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Statement of Dr. P. Roy Vagelos
President
Merck Sharp & Dohme Research Laboratories

Before the
Subcommittee on Courts, Civil Liberties and
The Administration of Justice

Committee on the Judiciary
United States House of Representatives

on

H.R. 6933, H.R. 2414, H.R. 3806, H.R. 6934
and
Other Patent Policy Issues

April 15, 1980

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INTRODUCTION

Mr. Chairman and members of the Subcommittee, my name is P. Roy Vagelos. I am President of Merck Sharp & Dohme Research Laboratories, a division of Merck & Co., Inc. Before joining Merck in 1975, I was Director of Washington University School of Medicine's Division of Biology and Biomedical Sciences and Chairman of its Department of Biological Chemistry. My curriculum vitae is attached as Exhibit 1. I am accompanied by Rudolph J. Anderson, Jr., Associate General Counsel and Director of Patents of Merck.

I appreciate the opportunity to testify during the Subcommittee's hearings on our patent system and U.S. patent policies. At the outset, let me issue a disclaimer. I am not an expert on the patent system. I am a physician; my background is in academic medicine and pharmaceutical research and development. But as someone whose work is directly affected by the patent system, I hope my observations concerning how the patent system impacts innovation in my industry will be helpful to the Subcommittee.

Our patent system today has changed little from the system designed in 1836. Tremendous strides in scientific and medical knowledge have been and continue to be made. In recent years, these strides have permitted, and the public interest has demanded, more intensive premarketing investigation and regulatory review of drugs. This has caused great changes in the manner in which pharmaceutical research and development is conducted in the United States.

The combination of a static patent law, dynamic research and growth of regulatory review demands congressional attention, and I am happy to have a chance to discuss the problem with you. The economic incentives provided by the patent system -- incentives essential for research and innovation -- are declining at the very time we have within our grasp major new medical advancements, particularly in the field of biomedical research. There are disturbing trends within our industry with respect to declines in domestic research by U.S. based firms and the growth of German, Swiss and Japanese firms as innovation leaders. ^{1/} These trends could become irreversible if the incentives and disincentives to American innovation are not soon addressed legislatively.

While many factors affect these trends, an effective U.S. patent system is of paramount importance. New discoveries made possible by research breakthroughs may not be within the scope of our present patent statute. Improved health and safety testing methods, reflected in regulatory premarketing approval

requirements, have effectively reduced the patent term to 10 years or less in the pharmaceutical industry.^{2/} And the patent issuance process produces unreliable patents, thereby creating uncertainty within corporate decisionmaking processes which can result in less money for research and development.

THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry thrives on innovation and discovery. It is, and has been at least since World War II, one of the most research intensive of all U.S. industries. Overall, on average U.S. pharmaceutical companies spend six percent of their total sales on research and development, compared to two percent for all industry.^{3/} We at Merck spend more.

The health of the American people has benefitted tremendously from this commitment to research and development. Cures or vaccines for some of mankind's most dreaded diseases are now taken for granted, and we are on the verge of important breakthroughs for many of our remaining major health problems.

The U.S. economy has also been a beneficiary. Reduced health care costs through both prevention and treatment of illness by drugs has almost incalculable economic benefit. For example, Americans spend in excess of \$1 billion a year treating pneumococcal pneumonia; the average hospital cost per patient in 1976 was about \$1600.^{4/} A vaccine, effective for at least 3-5 years against the strains that account for 80% of the cases of the disease, introduced by Merck in late 1977 and sold for approximately \$5.00 per dose, should enable

the nation to reduce these costs substantially. The pharmaceutical industry also contributes positively to our balance of trade, adding \$1,150,000,000^{5/} in 1979.

MERCK & CO., INC.

Merck is one of the U.S. pharmaceutical firms whose major emphasis is on research to invent and develop new pharmaceuticals. Our research and development budget has increased for 25 consecutive years. In the past decade, we spent nearly \$1.2 billion. In 1979, we spent in excess of 10 cents of every sales dollar received from drug sales on research for new drugs. This year, we will spend another \$227,000,000. In a word, our business strategy is innovation. The following table illustrates our commitment to research and development:

Merck & Co., Inc.

