STATEMENT OF
OF
NORMAN J. LATKER
PATENT COUNSEL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE before the
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MAY 26, 1977

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE. MY OFFICE IS ASSIGNED TO THE BUSINESS AND ADMINISTRATIVE LAW DIVISION OF THE OFFICE OF GENERAL COUNSEL, WHICH HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION TO SPEAK TO THE OPERATION OF GOVERNMENT PATENT POLICY, AS I BELIEVE IT TO BE A FUNDAMENTAL CONCERN TO THE LARGER ISSUES OF:

MAINTAINING A FAVORABLE BALANCE OF PAYMENT AND TRADE FOR OUR RESEARCH INTENSIVE INDUSTRIES,

ENHANCING TECHNOLOGY TRANSFER, AND

QUESTIONS OF INDUSTRIAL CONCENTRATION AND CONSUMER PRICES.

IN MOST PART I HOPE TO UTILIZE THESE MOMENTS AS BEST I CAN TO SUGGEST THE IMPORTANCE OF PATENT PROTECTION IN BRINGING

TECHNOLOGY ARISING FROM GOVERNMENT SPONSORED RESEARCH AT UNIVERSITIES AND NON-PROFIT ORGANIZATIONS TO FRUITION. THIS IS AN AREA OF VITAL INTEREST TO HEW, SINCE THE DEPARTMENT IS THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH I" THE UNITED STATES, AND THE SUBSTANTIAL PORTION OF ITS RESEARCH BUDGET IS DEVOTED TO THIS CATEGORY OF RESEARCH.

THE MOST OBVIOUS PROBLEM AFFECTING ULTIMATE UTILIZATION OF INNOVATIONS RESULTING FROM DHEW FUNDED RESEARCH AT UNI-- VERSITIES AND OTHER NON-PROFIT ORGANIZATIONS IS THE FACT THAT THESE ORGANIZATIONS DO NOT ENGAGE IN THE DIRECT DEVELOPMENT AND MANUFACTURE OF COMMERCIAL EMBODIMENTS, AND IT IS INDUSTRY WHICH MUST BRING SUCH INNOVATION TO THE MARKETPLACE.

A FUNDAMENTAL PREMISE OF DHEW PATENT POLICY AND PRACTICE IS THE UNDERSTANDING THAT INHERENT TO THE TRANSFER OF THE INNOVATIVE RESULTS OF THE RESEARCH CONDUCTED IN UNIVERSITY LABORATORIES TO INDUSTRIAL DEVELOPERS IS A DECISION ON THE PART OF THE DEVELOPER THAT THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING OFFERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS RISK INVESTMENT. OF COURSE, NOT ALL TRANSFERS OF POTENTIALLY MARKETABLE INNOVATIONS FROM SUCH LABORATORIES REQUIRE AN EXCHANGE OF INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION, BUT IT IS UNPREDICTABLE IN WHICH TRANSFERS THE

ENTREPRENEUR WILL DEMAND AN EXCHANGE TO GUARANTEE ITS COLLABORATIVE AID. NOTWITHSTANDING, WHERE SUBSTANTIAL RISK INVESTMENT IS INVOLVED, SUCH AS REQUIRED IN DEVELOPING CLINICAL DATA FOR PRE-MARKET CLEARANCE OF POTENTIAL THERAPEUTIC AGENTS AND MEDICAL DEVICES, WHICH IS RARELY UNDERTAKEN IN ITS ENTIRETY AT GOVERNMENT EXPENSE, THERE IS AN IDENTIFIED LIKELIHOOD THAT TRANSFER WILL NOT OCCUR IF THE ENTREPRENEUR IS NOT AFFORDED SOME PROPERTY PROTECTION IN THE INNOVATION OFFERED FOR DEVELOPMENT. THIS POINT WAS MADE WITH SOME FORCE TO DHEW AFTER A 1968 GAO INVESTIGATION AND REPORT ON "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY."[1/] THIS LIKELIHOOD SEEMS EVEN MORE PREDICTABLE WHEN CONSIDERING THE EXTRAORDINARY ESCALATION IN THE ESTIMATED AVERAGE COST OF SUCCESSFULLY DEVELOPING A NEW DRUG FROM $534,000 IN 1962 TO 11.5 MILLION DOLLARS IN 1973 OR 24.4 MILLION DOLLARS WHEN INCLUDING THE COST OF RESEARCH ON PROJECTS WHICH DID NOT RESULT IN MARKETED DRUGS.[2/] ECONOMIST DAVID SCHWARTZMAN, WHO DEVELOPED THESE STATISTICS, AND OTHERS WHO HAVE REVIEWED THEM FURTHER AGREE THAT RETURN ON SUCH R & D

1/ PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT SPONSORED RESEARCH IN MEDICINAL CHEMISTRY, AUGUST 12, 1968, GAO REPORT B-164031(2).

