STATEMENT
OF
NORMAN J. LATKER
PATENT COUNSEL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
BEFORE
SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL
SCIENTIFIC PLANNING AND ANALYSIS
COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

SEPT. 29, 1976

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM THE PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE. MY OFFICE HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S 1.8 BILLION DOLLAR ANNUAL RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION, SINCE I HAVE HAD A DEEP INTEREST IN GOVERNMENT PATENT POLICY WHICH HAS LED ME TO SERVICE ON EVERY MAJOR REVIEW OF GOVERNMENT PATENT POLICY IN THE LAST SEVEN YEARS. IN THAT REGARD, I SERVED AS THE DRAFTSMAN FOR THE TASK FORCE WHICH DEVELOPED THE "ALTERNATE APPROACH" FOR ALLOCATING THE INVENTIVE RESULTS OF GOVERNMENT FUNDED RESEARCH AND DEVELOPMENT FOR THE 1971 COMMISSION ON GOVERNMENT PROCUREMENT. AS YOU WILL RECALL FROM HIS TESTIMONY, DR. FORMAN CONSIDERED THE "ALTERNATE APPROACH" THE CLOSEST EMBODIMENT OF HIS VIEWS AND RECOMMENDATIONS FOR CONGRESSIONAL ENACTMENT OF A UNIFORM NATIONAL GOVERNMENT PATENT POLICY.

IN ADDITION, I HAVE SERVED ON THE DRAFTING GROUPS THAT DEVELOPED THE ERDA PATENT PROVISIONS, THE FEDERAL PROCUREMENT PATENT AND LICENSING REGULATIONS WHICH YOU HAVE TAKEN NOTE OF AND WHICH WERE THE SUBJECT OF THE TWO PUBLIC CITIZENS CASES. BUT MOST RELEVANT TO MY STATEMENT TODAY, I AM THE CHAIRMAN OF THE UNIVERSITY PATENT POLICY SUBCOMMITTEE OF THE NOW ABOLISHED FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY (FCST). IT IS THIS INTERAGENCY SUBCOMMITTEE THAT WAS RESPONSIBLE FOR THE FEDERAL PROCUREMENT REGULATIONS ON UNIVERSITY PATENT POLICY NOTED BY MR. WOODROW IN HIS TESTIMONY AND NOW CIRCULATING FOR PUBLIC COMMENT. I HOPE TO ELABORATE ON THE DEVELOPMENT OF THESE REGULATIONS LATER IN MY STATEMENT.

MY SERVICE WITH THESE GROUPS AND MY DAILY INTERFACE WITH INNOVATORS AND THEIR ORGANIZATIONS HAS REINFORCED MY BELIEF IN THE FUNDAMENTAL PREMISES OF DHEW PATENT POLICY WHICH GIVEN THE FACT THAT COMMERCIALIZATION OF INVENTIONS MUST BE ULTIMATELY ACCOMPLISHED BY INDUSTRY SEEM CONCLUSIVE TO ME BUT, NOTWITHSTANDING, REMAIN A SUBJECT OF CONTINUING DEBATE. THUS, THE DEPARTMENT SUPPORTS THE BELIEF THAT A GUARANTEE OF SOME PATENT PROTECTION MAY BE NECESSARY TO AN INDUSTRIAL DEVELOPER IN ORDER TO ASSURE UTILIZATION BY OR TRANSFER TO SUCH DEVELOPER OF INVENTIVE RESULTS OF DEPARTMENT SPONSORED RESEARCH. THIS IS REFLECTED IN THE DEPARTMENT PATENT REGULATIONS 45 C.F.R., PARTS 6 THROUGH 8, AND, IN PARTICULAR, SECTIONS 6.6, 8.1(b) AND 8.2(b). FURTHER, THIS GUARANTEE MAY BE NECESSARY WHETHER THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT AND COMMERCIALIZATION WAS MADE BY A GOVERNMENT, UNIVERSITY OR INDUSTRY EMPLOYEE IN PERFORMANCE OF GOVERNMENT FUNDED RESEARCH. THESE PREMISES SEEM OBVIOUS TO ME, SINCE INHERENT TO THE COMMITMENT OF RISK CAPITAL TOWARD THE COMPLETION OF DEVELOPMENT IS A DECISION ON THE PART OF THE INDUSTRIAL

DEVELOPER ON WHETHER THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS INTERESTS. CONVERSELY, FAILURE TO PROVIDE SUCH GUARANTEE IN CASES WHERE IT IS NECESSARY MAY FATALLY AFFECT UTILIZATION OR TRANSFER OF A MAJOR INNOVATION. ACCORDINGLY, IT WOULD SEEM THAT THE RESEARCH AND DEVELOPMENT AGENCIES SHOULD BE UNDER A HEAVY OBLIGATION TO ASSURE AVAILABILITY OF PATENT PROTECTION WHEN PRIVATE RESOURCES ARE NEEDED TO ACHIEVE COMMERCIALIZATION.

