Norman

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Senator Adlai E. Stevenson
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LAST YEAR THE U.S. TRADE DEFICIT REACHED $28.5 BILLION. THE DOLLAR DECLINED. THE INTERNATIONAL MONETARY SYSTEM COLLAPSED. THE NATION CONTINUED TO SUFFER FROM INFLATION AND UNEMPLOYMENT.

CONVENTIONAL WISDOM ASSIGNS THE TRADE DEFICIT TO OIL IMPORTS. BUT NEARLY 40 PERCENT OF THAT DEFICIT IS WITH JAPAN, AND JAPAN IS NOT AN OIL EXPORTING COUNTRY. IT IS MORE DEPENDENT ON FOREIGN OIL THAN THE UNITED STATES.

OUR ECONOMIC MALADIES ARE ROOTED IN FAILURE TO FACE REALITIES OF GLOBAL INTERDEPENDENCE AND FIERCE COMPETITION FOR THE WORLD'S MARKETS AND SUPPLIES. INSTEAD OF FACING UP TO THE CHALLENGES OF A NEW ERA, WASHINGTON IS SERVING UP PRESCRIPTIONS BETTER SUITED TO THE BEHAVIOR OF MARKETS AND NATIONS IN THE 18TH CENTURY. INSTEAD OF REVITALIZING THE U.S. ECONOMY BY REVIVING OUR FLAGGING PRODUCTIVITY AND COMPETITIVENESS, IT PROPOSES TO DEPRESS THE ECONOMY FURTHER. INSTEAD OF STIMULATING U.S. EXPORTS, THERE IS TALK OF RESTRAINING DEMAND FOR IMPORTS, REDUCING TRADE AND COMMERCE AROUND THE WORLD, AS WELL AS AT HOME. THIS IS ECONOMIC AND POLITICAL FOLLY. WORLD ECONOMIC GROWTH, TRADE EXPANSION, TECHNICAL ASSISTANCE AND FINANCING FOR DEVELOPING ECONOMIES ARE NOT THE STUFF OF CHARITY. THEY ARE ELEMENTS OF A REALISTIC APPROACH TO ECONOMIC INTERDEPENDENCE IN AN UNSTABLE WORLD. THE TURMOIL WHICH

ACCOMPANIES POVERTY AND DISAPPOINTED EXPECTATIONS CAN ONLY BENEFIT OUR ADVERSARIES, AS EVENTS IN THE NEAR EAST AND THE HORN OF AFRICA ALREADY SUGGEST.

AMERICA'S DEVELOPMENT WAS FUELED BY CHEAP LABOR AND MONEY, ABUNDANT FUEL AND RAW MATERIALS, AS WELL AS OUR MUCH TOUTED YANKEE INGENUITY. THE COUNTRY EXPLOITED ITS ASSETS TO ACHIEVE A PREDOMINANCE THAT WAS UNCHALLENGED AND, FOR A TIME, SEEMED UNCHALLENGEABLE. ALL THAT IS CHANGED.

BUT THE WAYS WE CONDUCT OUR COLLECTIVE BUSINESS HAVE NOT CHANGED.

IN THE DECADES AFTER THE CIVIL WAR, INDUSTRIALIZATION AND THE OPENING OF THE WEST SOAKED UP THE "GREENBACKS" PRINTED TO FINANCE IT. INFLATION IS AN INVENTION OF RECENT TIMES. WE DID NOT SUFFER ESCALATING PRICES UNTIL WE LOST SOME OF OUR VISION AND SELF-CONFIDENCE. AND I DARESAY WE WON'T DEFEAT INFLATION UNTIL WE AGAIN BECOME A NATION OF BUILDERS, PRODUCERS, AND INVENTORS. INSTEAD OF GOING ALL OUT TO BEAT THE FOREIGN COMPETITION, EXPAND PRODUCTION, AND SPUR PRODUCTIVITY, THE U.S. IS TAKING COVER BEHIND PROTECTIONISM AS IT DID IN THE '20'S. IT IS KILLING INVESTMENT WITH 13 PERCENT INTEREST RATES AND SUPPRESSED DEMAND FOR GOODS AND SERVICES -- EVEN THOUGH EXCESSIVE DEMAND IS NOT THE SOURCE OF INFLATION.

