

Prostate Cancer:

What Every Man
Over 40,
Should Know



An Educational Service of
The Prostate Health Council

A Council of The American
Foundation For Urologic Disease, Inc.



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New York Yankees

BOB WATSON
VICE PRESIDENT, GENERAL MANAGER



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SEPTEMBER 23, 1997

TO: THE UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
FROM: BOB WATSON, VICE PRESIDENT AND GENERAL MANAGER OF THE NEW YORK YANKEES
RE: PROSTATE CANCER
(Written Testimony)

IN THE SPRING OF 1994, AFTER THREE DECADES IN PROFESSIONAL BASEBALL, I WAS LIVING THE LIFE OF MY DREAMS. MY WIFE, CAROL, AND I HAD RECENTLY CELEBRATED OUR 25TH ANNIVERSARY AND AS THE FIRST MINORITY TO BE PROMOTED TO THE POSITION OF GENERAL MANAGER OF A PROFESSIONAL BASEBALL TEAM (THE HOUSTON ASTROS); I WAS AT THE HIGHEST ESCHELON OF MY PROFESSION. THE DATE FOR MY ANNUAL TEAM PHYSICAL FELL ON SUNDAY, APRIL 10TH, WHICH ALSO HAPPENED TO BE MY 47TH BIRTHDAY. BUT INSTEAD OF GOING TO THE DOCTOR, I ELECTED TO SPEND THAT FINE SPRING DAY WITH MY WIFE. I FINALLY RESCHEDULED THE APPOINTMENT FOR MAY, AND AS PART OF THE EXAM, I ASKED THE DOCTOR TO GIVE ME A PSA (PROSTATE SPECIFIC ANTIGEN) TEST IN ADDITION TO THE DRE (DIGITAL-RECTAL EXAM). SEVERAL SCOUTS I KNEW HAD BEEN DIAGNOSED WITH PROSTATE CANCER THE YEAR BEFORE AND THEY HAD URGED ME TO ASK FOR THE

TEST. THE DOCTOR SAID, "NO, NO, YOU'RE TOO YOUNG TO DO THAT. WE DON'T START GIVING THE PSA BLOOD TEST UNTIL YOU'RE FIFTY OR SO; WE'LL JUST DO THE DIGITAL-RECTAL EXAM. I INSISTED. "NO," I SAID. "DO THE PSA." WELL, THE RESULTS CAME BACK AT 5.8, WHICH ALARMED OUR TEAM UROLOGIST, WHO ORDERED MORE TESTS AND A BIOPSY. OUT OF THE SIX CORE BIOPSIES, ONE OF THE BIOPSIES CAME BACK POSITIVE. IT WAS A PARTICULARLY AGGRESSIVE FORM OF CANCER. WHEN I HEARD THE DIAGNOSIS, A THOUSAND FEARFUL THOUGHTS RACED THROUGH MY MIND. I INQUIRED ABOUT SURGERY, AND ALL OF THE OTHER ALTERNATIVES APPROPRIATE TO THIS SITUATION. AFTER CONSIDERING MY RELATIVELY YOUNG AGE AND THE FACT THAT THE CANCER APPEARED TO BE CONFINED TO THE CAPSULE OF THE PROSTATE GLAND, MY DOCTOR RECOMMENDED SURGERY SO THAT THE CANCER WOULD NOT SPREAD TO THE LYMPH NODES. AFTER DISCUSSIONS WITH MY WIFE AND THE OWNER OF THE TEAM, I DECIDED TO GO AHEAD AND GET IT DONE. I HAD SURGERY ON JULY 6TH, 1994, AND THE CANCER WAS INDEED CONFINED TO THE GLAND; I DID NOT NEED ANY ADDITIONAL TREATMENT. MY PSA TEST WAS 0.02, AND TODAY I AM CANCER FREE AND FEELING GREAT. BECAUSE OF EARLY DETECTION AND THE FACT THAT I AM A VICE PRESIDENT AND GENERAL MANAGER OF A PROFESSIONAL BASEBALL TEAM I CAN STAND AND DELIVER MY PERSONAL TESTIMONY ABOUT RECOVERY AND HELP TO EDUCATE OTHERS ABOUT PROSTATE CANCER. PROSTATE CANCER CAN HIT ANY

MAN FROM ANY WALK OF LIFE. IF YOU HAVE A FAMILY HISTORY OF PROSTATE TROUBLE OR CANCER YOU ARE AT AN EVEN GREATER RISK. THE FACTS HAVE ALSO INDICATED THAT MEN OF MEDITERANEAN AND AFRICAN-AMERICAN EXTRACTION HAVE A HIGHER INCIDENCE OF PROSTATE CANCER. THIS IS A DISEASE THAT ALL MEN MUST ACKNOWLEDGE AS A THREAT. THE BEST DEFENSE AGAINST THIS DREADED DISEASE IS EARLY DETECTION AND EDUCATION. GETTING SCREENED WITH BOTH THE PSA BLOOD TEST AND THE DRE BY AGE 40 IS IMPERATIVE. THERE ARE AT LEAST 78,000,000 BABY BOOMERS COMING OF AGE AND AT LEAST 60% OF THIS DEMOGRAPHIC WILL BE AFFECTED BY SOME FORM OF CANCER. IN THIS YEAR ALONE 41,000 MEN WILL DIE FROM PROSTATE CANCER. TO PUT THIS INTO PERSPECTIVE THAT IS MORE THAN A SELL OUT CROWD IN THE FAMED FENWAY PARK IN BOSTON, MASSACHUSETTS. MY UROLOGIST TOLD ME THAT WITH THE KIND OF MALIGNANCY THAT I HAD A DIGITAL EXAM ALONE WOULD HAVE PROBABLY MISSED MY CANCER. IF THERE IS ONE MESSAGE THAT I CAN LEAVE WITH YOU IT IS THIS:

MAKE AN INFORMED CHOICE REGARDING YOUR HEALTH, DO NOT LET THE FEAR OF THE DIGITAL EXAM KEEP YOU FROM GETTING REGULAR CHECK-UPS. USE THE THREE-FOLD APPROACH AND ALLOW THE USE OF EARLY DETECTION, EDUCATION, PSA AND DRE EXAMS TO SAVE YOUR LIFE.

SEPTEMBER 23, 1997

TO: THE UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
FROM: CAROL L. WATSON, SPOUSE OF BOB WATSON
RE: A TRAIL THAT LED TO PROSTATE CANCER
(Written Testimony)

MY EXPOSURE TO THE TERRIFYING WORLD OF CANCER CAME TO ME IN A VERY UNEXPECTED WAY. MY SAGA UNFOLDS AROUND MY HUSBAND ACCEPTING A COACHING JOB WITH THE OAKLAND A'S AS THEIR MAJOR LEAGUE HITTING INSTRUCTOR. WE HAD MOVED FROM ATLANTA, GEORGIA TO AN AREA IN OAKLAND, CALIFORNIA CALLED MONTCLAIR. I MET A LOVELY BRILLIANT WOMAN NAMED BEV R. WHO LIVED ACROSS THE STREET FROM US. WE BECAME CLOSE CARING AND SHARING FRIENDS. DURING ONE OF OUR MANY DISCUSSIONS SHE HAD TOLD ME THE STORY OF HER BOUT WITH BREAST CANCER AND HER RECOVERY. BECAUSE OF HER HONESTY AND COURAGE I BEGAN TO LEARN ABOUT CANCER. WITH A VENGEANCE I READ BOOKS ON CANCER FROM DIETS TO CURES, FROM MIRACLES TO DEATH AND DYING. UNTIL OUR FRIENDSHIP CANCER WAS ONLY THE BIG "C" WORD. DURING THAT YEAR I ALSO HAD MADE ANOTHER FRIEND NAMED MARY S. FOUR MONTHS INTO THE FRIENDSHIP WITH MARY S. SHE TOLD ME THAT HER YOUNGER SISTER WHO WAS IN HER EARLY 20'S HAD CANCER AND WAS PREPARING TO

HAVE CHEMOTHERAPY AND HAIR LOSS AS A RESULT OF THE TREATMENT. WITH THIS IN MIND I SPENT A VERY TENDER TIME WITH HER SISTER TEACHING HER HOW TO TIE HER HEAD IN SCARVES. THE WORLD OF BASEBALL AND LIFE WERE STILL MOVING FORWARD. I WAS PULLING INTO MY GARAGE ONE DAY AND SIMULTANEOUSLY A TAXI PULLED UP WITH BEV R. MY NEIGHBOR IN IT. I LOOKED ACROSS THE STREET INTO BEV'S FACE AND I COULD SEE THAT SHE WAS VISIBLY SHAKEN, PALE AND WEARY. I WENT ACROSS THE STREET AND TOLD HER THAT I COULD SEE THAT SHE WAS STRESSED AND I ASKED HER IF SHE NEEDED ME FOR ANYTHING. SHE HESITATED FOR A MOMENT, FINALLY SHE SAID, "YOU KNOW HOW MY SIDE HAS BEEN HURTING ON AND OFF FOR THE LAST SEVERAL MONTHS"? I SAID, "YES". SHE SAID, "WELL THE CANCER IS BACK". WITHIN A RELATIVELY SHORT AMOUNT OF TIME, CANCER TOOK ITS TOLL AND TOOK MY FRIEND. WITHIN SIX MONTHS OF HER DEATH MY STEP FATHER EDDIE WHO WAS IN HIS 60'S CONTRACTED LUNG CANCER. INITIALLY WE THOUGHT IT WAS HIS CHILDHOOD DIABETES REARING IT'S HEAD. VERY SHORTLY AFTER THE DISCOVERY OF THE CANCER HE PASSED AWAY. FOUR MONTHS AFTER EDDIE'S DEATH BOB ACCEPTED A JOB WITH THE HOUSTON ASTROS AS THE FIRST MINORITY ASSISTANT GENERAL MANAGER IN BASEBALL. BOB AND I HAD LIVED IN HOUSTON HAD BEEN A PART OF THE ASTRO ORGANIZATION FOR 15 YEARS WHEN HE WAS A BALLPLAYER. UPON OUR RETURN TO HOUSTON I RENEWED AN OLD FRIENDSHIP WITH ONE OF THE SAGES AND COMEDIENNES IN MY LIFE

NAMED MARY R. MARY R. WAS IN HER 60'S BUT BEFORE WE WOULD HAVE A CHANCE TO RENEW OR NURTURE OUR RELATIONSHIP SHE SUCCUMBED TO HER SECOND BOUT OF CANCER IN THIRTEEN YEARS. AFTER HER DEATH ANOTHER FRIEND GENITA P. CALLED ME WITH THE NEWS THAT SHE HAD CANCER AGAIN FOR THE THIRD TIME. ADDING SHOCK TO SURPRISE TO HEART FELT SICKNESS WAS THE CALL I RECEIVED FROM ONE OF MY DEAREST HIGH SCHOOL FRIENDS JUDY McC. JUDY LIVES IN NASHVILLE, TENNESSEE. THE NEWS WAS BREAT CANCER. SHE HAD A LUMPECTOMY AND HER PROGNOSIS WAS GOOD. THREE MONTHS AFTER JUDY'S TELEPHONE CALL, MY FRIEND PAUL A. WAS DIAGNOSED WITH LUNG CANCER. PAUL A. DIED FROM LUNG CANCER. ONE YEAR TO THE DAY, JUDY McC. CALLED TO SAY THAT THE CANCER HAD RETURNED. MORE DISMAY, SHOCK AND SURPRISE CAME WHEN MY FATHER, EMILE L. CALLED TO SAY THAT HE HAD THROAT CANCER. IN SHORT ORDER HE DIED FROM THAT SAME THROAT CANCER. MY BROTHER PHILLIP L. DIED SIX MONTHS LATER. ON OCTOBER 25, 1993 WHICH WAS OUR 25TH WEDDING ANNIVERSARY MY HUSBAND WAS NAMED GENERAL MANAGER OF THE HOUSTON ASTROS. WE SAIL ALONG FOR A WHILE AND A FEW OTHER CANCER SCARES FROM CLOSE FRIENDS ARE REVEALED. APRIL OF 1994 LOCKED MY SIGHTS ON TO A CONSUMPTIVE AND ENCOMPASSING TRAIL. THE TRAIL OF CANCER HAD CROSSED BOUNDARIES, CULTURES, AGE AND TIME LINES. IT TWISTED AND WOUND ITSELF FROM SOME DISTANT FOG-COVERED, UNNAMED MOUNTAINTOP THAT FOSTERED AN

AVALANCHE THAT LED DIRECTLY INTO MY HOME AND BEDROOM DOOR. IN SPITE OF ALL OF MY READING AND EXPERIENCE THIS ONSLAUGHT PRODUCED A VERY DANGEROUS POISONOUS SNAKE THAT I DID NOT KNOW EXISTED. THIS WAS STARTLING TO SAY THE LEAST. WE ASKED OUR TEAM PHYSICIANS WHAT OPTIONS AND CHOICES DID BOB HAVE WITH THE AGGRESSIVE CANCER THAT HE HAD CONTRACTED. WE WERE TOLD THAT WAITING WAS ONE OPTION, RADIATION AND RELATED TREATMENTS ANOTHER AND LAST BUT NOT LEAST A RADICAL PROSTATECTOMY. AFTER MUCH DISCUSSION WE CHOSE THE PHYSICIAN WHO INVENTED THE PSA (PROSTATE SPECIFIC ANTIGEN) BLOOD TEST, DR. WILLIAM CATALONA TO PERFORM SURGERY. EVEN THOUGH HE PRACTICES MEDICINE AT WASHINGTON UNIVERSITY, IN ST. LOUIS, MISSOURI, HE MAILED TO US VIDEOTAPES AND PAMPHLETS, AS WELL AS CALLING BOB ON THE TELEPHONE SEVERAL TIMES. WE WERE BOTH VERY WELL INFORMED ABOUT THE POSSIBILITIES OF INCONTINENCY AND IMPOTENCY AND ABOUT THE TIME, ENERGY AND EFFORT ON BOTH OF OUR PARTS THAT AFTERCARE WOULD ENCOMPASS. THE TRUTH HELPED ME TO ADJUST MY THINKING ABOUT THIS EMOTIONALLY DEVASTATING AND JOLTING EVENT THAT TUMBLED INTO OUR LIVES FROM THE AVALANCHE. I AM AND SHALL BE AN ADVOCATE OF EARLY DETECTION, EDUCATION, RESEARCH AND CHOICES.