IT IS MY OWN BELIEF THAT ANY CONTROVERSY OVER GOVERNMENT PATENT POLICY, AT LEAST IN THE RESEARCH AND DEVELOPMENT AGENCIES, IS NOT, AS COMMONLY STATED, WHETHER THE GOVERNMENT SHOULD TAKE "TITLE" OR "LICENSE" TO INVENTIVE RESULTS IT HAD FUNDED, BUT WHEN AND TO WHAT EXTENT THE GUARANTEE OF PATENT PROTECTION NOTED ABOVE SHOULD BE MADE TO INDUSTRY. ACCORDINGLY, EVERY RESEARCH AND DEVELOPMENT AGENCY THAT HAS TESTIFIED, INCLUDING DHEW, BELIEVES IT HAS THE DISCRETION WHETHER DERIVED FROM STATUTE, AGENCY REGULATION OR THE PRESIDENT'S STATEMENT ON PATENT POLICY, TO WAIVE OR LICENSE PATENT RIGHTS WHEN IT IS DEEMED APPROPRIATE TO ACHIEVE COMMERCIAL UTILIZATION. IN DHEW THAT DISCRETION IS DERIVED FROM DEPARTMENT REGULATIONS AND THE PRESIDENT'S STATEMENT RATHER THAN STATUTE. THERE IS NO DIFFERENCE OF OPINION AMONG THE RESEARCH AND DEVELOPMENT AGENCIES THAT THIS DISCRETION SHOULD EXIST.

THE MORE MEANINGFUL PROBLEM IS SIMPLY THAT THE AGENCIES HAVE NOT UTILIZED THIS DISCRETION ON A UNIFORM BASIS IN SIMILAR FACT SITUATIONS TO THE EXTENT THAT SOME AGENCIES HAVE NOT FELT IT NECESSARY TO DEVELOP A

MANAGEMENT MECHANISM TO ENTERTAIN REQUESTS FOR LICENSES OR WAIVERS ON ANY BASIS. THIS IS EVIDENCED BY THE LACK OF ACTIVITY NOTED IN LICENSE AND WAIVER CATEGORIES FOR SOME AGENCIES IN THE "ANNUAL REPORT ON GOVERNMENT PATENT POLICY" PUBLISHED BY FCST.

I WOULD NOW TURN MY ATTENTION TO THE ALLOCATION OF INVENTIONS ARISING FROM GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. THIS IS AN AREA OF VITAL INTEREST TO DHEW, BECAUSE THE DEPARTMENT IS BY FAR THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND PROBABLY THE WORLD, AND FURTHER, BECAUSE THE SUBSTANTIAL MAJORITY OF ALL ITS RESEARCH FUNDS ARE USED TO SPONSOR RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. WHILE THE ALLOCATION OF RIGHTS OF INVENTIONS MADE BY DEPARTMENT EMPLOYEES AND FOR-PROFIT CONTRACTORS IS AN IMPORTANT MATTER, I WILL ONLY NOTE THAT THE POLICIES COVERING THIS AREA IN THE DEPARTMENT ARE SIMILAR TO THOSE OF NASA AND ERDA. DIFFERENCES ARE EVIDENT ONLY IN APPLICATION AND RESULT.

IN THE HISTORICAL 1939 LETTER FROM DR. EINSTEIN TO PRESIDENT ROOSEVELT POINTING OUT TO THE PRESIDENT THE IMMINENCE OF THE FIRST CONTROLLED NUCLEAR CHAIN-REACTION AND THE ADVENT OF THE ATOMIC AGE, DR. EINSTEIN MADE

THE FOLLOWING RECOMMENDATIONS WITH A VIEW TOWARD EXPEDITING THE WORK:

"IN VIEW OF THIS SITUATION YOU MAY THINK IT DESIRABLE TO HAVE SOME PERMANENT CONTACT MAINTAINED BETWEEN THE ADMINISTRATION AND THE GROUP OF PHYSICISTS WORKING ON CHAIN REACTIONS IN AMERICA. ONE POSSIBLE WAY OF ACHIEVING THIS MIGHT BE FOR YOU TO ENTRUST WITH THIS TASK A PERSON WHO HAS YOUR CONFIDENCE AND WHO COULD PERHAPS SERVE IN AN UNOFFICIAL CAPACITY. HIS TASK MIGHT COMPRISE THE FOLLOWING:

a) TO APPROACH GOVERNMENT DEPARTMENTS, KEEP THEM INFORMED OF THE FURTHER DEVELOPMENT, AND PUT FORWARD RECOMMENDATIONS FOR GOVERNMENT ACTION, GIVING PARTICULAR ATTENTION TO THE PROBLEM OF SECURING A SUPPLY OF URANIUM ORE FOR THE UNITED STATES;

b) TO SPEED UP THE EXPERIMENTAL WORK, WHICH IS AT PRESENT BEING CARRIED ON WITHIN THE LIMITS OF THE BUDGETS OF UNIVERSITY LABORATORIES, BY PROVIDING FUNDS, IF SUCH FUNDS BE REQUIRED, THROUGH HIS CONTACTS WITH PRIVATE PERSONS, WHO ARE WILLING TO MAKE CONTRIBUTIONS FOR THIS CAUSE, AND PERHAPS ALSO OBTAINING THE COOPERATION OF INDUSTRIAL LABORATORIES, WHICH HAVE THE NECESSARY EQUIPMENT."