2/ SCHERER, "THE ECONOMIC EFFECT OF MANDATORY PATENT LICENSING," P. 59, U. S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION, PUBLIC MEETING 1/12/77 AND SCHWARTZMAN, "INNOVATION IN THE PHARMACEUTICAL INDUSTRY," P. 66, 70 and 71.

INVESTMENT HAS FALLEN SHARPLY SINCE 1960 TO AS LOW AS POSSIBLY 3.3 PERCENT.[3/] WHEN IT IS RECOGNIZED THAT COSTS TO SECOND ENTRANTS INTO THE MARKET AFTER PATENT EXPIRATION ARE A SMALL FRACTION OF THE ORIGINAL DEVELOPER'S COSTS, SINCE THE SECOND ENTRANT NEED NOT UNDERTAKE THE SAME R & D RISK, IT IS DIFFICULT TO DISAGREE WITH SCHWARTZMAN'S COMMENT THAT, "WITHOUT PATENTS THE RETURN FROM INVESTMENT IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT WOULD FALL TO ZERO, AND PRIVATE COMPANIES WOULD NO LONGER ENGAGE IN RESEARCH AND DEVELOPMENT."[4/] THIS HAS BEEN ILLUSTRATED BY THE IMMEDIATE MARKET ENTRY OF COMPETITORS UPON EXPIRATION OF PATENTS ON WIDELY SOLD ANTIBIOTICS, WHERE SUCH COMPETITION DOES NOT EMERGE UNDER SIMILAR CONDITIONS IN THE AIRCRAFT OR AUTOMOTIVE INDUSTRIES WHERE COST OF DUPLICATING THE ORIGINAL DEVELOPER ARE NEARER EQUIVALENT.

THE DEPARTMENT HAS VIEWED ITS ROLE IN THE NATION'S MEDICAL RESEARCH EFFORT AS COMPLEMENTARY TO THE ACTIVITIES OF THE OTHER ELEMENTS WITHIN OUR SOCIETY, BOTH PUBLIC AND PRIVATE, THAT ALSO SUPPORT SUCH RESEARCH AND DEVELOPMENT. IT HAS SEEMED TO THE DEPARTMENT THAT THE INTERESTS OF THE AMERICAN PEOPLE ARE BEST SERVED WHEN THE VARIOUS ELEMENTS OF THIS MEDICAL RESEARCH STRUCTURE CAN INTERACT. THE MOST EFFECTIVE INTER-

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3/ IBID P. 160, SCHWARTZMAN AND HENRY G. GRABOWSKI; DUKE UNIVERSITY.

4/ IBID P. 4, SCHWARTZMAN.

RELATIONSHIP RESULTS WHEN THE PARTICULAR CAPABILITIES OF THE VARIOUS ELEMENTS, FEDERAL AND NON-FEDERAL, CAN BE UTILIZED TO THE FULLEST EXTENT.[5/] IT SEEMS CLEAR THAT THIS COLLABORATIVE RELATIONSHIP CAN ONLY EXIST IF EACH ELEMENT RECOGNIZES TO THE EXTENT FEASIBLE THE FUNDAMENTAL NEEDS OF THE OTHER ELEMENTS.

IN THIS SPIRIT DHEW HAS CONSCIOUSLY MADE EFFORTS TO CLOSE THE IDENTIFIED GAP BETWEEN THE FUNDAMENTAL INNOVATORS THE DEPARTMENT SUPPORTS AND THE PRIVATE INDUSTRIAL DEVELOPERS WHO MAY BE NECESSARY TO THE DELIVERY OF END ITEMS TO THE MARKET-PLACE. THE STAKE IN CLOSING THIS GAP IS VERY HIGH. IN 1975 APPROXIMATELY 3.2 OF THE 13 BILLION DOLLARS, OR ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES. THE MAIN THRUST OF DEPARTMENT PATENT POLICY AS APPLIED TO UNIVERSITIES HAS BEEN DIRECTED TOWARD:

1. ESTABLISHMENT OF PATENT MANAGEMENT FOCAL POINT IN THE INNOVATING ORGANIZATION TRAINED TO ELICIT INVENTION REPORTS AND ESTABLISH RIGHTS IN INTELLECTUAL PROPERTY ON A TIMELY BASIS FOR POSSIBLE

5/ TESTIMONY BY DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BEFORE THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMMITTEE ON THE JUDICIARY, AUGUST 17, 1965.