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STATEMENT OF NEVADA GOVERNOR BOB MILLER

BEFORE THE UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

SEPTEMBER 23, 1997

STATEMENT OF NEVADA GOVERNOR BOB MILLER
BEFORE THE UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
SEPTEMBER 23, 1997

Mr. Chairman, Distinguished Members of the Committee:

Good Morning.

I am Bob Miller, Governor of the State of Nevada. Thank you for allowing me to speak on one of the most important health issues facing American men.

I come before you as a survivor of prostate cancer. My main mission today is to speak to the importance of early detection of prostate cancer and to urge that additional resources be brought to bear against this often fatal disease.

I am a living example of the benefit of early detection of prostate cancer. Had it not been for early detection, I would probably be walking around today with a malignant time bomb inside of me, ready to spread lethal cells throughout my body.

Instead, due to the diligence and alertness of my personal physician, Dr. Elias Ghanem of Las Vegas, the time bomb was quickly defused. I am free of prostate cancer, and my prognosis is excellent.

It was just about a year ago that I had my annual physical examination by Dr. Ghanem. He told me my PSA level was up a little: 4.1. On his advice I visited a urologist. That examination and the ultrasound proved negative. But Dr. Ghanem, ever diligent, prescribed that a biopsy be performed....just to be overly cautious. The results would almost certainly be negative, too.

It was early October, 1996. I had just delivered a eulogy for a friend who had died of cancer. I was no stranger to the terrible toll of the disease, having lost both of my parents to it years before....and having worked actively in support of the American Cancer Society for 25 years. A cancer education center in Las Vegas bears my family name.

On that October afternoon, I placed a call from my car phone to get my biopsy results. The only word that describes my feeling is shock. There was no doubt. I had cancer.

But I also had a better than fighting chance of beating this thing, because of early detection. And that early detection was made possible through a simple, painless blood test called the PSA. This is why the word must go out to all men of middle age or older that they get a PSA test. It can be, as I know so well, a matter of life, rather than death.

I had the tremendous advantage of early detection, but I realized I was totally uninformed about treatment options. A close friend who survived prostate cancer asked me what my Gleason was. The only Gleason I knew was Jackie. Later I would learn that the Gleason results tell you the severity of your case.

With the steadfast help of my wife, Sandy, I embarked on a search for answers that would lead to the best choice of treatment for me.

The search led us to Dr. Stuart Holden of Cedars Sinai Hospital in Los Angeles. Dr. Holden is Medical Director of CaPCURE, a foundation dedicated to conquering prostate cancer.

He presented a variety of treatment options, including surgery and also radiation seed implants. He urged me to take some time and weigh my options. My father-in-law, also a prostate cancer survivor, had chosen radiation implants. I chose, however, a radical prostatectomy, even though there is some risk of long-term impotence or incontinence despite recent surgical improvements that spare critical nerves.

One of the cruelties of prostate cancer is that it strikes not only the body, but at our self-esteem and self-image. No one likes to be stigmatized by a disease that brings to mind the chance of impotence or incontinence. And, certainly, it's not a discussion you like to have in public.

But as a governor, I had the responsibility to share my diagnosis--and the medical ramifications---as publicly as I could. A few days after learning of diagnosis, I held the longest news conference of my life...the reporters were sensitive to the personal nature of my condition and reported it responsibly...but the news conference got down to the nitty gritty. Let me say that the questions demanded answers that were, how shall I say?...anatomically correct.

But my candor paid off. It attracted a great deal of attention in Nevada to prostate cancer...and to the critical importance of early detection. Men by the droves went in for PSA tests. Some of those tests were positive, detecting the disease and giving these men the advantage of time in fighting it. This is why I never turn down an interview on this topic, and why I speak about it whenever I can.

In turn, I have received the support of hundreds of people with whom I have the common bond of experiencing the fear and uncertainty of being diagnosed with prostate cancer. I continue to be deeply moved by the advice and support that comforted me so much.

Today, my PSA is zero and I feel great. The surgery limited my activities for a while, but within a few months I was back to the gym and the basketball court. As I approach the anniversary of my bout with prostate cancer, I have no significant remaining problems. I feel I'm a walking billboard for why men should have the PSA test. At age 52, they say my life expectancy is not changed by the fact I had prostate cancer. Again, early detection and treatment made this possible.

It is my belief that those of us who've had prostate cancer must talk about it and publicize it as much as we can. Even today, men typically do not know enough to protect themselves against it. Overcoming ignorance and misconceptions about prostate cancer is one of the keys to reducing the large number of those who die from it. 41,000 men lost lives last year. 317,000 new cases were diagnosed. Those are numbers we don't have to put up with. Early detection and treatment can dramatically reduce this tragic toll.

Those of us who've survived prostate cancer can take our lead from survivors of breast cancer. Like prostate cancer, breast cancer was once a topic to be avoided. But the brave, women who have stepped forward to confront the disease publicly and urge support for early detection, treatment, prevention, and research have saved countless lives. While breast cancer remains a formidable enemy, and we need all the resources available to fight it, progress is being made.

Members of the Committee, I urge you to do all you can to advance the cause of beating prostate cancer, through early detection and research. I understand that promising research is under way which deserves more of this nation's support. The grim toll of prostate cancer is not a specter future generations have to face, if public awareness, prevention, and research are supported to the best of our ability.

Again, thank you for this opportunity to appear before you today and share with you my experience.

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"PROSTATE CANCER, MY STORY"

A PRESENTATION

BY

LEN DAWSON

TO THE SENATE SPECIAL COMMITTEE ON AGING

SEPTEMBER 23, 1997

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Good morning Senators Grassley and Shelby and members of the Committee. My name is Len Dawson, I am here as a prostate cancer survivor and as a representative of the American Foundation for Urologic Disease, also known as the A.F.U.D..

The A.F.U.D. is a charitable 501(c)3 organization whose mission is the prevention and cure of urologic diseases through the expansion of research, education, and public awareness. In its 10-year history, the foundation has funded over \$18 million in research grants to innovative investigators as they launched their careers in urologic science; it has distributed over 6 1/2 million patient education brochures; and has been in the forefront of the battle to bring increased public awareness to urologic diseases, including prostate cancer.

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As a result of my own experiences with prostate cancer, I have been a spokesman for the "Team Up Against Prostate Cancer" programs sponsored by the A.F.U.D. for the past four years. These programs have reached millions of American men and their families.

I would like to thank Congress for adding prostate cancer early detection as a Medicare benefit in the recently enacted Balanced Budget Act of 1997. However, this benefit will not be effective for two years. I hope this Committee could urge Congress to accelerate that implementation date.

It is vital that American men have the benefits of prostate cancer early detection as soon as possible. I could sit here and quote facts and figures, but my own story makes the point.

I consider myself a very lucky person...I am the 7th son of the 7th son...In the Spring of 1991, I had a complete physical, came home and told my wife Linda that I was in top shape. A few months later she asked if I had a prostate examination during that physical, because she had just seen Senator Bob Dole on television talking about the importance of the use of both the PSA blood test and the digital rectal examination or DRE for the detection of prostate cancer. My physical had included a Dre but not the PSA blood test.

The following day Linda read an article regarding free prostate cancer screening to occur later that month. Linda was adamant that I have the test and called and made and appointment for met to have both the DRE and PSA tests.

During my visit on the 19th, my doctor found my PSA to be regular. It was during my DRE exam that he thought he found something. Further testing showed that I had early stage prostate cancer. Fortunately, the cancer was caught in its earliest and most treatable stages. My prostate was removed five years ago and I'm doing fine.

It is an honor for me to be here this morning with Senator Dole. I believe that I owe my life to the fact that my wife heard his message and encouraged me to have a prostate examination.

It saddens me to report that my brother Ron died of prostate cancer two years ago. His cancer was diagnosed at a much later and more virulent stage than mine. This fact has made me even more of an advocate for the early detection of prostate cancer.

At this time, the greatest opportunity we have to present the best chance to cure prostate cancer is through early detection. According to the latest statistics published by the American Cancer Society, if prostate cancer is diagnosed and treated in its earliest stages, a man has a 99% probability of living another five years. If the cancer is diagnosed at distant sites such as the spine or brain, his probability of living five years is reduced to 30%.

It is clear that we can make a difference to men and their families, if only they can get the message. Now that Medicare is going to cover early detection, let's make sure that Medicare beneficiaries are aware that they have this new benefit. This could be in the form of educational materials from Medicare or even simple announcements in with their Medicare statements or Social Security checks.

For those men diagnosed with prostate cancer, it is critical that they have access to all appropriate cancer therapies. Many cancer treatments bring significant financial hardships to families who rely solely on Medicare benefits. Many of these folks have saved all their lives, and now must pay out of pocket for medically sound treatments that are not reimbursed by Medicare. Medicare should be amended to provide reimbursement for all FDA approved cancer therapies.

Today, Medicare is denying payment for approved therapies for the treatment of advanced stage prostate cancer on the basis on cost alone. If it takes an Act of Congress to ensure that medical providers and insurers, including Medicare, not be allowed to determine cancer treatments by the lowest alternative cost, it should be done! There is much more to determining therapies for cancer than cost...People's lives are at stake!

The health care needs of American citizens have changed dramatically since the inception of Medicare over 30 years ago. I urge that adequate provisions be made for the Medicare reimbursement of all approved cancer treatments.

It has been good to see the federal research funding for prostate cancer rising. There is still a long way to go for the disease to receive the research allocations appropriate to the leading cancer diagnosed and the second leading cause of cancer related deaths in American men.

In order to make the most effective use of each research dollar, Congress should direct the National Institutes of Health to develop a comprehensive prostate cancer research plan that encompasses all of its institutes.

Congress should also direct the Centers for Disease Control to establish prostate cancer registries throughout the country to collect information on all diagnosed cases of this disease. This vital information could be widely shared, disseminated and could become the basis for invaluable prostate cancer research data bases.

Let's Team UP and support these initiatives that rightfully address prostate cancer as a disease that has a profound impact on American families. Only then will we be able to eliminate it as a disease of serious concern. Thank you for this opportunity of speaking to you today.

**SENATOR DOLE'S TESTIMONY
FOR THE SENATE SPECIAL COMMITTEE
ON AGING
SEPTEMBER 23, 1997**

**SENATOR DOLE'S TESTIMONY
BEFORE THE SENATE SPECIAL COMMITTEE ON AGING
SEPTEMBER 23, 1997**

THANK YOU FOR INVITING ME THIS MORNING. WHEN I LEFT CONGRESS 15 MONTHS AGO, I VOWED THAT I WOULD NOT LOBBY FOR ANY "SPECIAL INTERESTS." SO, WHEN ASKED TO TESTIFY ABOUT PROSTATE CANCER THIS MORNING, I WAS A LITTLE RELUCTANT. BUT, AS YOU ALL KNOW, WHEN SENATOR GRASSLEY WANTS SOMETHING, HE IS VERY PERSUASIVE. SO, I AM HERE ALONG WITH OTHERS TO SIMPLY SPEAK ABOUT OUR PERSONAL EXPERIENCES WITH PROSTATE CANCER.

ALMOST SIX YEARS AGO, I WAS ONE OF THE MORE THAN 300,000 MEN WHO HAD TO HEAR PERHAPS THE MOST DREADED WORDS ONE CAN HEAR FROM ONE'S DOCTOR, "YOU HAVE PROSTATE CANCER." IT GOES WITHOUT SAYING

THAT I WAS STUNNED. MY FIRST REACTION WAS TO THINK IT MUST BE A MISTAKE. HE MUST BE TALKING ABOUT SOMEONE ELSE. BUT, IT WAS ME.

I HAVE TO ADMIT, I WASN'T EVEN CERTAIN I KNEW WHAT A PROSTATE WAS -- LET ALONE THAT IT MIGHT THREATEN MY LIFE. BUT, I DID KNOW THAT I HAD BEEN GETTING UP A LOT EVERY NIGHT. THAT, ALONE, WAS MY ONLY SYMPTOM. I MENTIONED IT TO THE CAPITOL PHYSICIAN, DR. KRASNER, DURING MY ANNUAL PHYSICAL. DR. KRASNER FOUND NOTHING SUSPICIOUS DURING MY EXAM, BUT HE DID GIVE ME A BLOOD TEST, CALLED A PROSTATE SPECIFIC ANTIGEN TEST OR PSA TEST. THE FIRST TEST TURNED UP A LEVEL OF 4.8. THIS, I WAS TOLD, WAS CONSIDERED TO BE ELEVATED, BUT NOT BY MUCH. USUALLY 0 TO 4 IS A NORMAL LEVEL. DR. KRASNER

RECHECKED THE LEVEL IN A FEW MONTHS, AND
SUBSEQUENT TESTS SAW THE PSA LEVEL RISING TO 6.9 AND
THEN TO 8. A RISING LEVEL OF PSA, I WAS TOLD, CAN
SIGNIFY AN INCREASE IN THE VOLUME OF A SUSPECTED
TUMOR.

A BIOPSY WAS DONE. THE RESULT WAS POSITIVE. AND,
ON DECEMBER 18, 1991 I UNDERWENT A RADICAL
PROSTATECTOMY BY DR. DAVID MCLEOD, WHO WILL
TESTIFY LATER THIS MORNING. DR. MCLEOD ADVISED ME
THAT MY CANCER HAD BEEN CAUGHT EARLY WHILE IT
WAS STILL CONFINED TO THE PROSTATE GLAND. AND, THE
GOOD NEWS WAS I WOULD NEED NO FURTHER TREATMENT
OTHER THAN PERIODIC PSA TESTS. ALMOST SIX YEARS
LATER, MY PSA LEVEL REMAINS AT ZERO.

AFTER MY SURGERY WAS COMPLETE, I WAS IMMENSELY RELIEVED, BUT WANTED TO KNOW MORE ABOUT THIS DISEASE. IF I, THE SENATE REPUBLICAN LEADER, A MEMBER OF THE FINANCE COMMITTEE WHERE HEALTH CARE ISSUES FREQUENTLY DOMINATE THE AGENDA, AND AN INDIVIDUAL WHO HAD A GREAT DEAL OF PERSONAL EXPERIENCE WITH HEALTH CARE, HAD NEVER REALLY HEARD OF THIS DISEASE, WOULD NOT HAVE KNOWN TO ASK FOR A PSA TEST OR ANY OTHER TEST FOR THAT MATTER, AND WHO REALLY HAD ALMOST NO SYMPTOMS, HOW MANY OTHER MEN WERE OUT THERE WHO DIDN'T KNOW TO GO TO THEIR DOCTOR AND GET CHECKED. I COULDN'T POSSIBLY BE THE ONLY PERSON TO HAVE HAD PROSTATE CANCER. BUT, WHY HAD I NEVER HEARD OF ANYONE ELSE DISCUSSING IT?