TODAY THERE IS SCARCELY AN INDUSTRIAL SECTOR WHICH DOES NOT FACE VIGOROUS COMPETITION FROM ABROAD. IN THREE DECADES THE JAPANESE AND THE EUROPEANS HAVE RECOVERED FROM WORLD WAR II TO CHALLENGE OUR DOMINANCE EVEN IN THOSE INDUSTRIES WHERE WE HAD NO PEERS -- ELECTRONICS, COMMUNICATIONS AND AVIATION. JAPAN IS TAKING STEPS TO SURPASS US IN INTEGRATED CIRCUITS AND COMPUTERS, THE HIGHEST OF HIGH TECHNOLOGIES. THE FRENCH, GERMANS AND JAPANESE ARE MAKING RAPID STRIDES IN SATELLITE COMMUNICATION SYSTEMS, WHILE THE U.S. LACKS THE IMAGINATION TO EXPLOIT THE SPACE SHUTTLE IT WILL LAUNCH NEXT YEAR. AMERICAN INDUSTRY IS ABANDONING SUCH PRODUCTS AS VIDEO TAPE RECORDERS TO ITS COMPETITORS AND FAILING TO DEVELOP INDUSTRIES FOR THE FUTURE SUCH AS COMPUTER AIDED MANUFACTURING AND ADVANCED AIRCRAFT TECHNOLOGIES.

NOW THE INDUSTRIALIZED NATIONS FACE A WAVE OF COMPETITION FROM DEVELOPING COUNTRIES COMBINING LOW LABOR COSTS AND NATURAL RESOURCES WITH TECHNOLOGY AND PRIORITIES THAT RANK SOCIAL BENEFITS BEHIND DEVELOPMENT. SIX OF THE SO-CALLED LDCs MORE THAN TRIPLED THEIR SHARE OF WORLD MANUFACTURING EXPORTS BETWEEN 1963 AND 1976, FROM 1.5 PERCENT TO 5 PERCENT.

THIS IS A RICH AND RESOURCEFUL COUNTRY, BUT IT IS NOT WELL LED. OUR SPIRIT OF ADVENTURE AND INVENTION MAY BE DRYING UP. NATIONS FAIL WHEN THAT HAPPENS. IF ALL WE CAN OFFER OURSELVES BY WAY OF INSPIRATION IS A BALANCED BUDGET IN 1981, THEN SURELY THE DECLINE HAS SET IN.

THE UNITED STATES MUST AROUSE ITSELF. IF IT IS TO PROSPER, RESTORE ITS AUTHORITY IN THE WORLD AND RISE TO HIGH ENDEAVORS, IT MUST MAINTAIN A PREEMINENT CAPACITY TO PUSH AHEAD THE FRONTIERS OF KNOWLEDGE AND APPLY THE RESULTS. IT HAS THE INTELLECTUAL CAPACITY TO ADVANCE SCIENCE AND TECHNOLOGY. IT HAS THE FINANCIAL RESOURCES FOR PRODUCTIVE INVESTMENT. IT HAS THE ENTREPRENEURIAL AND MARKETING SKILLS FOR WORLD TRADE. BUT THE WILL MAY BE SAPPED BY THE OUTDATED ORTHODOXIES OF ECONOMICS AND POLITICS, INADEQUATE FINANCIAL INCENTIVES, EXCESSIVE REGULATION, AND ALL THE PRESSURES TO COPE WITH THE IMMEDIATE AT THE EXPENSE OF POSTERITY.

AFTER TWO YEARS OF HEARINGS AND STUDIES BY THE SENATE SUBCOMMITTEE ON INTERNATIONAL FINANCE, I WILL SOONISSUE A REPORT THAT DOCUMENTS THE EROSION OF OUR COMPETITIVE POSITION. I WILL ALSO INTRODUCE LEGISLATION TO ESTABLISH A STRONG EXPORT POLICY FOR THE UNITED STATES. I WANT TO GENERATE AN EXPORT FEVER, A WILL TO COMPETE. IT IS CRUCIAL TO THE NATION AND THIS STATE, THE NATION'S LARGEST EXPORTER. OVER 600,000 ILLINOIS JOBS, ROUGHLY ONE IN FIVE, ARE EXPORT-RELATED. FOREIGN SHIPMENTS OF OUR MANUFACTURED PRODUCTS ARE VALUED AT $7.5 BILLION.

