

THE
PHARMACEUTICAL
MANUFACTURERS
ASSOCIATION
FOUNDATION,
INC.

**annual
report
1965**

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*Dr. Austin Smith served as President until December 7, 1965.

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THE PAST QUARTER CENTURY has witnessed the most dramatic progress in the history of therapeutics. Advances in the chemotherapy of disease have been especially significant.

But as new drug products have been identified, developed and placed in widespread use, it has become increasingly apparent that the very high potency of many of these agents is coupled with a substantial capacity to inflict injury, if they are used in extraordinarily sensitive patients, if their actions are poorly understood, or if they are improperly employed.

A desire to attack these problems with the best available talents prompted the Pharmaceutical Manufacturers Association to establish the Commission on Drug Safety, in the fall of 1962. The PMA is a trade association composed of manufacturers of ethical pharmaceuticals. Its member companies produce more than 90 per cent of the nation's prescription drug supply, and conduct or fund the bulk of the nation's applied research in drug therapy.

The Commission on Drug Safety operated for approximately eighteen months, until the spring of 1964. Meeting monthly, it became a responsible spokesman for the major scientific and professional organizations in the U. S. in the area of drug safety, and coordinated U. S. drug safety information and developments with appropriate organizations around the world. It sponsored a conference of professional and scientific societies on drug safety, a conference on prenatal effects of drugs, and a workshop on teratology. It advised government on the implementation of new drug laws, and produced a teratology manual, a number of reports, and other publications. On the Commission's recommendation, its work was assumed by the Drug Research Board of the National Academy of Sciences—National Research Council, created for the purpose early in 1964.

Among the most important contributions of the Commission were the observations and recommendations included in its final report. There the Commission stated that "the very complexity of the newer agents and the sophistication with which they must be used pose new problems which must be met. They can be met, but only if we give to toxicology, pharmacology and experimental therapeutics—and to the problem of education in drug

usage—some measure of the kind of support and some of the urgency now accorded to our machinery for drug discovery.”

The authors went on to identify several specific areas which in their judgment were in need of attention. Among them are the following:

- (a) “The drug safety issue, in all of its aspects, quickly reduces to a question of knowledge: the need for greater understanding of the fundamental mechanism of drug action; the need for better exchange and distribution of information; the need for better use of available information.
- (b) “More fundamental research across a broad base of biology and chemistry is imperative to gain needed understanding of the implications of drug therapy.
“Present animal tests must be reassessed to determine the value of the information they provide, and more predictive animal tests must be developed.
- (c) “More financial support and professional encouragement must be channeled to the university to stimulate both basic research and the training of investigators.
“The short-term scientific manpower shortage can be offset, in part, by greater cooperation in recognizing manpower priorities among government, industrial, educational, and medical establishments; by pooled research efforts in noncompetitive areas; by elimination of the necessity to conduct obsolete and outmoded but time-consuming tests to meet Federal requirements governing New Drug Applications.
- (d) “Great emphasis must be placed on drug studies in the medical curriculum, and a few medical schools should establish centers for intensified training in the disciplines associated with clinical testing and drug development.
- (e) “More effort should be made to develop effective ways of keeping the practicing physician abreast of drug developments, and medical schools and the medical profession should share this responsibility with the drug manufacturers.
- (f) “The information requirements of research scientists, clinical investigators, and all other physicians need to be reviewed thoroughly, especially in the light of the data-retrieval and statistical-analysis potentials of modern information systems.
- (g) “Vast quantities of filed-away drug research information should be re-examined and re-evaluated.”

The Commission and several of its committees appealed for still more interest on the part of drug companies in the conduct of

basic studies in drug toxicity, possibly through cooperative sponsorship of fundamental projects. This might include retrospective work aimed at uncovering possible ways in which clinical findings could have been more accurately anticipated, through better animal testing or observation of illusive but significant manifestations.

A number of alternate mechanisms that could implement its recommendations were suggested by the Commission. One was the establishment of a foundation. The alternatives were considered for some months following publication of the Commission's Report. On May 31, 1965, the Pharmaceutical Manufacturers Association announced that it had established The Pharmaceutical Manufacturers Association Foundation, Inc.

