TESTIMONY OF SYDNEY E. SALMON, M. D. OF TUCSON, ARIZONA ON APRIL 11, 1979

RELEVANT TO THE "SMALL BUSINESS NON-PROFIT ORGANIZATION PATENT PROCEDURES ACT" OF SENATORS DOLE AND BAYH

I AM DR. SYDNEY E. SALMON, M. D., PROFESSOR OF INTERNAL MEDICINE AND DIRECTOR OF THE UNIVERSITY OF ARIZONA CANCER CENTER IN TUCSON. MY ACADEMIC CAREER HAS BEEN DEDICATED TO CLINICAL AND LABORATORY CANCER RESEARCH, AND I HAVE PUBLISHED IN EXCESS OF 100 ORIGINAL SCIENTIFIC ARTICLES. I WISH TO TESTIFY IN SUPPORT OF THE BILL INTRODUCED BY SENATORS DOLE AND BAYH AS I BELIEVE THAT PASSAGE OF THIS BILL WILL CLEARLY FACILITATE THE DELIVERY OF IMPORTANT NEW INVENTIONS TO THE PUBLIC AS WELL AS AIDING THE GOVERNMENT IN GAINING RETURN OF ITS INVESTMENT IN FEDERALLY SUPPORTED UNIVERSITY AND SMALL BUSINESS PROGRAMS. PASSAGE OF THIS BILL INTO LAW WILL ALSO IMPROVE OUR COUNTRY'S CAPABILITY TO MAINTAIN TECHNOLOGICAL LEADERSHIP AND FAVORABLY INFLUENCE OUR BALANCE OF PAYMENTS IN AN INCREASINGLY COMPETITIVE ENVIRONMENT.

MY OWN PERSONAL EXPERIENCE IN RELATION TO THE PROBLEMS OF A UNIVERSITY SCIENTIST ATTEMPTING TO PATENT AN INVENTION DESIGNED TO IMPROVE THE CARE OF CANCER PATIENTS SHOULD PROVIDE USEFUL SUPPORTIVE DATA INDICATING THE NEED FOR YOUR BILL. I WANT TO EMPHASIZE AT THE OUTSET THAT THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE DEFINITELY DID COME TO MY AID AND TO THE UNIVERSITY OF ARIZONA SO THAT WE WERE ABLE TO SUBMIT A PATENT AND GAIN RIGHTS TO AN INVENTION, HOWEVER THE TIME DELAYS INVOLVED WERE NOTEWORTHY, AND NEED TO BE REVIEWED.

IN APRIL, 1975, I RECRUITED DR. ANNE HAMBURGER TO WORK WITH ME ON A NEW PROJECT. I PROPOSED THAT WE DEVELOP A BIOASSAY TO PERMIT GROWTH OF HUMAN TUMOR STEM CELLS. TUMOR STEM CELLS WHICH COMPRISE LESS THAN ONE PERCENT OF THE CELLS IN A CANCER ARE THE KEY CELLS WHICH ARE RESPONSIBLE FOR A CANCER'S ABILITY TO UNDERGO CONTINUED GROWTH AND SPREAD THROUGH THE BODY IN A PROCESS CALLED METASTASIS. STUDIES IN EXPERIMENTAL ANIMALS

SUGGESTED THAT THE RESPONSE OF TUMOR STEM CELLS TO TREATMENT COULD BE PREDICTIVE OF THE RESPONSE OF THE ANIMAL TO CANCER TREATMENT. DR. HAMBURGER JOINED MY LABORATORY IN AUGUST, 1975. IN LESS THAN 1 YEAR WE DEVISED A TECHNIQUE WHICH PERMITTED COLONY FORMATION BY HUMAN TUMOR STEM CELLS PERMITTING US TO ACCURATELY MEASURE THE EFFECTS OF ANTICANCER DRUGS PRESENT IN BIOPSY SAMPLES. AT FIRST WE TRIED THE TEST ON MULTIPLE MYELOMA AND OVARIAN CANCER, BUT HAVE SUBSEQUENTLY FOUND IT USEFUL ALSO IN A WIDE VARIETY OF CANCERS, AND TO BE PREDICTIVE OF THE PATIENT'S RESPONSE TO TREATMENT. THE INITIAL WORK WAS SUPPORTED LARGELY BY DONATED FUNDS, BUT FEDERAL FUNDS DID SUPPORT DR. HAMBURGER'S SALARY AS A BEGINNING RESEARCH ASSOCIATE IN MY LABORATORY. BECAUSE OF OUR CONTINUED SUCCESS WITH THIS RESEARCH AND THE OBVIOUS POTENTIAL OF OUR DISCOVERY TO IMPROVE THE MANAGEMENT OF CANCER PATIENTS AND FACILITATE THE DEVELOPMENT OF NEW ANTICANCER DRUGS, WE DECIDED TO DISCLOSE OUR INVENTION TO THE UNIVERSITY. A DECISION WAS REACHED THAT THE DISCOVERY SHOULD BE PATENTED. INASMUCH AS SOME LIMITED HEW FUNDS HAD BEEN USED IN SUPPORT OF OUR WORK, THE UNIVERSITY WAS OBLIGATED TO REQUEST PERMISSION TO GAIN AND ADMINISTER RIGHTS TO THIS INVENTION IN RELATION TO THE PATENT PROCESS. THE PETITION WAS SUBMITTED ON JULY 5, 1977, AND FILED BY THE NIH PATENT ATTORNEY, MR. LATKER, ON JULY 20, 1977. OUR FIRST SCIENTIFIC ARTICLE ON THE BIOASSAY WAS PUBLISHED IN THE JOURNAL, SCIENCE, ON JULY 29, 1977.

