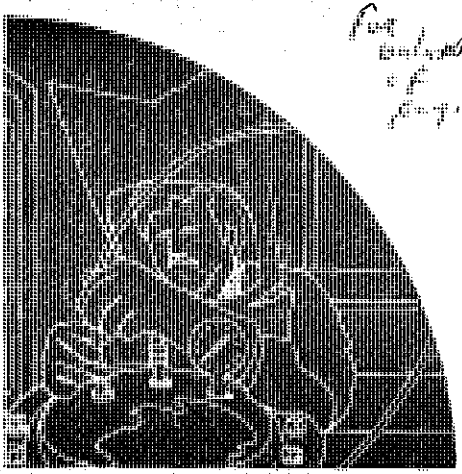
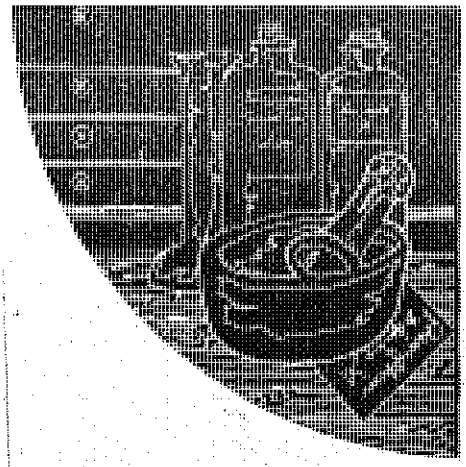
Prescription Drug Industry

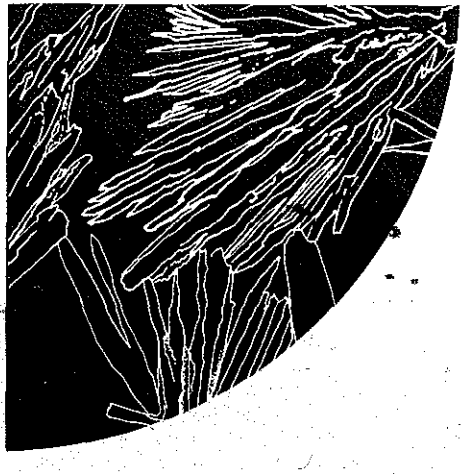
FACTBOOK'76

see P.63 for balance of segments









Pharmaceuticals, medical devices and diagnostic products

FACTBOOK

This publication is a reference guide for persons interested in the social and economic aspects of manufacturing and distribution of prescription pharmaceuticals, medical devices and diagnostic equipment and materials.

Facts in this book are based on information available in the spring of 1976.

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1976 Edition

Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W., Washington, D.C. 20005

THE PMA

The Pharmaceutical Manufacturers Association is a non-profit scientific, professional and trade organization. Its active membership comprises 130 firms that are principally engaged in the manufacture of prescription pharmaceutical, medical device and diagnostic products. They promote these products primarily to medical and dental practitioners licensed by law to administer and prescribe them. Licensed pharmacists dispense the prescription drugs; the other medical products are typically distributed through other professional channels. Financial support is derived mainly from dues based on the annual sales volume of member firms.

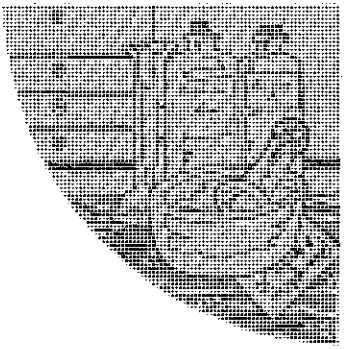
Membership in PMA is voluntary and consists predominantly of manufacturers who produce ethical pharmaceuticals for their own labels and also are engaged in significant research effort. The present members account for the research, development and introduction of more than 90 percent of the new prescription drugs introduced in the United States, as well as half of the free world's supply. These companies also conduct research in medical devices and diagnostic products.

PMA was founded in 1958. It is the successor to the American Association of Pharmaceutical Chemists, organized in 1907 and renamed the American Pharmaceutical Manufacturers' Association in 1922; and to the National Association of Manufacturers of Medicinal Products, founded in 1912 and called the American Drug Manufacturers Association after 1916.

PMA is governed by a 32-member Board of Directors, one third of whom are elected each year at an annual meeting of the membership. There cannot be more than one Board member from any one firm and two new members must be selected each year. Facilitating the Association's work are 12 functional units, known as Sections; these are composed of representatives of member firms and organizations who work closely with the permanent staff on numerous projects. The staff of PMA is organized into six major divisions: Research and Planning, Legal, Scientific and Professional Relations, Public Relations, International, and Medical Devices and Diagnostic Products.

KEY DATA

I. INTRODUCTION



The U.S. pharmaceutical industry, with projected global sales[1] of $12 billion in 1975, emerged as a major industry less than 40 years ago. Until the 1930s, its accomplishments were few. The depression claimed some 3,500 pharmaceutical firms and by 1939, the existing 1,100 companies represented total sales of only $150 million at the manufacturers' level.

Leadership in the industry, in total sales as well as in new drug discoveries, shifted from Europe to the United States during World War II. This increased American involvement resulted from a strong commitment to research and development—the cornerstone of industry progress.

The discovery of sulfa drugs in the 1930s acted as a catalyst for expanded interest in pharmaceutical research and set the stage for the successful development of penicillin, the greatest of many World War II drug developments. Sulfa drugs and antibiotics saved the lives of at least one million Americans during this period. The 15 years between 1938 and 1953 are known as "the Age of Antibiotics"—when a variety of useful new anti-infectives were discovered.

The continued growth of the U.S. pharmaceutical industry will depend, to a large extent, on the success of its research. Although global R&D by U.S. firms topped the $1 billion mark in 1975,[2] one recent survey estimated that the cost of developing a new single chemical entity drug rose from $1.2 million in 1962 to $11.5 million in 1972 and $24.4 million in 1974, a twentyfold increase.[3] Some major causes included the accelerating cost of medical care associated with clinical trials, more elaborate toxicology studies required by stricter government regulation, inflation and the requirement for more complex and sophisticated research techniques.

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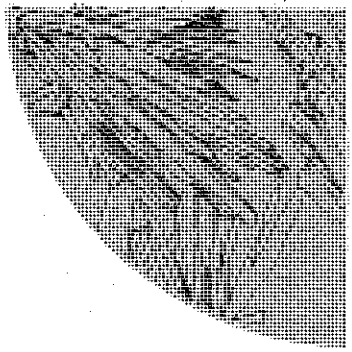
(1) Reference is to sales of ethical pharmaceuticals. "Ethical" pharmaceuticals are those drug products that are promoted only to medical professionals. Most ethical preparations are available to consumers only by prescription. Some, however, can be purchased over-the-counter in a pharmacy; these products are designated as OTC ethical.

(2) Data on R&D expenditures is based on published survey reports of PMA members. PMA members account for the bulk of pharmaceutical R&D conducted in the United States.

(3) David Schwartzman. *The Expected Return from Pharmaceutical Research.* Washington, D.C. American Enterprise Institute for Public Policy Research, 1975.

II. INNOVATION



RESEARCH AND DEVELOPMENT EXPENDITURES

Research and development programs conducted and financed by the industry are largely responsible for new and improved prescription products.

In the last 24 years, research and development expenditures for human-use pharmaceuticals have increased by an average of 12 percent per year *(Figure 1)*.

Company-financed research and development for ethical pharmaceuticals was budgeted at $1,028 million for 1975, a 10 percent increase over the $932 million actually spent in 1974. Research in veterinary products accounted for $74 million, or 8 percent of the 1974 total. Companies spent $133 million, 15 percent, in foreign countries for research on human-use pharmaceuticals. This compares with 7 percent in 1963, 9 percent in 1968 and 10 percent in 1972.

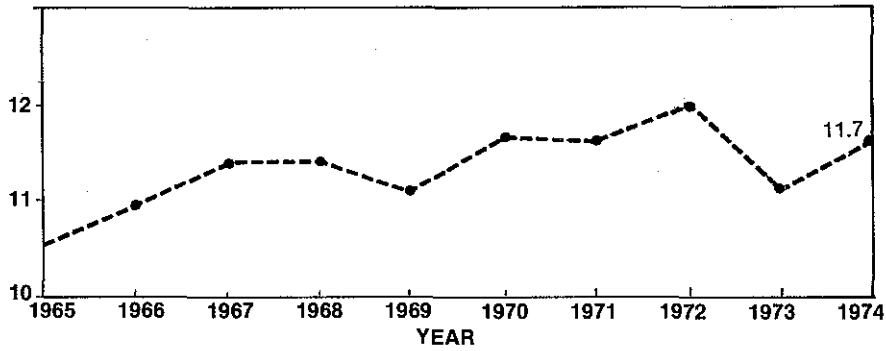
Although companies finance the bulk of R&D, firms also conduct research under contract for the federal government. These government-funded, company-conducted projects involved annual expenditures ranging from $7 to $12 million over the last five years. In 1974, federally financed R&D amounted to $8.6 million or less than one percent of the total spent for human and veterinary-use pharmaceutical R&D.

R&D/SALES RATIO

The ratio of annual R&D expenditures to sales provides a measure of company commitment to research.

Until 1973, there was a slight increase in the annual ratio of company-funded, domestic R&D to sales. In 1973, however, the ratio was 11.2 percent, representing a reduction from the peak 12.1 percent figure in 1972 *(Figure 2)*.

Figure 2. R&D sales ratios, 1965-1974[a]



[a]The PMA collects data on the yearly expenditures of its member companies for R&D in ethical pharmaceuticals, devices and diagnostics. In its *Annual Survey Report*, the Association publishes aggregate R&D expenditure figures for each of these categories. Its R&D/sales ratio for U.S. pharmaceuticals is the ratio of total U.S. pharmaceutical R&D to total sales of pharmaceuticals in the U.S. This includes export sales of U.S. plants but not the sales of overseas affiliates and subsidiaries. It covers research-performing firms only; sales of companies without R&D activities are excluded. Most importantly, it is a homogenous ratio: nonpharmaceutical R&D and nonpharmaceutical sales are excluded. This makes it difficult to compare with other industries, surveyed by the National Science Foundation, for which R&D is given as a ratio of total corporate sales.

Sources: Published PMA survey reports.

ALLOCATION OF RESEARCH FUNDS

Allocation of research effort can be measured in several different ways. PMA, in its surveys, differentiates between expenditures for product innovation and expenditures related to existing products.

The largest share of pharmaceutical industry R&D, approximately 80 percent, is devoted to the quest for new scientific knowledge and the development of new therapies. The remainder is allocated to the improvement of existing products *(Table 1)*.

Table 1: Allocation of R&D expenditures in the United States, 1973-1974

	Human and veterinary-use R&D	
	1973	1974
Research for advancement of scientific knowledge and development of new products and related services	81.2%	81.3%
Significant improvement and modifications of existing products	18.8%	18.7%
Total U.S. R&D	100.0%	100.0%

Sources: Published PMA survey reports.

Table 2: Pharmaceutical industry in U.S. basic research, 1974

Industry	Percentage of basic research conducted by all U.S. industry	Percentage of basic research in each industry funded by U.S. government	Basic research as percentage of all R&D in each industry
Industrial chemicals	23%	33%[a]	12.0[a]
Drugs and medicines	13	5[a]	12.4
Other chemicals	3	5[a]	6.2
Total chemicals and allied products	39	18	11.3
Electrical equipment and communications	27	35	3.3
Aircraft and missiles	8	36	1.0
Machinery	4	[b]	1.0
Petroleum refining and extraction	5	[b]	5.4
Food and kindred products	3	[b]	7.5
Professional and scientific instruments	3	50	2.2
Motor vehicles, transportation equipment	1	[b]	0.4
Stone, clay and glass	2	0	6.4
Other manufacturing industries	4	[b]	[b]
Nonmanufacturing industries (mining, construction, etc.)	4	50	3.3
Total	100%		

[a]Not broken out in 1974; percentage given here is based on 1972 data.

[b]Not available separately.

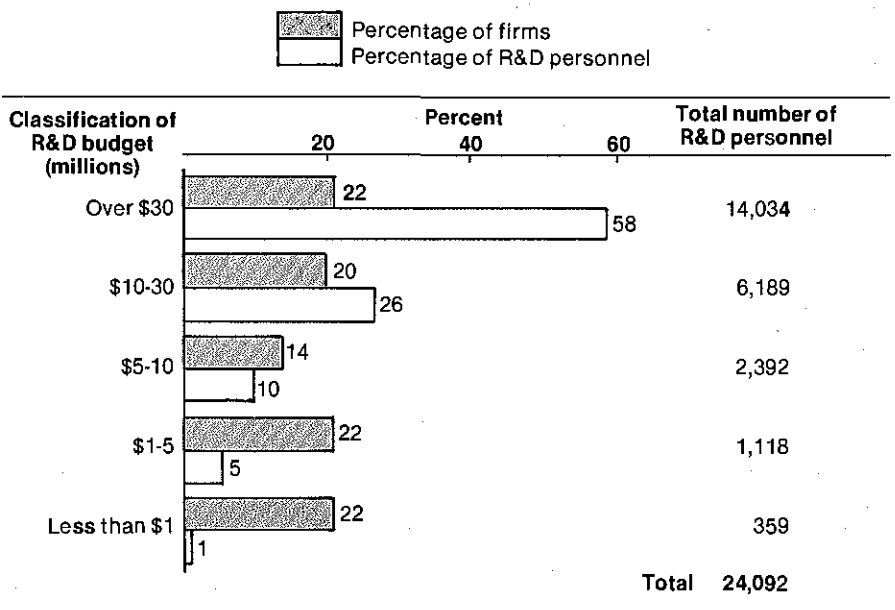
Source: National Science Foundation, *R&D in Industry, 1974.*

Of the total scientific and professional staff in 1974, 4,642 or 37 percent, held doctoral degrees. A slightly larger number, 4,970 held bachelor degrees only, while 2,379 had master's degrees. Approximately 5 percent without bachelor degrees have obtained both the necessary experience and training to qualify for scientific and professional status.

Among the firms reporting research activities, nearly one half had 1974 R&D budgets exceeding $10 million. R&D manpower, according to budget-size classes, is tabulated in *Figure 3.* Comparisons with previous years should be made with caution because budget-size classes have been changed to reflect both inflation and larger R&D budgets.

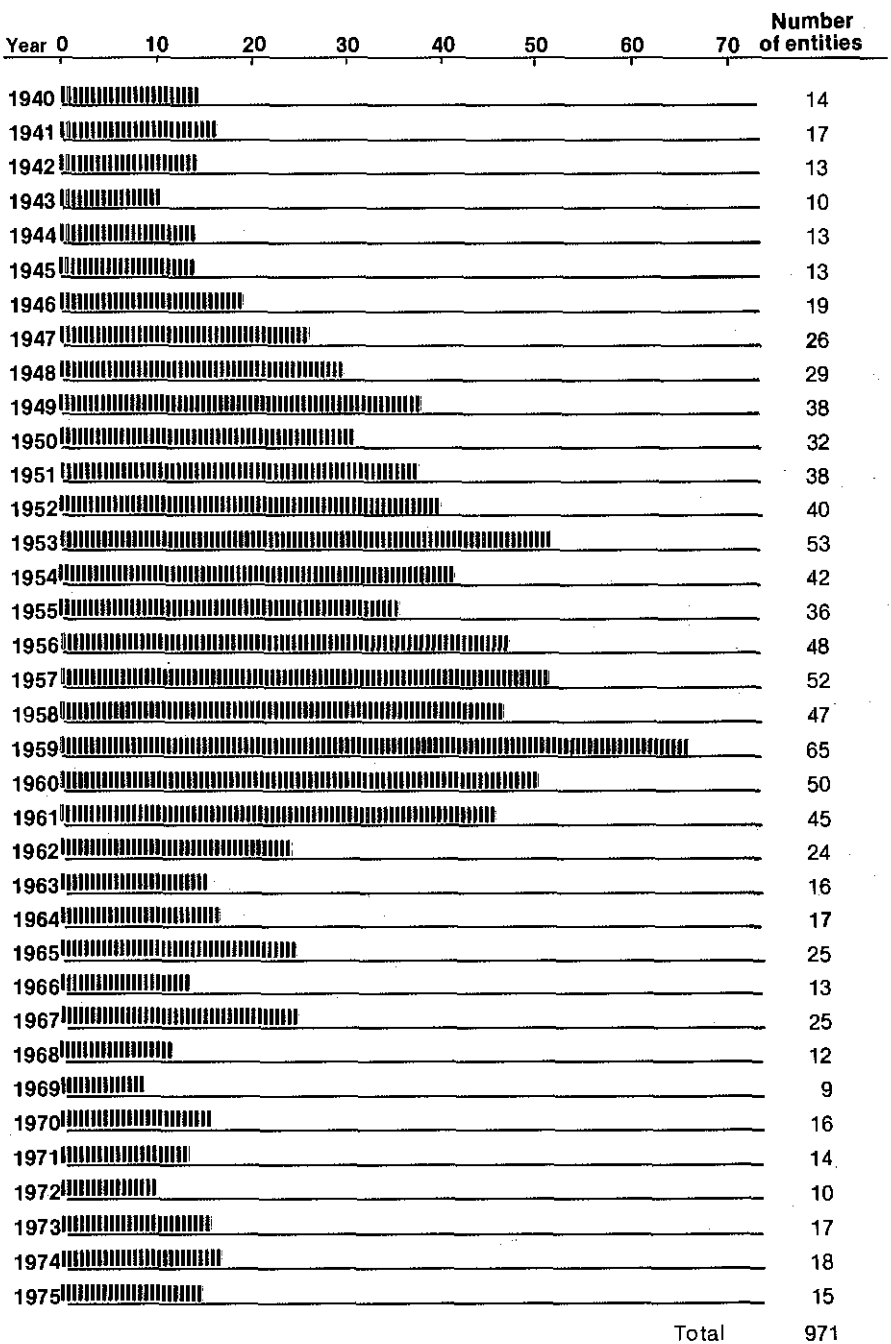
From 1971 to 1973, only firms with R&D budgets in the $10–20 million range increased their total research force, raising employment from an average of 4,300 to 5,200 workers. Companies in the $5–10 million group reduced their research force to 1,564 in 1973, compared to 3,145 in 1971.

Figure 3. U.S. R&D manpower by R&D budget group, 1974



Sources: Published PMA survey reports.

Figure 4. New single entity drug introductions to U.S. market 1940-1975



Source: *Pharmacy Times*, April 1976 (based on data from Paul de Haen, Inc.).

with FDA in the fiscal years 1966 and 1969 through 1975. The tempo of this activity is often dictated by new rules, and changes in data shown may be the result of regulatory or administrative adjustments. Not all INDs lead to new drugs; also, some NDA's are withdrawn by those who submit them. Data in this table relate to only those R&D projects that reach the advanced stage of clinical trials or final submission for new drug approvals. FDA approvals of NDAs show a marked increase for 1974 and 1975.