OUR AGRICULTURAL EXPORTS REACHED $2.5 BILLION IN FISCAL 1977. THESE FIGURES REPRESENT A SOLID ACHIEVEMENT, BUT THEY SHOULD BE ONLY A BEGINNING.

TODAY I WANT TO CONFINE MY COMMENTS ABOUT WHAT NEEDS TO BE DONE TO TECHNOLOGICAL INNOVATION IN AMERICA -- PROBABLY THE MOST CRITICAL ELEMENT OF OUR COMPETITIVENESS IN WORLD MARKETS. IN THIS CENTURY, THE DEVELOPMENT OF NEW PRODUCTS, SERVICES AND INDUSTRIAL PROCESSES BASED ON ADVANCES IN KNOWLEDGE CONTRIBUTED MORE THAN ANYTHING ELSE TO THE NATION'S PRODUCTIVITY GROWTH AND TRADE PERFORMANCE. WITH THE RATE OF GROWTH DECLINING AND THE U.S. BALANCE OF TRADE TURNING NEGATIVE WE FIND THAT INNOVATION IS LAGGING. THE GROWTH INDUSTRIES IN OUR COUNTRY ARE LAW, ACCOUNTING, CONSULTING AND, OF COURSE, GOVERNMENT ITSELF. THE U.S. MANUFACTURING SECTOR, ONCE THE MOST VITAL IN THE WORLD, LANGUISHES.

IN STEEL AND OTHER SECTORS AMERICAN COMPANIES HAVE FAILED TO ADOPT TECHNOLOGIES WHOSE FEASIBILITY, AND PAY-OFFS HAVE BEEN CLEARLY DEMONSTRATED BY THE JAPANESE AND WEST GERMANS.

HIGH RISK VENTURES THAT OVER A LONG TERM LEAD TO NEW MARKETS AND NEW INDUSTRIES HAVE BEEN DISCOURAGED. INDUSTRY IS SHIFTING INVESTMENT FROM BASIC RESEARCH AND INNOVATION TO MINOR PRODUCT AND PROCESS DEVELOPMENT. EXECUTIVES PLAN FOR THE NEXT YEAR'S PROFIT AND LOSS STATEMENT AND NEGLECT THE NEXT DECADE.

SMALL, HIGH TECHNOLOGY COMPANIES HAVE INTRODUCED A DISPROPORTIONATE SHARE OF NEW PRODUCTS AND MANUFACTURING TECHNIQUES. A DECADE AGO HUNDREDS OF VENTURE COMPANIES ENTERED THE STOCK MARKET WITH NEW ISSUES EACH YEAR. IN 1977 THERE WERE 46. AT THE SAME TIME AS PRIVATE SECTOR SUPPORT FOR INNOVATION HAS DECLINED, FEDERAL GOVERNMENT EXPENDITURES FOR R & D HAVE DROPPED MORE THAN 16% OVER THE LAST DECADE.

THESE TRENDS DO NOT SIGNAL OUR LOSS OF TECHNOLOGICAL LEADERSHIP ACROSS THE BOARD. BUT THEY ARE A WARNING. IF INNOVATION IS NOT ENCOURAGED, THE ECONOMY WILL STAGNATE, INFLATION WILL CONTINUE.

THE SECRETARY OF COMMERCE AND HER ASSISTANT SECRETARY FOR SCIENCE AND TECHNOLOGY HAVE CONVENED A SCORE OF TASK FORCES TO STUDY INNOVATION AND INFLUENCES RANGING FROM TAX AND REGULATORY POLICY TO PATENT ADMINISTRATION AND INFORMATION SERVICES. BUT WE CANNOT DEPEND ON THIS REVIEW ALONE TO PROVIDE ANSWERS. ORGANIZATION AND PROCESS FREQUENTLY OVERWHELM SUBSTANCE IN THE BUREAUCRACY, STIFLING ORIGINALITY IN A RUSH TO REACH A CONSENSUS THAT APPEASES THE TECHNOCRATS IN OMB.