(EMPHASIS ADDED)

IN THESE FEW WORDS DR. EINSTEIN SEEMS TO HAVE PROPERLY IDENTIFIED AND ASSIGNED TO EACH ELEMENT OF THE COLLABORATIVE TEAM HE DEEMED NECESSARY TO THE COMPLETION OF DEVELOPMENT, THE DUTY WHICH EACH WOULD

PERFORM BEST. THUS, HE SUGGESTS THAT THE UNIVERSITIES BE AIDED IN COMPLETING THEIR EXPERIMENTAL OR FUNDAMENTAL RESEARCH, THAT INDUSTRIAL LABORATORIES BE TAPPED FOR THEIR ABILITY TO BRING SUCH FUNDAMENTAL FINDINGS INTO PRACTICAL APPLICATION THROUGH THE USE OF THEIR EQUIPMENT AND THE GOVERNMENT ACT AS THE CATALYST OR IMPRESARIO IN BRINGING THESE FACTORS TOGETHER.

AS SIMPLE AS DR. EINSTEIN'S FORMULA FOR DELIVERY OF THE RESULTS OF FUNDAMENTAL RESEARCH INTO PRACTICAL USE APPEARS, THE DEPARTMENTS AND AGENCIES OF THE EXECUTIVE HAD DONE LITTLE TO FORMULIZE IT UNTIL RECENT YEARS. THE CLOSING OF THE ENORMOUS GAP BETWEEN THE FUNDAMENTAL FINDINGS OF UNIVERSITIES IN NEW FIELDS OF KNOWLEDGE AS DRAMATICALLY INNOVATIVE AS RADAR, COMPUTER MEMORY CORES, LASERS, ANTIBIOTICS, ETC., AND THEIR PRACTICAL IMPLEMENTATION BY INDUSTRY, WITH THE EXCEPTION OF THE FEW CASES WHERE THE GOVERNMENT HAS DETERMINED TO PROVIDE THE CONTINUED FUNDING TO INDUSTRY FOR DEVELOPMENT OF SUCH FINDINGS, HAS BEEN LEFT TO RANDOM AND HAPHAZARD EXECUTION.

FROM THE VIEWPOINT OF THE GOVERNMENT AND THE PUBLIC, THE STAKE IN CLOSING THIS GAP IS VERY HIGH. THE SHEER MAGNITUDE OF GOVERNMENT SUPPORT OF RESEARCH AND DEVELOPMENT AT UNIVERSITIES APPEARS TO DEMAND EVIDENCE OF USEFUL RESULTS IF IT IS TO BE CONTINUED IN THE PREVAILING COMPETITION FOR THE FEDERAL DOLLAR. IN FISCAL YEAR 1972 APPROXIMATELY $3.1 BILLION OF THE $12 BILLION, OR OVER ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT

IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES. OF THE $3.1 BILLION, THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE WAS RESPONSIBLE FOR ADMINISTERING $1.2 BILLION.

ON SEPTEMBER 23, 1975, THE FEDERAL COUNCIL ON SCIENCE AND TECHNOLOGY'S COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDED, ON THE BASIS OF ITS UNIVERSITY SUBCOMMITTEE'S STUDY, THAT ALL AGENCIES OF THE EXECUTIVE BRANCH PROVIDE TO UNIVERSITIES A FIRST OPTION TO SUBSTANTIALLY ALL FUTURE INVENTIONS GENERATED WITH FEDERAL SUPPORT, SUBJECT TO STATUTORY AUTHORITY TO THE CONTRARY, PROVIDED THAT THE INVENTING ORGANIZATION IS FOUND TO HAVE AN IDENTIFIED TECHNOLOGY TRANSFER FUNCTION. THIS FIRST OPTION TO OWNERSHIP IS SUBJECT TO A NUMBER OF CONDITIONS, THE MOST IMPORTANT OF WHICH ARE THE STANDARD LICENSE TO THE GOVERNMENT, A LIMIT ON THE TERM OF ANY EXCLUSIVE LICENSE GRANTED, AUTHORITY TO WITHDRAW SPECIFIED PROJECTS FROM THE OPTION, A REQUIREMENT THAT ROYALTY INCOME BE UTILIZED FOR EDUCATIONAL OR RESEARCH PURPOSES, WITH THE EXCEPTION OF A REASONABLE SHARE TO THE INVENTOR, AND THE RIGHT OF THE AGENCY TO REGAIN OWNERSHIP DUE TO PUBLIC INTEREST CONSIDERATIONS OR THE UNIVERSITIES' FAILURE TO TAKE EFFECTIVE STEPS TO COMMERCIALIZE THE INVENTION.

IN ADDITION, THE COMMITTEE ALSO DIRECTED THAT AN INTERAGENCY COMMITTEE BE FORMED FOR THE PURPOSE OF JOINT AGENCY IDENTIFICATION OF UNIVERSITIES HAVING A SATISFACTORY TECHNOLOGY TRANSFER FUNCTION. AS NOTED, IMPLEMENTATION OF THE COUNCIL'S RECOMMENDATION IS NOW BEING CIRCULATED FOR PUBLIC COMMENT IN THE FORM OF A PROPOSED FEDERAL PROCUREMENT REGULATION.

