Compassionate
Oncology Medical Group

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THB UPDATE: THE DEMISE OF THE (FOOL'S) GOLD STANDARD; THE RISE OF THE "PLATINUM AND DIAMOND STANDARD"

(Father's Day 2008)

The use of Triple Hormone Blockade® as initial therapy is a noninvasive, conservative approach to treating prostate cancer patients with side effects that are almost always completely reversible when hormone blockade is completed. Since hormone blockade is systemic therapy, it not only kills prostate cancer cells in the prostate, but can also kill prostate cancer cells that have spread away from the prostate gland and most typically are found in multiple bones. Less frequently, lymph glands in the pelvis and/or abdomen are found to contain metastatic deposits of prostate cancer cells. Unless a patient has developed metastatic hormone refractory prostate cancer, it is unusual for prostate cancer cells to be identified in the lungs, liver and/or brain, although other types of cancer (lung, melanoma, kidney, colon, breast) may frequently involve one or more of those organs.

Triple Hormone Blockade® (THB) consists of 13 months treatment with an LH-RH agonist, an antiandrogen, and finasteride, 5 mg per day. Prior to the availability of Casodex, I used two 125 mg capsules of Eulexin three times per day. Shortly after Casodex became commercially available, I urged all patients to be treated with Casodex, 50 mg tablets, three per day all at one time, rather than Eulexin. For men unable to afford Casodex, as well as being ineligible for the Casodex Patient Assistance Program, and if our Casodex free samples cabinet was already depleted, then patients still unable to afford Casodex were treated with flutamide, six per day in three divided doses. I strongly preferred six Eulexin per day rather than one Casodex, but I strongly preferred and urged that if at all possible, all patients should try to take three Casodex per day. Since 1998, most patients received Casodex. All patients were also treated with Proscar, 5 mg once each day. After 13 months of Triple Hormone Blockade®, men continued to take Proscar, 5 mg once each day, so-called Finasteride Maintenance® Therapy, but their LH-RH agonist and antiandrogen (AA) were discontinued. Our patients remained on their AA until 30 days after their final dose of LH-RH agonist, or for 12 weeks after their final LH-RH agonist injection if the final dose given was a three-month dose.

I wrote in 2005 that there is **no** evidence any type of radical local therapy extends life, while there is overwhelming evidence that these therapies can and often do cause permanent toxicity, with a marked decrease in quality of life. No prospective randomized study had ever shown any form of radical local therapy to be both necessary and effective. An article in the March 18, 2008, *Annals of Internal Medicine*, Volume 148, Number 6, pages 435-448, by Wilt, T., et al., critically and accurately illuminates our search to discover the answers to "our" prostate cancer questions. It is a "Review" article: "Comparative Effectiveness and Harms of Treatments for Clinically Localized Prostate Cancer." The authors reviewed all randomized controlled trials (RCTs) published in any language, and all observational studies published in English (473 trials) that evaluated treatments and reported clinical or biochemical outcomes in localized prostate cancer.

From September 1991 through January 2005, we prospectively treated 212 men, consecutively seen, who presented with clinically localized or locally advanced, biopsy-proven prostate cancer using primary androgen deprivation therapy alone. Any patient who was previously treated with any form of local therapy for prostate cancer such as radical prostatectomy, radiation therapy, seeds, cryotherapy, HIFU, microwave, PVP and/or cryotherapy was excluded. Additionally excluded were patients who had previously been treated with any form of hormone blockade for prostate cancer. Prior treatment with Proscar or Avodart was allowed. The vast majority of the men in our series were treated with 13 months of Triple Androgen Blockade® followed by Finasteride Maintenance® Therapy as their only treatment. All men had refused local therapy. During the first five years of the study, there were a number of men who had received one to three months of Lupron or Zoladex monotherapy or combined androgen blockade prior to transferring their care to us, at which time we changed their treatment to Triple Hormone Blockade®. We decided to include these men in this analysis of our study results. Our database includes all men consecutively seen in our practice who had been treated with primary hormone blockade, although we excluded patients who were treated with hormone blockade (not Triple Hormone Blockade®) for longer than a few months prior to consulting with us and switching to THB.

