**The Great Prostate Hoax – Richard Albin, PhD**

**“How Big Medicine Hijacked the PSA Test and Caused a Public Health Disaster”**

**A Re-cap of this important book by Ken Malik, Executive Director & Founder of the Prostate Awareness Foundation**

**“A story of greed, damaged men and government failure”**

* 1970 Richard Albin, PhD discovered the PSA molecule (Prostate Specific Antigen)
* The book in part is an apology to 30 million men who undergo routine PSA screening for prostate cancer. The result: 1 million needle biopsies per year, 100,000 radical prostatectomies most of which are unnecessary!
* This book concerns the misuse of the PSA test to screen “healthy” men for prostate cancer!
* The Numbers: 50% of men over 50 have prostate cancer,

Average age at diagnosis: 67 years old, 240,000 cases diagnosed annually, 3% of men will die from prostate cancer, 97% of men will survive a prostate cancer diagnosis and die from something else.

* Screening advocates: Say that early detection saves lives, catch it while it is still treatable.
* But the facts indicate that early treatment does not lead to cure. The recurrence rates after conventional treatment are extremely high.
* The way the PSA test has been misused for the past 30 years amounts to the most damaging false positive in American medical history (78% false positives!)
* Fear fuels the prostate “industry”!
* A Gleason score of 7 after a biopsy will haunt a man for a lifetime
* Without Radical Prostatectomy and biopsies half of the urology practices in the USA would go out of business!
* There is no normal PSA level.
* What is wrong with the current use of PSA:

1. It doesn’t diagnose prostate cancer
2. PSA is not cancer specific
3. Cannot differentiate between rabbit (fast growing) and turtle (slow growing) cancer

* Prostate cancer is an age related disease
* It has value as a monitoring device for:

1. Monitoring possible disease progression in men who have been already diagnosed with prostate cancer
2. A tool to determine if an intervention has been successful. If PSA continues to climb it was not!

* 1979 - Hybritech, Inc a biotech startup was formed to develop a PSA test with the help of the Roswell Park Cancer Institute. Roswell received a patent for an immunoassay blood test for prostate cancer called the *Hybritech Tandem R PSA test.* They wanted a test that could determine if a man had prostate cancer. Hybritech was purchased by Eli Lily pharmaceutical company in 1985. A Big Pharma giant.
* Hybitech’s business plan called for entering the lucrative market for pharmaceutical cancer drugs. Their development of the PSA was a first step.
* The morphing of Science and Industry – a big time conflict of interest. The PSA approval by the FDA is one of the first examples of this marriage.
* Hybitech/Eli Lily was not satisfied. They wanted PSA to be a diagnostic tool for prostate cancer with the added revenue it would bring if every man over 50 were screened!
* 1986 – The FDA approves the PSA as monitoring aid for men with prostate cancer, not as a diagnostic tool to determine if a man has prostate cancer.
* 1987 – Thomas Stamey, MD Chief of Urology at Stanford publishes the first study on PSA in the New England Journal of Medicine. He compared PSA and PAP (a forerunner to PSA) and found it was more sensitive than the PAP test for detecting prostate cancer.

Not long afterward he realized and published information that prostate cancer is age related and that the PSA is not a valid diagnostic tool for prostate cancer.

* The PSA began to be used as an off-label (not approved for this use) test for prostate cancer.
* William Catalona, MD a urologist and paid spokesman for Hybritech gave the primary arguments to the FDA in favor of PSA approval.
* 1993 – The FDA, against the recommend of it’s advisory, approved the PSA as a diagnostic tool. There was no proven benefit for using PSA as a diagnostic tool!
* Dr Catalona was also instrumental in setting 4.0 as the magic PSA number for biopsy. He admitted from the beginning that this was “sort of arbitrary” with no supporting evidence.
* As we know there are other factors that raise PSA: sexual intercourse 24-48 hours prior to the test, infection (prostatitis), BPH, riding a bike, age!
* PSA was only approved as a screening tool for prostate cancer in men over 50. With a caveat and a requirement for post market surveillance and post approval studies as to its efficacy for that purpose. THIS NEVER HAPPENED!
* The FDA has an obligation to ensure that approved devices are safe and effective in the open market. For the PSA this was an empty and broken promise!
* Why was it approved: The mantra was “Early detection saves lives”.

1. Millions of dollars spent on lobbying
2. Advocacy groups crying for approval (Us Too, Man to Man, American Cancer, Zero)

All with major funding from Big Pharma and the AUA – American Urologic Association

1. Michael Milliken of “Junk Bond” fame runs the wealthiest prostate foundation in the USA. His million dollar foundation is a good example of the financial connectivity between advocacy organizations, Big Pharma and the FDA.
2. The FDA’s willingness to be influenced
3. Emotion won out over Science!

* The FDA allowed device makers and the urology community to run wild with the off label use of PSA even though the false positive rate approaches 78%
* Profit was put first over the welfare of unsuspecting men. 30 million men subjected to trauma annually!
* The benefits of screening must outweigh the potential harms associated with false positives. The FDA did not do its job.
* The truth about PSA misuse and the subsequent profiteering by the prostate cancer industry is the biggest medical story of the past 30 years.
* Although the Hybritech PSA assay was the only one approved by the FDA, other companies introduced their own PSA. As we know PSA numbers differ from lab to lab

From between 5 & 40%.

* The damaging side effects of needle biopsy: infection, emotional trauma
* The damaging effects of treatment: incontinence and sexual dysfunction
* No evidence that PSA screening impacts survival rate

The prostate cancer industry is now a $28 billion annually

* The pharmaceutical industry has gained unprecedented control over the evaluation of it’s own products. They often design the studies and perform the analysis.
* Biopsies and treatment are the cash cows of most urology practices
* 2/3’s of prostate cancer is diagnosed is by PSA leading to a biopsy
* Most prostate cancer in healthy men is pretty harmless, but treatment has been encouraged by doctors over watchful waiting.
* Men got swept into the “early detection leads to a cure” mentality.

Dollars & Cents:

* The USA has the most expensive medical system in the world: $8,000 per person per year. Norway is next at $4,000.
* According to the World Health Organization we are ranked 38th out of 191 nations rated for health care.
* Big Pharma spends more on advertising than Research and Development
* Big Pharma hijacked the PSA test. There are now 16 different assays.
* The average cancer patient in the United States spends about $9,000 out of pocket for

treatment.

* President Eisenhauer warned against the Military Industrial Complex in 1960
* We should be worrying about the Medical Industrial Complex
* There has never been a study comparing various treatment options head to head. Why not?
* Examples of Industry cost and marketing hype:

1. Proton Beam Radiation. First one at Loma Linda University. There are now 11 centers around the USA. They cost $200 million each. There is no indication that this procedure works better than IMRT. The cost of Proton Beam Treatment: $32,000. The cost of IMRT: $18,000. There are no difference in side effects
2. It’s all MARKETING
3. Direct to Consumer marketing has been a big change
4. The USA pays more per unit for health care than anywhere in the world
5. Without the PSA screening and the fear and rush to treatment it creates the prostate industry would dry up?
6. Da Vinci Surgical System (Intuitive Surgical) (Robotic Surgery): Marketed it as less blood loss, quicker recovery time. The cost to install the system $2 million dollars plus a $100K service agreement.
7. The FDA approved Da Vinci for Gall Bladder surgery not for prostate cancer treatment! (Off Label)
8. Health professionals are given a 1 hour on-line course, 2 videos and 7 hours of training on a pig before they can use the device.
9. Like most procedures, it takes at least 100 procedures to begin to be proficient.
10. The procedure can be done over and over again.
11. The results have been a disaster, but there were over 400,000 done in 2012.
12. There has been no difference in recurrence rates compared to radical prostatectomy

* HIFU: High Intensity Focused Ultrasound; They next big thing or the next big marketing hype?

Other Industries: Incontinence products (4 million men dealing with incontinence from treatment of prostate cancer

* Aids for Sexual Dysfunction
* Average Biopsy @ $2,000
* Average Radical Prostatectomy @ $30,00
* The FDA MAUDE website: voluntary reports on failures.
* Baby Boomers 1946 – 1964. There will be 77 million people arriving at Medicare eligibility in the next few year.

What we need to learn about prostate cancer:

* What causes prostate cancer?
* What initiates disease progression and what slows progression down?
* Find a treatment that works
* Find a better and more accurate test that will differentiate between the “buzzards” and the “turtles”.