A YEAR AGO THE SENATE SUBCOMMITTEE ON SCIENCE, TECHNOLOGY AND SPACE BEGAN A REVIEW OF AMERICAN INDUSTRIAL TECHNOLOGY. IT CONTINUES. AND WE NEED YOUR SUGGESTIONS. OUR FINDINGS ARE TENTATIVE. BUT WE INTEND THIS YEAR TO MAKE RECOMMENDATIONS FOR A NEW FEDERAL COMMITMENT TO INNOVATION.

PATENTS PLAY A MAJOR ROLE IN THIS PROCESS AND HAVE SINCE THE FOUNDING OF THE REPUBLIC. BUT THE PATENT OFFICE HAS LONG REGARDED ITSELF AS A REPOSITORY RATHER THAN A RESOURCE. OUR COMMISSIONER HAS BEGUN TO CHANGE THAT. PATENT FILES ARE A POTENTIAL GOLDMINE OF NOT JUST TECHNICAL DATA, BUT INDICATORS OF BUSINESS OPPORTUNITIES AND PROSPECTIVE FOREIGN COMPETITION. THE COMMISSIONER HAS OBTAINED ACCESS TO PATENT INFORMATION IN NEARLY ALL THE INDUSTRIALIZED COUNTRIES, AND I COMMEND HIM FOR HIS INITIATIVE IN MAKING THIS DATA AVAILABLE. IT WILL BE USEFUL TO GOVERNMENT DECISION-MAKERS, INVESTORS, R & D MANAGERS, INVENTORS AND BUSINESS EXECUTIVES ALIKE.

IDEALLY, PATENT OFFICE REPORTS SHOULD BE PART OF A SOPHISTICATED WORLD-WIDE INDUSTRIAL INFORMATION SYSTEM COORDINATED BY THE DEPARTMENT OF COMMERCE. THE GOVERNMENT'S PRESENT CAPABILITIES COMPARE POORLY WITH THE NEED FOR ASSESSMENTS OF SECTORAL PROBLEMS, EVALUATIONS OF COMMERCIAL POTENTIAL OF NEW TECHNOLOGIES, IDENTIFICATION OF EXPORT OPPORTUNITIES AND FOREIGN INDUSTRIAL INTELLIGENCE.

TECHNOLOGY TRANSFER IS A TWO WAY STREET. FOREIGN NATIONS HAVE SUCCESSFULLY EXPLOITED OUR INVENTIONS; JUST AS AGGRESSIVELY, THE U.S. MUST SEEK OUT AND ACQUIRE TECHNOLOGIES FROM ABROAD. WHILE CONGRATULATING OURSELVES FOR OUR MOON LANDINGS, WE LOSE SIGHT OF THE FACT THAT TWO-THIRDS OF ALL RESEARCH AND DEVELOPMENT TODAY IS PERFORMED IN FOREIGN COUNTRIES.

THE ACTIVITIES OF ECONOMISTS, TECHNICIANS, BUSINESS STRATEGISTS AND TRAINED FOREIGN SERVICE OFFICERS SHOULD BE COORDINATED IN OUR GOVERNMENT TO HELP INFORM DECISIONS ABOUT R & D INVESTMENTS, EXPORT CONTROLS, REGULATIONS, TAX POLICY AND ANTI-TRUST ACTIONS. THE ROLE OF GOVERNMENT IN PROVIDING INFORMATION AND ADVICE TO PRIVATE INDUSTRY, PARTICULARLY SMALL AND MEDIUM SIZE BUSINESSES, SHOULD NOT BE NEGLECTED.

INDEED, THE TIME HAS COME TO PUT THE ADVERSARIAL RELATIONSHIP BETWEEN GOVERNMENT AND INDUSTRY BEHIND US. OTHER NATIONS ARE NOT SO FASTIDIOUS ABOUT COOPERATION. THEY COORDINATE INDUSTRIAL R & D ACTIVITIES SO THAT COMPANIES CAN SHARE INFORMATION AND AVOID DUPLICATION OF EFFORT IN ORDER TO PUSH AHEAD.