Approximately one-third of our patients presented with one or more high-risk features. These include 25 men presenting with Gleason scores of 8 to 10; an additional 33 men had Gleason

4+3=7 which, in more recent years, has been considered high risk. Most prostate cancer experts believe that Gleason 4+3 clinically behaves much more like a Gleason 4+4=8, whereas Gleason 3+4 typically resembles the clinical behavior of a Gleason 3+3=6. Since this distinction was not recognized until approximately 2005, for this study, we categorized all of our Gleason 7 patterns as an intermediate-risk prognostic factor. For new patients presenting since 2005, we have considered Gleason 4+3 to be an independent negative high-risk prognostic factor. Thirty-two men had a baseline PSA of 20 or higher, and 20% presented with locally advanced disease as a high-risk factor. For the 32 men whose PSA was over 20, their average PSA was 28.8.

As of March 2005, 19 of the 212 men had been treated with a second cycle of androgen deprivation therapy. Eighteen of these 19 patients presented with at least one high-risk negative prognostic factor. Of the 19 men who required a second cycle of hormone blockade, almost one-half of them had two or more high-risk negative prognostic factors. Ten of these high-risk patients presented with PSA's higher than 20; eight had T3 lesions, and nine of these patients had Gleason scores of 8, 9, or 10. Only one of the high-risk patients developed progressive, metastatic prostate cancer, and subsequently died from androgen-independent prostate cancer. This patient presented with very high-risk disease which, in retrospect, was likely metastatic at the time of diagnosis. His baseline bone scan was abnormal, and he also presented with an elevated prostatic acid phosphatase, which usually indicates the presence of at least occult metastatic disease. This patient survived prostate cancer for nearly seven years. He is the only prostate cancer death in our series and, by definition, our disease-specific survival was greater than 99.5% at a median follow-up of seven years (as of 2005).

Since approximately 2005, a fourth high-risk negative prognostic factor has been identified and is accepted by most prostate cancer experts. If 50% or more of the prostate cancer biopsy core specimens are found to contain prostate cancer, this represents a fourth independent high-risk negative prognostic factor. The presence of any one high-risk negative prognostic factor, by definition, places a man in the high-risk category. However, since the percent of cores involved by prostate cancer was not identified as a high-risk factor when we published our initial Triple Hormone Blockade® results in 2001 in the peer reviewed medical journal, "*The Oncologist*,"

Volume 6, pages 177–182, April 2001, I am not considering this a high-risk factor for this paper. However, patients presenting to us since approximately 2005 with 50% or more biopsy cores showing prostate cancer are considered to have high-risk disease. If we staged men using today's accepted prognostic factors, our series would have a higher number and percent of men with high-risk disease and would make our results even more impressive.

The average baseline testosterone in our series was approximately 400. A baseline testosterone was available for 136 of these 212 patients. A majority of patients who began treatment prior to 1998 did not have baseline testosterone levels recorded, and almost 100% of patients who were already on hormone blockade when first seen by us did not have baseline testosterone levels obtained prior to being started on hormone blockade (HB) by the doctor who first initiated their HB.

After completing HB and recovering from testicular suppression, the mean testosterone rose to 492. This level is almost 25% higher than pre-hormone blockade treatment levels. All of these men are being treated with a 5-alpha reductase inhibitor. Most are on Proscar, 5 mg per day, so-called Finasteride Maintenance® Therapy. A few men are taking dutasteride (Avodart), 0.5 mg one each day, as their 5-alpha reductase maintenance therapy, and a few take one Proscar and one Avodart each day. Both Proscar and Avodart raise testosterone levels.

As of April 2005, the first 177 patients on this study had an average follow-up of 63 months (over five years), and had a mean PSA of 2.663. The first 113 men treated had a mean follow-up of 77 months (almost six and one-half years). Their mean PSA was 3.147. If we restrict our analysis to patients who have been off therapy for at least six years, there are 65 men in this group, with a mean follow-up of 90.4 months (just over seven and one-half years). Their mean PSA was 3.385. The first 43 patients, with at least a seven-year follow-up, had a mean follow-up of approximately 97 months (over eight years). Their mean PSA was only 3.028!!