The Bylaws of the Foundation include among its purposes the promotion of the public health through the study and development of the science of therapeutics. The Board of Directors of the PMA voted to provide temporary operating funds, and to employ the President of the PMA as Foundation President, together with additional staff personnel as required. A seven-member Board of Directors for the Foundation was elected from the membership of the PMA Board. The Foundation was incorporated in the District of Columbia, the various administrative requirements, including a ruling from the Internal Revenue Service granting tax exempt status, were accomplished, and the task of defining specific interests and programs began.

purposes

SOME might question the founding of a new foundation at a time when medical research is so heavily funded by government agencies. Actually, many who have long been active in foundation work have welcomed this governmental participation, because, they feel, it frees private groups to conduct and support work that they previously turned down, in the face of more pressing but not more worthy demands from other sources.

The PMA Foundation does not expect to compete with public agencies, or with other private ones, in making grants. PMAF expects the number, as well as the size, of the grants it will be able to award will be relatively modest.

But the Foundation recognizes that its private nature gives it advantages over public institutions, and it intends to make full use of them. It hopes to be flexible and adaptable to the changing

needs of the fields supported. Since it is free of political pressure, it need not fear criticism of the courses it chooses to follow, nor must it unswervingly avoid the risk of supporting concepts that will fail. It need not support only the kinds of work that appear to be in current esteem. It can offer a promising program the security of adequate support over a substantial period of time, if that appears warranted. And finally, the Foundation can encourage both work that results in short-term good, and that which is of high long-term value.

As its Bylaws provide, the Foundation will plan and initiate scientific and medical research activities, collect and disseminate the results of those activities, provide financial aid to individuals or institutions whose purposes are scientific, educational or charitable, and, of course, receive voluntary donations from individuals and corporations.

PMAF will not conduct research on specific drugs, but rather on the broad field of therapeutics, pioneering new studies, pointing directions, and setting guidelines.

Through much of 1965, at regular meetings of the Board of Directors, and in discussions with representatives of the scientific sections of the PMA, consideration was given to the directions and programs the Foundation could realistically and effectively pursue.

Present pharmaceutical industry activities in scientific work, education and philanthropy, and those of government, were reviewed. The Board found the advice of the PMA Biological, Medical, and Research & Development Sections particularly valuable. These working elements of the PMA convened committees to define, at the Board's request, gaps that exist in basic medical and health-related knowledge, and they assigned priorities for research on them. Their suggestions were reviewed by a committee of the PMA Board, consisting of Mr. Creasy as chairman, Dr. Cutter, Dr. Klumpp and Mr. Duncan.

Out of these deliberations came the conclusion that the Foundation should concentrate on the support of projects in two major areas: (1) Fundamental research in toxicology and (2) Research and training of personnel in the fields of clinical pharmacology and drug evaluation. The Board voted approval of these goals. It felt that further advice from PMA scientific and other sections would be required, and that assistance from non-industrial groups would also be needed from time to time.

The Foundation is aware of the size of the problems it proposes to treat. As in improving clinical pharmacology and drug

evaluation, a series of palpable breakthroughs in drug toxicity matters is not to be expected. What is needed, and what the Foundation hopes to provide, is consistent, patient effort, with an element of imagination and boldness in seeking advances of significance.

activities

THE FIRST ACTIVITY of the Foundation was the assumption of the drug industry responsibility for support of a Registry of Tissue Reactions to Drugs. The Registry is located at the Armed Forces Institute of Pathology in Washington, and is co-sponsored with the U. S. Food and Drug Administration and the American Medical Association. It obtains autopsy and biopsy tissue specimens from suspected drug reaction cases, subjects them to all available methods of pathological and toxicological examination, and reports its findings to the sponsors and the physician who submits the material. The information is catalogued by data-processing techniques and is made available to identify drug-related reactions, the diagnosis of reactions, and for other scientific investigations.

Another activity involves the sponsorship of a workshop on the principles and methodology of drug metabolism, to be conducted at the New York University Medical Center May 23-27, 1966. The program will be under the auspices of the Drug Research Board. Intended for pharmacologists, biochemists, toxicologists, teratologists and clinical pharmacologists who lack understanding of drug metabolism, the workshop will include presentations on the physical properties of drugs, the principles and techniques of drug metabolism, drug enzymology, the role of genetics in metabolism and related subjects. The faculty will include men from the University of London, the Wellcome Research Laboratories, the National Institutes of Health, George Washington University, the University of Minnesota, the University of North Carolina, and Yeshiva University, in addition to the staff of New York University.