LICENSING OF INDUSTRIAL DEVELOPERS. THIS HAS BEEN ACCOMPLISHED IN THE MAIN BY EXECUTION OF INSTITUTIONAL PATENT AGREEMENTS (IPA) WITH UNIVERSITIES WILLING TO CREATE AND MAINTAIN SUCH A FOCAL POINT. THE IPA PROVIDES AS AN INCENTIVE TO ESTABLISHMENT OF A PATENT FOCAL POINT, A FIRST OPTION TO OWN ALL FUTURE INVENTIONS ARISING FROM DHEW GRANT SUPPORTED RESEARCH. WE PRESENTLY HAVE 70 IPA, AND

2. ASSURANCE THAT THE INNOVATING GROUP HAS THE RIGHT TO CONVEY WHATEVER INTELLECTUAL PROPERTY RIGHTS ARE NECESSARY TO ACCOMPLISH A TRANSFER TO AN INDUSTRIAL DEVELOPER. (THIS IS ACCOMPLISHED IN THE MAIN THROUGH THE IPA HOLDERS' FIRST OPTION TO OWN HEW-FUNDED INVENTIONS AND OUR WAIVER PROGRAM, WHICH PROVIDES FOR OWNERSHIP IN PETITIONING UNIVERSITIES NOT HAVING AN IPA WHO COME FORTH WITH AN ACCEPTABLE DEVELOPMENT PROGRAM FOR AN IDENTIFIED INVENTION.)

DHEW HAS CAREFULLY CIRCUMSCRIBED THE CONDITIONS OF LICENSING WITHIN WHICH A UNIVERSITY PATENT MANAGEMENT FOCAL POINT OR SUCCESSFUL PETITIONER CAN FUNCTION. THESE CONDITIONS HAVE

BECOME WELL KNOWN TO INDUSTRIAL DEVELOPERS AND HAVE BEEN GRADUALLY ACCEPTED IN LICENSING ARRANGEMENTS BY A WIDENING CIRCLE OF SUCH DEVELOPERS. THIS COMPARES TO THE VIRTUAL BOYCOTT REPORTED BY GAO OF DEVELOPMENT OF NIH GENERATED DRUG LEADS BY INDUSTRY DURING THE 1962-1968 PERIOD COVERED BY THEIR REPORT. A MUCH MORE DETAILED DISCUSSION OF THE PHILOSOPHY BEHIND THE DEPARTMENT'S PATENT POLICY WAS MADE IN MY TESTIMONY BEFORE YOUR SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS ON SEPTEMBER 29, 1976.

SINCE 1969 THROUGH THE FALL OF 1974 WE ESTIMATE THAT THE INTELLECTUAL PROPERTY RIGHTS TO 329 INNOVATIONS EITHER INITIALLY GENERATED, ENHANCED OR CORROBORATED IN PERFORMANCE OF DHEW-FUNDED RESEARCH WERE IN THE HANDS OF UNIVERSITIES' PATENT MANAGEMENT OR SUCCESSFUL UNIVERSITY PETITIONERS FOR THE PURPOSE OF SOLICITING FURTHER INDUSTRIAL DEVELOPMENT SUPPORT. WE WERE ADVISED THAT DURING THE 1969-1974 PERIOD THESE UNIVERSITIES HAD NEGOTIATED 44 NON-EXCLUSIVE AND 78 EXCLUSIVE LICENSES UNDER PATENT APPLICATIONS FILED ON THE 329 INNOVATIONS. WE UNDERSTAND THAT THE 122 LICENSES NEGOTIATED HAD GENERATED COMMITMENTS IN THE AREA OF 75 MILLION DOLLARS OF PRIVATE RISK CAPITAL. SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES HAS SUBSTANTIALLY INCREASED TO 517.