AT THE OUTSET OF ITS STUDY, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED SOME GENERAL PREMISES FROM WHICH IT WOULD BE NECESSARY TO PROCEED. AS YOU WILL NOTE, ALL OF THESE PREMISES WERE INTUITIVELY UNDERSTOOD BY DR. EINSTEIN IN 1939.

FIRST, A SYMPATHETIC AND ENCOURAGING FEDERAL CLIMATE IS VERY IMPORTANT TO TECHNOLOGICAL PROGRESS. THUS, IN CASES WHERE THE REQUIREMENT FOR UNIVERSITY/INDUSTRY RELATIONS IS NOT MET IN A SATISFACTORY MANNER, GOVERNMENT CAN HAVE AN IMPORTANT ROLE TO PLAY AS A CATALYST OR "IMPRESARIO" IN CREATING THE FRAMEWORK WITHIN WHICH REGULAR CONTACTS TAKE PLACE BETWEEN UNIVERSITY AND INDUSTRY.

SECOND, THE UNIVERSITY COMMUNITY AND INDUSTRY, LEFT TO THEIR OWN INITIATIVES, WILL PROBABLY BE UNABLE TO GENERATE THIS ATMOSPHERE. PRIVATE BUSINESS, EVEN THOUGH CONCERNED WITH INSTITUTIONAL BARRIERS THAT PRECLUDE SYSTEMS INNOVATIONS, CAN'T DO MUCH ABOUT IT. THEY ARE RESPONSIBLE FOR OUTPUTS OF THEIR BUSINESSES AND MUST ORDINARILY WORK WITHIN THE NARROW CONFINES OF THE COMPANIES' RESPONSIBILITIES TO MAXIMIZE PROFITS AND MINIMIZE RISKS FOR THE FIRM.

THIRD, THERE APPEARS TO BE AN ABSOLUTE NEED FOR INDUSTRIAL COLLABORATION WITH UNIVERSITIES IF THE RESULTS OF GOVERNMENT-SPONSORED UNIVERSITY RESEARCH ARE TO REACH THE MARKETPLACE. THIS IS TRUE, SINCE MUCH OF THE WORK PERFORMED UNDER GOVERNMENT-SPONSORED GRANTS AND CONTRACTS AT UNIVERSITIES IS BASIC, AS OPPOSED TO APPLIED RESEARCH. INVENTIONS ARISING OUT OF BASIC RESEARCH INVOLVE AT MOST COMPOSITIONS OF MATTER WITH

NO CLEAR UTILITY, PROTOTYPE DEVICES, OR PROCESSES WHICH USUALLY REQUIRE MUCH ADDITIONAL DEVELOPMENT. UNIVERSITIES THEMSELVES DO NOT UNDERTAKE THE COMPLETE DEVELOPMENT OF SUCH INCHOATE INVENTIONS, AS DEVELOPMENT LEADING TO COMMERCIAL MARKETING IS NOT ORDINARILY WITHIN THE SCOPE OF THEIR MISSIONS OR PHYSICAL CAPABILITY. FURTHER, FINANCING OF THAT TYPE OF DEVELOPMENT WORK NEEDED IS NOT GENERALLY AVAILABLE FROM GOVERNMENT SOURCES. THERE ARE MANY MORE INVENTIVE IDEAS THAN FEDERAL RESOURCES FOR DEVELOPMENT PURPOSES. CONSEQUENTLY, DEVELOPMENT OF SUCH INVENTIONS WILL GENERALLY BE ACCOMPLISHED ONLY WHERE INDUSTRY HAS KNOWLEDGE OF THEM AND HAS AN INCENTIVE TO UTILIZE ITS RISK CAPITAL TO BRING THEM TO THE MARKETPLACE.

LAST, THE DIFFICULTY OF COLLABORATION IS COMPOUNDED WHEN THOSE WHO NOW PERFORM ESSENTIAL PARTS OF A FUNCTION REFUSE TO MODIFY THEIR OPERATIONS TO MEET THE NEEDS OF THE WHOLE SYSTEM. (THE RESEARCH AND DEVELOPMENT AGENCIES WERE NOT EXCLUDED AS ONE OF THE PRINCIPALS WHO MUST MODIFY ITS OPERATIONS.) THESE VESTED INTERESTS CONSTITUTE THE MOST SERIOUS INSTITUTIONAL BARRIERS TO SOCIALLY IMPORTANT INNOVATIONS. ORDINARILY, THE PRINCIPALS CAN'T BE ORDERED TO COLLABORATE. NOR WILL THEY DO SO UNLESS THEY SEE SOMETHING IN IT FOR THEMSELVES. THE PROBLEM PERCEIVED WAS HOW TO PROVIDE THE MEANS FOR INDUCING THEM TO INTEGRATE VOLUNTARILY INTO A SYSTEM THAT PERFORMS A SOCIALLY DESIRABLE FUNCTION.