ELIZABETH AND I DISCUSSED IT, AND WITH HER ENCOURAGEMENT, I DECIDED TO GO PUBLIC WITH MY STORY. WOMEN WERE VERY FORTUNATE TO HAVE PIONEERS LIKE BETTY FORD, WHO CANDIDLY AND COURAGEOUSLY DISCUSSED HER EXPERIENCE WITH BREAST CANCER. WHO KNOWS HOW MANY THOUSANDS OF LIVES BETTY FORD SAVED WITH HER CANDOR AND HOW MANY WOMEN TODAY REMAIN THE BENEFICIARIES OF EARLY DETECTION.

FOR ME THE QUESTION WAS, WHERE DO I BEGIN? WHAT I STARTED TO DO WAS BEGIN EVERY SPEECH I GAVE BY ENCOURAGING ALL THE MEN OVER THE AGE OF 40 IN THE AUDIENCE TO ASK THEIR DOCTOR ABOUT A PROSTATE CHECK-UP, AND TO ASK ABOUT THE PSA TEST. I ALSO ADDRESSED THE WOMEN IN THE AUDIENCE. WOMEN ARE SO MUCH BETTER ABOUT TAKING CARE OF THEIR HEALTH

AND SEEING A DOCTOR REGULARLY. I CONCLUDED,
MAYBE THE WIVES OR DAUGHTERS OF MEN WOULD
ENCOURAGE A VISIT TO THE PHYSICIAN'S OFFICE.

BEFORE LONG, THE MEDIA STARTED PICKING UP ON
THESE MESSAGES I WAS DELIVERING, AND I FOUND MYSELF
ON "THE LARRY KING SHOW" AND THE NETWORKS -- NOT
TALKING ABOUT POLITICS, BUT INSTEAD TALKING ABOUT
PROSTATES. I STARTED REFERRING TO MYSELF AS THE
"PROSTATE PIN-UP BOY", AND BEFORE LONG, THE LETTERS
AND PHONE CALLS CAME POURING IN. NEARLY EVERYONE
WANTED TO KNOW EVERYTHING ABOUT PROSTATE CANCER
AND HOW TO TREAT IT -- IT'S SIDE EFFECTS, SUCH AS
INCONTINENCE AND IMPOTENCE -- I LEARNED MUCH MORE
ABOUT PROSTATE CANCER IN THE PROCESS.

WHILE MY OFFICE WAS QUICKLY BECOMING, IN A SENSE, A DISSEMINATION CENTER ON PROSTATE CANCER INFORMATION, IT OCCURRED TO ME THAT MUCH OF THIS WAS HAPPENING BECAUSE OF THE VOID OUT THERE ON MEN'S HEALTH ISSUES. IT BECAME A PERSONAL CRUSADE TO INCREASE AWARENESS ABOUT PROSTATE CANCER.

BY AUGUST OF 1992, ABOUT 8 MONTHS AFTER MY SURGERY, I SPONSORED THE FIRST "BOB DOLE PROSTATE CANCER SCREENING BOOTH." IN A FEW DAYS, WITH THE HELP OF VOLUNTEERS, INCLUDING DR. MARK AUSTENFELD, A YOUNG UROLOGIST AT THE UNIVERSITY OF KANSAS, ABOUT 300 FREE PSA TESTS WERE DONE. WE RECEIVED SOME MEDIA ATTENTION BECAUSE THIS PROSTATE SCREENING BOOTH WAS NEAR THE CONVENTION FLOOR AT THE REPUBLICAN NATIONAL CONVENTION IN HOUSTON.

SINCE THEN, I HAVE SPONSORED MANY SCREENING BOOTHS AT PLACES SUCH AS THE KANSAS STATE FAIR, THE TRADING FLOOR OF THE CHICAGO MERCANTILE, AND AGAIN AT THE 1996 REPUBLICAN CONVENTION. WE EXPANDED OUR SERVICES TO INCLUDE FREE MAMMOGRAMS. THANKS TO THE CANCER RESEARCH FOUNDATION OF AMERICA, ENOUGH MONEY WAS RAISED TO SCREEN ABOUT 20,000 MEN FOR PROSTATE CANCER AND ABOUT 5,000 WOMEN FOR BREAST CANCER.

SO, I'VE LEARNED A GREAT DEAL ABOUT PROSTATE CANCER SINCE 1991. BUT, I'VE ALSO LEARNED A LOT ABOUT ALL CANCERS. AND, THOUGH I'M NOT A DOCTOR OR A SCIENTIST -- I'VE BEEN TOLD BY THE EXPERTS THAT THE CURE FOR PROSTATE CANCER, OR BREAST CANCER, OR ANY

OTHER TYPE WILL COME WHEN WE FOCUS ON THE CURE
FOR ALL CANCERS.

I'VE SAID IT ALL ALONG THAT THERE IS NOTHING TO
BE GAINED BY PITTING ONE CANCER AGAINST ANOTHER.
OR FOR THAT MATTER, ONE DISEASE AGAINST ANOTHER.

EVERY CANCER CAN PROBABLY BENEFIT FROM MORE
RESEARCH DOLLARS. AND, I HOPE IN THE NEAR FUTURE, A
WAY WILL BE FOUND TO MAKE THAT HAPPEN.

LET ME CONCLUDE BY EMPHASIZING HOW IMPORTANT
EARLY DETECTION IS TO SAVING LIVES. I HAVE TO ADMIT,
AT THE BEGINNING TALKING ABOUT PROSTATE CANCER
AND THE POSSIBLE SIDE EFFECTS WAS DIFFICULT AND AT
TIMES AWKWARD. BUT, WHEN YOU OPEN A LETTER FROM A

MAN WHO WRITES TO THANK YOU FOR SAVING HIS LIFE,
THERE IS NO SUCH THING AS AWKWARDNESS. SO, ON
BEHALF OF ALL THE MEN, AND THEIR FAMILIES, WHO WILL
BENEFIT FROM THIS HEARING THIS MORNING -- AND WHO
MAY EVEN, THEMSELVES, BECOME THE NEXT BENEFICIARY
OF EARLY DETECTION, I WOULD LIKE TO EXPRESS MY
WHOLE- HEARTED APPRECIATION FOR THIS COMMITTEE,
PARTICULARLY SENATORS GRASSLEY AND SHELBY, FOR
BRINGING TOGETHER THIS VERY IMPRESSIVE GROUP OF
WITNESSES.

I GUARANTEE THIS HEARING WILL MAKE A
DIFFERENCE FOR MEN ALL ACROSS AMERICA.



United States
of America

Senator John Breaux

Democrat-Louisiana

Contact: Bette Phelan, Laine Glisson, 202-224-4623; Bob Mann, 504-382-2050

FOR IMMEDIATE RELEASE
Tuesday, September 23, 1997

Contact: Barry Phelps
202-224-1467

BREAUX CO-CHAIRS HEARING ON PROSTATE CANCER

Former Senator, Presidential Candidate Dole Testifies

Washington, DC (September 23, 1997) -- Sen. John Breaux (D-La.) today co-chaired a hearing of the Special Committee on Aging to promote awareness of prostate cancer and to examine recent advances in treatment options. Former Senate majority leader and 1996 presidential candidate Bob Dole — a prostate cancer survivor — was the lead witness at the hearing.

"One of the worst pieces of news men can hear is that they have prostate cancer," said Sen. Breaux, ranking member on the aging committee. "Unfortunately, it is news that is all too common, with as many as 20 percent of all men likely to face the disease. One of the options we should consider is making prostate cancer screenings for men over 50 as routine as mammograms for women. As Senator Dole and others have shown, the disease can be treated successfully if detected early."

The hearing was scheduled today to focus attention on Prostate Cancer Awareness Week. With more than 330,000 new cases diagnosed each year, prostate cancer is the second leading cause of cancer deaths among men. But there have been major advancements in treatment options available to those who suffer from the disease. In addition to former Sen. Dole, witnesses included NFL Hall of Fame quarterback Len Dawson, New York Yankees General Manager Bob Watson and Nevada governor Robert Miller.

"In the past, men have generally been reluctant to have prostate cancer screenings," Sen. Breaux said. "But Sen. Dole and our other witnesses today have done a great public service for us and our families by highlighting the importance of early diagnosis and treatment. And with passage of the balanced budget agreement, Medicare will begin covering yearly screenings for beneficiaries."

Sen. Breaux has served as the ranking member of the aging committee since January. He is also a member of the Finance Committee, which oversees spending on Medicare, Medicaid and other entitlement programs.

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Prostate Cancer File

November 7, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Chris Jennings

SUBJECT: Prostate Cancer

cc: Bruce Reed

Responding to your interest in developments on the prostate cancer front, this memo summarizes our response to the issues that were raised with you recently and also provides an update on actions the Administration can take to help advance the fight against prostate cancer.

BACKGROUND

This year over 210,000 men are expected to be diagnosed with prostate cancer and over 42,000 men are projected to die from this disease (virtually the same number of women who die from breast cancer). Only lung cancer claims more cancer deaths for men.

Prostate cancer does not manifest itself in most men until they have reached traditional retirement age and, when it does, there are great disparities among minorities relative to incidence. In fact, fully 80 percent of those diagnosed with this disease are over age 65. African American men have an incidence rate over 35 percent higher than white men. Interestingly, Asian-Americans have an incidence rate that is less than half of white Americans. (Clinical trials are underway at NIH to determine the causes of these differences.)

CONCERNS RAISED BY PROSTATE CANCER ADVOCATES

The concerns that were recently raised to you and echoed by prostate cancer patient advocates, such as the American Cancer Society's Man to Man, USTOO, CaPCure (Michael Milken's foundation for prostate cancer), and Beth Kobliner Shaw are as follows: (1) Federal funding for prostate cancer research is inadequate, particularly relative to breast cancer and AIDS, (2) administrative shortcomings have unacceptably delayed the allocation of Defense Department prostate cancer research funds to scientists, and (3) there has been insufficient high level Administration attention paid to this devastating disease (some have suggested a White House-sponsored conference). The following responds to the concerns that have been raised.

Issue: Prostate Cancer Research is Inadequately Funded. *Response: Probably true, but depends on how you look at the numbers. The overall dollars for funding are low in comparison to some highly-publicized diseases such as breast cancer and AIDS. However, relative to other diseases, prostate cancer has increased significantly since you took office. Moreover, this issue is more complicated than simple dollar comparisons. Overall spending on breast cancer still is more than four times that of prostate cancer research (\$625 million versus over \$140 million). According to NIH, this is due in part to limited opportunities for scientifically-sound prostate cancer-specific research. They also argue that there is a great deal of overlap in cancer research, so that the most promising leads in prostate cancer research may in fact result from dollars spent in research for another cancer. It seems clear though that the large amount of public attention to breast cancer has had a major impact on funding.*

Notwithstanding the disparity of investments, significant increases in prostate cancer funding have occurred under your Administration and, as will be discussed below, more dollars are likely to be recommended in the very near future. Prostate cancer research has increased about 60 percent since 1993. Such an increase is substantial when compared with other major diseases, such as diabetes (11 percent increase) and heart disease (21 percent increase). Despite these numbers, it does appear that a good case can be made that research funding this type of cancer is inadequate.

Issue: DoD Needs to Allocate Their Prostate Cancer Funding More Quickly.

Response: Partially true, but understandable since DoD has never had such funding before. In an attempt to address the limitations in research spending imposed by the budget caps, the Appropriations Committees began in the early 1990s to allocate breast cancer research dollars in the Defense budget. Building on the Congress' build-up of breast cancer research at the DoD, Congress appropriated about \$45 million for prostate cancer in FY'97 and again this year. (Since the DoD believes biomedical research is not their mission, OMB has never suggested using DoD dollars for research in any budget proposal; however, this is something we might want to discuss in this year's budget.)

Although there has been excessive delay in getting these dollars out, DoD did just complete a multi-month consultative process with prostate cancer experts, patients, and advocates to find the best ways to fund top-of-the-line research. They have received over 600 grant proposals and plan to fund as many peer reviewed grants as possible by no later than next April.

Issue: Prostate Cancer Needs a Higher Level Administration Focus. *Response: We agree, and, in fact, the National Cancer Institute has already convened a high-level panel that will provide recommendations next Spring about new research opportunities and the need for more funding.* This process was pulled together in order to assess how to best move forward on some promising recent break-throughs in prostate cancer made in the last year, including: (1) the discovery of a new hormone therapy which given after radiation therapy can prolong survival of patients with locally advanced prostate cancer; (2) the general location of the first heredity prostate cancer gene; and (3) the identification of hundreds of genes expressed in prostate cancer as the first cancer studied in the recently-launched Cancer Genome Anatomy Project (CGAP) at NIH.

NEW ACTIONS UNDER REVIEW ON PROSTATE CANCER

Increases in Prostate Cancer Research Funding. The panel discussed above is scheduled to be completed by March and Dr. Rick Klausner, the NCI Director, fully expects that it will result in greater attention to and more funding of this disease. We are reviewing options to give this work even a higher profile. Preliminary discussions with NCI have led us to conclude that it may be possible for you to announce their Spring recommendations for more funding of prostate cancer research.

Legislation for Medicare Coverage of Cancer Clinical Trials. One of the highest priorities by the cancer research advocacy community is enacting a bill that would allow Medicare, for the first time, to cover cancer clinical trials. Having Medicare cover clinical trials would be particularly helpful to those with prostate cancer because: (1) most of the prostate victims are Medicare beneficiaries; (2) the lack of participation of elderly men in trials has undermined clinical research for the treatment, prevention, and screening for this disease; (3) given the promising new findings, NCI expects there will be an increase in clinical trials for prostate cancer, creating a need for even more participants.

We are working with HCFA, NIH, and OMB to develop a policy proposal, to cost it out, and to develop Medicare offsets. As of this writing, it appears that the policy we are considering could cost between \$1.5 billion and \$3 billion over 5 years. Even by Medicare standards, this option is a significant investment, particularly for a targeted new benefit. Having said this, it would have the dual benefit of increasing the number of cancer clinical trials and, in so doing, likely help encourage private sector plans to increase their coverage of these trials. This policy would be widely heralded by the scientific community, cancer patient advocates, and Senators' Mack and Rockefeller. If you decided you want us to pursue this initiative, we would of course have to determine how best to pay for it, whether to include it in your FY'99 budget and when best to announce it.