I HAVE ATTACHED TO THESE COMMENTS SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING INVOLVES COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 80 MILLION DOLLARS. AS YOU WILL NOTE, THERE ARE A NUMBER OF PHARMACEUTICAL PRODUCTS ON THIS LIST. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT OF 1968. I WOULD CONJECTURE THAT THIS NUMBER WILL INCREASE IN SUBSEQUENT YEARS DUE TO THE OPPORTUNITY OF THE PHARMACEUTICAL INDUSTRY TO CAPITALIZE ON POSITIVE LEADS FROM THE NON-PROFIT SECTOR WHICH COULD RESULT IN REDUCTION OF THE INDUSTRY'S ESCALATING R & D COSTS BY ELIMINATING A NUMBER OF BLIND LEADS. (THE ULTIMATE SAVING WOULD BE THE DIFFERENCE BETWEEN THE 11.5 AND 24.4 MILLION DOLLARS PER SUCCESSFUL DRUG DEVELOPMENT MENTIONED PREVIOUSLY.) THE RISE IN SUCCESSFUL DEVELOPMENT BY INDUSTRY OF UNIVERSITY GENERATED INVENTIONS IS ALSO CONSIDERED SIGNIFICANT WHEN NOTING THE STEADY DECLINE IN INTRODUCTION OF NEW DRUG ENTITIES IN THE UNITED STATES FROM 65 IN 1959 TO 15 IN 1975.[6/] THIS SLIDE MIGHT ALSO BE ATTRIBUTED TO THE INCREASED COST OF DRUG DEVELOPMENT.

6/ PHARMACEUTICAL TIMES, APRIL 1976 (BASED ON DATA FROM PAUL de HAEN, INC.) AND HENRY G. GRABOWSKI, "DRUG REGULATION AND INNOVATION IN EMPIRICAL EVIDENCE AND POLICY OPTIONS," AMERICAN ENTERPRISE FOR PUBLIC POLICY RESEARCH, WASHINGTON, D. C.

IN THIS CONTEXT IT IS APPARENT THAT THE EXISTENCE OF A LICENSABLE PATENT RIGHT IS PROBABLY A PRIMARY FACTOR IN THE SUCCESSFUL TRANSFER OF A UNIVERSITY INNOVATION TO INDUSTRY AND THE MARKETPLACE, AND FAILURE TO PROTECT SUCH RIGHT MAY FATALLY AFFECT A TRANSFER OF A MAJOR HEALTH INNOVATION.

I BELIEVE SOME MEMBERS OF THE COMMITTEE ARE AWARE OF THE SPECULATION THAT PRIVATE DEVELOPMENT AND MARKETING OF PENICILLIN WAS FORECLOSED FOR OVER 11 YEARS DUE TO THE LACK OF A PROPRIETARY POSITION NECESSARY TO THE PROTECTION OF THE LARGE RISK INVESTMENT INVOLVED.[7/] IT WAS ONLY AFTER THE UNITED STATES GOVERNMENT UNDERTOOK THIS RISK UNDER THE PRESSURE OF WORLD WAR II THAT PENICILLIN's CURATIVE POWERS WERE MADE AVAILABLE TO THOSE SUFFERING FROM INFECTION.

IN ADDITION TO INITIAL ADMINISTRATION OF THE IPA AND WAIVER PROGRAM DISCUSSED, THE DHEW PATENT BRANCH ACTS AS THE PATENT MANAGEMENT FOCAL POINT FOR ALL INNOVATIONS TO WHICH THE DEPARTMENT RETAINS TITLE. THE DEPARTMENT'S PATENT PORTFOLIO PRESENTLY CONSISTS OF APPROXIMATELY 400 PATENTS AND PATENT APPLICATIONS, WHICH IN THE MAIN ARE DERIVED FROM DHEW EMPLOYEE INVENTIONS. A LESSER NUMBER ARE ATTRIBUTABLE TO INVENTIONS MADE BY EMPLOYEES OF UNIVERSITIES OR COMMERCIAL CONCERNS FUNDED

7/ DAVID MASTERS, MIRACLE DRUG, THE HISTORY OF PENICILLIN, PUBLISHED BY GYRE & SPOTTI, WOODE, LONDON (1946), PP. 104-105 AND
THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS, FORMAN, EDITOR, PUBLISHED BY CENTRAL BOOK CO., NEW YORK (1967).

BY DHEW GRANTS OR CONTRACTS WHICH THEY DID NOT CHOOSE TO MANAGE OR WERE NOT PERMITTED TO MANAGE. SINCE 1969 WE HAVE GRANTED 19 EXCLUSIVE LICENSES AND 90 NON-EXCLUSIVE LICENSES UNDER OUR PATENT PORTFOLIO. UNFORTUNATELY, WE HAVE NO STATISTICS ON THE AMOUNT OF RISK CAPITAL COMMITTED TO DEVELOPING THESE INVENTIONS TO THE MARKETPLACE, THOUGH WE BELIEVE IT TO BE SURELY MEASURED IN MILLIONS OF DOLLARS.