WITH THESE PREMISES IN MIND, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED THE FOLLOWING AS THE PRIMARY PROBLEMS THAT NEEDED TO BE OVERCOME BEFORE OPTIMUM RESULTS IN TRANSFERRING TECHNOLOGY COULD BE ACHIEVED.

FIRST, AND THOUGHT TO BE THE MOST IMPORTANT, WAS THE CONCLUSION THAT UNIVERSITIES DO NOT GENERALLY HAVE AN ADEQUATE MANAGEMENT CAPABILITY TO FACILITATE THE TIMELY IDENTIFICATION, PROTECTION AND THE TRANSFER OF THEIR INVENTIVE RESULTS TO INDUSTRIAL CONCERNS THAT MIGHT MAKE USE OF THEM. EVEN THOSE ORGANIZATIONS HAVING THE RIGHT TO TRANSFER A DEGREE OF PATENT PROTECTION DESIRED BY INDUSTRY MAY WELL FAIL TO SUCCEED IN ENCOURAGING UTILIZATION IF AN ADEQUATE, ORGANIZED EFFORT TO IDENTIFY, PROTECT AND COMMUNICATE THESE RESULTS IS NOT MADE.

IT WAS PERCEIVED THAT THE MERE EXISTENCE OF A BODY OF RESEARCH PUBLICATIONS AND OTHER TECHNICAL INFORMATION WAS NOT ENOUGH TO RESULT IN SIGNIFICANT INDUSTRIAL INVOLVEMENT IN FURTHERING DEVELOPMENT.

SECOND, WAS THE "NOT-INVENTED-HERE" SYNDROME. INDUSTRIAL ORGANIZATIONS HAVE COMMERCIAL POSITIONS IN MOST AREAS OF THEIR RESEARCH. ACCORDINGLY, THERE IS AN IN-HOUSE INCENTIVE FOR SUCH ORGANIZATIONS TO FURTHER DEVELOP THE RESULTS OF THEIR RESEARCH IN ORDER TO IMPROVE THEIR COMMERCIAL POSITION. THIS INCENTIVE STEMS FROM THE ORGANIZATION'S ABILITY TO CONTINUOUSLY EVALUATE THEIR RESEARCH THROUGH ALL STAGES OF ITS DEVELOPMENT. IT FOLLOWS THAT THERE WILL BE A LESSER INCENTIVE FOR INDUSTRY TO FURTHER DEVELOP THE RESULTS OF UNIVERSITY RESEARCH WHERE SUCH RESEARCH WILL NOT BE UNDER ITS INITIAL REVIEW OR CONTROL. IT WAS SUGGESTED THAT THIS BIAS TOWARD INVESTMENT IN FURTHER DEVELOPMENT OF ITS OWN IDEAS, RATHER THAN IDEAS FROM OUTSIDE SOURCES, MIGHT BE LESSENED BY EARLY IDENTIFICATION BY INDUSTRY OF UNIVERSITY INVESTIGATORS WHO MAY BE WORKING IN THEIR AREAS OF INTEREST.

THIRD, WAS THE UNCERTAINTY OVER OWNERSHIP OF INVENTIONS MADE AT UNIVERSITIES THAT MAY BE COLLABORATIVELY DEVELOPED OR ARE INITIALLY GENERATED THROUGH A COLLABORATIVE RELATIONSHIP.

DHEW HAD NOTED SITUATIONS OF INDUSTRY REFUSAL TO COLLABORATE WITH UNIVERSITIES IN BRINGING DHEW-FUNDED INVENTIONS TO THE MARKETPLACE UNLESS PROVIDED SOME PATENT PROTECTION AS QUID PRO QUO FOR ADDITIONAL INVESTMENT AND DEVELOPMENT REQUIRED.

THIS WAS SUBSTANTIATED BY THE HARBRIDGE HOUSE STUDY AND A 1968 GAO REPORT NO. B-164031(2) ENTITLED "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY." BOTH OF THESE STUDIES INDICATED A VIRTUAL INDUSTRY-WIDE BOYCOTT BY PHARMACEUTICAL FIRMS TO TEST COMPOSITIONS OF MATTER SYNTHESIZED OR ISOLATED BY DHEW GRANT-SUPPORTED INVESTIGATORS DUE TO DHEW'S PATENT PRACTICES AT THAT TIME. INDUSTRY FELT DHEW PATENT PRACTICES FAILED TO TAKE INTO CONSIDERATION THE LARGE PRIVATE INVESTMENT BEFORE SUCH COMPOSITIONS COULD BE MARKETED AS DRUGS. SIMILAR SITUATIONS HAD OCCURRED IN THE AREA OF MEDICAL HARDWARE DEVICES.

IT WAS DETERMINED FROM THE EXPERIENCES NOTED IN UNIVERSITY DEALINGS WITH THE PHARMACEUTICAL INDUSTRY AND MEDICAL DEVICE MANUFACTURERS THAT THERE WILL BE THE SAME RELUCTANCE TO COLLABORATE WITH UNIVERSITIES IN BRINGING OTHER HIGH-RISK INVENTIONS TO THE MARKETPLACE IF SOME PATENT EXCLUSIVITY IS NOT FIRST PROVIDED TO THE DEVELOPER.