Table 7: Applications Filed with FDA, Fiscal Years 1966, 1969-1975

Type of application	1966	1969	1970	1971	1972	1973	1974	1975
Investigational new drugs (INDs)	714	835	1120	938	976	913	842	818
New drug applications (NDAs) Original	147	—[a]	92	99	297	146	106	132
Resubmission	239	—	114	130	—	131	159	157
Final printed labeling	—	—	—	—	—	55	68	49
Total	386	—	206	229	448[b]	332	333	338
Total approved NDAs	40	—	51	62	57	50	85	71
Supplemental NDAs	—	—	—	2172	3258	2447	2461	2705
Abbreviated NDAs (ANDA's)	—	—	—	—	—	1981	1576	924
Total ANDAs approved	—	—	—	—	—	292	311	268

[a] not available.

[b] Includes 114 radioactive drugs newly transferred from the Atomic Energy Commission to FDA jurisdiction, and 94 amphetamine drugs to be used for obesity.

Source: FDA Annual Reports and FDA unpublished data.

Patent activity also is an indicator of the intensity of the research process. Patents are obtained for new processes as well as new chemical discoveries, and a new drug may be a composite of several patents. Tables *8, 9* and *10* show patent activity in drugs and medicines for the years 1963-1975. Noteworthy is the decrease in the relative share of U.S. origin patents issued for "Drugs and Medicines," from 66 percent in 1963 to 54 percent in 1975.[4]

(4) Patent Office credits patents to the country of residence shown by the inventor on the patent application. Paul de Haen, Inc. gives credit for "origin" to the country where a discovery was made. These two methods for assigning credit may or may not coincide.

Table 3. Drugs and medicines, patent activity, United States, 1963-1975

	Number of new patents issued (percentages)[a]												
	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975
Total patents	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Originating in the United States	66	66	64	68	68	71	64	64	61	59	57	54	54
Originating in other countries	34	34	36	32	32	29	36	36	39	41	43	46	46
Patents originating in the United States	66	66	64	68	68	71	64	64	61	59	57	54	54
Owned by United States corporations	59	62	59	62	63	64	58	58	56	51	51	47	49
Owned by United States individuals	4	3	4	5	4	3	3	4	4	7	4	5	3
Owned by United States government	2	1	1	1	1	1	1	1	1	1	1	1	1
Foreign owned	1	–	–	–	1	2	1	1	–	–	–	–	1
Patents originating in other countries	34	34	36	32	32	29	36	36	39	41	43	46	46
United States owned	6	7	8	6	6	7	8	9	7	6	7	8	8
Foreign owned	27	27	27	26	25	23	28	27	32	35	37	38	38
Foreign corporations	25	25	25	24	23	21	26	24	29	29	32	34	35
Foreign government	0	–	–	0	–	–	–	–	–	0	0	–	–
Foreign individuals	3	2	3	2	2	2	2	2	3	5	4	4	3

[a]Percentages are rounded off and, therefore, may not always give totals indicated. See *Table 8* for actual numbers.

Source: U.S. Patent and Trademark Office, Office of Technology Assessment and Forecast, published and unpublished data.

Historically the United States has assumed a strong leadership position in drug innovation and still accounts for 64 percent of the new chemical entities introduced in this country since 1940. Switzerland is the second largest originator with 7 percent, followed by the United Kingdom and Germany *(Table 11).*

Table 11: New single chemical entity drugs introduced to U.S. market 1940-1975, by country of origin

Country of origin	Solely National Origin (A)	Country of origin shared: Shared Products (B)[a]	Country of origin shared: Equivalent Number (C)[b]	Accreditation (Col. A + C)	Percentage of Total 971 New Drugs
United States	613	8	4.0	622.0	64.0%
Switzerland	67	2	1.0	68.0	7.0
United Kingdom	50	3	1.5	51.5	5.4
Germany	46	4	2.0	48.0	4.9
France	27			27.0	2.9
Denmark	14	1	0.5	14.5	1.5
Belgium	12			12.0	1.2
Sweden	12			12.0	1.2
Holland	10			10.0	1.0
Japan	10			10.0	1.0
Mexico	9	2	1.0	10.0	1.0
Italy	5			5.0	0.5
Austria	3			3.0	0.3
Canada	3			3.0	0.3
Australia	2			2.0	0.2
Hungary	2			2.0	0.2
Czechoslovakia	1	1	0.5	1.5	0.1
Argentina	1			1.0	0.1
India	1			1.0	0.1
Europe (specific nation unknown)	0	1	0.5	0.5	[c]
Source not ascertained	67			67.0	7.1
TOTAL	**960**	**22**	**11.0**	**971.0**	**100.0%**

[a]Column B lists the number of drugs for which a country shared the credit with one or more other countries in the origination of a chemical entity.

[b]For purposes of "accreditation," Column C represents the equivalent single product credit attributed to a country for its role in the origination of the chemical entity (i.e., column B divided by 2).

[c]Less than 0.1%.

Source: *Pharmacy Times*, March 1976. Based on data from Paul de Haen, Inc.

(Continued from p. 18)

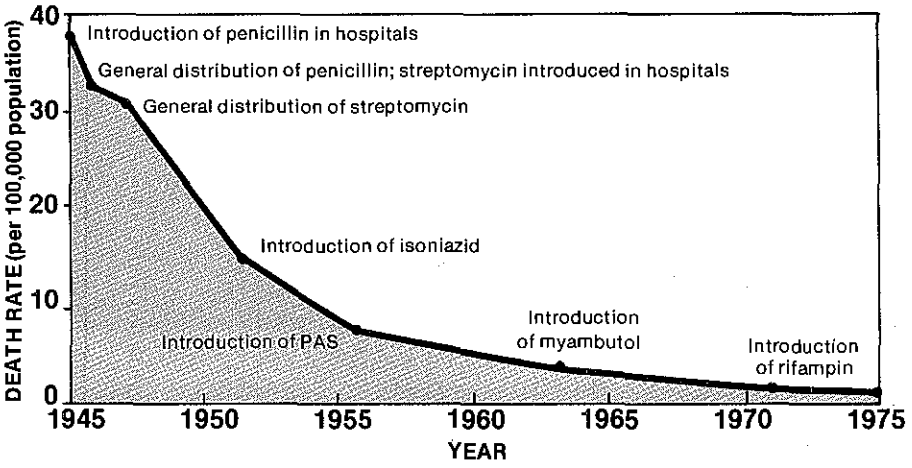
Therapeutic Class	No. in group	No. in subgroup	Percentage
Antimalarials		7	
Antituberculars		17	
Fungicides—systemic		6	
Sulfonamides		33	
Antiparasitics		1	
Topical disease—general		1	
Anti-inflammatory agents (nonhormonal)	6		0.6%
Antinauseants	12		1.2
Anti-obesity preparations	17		1.8
Amphetamines		10	
Other		7	
Antivirals	1		0.1
Ataraxics	52		5.4
Bronchodilators	13		1.3
Cancer chemotherapy	30		3.1
Immunosuppressants	1		0.1
Cardiovascular preparations	71		7.3
Anti-arrhythmics		2	
Cardiotonics		2	
Hypertensives		7	
Hypotensives		21	
Alkaloids		12	
Vasoconstrictors		1	
Vasodilators			
Coronary		7	
Microcirculatory		1	
Peripheral		9	
Xanthine derivatives		5	
Other cardiovasculars		4	
Cholesterol affecting agents	9		0.9
Lipotropics		3	
Other		6	
Coagulants	4		0.4
Convulsants	1		0.1
Cough and cold preparations	24		2.5
Cough preparations		12	
Nasal decongestants		12	
Dermatologic preparations	42		4.3
Antipruritics			
Local		3	
Systemic		2	
Corticoids—local		11	
Fungicides—topical		16	
Other		10	
Diabetic therapy	9		0.9
Hypoglycemics		8	
Hyperglycemics		1	
Diuretics	35		3.6
Benzothiazides		11	
Other		24	

(Continued on p. 20)

BENEFITS OF RESEARCH

Within the past generation alone, the discovery and production of new pharmaceutical products have increased greatly. Improvements in medical care resulting from the introduction of new and better medicines, devices and diagnostic products have enriched and saved many lives. One dramatic example of how new drug introductions have reduced mortality is the declining death rate for tuberculosis *(Figure 5)*.

Figure 5. Decline in TB death rate, 1945-1975



Source: National Center for Health Statistics.

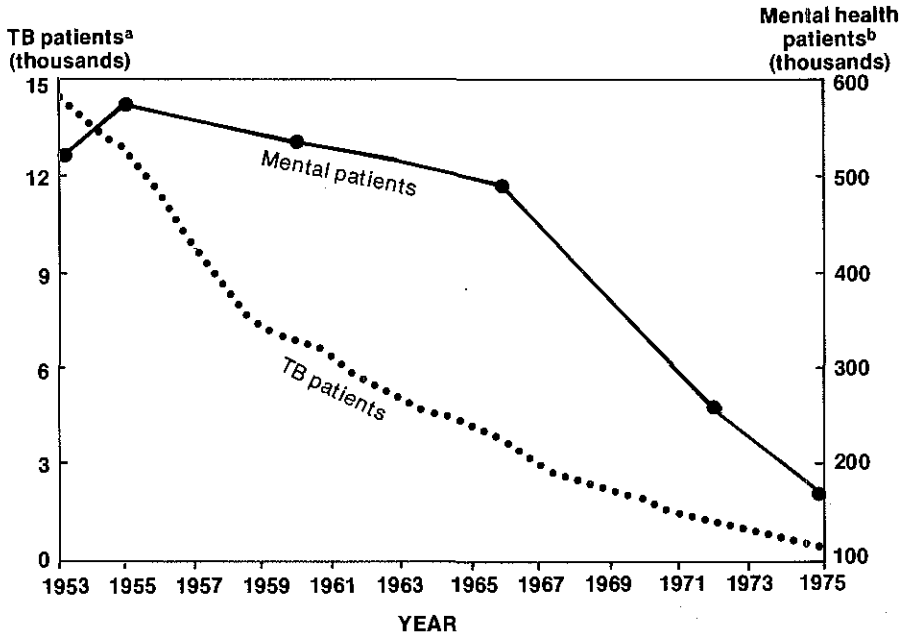
New and improved drug products have contributed to cures for many other diseases. Four of the 10 leading causes of death in 1900 are no longer major causes, as *Table 13* shows. Research by the pharmaceutical firms focuses primarily on drugs to fight the principal ailments of mankind.

Improvements in medical care are most dramatic in certain diseases. *Table 14* lists selected causes of mortality for which drug therapy has been most effective.

As a result of advances in medical treatment, including chemotherapy, in the past three decades the number of patients hospitalized for various conditions and the average length of the hospital stay have declined substantially. *Figure 6* illustrates the reduction in the number of persons hospitalized annually from 1954 to 1974 for tuberculosis and mental illness. The hospital load for tuberculosis patients has declined markedly, and the average annual number of mentally ill patients hospitalized has been reduced by two thirds. New medicines helped cut the average tuberculosis patient's hospital stay from 461 days in 1950 to about 78 days in 1973. The total cost for the typical TB patient today including treatment expenses and lost income is half the cost recorded in 1950.

Major advances have also occurred in the treatment of cancer with drugs. In the 1970s, the use of anticancer drugs in combination has begun to make inroads against several kinds of cancer, including Hodgkin's disease and cancer of the stomach and breast. A survey of

Figure 6. Medicines help reduce hospital load

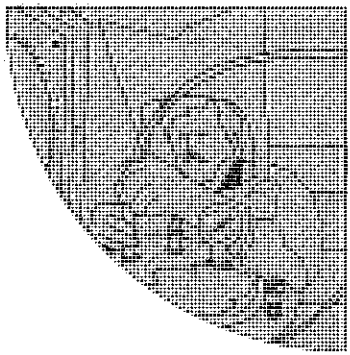


[a]Veterans Administration resident TB patients on annual census dates.

[b]Number of resident patients in state and county mental hospitals.

Sources: Veterans Administration; National Institute of Mental Health.

III. QUALITY ASSURANCE



Although mass production and large-scale operations characterize the pharmaceutical industry, it adheres to strict quality assurance standards—both internal and external. A poorly manufactured drug product may be worse than merely ineffective; it may be dangerous. For this reason, reputable producers develop systems of total quality control to define, produce and maintain a specified quality standard for each unit of every product they offer. This total system may begin with the first pilot production plans and includes the selection and training of personnel, the design of the product, the establishment of specifications and procedures, the design and maintenance of facilities and equipment, the selection, assay and sampling of materials and the design and maintenance of records.

General standards for drug manufacture are published as official "current good manufacturing practice" regulations. For some products, notably antibiotics, vaccines and insulins, the producer's in-process controls are supplemented by batch testing of samples in government laboratories. While official standards for analysis of finished products are invaluable, they are not intended to supplant in-process controls. There have been numerous examples of therapeutic failure of products which conform to official standards, and there are occasional recalls of government-certified products as well.

Batch certification by the FDA determines whether a given sample conforms to official chemical standards. It is not an assurance that the entire production so conforms. More importantly, it does not involve blood level studies to determine whether the product is the bioequivalent of the standard drug. Several antibiotic products, although batch-certified, have had to be recalled when subsequent tests revealed failures in bioavailability.

Although quality control checks vary considerably from product to product, many medicines must be subjected to hundreds of tests, by specialists in quality control using sophisticated equipment, throughout the manufacturing process.

reports. FDA may require additional details concerning the test performed and may specify supplementary testing. Some of these procedures take a great deal of time. Consequently, years may elapse before FDA finally approves a drug for human use.

EQUIVALENCE AND BIOAVAILABILITY

One important measure of drug quality is *bioavailability*. Simply stated, bioavailability is a measure of the degree to which a drug is absorbed by the body to produce the therapeutic effect desired. Physical differences among patients such as age, sex and general state of health, and variations in the ingredients of the drug product (including the inactive ingredients), may cause the absorption of the product to vary from one patient to the next. These considerations are especially significant with prescription drugs because of their potential toxicity and side effects. Drugs with the same bioavailability are considered bioequivalent.

For more than a decade, scientific and political debate has centered on the question of bioavailability. In response to this debate, the U.S. Congress asked the Office of Technology Assessment (OTA) to study and report on drug bioequivalence as it affects prescription drugs on the U.S. market. This study reported that "current standards and regulatory practices do not assure bioequivalence for drug products."[6]

Actual or potential inequivalence of different drug product formulations has been demonstrated or suggested in many widely prescribed drugs. One study[7] lists 73 drug substances with actual or potential problems. More than half of the top 10 generically available products in 1973 are included in this group and account for 51 percent of the 76 million new prescriptions written for all generically available drugs.[8] The FDA, in issuing regulations on bioavailability in June 1975, listed 193 drug dosage forms with a potential for inequivalence.

GENERIC PRESCRIBING

A physician may prescribe a drug by its brand name or by the official or generic name of the basic chemical ingredients contained in that drug. For commonly prescribed drugs that are not patentable or for which the patent has expired, the physician will often prescribe

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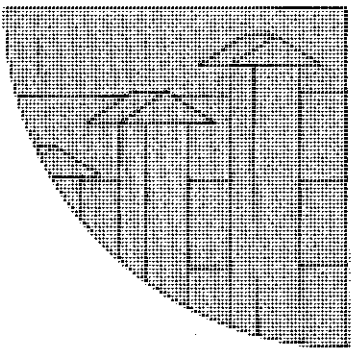
6) U.S. Congress Office of Technology Assessment. *Drug Bioequivalence*. Washington, D.C.: U.S. Government Printing Office, 1974, p. 1.

7) D.J. Chodos & A.R. DiSanto. *Basics of Bioavailability*. Kalamazoo, Mich.: The Upjohn Company, 1973.

8) *Pharmacy Times*, April 1974.

IV. SALES AND GROWTH



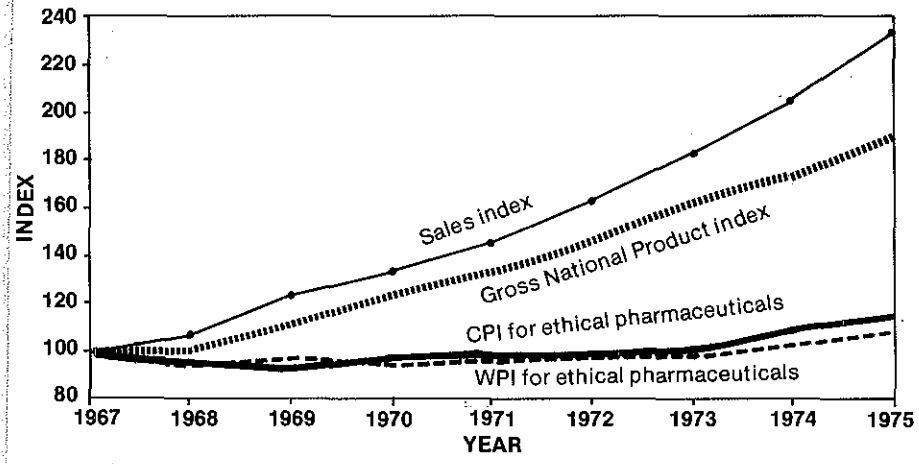
While relatively small in comparison to many industries, the prescription drug industry is significant in its scope and importance and is growing rapidly. Worldwide sales of ethical pharmaceuticals by U.S. manufacturing firms totaled $10.5 billion in 1974, an increase of more than 14 percent over 1973. In 1974, the international operations sector recorded the greatest rise in sales, increasing 20 percent over 1973; exports and sales abroad totalled $3,940 million, compared to $3,278 million in the preceding 12 months. Sales in the United States reached $6.6 billion, with $280 million coming from products for veterinary use and an additional $190 million from bulk form human-use products. U.S. sales of dosage form ethical pharmaceuticals for human use climbed to $6.1 billion in 1974, an increase of 119 percent over the past decade *(Table 17).*

The growth rate of U.S. sales of ethical pharmaceuticals exceeded the growth of the Gross National Product (GNP) by an average of 15 percent between 1967 and 1974, and the difference between the two indexes continues to widen. Furthermore, it appears that little of the growth of the pharmaceutical sales is a result of inflation. According to the government's Wholesale Price Index (WPI), manufacturers' prices for prescription drugs remained essentially unchanged from 1967 to 1973.

In the last half of 1974 and during 1975, however, accumulated cost increases for manufacturers and retail pharmacies were translated into unaccustomed price increases for prescription drugs, both at the manufacturers' and the retail levels. Yet both wholesale and retail price indexes for prescription drugs rose by less than those for other goods and services. Thus, in 1975, the All Industrial Commodities of the Bureau of Labor Statistics (BLS) Wholesale Price Index rose by 11.5 percent over 1974, while the BLS index component for Ethical Pharmaceuticals rose by only 8.6 percent *(Figure 7).*

In the case of the consumer price index for prescriptions, the BLS index rose 6.2 percent in 1975. This compares with a 9.1 percent increase for the BLS All Items Consumer Price Index.

Figure 7. Index comparison: Sales, CPI and WPI, 1967-1975



Sources: U.S. Department of Commerce; Bureau of Labor Statistics.

DISTRIBUTION

Manufacturers distribute ethical pharmaceuticals in many different ways, depending on the ultimate dispensing agency, company policy, geographical location and destination of products. Three quarters of the sales are direct either to wholesalers or to retailers. Shipments to wholesalers declined from 59 percent of all sales in 1954 to 45 percent in 1974, and the share of the retailer decreased slightly from 30 percent in 1954 to 28 percent in 1974. The hospital share increased steadily from 9 percent in 1954 to 23 percent in 1974.