Currently, HCFA has the authority to pay for trials on procedures they believe have the potential to no longer be experimental. (This is different than payment for experimental trials, mentioned above, on drugs and devices not yet given FDA approval for certain kinds of treatments.) You recently saw a *USA Today* article referencing possible coverage for a trial on cryotherapy, a treatment that some think has the potential to reduce prostate cancer where the cancer has not yet spread. We have since learned that both HCFA and NIH are skeptical that the procedure merits coverage and may not authorize it. Having said this, it is encouraging that HCFA and NIH are working together to target such procedures for coverage.

Revenue from the National Tobacco Legislation for a Major Increase in Research Funding and/or Raise Funds from Other Revenue Sources. Another option currently being developed in the policy process is to call on the Congress to dedicate much of the new revenue from any tobacco legislation to a Trust Fund designed to vastly increase investments in biomedical research, including new increases in prostate cancer research. Senator Kennedy has just introduced his tobacco legislation bill, which includes provisions to use his assumed and unrealistically high tobacco revenue to be used, in part, to double the NIH budget. Senator Mack and Senator Harkin are also calling for a doubling of the budget. In addition, Donna Shalala's budget submission includes a new insurance premium tax to be used to eventually double the NIH budget. (If you are interested, I can send you a pro/con memo on this proposal.)

Certainly any such actions could be incorporated into a number of events that would visibly associate the Administration with an unprecedented new commitment to cancer research in

general, and prostate cancer in particular. We will keep you informed of developments.

**STATEMENT OF
THOMAS V. HOLOHAN, M.D., F.A.C.P.
CHIEF PATIENT CARE SERVICES OFFICER
VETERANS HEALTH ADMINISTRATION
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING**

**HEARING ON
PROSTATE CANCER DETECTION AND TREATMENT**

SEPTEMBER 23, 1997

Mr. Chairman and Committee Members:

I am pleased to have the opportunity to discuss the Department of Veterans Affairs' (VA) Prostate Cancer Detection and Treatment Programs. Cancer is second only to cardiovascular disease as a cause of mortality and morbidity in veterans. Because of this significant health challenge to veteran patients, a number of formal programs as well as specific designations of facilities based upon the available expertise in treating cancer have been established. Throughout VA, 103 facility-based cancer programs treat an estimated 50,000 new cases each year. Of those, approximately 9,000 are patients with newly-diagnosed prostate cancer. The total number of all cases of prostate cancer under care by VA is approximately 70,000; about 6,000 are treated on an inpatient basis each year. More than 60 VA facility-based cancer programs are approved by the American College of Surgeons (ACoS) Commission on Cancer. VA's Under Secretary for Health, Dr. Kenneth W. Kizer, has communicated his expectation of a significant increase in the number of sites achieving that recognition.

In 1992, VA headquarters prepared a set of standards for oncology programs that were based upon the ACoS requirements and were subsequently published in VA's policy manual. It is worthwhile to provide some details regarding this process, since promulgation of standards, such as those of the ACoS, is critical to provision of the highest quality of medical care. The goals of establishing those criteria for VA facilities were:

- to provide state-of-the-art multidisciplinary and humane care;
- to improve patient access to comprehensive care;
- to ensure coordination of approaches to cancer care among the numerous specialists;
- and to develop cost-effective outpatient programs, including access to lodging facilities where appropriate.

Three levels of cancer care were established. Each medical center is classified as providing primary, secondary, or comprehensive cancer care. It is our intent that each of VA's 22 Veterans Integrated Service Networks (VISN) will have at least one Comprehensive Cancer Center (CCC) which is either certified by the College of Surgeons or possesses conditional approval.

Currently, 40 facilities are designated as Comprehensive Cancer Centers.

Briefly defined, a primary care center has diagnostic capabilities focused on screening and prevention programs and has a referral relationship with a Comprehensive Cancer Center.

A secondary level program treats over 100 new cancer cases annually and has the capability to provide some chemotherapy and cancer surgery. Prevention and screening programs are available, as are routine radiology, nuclear medicine, and pathology diagnostic services.

Radiation oncology services must be available either in the facility itself or by contract or sharing agreements with an adjacent entity.

A Comprehensive Cancer Center treats over 300 new cancer cases annually. In addition, three additional broad groups of requirements are met.

First, the center meets specified staffing requirements, personnel possess expertise in cancer management, and the center provides a wide range of services to assure the provision of state-of-the-art care. This encompasses diagnostic services including a complete clinical laboratory with cytology, immunopathology and blood bank capabilities, with access to other more specialized testing capabilities. Diagnostic services include invasive and noninvasive radiology, including

computerized tomography, magnetic resonance imaging services, and nuclear medicine capabilities; single photon emission computed tomography (SPECT) is recommended.

Second, these centers must provide a complete range of therapeutic services including:

- surgical oncology and surgical subspecialties (e.g., thoracic, head and neck surgery, urologic surgery etc.);
- medical oncology with chemotherapy, including demonstrated familiarity and experience with investigational protocols, and a full complement of internal medicine specialties and services (e.g., pulmonary medicine, cardiology, dialysis, etc.);
- radiation therapy services including electron beam and interstitial therapy;
- a nutritional support team;
- a number of specific residency training programs;
- a complete pharmacy service that specializes in the preparation of chemotherapeutic agents (using laminar flow hood equipment).

Each CCC program is encouraged, but not required, to have an inpatient oncology unit or its equivalent.

Finally, Comprehensive Cancer Centers are also expected to provide:

- social work services; counseling; pain management; nutritional education and support;
- in- and outpatient rehabilitation;
- formal interaction with available hospice services;
- special lodging arrangements for ambulatory patients receiving extended treatment.

Leadership is provided by a multidisciplinary committee which includes representatives from medical and radiation oncology, diagnostic radiology, surgery, and pathology. The committee's responsibility is to monitor quality management and provide for improved care, and to supervise the cancer registry. Interdisciplinary cancer conferences, wherein specific patient case management issues are discussed, are required at regular intervals; these must comprise a

minimum of 10 percent of all cases seen at the Center. We have previously provided the Committee a portion of the annual cancer report from the VA Medical Center Long Beach, California, which illustrates the clinical and research activities underway at such centers.

Formal cancer registries are considered critical elements in a cancer program. They provide important epidemiologic information, data on staging, patient demographics, survival statistics, and other clinical outcome data. Currently, there are more than 85 VA healthcare facilities with formal cancer registries, and more than 55 certified tumor registrars. Establishment of a central tumor registry is underway and will enable compilation of accurate incidence statistics, planning for resource allocation, comparison of incidence and outcomes with national standards, analyses of specific management and outcomes, assistance in reporting to the VA Secretary and Under Secretary for Health, and Congress, and contributions to the National Cancer Data Base.

Diagnostic and Treatment Options for Prostate Cancer:

Despite the high prevalence of prostate cancer, there are significant gaps in the evidence base regarding screening, diagnosis and treatment. While the number of diagnosed cases of prostate cancer has increased, there has not been a concomitant increase in mortality rates; therefore, some investigators have concluded the data include a disproportionate number of diagnoses of "non-lethal" cancers. Autopsy studies have demonstrated that a large fraction of elderly men die with, but not from, prostate cancer, and a number of population-based studies have indicated that more cases of prostate cancer that seem to have little likelihood of reducing survival are being detected in screening studies. The essence of the problem is that many early non-aggressive cancers that have limited potential to affect survival are detected (and likely treated); moreover, the early detection of aggressive cancers and those that have already spread and are poorly responsive to current treatment is unlikely to improve outcomes. Indeed, it is still uncertain whether radical prostatectomy or radiation therapy for many early stage prostate cancers will result in survival superior to that provided by careful observation without immediate treatment. Earlier detection of malignancy that is unresponsive to any treatment will result in an apparent increase in survival time (so-called lead-time bias) which is totally unrelated to any

intervention(s). Notwithstanding, providing no active treatment to all early stage disease may obviate potentially curative treatment for some cases destined to otherwise progress.

There are a number of appropriate treatment options for each stage of prostate cancer. Selection of specific therapy is therefore dependent upon patient-specific clinical factors, the patient's personal preferences, the clinician's experience and best judgement, and the available technology.

For Stages I and II prostate cancer, it remains uncertain as to whether prostatectomy (with or without lymph node dissection), external beam radiotherapy, brachytherapy, or careful observation will provide the longest survival. Under various circumstances, all approaches could be supportable based upon current evidence. Stage III disease has spread beyond the gland, and the results of prostatectomy are much poorer than in Stages I and II. Nonetheless, for selected patients surgery may be appropriate. Radiation therapy is the most common treatment for this stage, and offers the possibility of cure. Acceptable options also include, for carefully selected cases, observation with treatment provided only for symptoms.

Advanced prostate cancer presents significant therapeutic difficulties. Surgery is not indicated save for local symptomatic problems such as pain or urinary obstruction. Radiation may prove beneficial for the same purposes. Hormonal therapy will provide palliation, and possibly extend survival, but is not curative; and chemotherapy remains primarily investigational at this time. For asymptomatic patients, careful observation may be appropriate.

Therefore, it is not possible to construct definitive statements selecting any specific treatment plan for any stage of prostate cancer. Indeed, if clinicians always selected the most appropriate treatment for each individual patient, it would be apparent that for any patient classification scheme - by disease stage, by age, etc. - a wide variety of therapeutic strategies would be employed in each category.

The major difficulty in formulating rational treatment plans is the nearly total absence of

randomized, controlled trials of various therapies. Almost all of the data exist in the form of case series, usually with inadequate description of patient selection criteria and absent direct comparisons of alternative treatments. Patient selection factors often have influenced the choice of treatment and thus make comparisons of therapeutic strategies problematic; for example, it appears that Stage I and II patients treated with radiation therapy have had worse prognostic factors than those provided surgery. Unfortunately, such data constitute the foundation upon which some clinicians have formed their opinions regarding clinical management. Patients, too, form their own convictions based upon incomplete information, which may often derive from sources of questionable reliability and accuracy.

Screening for prostate cancer is a topic of great contemporary interest. The value of early detection and treatment of prostate cancer remains unclear, and the issue is controversial. Routine screening is not recommended by the U.S. Preventive Services Task Force, the Canadian Task Force on the Periodic Health Examination, or the American College of Physicians. Also, the American Cancer Society does not promote mass screening. Screening is, however, recommended by the American Urological Association, and the American College of Radiology. Prior to its demise, the U.S. Congress' Office of Technology Assessment concluded that the choice to accept or forego screening should depend on an individual patient's values. Current VA policy regarding prostate cancer screening for veterans is contained in an Information Letter issued by the Under Secretary for Health on January 8, 1997. That document states that the decision to screen, using modalities such as digital rectal examination, prostate-specific antigen (PSA), and transrectal ultrasound imaging with or without ultrasound-directed biopsies, should be made by the patient subsequent to an explanation by the physician of the controversy regarding the value of such testing and the potential benefits and risks of screening.

Clinical Guidelines:

It is our intent that physicians routinely provide the best available care to every one of the 9,000 new prostate cancer patients seen in VA healthcare facilities every year. VA is cognizant of the

utility of guidelines for the purpose of providing best practices to our patients. The development of useful clinical practice guidelines is a complex and difficult procedure. Recommended best practices can only be as valid and reliable as the evidence upon which they are based. Moreover, guidelines require frequent review and revision as new information becomes available, and thus obsolescence is a constant problem. In addition, the guidelines must be promulgated and disseminated widely and in a timely fashion, be easily accessible, and "user-friendly" to busy clinicians. For all of these reasons, as part of a newly developed VA National Cancer Strategy requested by VA Under Secretary for Health, Dr. Kenneth W. Kizer, we have selected the Physicians Data Query system (or PDQ), provided by the National Cancer Institute through the National Library of Medicine as representing the standard of care to be provided by VA. In essence, PDQ is our national cancer care guideline. PDQ recommended diagnostic and therapeutic interventions are the result of a comprehensive review process by an editorial board of cancer experts and are based on published studies which are carefully evaluated according to the strength of their evidence (see enclosed PDQ statement). PDQ statements and their supporting evidence are re-assessed by the editorial boards at two-to-four-month intervals, thus assuring contemporaneous information. This database is stored by the National Library of Medicine in electronic format and is available virtually instantaneously, 24 hours a day, at every VA medical facility. The information can be reviewed on a personal computer, or hard copies can be printed for future reference. This database provides an up-to-date summary of the best practices in oncology.

Prostate Disease Research in VA:

Recognizing the importance of prostate disease to the veteran population and the large number of unresolved questions from basic biology to its optimal treatment, VA has committed substantial resources to research on prostate disease. Prostate disease research expenditures have grown from \$3 million in FY 1995 to over \$9 million in FY 1996, an estimated \$12.8 million in FY 1997, and a projected \$15.1 million in FY 1998. An additional \$7.3 million was obtained by VA investigators from non-VA sources in FY 1996 to support prostate cancer research projects,

further leveraging the VA's direct investment in this field.

Selected examples of VA research include:

Clinical Trials - An ongoing project, The Prostate Cancer Intervention Versus Observation Trial (PIVOT), is a collaboration between VA's Cooperative Study Program, the National Cancer Institute, and the Agency for Health Care Policy and Research. Men 75 years of age or younger who have clinically localized prostate cancer are eligible for the study. Participants are randomly assigned to receive radical prostatectomy with additional treatment for residential or recurrent disease or expectant management with treatment for symptomatic progression or metastatic disease. The goal is to determine which treatment approach is better for patients.

Risk, Screening, and Treatment Preferences - A research investigator in Houston is studying relatives of men with prostate cancer to determine the familial risk of prostate cancer. Investigators in West Haven are evaluating the effectiveness of screening for prostate specific antigen (PSA) for identifying patients with early prostate cancer. They hope to determine whether screening can improve survival rates. A Gainesville investigator is using endorectal magnetic resonance imaging of the prostate as a new way to screen for prostate cancer and to monitor response of the prostate to cancer therapy. Research investigators in Milwaukee are analyzing patient preferences for treatment of localized prostate cancer. They found that the most important factors in making a treatment decision were the doctor's recommendation, life expectancy, and experience of friends or family. Another Houston project is assessing patient preferences associated with treatment of advanced prostate cancer. Since no available treatment can cure these patients, analysis of quality of life among the patients choosing particular treatments might help future patients to make treatment choices.