FOURTH, IS THE PROBLEM OF CONTAMINATION. AS USED BY INDUSTRY AND UNIVERSITY INVESTIGATORS, "CONTAMINATION" MEANS THE POTENTIAL COMPROMISE OF RIGHTS IN PROPRIETARY RESEARCH RESULTING FROM EXPOSURE OF INDUSTRY TO

IDEAS, COMPOSITIONS, AND/OR TEST RESULTS ARISING FROM GOVERNMENT-SPONSORED RESEARCH. FOR EXAMPLE, AN INVENTION MADE AT A UNIVERSITY UNDER A GOVERNMENT-FUNDED RESEARCH PROGRAM IS LOOKED INTO BY A COMPANY DOING PARALLEL RESEARCH. IF THE COMPANY INCORPORATES INTO ITS RESEARCH PROGRAM SOME OF THE RESEARCH FINDINGS OF THE UNIVERSITY AND THEN DEVELOPS A MARKETABLE PRODUCT PATENTABLY DISTINCT FROM THE UNIVERSITY'S INVENTION, THE COMPANY FEARS THAT THE GOVERNMENT IS IN A POSITION TO ASSERT CLAIMS TO THEIR PRODUCT.

TO OVERCOME THESE BARRIERS TO TECHNOLOGY TRANSFER, IT WAS DEEMED ESSENTIAL TO THE SUBCOMMITTEE THAT THE GOVERNMENT PERSUADE UNIVERSITIES TO PROVIDE A MANAGEMENT CAPABILITY WITHIN THE INSTITUTION THAT WILL SERVE AS A FOCAL POINT FOR IDENTIFICATION, RECEIPT AND PROMPT PROTECTION OF THE INVENTIVE RESULTS OF UNIVERSITY RESEARCH FOR LATER DISSEMINATION BY ITSELF OR OTHER MANAGEMENT ORGANIZATIONS TO THOSE INDUSTRIAL CONCERNS MOST LIKELY TO UTILIZE SUCH RESULTS. IT WAS THE CONCLUSION OF THE SUB-COMMITTEE THAT THIS MIGHT BE ACCOMPLISHED BY GUARANTEEING TO UNIVERSITIES AT THE TIME OF FUNDING, PATENT RIGHTS IN GOVERNMENT-SUPPORTED INVENTIONS IN RETURN FOR ESTABLISHMENT OF SUCH A MANAGEMENT CAPABILITY.

I BELIEVE THAT ONE OF THE PRIMARY BASES FOR THE RECOMMENDATION WAS THE REALIZATION THAT A SUBSTANTIAL MAJORITY OF INVENTIVE IDEAS REQUIRES "ADVOCATES" IN ORDER TO REACH THE MARKETPLACE, AND THAT EXPERIENCE INDICATES THAT THE INVENTING ORGANIZATION, IF INTERESTED, IS A MORE LIKELY "ADVOCATE" THAN A LESS PROXIMATE AND NOT AS EQUALLY CONCERNED GOVERNMENT STAFF.

HISTORY IS REPLETE WITH EXAMPLES OF INVENTIONS NOW ACCEPTED AS PART OF OUR CULTURE, WHICH REACHED FRUITION ONLY DUE TO THE PERSEVERANCE OF AN ADVOCATE. IT IS SAID THAT THE INVENTOR OF XEROX, CHESTER CARLSON, CONTACTED OVER 100 CONCERNS BEFORE HE WAS ABLE TO OBTAIN A FINANCIAL COMMITMENT FOR DEVELOPMENT. SIMILARLY, SAMUEL B. MORSE ARGUED THROUGH FIVE YEARS BEFORE HE WAS ABLE TO OBTAIN $30,000 FROM CONGRESS TO BUILD A TEST LINE FOR HIS TELEGRAPH BETWEEN WASHINGTON AND BALTIMORE. THERE IS NO EVIDENCE THAT A GOVERNMENT ORGANIZATION WOULD BE WILLING TO DUPLICATE THAT KIND OF EFFORT, NOR IS IT APPARENT THAT MANY ORGANIZATIONS OR PERSONS WOULD, ABSENT A PROPERTY RIGHT.

THE GUARANTEE OF PATENT RIGHTS TO THE UNIVERSITY CARRIES WITH IT THE RIGHT TO LICENSE COMMERCIAL CONCERNS, THUS CREATING THE INCENTIVE NECESSARY FOR DEVELOPMENT IN THOSE SITUATIONS WHERE COLLABORATION WOULD NOT OTHERWISE BE ACCOMPLISHED AND LESSENING OR ELIMINATING INDUSTRY FEAR OF CONTAMINATION. FURTHER, UNDER SUCH A POLICY, COLLABORATIVE ARRANGEMENTS COULD BE MADE WHEREIN INDUSTRY'S PARTICIPATION IS PROTECTED BEFORE IT IS EVEN CLEAR WHETHER OR NOT INVENTIONS WILL BE MADE. SUCH PRIOR ARRANGEMENTS SHOULD MINIMIZE THE PROBLEM OF THE "NOT-INVENTED-HERE" SYNDROME, SINCE A COLLABORATOR WOULD NOT BE VIEWED AS AN "OUTSIDER." THE PROSPECT OF A ROYALTY RETURN IS MEANT TO ASSURE THE INVENTOR'S CONTINUED INVOLVEMENT.