Since some hospitals, nursing homes, governmental institutions, and dispensing physicians purchase from wholesalers, the share of prescription drugs dispensed through drug stores is probably less than the 73 percent (i.e., 45 percent to wholesalers plus 28 percent sold directly to retailers) indicated in *Figure 8.*

The scope of industry activity is also measured by the value of shipments, in accordance with standard U.S. Bureau of the Census data-collection techniques used in the Census of Manufacturers and Current Industrial Reports (CIR). These shipments of pharmaceutical preparations fall into eight therapeutic classes. Products affecting the central nervous system and the sense organs continue to represent

Table 18: Value of domestic shipments, dosage form, ethical pharmaceuticals by therapeutic class (SIC 2834)

Pharmaceutical preparations for:	1970 Millions of dollars	1970 Percentage	1974 Millions of dollars	1974 Percentage
Central nervous system and sense organ diseases	[illegible]	[illegible]	[illegible]	[illegible]
Parasitic and infectious diseases	[illegible]	[illegible]	[illegible]	[illegible]
Neoplastic, endocrine, and metabolic diseases	[illegible]	[illegible]	[illegible]	[illegible]
Digestive, genito-urinary system diseases	[illegible]	[illegible]	[illegible]	[illegible]
Cardiovascular system diseases	[illegible]	[illegible]	[illegible]	[illegible]
Vitamins, nutrients, and hematinics	[illegible]	[illegible]	[illegible]	[illegible]
Respiratory system diseases	[illegible]	[illegible]	[illegible]	[illegible]
Skin diseases	[illegible]	[illegible]	[illegible]	[illegible]
Veterinary	[illegible]	[illegible]	[illegible]	[illegible]
Total	[illegible]	[illegible]	[illegible]	[illegible]

Source: Department of Commerce, "Current Industrial Reports."

Table 19: Shipments of biologicals, medicinals and botanicals

Product class	1970	1973	Change
Biological products (SIC 283)	350.9	559.2	+ 83%
Blood and blood derivatives, for human use	80.0	153.3	+ 92
Vaccines and antigens, for human use	84.7	83.0	- 2
Antitoxins, therapeutic immune serums, for human use	13.6	17.3	+ 27
Diagnostic substances, other biologics, for human use	124.9	201.9	+ 62
Biological preparations for veterinary use	45.1	86.9	+ 93
Biological products, not specified by kind	(2.6)[a]	16.8	—
Medicinals and botanicals (SIC 2831)	747.1	985.5	+ 32
Synthetic organic medicinal chemicals, in bulk	605.0	814.9	+ 35
Medicinal chemicals and botanical products, in bulk, n.e.c.[b]	121.1	157.1	+ 30
Medicinals and botanicals, not specified by kind	(20.9)[a]	13.5	—

[a] "These figures have associated standard errors exceeding 15 percent, or are not consistent with other census series."

[b] Not elsewhere classified.

Source: U.S. Department of Commerce, Census Bureau.

Sales of veterinary drugs gained 36.8 percent between 1968 and 1974 with most of the increase in dosage form product. Bulk pharmaceuticals for animal use increased by about 15 percent in these six years *(Table 21)*.

Table 21: Domestic sales, veterinary products

	1968		1974		
	Millions of dollars	Percent of all pharmaceutical sales	Millions of dollars	Percent of all pharmaceuticals sales	Percent dollar increase
Dosage form	[illegible]	[illegible]	[illegible]	[illegible]	57.2%
Bulk	[illegible]	[illegible]	[illegible]	[illegible]	14.9
Total	[illegible]	[illegible]	[illegible]	[illegible]	**36.8%**

Sources: Published PMA survey reports.

Concentration in "Pharmaceutical Preparations" is considerably below that of a majority of industries. Among the 453 industries analyzed in 1972, 294 had higher 4-firm concentration ratios, 14 had the same, and 145 had lower ratios.

As with any industrial sector, the concentration rate is higher when the industry is subdivided into subcategories. Thus, the 4-firm concentration rate for drill presses would be higher than the rate for all machine tools. But when the pharmaceutical industry is analyzed according to major product classes (e.g., anti-infectives, anti-inflammatory agents, analgesics, psychopharmaceuticals), there is no evidence of a trend toward greater concentration. Indeed, an examination of the market share held by the top four firms of these "relevant markets" shows a slight decline, for the five-year period 1967-1971, compared to that of the previous five years. There has been a marked reduction, since the 1962 amendments to the Food, Drug and Cosmetics Act, in the number of firms successful in obtaining government approval for compounds. This does not appear to have been matched by a similar trend toward concentration in product sales. It is evident that major firms have been broadening out.

PMA estimates that in 1974, approximately 750 companies were manufacturing prescription products. Most of these are small, since PMA's 130 member firms, which include virtually all of the R&D-based manufacturers, accounted for 93 percent of domestic pharmaceutical sales in 1974. Market shares by sales groups, based on 1974 PMA surveys, appear in *Table 23.*

Table 23: U.S. market shares, ethical pharmaceuticals, by sales size group, 1974

Firm sales size (millions)	Percent of domestic market
[illegible]	[illegible]
Total	**100.0%**

Sources: Published PMA survey reports.

A recent study[11] measures entry into 17 therapeutic drug markets from 1963 to 1972 *(Table 25)*. On the average, 10 percent of 1972 sales came from companies not competing in these markets in 1963. In two therapeutic drug markets, over one third of 1972 sales were accounted for by firms which were not competing in those markets in 1963. This study suggests that the market power of existing firms does not bar entry.

Table 25: Entry of new firms into therapeutic markets, 1963-1972

Market	Entry measure 1963-1972[a]	Number of firms[b]
Anorexics	4.24%	38
Anthelmintics	18.28	4
Antibiotics (B&M)	12.84	56
Anticonvulsants	0.33	7
Antihypertensives	4.85	30
Ataraxics	2.63	28
Bronchial dilators	3.76	43
Coronary vasodilators	12.19	43
Diuretics	33.39	19
Oral contraceptives	43.34	6
Oxytocics	1.46	2
Penicillins	7.65	30
Psychostimulants	10.30	9
Sedatives and hypnotics	2.45	39
Sulfonamides	3.17	29
Thyroid preparations	0.44	11
Trichomonacides	16.11	9
Unweighted average	**10.44%**	

[a]Represents the 1972 market share of successful entering firms that were not in the market in 1963.

[b]Represents the number of successful entrants that make up the entry measure.

Source: A.T. Kearney, Inc., "Study of the Economics of Entry and Exit in the Pharmaceutical Industry," 1974.

ASSETS

The Internal Revenue Service (IRS) periodically compiles data on the assets of drug manufacturers. *Table 26* shows the IRS distribution in seven groups. IRS data show that 1,139 drug manufacturers filed tax returns in 1971.

(11) A.T. Kearney, Inc. *Study of Economics of Entry and Exit in the Pharmaceutical Industry*, 1974.

According to the Federal Trade Commission's *Quarterly Financial Reports,* the average rate of after-tax earnings of drug manufacturers regularly exceeds the average of manufacturing industries as a whole by a substantial margin, which declined between 1970 and 1974 and showed a slight increase in 1975 *(Table 27).*

Although the rate of return on stockholders' equity or net worth is more meaningful than the rate of return on sales, it still has shortcomings. It measures the accounting rate of return, which may be quite different from the true economic rate of return. The difference is particularly pronounced when all manufacturing industries are compared with industries with a high rate of investment in "intangibles," whether in research and development or in marketing. In either case, the firm is investing—setting aside present earnings for projects which may not bear fruit (if at all) for years to come. In this sense, the economist would recognize that the firm is investing exactly as though it were spending the same funds for new plant and equipment. The accounting treatment in the two cases, however, is quite different. Plant and equipment are added to the asset base. They become a part of the stockholders equity or net worth. But when the firm spends money on the salaries of research scientists, the accountants treat this as a current expense, even though a team of expert research scientists may be one of the most important "assets" of a research-based firm.

Table 27: Aftertax earnings as percent of stockholders equity, 1970-1975

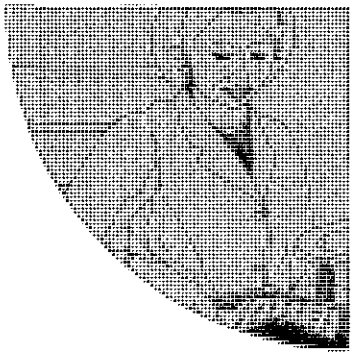
Year	Drugs	All manufacturing
1975	[illegible]	11.5%
1974	[illegible]	14.8
1973	[illegible]	12.9
1972	[illegible]	10.6
1971	[illegible]	9.7
1970	[illegible]	9.3

Source: Derived from Federal Trade Commission, "Quarterly Financial Reports."

This aspect is significant when comparing the rate of return on investment of industries with little or no R&D to that of the pharmaceutical industry, which has the highest ratio of company-funded R&D to sales of all manufacturing. In a recent memorandum, the Federal Trade Commission observed that "the expensing of R&D costs usually leads to an overstatement of profitability with the overstatement increasing with the intensity of the R&D effort."[12]

(12) U.S. Federal Trade Commission, Bureau of Economics Staff. *Statement of Purpose, Annual Line of Business Report Program,* August 3, 1973, p. 6.

VI. EMPLOYMENT AND PRODUCTIVITY



EMPLOYMENT

Worldwide employment in the U.S.-based prescription drug industry in 1974 reached 264,000 according to a PMA survey. Of the total, 153,100 persons were employed in the United States and its dependencies, and 110, 900 in foreign countries.

This employment has grown steadily in the past decade. *Table 28* shows domestic and foreign employment in 1964 and annually from 1969 through 1974. From 1964 to 1974 it increased by 31 percent in the U.S. and by 54 percent overseas. During this period, U.S. employment represented about three fifths of total employment, with small annual fluctuations.

Table 28: U.S. prescription pharmaceutical industry domestic and foreign employment[a] 1964 and 1969-1974

Year	U.S. Number	U.S. Percent	Foreign Number	Foreign Percent	Total Number	Total Percent
1964	[illegible]	[illegible]	[illegible]	[illegible]	189,000	100%
1969	[illegible]	[illegible]	[illegible]	[illegible]	230,900	100
1970	[illegible]	[illegible]	[illegible]	[illegible]	243,430	100
1971	[illegible]	[illegible]	[illegible]	[illegible]	240,620	100
1972	[illegible]	[illegible]	[illegible]	[illegible]	257,020	100
1973	[illegible]	[illegible]	[illegible]	[illegible]	260,010	100
1974	[illegible]	[illegible]	[illegible]	[illegible]	264,000	100

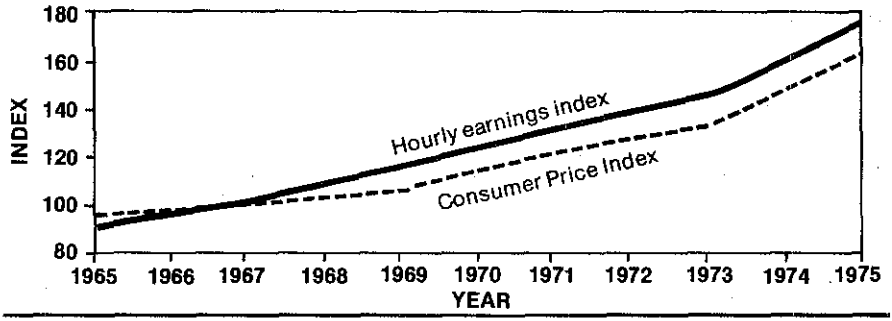
[a]Included are employees of domestic and foreign prescription drug divisions of manufacturers headquartered in the United States and employment in the United States divisions of manufacturers headquartered abroad.

Sources: Published PMA survey reports.

EMPLOYMENT EARNINGS

The Labor Department reports average hourly earnings of production workers in various industries. In 1975, these earnings were $5.13 for production workers in the manufacture of pharmaceuticals, an increase of 11 percent over 1974, and more than double the 1964 average of $2.55. *Figure 9* shows that hourly earnings gained by a larger margin than the rise in the consumer price index, reflecting an increase in real wages during the past decade. Large productivity gains have allowed real wages to rise despite relatively stable prescription drug prices.

Figure 9. Index of hourly earnings for production workers in the pharmaceutical industry and the Consumer Price Index (1967 = 100)



Source: U.S. Bureau of Labor Statistics, *Employment and Earnings, United States, 1909-1975.*

PRODUCTIVITY

Labor productivity, per employee hour, for all employees in the pharmaceutical industry increased at an annual average of 5.9 percent from 1967 to 1974, compared with an average annual increase of 1.6 percent for the overall private, nonfarm economy. While there have been wide year-to-year variations, as shown in *Figure 10,* labor productivity growth for all employees in the drug industry was generally more than double the gain in the overall private nonfarm economy during the past decade.

Table 31 compares the increases in output and employee-hour in the pharmaceutical industry for all employees and for production workers only. Hours worked increased more rapidly for all employees than for production workers alone, particularly in the 1970s. At the same time output of production workers rose more quickly. This reflects continuing efforts to upgrade technology in manufacturing. Productivity

bringing economies of scale, and improvement in production and quality control technologies have contributed to advances in labor productivity.

Total output of pharmaceutical products rose in response to a ready increase in demand during the late 1960s and early 1970s. The relative increase in the young and particularly in the older age groups is a partial explanation of the increased consumption. The expansion of public and private health insurance funds has been another contributing factor.

No less important is the invention and introduction of new drugs. In such categories as oral contraceptives and medicines for diseases of the circulatory system for instance, new discoveries have broadened the market in areas where medicines did not previously exist.

Labor productivity increases are also due, in part, to the substitution of capital for labor. But improvements in production and quality control technologies have required large capital investments. New capital expenditures in the pharmaceutical industry in 1973 were nearly two and one-half times higher than in 1964, compared with a less than twofold increase for the total manufacturing sector.[16] These investments increased substantially with the advent of the national Medicare and Medicaid programs.

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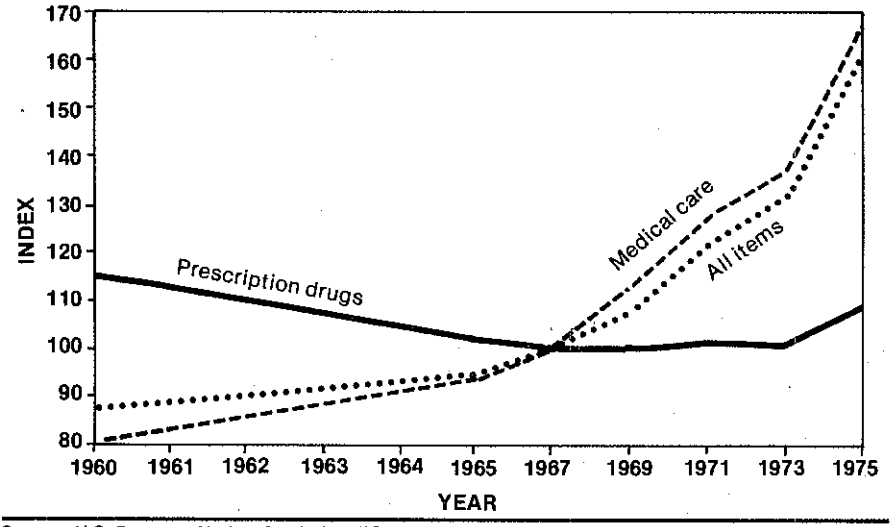
(16) U.S. Bureau of the Census, *Annual Survey of Manufactures.* Washington, D.C.

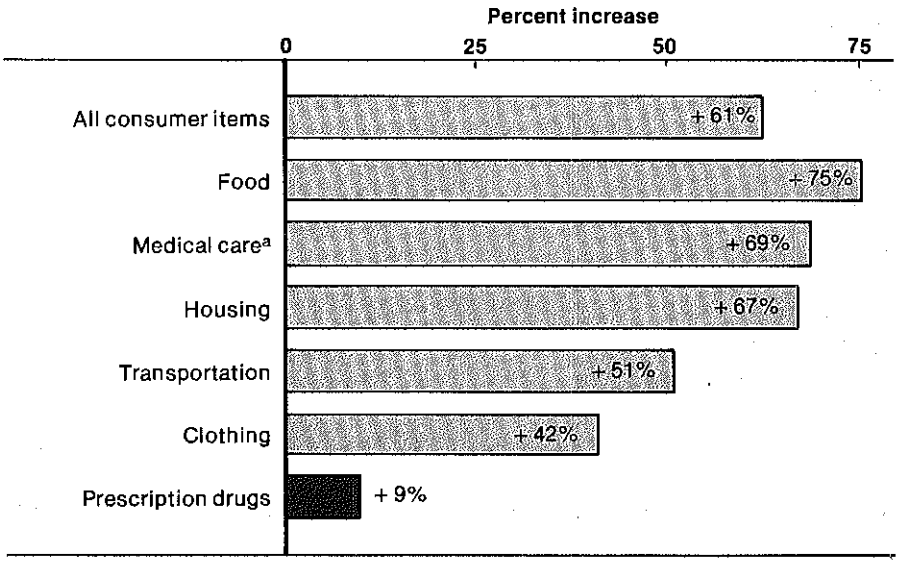
Figure 11. Consumer price index, 1960-1975 (1967 = 100)



Source: U.S. Bureau of Labor Statistics, "Consumer Price Index."

A comparison of relative price increases for various consumer items from 1967 to 1975 is shown in *Figure 12.*

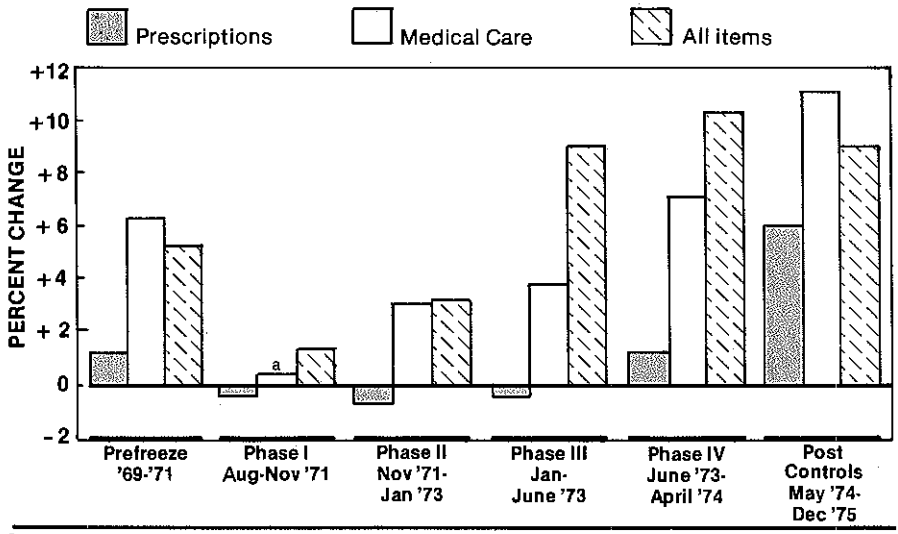
Figure 12. Rate of price increase of selected consumer items 1967-1975



[a]Includes prescription drugs.
Source: U.S. Bureau of Labor Statistics, "Consumer Price Index."

and the cost of all items listed in the CPI rose 3.6 percent annually, with total medical care increasing 3.4 percent. Prescription drugs continued to decline, this time at a rate of 0.9 percent.