IN THE PAST OUR OWN COMPARATIVE ADVANTAGE IN TECHNOLOGY OFTEN RESULTED FROM THE GOVERNMENT'S ROLE AS A SUPPORTER AND PROCURER OF R & D. THE COMMERCIAL BENEFITS OF MILITARY AND SPACE PROGRAMS FOR ELECTRONICS, JET AIRCRAFT AND TELECOMMUNICATIONS CAME LARGELY BY COINCIDENCE. TODAY COMPANIES AND UNIVERSITIES AVOID GOVERNMENT CONTRACT RESEARCH AND DEVELOPMENT BECAUSE OF RED TAPE, CONFLICT OF INTEREST RULES AND RESTRICTIVE LICENSING AND PATENT POLICIES.

IMAGINE WHAT WE MIGHT ACCOMPLISH IF WE SET OUR MIND TO DEVELOPING TECHNOLOGIES, NOT ALONE FOR MILITARY AND OTHER GOVERNMENT OBJECTIVES BUT FOR OUR COMMERCIAL AND INDUSTRIAL

MIGHT. I WILL PROPOSE INSTITUTES TO BRING INDUSTRY, GOVERNMENT AND UNIVERSITIES TOGETHER IN A NEW COOPERATIVE EFFORT TO IDENTIFY MARKETS, DEVELOP THE PROCESSES AND PRODUCTS TO EXPLOIT THEM AND CREATE NEW ENTERPRISES.

THIS NOTION OF COOPERATION FOR PRIVATE AND PUBLIC GAIN IS AT ODDS WITH THE LAISSEZ FAIRE ATTITUDES OF THE RIGHT AND LEFT. IT MAY FALL VICTIM TO THE PREVAILING TENDENCY TO CAST EVERY ISSUE IN BLACK OR WHITE, BUT I CAN REPORT SOME HOPEFUL SIGNS. NASA IS CONSIDERING NEW WAYS TO INVOLVE THE PRIVATE SECTOR IN DEVELOPMENT OF THE SPACE SHUTTLE ERA. THE PROSPECT OF SIXTY SHUTTLE FLIGHTS A YEAR OPENS BOLD NEW OPPORTUNITIES FOR REMOTE SENSING, COMMUNICATIONS, ELECTRIC POWER GENERATION AND EVEN SPACE MANUFACTURING. U.S. INDUSTRY AND PRIVATE CAPITAL SHOULD BE ALLOWED TO DEVELOP AND MARKET THESE GOODS AND SERVICES.

LEGISLATION HAS BEEN INTRODUCED IN THE SENATE TO ESTABLISH A UNIFORM PATENT POLICY THAT WOULD PROMOTE THE COMMERCIALIZATION OF GOVERNMENT SUPPORTED INVENTIONS. IT AVAILS THE GOVERNMENT LITTLE TO INSIST UPON TITLE TO PATENTS THAT GO UNUSED. PATENT POLICY WILL RECEIVE ATTENTION IN THIS CONGRESS. SOME MEANS SHOULD BE CONTRIVED TO GIVE GRANTEES TITLE BUT ALSO PROVIDE BENEFITS TO THE TAXPAYERS AFTER INVESTOR AND INVENTOR HAVE BEEN AMPLY REWARDED.

THE NEW CAPITAL GAINS RATES WILL HELP RESTORE A FAVORABLE ECONOMIC CLIMATE FOR THE CREATION AND GROWTH OF HIGH TECHNOLOGY COMPANIES. BUT MORE SPECIFIC TAX INCENTIVES MAY BE NECESSARY. THEY ARE USED TO GOOD EFFECT IN OTHER COUNTRIES. WE OUGHT TO ESTABLISH DEPRECIATION SCHEDULES THAT GO BEYOND RECOVERY OF THE COST FOR SUCCESSFUL VENTURES. WE ARE ALSO EVALUATING EXPERIMENTAL PROGRAMS OF THE NATIONAL SCIENCE FOUNDATION TO SEE IF DIRECT GOVERNMENT ASSISTANCE TO NEW VENTURES MERITS EXPANSION. THE POSSIBILITIES INCLUDE THE ESTABLISHMENT OF UNIVERSITY-BASED INNOVATION CENTERS AND GRANTS TO SMALL BUSINESSES TO DEVELOP TECHNOLOGIES TO THE POINT OF ATTRACTING PRIVATE CAPITAL.