We believe that our results are superior to any series of men treated by any form of radical local therapy, in spite of the fact that our patients presented with more aggressive baseline prognostic factors compared to Dr. Walsh's surgically treated patients. We believe our series is the largest community based series of patients anywhere who have been treated with primary hormone blockade.

In the original version of this paper, many of the patients in this series were managed by us, but treated by their local doctors. After they completed hormone blockade, they were often only followed by their local doctors. If all the patients came to our office for their follow-up lab tests, obtaining and managing the database would be much easier. Instead, we have to contact each patient individually in order to get the necessary follow-up information. We would like to thank Mr. Nathan Roundy, and acknowledge all the time he has spent, the tireless efforts he has expended, and his extremely impressive expertise that was apparent in everything that he did. He volunteered his time to review and authenticate all the pertinent data that made it possible for us to present our study results at the February 2005 multidisciplinary (American Society of Clinical Oncology/American Urological Association/American Society for Therapeutic Radiology and Oncology) Prostate Cancer Symposium in Orlando, Florida and at the ISICAP (International Study of Intermittent Therapy for Cancer of the Prostate), in London, England in March 2005. Thank you so much for your help, Nathan.

And in May 2008, we are again indebted to Mr. Nathan Roundy for volunteering to update our data base. He has been working diligently, tirelessly, and always with a smile on his face gathering the information that will allow us to submit for publication an updated analysis of our results using Triple Hormone Blockade® as sole primary treatment for patients presenting with clinically localized or locally advanced prostate cancer.

There are six patients in this Triple Hormone Blockade® series who later elected to be treated with deferred local therapy years after receiving Triple Androgen Blockade®. While we rarely recommend any form of local therapy (radical prostatectomy, radiation therapy, seeds and/or cryosurgery), it is important to understand that starting with Triple Androgen Blockade® does not preclude utilizing local options at some future time. Dr. Bob believes that for most men, “The best local therapy is systemic therapy.” The patients who proceeded to have deferred local treatment were generally in their mid-60's, and had presented with intermediate-risk disease. Four of these patients received seed therapy; one received proton-based therapy, and one underwent radical prostatectomy. As a generalization, these men underwent their local therapy between four and seven years after receiving their single cycle of Triple Androgen Blockade®.

One randomized controlled trial enrolled men mostly with abnormal digital rectal exams and without PSA-detected disease which means these patients presented with much more advanced disease than seen in the USA today. Compared to watchful waiting, radical prostatectomy reduced all cause mortality 24% versus 30% at ten years. It the patients had been diagnosed by PSA rather than DRE, in all probability, it would have taken an extra five to seven years before any benefit would be found, and 1,000 men would have had to have a radical prostatectomy in order to improve the survival of 60 men. Benefit was only seen in men younger than 65. The only other prospective randomized controlled trial compared radical prostatectomy plus a placebo pill to a placebo pill alone, and it found no survival advantage with radical prostatectomy. Moreover, radical prostatectomy did not reduce the risk for men to develop metastatic disease, nor did it reduce the risk for dying from prostate cancer.

The authors of this Review article note that there is insufficient information in the medical literature to allow them to compare the effectiveness and harms of localized prostate cancer treatments and, therefore, as of March 2008, there is no evidence in the medical literature that proves any form of treatment for prostate cancer is superior to 13 months of Triple Hormone Blockade® followed by Finasteride Maintenance Therapy®.

I know it must be difficult, if not impossible, for you to understand how is it possible that so many patients every year allow themselves to undergo so many radical local procedures (surgery, radiation, seeds, etc.) when as of March 18, 2008, the belief that radical local therapy is both necessary and effective is based on opinion, <u>not</u> on proven scientific fact? In all other types of cancer, studies must first be done proving the benefit of a particular treatment before it is accepted. And the more radical the treatment, the stronger the requirements should be to prove that the benefits of treatment outweigh the harms. In prostate cancer, it seems to me that the major explanation offered is: “We do this type of treatment because this is the way we have always treated prostate cancer.” Shouldn’t you demand proof before risking permanent side effects such as urinary and/or fecal incontinence, impotence, and I wonder how many of my readers were informed of the risk to develop “climacturia” after a radical prostatectomy? The most recent urologic literature reports that 48% of patients have this after their radical

prostatectomy. Climacturia means that at the time a man climaxes (has an orgasm), he **leaks urine!!**

This *Annals* article should be used by prostate cancer patients to protect themselves from being "brainwashed" and/or allowing themselves to be coerced into hasty treatment decisions. Show the article to your prostate expert and have them provide you with medical references that disprove this article. They do not exist. As your consultant tries to convince you to ignore the facts and trust their opinion, remember two famous quotes: 1, "The greater the ignorance, the greater the dogma," Sir William Osler; and 2, "Everyone is entitled to their own (wrong) opinion," Sir Dr. Bob.

In the mid-1990's, I speculated in one of my papers (posted on my website) that logically men presenting with more aggressive baseline prognostic factors (PSA, Gleason score, etc.) will have rising PSA's much earlier and to higher levels after radical prostatectomy or radiation therapy than men who presented with less aggressive disease. I predicted that these patients would also develop metastatic disease sooner (and by inference have shorter survivals).

At that time, Dr. Pat Walsh from Johns Hopkins Hospital had published his radical prostatectomy results, and reported that there were very few PSA failures between the fifth and tenth year following surgery. The obvious conclusion he wanted to convey was that these men were "cured." But, the expressions, "The devil is in the details," when added to "Statistics do not lie; statisticians do," may change a conclusion from white to gray or black.

At the time of his analysis, the average follow-up was less than four years, although the longest follow-up was over ten years (for a few patients). He reported seven-year follow-up results as well as up to ten-year failure rates. How you state you have seven-year follow-up results with less than a four-year mean follow-up requires using "actuarial" analysis. Admittedly, this is a commonly used method to report statistical results. But actuarial projections are based on early and limited follow-up results. Life insurance companies base their premiums on actuarial analysis. They use your pertinent prognostic baseline factors and plot them on an actuarial table to determine how much to charge you for your life insurance. The prognostic factors may include sex, age, health, etc. When smoking became recognized as a health

factor, it was added. Obesity is now a major risk factor. If your actuarial projections do not include important unknown prognostic factors, your conclusions will be erroneous.

Dr. Walsh may not have realized how important baseline PSA and Gleason scores were for calculating recurrence rates five years and more following radical prostatectomy. This is ironic since he has always been accused of "cherry picking" his radical prostatectomy patients in order to achieve higher "success" rates. I have been told (without independent verification) that he will rarely, if ever, operate on patients with a Gleason score over 6; a PSA of 10 or higher, or locally advanced disease. He recognized that low Gleason and low PSA patients had better postop PSA results. At the time he published this paper, I think he believed that if you were failure free at five years, you were cured. He did not realize that when low-risk patients recur, their recurrences would often be late (beyond five years).

Several years later, he wrote a follow-up paper on this same series of patients, and reported that more patients were now recurring between five and ten years postop, and well beyond. It is also now known, unfortunately, that just like women with breast cancer, men continue to have an increased risk of prostate cancer PSA recurrence for the rest of their lives compared to men without known prostate cancer. PSA recurrence graphs show new failures manifesting themselves with each year of follow-up. The graph never levels off. This tells us that prostate cancer is not likely to be a curable disease using only local treatment. Since prostate cancer continues to recur 15 or more years after radical prostatectomy or radiation therapy, it tells us that prostate cancer is a systemic disease for most men at the time it is diagnosed. Our (former) Gold Standard is now forever tarnished. Use Triple Hormone Blockade® (systemic therapy), what I call, "The Platinum and Diamond Standard," rather than the tarnished, flawed, old self-declared (Fool's) Gold Standard.

The average age of our patients was 66, with an age range from 44 to 88. The average baseline PSA was approximately 11.1 ng/ml. The range of baseline PSA's was 0.39 to 59.8. The median Gleason score was 7. Approximately 80% of our patients presented with digital rectal exam clinical stage T1c or T2a, but one in five men presented with locally advanced, clinical stage T2b or higher. No patient had overt evidence of metastatic disease, although baseline scans were only rarely

obtained prior to 2003 since the likelihood of finding an abnormal scan in most patients with low or intermediate-risk disease is low and not considered cost effective by most.

In February 2005, the multidisciplinary Prostate Cancer Symposium was held in Orlando, Florida. This meeting was sponsored by the American Society of Clinical Oncology (ASCO), the American Urological Association (AUA), the American Society of Therapeutic Radiology and Oncology (ASTRO), and other prestigious organizations.

Compassionate Oncology submitted an abstract to this meeting. Between 2000 and 2005, Compassionate Oncology submitted yearly abstracts to each ASCO meeting. Prior abstracts were usually accepted for publication and appeared in that year's ASCO Annual Meeting Proceedings. We were always grateful to see our abstracts published, but were disappointed that we were not allowed to present our paper as a "Poster Presentation" or an "Oral Presentation." We always rationalized that using Triple Hormone Blockade® as primary therapy for prostate cancer was so far ahead of its time that it threatened conventional concepts. It reminded me of breast cancer in 1978 when I began to advise women that results from lumpectomy/radiation therapy were at least as good as results from radical mastectomy. It took until 1995 for the National Cancer Institute to send a letter to doctors advising that lumpectomy/radiation had become the **preferred treatment for breast cancer.**

At this Orlando meeting, we were accepted for a Poster Presentation. Our updated Triple Hormone Blockade® results were presented at this meeting. Being accepted is a great honor and accomplishment that means using Triple Hormone Blockade® as primary therapy for clinically localized prostate cancer was being increasingly recognized, utilized, and accepted as an appropriate prostate cancer treatment option.

Approximately one month before the meeting, I was contacted by Dr. Fernand Labrie, who asked me for a recent update on our THB results. Dr. Labrie is one of the handful of physicians whose work most influenced my development, approach, and evolution as a prostate cancer subspecialist. As the Father of Combined Androgen Blockade, he pioneered the use of Lupron plus the antiandrogen flutamide. Prior to Dr. Labrie, the only hormone blockade used was monotherapy. I think he may even have the patent for flutamide (I never asked if this is accurate or not). He is the doctor who was involved in the treatment of

Lloyd Ney, the founder of the nonprofit organization and prostate cancer patient newsletter, PAACT (Patient Advocates for the Advanced Treatment of Cancer). If you are not a member of PAACT, I strongly urge you to join: Phone – (616) 453-1477; Email – PAACT@PAACT.org. Their newsletters are always informative, and they have literature, videos, and other free information for prostate cancer patients.

At this Orlando meeting, Dr. Labrie gave an oral presentation and reported his combined hormone blockade treatment results. He believes that we can cure prostate cancer using hormone blockade alone, but believes it takes approximately six to eight years of combined androgen blockade to achieve cure.

I was not at the meeting, but approximately 1,000 doctors were in attendance during Dr. Labrie's lecture. As he showed his last slide from his own study, Dr. Labrie said (to paraphrase): "If you think my results are good, wait until you see these." He then showed a slide he had made with our Compassionate Oncology Triple Hormone Blockade® results and (again paraphrasing) said, "These results are even better. I strongly recommend that everyone in the audience see the Poster Presentation with the results from the Triple Hormone Blockade® Protocol."

These compliments were coming from one of the best known and most respected, internationally recognized experts on prostate cancer hormone blockade treatment, and were delivered to an audience of our peers. This meant Triple Hormone Blockade® had come full circle for me. Dr. Labrie started as my teacher, and now he was honoring the results from the "lifelong work" of a student of his, my Triple Hormone Blockade® results. Some of the doctors in the audience had previously ignored, criticized, and even ridiculed me. Dr. Labrie changed my image from "dangerous maverick" to "pioneer" -- miracle of miracles -- and thank you, Dr. Labrie.

In early March 2005, I was invited to London for the "First International Conference for Intermittent Androgen Blockade (IAB) Therapy for Prostate Cancer." This meeting was held to review the 11 published series on IAB, and to combine all of the patients in these studies, in order to do a meta-analysis. The larger the number of patients analyzed, the more meaningful the conclusions. This is what a meta-analysis does. A total of 1,705 patients were included in the 11 studies; 1,113 did not have any prior therapy, although 270 of them presented with

metastases. Seven hundred and ninety-two patients had localized disease only. All of our patients were in this category.

In most of the individual studies, patients were treated with combined androgen blockade, although in one study, patients were primarily treated with Lupron alone. Our Compassionate Oncology patients were the only ones treated with Triple Hormone Blockade®/Leibowitz Protocol, and the only ones treated with Finasteride Maintenance® Therapy. The results are, to say the least, astonishing. An average of 18% of the patients in the other ten studies developed hormone resistance. An average of 20% of the patients in the other ten studies died from prostate cancer. In our Compassionate Oncology series, only 0.48% of patients developed hormone resistance, and only 0.48% of patients died from prostate cancer. Our Compassionate Oncology series consisted of 207 patients.

One of the other extraordinary results was the average time off androgen blockade in cycle #1. The average from the ten series was 55%. This means that 45% of the time, they were on hormone blockade; 55% of the time, they were off hormone blockade. In our series, patients were off hormone blockade more than 85% of the time and still counting. Compassionate Oncology is the only practice that recommends using antiangiogenic medicines and other supportive medicines to postpone or prevent the need to go back on hormone blockade. A prior paper of mine explains why I am certain that the worst form of hormone blockade is continuous HB; the second worst type is intermittent androgen blockade (IAB). Far and away, the best (and only type of hormone blockade that should be used) is one single cycle of HB (preferably THB/Leibowitz Protocol). Then if the PSA is rising too fast or goes too high, you use everything possible to postpone and hopefully avoid the need to start another cycle of HB. If, in spite of these efforts, a patient does have to be treated with another cycle of HB, use everything possible to help ensure that this will be the last cycle of HB necessary. Some of my most effective treatment insights include only using nine months of hormone blockade for any cycle of HB after the first cycle, and never using an antiandrogen a second time. Instead use ethinylestradiol (my first choice), or aminoglutethimide with hydrocortisone, or ketoconazole/ hydrocortisone. My patients also receive 15 doses of weekly low-dose chemotherapy with Taxotere/Emcyt/carboplatinum. All patients are also treated with my prostate cancer antiangiogenic cocktail, and also receive full-dose

anticoagulation with low-molecular weight heparin (not Coumadin or warfarin).

If you never go back on hormone blockade, you cannot develop hormone refractory prostate cancer. I have been using this approach since 1993. I am certain that Compassionate Oncology is the only practice anywhere in the world that utilizes this treatment philosophy.

One of the attendees at the meeting was Dr. Nick Bruchovsky, the now retired Canadian investigator who is acknowledged as the Father of Intermittent Androgen Blockade. He began reporting results with laboratory models for IAB beginning in the 1970's. Dr. Bruchovsky is the single most influential doctor whose work helped nurture, mold, and evolve my prostate cancer hormone blockade treatment approaches. During the morning session, he reported on a Canadian trial of IAB. In the afternoon, he was asked to speak about the basic science supporting the use of IAB. During that afternoon session, he literally used my name on at least six occasions to let the audience know that my results are far and away the best of anyone, and are the way that he would recommend that patients be treated. He complimented me over and over again, praising my innovative therapies, treatment approaches, and unsurpassed results. I was overwhelmed with so many emotional feelings, especially knowing that I had been ridiculed, attacked and/or ignored since the early 1990's. To be complimented again and again in front of my peers was one of the most gratifying and happiest professional experiences I have ever had.

In April 2005, I gave a lecture in San Jose, California, and most of the first part of the lecture was titled, “The Demise of the Gold Standard.”