Figure 13. Prescription prices under economic controls (CPI)



[a]Decrease due to annual adjustment in the medical care index for the price of health insurance which is not shown as a component of the index but is a factor used in its calculation.

Source: Office of Research and Statistics, Social Security Administration, "Monthly Statistical Report," December 1975-January 1976, based on "Consumer Price Index" data.

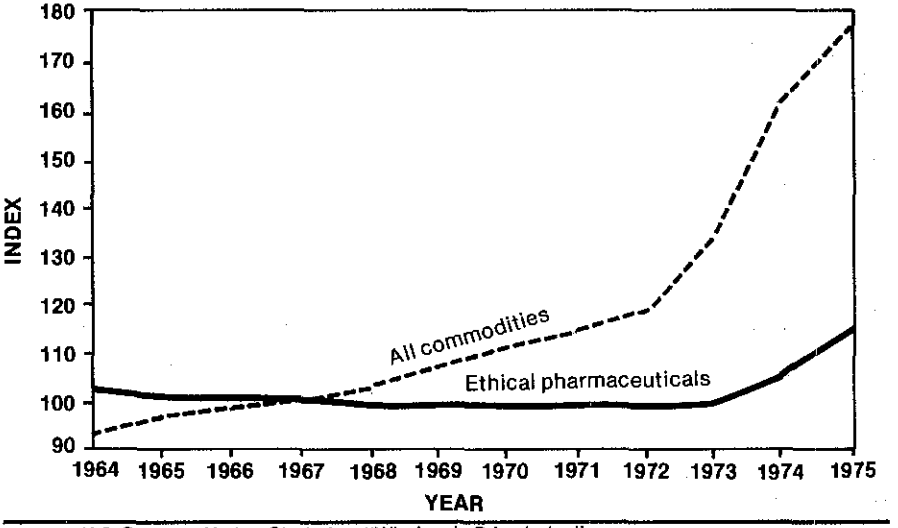
During Phase III, wage-price controls in the health care field remained in effect, while in most other areas mandatory controls were lifted in favor of voluntary compliance. The annual rate of increase for all items during this period was 9.1 percent and for medical care, 3.8 percent. Prescription drugs decreased again, at the annual rate of 0.5 percent.

Retail prescription prices remained stable during Phase IV controls with an increase of only 1.4 percent annually. Overall consumer prices and medical care costs continued to rise at an annual rate of 10.5 percent and 7.6 percent, respectively. All wage and price controls under the Economic Stabilization Program were lifted at the end of Phase IV in April 1974.

In the year and a half that followed, the price of prescription medicines rose at an annual rate of 6.0 percent. At the same time, the annual rate of increase for medical care was 11.6 percent and for all items (including medical care) 9.1 percent.

In 1975, with widespread inflation, the government's "Ethical Pharmaceuticals' component of the WPI rose 8.6 percent above the 1974 average. By comparison, "All Commodities" in the WPI rose 9.3 percent and "All Industrial Commodities" rose 11.5 percent.

Figure 14. Wholesale price index, all commodities and ethical drugs, 1964-1975 (1967 = 100)



Source: U.S. Bureau of Labor Statistics, "Wholesale Price Index".

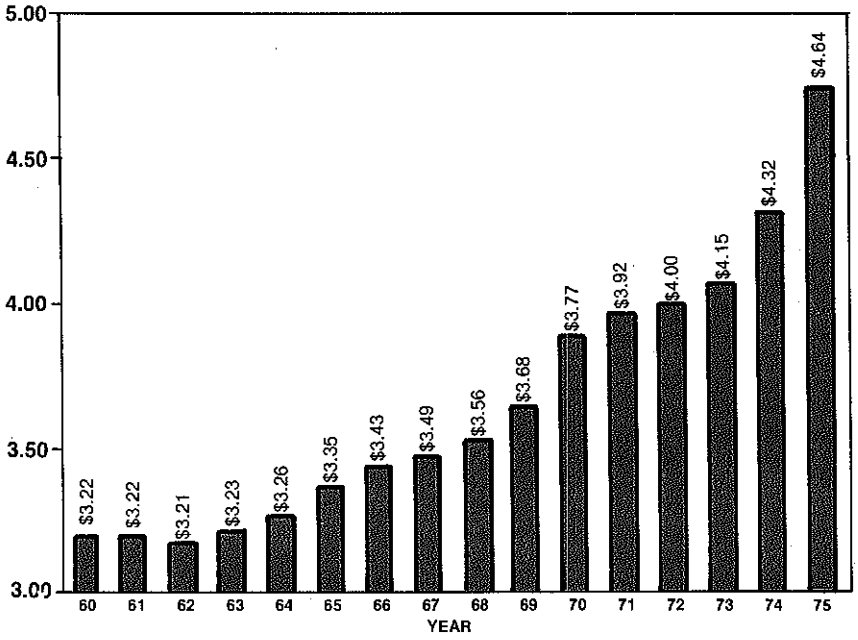
FIRESTONE PRICE INDEXES (MANUFACTURERS' AND RETAIL LEVELS)

Dr. Firestone has for years prepared for PMA comprehensive price indexes on ethical pharmaceuticals, at both the manufacturers' and retail levels. These compilations are based on much larger samples of products than those used by the Bureau of Labor Statistics for the prescription component of the CPI and the ethical pharmaceuticals portion of the WPI. Use of these larger samples resulted in indexes showing larger increases than those measured by BLS, both at wholesale and retail, between 1967 and 1974.

For the year 1975, Firestone again reported a higher increase than BLS at the retail level. With 1967 = 100 in both cases, the Firestone index of 112.2 based on 699 items, was 6.6 percent above the index for 1974, whereas the BLS/CPI index of 109.3 was only 6.2 percent higher than the corresponding 1974 index *(Table 34)*. In either case, the increase — although much higher than in past years—was modest compared to the 9.1 percent increase in the "All Items" CPI and the 12.0 percent increase in the entire "Medical Care Components" of the CPI.

The apparent contradiction between the rising average prescription charge and the stable or declining price index during most of the period since 1960 may seem puzzling. The explanation is that the average prescription charge, which is a measure of unit expenditure, also contains nonprice factors. The most important is the continuing increase in the size (number of doses) of the average prescription. To compare the average prescription charge of 1960 with that of 1975 is like comparing the price of one quart of milk in 1960 with that of 1.56 quarts in 1975.

Figure 15. Average prescription price, 1960-1975

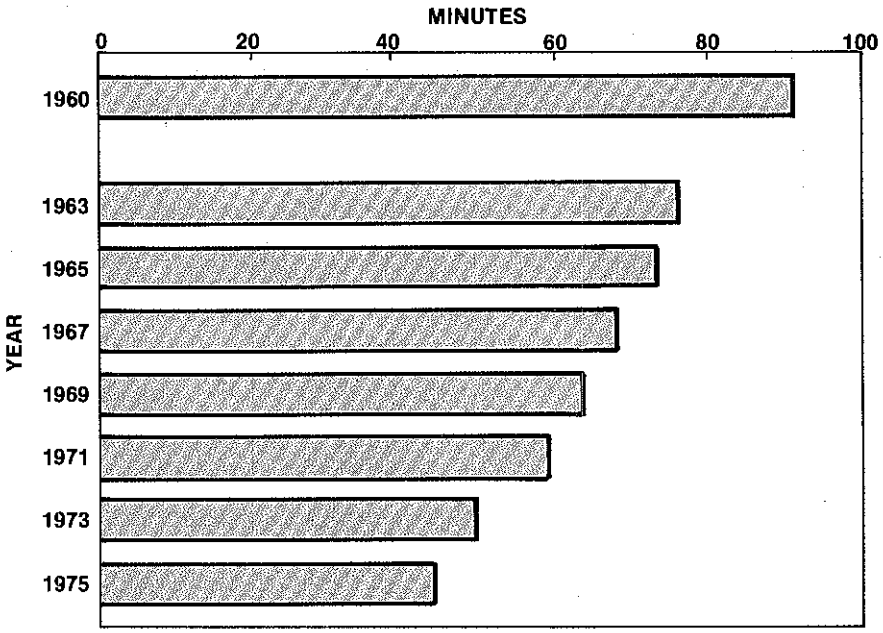


Sources: *American Druggist*, annual prescription surveys.

In addition to preparing price indexes for ethical pharmaceuticals, at both the manufacturers and retail levels, Dr. Firestone has also developed an index based on the average charge for new prescriptions adjusted to allow for size changes. This study, based on pharmacy prescriptions sales audits, shows that the typical 1975 prescription contained 38 percent more medication than its 1965 counterpart, and 56 percent more than in 1960 *(Figure 16).*

This increase has boosted the average charge to the patient in spite of the overall decline in prescription prices, as reflected in the CPI. The smaller decline in the adjusted prescription charge, when compared with the retail price index, is believed to be due to the effect of doctors shifting to newer products, a nonprice element that exerts an upward influence on the average prescription charge but not on the price index.

Figure 17. Working hours required for average prescription purchase adjusted to the size of the 1960 prescription[a]



[a]Data based on a person with three dependents working in a manufacturing establishment.

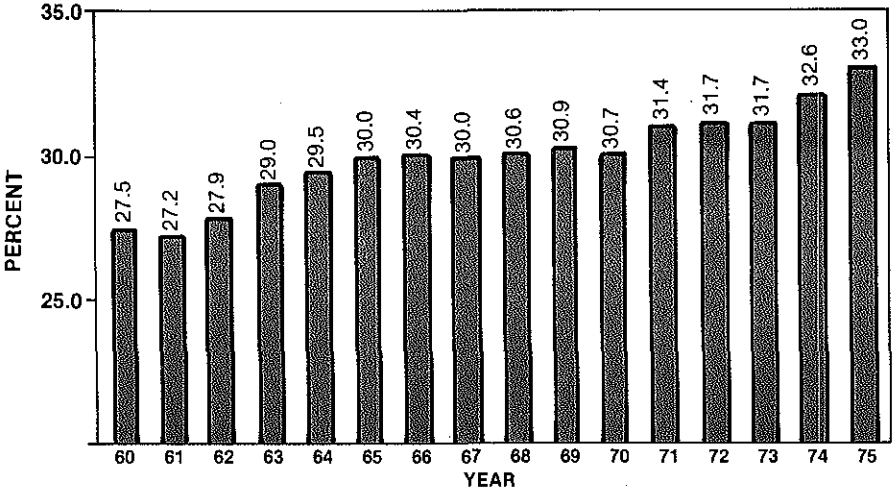
Source: Derived by dividing data in *Figure 16* by earnings figures from U.S. Bureau of Labor Statistics, *Handbook of Labor Statistics 1975,* pp. 176 and 258.

The share of the consumer's prescription dollar received by the manufacturer, the wholesaler and the retail druggist varies from one product to another. One factor is the manufacturer's price. On the more expensive drugs, the retailer's percentage margin is typically lower. Some manufacturers market through wholesalers while others typically sell direct, in which case there is no wholesaler's share. Finally, the same product, sold by a manufacturer or wholesaler at the same price, may retail at different prices depending upon the pharmacy location, costs, prescription volume and services offered.

It is possible, however, to determine the average share going to manufacturer, wholesaler and retailer for a representative group of the most widely prescribed drug products, based on nationwide audits of pharmacy invoices and of prescription sales. A market research firm (IMS, America, Ltd) undertook this research on the top 50 prescription drug products in 1969, 1973, 1974 and 1975 *(Table 35).* The manufacturers' share varies from 42 to 46 percent. The small average share going to

drugstore sales, accounting for 50 percent of sales volume in independent pharmacies in 1975. When one includes chains as well as independents, however, the share of prescription drug sales is reduced to about one third of total drugstore sales[19] *(Figure 18).*

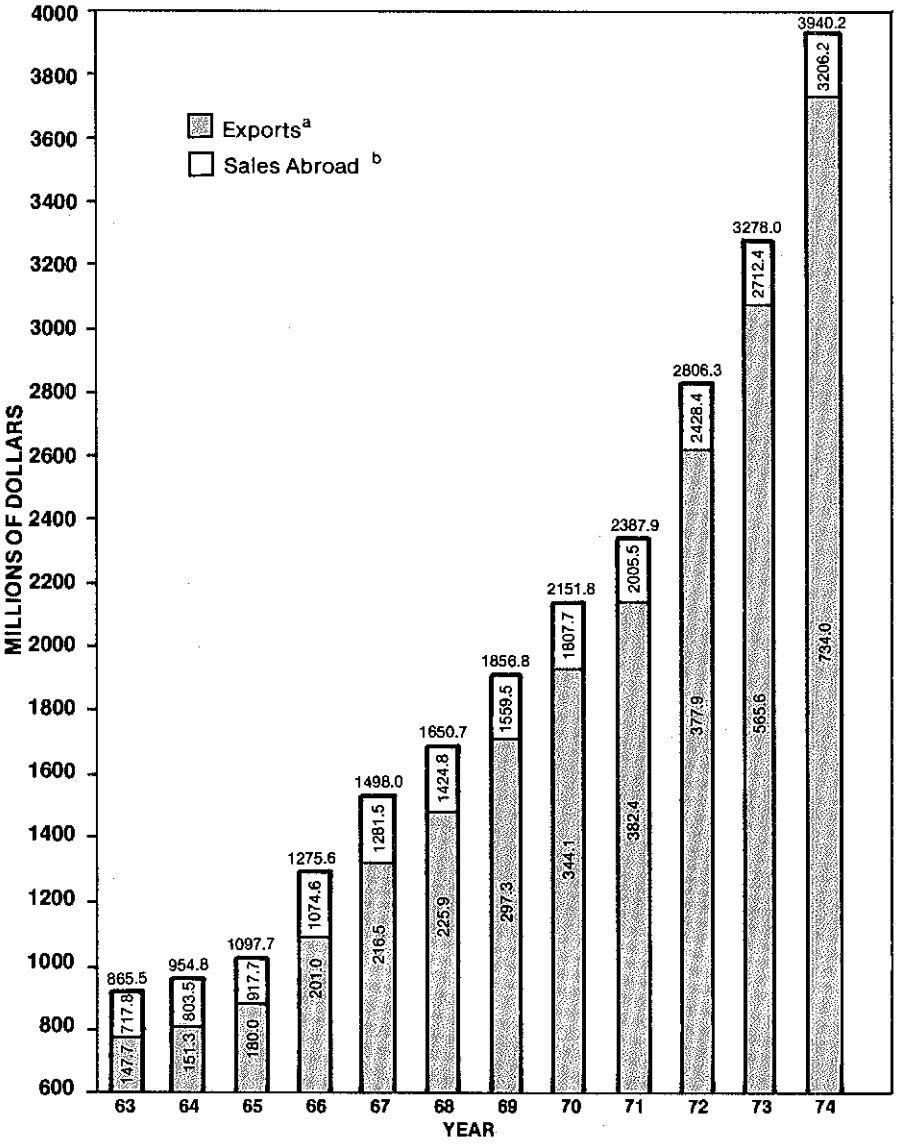
Figure 18. Prescription sales as a percent of total drugstore sales average per pharmacy, 1960-1975



Sources: *American Druggist,* annual prescription surveys, 1960-1975.

(19) *American Druggist,* August 1975, pp. 55-56.

Figure 19. Foreign sales of ethical pharmaceuticals by U.S. firms 1963-1974

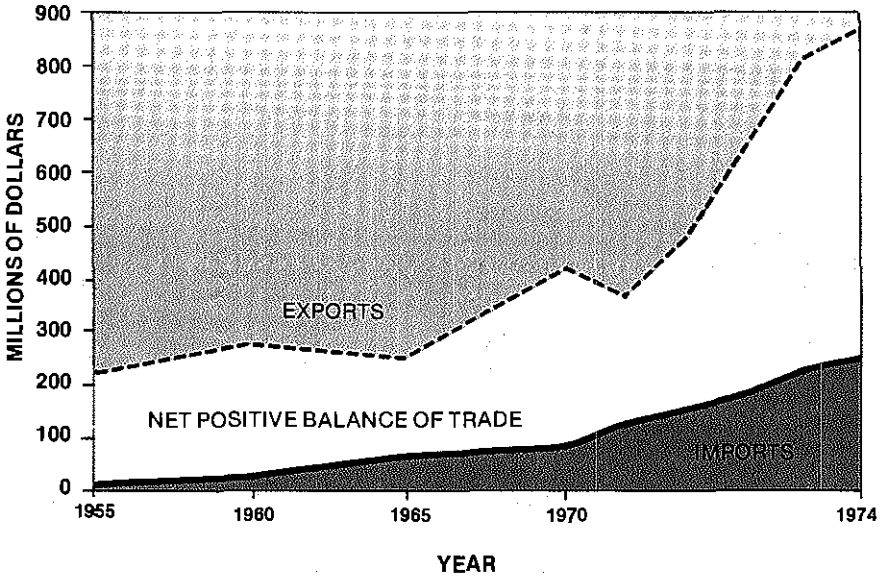


[a] "Exports" includes shipments to subsidiaries as well as exports to nonaffiliated firms.

[b] "Sales Abroad" refers to sales in a foreign area by subsidiaries or other corporate operations, adjusted to eliminate double-counting of intra-firm transactions. Also excluded are sales outside the U.S. by foreign-owned firms which have subsidiaries in the U.S.

Sources: Published PMA survey reports.

Figure 21. U.S. drug exports and imports, 1955-1974[a]



[a]Data may differ from PMA material in Figure 19 since Figure 21 includes proprietary as well as ethical pharmaceuticals; PMA statistics are based on surveys of companies, whereas Census Bureau data is derived from export-import documentation.

U.S. TRADE POSITION

The U.S. pharmaceutical industry represents an important positive factor in the U.S. trade balance. Further, its exports of technology, management skills and engineering services, and its licensing of patents and underlying know-how, net the U.S. substantial additional foreign exchange earnings.

On the basis of 1974 data, the United States ranked second only to West Germany in total prescription and nonprescription pharmaceutical exports as well as in net exports (i.e., excess of exports over imports). *Table 36* shows the 1974 positions of the leading countries in pharmaceutical trade.

Table 37: Company financed R&D expenditures in foreign countries (millions of dollars)

	Human use		Veterinary use	
	Actual 1974	Budgeted 1975	Actual 1974	Budgeted 1975
Amount spent within firms in foreign countries	[illegible]	[illegible]	[illegible]	[illegible]
Amount outside firms in foreign countries	[illegible]	[illegible]	[illegible]	[illegible]
Total	**$132.5**	**$148.2**	**$15.2**	**$17.2**

Sources: Published PMA survey reports.

Table 38: Domestic and foreign shares of company-funded R&D expenditures, 1973-1974

R&D expenditures, human and animal-use pharmaceuticals	1973	1974
Domestic	85.6%	84.2%
Foreign	14.4	15.8
Total	**100.0%**	**100.0%**

Sources: Published PMA survey reports.