Basic Medical Research - Research investigators are identifying markers for differential diagnosis and aggressiveness of prostate tumor cells (Washington) while others are developing a panel of biomarkers that will detect individuals at high risk for development of prostate cancer

(Oklahoma City). Stimulation and inhibition of growth of prostate cells is influenced by hormones and by various growth factors and their receptors. Studies focusing on specific growth factors include fibroblast growth factor (New York), insulin-like growth factor (Seattle), epithelial growth factor receptor (Birmingham), and transforming growth factor and parathyroid hormone (Loma Linda). Other projects (Minneapolis, Chicago) are focused on enzymes that may increase the ability of prostate tumor cells to grow in new sites in the patient (metastasis). A Madison group is studying the role different cells have in initiating prostate tumor cell growth. The investigators believe that naturally-occurring enzymes may allow the cells to grow in different parts of the body. These studies may provide new targets for better anticancer treatments.

Other research investigators are concentrating on hormones and their receptors on prostate (Washington) to understand the mechanisms underlying the transition of prostate cell growth from androgen-dependent (treatable) to androgen-independent (fatal).

Some projects concentrate on animal models such as the rat (Atlanta) or mouse (Iowa City) for prostate cancer. Other studies are looking at the role of the immune system and its interaction with prostate cells. Projects include the development of active immunization against prostate cancer cells (Baltimore) and the use of immune cells to destroy prostate cancer cells (Iowa City).

In addition to the ongoing projects described above, a joint VA/DoD planning committee has been formed to set priorities for prostate disease research, issue invitations for investigators to submit proposals, and conduct scientific reviews of proposals prepared by VA and DoD investigators. This committee has drafted a Request for Proposals for a VA/DoD Collaborative Research Program on prostate diseases including cancer that is now undergoing concurrence by both agencies. Scientific review committees are also being assembled to conduct the review of proposals anticipated in response to this RFP. Separately, the VA Cooperative Studies Program is preparing an Announcement soliciting proposals for new treatment trials of prostate cancer that will be released by the second quarter of FY 1998.

VA has recently established three Epidemiological Research Information Centers (ERIC's) through its Health Services Research and Development program. Within the ERICs, one study on "Risk of Mortality in Prostate Cancer" has already been funded (West Haven), a "Prospective Cohort Study of Early Stage Prostate Cancer" is projected to be funded in FY 1998 (Boston/Brockton), and a proposal for a "Case Control Study of Prostate Cancer in Black and White U.S. Veterans" is now pending review for scientific merit (Durham).

These new initiatives will continue the strong trend of increasing VA funding of prostate cancer research into FY 1998.

Interagency Agreement with the National Cancer Institute (NCI):

We believe veteran patients should be provided with the most recent state-of-the-art care and should have the option of participating in promising, novel treatment plans which may become the standard of care for the future. To that end, VA and NCI have signed an Interagency Agreement. The purposes of this agreement are to provide veteran patients with access to the full range of new approaches to prevention, diagnosis and treatment, while increasing VA clinical research and accrual of patients into NCI-sponsored national clinical trials. This agreement will build upon already existing cooperation between VA and NCI. There are currently 22 VA hospital affiliations with NCI-designated cancer centers and 90 formal associations between VA medical centers and various NCI Cooperative Study Groups.

That concludes my statement, Mr. Chairman. Dr. Feussner and I will be pleased to answer any questions you or Members of the Committee may have.

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After completing a urology residency at The University of North Carolina, he completed a 3 year fellowship in the field of Urologic Oncology. He has practiced urologic oncology exclusively for the last 17 years. Dr. Babaian has authored or co-authored over 120 scientific publications the majority of which focus on prostate cancer. He has a wide range of experience in the early detection, diagnosis, staging and management of prostate cancer. He is experienced in the technique of cryosurgery and has utilized this modality in the treatment of prostate cancer both as primary therapy and as salvage following radiation therapy. M.D. Anderson Cancer Center, where Dr. Babaian has spent the last 13 years of his career, has extensive experience with cryosurgery. In excess of 200 procedures have been accomplished at that institution; approximately 25% of which were performed personally by Dr. Babaian.

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

To: The Honorable Charles E. Grassley, Iowa
Chairman
Special Committee on Aging
United States Senate

CONGRESSIONAL HEARINGS ON PROSTATE CANCER
Testimony by Richard J. Babaian, M.D.
The University of Texas M.D. Anderson Cancer Center

**The Potential Role of Cryosurgery as a Treatment Alternative for
Prostate Cancer**

Historical Perspective

Cryosurgery, or freezing of the prostate, was first reported by Soanes and Gonder in 1964. Thereafter, several other investigators in the 1970s employed this technique to treat prostate cancer. In this era, cryoablation of the prostate was achieved by circulating liquid nitrogen through probes that were designed for placement intraurethrally or transperineally. Although the extent of tumor destruction was most impressive, the

delivery system was cumbersome and did not allow the operator to control precisely the extent of the freezing process, frequently resulting in extensive damage to the surrounding tissues. This, therefore, resulted in severe complications such as urethrocutaneous and urethrorectal fistulas, as well as prolonged intraurethral tissue sloughing with urinary obstruction. Despite its promise as a method of destroying prostate tissue, the early technique of cryoablation was abandoned because of its associated morbidity. The mechanism by which cryosurgery produces tissue destruction is intracellular dehydration, toxic electrolyte concentration, crystallization with secondary membrane rupture, denaturation of proteins, thermal shock and vascular stases.

Modern Era of Cryosurgery

In 1992, there was a reemergence of interest in the application of cryoablation of the prostate because of a series of technical advances which modernized the procedures for cryoablation. In the late 1980s, transrectal ultrasonography of the prostate became wide-spread with urologists becoming adept at prostate imaging and ultrasound-guided biopsies of this organ. As a consequence of the ultrasound technology, the procedure for cryoablation could be performed with real-time visualization of the prostate and surrounding structures. The resolution of this technology allowed safe and accurate placement of cryoprobes directly into the prostate. In the early 1990s, Onik and Associates demonstrated that the extent of freezing and consequently tissue destruction could be monitored and precisely controlled employing transrectal ultrasound. This was

possible because of the ice ball phenomenon which resulted in a striking acoustic image. Therefore, as a direct consequence of modern ultrasound technology, cryoablation could be performed with less risk of the severe complications which led to its abandonment in the 1960s and 1970s. In addition to the technological improvements in ultrasound, advances have also occurred in percutaneous instrumentation (needles, guide wires, dilators, and sheaths) resulting in marked improvement of transperineal insertion of the temperature probes into the prostate. As previously mentioned, the initial cryosurgery units were cumbersome and have been replaced by more innovative systems which can circulate liquid nitrogen or argon in up to eight slender probes at individually controlled rates. Temperature monitoring has also been recently introduced to facilitate the monitoring of the freezing process.

A Summary of Recent Clinical Experience with Cryoablation of the Prostate

Our experience at The University of Texas M.D. Anderson Cancer Center with patients undergoing salvage cryotherapy of the prostate was recently published in the March, 1997 issue of *The Journal of Urology*. Short-term PSA follow-up in our patient population revealed that 31 percent of patients have a persistently undetectable PSA. Patients who had a local recurrence following radiation therapy and who were treated with a double freeze-thaw cycle of cryoablation had a 93 percent negative biopsy rate six months following cryoablation. This was significantly better than the negative biopsy rate

of 71 percent in those men who were treated with only a single freeze-thaw cycle of cryoablation. In the 150 patients we reported, there were no operative deaths and no bleeding that required transfusion. There was a 1 percent incidence of fistula formation in this pre-treated group of men with a 3 percent incidence of ostitis pubis, a 1 percent incidence of prostatic abscess formation, and a 17 percent rate of urinary obstruction requiring transurethral prostatectomy. The major complications of salvage cryotherapy reported by patients who responded to a questionnaire were urinary incontinence occurring in 73 percent, impotency in 72 percent, obstructive symptoms in 67 percent, and severe perineal pain in 8 percent.

In a smaller group of men treated at The University of California in San Diego following relapse after radiation therapy, 86 percent of the men were found to have negative biopsies 3 and 6 months following cryoablation. A serum PSA of less than 0.5 ng/ml was reported in 40 percent of these men. The three-month positive biopsy rate in men undergoing cryoablation for radiation therapy failure reported by Onik, Miller, and Cohen from Allegheny General Hospital was 27.3 percent.

Primary Therapy of Localized Prostate Cancer Using Cryoablation

A preliminary study reported by Shinohara and Associates from The University of California at San Francisco reveals an undetectable PSA at 6-months in 48 percent of patients and a 70 percent negative post-cryotherapy biopsy rate. Excluding impotence,

they reported an overall complication rate of 51 percent. The two most common symptoms were urinary obstruction requiring transurethral resection in 23 percent and penile numbness in 10 percent. It is important to note that the incidence of incontinence in this group of men treated with primary cryotherapy was only 4 percent. A report from The University of California at San Diego with short-term follow-up for patients with localized cancer of the prostate who have received cryoablation reveals that approximately 40 percent of patients have PSAs less than 0.5 ng/ml which is exceedingly low and that the negative biopsy rate in patients undergoing cryoablation as their primary form of treatment was 86 percent. In a report on primary cryotherapy for men with localized prostate cancer using adjuvant hormonal therapy and temperature monitoring, Lee and Associates from Crittenton Hospital report a positive biopsy rate of 3.3 percent one-year following cryotherapy. They also report that one-half of the patients with negative biopsies had an undetectable PSA. Approximately 80 percent of all the patients with negative biopsies had a PSA less than or equal to 0.5 ng/ml. The complication rates reported at one year in their 347 patients included an operative mortality rate of 0 percent, a 0.33 percent urethral-rectal fistula rate, an incontinence rate of 0.33 percent, with a 3.2 Percent incidence of outlet obstruction. In an unpublished update of their results the distribution of failures by pre-operative PSA levels reveals that 8 percent of men with a PSA of less than 4 have failed. The failure rates in men with a pre-treatment PSA between 4.1 and 10 and greater than 10 were 11 percent and 23 percent respectively. In an unpublished report presented at the *Endourology World Congress* in September of 1997,

Orihuela and Associates from The University of Texas Medical Branch at Galveston reported a comparison of the results in 167 consecutive patients with localized prostate cancer who were treated between July, 1992 and April, 1996 by cryosurgery, radical prostatectomy, and radiation therapy.

This preliminary data at 24 months of follow-up shows that the disease-free survival measured by PSA was comparable for radical prostatectomy and cryosurgery (78 percent versus 74 percent, respectively) and was superior to the group receiving radiation therapy (51 percent). These investigators reported that significant complications were more frequently seen in men undergoing radical prostatectomy.

Conclusion

I believe that there is indisputable evidence that freezing destroys cancer cells. The modern techniques of percutaneous instrumentation and ultrasound have been readily adapted for use in cryosurgery of the prostate. There is considerable potential that the use of temperature monitoring which has only recently become available will enhance the treatment outcomes in patients who elect to undergo cryosurgery. While the complication rate for cryosurgery following radiation therapy is formidable, it appears to be considerably lower when used as the primary treatment modality. While the preliminary results with primary cryotherapy are encouraging, clinical trials and long-term follow-up are required before the exact role of this treatment modality for localized prostate cancer can be determined.

**STATEMENT FOR THE
US SENATE SUBCOMMITTEE ON AGING
HEARING ON PROSTATE CANCER SCREENING**

Harold Sox, M.D.

Dartmouth Medical School

September 23, 1997

My name is Harold Sox. I am a specialist in internal medicine and chair of the department of medicine at Dartmouth Medical School. I am President-elect of the American College of Physicians, which issued guidelines on prostate cancer screening in 1997. I chaired the United States Preventive Services Task Force from 1990 to 1996. The Task Force issued its prostate cancer screening guidelines in 1995. The Task Force is a federally sponsored panel now administered by the Agency for Health Care Policy and Research. Most people consider the Task Force to be the definitive resource for evidence-based prevention guidelines, owing to its rigorous methods for evaluating the evidence and its reputation for impartiality. The Task Force's recommendations strongly influence coverage decisions in the private sector as well as the patient care quality standards of organizations, such as the National Council for Quality Assurance.

Mr. Chairman, this hearing and related efforts have a critical message to impart: that screening and other preventive services can be life-enhancing and, indeed, life-saving. Congress recognized the value of preventive care when it significantly expanded Medicare coverage in the Balanced Budget Act. With this legislation, Congress has made it possible for many people to receive important services. It is now up to the medical profession to decide the often very complex issues of whom to screen and how often, so that the American people receive good value for the support they provide to preventive services under Medicare.

The issue of whom to screen and how often is nowhere more complex than with prostate cancer, the subject of today's hearing. I wish that I had an easy answer for the committee. I wish that physicians knew enough about prostate cancer and its treatment to provide uniform

advice to patients, as we do regarding breast cancer screening for some women. There is very high quality evidence that breast cancer screening reduces the death rate from breast cancer in women aged 50-69 years. There is broad agreement that this evidence is compelling and that physicians should encourage women in this age group to undergo mammography.

In comparison, the evidence for prostate cancer screening, like many other areas of medicine, is very weak, and there is no broad professional consensus that prostate cancer screening is effective. Absent firm scientific grounding, it is not possible or desirable, in my opinion, to promote a uniform policy on screening. As I will discuss, our uncertainty about the value of prostate cancer screening means that physicians make screening decisions on an individual basis. The best policy is shared, informed decision making, in which a physician treats each patient as an individual, teaching him about prostate cancer and helping him to decide. Prostate cancer screening is not for everyone.

Prostate cancer is, in many respects, a more complicated disease than breast cancer or colon cancer, for which we have generally agreed-upon screening policies. Prostate cancers vary in their rate of growth; half of prostate cancer patients have very slow growing tumors. Prostate cancer is largely a disease of older men, many of whom have other serious diseases. Therefore, most men with prostate cancer die of something else. The side effects of prostate cancer treatment are more frequent, more long-lasting, and more serious than the treatment of cancer of the breast or colon.

The components of screening are the screening test, a test to verify the diagnosis when the screening test is abnormal, and treatments for proven prostate cancer. The two screening tests are digital rectal examination (DRE) and prostate specific antigen (PSA). Positive results are confirmed by a biopsy of the prostate. Patient with a positive biopsy may undergo staging tests, such as MRI and bone scan, to determine the extent of tumor spread. If these tests are negative, the cancer is "clinically localized," and the patient must decide whether to undergo

potentially curative treatments, such as radical prostatectomy or radiation therapy, or to choose no treatment.