IN SOME INSTANCES INNOVATIONS DERIVED FROM SCIENCE AND TECHNOLOGY ARE SUBJECT TO MISUSE OR POSE UNINTENDED HAZARDS TO HEALTH, SAFETY AND THE ENVIRONMENT. THE TRADITIONAL RESPONSE TO THESE PROBLEMS IS GOVERNMENT REGULATION -- AND IT HAS COME UNDER INCREASING CRITICISM FOR DIVERTING TOO MANY RESOURCES FROM MORE PRODUCTIVE INVESTMENTS, FOR ONLY MIDDLING RESULTS. YET SCIENCE AND TECHNOLOGY ARE STEADILY EXPANDING OUR ABILITY TO DETECT AND EVEN ANTICIPATE NEW DANGERS. REGULATORY DECISIONS SHOULD BE BASED ON THE BEST SCIENTIFIC ANALYSIS AND TECHNICAL

INFORMATION. ALTERNATIVE REGULATORY POLICIES SHOULD BE ASSESSED IN ORDER TO DETERMINE HOW BEST TO ENCOURAGE THE USE OF TECHNOLOGIES SERVING ENVIRONMENTAL, SAFETY AND HEALTH OBJECTIVES WITHOUT IMPEDING OTHER INNOVATION AND CRIPPLING THE ECONOMY. THE CONVENTIONAL REGULATORY REFORMS ADD TO DELAY AND UNCERTAINTY. SUNSET LAWS AND IMPACT STUDIES ON NEW REGULATIONS ENTAIL MORE BUREAUCRACY, NOT LESS.

WHAT IS NEEDED ARE SOME NEW APPROACHES. THE TIME HAS COME FOR POLITICAL LEADERS TO SEE THE WORLD AROUND US AS IT REALLY IS, AND TO SPEAK THESE TRUTHS. ONLY THEN CAN WE HOPE TO RECAPTURE THE SPIRIT AND COURAGE THAT BUILT AMERICA.

STATEMENT OF DR. CHARLES L. FOX, JR., M.D.
PROFESSOR OF SURGERY AND MICROBIOLOGY
COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS & SURGEONS
NEW YORK, NEW YORK

AT THE JOINT PRESS CONFERENCE OF
SENATOR ROBERT DOLE OF KANSAS
AND
SENATOR BIRCH BAYH OF INDIANA

ANNOUNCING

THE INTRODUCTION OF A BILL ESTABLISHING A FEDERAL PATENT POLICY
FOR UNIVERSITIES AND SMALL BUSINESSES TO DEVELOP
INVENTIONS FUNDED WITH GOVERNMENT SUPPORT

CONFERENCE HELD IN ROOM 318 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, D. C.

AT 9:30 A.M.
WEDNESDAY, 13 SEPTEMBER 1978

STATEMENT OF DR. CHARLES L. FOX, JR., M.D.

I AM CHARLES L. FOX, JR., M.D., PROFESSOR OF SURGERY AND MICROBIOLOGY, AT COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS & SURGEONS, NEW YORK, NEW YORK. I AM GRATEFUL FOR THE OPPORTUNITY TO BE WITH YOU TODAY. I AM THE INVENTOR OF SILVER SULFADIAZINE, A LIFE-SAVING AGENT FOR THE TREATMENT OF BURNS. I AM HERE TO TELL YOU OF THE IMPORTANCE OF SILVER SULFADIAZINE, HOW IT WAS DEVELOPED, SUPPORTED, AND FINALLY MADE AVAILABLE TO BURNED PATIENTS IN HOSPITALS AND AT MILITARY INSTALLATIONS.