Table 39: Percent distribution of total national health expenditures by type of expenditure, fiscal years 1960 and 1975

Type of expenditure	Fiscal year 1960	Fiscal year 1975[a]
Total—million of dollars	$25,856	$118,500
Total—percent	100.0%	100.0%
Health services and supplies	93.5%	93.9%
Hospital care	32.9	39.3
Physicians' services	21.6	18.6
Dentists' services	7.5	6.3
Other professional services	3.3	1.8
Drugs and drug sundries	13.9	8.9
Eyeglasses and appliances	2.9	1.9
Nursing home care	1.9	7.6
Expenses for prepayment and administration	3.1	3.9
Government public health activities	1.5	2.9
Other health services	4.9	2.5
Research and medical-facilities construction	6.6%	6.1%
Research[b]	2.3	2.3
Construction	4.3	3.8
Publicly owned facilities	n/a	2.3
Privately owned facilities	n/a	2.7

[a]Preliminary estimates

[b]Research expenditures of drug companies in "drugs and drug sundries" excluded from "research expenditures".

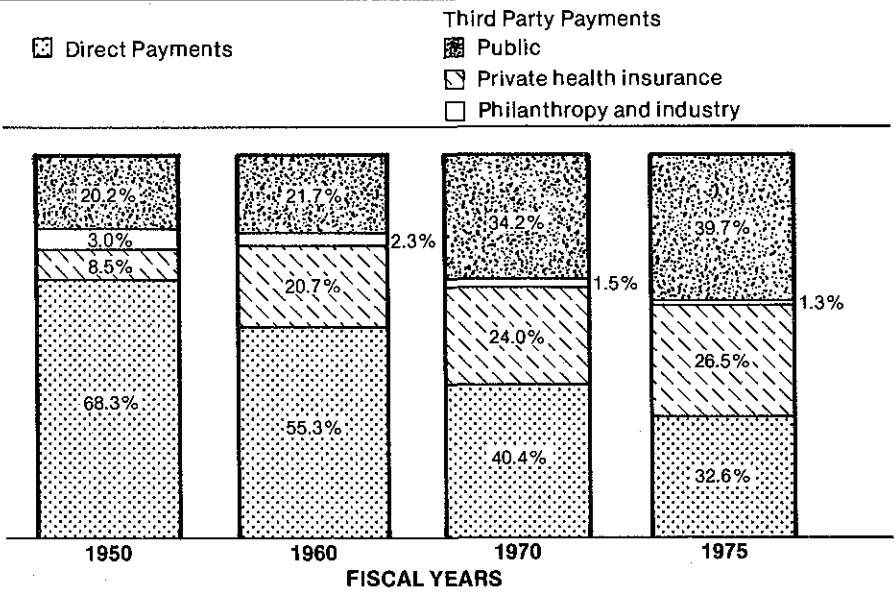
Source: "National Health Expenditures", Report prepared annually by Office of Research and Statistics, Social Security Administration and published annually in Social Security Bulletin, latest edition appearing in February 1976 issue. Percentages computed by PMA from dollar figures in the report.

THE GROWING GOVERNMENT ROLE IN HEALTH CARE FINANCING

After climbing steadily during the 1960s, the share of national health expenditures in the Gross National Product leveled off in the early 1970s and actually declined slightly (from 7.9 to 7.7 percent between 1972 and 1974). In the fiscal year 1975, however, the share rose to 8.3 percent *(Figure 22).*

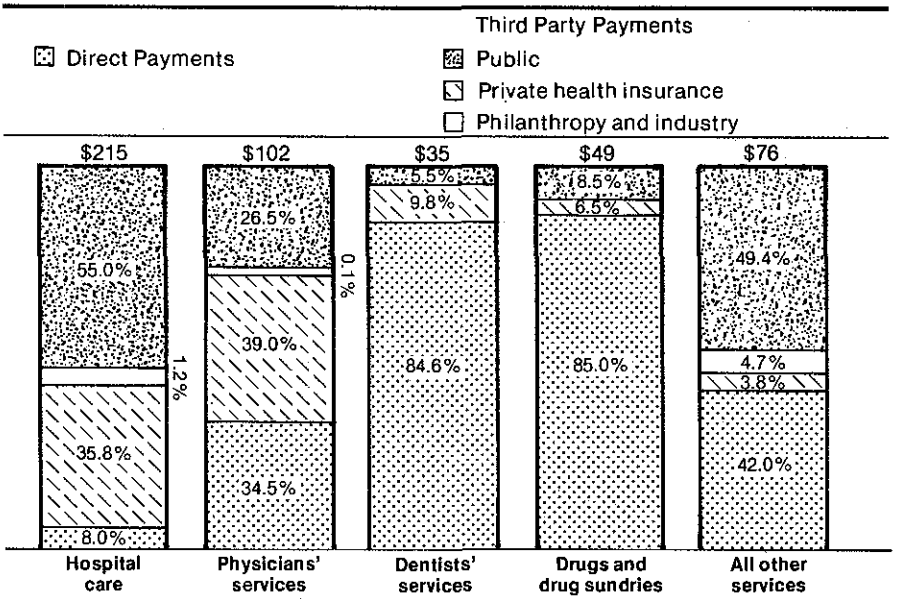
Much of the increase in the 1960s came from third-party payment programs. In addition, the development of government health and income or transfer programs has expanded medical utilization by indigent,

Figure 23. Distribution of personal health care expenditures, by source of funds, selected fiscal years, 1950-1975



Source: "National Health Expenditures," *Social Security Bulletin*, February 1975, p. 17 and February 1976, p. 14.

Figure 24. Percentage distribution of per capita personal health care expenditures, by type of expenditure and source of funds, fiscal year 1975



Source: "National Health Expenditures," *Social Security Bulletin*, February 1976, p. 15.

Table 41: Selected health care establishments and suppliers, 1972

Type of facility	Number
Total hospitals (general and specialty)	7,481
Government	2,770
Federal	405
State and Local	2,365
Proprietary	986
Nonprofit	3,725
Church	854
Other	2,871
Nursing and related care homes[a]	22,004
Other inpatient facilities[a]	4,769
Blood banks[a]	5,400
Community pharmacies[a]	50,602
Drug manufacturers (SIC 2834)	756

[a]1971 data.

[b]January 1, 1973.

Sources: U.S. National Center for Health Statistics, "Health Resources Statistics, 1974" and Department of Commerce.

The program has two parts: a compulsory hospitalization insurance that is financed by contributions from employees and employers, and a voluntary medical insurance that can only be obtained through enrollment.

In January 1976 over 24.3 million aged and disabled persons were entitled to hospital insurance provided by Medicare. Almost all of these individuals were also enrolled in the voluntary medical care program.

A total of $14.8 billion was paid in benefits during FY 1975. This is a gain of 68 percent over 1972. Three quarters of the increase was for hospital care, reflecting the overall rise in hospital prices and costs.

Medicaid expenditures (Title XIX of the Social Security Act) for the medical assistance of persons who, regardless of age, are unable to afford needed health care, constituted 28 percent of all health outlays from public funds in FY 1975. About $28 billion, or 62 percent of the public medical bill was paid by Medicare and Medicaid combined.

Most state public assistance payments for medical care are made in the form of vendor payments to suppliers of such care, i.e., hospitals, nursing homes, physicians, dentists and pharmacists. Vendor payments for prescribed drugs under federally aided public assistance programs are presented by state in *Table 42.*

(Continued from p. 72)

State	Total medical care	Prescribed drugs	% of 1975 total	% of 1970 total
Vermont	31,622	2,414	7.6	10.3
Virgin Islands	2,181	301	13.8	[f]
Virginia	183,640	13,911	7.6	13.2
Washington	172,149	11,891	6.9	7.5
West Virginia	33,461	3,710	11.1	16.2
Wisconsin	360,571	16,788	4.7	6.6
Wyoming[a]	5,478	n/a	n/a	n/a

[a]Do not cover prescription drugs.

[b]Arizona had no Title XIX program; enabling Medicaid legislation passed the state legislature and became effective October 1, 1975. Prescribed drugs were covered. The Arizona House voted in the Spring of 1976 to repeal the Medicaid program and the repeal bill was expected to go to conference with the Senate in late May or June.

[c]Added prescription drug coverage on September 1, 1973.

[d]Cash payments are made to recipients.

[e]Added prescription drug coverage on July 1, 1974.

[f]Two states did not specify expenditures for prescribed drugs in 1970: Idaho; Texas. Expenditures for Indiana, and the Virgin Islands are included in the total column only for 1970.

Source: National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Program, 1976" (based on Social Security data).

On July 1, 1974, South Dakota added prescription drug services to its Medicaid programs. This brought to 50 the number of jurisdictions offering drug benefits. Alaska, Arizona, Oklahoma and Wyoming do not provide any vendor payments for prescription drugs. Oklahoma, however, pays cash grants to Title XIX recipients to cover such costs. Arizona is the only state that had no Title XIX programs in 1974, but enabling legislation was enacted and became effective October 1, 1975, thus completing the Medicaid map of the entire United States.

Total Medicaid vendor payments have increased about 800 percent since 1965 and 130 percent since 1970. *Tabled 43* shows a breakdown of these payments by type of service.

As in the case of total national health expenditures, the prescription drug component is increasing in dollar volume but continuing to decrease as a percentage of total Title XIX benefits.

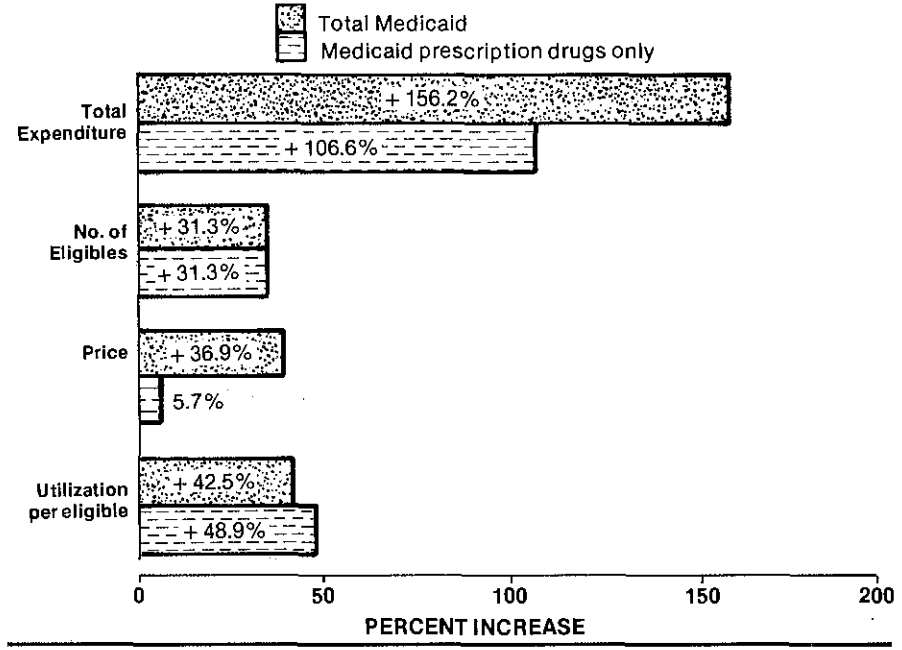
SIGNIFICANCE OF PRICE, ELIGIBILITY AND UTILIZATION IN MEDICAID EXPENDITURE GROWTH

The growth of expenditures for governmental health care programs may be due to a combination of factors: (a) increase in the number of eligibles, (b) increase in the utilization of services per eligible and (c) increase in price per service. In the United States, Medicaid has been the only comprehensive nationwide medical care program including prescription drug services. A comparison of the growth rates for the three components of expenditure mentioned above, between fiscal years 1970 and 1975 inclusive, illustrates the contrast in the relative importance of price and the other factors in the case of total Medicaid expenditure and expenditure for Medicaid out-of-hospital drugs.

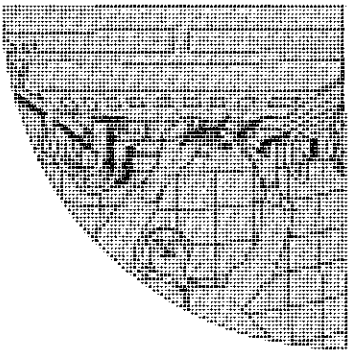
Expenditures rose substantially more for total Medicaid expenditures than for the prescription drug expenditure, despite the fact that utilization per eligible grew more in the case of prescriptions than for other services. What caused expenditure for prescribed drugs to rise less was the fact that the increase in prescription prices (5.7 percent according to the BLS price index) was so much more modest than in the case of Medicaid services as a whole, where prices rose almost 37 percent.

The growth in expenditures, and of the separate components of expenditures, may be illustrated in the following bar graph *(Figure 25).*

Figure 25. FY 1970-1975 Medicaid expenditure growth



X. MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS



INDUSTRY DATA

Many pharmaceutical companies are entering the rapidly growing medical devices and diagnostic products market. The U.S. Department of Commerce estimates that total industry[26] shipments for 1975 reached $4.4 billion.[27] As *Table 44* shows, there was a 148 percent increase in value of industry goods shipped from 1967 to 1975. The largest increase over the eight year period were registered by X-ray equipment and surgical and medical instruments (166 percent and 167 percent, respectively). The industry increase of shipment value between 1974 and 1975 was 11 percent. Significant gains in medical device industry activity are also forecast through the end of the decade by the Bureau of Domestic Commerce. They expect industry shipments to reach nearly $7 billion by 1980, an average annual gain of 9.6 percent from 1974.

PMA MEMBER FIRMS DATA

Over half of PMA companies are currently engaged in research and development, manufacturing and marketing of medical devices and diagnostic products. PMA *Annual Surveys* include selected information on PMA member operations involving medical devices and diagnostic products. Sales and R&D presented are based on responses in 1975 from 37 PMA member firms active in this area, which provided sufficiently detailed and comparable data to include in the aggregates.[28] Degree of involvement of these companies in sales and

(26) This includes SIC Codes considered relevant to Medical Devices and Diagnostic Products Industry: 3693, 3841, 3842, 3843 and 3851. Some of the products included in these categories may not be medical devices as defined in most recent legislation. Diagnostic products are not identified as such under the SIC Codes indicated above. ("Diagnostic substances" are cited under SIC Code 2831, *Biological Products*). Also, there may be medical devices and diagnostic products for which there is no SIC Code. PMA in its surveys makes a distinction between *in vivo* and *in vitro* diagnostic products.

(27) Excludes ophthalmic products.

(28) Response to the PMA *Survey* did not include some of the largest manufacturers of devices. Tables 45-50 include data from respondents of surveys only.

Table 45: Medical devices and diagnostic products, sales and research activity by company, 1974

s: firms reporting sales r: firms reporting R&D

Company	Medical devices		Diagnostic products	
	Domestic	Foreign	Domestic	Foreign
A				
B				
C				
D				
E				
F				
G				
H				
I				
J				
K				
L				
M				
N				
O				
P				
Q				
R				
S				
T				
U				
V				
W				
X				
Y				
Z				
AA				
BB				
CC				
DD				
EE				
FF				
GG				
HH				
II				
JJ				
KK				
Totals:				
s only				
r only				
sr				
Grand total	**28**	**17**	**27**	**16**

[a] s: firms reporting sales
r: firms reporing R&D

Sources: Published PMA survey reports.

Table 48: R&D expenditures for diagnostic products and medical devices, 1974 actual and 1975 budgeted Selected U.S. companies

	1974 Actual (millions of dollars)	1975 Budgeted (millions of dollars)
Company-financed R&D expenditures for diagnostic products:		
In the United States	$39.8	$54.4
In foreign countries	1.4	1.6
Total diagnostic products R&D	**$41.2**	**$47.0**
Company-financed R&D expenditures for medical devices:		
In the United States	$34.4	$39.3
In foreign countries	[a]	[a]
Total medical devices R&D	**$34.4**	**$39.3**
U.S. Government grants and contracts for company-conducted R&D:		
Diagnostic products	$ .4	$ .6
Medical devices	.9	.5
Total Government grants and contracts	**$ 1.3**	**$ 1.1**
Total R&D expenditures for diagnostic products and medical devices	**$76.9**	**$87.4**

[a]Under $50,000.

Sources: Published PMA survey reports.

Table 49: R&D expenditures, diagnostic products and medical devices Selected U.S. companies

	1973	1974	Percent change '74: '73
	(millions of dollars)		
Company-financed, for diagnostic products:			
Amount spent in United States	[illegible]	[illegible]	+35.4%
Amount spent in foreign countries	[illegible]	[illegible]	+55.6
Company-financed, for medical devices:			
Amount spent in United States	[illegible]	[illegible]	+33.3%
Amount spent in foreign countries	[illegible]	[illegible]	—

[a]Under $50,000.

Sources: Published PMA survey reports.

GLOSSARY

This glossary includes definitions of terms used primarily in PMA source materials.

Bulk: For use as a pharmaceutical or medicinal product in further manufacture or in packaging by another company, or for processing in animal feeds (but not as nutritional ingredients), or in prescription compounding, etc.

Company or Firm: Manufacturers including parent, affiliated and subsidiary companies, without duplication engaged in production of ethical pharmaceuticals, biologicals, diagnostic products and medical devices.

Diagnostic Agents (in vivo): Diagnostic products used in living body.

Diagnostic Products (in vitro): Those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body.

Employment: All full-time production workers as well as officers of the company, including employees engaged in the following activities: factory supervision above the working foreman level, sales, advertising, financial, clerical, executive, purchasing, legal, personnel, professional and technical.

- *Production Workers:* Employees up through the working foreman level engaged in fabricating, processing, assembling, receiving, inspection, quality control, handling, packing, warehousing and storage, shipping, maintenance, repair, janitorial, watchman service, production development, record keeping, and other services associated with the production operations.
- *Medical Research and Development:* Personnel engaged in research, research administration, clinical evaluation and development; excludes personnel in promotion, sales, market research, business administration, production and quality control.

Sales and Marketing Research Employees: Personnel in sales, advertising, sales promotion, market research, etc.

R&D Manpower: Personnel engaged in research, research administration, clinical evaluation and development: excludes personnel in promotion, sales, market research, business administration, production and quality control.

Research and Development Scientific and Professional Staff: Includes all persons whose work requires the application for research and development of knowledge, skills and scientific techniques, in the life, physical, engineering, or mathematical sciences, acquired through the completion of a four-year college course (or its equivalent) with a major in these fields or in medicine or other health professions. Excludes persons who have formal training in the sciences but who are not actively engaged in research and development.

Research and Development Supporting Staff: Includes persons who provide literature, clinical, statistical, or other services specifically for R&D staff and technicians.

Research and Development Technicians: Includes persons actually engaged in technical work at a level which requires knowledge of the life, physical, engineering, or mathematical sciences comparable at least to that acquired through technical institutes, junior colleges, or other formal post-high school training less extensive than four-year college training, or through equivalent on-the-job training or experience. However, also included are persons who hold an academic degree at the bachelor's level or above.

Research, Applied: Includes investigations directed to discovery of new scientific knowledge which have specific commercial objectives with respect to either products or processes.