Research and Development Expenditures

1970 - 1980

1970 - \$ 69 million	1976 - \$134 million
1971 - \$ 71 million	1977 - \$145 million
1972 - \$ 80 million	1978 - \$161 million
1973 - \$ 91 million	1979 - \$188 million
1974 - \$103 million	1980 - \$227 million
1975 - \$125 million	

Merck's commitment to research has resulted in a number of major medical breakthroughs. Early achievements

included important sulfa drugs, the development of streptomycin, the synthesis of cortisone and the discovery of vitamin B₁₂, a life-saver for persons with pernicious anemia. Other Merck inventions, Diuril and Aldomet, revolutionized the treatment of high blood pressure in the 1950's and 1960's. Major improvements in the treatment of the symptoms of arthritis came from the invention of later steroids such as Decadron. The development of the non-steroidal antiinflammatory drugs Indocin and, more recently, Clinoril have further improved arthritis treatment. Our Timoptic is the most widely prescribed drug for the treatment of glaucoma; and it has vastly improved the treatment of this disease which is the leading cause of blindness in the United States.^{6/} Merck's research in viral and bacterial vaccines has led to the development of vaccines against a broad range of infectious diseases, including measles, rubella and mumps. As earlier mentioned, we have recently developed a vaccine for the prevention of most forms of pneumococcal pneumonia which claims the lives of 54,000 Americans each year,^{7/} and we have in late development stages a vaccine to protect against hepatitis caused by Hepatitis-B virus.

FUTURE ADVANCES

These achievements of Merck research and many others from other members of the United States pharmaceutical industry have been truly spectacular. However, much remains

to be done. The unfinished agenda of modern biomedical science includes some formidable problems. Heart disease, cancer, stroke, schizophrenia, arthritis, kidney failure, and the degenerative diseases of aging are among the remaining health problems yet to be fully addressed.

As difficult as these problems are, I am tremendously optimistic about the scientific possibilities for the future. We now have in sight a fundamental understanding of many body functions that should unlock the mystery of treating and preventing many of our existing major health problems. There is a tremendous optimism about what inventions may lie ahead for the treatment of human disease.

Understanding of cell surfaces, including receptors for hormones and drugs, of the method by which cells communicate, of the nervous impulse, and the recent discovery of peptides in the brain that act as natural opiates for the relief of pain represent the kind of information that is now available. We are just beginning to test in the clinic a drug which lowers plasma cholesterol by specifically inhibiting the biosynthesis of this substance. We believe this drug will be useful in prevention of arteriosclerosis with its multiple complications such as coronary heart disease and stroke.

Immunologists are unraveling the cellular and molecular events responsible for the immune response, and for the

first time one can begin to probe the possible involvement of immunological factors in such areas as cancer, chronic infections, rheumatoid arthritis, and even the process of aging. We now have under development in our laboratories, vaccines to prevent meningitis, gonorrhoea and chicken pox as well as infections caused by herpes and hepatitis-A viruses.

RESEARCH AND DEVELOPMENT COSTS

Substantial financial commitments by companies such as Merck will be necessary if we are to translate the many basic research observations into drugs that cure or prevent disease.

As the President of Merck Sharp & Dohme Research Laboratories, I head a group of more than 2300 biochemists, physicians, biologists and other research scientists. Many of them are preeminent in their fields and major scientific honors have been awarded for their work. On the staff today are recipients of The Albert Lasker Medical Research Awards, the American Chemical Society's Alfred Burger Award in Medicinal Chemistry and the Prix Galien Award of France. My predecessor, Dr. Lewis H. Sarett, was recently elected to the National Inventors Hall of Fame.

To attract and support the work of such scientists we must be able to fund the most modern laboratory facilities and instruments. This necessitates large investments of capital. For facilities alone Merck has recently completed a major

building program, involving \$60 million of capital investment over a five-year period. During this same period, we have modernized and renovated existing laboratories at a further cost of \$40 million. We are now starting on the next phase and have already approved \$50 million for further laboratory expansion.

Good laboratories are, however, only places where work can be done. Pharmaceutical research and development requires a commitment of people and funds for projects which may take a decade or more to reach fruition. In 1962, it took about two years and \$4 million to bring a new pharmaceutical product from discovery to marketing; now it takes about 8 years and \$50 million.^{8/} Merck's expenditure of \$190 million on research and development last year required the investment of almost two-thirds of our net income.

The commitment of such funds is made with no guarantees as to result. While we are using our greater scientific understanding to become more systematic in our research, serendipity plays a role, as indeed it must in any research. For example, a few years ago Merck scientists were working on a promising new product candidate for lowering blood pressure. We succeeded, and due to observations made with respect to the compound by a group working on ophthalmic research, we also ended up with a major breakthrough for the treatment of glaucoma.

Unfortunately, oftentimes our research leads to dead ends rather than such fortuitous results. In the ten-year period

1966-1976, Merck invested over \$800 million in research and development and introduced only one major new marketable drug. If our management had not had great confidence that economically important new products would result from the work then underway in our laboratories, they could not have justified that large ongoing expense.

Merck's experience is not unique. Dead ends are part of the nature of the scientific process. In 1970, members of the Pharmaceutical Manufacturers Association tested 704,000 compounds for pharmacological activity. Of these, barely a thousand proved promising and safe enough after testing in animals to move into clinical tests. Only about 12% of the compounds which were tested in humans ever reached the market.^{9/} Thus, the development of a drug is a long and tortuous process -- one which can lead to disappointment at any turn. Of course, at any time during the development process, competitors may introduce products which can drastically change the need and desirability of our products.

As I indicated earlier, it takes much longer today to develop a pharmaceutical product and there is no reason to believe that the situation will change. The increase of time stems from two factors: first, the sophistication of the chemical and biological research now required for the drugs we are developing; and second, the substantial length of time necessary to secure regulatory approval for a

new drug. Underlying the longer regulatory review period are two factors: (1) increasingly sophisticated scientific knowledge and tests that discern actual and potential adverse reactions simply not discernible 20 years ago; and (2) a general reticence to approve new drugs without satisfying higher and higher standards of proof concerning health benefits and safety risks.

As a physician and biologist, I see the tremendous potential for great strides in disease treatment and prevention which lie just beyond the horizon. As a manager and planner, I know that the dollars must be there to fund our ongoing research if these potentials are to be realized. The profits we realize from our research successes must be sufficient to be the source of such funding.

DECLINING RESEARCH AND DEVELOPMENT

As research and development becomes increasingly expensive, the rewards for success cannot be allowed to decrease. Unhappily, this seems to be the case in the United States. Research and development expenditures in the U.S. have been steadily declining. In 1964, the U.S. spent 3 percent of its GNP on research and development; in 1978 research and development was only 2.3 percent of the GNP. During the same period, the research and development per GNP ratio for West Germany increased from 1.6% to 2.3% surpassing the U.S. in 1975, and Japan's ratio grew from 1.5% in 1964 to 1.9% in 1976.^{10/}

The final report of the Advisory Committee on Industrial Innovation and the President's Message to Congress on Industrial Innovation provide statistics on the declining research and development trend in the United States and the decline in innovation.^{11/} I do not intend to repeat those statistics. Let me just say that some decline in innovation is manifesting itself in the pharmaceutical industry as well as elsewhere. A decade and a half ago new chemical entities were introduced at a rate of 42 a year on average; today, the rate has decreased by 62 percent, down to just 16 per year.^{12/} Studies by a number of experts have demonstrated the U.S. is lagging significantly behind Great Britain and other industrialized countries in the introduction of new drugs, a disturbing result even though reasons for the differential have been advanced.^{13/}

The increasing costs of new drug research and development have had a particularly severe impact on the small companies. This, of course, decreases the competition for new and better drugs, the most important form of competition in our industry.

Disturbingly, fewer and fewer U.S. companies are evidencing a continued commitment to vaccines. Fifteen years ago there were 9 manufacturers of the 4 most widely-used vaccines.^{14/} Today, Merck is almost alone in the U.S. in committing a major research effort to new vaccines.

The real rate of growth in domestic research and development expenditures has declined severalfold from the very high growth rates prevalent in the late 1950's and the 1960's. At

the same time, foreign research and development expenditures by U.S. pharmaceutical firms have grown at a rapid rate.^{15/}

The following table illustrates that our overseas competitors threaten the U.S. pharmaceutical industry's position of world-wide preeminence:

Estimated 1979 Research and Development Spending

<u>Company</u>	<u>Amount</u>
Hoechst (W. Germany)	\$260 million
Roche (Swiss)	\$225 million
Ciba-Geigy (Swiss)	\$225 million
Merck (U.S.)	\$190 million
Eli Lilly (U.S.)	\$165 million
Sandoz (Swiss)	\$135 million
Pfizer (U.S.)	\$130 million
Upjohn (U.S.)	\$130 million
Takeda (Japan)	\$ 90 million
Bayer (W. Germany)	\$ 80 million
American Home Products (U.S.)	\$ 80 million

Source: Forbes, November 26, 1979, p. 41

As you can see, only 2 U.S. firms are within the top 5 measured by research and development spending. Similarly, of the largest pharmaceutical companies in the world measured by sales, only 2 of the top 5 are U.S. firms, contrasted to 3 in 1972.^{16/} Merck is one of the two.

The reasons for the decline in U.S. innovation and some shift of research and development efforts abroad by U.S.

companies are complex. Certainly, governmental policies and attitudes about research and development are key considerations. Many of the leading industrial countries have policies which encourage and support high-technology industries. Special tax incentives for research and development contrast with the lack of such incentives in the U.S.^{17/}

Just as the reasons for declining U.S. research and development are complicated, so too are the solutions. There is no cure-all for the present unhappy state of affairs. However, this committee's area of responsibility, U.S. patent policy, offers for research-intensive firms a most important area for bringing about improvements.

PATENT POLICY

The patent system provides a major motivation and incentive for research and innovation by our company and by others in the biological sciences. The innovative company receives its financial return on research and development from the sales of its patented products free from unlicensed competition. Clearly, we cannot structure an organization to undertake the massive research involved in developing new pharmaceutical products and to introduce them to the medical profession and then compete on a price basis with other companies who could immediately copy our successes. I can assure you that a major factor underlying my decisions to commit research and development funds is the extent to which the fruits of our

work can and will be protected by a patent. I know that my research budget authorized by Merck's Board of Directors is directly related to the rewards dependent upon our patent system.

Unfortunately, developments over the last several decades have eroded the rights patentees have traditionally enjoyed and which have assured them the basis for their commitment to research. I would like to share with you today particular concerns we have about the effectiveness of the present patent system as it applies to our industry.

A. PROPOSED LEGISLATION

At the outset, let me state that Merck supports certain fundamental principles which are addressed in H.R. 6933, 2414 and 3806. We support the principle of a uniform patent policy which enables inventions in the biomedical and other fields to enter the stream of commercial development for the benefit of mankind. We specifically support the provisions of H.R. 2414 and H.R. 6933 which provide to universities and small business ownership of the results of their research. Since Merck's research is self funded -- and not dependent upon Government research funds -- we do not expect to be affected by the uniform patent policy provisions of H.R. 6933 otherwise affecting large industrial concerns. We are not certain, however, whether these provisions are workable because of the extreme difficulty we foresee in administering the grant of exclusive licenses in limited fields of use and in the enforcement of any patent so licensed.

Since at least 1973, Merck has publicly supported the concept that beneficiaries of the patent system bear a significant cost of operating the system. We therefore supported the Senate-passed version of maintenance fees during the 93rd Congress. We continue to be prepared to accept the principle of maintenance fees and the need for patent applicants to bear a major cost of operating the patent system. We have no information, however, with respect to the Administration's rationale for selecting a 60% recovery requirement rather than the 50% of earlier legislation nor for the timing of the maintenance fee payments and therefore cannot comment on either at this time.

A fundamental prerequisite to restoring the necessary incentives to research and development is to restore the reliability of the patent. I and my management colleagues must have definitive answers regarding the rights we own from granted patents. Today's system seems to require counsel to frequently provide an opinion forecasting how a court may construe a patent based upon whether literature was or was not considered by the Patent & Trademark Office in its original examination; or worse, to provide different opinions on patent validity questions dependent upon the part of the country where the patent rights may be litigated. Several proposals before the Subcommittee which Merck supports address this problem and are discussed in greater detail later in my statement.

B. PROPOSALS FOR CHANGE

As wide-ranging as the proposals before the Committee are, however, I believe that they fail to address many fundamental issues which must be addressed to truly bring the patent system up-to-date and ready for the 21st century. Certainly the Administration's centerpiece, uniform government patent policy, however laudable and important, will do little to redress the fundamental inadequacies we find in today's patent system. To do justice to the subject of patents and restore the incentives necessary to stimulate research and development requires the same attention this Committee recently provided the field of copyrights. Careful consideration must be given to the full complement of recommendations made by the Patent Subcommittee of the Advisory Committee on Industrial Innovation.^{18/}

Ranked in order of probable contribution to restoring the incentives intended by our founding fathers when providing for the establishment of a patent system in Article 1, Section 8 of the Constitution, we recommend that the Committee consider the following legislative initiatives:

1. Restoration of Patent Term

An overriding concern to us is the loss of effective patent life for products subject to premarketing regulatory review. To assure statutory protection for our scientific breakthroughs and to enable publication of our discoveries to our scientific colleagues at an early date, we are obliged

to seek patent protection very soon after a potentially effective new drug is discovered. The subsequent phases of development and clinical testing and the time interval required to obtain FDA's approval to market a drug now typically consume in aggregate about eight years. As a result, we are left with less than a decade of patent protection for marketing the products of our research -- an insufficient period to permit funding of research projects of the future to the extent required by their potential and society's needs. We seek legislative attention to this problem.

Those of us who innovate in the biological sciences should have the benefits of the full 17-year patent period originally contemplated by Congress in the patent statute enacted in the early days of the nation's history. Unfortunately, Congress, in enacting laws providing for premarketing regulatory review for products useful in medicine and agriculture, seems not to have taken into account the effects of this new process on the patent term. Congress needs to recognize that the time required for safety and efficacy testing and the review process have effectively reduced the patent term and make the necessary adjustments.

2. Increased Reliability of Patents

For the reasons outlined earlier, we also strongly recommend that legislative action be taken to enhance the reliability of the statutory rights granted under the patent laws.

a. Upgrading Examination Process

First and foremost is a need to upgrade the present system of examination in the U.S. Patent and Trademark Office. This

will require more adequate funding for the Office and an investment in search facilities and techniques, including the development of a data base and computer technology, adequate to provide the patent examiner with more effective access to the constantly growing body of scientific and other literature. Section 2 of H.R. 6933 should provide better funding of the Office, but the capital investment necessary to modernize searching requires additional Congressional attention.

b. Independent Agency

Accomplishment of these goals may further require the establishment of the Patent and Trademark Office as an independent agency as has been proposed in S. 2079. At the very least it requires enhancement of the present stature of the Commissioner of Patents and Trademarks and his office within the executive branch of government.

c. Re-examination

A major step towards enhancing the reliability of patents will be the enactment of legislation for re-examination of existing patents in a relatively inexpensive and timely manner. Such re-examination will provide to management the benefits of the views of the U.S. Patent and Trademark Office on the relevance of newly discovered literature to the claims of a granted patent. We have supported the enactment in the Senate of H.R. 2446 and recommend adoption of that bill by the Committee in lieu of Section 1 of H.R. 6933 because of the inclusion in the Senate bill of Sections 309 and 310 and other technical but important differences.

d. Patent Court

Another recommendation of the Advisory Committee which we support is Proposal III, the creation of a specialized appellate court for patent cases. Such a court should eliminate geography-dependent patent opinions. To that extent, we support H.R. 3806.

3. New Uses for Previously Known Chemical Compounds

One further area of concern to me is whether we may obtain proprietary rights for products which have as their scientific basis the discovery of new uses for previously known chemical compounds. The issue of whether the present patent statutes provide proprietary rights for such products is, as you know, presently pending before the Supreme Court. If the Supreme Court finds that the patent statutes of today do not extend to such proprietary rights, a legislative solution to the problem will be required as recommended by the Advisory Committee in Proposal VIII B.

4. Recombinant DNA Technology

Finally, I would be remiss not to speak on the issue of the availability of patent protection for inventions in the new but rapidly developing field of recombinant DNA technology. Depending upon the decision of the Supreme Court concerning patentability of inventions in this field, a legislative solution may be required to permit the grant of patent rights for such inventions. This too was recommended by the Advisory Committee (Proposal VIII A).

CONCLUSION

These patent overview hearings are an important first step in bringing about much needed changes to our patent system. Such changes are essential to reinvigorate the commitment to research and development by U.S. industry. New advances in biomedical research continue to provide us with insights into major new treatments and cures for some of our most pressing health problems. From the patent system we must be assured of corporate income from the sales of products we invent to enable us to continue to commit large sums to research and development over extended periods. If not, substantial delays in converting these exciting discoveries into practical applications will result. Every day, I have to make hard choices about Merck's research and development priorities. I am frequently faced with the frustrating duty of electing between promising projects because of budgetary limitations. Unless economic incentives for research and innovation are improved through changes in the patent system and elsewhere, I fear that such decisions will become more and more frequent both at Merck and elsewhere in the U.S. pharmaceutical industry. I am always concerned about the potential human health costs which may result from such deferrals.

I hope this Subcommittee and the Congress will recognize the urgency of our requested changes in the present patent system. They could mean the difference between a pharmaceutical industry growing in innovation and in the number of innovative

firms or an industry with more and more members depending on existing and imitative drugs to survive. Worse yet, present trends could ultimately lead to predominantly government funded and directed research which lacks the benefits of today's competitive research efforts.

FOOTNOTES

1. Gibson, Being Good Isn't Enough Anymore, FORBES, November 26, 1979, at 40.
2. Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 Before the Subcomm. on Health and Environment of the House Interstate and Foreign Commerce Comm., 95 Cong. 2d Sess. 2267; See also D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY at 67 (1976); HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 67 (Sept. 1979).
3. HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 57 (Sept., 1979).
4. Donald R. Roden & W. Gerald Platt, A Study to Estimate the Prevalence and Costs of Pneumonia, at 4, 5 (Feb., 1978) (Study prepared by PraCon Incorporated).
5. Bureau of the Census, United States Dep't. of Comm., Highlights of U.S. Export-Import Trade (1979).
6. National Center to Prevent Blindness, Press Release (March, 1980).
7. Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention (1979) at 7-13 (annual report to the Dep't of Health, Education and Welfare).
8. HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 67 (Sept., 1979).
9. Id. at 58.
10. NATIONAL SCIENCE BOARD OF THE NATIONAL SCIENCE FOUNDATION, SCIENCE INDICATORS 1978 at 5 (1979) (annual report).
11. President Carter's Message on Industrial Innovation, Message to Congress (October 31, 1979); See also NATIONAL SCIENCE BOARD OF THE NATIONAL SCIENCE FOUNDATION, SCIENCE INDICATORS at 6, 7 (1979) (annual report); HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 58, 59 (March, 1979).

12. HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 67 (March, 1979).
13. Id. at 67; See also D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY at 171-173 (1976).
14. Office of Technology Assessment, Congress of the United States, A Review of Selected Federal Vaccine and Immunization Policies at 5 (Sept., 1979); See also A Risky Exodus From Vaccines, BUSINESS WEEK, April 10, 1978 at 118.
15. H. Grabowski, Effect of Regulatory Policy, THIRD SEMINAR ON PHARMACEUTICAL PUBLIC POLICY ISSUES at 53, 54 (1976).
16. HEALTH AND SAFETY INDUSTRIAL SUBCOMM. OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 58, 59 (Sept., 1979).
17. Id. at 58.
18. INDUSTRIAL ADVISORY SUBCOMM. ON PATENT AND INFORMATION POLICY OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT at 147-193 (Sept., 1979).