IT IS BELIEVED THAT THE COMMITTEE'S RECOMMENDATIONS PROVIDE THE MEANS TO INDUCE VOLUNTARY INTEGRATION INTO A SYSTEM THAT WILL OPTIMIZE TECHNOLOGY TRANSFER THROUGH RECOGNITION OF THE EQUITIES OF ALL THE PARTIES.

TO A LARGE EXTENT THE SEPTEMBER 23RD RECOMMENDATIONS OF THE COMMITTEE ON GOVERNMENT POLICY ARE A RATIFICATION OF THE PRACTICES IMPLEMENTED BY DHEW SINCE 1969 AND THE NATIONAL SCIENCE FOUNDATION SINCE 1974. THE DHEW PRACTICES, IN TURN, WERE INITIATED IN PART THROUGH THE IMPETUS CREATED BY THE CRITICAL REMARKS FROM THE 1968 GAO STUDY MENTIONED PREVIOUSLY ON THE LACK OF TIMELINESS IN PROCESSING PETITIONS FOR WAIVERS OF IDENTIFIED INVENTIONS AND THE NEED TO CLARIFY THE USE OF INSTITUTIONAL PATENT AGREEMENTS WHICH GUARANTEE FUTURE INVENTION RIGHTS TO UNIVERSITIES WITH TECHNOLOGY TRANSFER CAPABILITIES.

IN OCTOBER 1974 THE DEPARTMENT COLLECTED SOME ROUGH STATISTICS ON MANAGEMENT OF PATENT RIGHTS LEFT TO UNIVERSITIES. THIS STUDY INDICATED THAT 167 PATENT APPLICATIONS WERE FILED SINCE 1969 BY INSTITUTIONS WHO CHOSE TO EXERCISE THEIR FIRST OPTION TO INVENTION RIGHTS UNDER THEIR INSTITUTIONAL PATENT AGREEMENT. UNDER THE 167 PATENT APPLICATIONS FILED, THE UNIVERSITIES HAVE NEGOTIATED 29 NONEXCLUSIVE LICENSES AND 43 EXCLUSIVE LICENSES. SEVENTEEN JOINT-FUNDING ARRANGEMENTS WITH COMMERCIAL ORGANIZATIONS, INVOLVING ONLY THE POSSIBILITY OF RIGHTS TO FUTURE INVENTIONS, HAVE BEEN MADE. THIS IS AN IMPORTANT STATISTIC, SINCE IT INDICATES A WILLINGNESS TO MAKE ARRANGEMENTS PRIOR TO THE TIME THAT INVENTIONS HAVE BEEN MADE ON THE BASIS THAT THE INSTITUTION HAS THE FLEXIBILITY OF PROVIDING TO THE CONCERN SOME INVENTION RIGHTS IF AN INVENTION SHOULD EVOLVE FROM THE JOINTLY FUNDED EFFORT. THE INSTITUTION GAINS THIS ABILITY TO NEGOTIATE BY VIRTUE OF ITS INSTITUTIONAL PATENT AGREEMENT. WE WERE ADVISED THAT ON THE BASIS OF ALL THE AGREEMENTS NOTED,

APPROXIMATELY 24 MILLION DOLLARS OF RISK CAPITAL MAY BE COMMITTED TO THE DEVELOPMENT OR MAKING OF INVENTIONS EVOLVING WITH DHEW SUPPORT.

UNDER OUR DEFERRED DETERMINATION POLICY, WHICH IS APPLICABLE TO ALL UNIVERSITIES WHO HAVE NOT YET ESTABLISHED A TECHNOLOGY TRANSFER CAPABILITY, IT WAS DETERMINED THAT SINCE JULY 1, 1968, 178 PETITIONS FOR WAIVER OF AN IDENTIFIED INVENTION HAVE BEEN REVIEWED AS OF OCTOBER 1974. OF THESE 178, 162 PETITIONS WERE GRANTED. UNDER THE 162 PETITIONS GRANTED, THE INSTITUTIONS INVOLVED AND RESPONDING HAVE, TO OCTOBER 1974 GRANTED 15 NONEXCLUSIVE LICENSES AND 35 EXCLUSIVE LICENSES. THESE LICENSES HAVE GENERATED A POSSIBLE COMMITMENT OF RISK CAPITAL OF AS MUCH AS 53 MILLION DOLLARS.

