are considered official responses.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for PROVENGE comply with each applicable requirement of the Act and FDA implementing regulations.

If you choose to revise your promotional materials, APLB is willing to assist you in assuring that your revised materials comply with applicable provisions of the Act by reviewing your revisions before you use them in promotion.

Sincerely,

Robert A. Sausville
Director, Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Source: Zero – The Project to End Prostate Cancer

"One of the nice things about being imperfect is the joy that it brings to others."

"Millions long for immortality who don't know what to do on a rainy afternoon."

Susan Ertz

Prostate Cancer 101, Inc.
8 Alcazar Avenue
Kingston, NY 12401-4302

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Man to Man Group
Our brothers in support and education

Meetings are held the First Thursday of the month at the Central Hudson Auditorium on South Road in Poughkeepsie, starting at 6:30 p.m. Various doctors and speakers are on the agenda and one on one help is available after the meeting.

Contact
Paul Totta 845 297-7992
or Jim Kiseda 223-5007

If you need or want to help:

PCa 101 Seminar
First Tuesday of every month

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