Sales: Sales figures are reported as billed (before deducting cash discounts on sales and other marketing expenses), less returns and allowances. Includes sales value of products bought and resold without further processing or repackaging as well as the dollar value of products made from own materials for other manufacturers' resale. Excluded are all royalty payments, interest and other income.

Sales Abroad: Actual sales consummated in foreign countries other than "Sales for Exports to Other Firms." Such sales by affiliates and subsidiaries or other operations abroad reported in dollars, computed at December 31, 1974 rate of exchange (when possible). Where a partially owned subsidiary is involved, the firm's share is determined on a proportionate profit-sharing basis.

Sales, by Product Class: Estimated distribution of domestic sales of ethical pharmaceutical and biological dosage-form preparations in accordance with the classification system used in the Annual Census Value of Shipments of Pharmaceutical Preparations" (with the exception of "biologicals" and "diagnostic agents").



Pharmaceutical Manufacturers Association

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Sales to Governments: Sales or shipments made directly to federal, state or local government agencies, hospitals and clinics.

Sales to Private Sector: Sales through regular marketing channels for end-use other than by government agency administration or distribution.

4. *Administrative Employees:* Personnel responsible for general management, accounting, finance, planning, personnel, purchasing office services, legal, secretarial, etc.

Employment Abroad: Total number of full-time employees, whether U.S. citizens or not, of PMA member firms or any wholly owned overseas corporations, or corporations in which PMA member firms had a substantial or controlling interest.

Ethical Pharmaceuticals: Products, including biologicals and medicinal chemicals, used for the cure, alleviation, mitigation, treatment, prevention or diagnosis of disease in humans or animals, and promoted primarily to the medical, pharmacy and allied professions; includes products for over-the-counter ethical sales as well as for ultimate dispensing by prescription only.

Exports: "F.O.B.," U.S. PORT.

1. To other firms: sales to third parties only.
2. Intra-firm transactions: sales and shipments at billed (not end sales) value to subsidiaries and affiliates for further handling, processing or packaging.

Medical Devices: Instruments, apparatus, implements, machines, contrivances, implants, and other similar or related articles, including their components, parts, and accessories intended for use in the cure, mitigation, treatment, or prevention of disease or other physical condition. Also included are those devices intended to affect the structure or any function of the body which do not achieve any of the principally intended purposes through chemical action within or on the body and which are not metabolized in the achievement of any of those purposes. Reagents and related products are excluded.

Research and Development: The term includes basic and applied research as well as development activities carried on or supported in the pharmaceutical, biological, chemical, medical and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding diseases or in improving health.

R&D Expenditures: The total cost incurred for all pharmaceutical research and development activity, including cost of salaries, other direct costs, service, routine supplies, and supporting costs, plus a portion of overhead (administration, depreciation, space charges, rent etc.).

Costs of drug or medical research and development conducted on grant or contract for other companies are excluded. Conversely, total outlays for all research and development work contracted to others (manufacturers, independent research laboratories, academic institutions, etc.) are included.

Table 50: Firms with R&D expenditures for diagnostic products and/or medical devices Selected U.S. companies

R&D expenditures size category	Number of firms	Percentage of firms	
		1974	1973
Over $7 million	4		
$2-7 million	4		
$.5-2 million	11		
Less than $.5 million	13		
Total	**32**	**100.0%**	**100.0%**

Sources: Published PMA survey reports.

Table 46: U.S. and foreign sales, medical devices and diagnostic products[a]

Selected U.S. Companies, 1974

	(Thousands of Dollars)		
	U.S.	Foreign	Total
Medical devices	$335,942	$107,205	$443,147
Diagnostic products	197,124	73,917	271,041
Total	**$533,066**	**$181,122**	**$714,188**

[a]"Diagnostic Products" defined here as *in vitro* products; data presented include amounts shown prior to new definition in "product class" breakdown.

Sources: Published PMA survey reports.

Table 47: Domestic and foreign employment by selected U.S. companies, medical devices and diagnostic products, 1974

	U.S.	Foreign	Total
Medical devices	11,152	2,453	13,605
Diagnostic products[a]	5,606	1,439	7,045
Total	**16,758**	**3,892**	**20,650**

[a]Employees involved in work released to *in vitro* diagnostic products.

Sources: Published PMA survey reports.

In research dealing with medical devices, 49.1 percent of the funds were applied to the advancement of scientific knowledge and development of new products, and 50.9 percent to the improvement of existing products. The corresponding figures for research dealing with diagnostic products are 60.7 percent, and 39.3 percent, respectively.

Survey projections of R&D expenditures for 1975 for diagnostic products and medical devices showed significant increases, although the percentage increase was not expected to match increases for 1974. The amounts earmarked for research in these products abroad remained relatively small *(Table 48).*

Expenditures by company for R&D in diagnostic products and medical devices were generally under $2 million *(Table 50).*

Table 44: Value of shipments of medical devices by SIC category

SIC category	Millions of dollars 1967	1974	1975	Percentage growth[a] 1967-1975	1974-1975
3693 X-Ray Apparatus and Tubes					
3841 Surgical and Medical Instruments					
3842 Surgical Appliances and Supplies					
3843 Dental Equipment and Supplies					
3851 Ophthalmic Goods					
Total[c]	**$1,767**	**$3,960**	**$4,390**	**148%**	**11%**

[a]Estimated by Bureau of Domestic Commerce.

[b]n/a = not available.

[c]Total excludes ophthalmic goods.

Source: U.S. Department of Commerce, Bureau of the Census.

research is reflected in *Table 45.* As shown in *Table 46,* in 1974, the reporting firms had global sales of $443 million in medical devices and $271 million in diagnostic products. [29] Foreign sales constitute about one quarter of all sales of devices and 10 percent of sales of diagnostic products.

Over 11,000 employees in the United States were engaged in work related to medical devices and over 5,000 in work dealing with diagnostic products. These selected PMA companies employed close to 4,000 persons in these areas abroad *(Tabled 47).*

In 1974, 23 PMA member companies had R&D expenditures for diagnostic products. Such R&D budgets varied from $40 thousand to over $7 million. Nine companies had R&D budgets for diagnostic products in excess of $1 million. Less than four percent of these funds were spent in foreign countries.

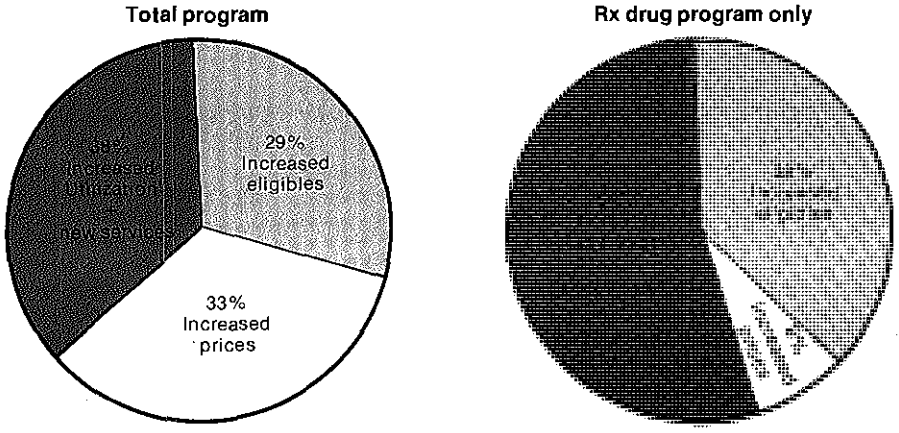
R&D expenditures for medical devices were reported by 21 PMA companies in 1974. Expenditures for this purpose varied from $15 thousand to over $10 million. Less than $50,000 of these funds were expended abroad *(Tables 48, 49).*

(29) Includes only *in vitro* diagnostic products.

Viewed from another aspect, the comparison can be illustrated in pie charts, in which the complete circles represent the total growth of expenditure for all Medicaid services and for Medicaid drugs only *(Figure 26).*

Figure 26. Medicaid expenditure growth analysis total U.S., FY 70-FY 75

PROPORTION OF TOTAL EXPENDITURE GROWTH DUE TO EACH FACTOR



Sources: (1) NCSS-B1 Reports, (2) NCSS-A2 Reports and Soc. Sec. *Bulletins,* (3) Bureau of Labor Statistics/Consumer Price Index (Medical Care Services; Prescription Prices).

Table 43: Vendor payments for medical care under federally aided programs by types of service, 1965, 1970, 1975

Type of service	Fiscal year 1975 Thousands of dollars	Percent	Fiscal year 1970 Thousands of dollars	Percent	Fiscal year 1975 Thousands of dollars	Percent
Inpatient hospital care	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Nursing home care	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Physicians' services	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Prescribed drugs	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Dental care	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Intermediate care facility services	[illegible]	[illegible]				
Outpatient hospital services	347,657	2.8				
Clinic services	391,507	3.2				
Other practitioners' services	120,228	1.0	These categories not broken out before 1975. Totals included under "other care" and "Type of Service Not Reported."			
Laboratory and radiological services	104,391	0.8				
Home health services	66,657	0.5				
Family planning services	72,615	0.6				
Other care	254,613	2.1	527,801	10.0	58,019	4.3
Type of service not reported			75,706		11	
Total	**$12,318,468**	**100.0%**	**$5,355,294**	**100.0%**	**$1,357,945**	**100.0%**

Source: National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Program, 1976" (based on Social Security data).

Table 42: Medicaid program—Vendor payments for medical care and prescription drugs, fiscal year 1975 (thousands of dollars)

State	Total medical care	Prescribed drugs	% of 1975 total	% of 1970 total
Total	**$12,318,468**	**$816,453**	**6.6%**	**8.0%**
Alabama	131,105	15,643	11.9	22.0
Alaska[a]	8,730	n/a	—	n/a
Arizona[b]	n/a	n/a	n/a	n/a
Arkansas[c]	92,632	11,960	12.9	c
California	1,365,529	96,156	7.0	8.1
Colorado	98,030	7,458	7.6	12.4
Connecticut	161,075	9,097	5.6	5.9
Delaware	14,626	1,342	9.2	13.1
District of Columbia	92,895	5,779	6.2	6.6
Florida	172,620	18,878	10.9	17.7
Georgia	254,669	25,929	10.2	12.2
Hawaii	36,953	2,747	7.4	.9
Idaho	24,460	1,503	6.1	f
Illinois	713,654	64,907	9.1	11.4
Indiana	172,434	12,505	7.3	f
Iowa	81,892	6,607	8.1	24.3
Kansas	101,966	8,364	8.2	15.0
Kentucky	107,293	12,009	11.2	21.5
Louisiana	145,033	25,755	17.8	15.4
Maine	63,305	3,825	6.0	7.7
Maryland	204,141	17,282	8.5	10.0
Massachusetts	524,706	28,776	5.5	9.1
Michigan	639,388	43,713	6.8	6.7
Minnesota	259,197	12,831	5.0	9.8
Mississippi	93,742	19,677	21.0	17.7
Missouri	99,284	12,923	13.0	16.5
Montana	29,245	1,706	5.8	9.5
Nebraska	52,070	4,709	9.0	16.2
Nevada	16,143	1,165	7.2	8.6
New Hampshire	28,237	2,738	9.7	21.4
New Jersey	368,130	24,509	6.7	8.0
New Mexico	29,564	3,130	10.6	17.0
New York	2,954,622	86,183	2.9	4.0
North Carolina	164,877	18,281	11.1	16.7
North Dakota	22,994	2,146	9.3	12.4
Ohio	366,325	34,339	9.4	14.3
Oklahoma[d]	140,647	14	–	0.2
Oregon	76,762	4,174	5.4	10.9
Pennsylvania	727,875	24,853	3.4	6.4
Puerto Rico	113,088	21,862	19.3	n/a
Rhode Island	72,079	5,304	7.4	11.2
South Carolina	75,691	7,371	9.7	12.6
South Dakota[e]	22,146	1,560	7.0	e
Tennessee	123,948	17,853	14.4	34.5
Texas	452,467	37,468	8.3	f
Utah	33,098	2,424	7.3	8.0

(Continued on p. 73)

HEALTH CARE MANPOWER AND FACILITIES

In 1973, approximately 4.4 million persons, equal to five percent of the total civilian labor force, were employed in the health professions *(Table 40).* Population growth and advances in medical and pharmaceutical services demand an ever-growing supply of health manpower. Physicians, veterinarians, pharmacists, nurses, technicians and many other specialists in the health field are employed by the pharmaceutical industry.

Table 40: Selected health industry personnel, 1973

Occupation	Active workers
Doctors of medicine	333,300
Doctors of osteopathy	12,000
Dentists	105,400
Pharmacists (active in practice)	132,900
Radiologic technicians and assistants	100,000
Optometrists	18,400
Registered nurses	815,000
Practical nurses	459,000
Administrators of health services	48,200
Veterinarians	26,900
Pharmaceutical industry personnel	153,450

Sources: U.S. National Center for Health Services, "Health Resources Statistics, 1974", pp. 9-12, and PMA, *Annual Survey Report, 1974-1975,* p. 9.

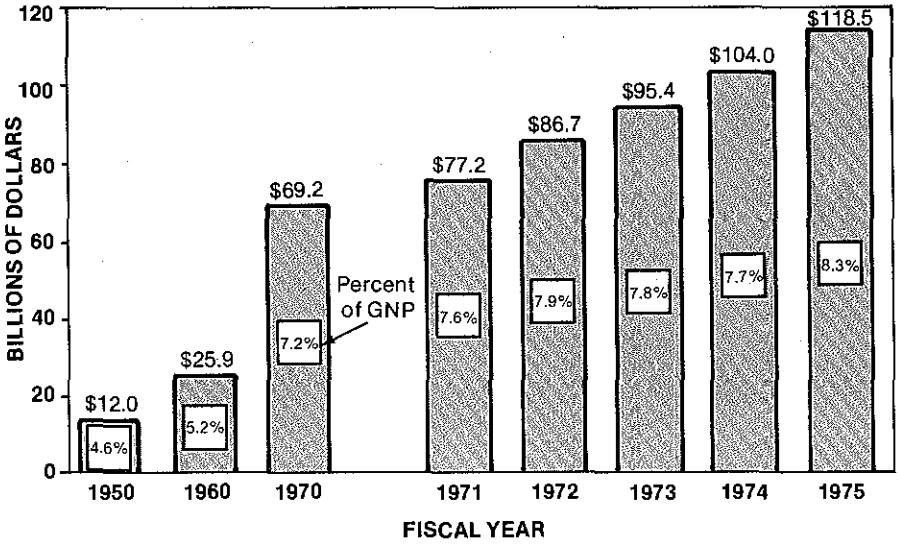
In 1873, the U.S. Bureau of Education completed the first count of U.S. health care facilities, which revealed the existence of only 178 hospitals. One hundred years later there were 7,481 general and specialty hospitals with more than 1.5 million beds and over 2.7 million employees. About 6,500 hospitals had their own pharmacies, three quarters of which employed full-time pharmacists.[25]
Table 41 presents a breakdown of health care establishments by type and number in the United States in 1972.

MEDICARE-MEDICAID PROGRAMS

The government's Medicare program for persons age 65 and over became effective July 1, 1966. Designed to protect the elderly against potentially high hospital and medical care costs, it has done much to enhance the dignity of the nation's elderly by providing coverage for hospital care regardless of personal resources.

(25) National Center for Health Statistics (1974) and American Hospital Association (1971, 1973).

Figure 22. National health expenditures and percent of gross national product, selected fiscal years, 1950-1975



Source: M.S. Mueller and R.M. Gibson, "National Health Expenditures, Fiscal 1975," *Social Security Bulletin*, Volume 39, Number 2 (February 1976) p. 5.

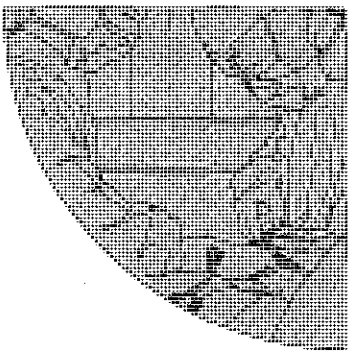
low-income and elderly persons who previously had not received adequate medical care.

Direct payments by consumers accounted for only 32.6 percent of overall personal health care expenditure *(Figure 23),* a 52 percent reduction from 1950 and a 20 percent reduction if compared with 1970.

Although per capita expenditures on hospitals in FY 1975 was $215.12 and on outpatient drugs and drug sundries was only $48.93 (approximately $30 for prescription drugs alone), the direct or out-of-pocket costs for hospitals averaged only $17.20 compared to $41.59[24] in the case of outpatient drugs and drug sundries *(Figure 24).* Hence, the perceived costs of drugs are higher, particularly for the elderly consumer, whose hospital and physicians services costs are largely covered by Medicare. This has two consequences for pharmaceutical manufacturing and distribution: the market is more competitive and the consumer is more critical than would be the case if expenditures were largely covered by third party programs.

(24) Calculated as follows: 8% of $215.12 and 85% of $48.93 respectively.

IX. THE HEALTH CARE INDUSTRY



NATIONAL HEALTH EXPENDITURES

With expansion of third-party coverage, national health care expenditures have been steadily rising. In January 1975, there were 186 million Americans, or 90 percent of the civilian population, who were protected by one or more forms of private health insurance. Medicaid and Medicare provided additional coverage to the elderly and indigent. With increased coverage, expanded employee health plans, and the development of government health programs, national health expenditures rose from $69.2 billion in 1970 to an estimated $118.5 billion in fiscal year 1975.[22] Approximately 38 percent or $45.6 billion represented government funding for state, local and federal programs.

As a share of total health expenditures, hospital care with 46.6 billion dollars is the largest component and has risen from 37.9 percent in fiscal 1973 to 39.3 percent in fiscal 1975. Physicians' services declined from 18.9 percent in fiscal 1973 to 18.6 percent in fiscal 1975. In government aggregated reports, out-of-hospital prescription drugs are included under "Drugs and Drug Sundries,"[23] and this broad category accounted for 10.6 billion dollars, or 8.9 percent of national health care expenditures in fiscal 1975, a decline of 5 percent when compared with its 9.4 percent share in 1973, and a decline of 36 percent if compared with 1960 *(Table 39).*

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(22) *Social Security Bulletin,* February 1976.

(23) The category "Drugs and Drug Sundries" as used by the Social Security Administration (SSA) is derived in part from the Department of Commerce calculation of personal consumption expenditures and includes prescription and ethical over-the-counter drugs, proprietary drugs and sundries. Prescription drugs as estimated by the SSA ("Medical Care Costs and Prices", SSA, 1972) account for 60% of this category, or $6.4 billion in 1975. This total does not include hospital drug expenditures. Other data on out-of-hospital prescription drug expenditures appear in trade journals: *Drug Topics* estimates $7.1 billion spent on prescription drugs in 1975, and *American Druggist,* $6.2 billion.

Hospital expenditures for drugs are estimated on the basis of American Hospital Association Surveys, and average between 3.5 and 4% of hospital costs.