ONE OF THE PETITIONS GRANTED INVOLVED A BURN OINTMENT DISCOVERED AT A UNIVERSITY, WHICH WAS PATENTED FOR THE UNIVERSITY BY RESEARCH CORPORATION, LICENSED TO A PHARMACEUTICAL COMPANY, CLINICALLY TESTED UNDER THE DIRECTION OF THE COMPANY, AND CLEARED BY THE FOOD AND DRUG ADMINISTRATION ON THE COMPANY'S INITIATIVE. THE DRUG IS NOW COMMERCIALLY AVAILABLE. TO MY KNOWLEDGE, THIS IS THE ONLY DRUG OUTSIDE THE CANCER CHEMOTHERAPY PROGRAM WHICH WAS INITIALLY DISCOVERED WITH DEPARTMENT SUPPORT AND HAS REACHED THE MARKETPLACE THROUGH THE INVESTMENT OF RISK CAPITAL FROM THE DRUG INDUSTRY.

WE ARE AWARE OF AT LEAST FIVE OTHER DRUGS OUTSIDE CANCER CHEMOTHERAPY AT VARIOUS STATES OF DEVELOPMENT WHICH WERE DISCOVERED WITH DEPARTMENT SUPPORT AND ARE NOW BEING DEVELOPED WITH PRIVATE SUPPORT UNDER LICENSE, SOME OF WHICH ARE CLOSE TO MARKET CLEARANCE. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT.

MUCH MORE SIGNIFICANT THAN THE FIGURES INVOLVED (WHICH I BELIEVE HAVE INCREASED SINCE OCTOBER 1974) IS INFORMATION PROVIDED BY THE UNIVERSITY COMMUNITY INDICATING THAT IN THE LAST FOUR YEARS INDUSTRIAL ORGANIZATIONS HAVE BEEN ACTIVELY PURSUING UNIVERSITY RESEARCH. I BELIEVE THIS TO BE CLEARLY THE RESULT OF THE UNIVERSITY COMMUNITY'S ACTIVE SOLICITATION OF COLLABORATIVE ARRANGEMENTS, WHICH IN TURN WAS PARTLY MOTIVATED BY THE FLEXIBILITY PROVIDED BY OUR PATENT POLICY.

IT IS HOPED THAT THE GROWING SUCCESS OF THE DHEW EXPERIENCE WILL BE EXPANDED TO THE REST OF THE EXECUTIVE BRANCH THROUGH THE COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDATIONS OF SEPTEMBER 23RD.

I HAVE MADE REFERENCE TO A NUMBER OF STUDIES AND REPORTS IN MY STATEMENT, WHICH I INTEND TO MAKE AVAILABLE TO YOUR COMMITTEE. I WOULD ALSO BE PLEASED TO MAKE ANY OF THESE AVAILABLE TO ANYONE CONTACTING ME AT (301) 496-7056, OR AT THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND 20014.

APPROXIMATELY 24 MILLION DOLLARS OF RISK CAPITAL MAY BE COMMITTED TO THE DEVELOPMENT OR MAKING OF INVENTIONS EVOLVING WITH DHEW SUPPORT.

UNDER OUR DEFERRED DETERMINATION POLICY, WHICH IS APPLICABLE TO ALL UNIVERSITIES WHO HAVE NOT YET ESTABLISHED A TECHNOLOGY TRANSFER CAPABILITY, IT WAS DETERMINED THAT SINCE JULY 1, 1968, 178 PETITIONS FOR WAIVER OF AN IDENTIFIED INVENTION HAVE BEEN REVIEWED AS OF OCTOBER 1974. OF THESE 178, 162 PETITIONS WERE GRANTED. UNDER THE 162 PETITIONS GRANTED, THE INSTITUTIONS INVOLVED AND RESPONDING HAVE, TO OCTOBER 1974 GRANTED 15 NONEXCLUSIVE LICENSES AND 35 EXCLUSIVE LICENSES. THESE LICENSES HAVE GENERATED A POSSIBLE COMMITMENT OF RISK CAPITAL OF AS MUCH AS 53 MILLION DOLLARS.

ONE OF THE PETITIONS GRANTED INVOLVED A BURN OINTMENT DISCOVERED AT A UNIVERSITY, WHICH WAS PATENTED FOR THE UNIVERSITY BY RESEARCH CORPORATION, LICENSED TO A PHARMACEUTICAL COMPANY, CLINICALLY TESTED UNDER THE DIRECTION OF THE COMPANY, AND CLEARED BY THE FOOD AND DRUG ADMINISTRATION ON THE COMPANY'S INITIATIVE. THE DRUG IS NOW COMMERCIALLY AVAILABLE. TO MY KNOWLEDGE, THIS IS THE ONLY DRUG OUTSIDE THE CANCER CHEMOTHERAPY PROGRAM WHICH WAS INITIALLY DISCOVERED WITH DEPARTMENT SUPPORT AND HAS REACHED THE MARKETPLACE THROUGH THE INVESTMENT OF RISK CAPITAL FROM THE DRUG INDUSTRY.

WE ARE AWARE OF AT LEAST FIVE OTHER DRUGS OUTSIDE CANCER CHEMOTHERAPY AT VARIOUS STATES OF DEVELOPMENT WHICH WERE DISCOVERED WITH DEPARTMENT SUPPORT AND ARE NOW BEING DEVELOPED WITH PRIVATE SUPPORT UNDER LICENSE, SOME OF WHICH ARE CLOSE TO MARKET CLEARANCE. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT.