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Finasteride Dilema: To Treat or Not To Treat?

IS THE HYPOCRATIC CODE OUTDATED?

You are listening to ReachMD XM 157, the channel for medical professionals. Welcome to the clinician's roundtable. I am your host, Dr. Morris Pickard and joining me today is the noted author, Dr. Stewart Justman. Dr. Justman is a Professor of Liberal Studies at the University of Montana, a lay member of The American Society of Clinical Oncology and the member of the committee 5-alpha reductase. He is also a survivor of cancer of the prostate himself.

DR. MORRIS PICKARD:

Thank you very much for joining us.

DR. STEWART JUSTMAN

Thank you for having me.

DR. MORRIS PICKARD:

We are going to be discussing your newest book Do No Harm - How a Magic Bullet for Prostate Cancer Became a Medical Quandary. Could you tell us first what led you to write this particular book?

DR. STEWART JUSTMAN

Well, I wrote a book more or less about my own experiences as a cancer patient not exactly that, but in 2004 or so and it was well received came to the attention of someone on the 5-alpha reductase committee that you mentioned at which point I was asked to join the committee and then immersed myself in the finasteride literature, which of course is what the committee was concerned with and I was first _____ to learn that I knew nothing about the finasteride question even though it momentarily burst into the press in 2003, but I guess the keyword is momentarily.

DR. MORRIS PICKARD:

Who did you write the book for?

DR. STEWART JUSTMAN

I certainly did hope that it would be read by concerned physicians like our own audience, but my informing assumption was that an issue this powerful and this profound had wider implications and I would hope this kind of issue that would speak to just concerned layman like myself.

DR. MORRIS PICKARD:

I started out by saying tongue in cheek possibly is the hypocratic code outdated because if you read it there is certainly a gender-specific language, human rights and civil liberties are not included, not to discriminate for race or religion or other grounds as far as providing health care is not covered.

DR. STEWART JUSTMAN

By definition, it is antiquated. It was written in antiquity, it is antiquated. And medicine can do things now that were completely undreamed of even a 100 years ago, much less than antiquity. So the question is, can we at this late date receive any guidance from a principle, you know as antiquated as that. But let me rephrase the question, I mean, if the question is should we throw out safety concerns. How about if I phrase it like that. I mean clearly the answer to that is no and may be you know this day when medicine is so much more powerful, thank heavens, then it was 100 years ago, may be it is important to be that much more mindful, not less, but more mindful of safety concerns. I know there are doctors who think that the rule Do No Harm, which is of course phrased categorically that it is way too inhibiting. It does not make any kind of sense and in fact it is rarely referred to, but it is referred to, that continues to be referred to on and off in the medical literature including the literature on prostate cancer. I encountered any number of references to it. I think it is used opportunistically. Well, I try to seek methodically, not opportunistically. How should we think about the prevention revolution, which is perhaps starting to get underway, I will say perhaps, in prostate cancer.

DR. MORRIS PICKARD:

You know, when I was leading up to there is a mixed message in the PCPT results, which might suggest that if you use a particular drug, you might cause harm even though that possibly the greater number of people might be benefited. That is what I was alluding to as far as the double message and To Do No Harm. Could you kind of tell us and bring us to the conclusions that we are now fighting with?

DR. STEWART JUSTMAN

Well, let me put it in stark mathematical terms as they emerged in 2003. If you treat 1000 men for 7 years with 5 mg of finasteride, you stand to spare 15 diagnoses of prostate cancer, that is 15 cases that would not happen; however, it appears that 3 additional cases of high-grade prostate cancer, the more dangerous kind, are created and so here is your tradeoff, it does sparing 15 cases justify inducing 3 cases of the more dangerous kind of prostate cancer. Now, believe it or not, there were those in 2003 who said yes, just look at the numbers. You know, there is 5 to 1 ratio there, look at the numbers. To me, that is an appallingly un-medical way to resolve that

question and I am very thankful that the urological world did not resolve given state of knowledge in 2003, it did not resolve the question that way. Doctors did not use as I am sure your listeners know. Doctors did not rush to use finasteride preventively.

DR. MORRIS PICKARD:

Which really brings up an interesting point that this year actually at the American Urologic Meeting this study was again re-looked at. Could you kind of tell us what the most recent information suggests about is there really an increase in the number of high-grade malignancies?

DR. STEWART JUSTMAN

From the beginning, there was a lot of suspicion among the PCPT researchers and perhaps the urological world at large that the inflated numbers of high-grade prostate cancer were probably due to some kind of detection bias, I mean after all the finasteride reduces the volume of the prostate and that in itself intuitively will make it easier to find the disease. It also has some other effects that would favor detection of the disease. So, the possibility that detection bias is some kind of another or even combination of detection biases is playing into the results that possibility has been out there in the literature since 2003 and it is of course still alive. Well, how do you correct for detection biases? One way is to examine instead of biopsy, I mean biopsy of the prostate has to be done, but it is crude and the information provided is crude compared to the information available to the pathologist who is examining radical prostatectomy specimens under the microscope. I mean at that point the prostate is an open book. One of the articles that appeared in cancer prevention research last month concerned or discussed results of the examination of 500 radical prostatectomy specimens and found no elevation of the cancer numbers on the finasteride side. So that finding as far as it goes and I would qualify it that way adds to the circumstantial evidence in favor of finasteride of which there is some.

DR. MORRIS PICKARD:

What are we to do if the research begins to show that this drug actually is beneficial, that indeed the reason for the high number of high-grade malignancies, the high Gleason that we are seeing have more to do with the shrinkage of the gland? Are physicians, the urologic community, the primary care physician suddenly going to be able to say you know I have been telling you since 2003 that this drug is not a drug that I want you to take, but now I want you to take it? How do we deal with that in the medical community?

DR. STEWART JUSTMAN

Well, let me back up because I do not think that the articles that appeared about a month ago in the cancer prevention research are as revolutionary as that. I do not think that they are going to make the prostate cancer world stop on a dime and you know reverse the course. I doubt that that is going to happen. When the results of the dutasteride trial come in and I think doctor that they are doing within the next 2 to 3 years something like that. Let me just back up, dutasteride inhibits both isoforms of 5-alpha reductase, it is more potent 5-alpha reductase inhibitor and we will see. I mean if the results of that experiment do not raise safety concerns, but do indicate the preventive value of dutasteride; I think at that point the urological world would probably embrace dutasteride.

DR. MORRIS PICKARD:

It is interesting that you mentioned that. I am puzzled what the medical community will do. This dutasteride will be on label, well because it has met the criteria of Federal Drug Administration. It will be quite expensive and yet Proscar, a drug that is now generic and is probably 2 dollars a pill will be off label and yet in the minds of many of us the off label prescription of Proscar may be indicated just for

the financial savings for so many people when you are talking about millions.

DR. STEWART JUSTMAN

Right, it puts the doctor in tough spot. I do not really know if dutasteride is vindicated lets say by the reduced trial. I am not certain about how quickly the FDA could be expected to approve it. Tamoxifen has been approved for chemoprevention by the FDA. Proscar as you say has not and I do not know how speedily the FDA will act in dutasteride's favor if it does, but it is funny, I mean, ethically I think the uppermost issue is to prescribe or not to prescribe and then the secondary issue is well if you are going to prescribe, do I prescribe dutasteride on label or Proscar off label, but that to me is the order of importance though.

DR. MORRIS PICKARD:

You know we kind of return to there are lot of healthy men who are asking possibly to take a medication for a disease they may never get and then if they do get it they might be better off having not had any treatment for it.

DR. STEWART JUSTMAN

Right.

DR. MORRIS PICKARD:

May be we are not looking at the right patients. May be there should be some way that we can look at different groups of men as risk and those are the men that we should pursue our investigation or possibly give a chemoprevention drug to.

DR. STEWART JUSTMAN

No doubt about it. I mean I think that is most sorely needed in prostate research, is clearly some more sensitive way than is now available to identify men at risk. I mean the way we got ourselves into the mess that we are in is as a result of the PSA revolution, which unleashed a tidal wave of diagnoses that no one anticipated. There is now no going back on that; however, there are serious defensible philosophical arguments against screening for condition such as prostate cancer in the state of our knowledge right now.

DR. MORRIS PICKARD:

Could you tell me what those are?

DR. STEWART JUSTMAN

Well, that experience has shown that the detection of prostate cancer result in massive over-treatment. One of the kind of statistical whatever anomaly that jumped out at me was that just because of the surveillance regimen that all men were under in the PCPT whether they are on the placebo side or the other side, they were regularly screened, DREs, followup biopsies, and then at the end, right

all of the men were asked to undergo a purely investigative biopsy. That is just a ton of screening. The result is that they found a tremendous amount of cancer, so much that even the finasteride takers in the PCPT had a rate or prevalence of prostate cancer that exceeded a man's lifetime risk. They were in the experiment for about 7 years. How did that happen? Well as a result of screening.

DR. MORRIS PICKARD:

So what you are really saying is look and you will find. It is almost like bill and they will come.

DR. STEWART JUSTMAN

Beware what you look for, you might find it.