Table 36: World trade in pharmaceuticals, 1974 (thousands of dollars)

Leading exporters Country	Exports	Imports	Balance of trade
West Germany	$1,035,953	$432,767	$603,186
United States	805,922	213,573	592,349
Switzerland	749,133	159,392	589,741
United Kingdom	706,444	216,072	490,372
France	502,173	309,201	192,972
Netherlands[a]	266,999	202,286	64,713
Denmark	123,962	92,531	31,431
Italy	335,344	309,513	25,831

Leading importers Country	Exports	Imports	Balance of trade
Japan	$137,147	$455,752	$-318,605
Spain	48,778	174,804	-126,026
Canada	54,636	162,346	-107,710
Austria	46,768	114,995	- 68,227
Sweden	86,948	153,801	- 66,853
Australia[a]	43,941	96,527	- 52,556
Belgium/Luxembourg	282,864	330,003	- 47,139

[a]1973 data.

Source: United Nations, "Yearbook of International Trade Statistics, 1974," Volume II, p. 99.

RESEARCH AND DEVELOPMENT

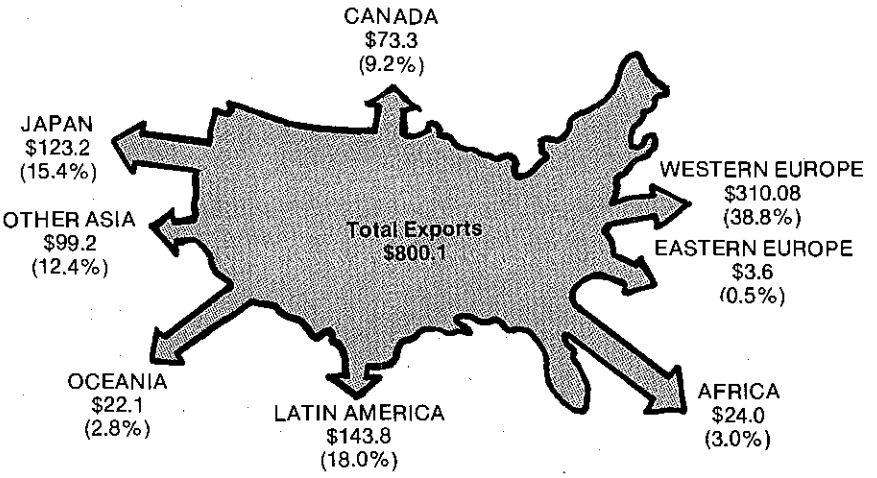
U.S.-based pharmaceutical companies spend a substantial portion of their R&D funds abroad in a wide range of both basic and applied R&D effort *(Tables 37 and 38).* The rising share of R&D being performed abroad is related to national regulatory pressures and to the fact that an increasing proportion of new pharmaceutical compounds discovered and developed by U.S. firms are being first introduced abroad, particularly in the United Kingdom and Germany.

competition and national laws and regulations. Most local managers employed by U.S.-based companies are nationals of the countries in which they work.

U.S. EXPORTS—IMPORTS

While the U.S. industry services foreign markets mainly by production abroad, exports from the U.S. are far from insignificant. For ethical pharmaceuticals, they amounted to about $566 million in 1973, and $734 million in 1974, about 19 percent of U.S. firms' foreign sales. Of the 1974 export total, $507.2 million (about 69 percent) comprised intrafirm exports and $226.8 million (about 31 percent) exports to other firms.[21] Export data by destination derived from United Nations statistics are shown in *Figure 20.*

Figure 20. Destinations of U.S. pharmaceutical exports, 1974 (millions of dollars; percentages shown in parentheses)

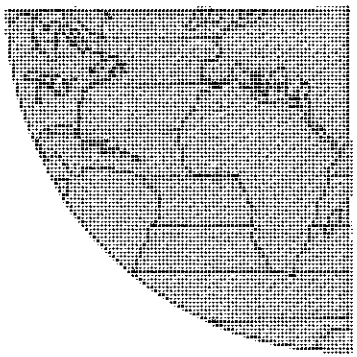


Source: United Nations, "Commodity Trade Statistics, 1974," Series D, Volume 24, No. 1-28, p. 159. Includes prescription and nonprescription pharmaceuticals.

As shown by Department of Commerce data *(Figure 21),* exports have at times declined, while imports have increased steadily. Overall, however, exports have far out-stripped imports. In 1975, the ratio of exports to imports, while smaller than in some earlier years, was about 4 to 1.

(21) Data on ethical pharmaceuticals from PMA *Annual Survey Report.*

VIII. INTERNATIONAL OPERATIONS



The international operations of the U.S. pharmaceutical industry are exceptionally important to U.S. firms and to the world. Foreign sales (including exports) have been increasing steadily, amounting to $3,940 million in 1974, or about 38 percent of global pharmaceutical sales. A further increase to about $4,751 million was estimated for 1975. Sales for the international sector are presented in *Figure 19.* Overseas R&D expenditures are also climbing. They amounted to 14.4 percent of the U.S. industry's global R&D financing in 1973, 15.8 percent in 1974, and were expected to reach 16.1 percent in 1975.

A majority of PMA member firms market their products in foreign countries, either by export from the U.S. or by manufacturing abroad. The U.S. industry makes its products available to virtually every country in the world, to a large extent through overseas manufacturing.

The reasons for foreign manufacture vary from country to country, but include foreign tariff or nontariff barriers to imports,[20] foreign laws or policies that make it difficult or impossible to market a product within a country unless it is produced there, easier servicing of foreign customers, and enhancement of competitive positions. The establishment of foreign manufacturing affiliates, however, induces the U.S. export of ingredients and bulk materials for foreign processing, as well as of parts and equipment. Since many foreign markets would not be accessible except through local manufacturing of final dosage form products, the effect of this foreign investment has been to increase U.S. employment and sales compared to what it would have been without such investment.

Overseas operations, of course, are characterized by variations in risks, costs, and other circumstances. Such operations, therefore, require many "on-the-spot" decisions by local managers, taking account of such factors as supply and production costs, tax rates, demand,

(20) A PMA survey of 21 multinational member firms showed negligible imports of finished drugs from foreign affiliates. For 1970, such imports amounted to 0.2 percent of domestic pharmaceutical sales. The survey also showed that more than 10 percent of domestic U.S. employees depended on foreign operations for their jobs.

wholesalers (5-6 percent) can in part be explained by the fact that a considerable proportion of prescription drugs are sold directly to pharmacies.

Table 35: Percent of consumer's prescription dollar spent on top fifty products

Year	Manufacturer	Wholesaler	Retail pharmacy	Total
1969	46	6	48	100
1973	43	5	52	100
1974	42	5	53	100
1975	46	6	48	100

Note: Calculations utilize the top 50 brand-specified prescription drugs on the market, using as a data base the audit of drug store invoices and the *National Prescription Audit.*

Source: IMS/America, Ltd.

This breakdown of the consumer's prescription dollar puts the issue of the manufacturer's profit into better perspective. His entire profit, including the share reinvested in the enterprise—which is relatively high by comparison with other industries—accounts for less than five cents of the consumer's dollar.

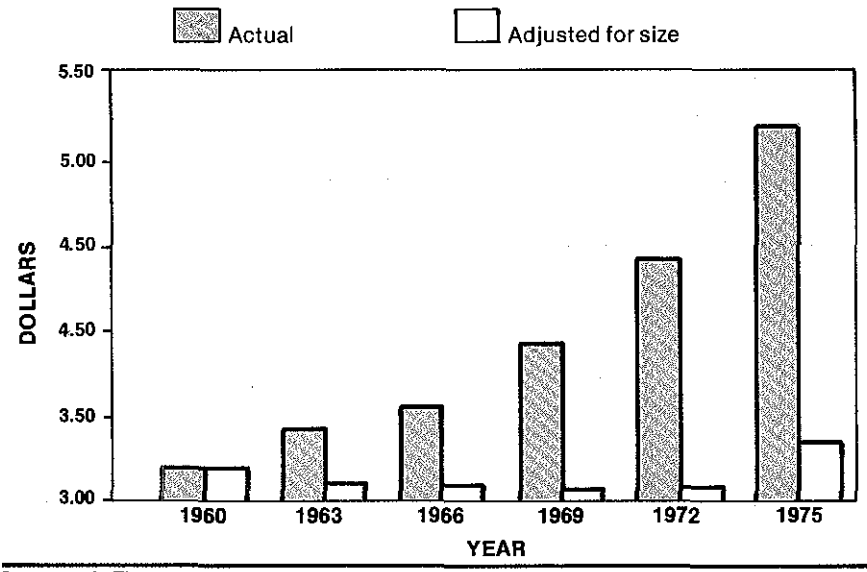
Similarly, the 48 cents received by the retail pharmacist should not be confused with net profit. Data are lacking on the average rate of profit on retail prescription sales, but the *Lilly Digest* survey reveals that in 1974 the average independent pharmacy received only 3.7 percent of net earnings on total sales (including prescriptions). During periods of inflation especially, the rise in costs (for salaries, taxes, insurance, etc.) is typically severe for services.

DRUGSTORE PRESCRIPTION SALES

Most prescription drugs are purchased through the nation's 50,500 community pharmacies. Of the more than 1.3 billion prescriptions filled in 1974, almost 25 percent were third party prescriptions, a 12 percent increase over the preceding year. The ratio of third-party to total prescriptions doubled in five years, from 11.9 percent in 1969 to 23.7 percent in 1974. This trend will undoubtedly continue as drug benefits are applied to health maintenance organizations and national health insurance.

Total pharmaceutical sales in community drug stores reached $5.7 billion in 1974, an 11.6 percent increase over the previous year's $5.1 billion. Prescription drugs represented a rising proportion of total

Figure 16. Average prescription charge, actual and adjusted for size, 1960-1975



Sources: J. Firestone, "Index of Manufacturers' Prices to Retailers for Ethical Pharmaceuticals, 1975," April, 1976, and IMS/America, *National Prescription Audit.*

THE PRESCRIPTION AND THE CONSUMER

In 1960, the take-home pay of a worker in a manufacturing establishment was $80.11, or $2.02 per hour, after deducting taxes and social security payments. In that year, the cost of the average new prescription, according to the National Prescription Audit, was $3.22. It took the worker 1 hour and 33 minutes to pay for it *(Figure 17).*

In 1975, the price of the average new prescription, according to the same survey, was $5.20. But this average was based on a universe containing many more effective and safer medicines not existing in 1960. More importantly, it was over 56 percent larger than the average prescription in 1960. If adjusted to the same size—the same number of tablets, capsules or doses—the price would drop to $3.33.

In the meanwhile, the take-home pay of the factory worker with three dependents had risen to $165.33, or $4.20 an hour. (The average hours worked per week, 39.4, was slightly lower than in 1960.) At this rate of pay, it now took the worker only 47 minutes to earn the cost of the same quantity of tablets or capsules as found in the 1960 prescription. The work-time cost had been cut in half.

Comparison of the work-time cost per prescription, at three-year intervals, for the size-adjusted average prescription, may be seen from *Figure 17.*

In the case of manufacturers' prices, again on a base of 1967 = 100, Firestone's index for 1975, of 116.2 including 789 items, was 6.3 percent above that of 1974, while the BLS/WPI index of ethical pharmaceuticals, at 113.2 was 8.6 percent higher. (The BLS wholesale price index for all industrial commodities rose 11.5 percent, to 171.5 on a 1967 base.) Thus, for 1975, in contrast to prior years, Firestone showed a smaller increase, at the manufacturers' level, than did BLS *(Table 34).*

Table 34: Firestone and BLS indexes of wholesale and retail pharmaceutical prices, 1964-1975 (1967 = 100)

	Wholesale		Retail	
Year	BLS	Firestone	BLS	Firestone
1964				
1966				
1968				
1970				
1972				
1974				
1975				

Sources: U.S. Labor Department; PMA.

AVERAGE PRESCRIPTION PRICE

Various surveys have been conducted to determine the average prescription price, with results varying according to methodology and the mix of drug stores sampled. For 1974, the results ranged from $4.77 for the *Lilly Digest,* sampling independent stores only, to $4.32, for *American Druggist* magazine. The *Drug Topics* survey reported $4.60 in 1974 and $4.93 in 1975. *The National Prescription Audit* (IMS America, Ltd.), surveying new prescriptions only (excluding refills), reported an average of $4.70 in 1974 and $5.20 in 1975.

Figure 15 illustrates the rise, through 1975, in the average prescription price reported by *American Druggist.*

According to the Government's National Health Expenditure estimates, the average per capita consumer expenditure on "drugs and drug sundries" purchased outside hospitals was $48.93 in fiscal year 1975. Subtracting over-the-counter drugs and sundries would leave approximately $29.53 for prescription drugs only, with an average of about 6.3 prescriptions per person.

MANUFACTURERS' PRICES (BLS/WPI)

The Wholesale Price Index (WPI) reflects prices at which dosage form products are sold by their producers. Like consumer prices, manufacturers' prices for ethical pharmaceutical have displayed unusual stability in recent years.

The "ethical" pharmaceutical component of the Wholesale Price Index includes about 50 items and comprises 15 therapeutic classes *(Table 33).* In 1975, the annual average for these 15 categories was 113.2, an 8.6 percent increase over the 1974 average of 104.2.[18] However, between 1964 and 1974 the wholesale price of the entire group increased only one third of one percent *(Figure 14).* If the 1974 price is measured against that of the year 1961, when this index was first established, there is found to be a 7 percent *decrease.* By comparison the "all commodities" measured by the Wholesale Price Index *increased* 69.0 percent during this 14 year period.

Table 33: Wholesale price index for ethical pharmaceutical preparations by therapeutic class (1967 = 100)

Therapeutic class	1974	1975
All ethical pharmaceutical preparations	104.2	113.2
Anti-infectives	84.6	90.6
Antiarthritics	150.5	188.6
Sedatives and hypnotics	125.3	142.2
Ataraxics	93.8	93.8
Antispasmodics and anticholinergics	114.3	130.1
Cardiovasculars and antihypertensives	114.7	119.6
Diabetic preparations	124.4	131.9
Dermatologicals	102.5	127.3
Hormones	100.0	106.7
Diuretics	119.7	100.0
Hermatinics	116.3	123.0
Internal analgesics	111.2	134.5
Antiobesity preparations	101.0	104.0
Cough and cold preparations	117.8	135.3
Vitamins	99.6	109.1

Source: U.S. Bureau of Labor Statistics, "Wholesale Price Index"

(18) Note that the price indexes for most therapeutic categories and in most years have risen more at the manufacturers' than at the retail level This is a result of the continuous increase in the average prescription size. The cost of dispensing a prescription for 30 capsules is only minimally higher than those for dispensing 20. The increase in prescription size tends to lower unit costs, though this effect may be offset by other cost increases. See *Figure 17.*

The CPI index for prescription drugs by therapeutic category is shown in *Table 32.* The price index for all prescriptions is lower than the average of the individual indexes for the various therapeutic classes. The reason is that the over-all prescriptions index is a weighted average. Those categories, such as antibiotics, which declined in price or (more recently) experienced more moderate increases had a larger share of total prescription sales and, hence, have a stronger influence in the weighted average.

Table 32: Consumer price index by therapeutic class, 1974 and 1975 (1967 = 100)

Therapeutic class of products	Annual average 1974	1975
Prescriptions	102.9	109.3
Anti-infectives	68.7	71.1
Sedatives and hypnotics	140.7	154.3
Ataraxics	104.9	106.0
Anti-spasmodics	110.9	124.2
Cough preparations	147.5	165.2
Cardiovasculars and antihypertensives	115.4	118.4
Analgesics, internal	112.7	118.9
Hormones	95.2	103.2

Source: U.S. Bureau of Labor Statistics, "Consumer Price Index."

PRICE CONTROLS AND PRESCRIPTION PRICES

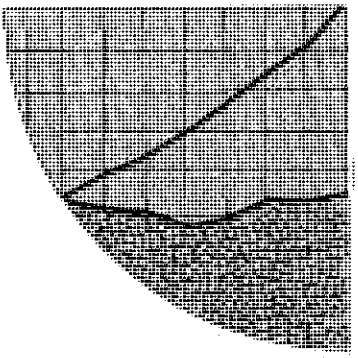
Economic problems have plagued the 1970s. During the first half of the decade the "All Items" consumer price index climbed steadily from 116.3 in 1970 to 161.2 in 1975 (base year 1967 = 100). Few items measured by BLS have resisted inflationary pressures successfully. One that has, however, is prescription medicines.

During the two fiscal years immediately preceding the start of the government's Economic Stabilization Program in August 1971, the CPI showed that, on an annual basis, all items increased 5.6 percent, and total medical care costs 6.7 percent. By contrast, the retail price of prescriptions advanced at an annual rate of only 1.2 percent.

Phases I, II, III, and IV of economic controls continued to reflect the stability of pharmaceutical price levels *(Figure 13).*

The Phase I wage and price freeze reduced the impact of inflation for all consumer items to an annual rate of 1.6 percent. In that period, prescription drug prices fell at a rate of 0.4 percent. Phase II replaced the freeze with mandatory economic controls on wages and prices,

VII. INFLATION AND PRESCRIPTION PRICES



Rx PRICES SHOW STABILITY

The Bureau of Labor Statistics (BLS) of the U.S. Department of Labor regularly prepares a number of indexes to measure price trends. These official government indexes—Consumer Price Index and Wholesale Price Index—show that prescription drug prices at both the patient's level and the manufacturer's level have remained remarkably stable over the years. Price trends can also be measured by the indexes prepared for PMA by Dr. John A. Firestone.[17]

CONSUMER PRICES (BLS/CPI)

The Consumer Price Index (CPI) reflects the retail prices at which products and services are sold. Currently, 14 prescription products are regularly priced by the BLS for use in the prescriptions component of the CPI.

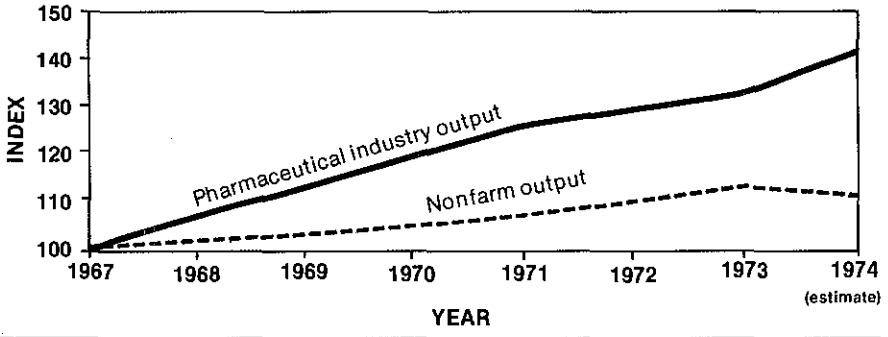
Between 1967 and 1974, the CPI shows that prices of prescription drugs increased by less than 3 percent. In contrast, medical care costs registered a 51 percent gain, while overall consumer prices rose by 48 percent during the same period *(Figure 1).*

In 1975, a year of general inflation throughout the economy, the CPI index for prescriptions rose by 6.2 percent above 1974. By comparison, the "All Items" Consumer Price Index rose 9.1 percent while the "Medical Care" component rose 12.0 percent.