FIRST, I WOULD LIKE TO TELL YOU A LITTLE SOMETHING ABOUT BURNS. PRIOR TO AN UNDERSTANDING OF THE PROBLEM OF BURN SHOCK IN THE MID-1930'S, MOST PATIENTS SUFFERING BURNS GREATER THAN 40% OF THE TOTAL BODY SURFACE DIED OF BURN SHOCK WITHIN 36 HOURS OF THE INJURY. WITH THE RECOGNITION THAT LARGE AMOUNTS OF FLUIDS WERE NECESSARY TO PREVENT THIS SHOCK IN LARGE AREA BURNS, PATIENTS WITH BURNS OF ALL SIZES BEGAN TO SURVIVE THE EARLY POST-BURN PERIOD. THESE PATIENTS WITH LARGE BURNS WHO SURVIVED THE INITIAL SHOCK PHASE, HOWEVER, WENT ON TO DIE FROM INFECTION IN 10-21 DAYS. THE PRIMARY CAUSE OF THIS INFECTION WAS IN THE BURN WOUND ITSELF.

WITH THE ESTABLISHMENT OF BURN WOUND INFECTION AS THE CAUSE OF DEATH IN THESE PATIENTS, METHODS TO CONTROL IT WERE SOUGHT IN THE LATE 50'S AND EARLY 60'S. THE FIRST APPROACH, SYSTEMIC ANTIBIOTICS, WAS FOUND TO BE OF LITTLE VALUE BECAUSE OF THE LACK OF CIRCULATION IN THE BURN WOUND AND THEIR INABILITY TO KILL THE PREDOMINANT BACTERIA. WITH THE FAILURE OF SYSTEMIC ANTIBIOTICS, LOCAL MEASURES WERE SOUGHT TO CONTROL THE SPREAD OF BACTERIA AND THE DEVELOPMENT OF LIFE-THREATENING INFECTION IN THE BURN WOUND.

DURING THE EARLY 1960'S SOME SUCCESS WAS FOUND IN THE USE OF TOPICAL SILVER NITRATE SOLUTION IN A 1/2% CONCENTRATION. AT THE SAME TIME, A SULFA COMPOUND, MAFENIDE, WAS DEVELOPED WHICH WAS ABLE TO HELP CONTROL BURN WOUND INFECTION. IT HAD A HIGH DEGREE OF ACTIVITY AGAINST MANY FORMS OF BACTERIA AND HELPED DECREASE MORTALITY IN MANY BURNS. BOTH OF THESE AGENTS, HOWEVER, HAD SEVERE SIDE EFFECTS WHICH MADE THEM NOT ONLY DIFFICULT TO USE BUT ALSO ADDED TO THE BURDEN OF THE PATIENT IN SOME CASES.

LATER ON IN THE 1960'S, WORKING IN MY LABORATORY AT COLUMBIA UNIVERSITY WITH PARTIAL FUNDING OF SOMEWHAT LESS THAN $100,000 ON THE PART OF NIH, I SYNTHESIZED AND SCREENED MANY MANY COMPOUNDS WHICH MIGHT BE EFFECTIVE IN THIS AREA OF BURN WOUND INFECTION. I FINALLY FOUND SILVER SULFADIAZINE TO BE THE MOST EFFECTIVE IN LABORATORY ANIMALS.

I THEN RECEIVED FROM A COMMERCIAL DRUG COMPANY THE NECESSARY MATERIALS FOR THE EVALUATION OF THIS COMPOUND IN HUMANS AND TO MEET THE MEDICAL NEEDS FOR BURN THERAPY OF THE PATIENT POPULATION IN SOUTH VIETNAM THAT WAS UNDER THE AUSPICES OF THE UNITED STATES STATE DEPARTMENT SURGICAL TEAM TREATMENT FACILITIES. BASED ON THE RESULTS FROM THE CLINICAL USE, IT BECAME APPARENT THAT SILVER SULFADIAZINE COULD POSSIBLY BE THE PRODUCT OF CHOICE FOR TREATING MAJOR BURNS. IT ALSO BECAME CLEAR THAT WE WOULD NEED THE CONTINUING SUPPORT OF PRIVATE ENTERPRISE IN THE FORM OF A REPUTABLE PHARMACEUTICAL MANUFACTURER IN ORDER TO DEVELOP THE OPTIMAL FORMULATION AND TO CONDUCT THE PRECLINICAL AND CLINICAL EVALUATIONS REQUIRED BY THE FOOD AND DRUG ADMINISTRATION. I FELT THAT SILVER SULFA_ DIAZINE COULD PROVIDE THIS COUNTRY WITH A MAJOR BREAKTHROUGH FOR TREATING