In the April 2005, *Journal of Urology*, Dr. Peter Carroll, Chairman of the Department of Urology at UC San Francisco, wrote the lead editorial, “Prostate Cancer: Overdiagnosis, Overtreatment, or Both??” I am in awe with admiration and respect for Dr. Carroll’s courage, insight, and intelligence for having the strength and conviction to be the first to take this stand. He wisely states that we must immediately uncouple prostate cancer diagnosis and treatment as they are two separate processes. He tells urologists that their subspecialty will be judged today and in the future by how they respond to this over-treatment of prostate cancer. He warns that if urologists do not recognize and correct this, some

government agency or other subspecialty (?medical oncology?) will impose their own guidelines. Dr. Carroll's message is reminiscent of words used by the Father of Urologic Oncology, Dr. Willet Whitmore, Chief of Urology at Memorial-Sloan Kettering in New York, who in the 1970's immortalized these words:

Is cure possible?

Is cure necessary?

Is cure possible only when it is not necessary?

Collectively, the information from February, March, and April 2005 made me feel that "The War was over," and Triple Hormone Blockade® as a legitimate primary treatment option for prostate cancer had won. The Platinum and Diamond Standard has begun to uncrown the Gold Standard. To be sure, major skirmishes and battles will continue and probably endure, even long after I retire. There is so much more to tell, but I have a pile of patient charts on my desk and it is really late. For the rest of the information on the Demise of the Gold Standard, please get a copy of my April 2005 San Jose lecture. You can order any of my lectures by calling my office at (310) 299-3555; they cost approximately $15.00 each.

As always —
Be happy,
Be well,
Live long and prosper,

DR. BOB

****** None of the above should be construed as medical advice or consultation, and anything discussed in this paper is meant for information only. All medical treatments, consultations, decisions and recommendations can only be made by the patient and his/her treating physician.

Revised 6/12/08

P.S. According to research presented at the American Urological Association's Annual Meeting, May 22, 2008, re-analysis of a drug trial found that finasteride (Proscar) reduces prostate cancer risk **without** boosting the odds of aggressive tumors. Researchers have followed more than 18,000 men, age 55 or over, and found that Proscar reduced prostate cancer risk by up to 25%. The original trial had been stopped in 2003 because some experts were concerned that Proscar was possibly encouraging higher grade cancers to develop even though the total number of prostate cancers had been reduced by 25%. However, re-analysis that was updated and presented at the May 2008 AUA meeting found that, in fact, Proscar was associated with significant declines in tumors with Gleason scores 5, 6, and 7, and those three Gleason scores comprise 72% of all prostate cancers that are diagnosed in the United States. The lead study author was Dr. Steven Kaplan, Professor of Urology, at Weill Cornell Medical College.

The patients who are either in my practice, or who are familiar with my website, lectures and/or papers that I have authored, have been aware for many years that I have been an enthusiastic supporter recommending that men be treated with a statin medication, specifically Crestor or Lipitor, for even mild elevations in cholesterol. I have explained that the benefits of statins go far beyond that of lowering cholesterol levels. At the May 2008 American Urological Association Annual Meeting, researchers reported on a study of 1,214 men who were taking statins. Not surprisingly, the researchers discovered that PSA levels were, of course, lower after starting statins, but they also found that patients treated with statins had PSA levels drop in proportion to the drop these men had in their cholesterol levels. It has previously been noted that patients on statins were less likely to develop advanced metastatic life-threatening prostate cancer, and that statins lowered the risks of dying from metastatic prostate cancer.

P.S.S. Recently we started a not-for-profit research foundation, "Compassionate Oncology Research Foundation." It has already been recognized and accepted by the IRS as a legal 501C fully tax exempt foundation. All contributions are fully tax deductible.

We are currently gathering our Triple Hormone Blockade® data for publication. We will use some of the funds to pay a statistician to analyze our data.

We are also involved in a study that has collected data on approximately 100 patients treated by Compassionate Oncology Medical Group with high-dose Testosterone Replacement Therapy.

Whenever we receive some additional funds, we plan to hire a data manager and statistician to allow us to analyze and then report on our results treating patients presenting with high-risk disease, recurrent, metastatic, hormone refractory, and other categories of advanced prostate cancer.

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