IN VIEW OF OUR PUBLICATION OF OUR FINDINGS (WHICH WE DID TO FACILITATE CANCER RESEARCH IN THIS IMPORTANT AREA), A STATUTE OF LIMITATIONS OF ONE YEAR IS AUTOMATICALLY APPLIED FROM THAT DATE WITH RESPECT TO FILING A PATENT. THE UNIVERSITY WAS UNDERSTANDABLY RELUCTANT TO FILE A PATENT WITHOUT RECEIVING GREATER RIGHTS DETERMINATION, AS WITHOUT THESE RIGHTS IT WOULD HAVE NO WAY OF REGAINING ITS INVESTMENT IN FILING THE PATENT. NO ACTION HAD BEEN TAKEN ON OUR PETITION AS THE FILING DEADLINE APPROACHED, UNTIL LATE SPRING 1978 AT WHICH TIME HEW DECIDED THAT IT WOULD UNDERWRITE THE COST OF FILING A PATENT ON OUR INVENTION. ACCORDINGLY, A PATENT

APPLICATION WAS FILED AT HEW'S EXPENSE ON JULY 7, 1978. WE APPRECIATED THIS ACTION BECAUSE IF IT HAD NOT BEEN TAKEN, OUR STATUTE OF LIMITATIONS WOULD HAVE RUN OUT. I DO NOT KNOW HOW OFTEN HEW TAKES SUCH ACTION IN SUPPORT OF ITS GREATER RIGHTS PETITIONERS

ALSO RELEVANT TO DEVELOPMENT OF OUR TEST WAS A PAPER WHICH WE PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE ON JUNE 15, 1978. IN THAT ARTICLE WE DEMONSTRATED THAT OUR TEST WAS PREDICTIVE OF THE RESPONSE OF CANCER PATIENTS TO A VARIETY OF ANTICANCER DRUGS. AS A RESULT OF THIS ARTICLE, THE EDITORIALS AND OTHER PUBLICITY WHICH RESULTED FROM THIS CLINICAL ARTICLE, A NUMBER OF PRIVATE COMPANIES EXPRESSED INTEREST IN INVESTING THE VENTURE CAPITAL NECESSARY TO BRING THIS INVENTION TO THE MARKET AS A CONVENIENT, DEPENDABLE DIAGNOSTIC DRUG TESTING PROCEDURE. HOWEVER, WHEN THEY LEARNED THAT THE UNIVERSITY DID NOT HAVE THE APPROVAL TO ADMINISTER RIGHTS TO THIS INVENTION, THEY QUICKLY LOST INTEREST IN ITS DEVELOPMENT, AND IT THEREFORE HAS REMAINED A LABORATORY RESEARCH EFFORT UP UNTIL THE PRESENT TIME. I AM PLEASED TO REPORT THAT ON MARCH 23, 1979, THE ASSISTANT SECRETARY OF HEALTH (JULIUS B. RICHMOND, M.D.) DETERMINED THAT THE UNIVERSITY OF ARIZONA MAY RETAIN RIGHTS TO THE INVENTION, SUBJECT TO A SERIES OF STANDARD TERMS AND CONDITIONS. THIS DECISION WILL CLEARLY HELP OUR INVENTION TO BE DEVELOPED AND APPLIED FOR THE GOOD OF THE PUBLIC. HOWEVER, A PERIOD OF LARGE SCALE TESTING AND CLINICAL TRIAL WILL STILL BE REQUIRED. IT IS IMPORTANT TO POINT OUT THAT A DECISION ON OUR RIGHTS DETERMINATION PETITION TOOK A TOTAL OF 20 MONTHS TO BE GRANTED. IN MY OPINION, THIS SLOW PROCESS OF GAINING APPROVAL FROM HEW HAD TO DELAY THE AVAILABILITY OF OUR INVENTION TO THE PUBLIC BY AT LEAST ONE YEAR. AT OUR PRESENT STAGE OF KNOWLEDGE, I BELIEVE THAT APPLICATION OF THIS INVENTION TO THE PUBLIC WILL SPARE CANCER PATIENTS FROM RECEIVING TOXIC DRUGS WHICH WE CAN PREDICT WOULD BE OF NO BENEFIT. WE BELIEVE THAT ONCE THIS INVENTION IS SYSTEMATICALLY APPLIED BY THE NATIONAL CANCER INSTITUTE, OUR NATION'S

CANCER CENTERS AND RESEARCH LABORATORIES AND THE PHARMACEUTICAL INDUSTRY, NEW AND EFFECTIVE ANTICANCER DRUGS WILL BE DISCOVERED AND DEVELOPED MORE RAPIDLY THAN EVER BEFORE, AND LEAD TO THE CURE OF MANY TYPES OF CANCER WHICH STILL REMAIN INCURABLE.

PLEASE ACCEPT MY TESTIMONY IN EVIDENCE AS SUPPORTING YOUR PLAN TO FACILITATE THE PROCESS OF RIGHTS DETERMINATION IN RELATION TO OTHER NEW INVENTIONS. I BELIEVE THAT YOUR BILL REPRESENTS A MAJOR STEP IN THE GENERAL INTEREST OF THE PUBLIC, INDUSTRY, UNIVERSITIES, AND THE GOVERNMENT ITSELF. I HOPE IT IS QUICKLY PASSED BY CONGRESS AND SIGNED INTO LAW.

THANK YOU.