Why might some patients with prostate cancer decide against potentially curative treatment? Presumably, they feel that the harms of treatment outweigh the benefits in their case. I believe that everyone would agree that the balance between the harms and benefits of screening should determine a patient's decision. We know some of the harms, but crucial information about benefits is missing.

Harms:

1. Treatment: In the U.S., we introduce new health care technology first and evaluate it only after it has become common practice. As a result, we know a great deal about the harms of radical prostatectomy but next to nothing about its benefits. The principal harms are urinary incontinence and sexual dysfunction. Urinary incontinence was a major problem in a study of Medicare patients who underwent prostate cancer surgery: 32% use pads or a penile clamp, 2% use an indwelling urinary catheter, and 6% require a surgical procedure for incontinence. Sexual dysfunction is widespread also: In the same study of Medicare patients, 91% had erections before surgery, but 61% had had no erection since surgery, and only 11% had erections firm enough for intercourse in the month preceding the interview. Finally, radical surgery for prostate cancer is the cause of death in 1% of patients.
2. The screening tests: Both PSA and digital rectal examination are inaccurate tests that frequently give misleading information. PSA, for example, detects only one-half of patients with clinically localized prostate cancer, so that a normal PSA can give false reassurance that cancer is not present. Because a PSA is abnormal in 10% of people who don't have prostate cancer, only one-third of men with an abnormal PSA have prostate cancer.

Benefits:

Cure of prostate cancer: Screening will have benefits only if it reduces the death rate from prostate cancer by identifying men who can benefit from an effective treatment. But we do not know the effectiveness of treating clinically localized prostate cancer in reducing the mortality rate from prostate cancer. The ideal way to find out is to randomly allocate selected prostate cancer patients to treatment or watchful waiting and measure the death rate from prostate cancer. Randomized clinical trials of screening have been completed for breast cancer, colon cancer, and lung cancer but not for prostate cancer treatment. Several studies are now underway in this country and in Europe. Recently, the American Urological Association Prostate Cancer Clinical Guidelines Panel (December 1995) reviewed all of the evidence and stated their findings as follows: "The panel found the outcomes data inadequate for valid comparisons of treatments." In other words, specialists in prostate cancer treatment agree that there is no proof that radical prostatectomy prolongs life from what it would be with no treatment.

We know that radical prostatectomy is not a perfect treatment because 28% of Medicare patients had undergone treatments for metastatic prostate cancer within 4 years of a radical prostatectomy, presumably because their cancers had recurred. Although many men are cured of a prostate cancer that would have caused them suffering and death, other men suffer the side effects of surgery for a slow-growing cancer that would not have caused either suffering or death. We don't know the balance between benefit and harm in prostate cancer surgery. We would have to tell a patient considering screening "if you have prostate cancer, I won't be able to tell you whether treatment is better than watchful waiting."

The role of patient counseling: The ethical principle of informed consent requires that patients with clinically localized prostate cancer learn about these known harms and potential benefits. Many believe that the same principle applies to the decision to undergo screening. The recently released guidelines of the American College of Physicians stated, "Rather than screening all men for prostate cancer as a matter of routine, physicians should describe the potential benefits and known harms of

screening, diagnosis, and treatment, listen to the patient's concerns, and then individualize the decision to screen." The underlying assumption is that the potential harms and benefits will differ from patient to patient, and therefore the balance of harms and benefits will also differ.

Furthermore, patients are likely to differ in how they value a benefit or harm and how they take account of the uncertainty about the benefits of radical treatment of prostate cancer.

Patients can understand complex information that may affect their health and use it to make decisions. In work done at Dartmouth, men at a veterans hospital were randomly assigned to learn about the benefits and harms of prostate cancer screening by watching a videotaped description or to a control group. Eighty percent of the patients who saw the videotape said that they would prefer no treatment if they had clinically localized prostate cancer. Only 40% of those who did not see the videotape said that they would prefer no treatment. This result shows that many patients have considerable ambivalence about prostate cancer treatment. Furthermore, learning more about the known harms and unknown benefits of treatment reduced the number who wanted treatment. This research argues strongly against a uniform policy of screening and strongly for informed, individualized decision making prior to screening.

*

What harm will a screening test do? Why not screen and then deal with the decision to accept treatment when the patient is fully informed about his own status?" In reply to these questions, I hold to the principle that one should not do something to a patient if it could not alter subsequent steps in evaluating him. Many fully informed patients will say, as many of my patients have, "I would not place myself at that much risk of incontinence or impotence unless I was more confident that I could benefit from surgery. There's no point in doing the PSA." The average man on the street believes that a PSA test is as innocuous as any other blood test. In fact, screening places the patient on a slippery slope, in which test results tend to propel the process of evaluation and treatment as physician and patient become caught up in the need to know. The



patient should know about the nature of that slippery slope before venturing out on it.

A number of expert panels have considered the question of prostate cancer screening. The US Preventive Services Task Force, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination have exhaustively reviewed the evidence and made recommendations. The US and Canadian Task Forces recommended against routine screening. The governments of England, Sweden, Australia, and the Netherlands have reached the same conclusion. As noted earlier, the American College of Physicians also recommended against routine screening but stated that patients need full information in order to make an individualized choice that takes into account their risks and preferences. The American Cancer Society recently changed its recommendation for routine annual screening starting at age 50 years. The current statement says that "screening should be *offered* starting at age 50" and that patient should be fully informed before deciding. The American Urological Association recommends routine screening starting at age 50 years.

This Congress has enacted legislation authorizing the Medicare program to cover prostate cancer screening. It is now up to the medical profession to use this enhanced coverage wisely, so that it benefits our patients. We will need all the help that we can get. The Health Care Financing Administration can help by framing their regulations for prostate cancer screening so that they acknowledge the uncertain balance of harms and benefits and strongly caution physicians to avoid routine screening. The Congress can help in several ways. Physicians enjoy talking with patients about difficult decisions, but the current health care environment does not reward the time required for counseling. We need to rethink the evaluation and management codes so that they encourage counseling about screening. We need support for research on what constitutes effective counseling and how it affects patients' decisions about prostate cancer screening. Finally, we should evaluate health care organizations on their success in informing patients about screening procedures, such as prostate cancer, in which the

balance of harms and benefits is uncertain and may vary from patient to patient.

I N T E R
O F F I C E

MEMO

To: Sarah Bianchi
From: Alex Wagner
Subject: Senate Committee on Aging: Prostate Cancer hearing
Date: September 23, 1997

General Observations: The issue of prostate cancer awareness garnered a great deal of congressional interest at today's hearing. At one point nine senators were in attendance: Sen. Breaux (RMM, D-LA), Sen. Reid (D-NV), Sen. Grassley (Chair, R-IA), Sen. Collins (R-ME), Sen. Shelby (R-AL), Sen. Hagel (R-NE), Sen. Craig (R-UT), Sen. Burns (R-MT), and Sen. Enzi (R-WY). The hearing had scheduled three panels.

The first included such notables as: Sen. Dole (Ret.), NFL Hall of Famer Len Dawson, Gov. Robert Miller of Nevada, and Mr. Bob Watson, General Manager of the New York Yankees. The intent in assembling this group was to cast a personal light on prostate cancer awareness as well as to draw media attention. The subsequent panels consisted of doctors who specialize in specific areas of prostate cancer. Due to a pressing floor vote, the committee was forced to adjourn shortly into the second panel, and therefore their written testimony was entered in the record.

Analysis:

The statements of Col. David McLeod, M.D., Harold Sox, M.D. and E. David Crawford, M.D. provided objective insight into possible treatment of prostate cancer and the role of innovations in improving patient outcomes. McLeod notes that the budget agreement of this year extended Medicare coverage to early detection of prostate cancer, to be effective in 2000; however, he hopes that date could be advanced. Currently the two main complications from treatment included urinary incontinence and impotence. For these reasons, not all patients diagnosed with prostate cancer choose definitive treatment. Detection of prostate cancer includes a prostate specific antigen (PSA) blood test and a digital rectal exam (DRE), usually followed up by a prostate tissue biopsy.

Dr. Sox is the only member of the panel to shy away from endorsing an extensive screening policy, citing that to many patients the adverse side-effects far outweigh the benefits of undergoing surgery to remedy clinically localized prostate cancer. Dr. Sox goes even further that PSA testing is more than an innocuous blood test, but it "places patient[s] on a slippery slope, in which test results tend to propel the process of evaluation and treatment as physician and patient become caught up in the need to know." His research argues strongly against uniform screening policies and emphatically for informed, individualized decision making prior to screening.

Dr. Crawford suggests several possible strategies to address prostate cancer. He first cites prevention. Research indicates that diet would seem to play a role in its development. Extremely low incidences occur in "Oriental cultures" such as Japan, China, and Singapore, while high fat

western diet not only yield higher mortality rates, but "when men from countries with low incidences move to the United States and partake of our diet, their incidence of prostate cancer dramatically increases." Recent studies suggest consumption of tomato products, soy, vitamin E, and selenium are linked to a reduction in prostate cancer cases. Prevention must also extend to the alarmingly high rate and increased mortality among African-Americans. Although lack of access to health care may remedy some cases, according to Dr. Crawford, further research has yielded the emergence of some other possible factors. In addition to prevention, two other possible strategies are viable. First, development into discovering a cure for advanced prostate cancer has been making progress, and with increased funding of research, "significant potential exists" in the future. Second, a strategy of detection, treatment, and cure results in the most immediate benefit. This includes programs that garner increased awareness and more accurate testing procedures.

Finally, the three doctors provide suggestions about what the federal government can do about prostate cancer. Dr. Sox suggests that HCFA can help by framing their regulation for prostate cancer screening so that they acknowledge the uncertain balance of harms and benefits and strongly caution physicians to avoid routine screening. He sees Congress "rethinking the evaluation and management codes so they encourage counseling about screening," and increased decision support about screening. Dr. McLeod notes several government imposed barriers that stand in the way of curing prostate cancer. The delay of Medicare coverage of the PSA test until 2000 in his opinion seems unnecessary; rather than having to undergo expensive and complicated procedures associated with the end-stages of the disease, early detection and treatment would allow for significantly decreased Medicare costs. Dr. McLeod also mentions that the present Medicare coverage of prostate treatment is inadequate: "Of particular concern is the failure of Medicare to cover oral anti-androgens that are now showing promise in neo-adjuvant therapy with radiation and possible surgery." In 1993 when Congress enacted coverage for oral cancer drugs it neglected to cover oral anti-androgens, since the definition was limited to drugs that *substituted* for injectable drugs, exclude those (like oral anti-androgens) that *supplement* injectable drugs. This failure highlights a considerable bias in Medicare payment in favor of less-effective forms of treatment. Finally, the gross underfunding of prostate research needs to be addressed if a cure is to be found. Dr. McLeod describes the prostate cancer research community as "starving."

Prostate Celebrities:

Johnny Unitas
Julius Erving
Chi Chi Rodriguez
Stan Musial
Harry Belafonte
Gen. Norman Schwarzkopf

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Buffalo, New York

Bernard C. Trueschler
Baltimore, Maryland

William R. Turner, Jr., M.D.
Charleston, South Carolina

President Emeritus
E. Darracott Vaughan, Jr., M.D.
New York, New York

Executive Director
Thomas M. Bruckman

File Prostate
Cancer

Copy for Sarah B.

SM

Melanne ✓
Jan Klein

Marsha -
Did someone
reply?

September 5, 1997

Marsha Berry
Communications Director for
the First Lady
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Ms. Berry:

September 22-27, 1997, will be Prostate Cancer Awareness Week.

Might I suggest that the First Lady hold a meeting of women involved in prostate cancer awareness during the week.

Mrs. Betty Gallo and Mrs. Carol Watson will be in Washington on September 23, in conjunction with a hearing on prostate cancer that is being called by the Senate Special Committee on Aging that will be chaired by Senator Richard Shelby, a prostate cancer survivor.

The enclosed "A.F.U.D. Prostate Cancer Resource Guide: 1997 Edition" is the most thorough compilation of prostate cancer references available. The American Foundation for Urologic Disease (A.F.U.D.) is pleased to send it to you for the First Lady's files and future use.

Sincerely,

M. Brooke Moran
Director
Patient Advocacy &
Government Affairs

A Fragmented War on Cancer

By Hamilton Jordan

IT has been 25 years since President Richard Nixon declared war on cancer. Having had two different cancers, I am a survivor of that war and a grateful beneficiary. My first, an aggressive lymphoma, was treated with an experimental therapy developed at the National Cancer Institute. Ten years later, my prostate cancer was detected early by the simple P.S.A. blood test, a diagnostic tool supported by Federal grants.

But I am also a symbol of the limited success of that war. The treatments I received were merely updated versions of the methods used 25 years ago. A powerful cocktail of chemicals killed my lymphoma while ravaging my body. A surgeon, using an elegant procedure with no permanent side effects, cut out my prostate.

Scientists are still looking for both the "magic bullet" that kills only

Hamilton Jordan, who was President Jimmy Carter's chief of staff, is a board member of Capcare, a non-profit organization that finances prostate cancer research.

cancer cells and the genetic switch that turns off random cancer growth or prevents genetic flaws from causing cancer. While significant progress has been made, twice as many people will be diagnosed with cancer this year as in 1979, and twice as many will die. One in three women and one in two men will have cancer in their lifetimes. The raw data suggest we are on the verge of an epidemic. What happened to the "war"?

Groups compete for a shrinking pie.

• Our rhetoric exceeded our commitment. Dr. Donald Coffey, a cancer researcher, says we promised a war but financed only a few skirmishes. The Federal budget expresses our national priorities. The Federal Aviation Administration, for example, will spend \$8.02 billion to make air travel safe. The chances of dying in an airline accident are one in two million. But the National Cancer Institute will spend only \$2.2 billion — one-tenth of a cent of every Federal tax dollar — to find a cure for the disease that kills

more Americans in a month than have died in all commercial aviation accidents in our history.

• We created expectations not based on scientific reality. Our political leaders failed to appreciate the simple reality that there is not just one cancer but more than 100 cancers that have all defied a single solution. At the same time, the numerous organizations representing those different cancers have fought among themselves for bigger slices of a shrinking pie instead of forging a consensus on behalf of a larger pie.