BURNED PEOPLE BUT WITH LESS INCIDENCE OF SIDE EFFECTS THAN CURRENTLY AVAILABLE THERAPY.

TO LOCATE A COMPANY TO ACCOMPLISH THESE OBJECTIVES, THE ASSISTANCE OF RESEARCH CORPORATION WAS ENLISTED. RESEARCH CORPORATION'S CONTRIBUTION WAS TWOFOLD. FIRST, THEY RECOGNIZED THAT EXTENSIVE PATENT PROTECTION MUST BE OBTAINED TO JUSTIFY THE SIGNIFICANT EXPENDITURE REQUIRED TO BRING SILVER SULFADIAZINE TO THE POINT WHERE IT COULD BE USED IN LIFE-THREATENING BURN SITUATIONS THROUGHOUT THE UNITED STATES AND, IN FACT, THROUGHOUT THE WORLD. RESEARCH CORPORATION ALSO DEVELOPED A SUCCESSFUL WORKING RELATIONSHIP BETWEEN MYSELF, COLUMBIA UNIVERSITY, THE NIH, AND A QUALIFIED COMPANY FROM THE AMERICAN PHARMACEUTICAL INDUSTRY. MOST MAJOR PHARMACEUTICAL COMPANIES WHO EXPRESSED INITIAL INTEREST HAD SERIOUS DOUBTS REGARDING PATENT VALIDITY, AND THE RESTRICTIONS WHICH WOULD LIKELY BE PLACED ON THEIR MARKETING EXCLUSIVITY TO WARRANT THE EXPENDITURE REQUIRED TO BRING IT TO THE MARKET PLACE AND THE PATIENT'S BEDSIDE.

FINALLY, LICENSING ARRANGEMENTS WERE MADE WITH MARION LABORATORIES OF KANSAS CITY TO DEVELOP, TEST AND SECURE FDA APPROVAL FOR A SUITABLE SILVER SULFADIAZINE TOPICAL PRODUCT. MARION WAS SUCCESSFUL IN DEVELOPING A FORM OF SILVER SULFADIAZINE FOR APPLICATION DIRECTLY TO BURNED PATIENTS.

THIS PRODUCT WAS STUDIED UNDER MARION'S DIRECTION IN 2500 CLINICAL CASES AT ALL MAJOR U.S. BURN CENTERS. FDA APPROVAL FOR MARKETING WAS GRANTED NOVEMBER 26, 1973, APPROXIMATELY FOUR YEARS AFTER THE LICENSE ARRANGEMENT WAS CONCLUDED. AS A CONSEQUENCE, SILVER SULFA DIAZINE IS NOW IN GENERAL USE.

IN SUMMARY, THE DEVELOPMENTS OF SILVER SULFADIAZINE IS AN EXAMPLE OF HOW IMPORTANT AND SOMETIMES LIFE-SAVING PRODUCTS, WHICH HAVE BEEN PARTIALLY FUNDED BY HEW, CAN MAXIMIZE CONTRIBUTION TO PUBLIC WELFARE.

IN PREPARING TO SPEAK TO YOU TODAY, AND AS A DOCTOR INVOLVED IN ALLEVIATING HUMAN SUFFERING AND PAIN, I WAS HAPPY TO LEARN THAT AFTER EXPENDITURE OF OVER 3 BILLION DOLLARS IN NIH GRANTS TO UNIVERSITIES, OF

THE 28,000 PATENTS IN THE PATENT OFFICE PORTFOLIO, "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 MARKET-PLACE THROUGH THE INVESTMENT OF RISK CAPITAL FROM THE DRUG INDUSTRY."