A great many suggested additional projects have been put forward, and many are under review. Among them are the following:

1. Studies to better correlate animal and human data concerning toxicity and effectiveness in an effort to provide better predictive value to the animal studies.
2. Study of comparative physiology and biochemistry of various groups of animals compared to that known for man to determine

whether certain species are more appropriate than others for various types of studies.

3. Studies to increase the significance of chronic toxicity findings such as early histochemical, electron microscope, and enzyme changes.
4. Studies to learn how to distinguish deviations from the normal due to drug effects from those due to natural changes.

With regard to clinical pharmacology and drug evaluation, it is expected that consideration will be given to:

1. A review of the programs of the 33 centers for training in clinical pharmacology now in existence to determine whether more fellowship support is indicated.
2. A survey of the teaching of pharmacology and therapeutics in medical schools and support of a study of ways and means of improving the courses of instruction.
3. A study of the reliability of clinical laboratory tests and of methods for improving them.
4. A study of possible means for establishing "base line" information concerning the occurrences of pathology and abnormal symptoms in the normal untreated population. This is regarded as essential to the proper evaluation of reports of alleged untoward reactions to drugs.

income and expenditures

CONTRIBUTIONS, which are tax-deductible, for the Foundation are accepted from any private source, so long as the source does not place restrictions on the use of its funds that place the donation outside the policies of the organization. There are no guides for contributing, except an arbitrary starting point suggested as a minimal figure for corporate donations. The Board felt corporations might minimally donate .015 per cent of their worldwide sales, on an annual schedule. The Board estimates that such a figure would yield a total of approximately \$500,000 annually for the Foundation's operating income.

Total receipts, including donations by individuals, for 1965 were \$136,500.00.

Obligations to support the Armed Forces Institute of Pathology's Registry of Tissue Reactions will approximate \$25,000 during 1966.

The budget for the New York University Workshop on Drug Metabolism is \$18,060.

**ARTICLES OF INCORPORATION
OF
THE PHARMACEUTICAL MANUFACTURERS
ASSOCIATION FOUNDATION, INC.**

We, the undersigned, being more than twenty-one years of age and desiring to organize a corporation pursuant to the District of Columbia Nonprofit Corporation Act, 76 Stat. 265, do hereby certify as follows:

ARTICLE I. NAME

The name of this corporation shall be The Pharmaceutical Manufacturers Association Foundation, Inc.

ARTICLE II. DURATION

The duration of this corporation shall be perpetual.

ARTICLE III. PURPOSES

This corporation is organized and shall be operated exclusively for the purposes of promoting the betterment of public health through scientific and medical research with particular reference to the study and development of the science of therapeutics.

ARTICLE IV. MEMBERS

This corporation shall have no members and shall issue no stock.

ARTICLE V. DIRECTORS

The affairs of the corporation shall be governed by a Board of Directors consisting of seven members. The Directors shall be elected in the manner prescribed in the Bylaws of the corporation, but the number of Directors specified herein shall not be altered except by amendment to these Articles of Incorporation.

ARTICLE VI. INITIAL DIRECTORS

The seven individuals whose names and addresses appear below shall serve as the initial Directors until their successors shall be elected in the manner prescribed in the corporation's Bylaws:

Name	Address
E. GIFFORD UPJOHN, M.D. <i>Chairman</i>	THE UPJOHN COMPANY 7000 Portage Road Kalamazoo, Michigan
WILLIAM N. CREASY <i>Vice Chairman</i>	BURROUGHS WELLCOME & CO. #1 Scarsdale Road Tuckahoe 7, New York

JOHN G. SEARLE
Secretary-Treasurer

G. D. SEARLE & Co.
P.O. Box 5110
Chicago 80, Illinois

GEORGE R. CAIN

ABBOTT LABORATORIES
1400 Sheridan Road
North Chicago, Illinois

LYMAN C. DUNCAN

LEDERLE LABORATORIES
DIVISION OF AMERICAN
CYANAMID COMPANY
Pearl River, New York

H. ROBERT MARSCHALK

RICHARDSON-MERRELL INC.
122 East 42nd Street
New York 17, New York

JOHN J. POWERS, JR.

CHAS. PFIZER & CO., INC.
235 East 42nd Street
New York 17, New York

ARTICLE VII. NOT-FOR-PROFIT CHARACTER

This corporation is not organized and shall not be operated for pecuniary gain or profit. No part of the net earnings, if any, of the corporation shall inure to the benefit of any private individual. Upon dissolution of the corporation, all of its net assets, if any, shall be distributed exclusively for charitable, scientific, or educational purposes to one or more organizations which qualify for exemption from Federal income tax under the provisions of Section 501(c)(3) of the Internal Revenue Code of 1954, or any similar or corresponding law then in effect.

ARTICLE VIII. PROHIBITED ACTIVITIES

This corporation shall not engage in any activities which would disqualify the corporation for Federal income tax exemption under Section 501(c)(3) of the Internal Revenue Code of 1954 and the Regulations thereunder, as from time to time amended or superseded. Specifically, but without limiting the foregoing, this corporation shall not directly or indirectly engage in carrying on propaganda, or otherwise attempting to influence legislation; nor shall this corporation directly or indirectly participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of any candidate for public office; nor shall this corporation engage in any "prohibited transaction" as defined by Section 503(c) of the Internal Revenue Code of 1954, as from time to time amended or superseded.

ARTICLE IX. REGISTERED OFFICE AND AGENT

The corporation's initial registered office shall be located at 1155 Fifteenth Street, N.W., Washington, D.C., and its initial registered agent at such address shall be Austin Smith, M.D.

ARTICLE X. INCORPORATORS

The names and respective addresses of the incorporators are:

Name	Address
AUSTIN SMITH, M.D.	4501 Connecticut Ave., N.W. Washington, D. C.
C. JOSEPH STETLER	7009 Whittier Blvd. Bethesda, Maryland
KARL BAMBACH, Ph.D.	6223-30th Street, N.W. Washington, D. C.

IN WITNESS WHEREOF, we have hereunto set our hands this 10th day of June, 1965.

Austin Smith /s/
Austin Smith, M.D.

C. Joseph Stetler /s/
C. Joseph Stetler

Karl Bambach /s/
Karl Bambach

DISTRICT OF COLUMBIA) ss.

I, Barbara Windon, a Notary Public in and for the District of Columbia, do hereby certify that on the 10th day of June, 1965, personally appeared before me Austin Smith M.D., C. Joseph Stetler, and Karl Bambach, who, being by me first duly sworn, declared that they signed the foregoing document as incorporators, and that the statements therein contained are true.

Given under my hand and seal this 10th day of June, 1965.

(SEAL)

Barbara Windon /s/
Notary Public

My commission expires July 31, 1968.

**THE PHARMACEUTICAL MANUFACTURERS
ASSOCIATION FOUNDATION, INC.
BYLAWS**

ARTICLE I. PURPOSES

The Pharmaceutical Manufacturers Association Foundation, Inc. (hereinafter referred to as the "Foundation"), is organized and shall be operated exclusively for the purposes of promoting the betterment of public health through scientific and medical research with particular reference to the study and development of the science of therapeutics.

In the furtherance of these purposes the Foundation shall:

- (a) Plan and initiate scientific and medical research activities;
- (b) Collect, correlate, evaluate and disseminate to the public generally the results of scientific and medical research activities;
- (c) Assist in the providing of financial aid to individuals, recognized schools or educational institutions, or to any corporation, trust, fund or foundation whose purposes and aspirations are scientific, educational, or charitable.
- (d) Receive donations and contributions.

ARTICLE II. BOARD OF DIRECTORS

Section 1. General Powers. The general control and management of all affairs of the Foundation shall be vested in a Board of Directors elected by the Board of Directors of the Pharmaceutical Manufacturers Association (hereinafter referred to as "PMA"), as hereinafter provided.

Section 2. Number, Method of Election, and Tenure. The Board of Directors shall consist of the Chairman, Vice Chairman, and Secretary-Treasurer of the Foundation, and four additional persons.

Directors of the Foundation shall be elected for a term of one year and shall serve until a successor is elected and takes office.

Directors need not be residents of the District of Columbia, but must be members of the PMA Board of Directors. Any Director who ceases to be a member of the PMA Board of Directors shall cease being a Director of the Foundation.

There shall be no limit on the number of terms which any individual may serve as a Director.

Section 3. Vacancies. In the event of a vacancy on the Board of Directors by reason of the death, disqualification, resignation, removal or disability of a Director prior to the expiration of his term of office, a majority of the members of the PMA Board of Directors may elect a successor for the balance of such unexpired term.

Section 4. Regular Meetings. A regular annual meeting of the Board of Directors shall be held as soon after the regular annual business meeting of PMA as practicable, at such place and at such time as may be designated by the Chairman then in office.

Section 5. Special Meetings. The Chairman may, and upon the written request of at least three of the other Directors shall, call a special meeting of the Board of Directors upon written notice no more than thirty, nor less than fourteen, days in advance at such place, within or without the District of Columbia, and at such time as shall be designated by the Chairman in the written notice.

Section 6. Quorum. Except as otherwise provided in these By-laws or by statute, a majority of the Board of Directors shall constitute a quorum and a majority of the Directors present at a meeting at which a quorum is present shall be authorized to conduct all affairs for and on behalf of the Foundation.

Section 7. Compensation. Directors shall not be paid compensation for their services as such, but by resolution of the Board of Directors, expenses of attendance, if any, may be allowed for attendance at regular or special meetings of the Board.

ARTICLE III. OFFICERS

Section 1. Elective Officers. The elective officers of the Foundation shall consist of a Chairman, a Vice Chairman, and a Secretary-Treasurer, who shall be elected for a term of one year at the regular annual meeting of the Board of Directors.

Section 2. Appointive Officers. The Board of Directors shall employ a President who shall be the person serving as President of the PMA and such other officers or employees as it deems advisable.

Section 3. Responsibilities. The Chairman shall exercise general and administrative control over the affairs of the Foundation between meetings of the Board of Directors, and in the event that any officer shall be prevented by unforeseen circumstances from fulfilling the obligations of his office, the Chairman is authorized to appoint any member of the Board of Directors other than him-

self to fill such office for the unexpired portion of such officer's term.

The Vice Chairman shall exercise all of the powers of the Chairman during the absence of the Chairman, or in the event of his disability.

The Secretary-Treasurer shall have custody of the Foundation's seal and shall provide for the preparation and retention of the records of all meetings of the Foundation, the Foundation's Board of Directors and any committees of the Foundation.

The President shall conduct the affairs of the Foundation under the direction of the Board of Directors, according to the policies of the Foundation. The President shall have custody of all funds and assets of the Foundation and shall make deposits and disbursements. The President shall be bonded and his accounts audited annually by a certified public accountant. His duties shall include the keeping of all accounts and records; the payment of all bills; the preparation and filing of the annual report required by §29-1083 of the District of Columbia Code and payroll tax and income tax returns; and the preparation of the operating budget and financial statements.

ARTICLE IV. COMMITTEES

Section 1. The Board of Directors may from time to time appoint such committees as it deems necessary or convenient to advise the Board in the performance of its functions hereunder, but such committees will have no authority to act on behalf of the Board.

ARTICLE V. OFFICE AND SEAL

Section 1. Principal Office. The principal office of the Foundation shall be located in the same state as the principal office of PMA.

Section 2. Seal. The Foundation shall have an official seal, an impression of which is affixed hereto.

ARTICLE VI. AMENDMENT

These Bylaws may be amended, altered, or repealed by the affirmative vote of at least 75% of the Directors then in office at a regular or a special meeting of the Board of Directors called for the stated purpose of voting on such amendment, alteration, or repeal, provided that at least thirty days written notice is given of such intention.

contributors

(As of December 31, 1965)

PMA Member Firms

ABBOTT LABORATORIES	\$30,000.00
C. B. FLEET Co., INC.	500.00
LEDERLE LABORATORIES	25,000.00
CHAS. PFIZER & Co., INC.	25,000.00
THE UPJOHN COMPANY	30,000.00

Personal and Other

S. BARKSDALE PENICK, JR.	\$1,000.00
PHARMACEUTICAL MANUFACTURERS ASSOCIATION	25,000.00

applications

The Foundation welcomes requests for support and suggestions for projects from qualified institutions and individuals.

It is suggested that an initial request for assistance take the form of an informal letter outlining in brief the subject, purposes, scope and estimated cost of the undertaking. Letters should be addressed to

C. JOSEPH STETLER, *President*

PHARMACEUTICAL MANUFACTURERS ASSOCIATION
FOUNDATION, INC.

1155 Fifteenth St., N. W.

Washington, D. C. 20005