• Huge successes with some cancers have been offset by rises in others. In addition, mortality from other diseases has declined, leaving an aging, cancer-prone population.

With adequate financing, breakthroughs in cancer prevention and treatment are likely over the next decade. Yet promising research that would have been automatically financed a decade ago is rejected today because of belt-tightening, discouraging brilliant young investigators from entering cancer research in the first place.

Is one-tenth of one cent enough to find a cure for a disease that will strike 40 percent of Americans? You will not think so when cancer strikes you or your loved ones. □

Journal of

FRANK RICH

Confidential Fax

December 20, 1997

To: Jerry Mande
Office Of The Vice-President

From: Hamilton Jordan *HJ*

Re: Response To Your Call

I appreciated your call several weeks ago, enjoyed our conversation and apologize for my delay in getting back to you.* Vice-President Gore is fortunate to have someone with your background and interest on his policy staff. I hope you will not mind if I take a little time and space here to put my own interests and motivations into some context.

My Story

In 1982, my wife and I started one of the first camps for children with cancer in the United States called Camp Sunshine. This non-profit effort has a professional staff and a year-round program that serves over one thousand families each year.**

Three years after starting Camp Sunshine, I developed non-Hodgkins lymphoma, probably a result of my exposure to Agent Orange in Vietnam where I was a volunteer in a "Peace-Corps"

*I assume you got my phone message about my daughter's illness which has sidetracked me emotionally and intellectually. She is actually doing very well, but our family has been preoccupied with getting her treatment organized.

** We take our Camp Sunshine kids on a Washington trip each Spring and Vice-President Gore has been kind enough to greet them at the White House on several occasions.

type organization [International Voluntary Services]. This was my first of three different cancers which I experienced by age fifty [lymphoma, prostate and melanoma], each discovered in the course of an annual physical examination. I would have been dead twice if I had accepted the initial treatment offered me. I underwent experimental treatment at NCI for my lymphoma and had my prostate removed at Johns Hopkins. I realize that I have had resources and access to information and treatment not available to every person.

The Power Of Cancer As An Issue

I am not sure if people in Washington fully appreciate the power of cancer as a public policy issue.

When you ask American citizens in an opened-ended, unaided survey, "What is your greatest fear?", the fear of cancer is their first choice. Despite the progress made in the detection and treatment of cancer, cancer in its numerous forms is synonymous with death in the minds of most Americans.

An Epidemic Of Cancer?

As you know, we are facing an epidemic of cancer in the United States, and the American people are simply not aware of it. Forty-per cent of all people living in the United States today will have cancer in their lifetimes, as a result of several factors.

- * First, we have an aging population and cancer is - disproportionately - a disease of age.
- * Secondly, there are sharp decreases in mortality from other diseases. [There has been a twenty-five per cent decrease in mortality from heart disease just in the past decade.]
- * Consequently, more and more people are living to be older and older.....and more and more will have cancer.

* Some scientists project that this 40% figure will become 50% by 2010 if present trends continue.

These statistics and projections fly in the face of public perception - fed by specific scientific discoveries and advances in dealing with some cancers - that we are making enormous progress in the war on cancer. The truth is that we have learned very little about preventing cancer and have learned only a little about curing it as cancer is a hundred different diseases which, to date, have defied a single or simple cure. [Close to 50% of persons diagnosed with cancer are cured.....up from 30% twenty-five years ago.]

While we are on the threshold of enormous scientific discovery and advances, our nation's investment in primary research for cancer is flat and arguably declining in real terms.

Consider these budget facts:

- * Our nation spends \$26 billion each year funding the CIA;
- * Our nation spends \$14 billion each year funding space travel;
- * We spend \$9 billion each year funding the FAA which means that here is only a 1 in 5 million chance of dying in a commercial plane crash;
- * The real costs of our involvement in Bosnia to date is estimated to be \$7 billion;
- * Yet, we spend less than \$2 billion a year [one-tenth of a penny out of every Federal tax dollar] to find a cure for cancer, a disease that will strike 40% of all Americans alive today - 125 million people.

Is one-tenth of a penny enough for cancer research?

You will not think so when cancer strikes you or someone you love.

What We Are Doing: Connecting The Dots

It is impossible to reconcile these facts about cancer and the inordinate fear that the American people have of cancer with the meager Federal investment we are making in cancer research.

Let me tell you quite simply and directly what I and some other people are doing. We are going to raise a lot of money and run a national campaign that "connects these dots" and tells the American people the facts: How serious the cancer problem is and how modest our Federal research effort has been and is.

I know that the President and Vice-President have been touched personally by cancer [as have most of the American people] and are genuinely motivated to do something significant on this issue. But let me tell you plainly and simply that they are way behind the curve today, both substantively and politically.

It is not even debatable that cancer research funding has been flat during the Clinton-Gore Administration. I would argue that the numbers do not tell the real story of what has happened at the bottom of the research food chain where only 20-25% of peer-reviewed cancer research grants are funded today versus 60% only a decade ago. Our best young scientists cannot find research funding for cancer.....many are going into other areas of research.

The Vice-President's Posture

If I were Vice-President Gore's political adviser, I would tell him that he would do better not to touch this issue unless he is willing to tackle the funding question head-on. Speeches and symbolic gestures are very important, but they will not substitute for increased research funding.

If Vice-President Gore gets out in front of this issue, he will have to either break new ground by announcing significant research funding increases or be left to defend the status quo which - I would respectfully suggest - is not defensible. The Clinton-Gore record is one of maintaining the status quo in cancer funding - admittedly in an difficult atmosphere of budget

cutting - and some would argue that Republicans in Congress have prevented actual decreases in cancer research funding.

Finally, please be assured that I am not looking for public recognition, a job nor compensation. I would simply like to see this challenge met. While I have the greatest respect for the Vice-President as a person and as a political leader and do not doubt for a moment his sincerity on this issue, please know that I will not pull any punches with you or him on this issue which has touched my own life - and millions and millions of others - in such a powerful way.

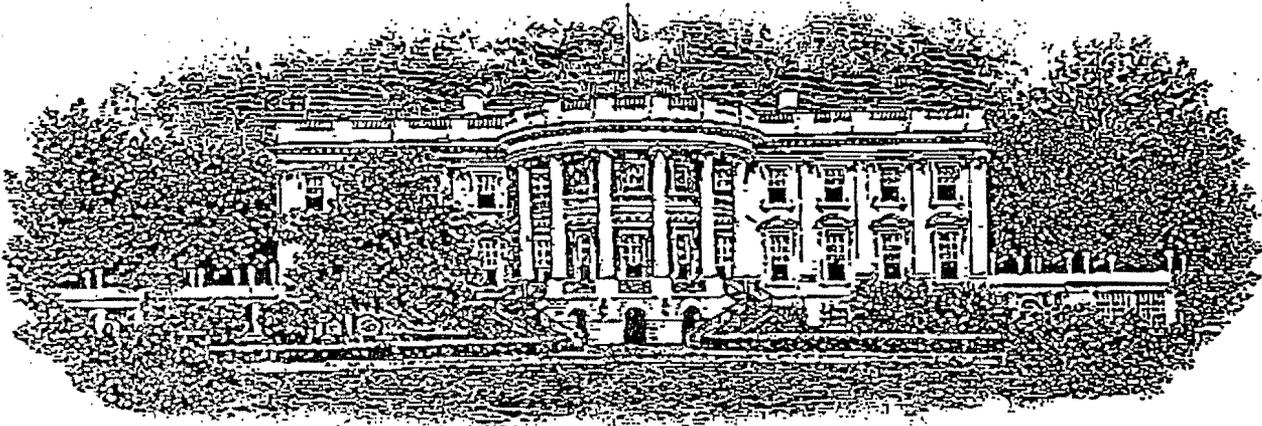
If I can help you in any way, please let me know.

P.S. My family and I will be in Washington between Christmas and New Year's for a family vacation. Don't know if you are in town for the holidays, but if you have time for an early morning cup of coffee, let me know. We will be staying at the Willard Hotel.

Mark Lowman

The White House

DOMESTIC POLICY COUNCIL



Vaccine

FAX COVER SHEET

To: Sarah

Phone: _____ Fax No: _____

From: Neil

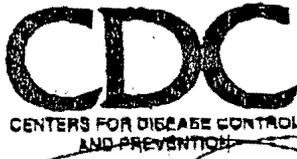
Phone: _____

Comments: _____

APR-22-98 21:32 From:OFFICE OF COMMUNICATIONS/CDC

+4046397392

T-598 P.02/04 Job-072



EMBARGOED: 4 PM ET
April 23, 1998

4/23
Jan - I wanted you to know what went out on this report as report as FBI - Marybeth

Contact: CDC Press Office
(404) 639-3286

ASTHMA RATES IN U.S. INCREASE

More Americans than ever before say they are suffering from asthma, according to a report released today by the Centers for Disease Control and Prevention. In 1993 and 1994, an average of 13.7 million persons reported that they experienced asthma-related conditions. Based on trends for the past 15 years, CDC estimates that today more than 15 million Americans suffer from asthma. The increase in asthma cases and deaths affects all ages, spans across all racial groups and occurs throughout the U.S. However, higher rates of hospitalization and emergency room visits were reported in the northeast; and blacks reported higher rates of emergency visits, hospitalization and deaths.

In a special CDC report entitled, "Surveillance for Asthma - United States, 1960-1995", CDC studied asthma from the perspective of how often people reported they had asthma; visited either their doctor's office or the emergency room; or were admitted to the hospital for treatment. Finally, researchers examined the number of asthma deaths that occurred throughout the U.S.

Asthma is a chronic lung disease characterized by temporary obstruction of airflow that leads to breathing difficulty, coughing, inflammation of the airways, and an increased sensitivity to a variety of triggers that can cause breathing difficulty.

CDC researchers also found that the overall picture of asthma is changing, and today's report recommended a comprehensive national monitoring system to identify these emerging trends on a state-by-state basis, especially to understand why some areas have lower rates of emergency room visits and hospitalization.

"Asthma is a complicated illness that adults and children live with daily. To prevent asthma, we need a

-2-

better understanding to unravel the mysteries of why some people develop it and others do not," said Claire V. Broome, M.D., Acting Director of CDC. "Promoting healthy home environments and sharing proven prevention strategies with health care providers to define the problems and causes is a key step towards prevention of this serious illness."

Other key findings in this report included:

Self-Reported Asthma Cases

- Rates increased 75% between 1980 and 1994. This increase was evident across all races, both sexes, and all age groups. Self-reported rates were 50.8 per 1,000 among whites and, and 57.8 per 1,000 among blacks.

Office Visits

- The number of doctor's office visits to treat asthma more than doubled between 1975 and 1995. These increases were evident in all groups of races, both sexes, and all age groups.

Emergency Room Visits

- In 1995 there were more than 1.8 million emergency room visits made for asthma. The rate was 48.6 per 10,000 among whites and 228.9 per 10,000 among blacks.

Hospitalization

- Between 1979 and 1994, hospitalization rates were highest for those from birth to 4 years old and lowest among persons 15-34. Among whites, hospitalization rates were 10.9 per 10,000 and among blacks the rate was 35.5 per 10,000 visits.

Death Attributed to Asthma

- Asthma-related deaths vary substantially by age group with the highest rates appearing in the elderly. Deaths due to asthma as the underlying cause were 15.1 per million among whites, and 38.5 per million among blacks.

-More-

-3-

CDC's role in asthma prevention programs is to ensure that proven, comprehensive asthma interventions and surveillance programs are implemented by the states and their partners. CDC shares this information with state health officials so that they can adapt what has worked in other regions of the country to their communities. Through CDC's educational efforts, public health officials will have a greater understanding of the environmental interventions and medical management tools such as patient education, demonstrating behavior changes to avoid asthma triggers, using drug therapies, and frequent medical follow-up to treat and identify asthma patients.

###



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

TO: SARAH BIANCHI
456-5557

FROM: DOUG TSAO

COMMENTS: SARAH, I PULLED TOGETHER SOME ADDITIONAL
BACKGROUND MATERIALS FOR TODAY'S MEETING. BRAD
CAMPBELL WILL NOT BE THERE, SO CHRIS WILL SPEAK
FOR THE WHITE HOUSE. ~~IT WOULD BE GREAT~~ ALL
HE NEEDS TO DO IS EMPHASIZE THE IMPORTANCE

Number of Pages to follow: _____
Date: _____
Time: _____

OF THESE ISSUES AND GIVE
W.H. BACKING TO THE TASK
FORCE'S EFFORTS. THANKS,
Doug

Transmission Number: (202) 260-3684
Verification Number: (202) 260-7960 or 260-9828

Office of the Administrator
401 M Street, S.W.
Room 1204 West Tower
Mail Code: 1101



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

File

Children's Environmental Health
OFFICE OF THE ADMINISTRATOR

April 24, 1998

NOTE TO CHRIS JENNINGS, DOMESTIC POLICY COUNCIL

From: Doug Tsao, Special Assistant to the Administrator

Re: Background on the Task Force on the Protection of Children from Environmental Health Risks and Safety Risks

The Task Force has identified four priority areas to address: asthma, unintentional injuries, developmental disorders, and cancer. Within these four areas, the Task Force will first address asthma. Both EPA and HHS are now seriously considering pursuing a budget initiative in the FY 2000 budget to address asthma and the Task Force would be the main vehicle for this inter-agency effort. While EPA and HHS will take the lead in this initiative, the goal would be to fulfill the Executive Order's mandate to include all of the departments and agencies that can make a contribution.

The Task Force selected asthma as its first priority because it has become one of the most important public health issues for children. Environmental factors have been shown to increase the frequency and severity of asthma attacks. The following are some facts on asthma:

- An estimated 4.8 million children (under 18) have asthma.
- The estimated cost of asthma related illness is \$6.2 billion annually. This breaks down into \$3.6 billion in direct medical costs and \$2.6 billion in indirect economic costs.
- Asthma has become the leading cause of school absenteeism due to chronic illness.
- 150,000 children are hospitalized annually due to asthma.
- The death rate from childhood asthma increased 78 percent from 1980-1993.
- Asthma disproportionately affects inner-city and, in particular, minority children.

If you have any additional questions please call me at 260-7960.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

APR 27 1998

Washington, D.C. 20201

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: *Sandra Bart*
Sandra Bart
Policy Coordinator/ES

SUBJECT: Children's Environmental Health Task Force Meeting--BRIEFING

TIME: Tuesday, April 28, 1998
2:00 p.m. to 4:00 p.m.