EXHIBIT 1

CURRICULUM VITAE

Name: Pindaros Roy Vagelos, M. D.

Date and Place of Birth: October 8, 1929; Westfield, New Jersey

Marital Status: Married; four children

Education: A.B., 1950, University of Pennsylvania
M.D., 1954, Columbia University

Brief Chronology of Employment:

- | | |
|------------------------|--|
| 1954-1955 | Intern in Medicine,
Massachusetts General Hospital,
Boston, Massachusetts |
| 1955-1956 | Assistant Resident in Medicine,
Massachusetts General Hospital,
Boston, Massachusetts |
| 1956-1959 | Sr. Assistant Surgeon,
Laboratory of Cellular Physiology,
National Heart Institute |
| 1959-1961 | Surgeon (Acting Chief, Section on Enzymes, 10/59-10/60),
Laboratory of Cellular Physiology,
National Heart Institute |
| 1961-1964 | Senior Surgeon,
Laboratory of Biochemistry,
National Heart Institute |
| 1962-1963 | Sabbatical year spent with Dr. J. Monod,
De Genetique Microbienne et de Biochimie Cellulaire,
Institut Pasteur,
Paris, France |
| 1964-1966 | Head, Section on Comparative Biochemistry,
Laboratory of Biochemistry,
National Heart Institution |
| 1966-May 1975 | Chairman, Department of Biological Chemistry,
Washington University School of Medicine,
St. Louis, Missouri |
| 1973-May 1975 | Director, Division of Biology and Biomedical Sciences,
Washington University,
St. Louis, Missouri |
| 1975-May 1976 | Senior Vice President,
Merck Sharp & Dohme Research Laboratories,
Division of Merck & Co., Inc.,
Rahway, New Jersey |
| June 1976 -
present | President
Merck Sharp & Dohme Research Laboratories
Merck & Co., Inc.
Rahway, New Jersey 07065 |

Military Service:

1956-1964 United States Public Health Service

Societies:

American Chemical Society
American Society of Biological Chemists *
Phi Beta Kappa
Alpha Omega Alpha
American Society of Microbiology

Honors and Other Special Scientific Recognition:

Enzyme Chemistry Award, American Chemical Society, 1967.
National Academy of Sciences, 1972 - present.
American Academy of Arts and Sciences, 1972 - present.
Chairman, Division of Biological Chemistry Section of the American Chemical Society, 1973.
Institute of Medicine of the National Academy of Sciences, 1974 - present.
NIH Molecular Biology Study Section, 1967-1971.
NIH Physiological Chemistry Study Section, 1973-1975.
Sloan Visiting Professor of Chemistry, Harvard University, 1973.
Commission on Human Resources, National Research Council, 1974-1976.
Scientific Advisory Committee, Massachusetts General Hospital, 1975 - 1979.
Advisory Council, Dept. Biochemical Sciences, Princeton University, 1974 - 1977.
Visiting Committee, Dept. Biology, Massachusetts Institute of Technology, 1975 - present.
Adjunct Professor of Biochemistry, College of Physicians and Surgeons, Columbia University, 1975 - 1978.
National Visiting Council for the Health Sciences Faculties, Columbia University, 1978 - present.

*serving as member of Equal Opportunities for Minorities Committee - 1978

Member of the Board of Trustees of The Rockefeller University
1976 - present; Standing Committee on Scientific Affairs

Member of Board of Trustees, Foundation for Microbiology
1976 - present

Member of the Board of Trustees, the Danforth Foundation
1978 - present

Fellow of the New York Academy of Sciences, 1977 - present

Editorial Boards

Journal of Lipid Research, 1964-1969

Biochimica et Biophysica, 1964-1975.

Journal of Biological Chemistry, 1964-1969; 1971-1972; 1975-1978;
Member of Publications Comm. 1978-

PAABA Revista, 1971 - present.

Biochimica et Biophysica Acta Reviews on Biomembranes, 1971-1975.

Editorial Advisory Board, Biochemistry, 1975-1978; 1979-81