PLACE: Grand Hyatt Hotel
1000 H Street, N.W.
Washington, D.C.

PARTICIPANTS

Outside HHS:

Carol Browner, EPA
Lynn Goldman, EPA
Ricardo Martinez, DOT
Philip Landrigan, EPA
Ramona Trovato, EPA
William Farland, EPA
Jerry Clifford, EPA
Lois Schiffer, DOJ
Sarah Hicks, DOI
Elinor Bacon, HUD
Fred Siskind, DOL
Brian Burke, USDA
Pamela Gilbert, Consumer Product Safety Commission
Brad Campbell, Council on Environmental Quality
Floyd Malveaux, Howard University College of Medicine
Rebecca Blank, Council of Economic Advisors
Nera Tanden, Office of the First Lady
OSTP Representative
OMB Representative

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HHS Participants:

David Satcher, OPHS
Peggy Hamburg, ASPE
Richard Jackson, CDC
Mark Rosenberg, CDC
Richard Klausner, NCI
Barry Johnson, ATSDR
Sheila Newton, NIH
Steve Redd, CDC

Adolfo Correa, OPHS
Dalton Paxman, OPHS
Phyllis Zucker, OPHS
LaSonya Hall, OPHS
William Raub, ASPE
Polly Hoppin, ASPE
Stacey, Katz, ASPE

EVENT

You and EPA Administrator Carol Browner will co-chair the second meeting of the Task Force on Environmental Health and Safety Risks to Children. Representatives from the Departments of Labor, Justice, Housing and Urban Development, Energy, Education, Agriculture, Transportation, and representatives from OMB, Council on Environmental Quality, Consumer Product Safety Commission, Council of Economic Advisors, OSTP, and other offices of the Executive Office of the President are expected to attend the meeting.

The Task Force meeting will: 1) review progress of the three work groups; 2) discuss the four priority health conditions identified by the Senior Staff Planning Committee; and 3) come to agreement on focus areas and next steps. The annotated agenda has been prepared in collaboration with EPA and is in Tab A.

OPHS staff learned today that in her closing remarks, Administrator Browner may raise EPA's plans for a FY 2000 Children's Environmental Health Budget Initiative, with a particular focus on asthma, and will invite participation from other Departments and Agencies. If you choose to raise the issue in your wrap-up remarks, OPHS has added a bullet in your annotated agenda that reads as follows: "I am excited about this effort. Carol and I look forward to working with all of you on a government-wide, crosscutting initiative on children's environmental health."

Your Role and Responsibilities

- Co-chair the meeting, provide introductory remarks, help guide discussion on priorities, and provide closing remarks.
- Obtain Task Force approval on priority health conditions for follow-up.
- Obtain Task Force approval on the proposed next steps.

Page 3 - The Secretary

BACKGROUND

The Task Force on Environmental Health and Safety Risks to Children, established in April, 1997 by Executive Order 13045, is co-chaired by you and EPA Administrator Browner. The Presidential Executive Order is in Tab B. The Task Force reports to the President (in consultation with other White House offices) and its membership includes nine departments, relevant White House offices, and any others designated by the President. The membership roster of the Task Force is in Tab C.

On October 9, 1997, the Task Force had its first meeting, which you co-chaired with Administrator Browner (agenda is in Tab D). The Task Force created three work groups: the Senior Staff Planning Committee, the Research and Data Needs Work Group, and the Program Implementation Work Group. Tab E is the background material on the Task Force work groups.

The Senior HHS staff involved with the initiative held a retreat on January 15 to consult with outside experts and reach agreement within the Department on areas of emphasis that would be most productive for the Task Force over the next several years. That retreat resulted in a vision statement and the proposal of four priority areas that were later endorsed by EPA and the other members of the Senior Staff Planning Committee at a second retreat on February 11.

The vision is to see all children in the United States living in healthy and safe environments. The four priority areas that will be recommended to the Task Force are: 1) asthma, 2) unintentional injuries, 3) developmental disorders, and 4) cancer. Discussion of the four priority areas will comprise most of the Task Force meeting. Tab F contains background information on each condition.

ISSUES

The Senior Staff Planning Committee will recommend the four priority areas noted above to the Task Force. In the retreat that identified the four areas, the only significant disagreement was over the exclusion of intentional injuries (violence). The majority of members considered violence outside the scope of the Executive Order.

Following the selection of the four areas for recommended action, EPA notified the Office of the First Lady that asthma would be a focus of the effort. The First Lady has a personal interest in asthma, and at the request of her office, staff from HHS and EPA have provided preliminary information to her staff about potential areas of opportunity for the First Lady's involvement in publicizing the issue and the work of the Task Force.

Page 4 - The Secretary

On the assumption that the Task Force will endorse the four recommended areas, work has begun to map out action plans. This work will be accomplished through the convening of ad hoc groups expert in the subject area. Their work plans will be reviewed and approved by the Senior Staff Planning Committee and coordinated with the Research and Data Needs and Program Implementation work groups.

STATUS OF WORK GROUPS

- The Research and Data Needs Work Group is developing an inventory of research being conducted and supported by the Federal government, as well as identifying data gaps.
- The Program Implementation Work Group created three teams: communication strategies, partnerships, and evaluation, to do the work in those areas.
- Both work groups intend to make their results available on-line.
- *Ad Hoc Work Group on Asthma.* This group will be co-chaired by HHS (CDC) and EPA and will have representation from all the relevant Departments. It will develop a government-wide initiative on the environmental aspects of asthma in children. The CDC co-chair (Steve Redd) will work closely with Bill Raub, who is leading a broader Department-wide Secretary's Asthma Initiative that includes children and the environment as well as adult asthma and issues that are not environmentally linked such as new drug development.

Next Steps

Congress has introduced several bills that are related to children's environmental health. The White House would like guidance from the Task Force on which bills, or sections of bills, should receive the Administration's support (See Tab G for bills submitted to this Congress). The Senior Staff Planning Committee has begun an analysis of pending Legislation. Most of the bills are aimed at EPA's activities.

Several White House offices (in particular, the Vice President's Office, the Office of the First Lady, the Council on Environmental Quality, and the Office of Science and Technology Policy) have expressed interest in planning Presidential or Vice-Presidential events around Task Force activities:

- OVP is planning an event around the asthma initiative.
- CEQ would like to tie Task Force activities into the President's Race Initiative.
- OSTP sees the Task Force as part of a larger children's research initiative.
- The Office of the First Lady would like to publicize the Task Force's efforts to address asthma.

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IMPORTANT MESSAGES

The HHS Work Group co-chairs developed a vision statement and a set of important themes that can be emphasized throughout the meeting. The vision is one of children living in safe and healthy environments. The themes are:

- Children suffer disproportionately from environmental health and safety hazards.
- Children's environmental health and safety risks are preventable.
- Prevention of children's environmental health and safety risks requires:
 - more integration of public health and environmental protection approaches;
 - development of coordinated initiatives at the federal, state, and local levels;
 - promotion of partnerships between public and private sectors;
 - development of a field of children's environmental health and safety.

ATTACHMENTS:

- TAB A Annotated Agenda and Opening Remarks for Task Force Meeting, April 28, 1998
- TAB B Background Material on Task Force
- TAB C Membership Roster of Task Force
- TAB D Agenda of October 9, 1997 Task Force Meeting
- TAB E Work Group Background
- TAB F Background on Proposed Priority Health Conditions
- TAB G Congressional Bills on Children's Environmental Health and Safety

A. Asthma

- | | | |
|---------------------------------------|------------------|---------|
| Overview | Floyd Malveaux | 5 min. |
| • Local Health Department Perspective | Margaret Hamburg | 5 min. |
| • Discussion | | 10 min. |
- Secretary Shalala may want to note some key points under this priority health condition (Asthma):
 - Asthma is the most common chronic condition among American children today.
 - Despite many advances in diagnosis, treatment, and understanding of risk factors, there has been a continuous rise in asthma rates.
 - Asthma is costly.
 - There is an urgent need to establish a surveillance system to determine the basis for trends, and to monitor the impact of interventions.

B. Unintentional injuries

- | | | |
|--------------------|------------------|--------|
| Overview | Mark Rosenberg | 5 min. |
| • DOT Perspective | Ricardo Martinez | 3 min. |
| • CPSC Perspective | Pamela Gilbert | 3 min. |
| • Discussion | | 7 min. |
- Secretary Shalala may want to note some key points under this priority health condition (Unintentional Injuries):
 - Injuries are the leading cause of childhood mortality.
 - There is a good understanding of causes, risk factors, and interventions.
 - What is needed is implementation and evaluation of effective interventions on a broader scale.

C. Cancer

- | | | |
|--------------|------------------|--------|
| Overview | Richard Klausner | 5 min. |
| • Discussion | | 7 min. |
- Secretary Shalala may want to note some key points under this priority health condition (Cancer):
 - Cancer incidence in children is relatively stable, yet cancer continues to be one of the leading causes of mortality in children.

- **The extent to which environmental factors may be associated with childhood cancer is unclear.**
- **The incidence rates of testicular cancer and non-Hodgkin's lymphoma in adults have been increasing.**
- **The extent to which environmental exposures in utero or childhood may be associated with such increases is unclear.**

D. Developmental disorders

Overview

Philip Landrigan

5 min.

• Discussion

7 min.

• **Secretary Shalala may want to note some key points under this priority health condition (Developmental Disorders):**

- **DD are a leading cause of morbidity in children:
2% of children have mental retardation, cerebral palsy, hearing impairment, vision impairment or autism,
10% of children receive special education services for DD**
- **Birth defects, one DD, are a leading cause of mortality in children.**
- **Although some DDs have been associated with environmental factors, the extent to which environmental factors impact DD is unknown.**
- **DD are costly.**

E. Summary

Lynn Goldman

5 min.

- **Dr. Goldman will summarize the consensus discussion.**

3:25 PM - 3:45 PM

Updates and Workplans

Ramona Trovato

- **Administrator Browner will introduce Ramona Trovato, Director, Office of Children's Health Protection, EPA.**
- **Ms. Trovato will introduce the presentations by Work Group Co-chairs and Dr. Satcher.**

Research and Data Needs

William Farland

5 min.

Program Implementation

Jerry Clifford
Barry Johnson

5 min.

Goal-Setting David Satcher 5 min.
Healthy People 2010

3:45 PM - 3:55 PM Next Steps Brad Campbell 10 min.

- **Ramona Trovato will introduce Brad Campbell, White House Council on Environmental Quality.**
- **Mr. Campbell will provide the White House perspective on congressional interest and proposed White House activities on children's environmental health.**

Legislative proposals

White House initiatives

3:55 PM - 4:00 PM Wrap-up Secretary Shalala
Administrator Browner

Secretary Shalala:

- **Pleased with meeting.**
- **Looking forward to continued progress from our Work Groups**
- **Need appropriate senior level representation to our content area work groups.**
 - **Our staff will be contacting you for your nominees.**
- ***I am excited about this effort. Carol and I look forward to working with all of you on a government-wide, cross-cutting initiative on children's environmental health.***

Administrator Browner will summarize the decisions of the Task Force and note that the next Task Force Meeting in October

**SECRETARY SHALALA'S OPENING REMARKS TO THE MEETING OF
THE TASK FORCE ON CHILDREN'S ENVIRONMENTAL HEALTH AND
SAFETY ON APRIL 28, 1998**

- **Good afternoon and welcome to the second meeting of the Task Force on Environmental Health and Safety Risks to Children, which EPA Administrator Browner and I co-chair.**
- **A year has passed since President Clinton signed the Executive Order (April, 1997) creating the Task Force on Environmental Health and Safety Risks to Children.**
 - **We had the first meeting of the Task Force last October.**
 - **We created three workgroups: the Senior Staff Planning Committee, Research and Data Needs Work Group and the Program Implementation Work Group.**
 - **At the last Task Force meeting we asked our Work Groups to focus their efforts on activities that can have a real impact on children's health.**
- **Over the past six months involving unprecedented interagency participation, our Work Groups have narrowed the immediate focus to four priority health conditions in which we can create meaningful change in the next several years.**
 - **These priority conditions are asthma, unintentional injuries, developmental disorders, and cancer.**
 - **The Work Groups recommended these conditions because they are important causes of morbidity or mortality among American children.**
 - **The Work Groups have also come up with a vision of seeing all children in the United States living in safe and healthy environments.**

- **Children's environmental risks are an important public health problem since children bear a disproportionate burden of the risk from exposure to environmental hazards.**
 - **Last Friday, CDC released a report demonstrating that despite numerous advances in the diagnosis and treatment of asthma, rates of the disease continue to increase.**
 - **The increase in asthma cases and deaths affects all ages, spans across all ethnic groups and occurs throughout the U.S.**
 - **However, asthma disproportionately affects children, particularly children from minority and low income families.**
 - **The CDC study reported that blacks had higher rates of emergency room visits, hospitalizations, and deaths from asthma.**
- **To address environmental health problems, we must take a public health approach and actively engage not only our federal partners but also communities in research, surveillance, education, outreach, and communication.**
- **By their very nature, children's environmental risks present a unique opportunity for building linkages.**
 - **We have several HHS agencies—NIH, CDC, FDA, ATSDR, and the Administration on Children and Families, among others, that are working together to make children's environmental health a very high priority.**
 - **We are also working with our Federal partners.**
 - **One such activity is a new collaboration between EPA, NIH, and CDC to support Centers for Children's Environmental Health and Disease Prevention Research. These grants are about to be awarded.**
 - **These Centers will develop multidisciplinary basic and applied research, in combination with community-based prevention research projects.**
 - **For these Centers, the government is facilitating a partnership between academia and community.**

- **My hope is that we build on these Centers and other such activities to create lasting partnerships across the country dedicated to this effort.**

- **The purpose of today's Task Force meeting is to review the progress of the three work groups, discuss the four priority health conditions recommended by the Senior Staff Planning Committee, and come to agreement on focus areas and next steps.**

- **Having celebrated Earth Day last week, I am reminded of the relevance of this Task Force to children.**
 - **Warm, sunny days, flowers, baseball, all rekindling the sense of wonder that is so much a part of being a child.**
 - **At this time, perhaps we can more clearly see the relationship between children and their environment.**
 - **For our Task Force, we should envision children growing up in an environment that possesses, in the words of F. Scott Fitzgerald, "all the iridescence of the beginning of the world."**

Carol?