This slow rate of increase is even more dramatic if the change in prescription prices is measured against 1960 levels. BLS made a major revision in its index in 1960, in order to reflect the introduction of a number of new and more therapeutically effective drugs. In 1975, despite its recent unaccustomed increase, the BLS/CPI index for prescriptions was still 5.2 percent lower than its 1960 level, while overall consumer prices had risen almost 82 percent during the same 16 years and the index of medical care costs had risen 113 percent.

(17) Professor of Economics at the City University of New York, consultant to government and industry. See pages 53-54 for a discussion of the Firestone indexes.

Figure 10. Indexes of output per employee-hour in the pharmaceutical industry and the private nonfarm economy (1967 = 100)



Source: U.S. Bureau of Labor Statistics.

Table 31: Indexes of productivity in the pharmaceutical industry (1967 = 100)

Year	Output index per employee		Employee-hours index	
	All employees	Production workers	All employees	Production workers
1963	84.5	84.7	85.9	85.5
1964	86.9	85.8	91.5	92.5
1965	93.1	92.7	94.9	95.2
1966	97.6	96.9	100.0	100.7
1967	100.0	100.0	100.0	100.0
1968	108.8	109.6	102.6	101.8
1969	115.6	114.5	107.8	108.9
1970	120.2	121.9	113.5	111.8
1971	129.1	138.3	114.4	106.7
1972	138.0	146.7	112.3	105.6
1973	135.7	146.7	120.1	111.0
1974 (est.)	141.8	154.6	124.1	113.9

Source: U.S. Bureau of Labor Statistics," Productivity Indexes for Selected Industries, 1975 Edition," (Bulletin 1890), pp. 53-54.

registered annual average gains for production workers of 6.7 percent between 1970 and 1974, well above the average for manufacturing industries as a whole.

Production in the pharmaceutical industry is characterized by large-scale operations under rigid quality controls. Increases in output,

Production workers make up the largest occupational category of the industry's employees, representing 48 percent of the domestic employment in 1974. *Table 29* shows the distribution of employees among four major job categories for 1972 and 1974.

Other statistics on employment are available from the Bureau of the Census and the Bureau of Labor Statistics (BLS). Data for selected years from 1970 to 1975, and a BLS projection for 1985, are shown in *Table 30.* Variations are due to differences in survey and analytic procedures. [15]

Table 29: Distribution of United States ethical pharmaceutical industry employment by job category, 1972 and 1974

Job categories:		
Total-U.S. Employment	143,985	153,100
Production, quality control, and related work	45%	48%
Marketing and distribution	25	25
Medical research and development	15	14
Administration and other	15	13
	100%	100%

Sources: Published PMA survey reports.

Table 30: Employment in the pharmaceutical industry 1970-1975, projected 1985

Year	Bureau of the Census SIC 283	Bureau of the Census SIC 2834	Bureau of Labor Statistics SIC 283	Bureau of Labor Statistics SIC 2834
1970				
1972				
1974				
1975				
1985				

[a]Decennial Census
[b]Not available
[c]Census of Manufactures
[d]Projection; preliminary data, subject to change.
Sources: U.S. Department of Commerce, Labor Department.

(15) The Bureau of Labor Statistics (Department of Labor) and the Census Bureau (Commerce Department) report employment by Standard Industrial Classification (SIC) Code. SIC 283, *Drugs,* includes 2831 biological produts, 2833 medicinals and botanicals, and 2834 pharmaceutical preparations.

Since accounting conventions typically treat R&D as a current expense rather than as a capitalized addition to the firm's asset base, assets are understated and hence the rate of return on assets of the research-intensive firm is overstated when compared to other manufacturing. Appropriate restating of assets to reflect R&D as capital has been shown to lower the earnings-to-investment ratio by several percentage points.[13]

Not all of the differential in the rates of return for pharmaceuticals and all manufacturing can be explained by the accounting treatment of R&D, although this appears to be the most important factor. Among other explanatory factors are the higher than average growth of demand and, therefore, sales and the higher than average growth of output per worker, or productivity. Another explanation may be that of the risk factor. Economists recognize that investments having higher risk, as in the dynamic, innovative drug industry, require a higher return to compensate for the high risk. A study by Gordon Conrad and Irving Plotkin of Arthur D. Little Inc., using data from 59 American industries showed a high correlation between average rates of return and one measure of risk, the variance of company rates of return above and below the average rate for each industry. The authors found that the drug industry had the fourth highest dispersion, or variance, of all the industries studied.[14]

Finally, some part of the earnings differential may be due to difference in the degree of product differentiation. A highly innovative industry is more likely to produce a larger share of unique products. Although these may enjoy a measure of patent protection, they are still subject to competition including price competition, from other products designed for the same purpose—in this case other compounds treating the same disease. But price competition is necessarily less perfect than with homogeneous products that are fully substitutable.

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(13) See Jesse J. Friedman & Murray N. Friedman. "Relative Profitability and Monopoly Power." *The Conference Board Record*, December 1972, *IX* (12).

(14) The study is found in part 5 of the 1967 hearings of the Senate Monopoly Subcommittee of the Small Business Committee on "Competitive Problems in the Drug Industry."

Table 26: Drug manufacturing firms by asset size, 1971

Assets	Number of firms	Value of assets (thousands of dollars)
[illegible]	[illegible]	[illegible]
All firms	**1,139[a]**	**$11,004,215**

[a]Variations in number of firms among PMA, Census and IRS reports is due primarily to differences in definition of manufacturing entities.

Source: U.S. Internal Revenue Service, "Source Book of Statistics of Income," data for 1971.

Almost two thirds of these firms were small, with less than $100,000 in assets. Only 24 had assets of $100 million or more. Eighty-nine, or 17 percent of the total, had assets valued at $1 million or more.

TAXES

The pharmaceutical industry, according to the Federal Trade Commission, paid almost a billion dollars in taxes in 1975 of which about 85 percent were paid to the federal government. Payments to foreign countries by companies with subsidiaries abroad added an estimated half billion dollars to U.S.-based industry's tax bill.

EARNINGS

The profitability of a company may be measured in many ways but most often the analysis is based on rate of return on sales or return on investment. The first measure may be useful in comparing two firms marketing, or distributing, a virtually identical product line, and it may be useful for a single firm in measuring its own performance over time. But it is not useful and may be misleading in comparing firms in different industries or fields of distribution, because the profit on sales is so much a function of the rate of inventory turnover and investment. Thus, a supermarket, with a very low rate of profit on sales, may be far more profitable based on investment than a jewelry store which, because of its low turnover, must have a much higher average markup. For this reason, economists consider the rate of return on investment (whether defined as stockholders equity or as total assets, including debt) as a more meaningful measure of comparison.

According to PMA surveys, the largest single producer of prescription drugs was responsible for 7.6 percent of domestic sales in 1974. This compares with 7.4 percent in 1973, 9.0 percent in 1959 and 12.7 percent in 1951, for firms holding the largest share in each of those years.

National Prescription Audit data on competition for new prescriptions measured in dollars and in numbers of new drug store prescriptions for 1971, 1972, 1973 and 1975 appear in *Table 24.* While in general the percentages in the table reflect a fair degree of stability between 1971 and 1973, there is a change for 1975, showing an increase for all groupings of companies.

Variations in concentration data between PMA surveys and the National Prescription Audit result from differences in inclusiveness and in method of data collection. PMA data cover all industry sales of ethical drugs, while the National Prescription Audit measures only retail sales by pharmacies, thus excluding the hospital, governmental and certain other sectors.

Table 24: Competition for new prescriptions measured in total *new prescription dollars,* at manufacturers' level

Company group	(Cumulative percentages) 1972	1973	1974	1975
Leading Company	7.5%	7.5%	7.6%	8.5%
5 largest	28.6	28.5	27.0	27.6
10 largest	45.3	44.6	42.6	42.9
20 largest	67.6	67.4	65.1	64.5
50 largest	88.3	89.7	88.8	88.5
100 largest[a]	99.2	99.2	99.1	99.3
All companies	100.0%	100.0%	100.0%	100.0%

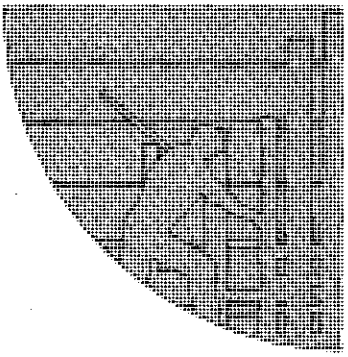
[a]Includes "unspecified" category, which averages 7.3 percent per year (range: 6.9-7.7 percent). "Unspecifieds" are not counted elsewhere in Table.

Source: *National Prescription Audit,* IMS Ltd. Company Reports, 1972-1975.

ENTRY IN THE MARKET

Competition within an industry may also be measured by entry of firms into markets in which they had not previously operated and by the exit of firms as more efficient, lower-priced newcomers enter the market. In competitive markets high expected rates of return will attract entry and increased competition will reduce the expected rate of return toward an equilibrium level. Where there is monopoly power, barriers to entry effectively deter new entrants.

V. INDUSTRY STRUCTURE



CONCENTRATION AND COMPETITION

Degree of concentration is one measure of competition within an industry. The most widely used method is the concentration ratio. Its computation requires ranking firms, starting with the largest company in the industry, and cumulatively calculating the percentage of total shipments or sales represented by the firms from largest to smallest. The U.S. Census Bureau periodically publishes concentration ratios for the largest 4, 8, and 20 firms in industries classified according to Standard Industrial Classification (SIC) codes.[10] SIC 2834—"Pharmaceutical Preparations"—includes most prescription and nonprescription drugs.

Table 22 shows the concentration ratios for "Pharmaceutical Preparations." In 1972, the 4 largest firms accounted for 25 percent of industry shipments, the 8 largest for 43 percent, and the 20 largest for 73 percent. The industry showed little change in concentration in firms 1958 to 1972; the lowest concentration ratios measured during this period were in 1963 for 4- and 8-firm concentration, and in 1967 for 20-firm concentration.

Table 22: Concentration ratios for firms manufacturing pharmaceutical preparations (SIC 2834)

Year	Number of establishments	Percent of value of shipments accounted for by: Four largest companies	Eight largest companies	Twenty largest companies
1958	1,114	25%	43%	71%
1963	1,011	22	37	71
1967	875	24	40	70
1972	756	25	43	73

Source: U.S. Department of Commerce, "1972 Census of Manufacturers."

Although variations in collection methodologies and category definitions cause some differences between the PMA and Census statistics, ranking by therapeutic class is the same. According to PMA data, the largest increase in share of market by therapeutic class was also in cardiovascular drugs; the largest decrease, however, occurred in anti-infective drugs. It should be noted also that PMA *Surveys* of ethical pharmaceutical production include biological, botanical and therapeutic agents. The Census Bureau Survey collects data on pharmaceutical preparations, biologicals (including diagnostic substances) and botanicals separately.

Table 20: U.S. sales, dosage forms, ethical pharmaceuticals by therapeutic class

Pharmaceutical preparations for:	1965 Millions of dollars	1965 Percentage	1974 Millions of dollars	1974 Percentage
Central nervous system	$ 664.5	26.4%	$1,395.9	26.5%
Anti-infectives	489.1	19.4	834.3	15.9
Neoplasms and endocrine	296.9	11.8	531.3	10.1
Digestives and genito-urinary	294.6	11.7	519.9	9.9
Cardiovasculars	168.1	6.7	479.6	9.1
Vitamins and nutrients	224.1	8.9	457.4	8.7
Respiratory system	173.9	6.9	335.9	6.4
Dermatologicals	45.5	1.8	178.5	3.4
Biologicals	67.9	2.7	141.5	2.7
Diagnostic agents	26.8	1.1	113.5[a]	2.2
Other pharmaceutical preps	66.8	2.6	273.0	5.1
Total	**$2,518.2**	**100.0%**	**$5,260.8**	**100.0%**

[a]Includes only *in vivo* diagnostic products. Because of a change in definition introduced in the 1974-1975 *Survey*, sales of *in vitro* diagnostic products are now reported elsewhere.

Sources: Published PMA survey reports.

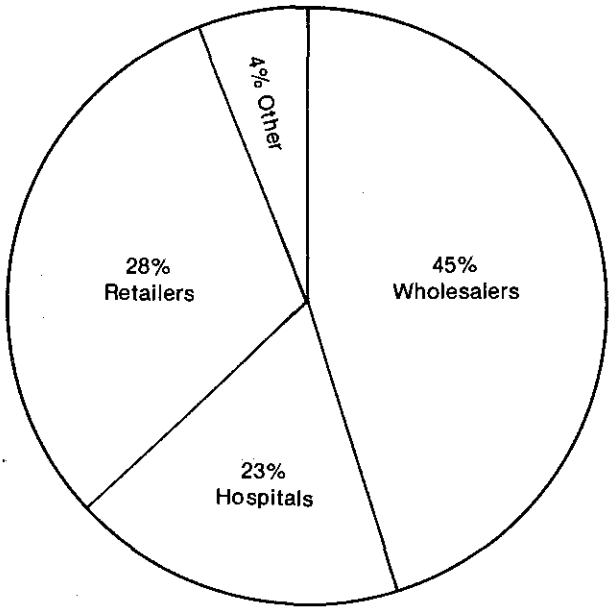
VETERINARY PHARMACEUTICALS

Although pharmaceutical preparations for veterinary use accounted for only about four percent of domestic sales (six percent of sales abroad), their significance to the economy is substantial, particularly for increasing meat production and in controlling animal disease.

Control of animal diseases that can affect man has greatly benefited human health. The use of drugs and vaccines has helped to decrease the incidence of diseases that are transmittable to man. Several of the most serious of these are *brucellosis,* which appears in man as undulant fever; *bovine tuberculosis,* which cripples the human spinal system; and *anthrax,* an especially virulent infection that usually causes death.

the largest class of therapeutic drugs—27 percent of all shipments in 1974, according to the CIR. Between 1970 and 1974, the largest gain was made by preparations for the cardiovascular system, from 8.1 percent of the market in 1970, to 10.4 percent in 1974. The largest

Figure 8. Manufacturers sales of human use drugs in the U.S., by class of customer, 1974



Sources: Published PMA survey reports.

decrease took place in drugs affecting the digestive, genito-urinary system—from 12.6 percent in 1970, to 11.2 percent in 1974 *(Table 18).*

The Annual Census of Manufactures also collects data on Biological products as well as Medicinals and Botanicals.[9] *Table 19* shows the increase in shipments from 1970 to 1974 in these two categories.

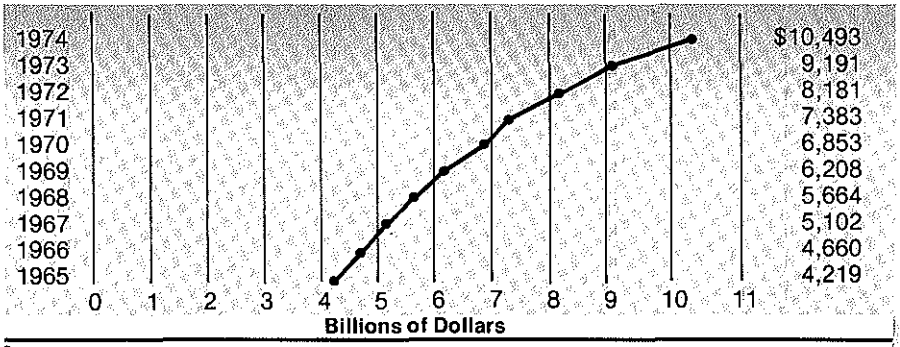
Similar data are available from PMA's *Annual Survey Reports* which also provide data by therapeutic class. *Table 20* compares the 1965 and 1974 *Surveys.*

(9) Pharmaceutical preparations are also covered by the *Annual Census of Manufactures* but not in the detail found in the *Current Industrial Report.*

Table 17: Ethical pharmaceutical sales, domestic and foreign, 1964-1974 (millions of dollars)

Year	Human Dosage	Human Bulk	Veterinary Dosage and Bulk	Total
Domestic sales				
1974	$6,083	$190	$280	$6,553
1973	5,507	137	269	5,913
1972	5,018	118	239	5,375
1971	4,667	129	199	4,995
1970	4,322	122	257	4,701
1969	4,008	127	216	4,351
1968	3,655	153	205	4,013
1967	3,226	167	211	3,604
1966	3,011	167	207	3,385
1965	2,779	161	181	3,121
Foreign sales[a]				
1974	$3,474	$209	$257	$3,940
1973	2,951	127	200	3,278
1972	2,504	99	203	2,806
1971	2,113	100	175	2,388
1970	1,890	91	171	2,152
1969	1,618	84	155	1,857
1968	1,417	77	157	1,651
1967	1,279	72	147	1,498
1966	1,077	85	113	1,275
1965	930	69	99	1,098

Total domestic and foreign sales



[a]Including exports.

Sources: Published PMA survey reports.

generically. The pharmacist then selects the version of the drug to dispense to the patient. There are numerous versions of many generic drugs, and the pharmacist makes a selection after considering availability, price, quality and source.

Generic prescribing has been increasing slowly but steadily in recent years. In 1975, new generic prescriptions accounted for 11.1 percent of the total 741 million new prescriptions. From 1966 through 1974, the volume of generic prescriptions rose 178 percent, while the volume of all prescriptions (brand and generic) increased 56 percent.

In spite of a higher volume of prescribing between 1967 and 1975, the number of generics listed in the top 200 prescription drugs remained stable.

Of the top 200 prescription drugs in 1967, 15 were prescribed generically without specifying the source. In 1970 there were 16 "generic unspecified" in the top 200, and in 1975, 15.

When a physician prescribes generically without specifying the manufacturer, he is delegating the selection of manufacturing source to the pharmacist. In the case of multiple-source drugs, which account for about 25 percent of the dollar volume of all prescription drugs, a generic prescription will frequently, though not always, result in a lower price. A study in 1974 by the market research firm, IMS/America, of the top 50 multiple-source drugs, revealed that, at the retail pharmacy level, the brand specified prescription averaged about 10.6 percent higher. Since generic prescribing can make no difference in price with the sole source drugs, the potential saving if all prescriptions were written generically, (i.e., if prescribers disregarded the risk of quality and service value-differences), would be about 2 percent of total consumer prescription expenditures.

REGULATION

Though the major responsibility for ensuring high quality pharmaceuticals lies with the manufacturer, government regulatory agencies legally enforce established drug product standards and determine whether new drugs have sufficient evidence of safety and effectiveness to be marketed.

The Food and Drug Administration has primary responsibility for monitoring industry compliance with drug laws passed by Congress. Aside from its role of closely monitoring drug research, new drug testing, drug development, marketing and consumption, the FDA inspects manufacturing plants, tests batches of selected drugs and examines drug imports. All these activities affect directly the operations of the manufacturers. As a result, the pharmaceutical industry is one of the most closely monitored and regulated industries in the United States.

In 1973, selected PMA member companies spent $160 million for quality control activities. Direct control functions accounted for 78 percent of these expenditures, while indirect quality control came to 22 percent, or $35 million. Approximately 82 percent of all expenditures relating to quality were made by companies with sales of at least $100 million. These firms employed the equivalent of 10,000 full-time workers to conduct and monitor quality control checks, with 77 percent assigned to direct control functions. One out of every seven production workers employed by PMA firms has specific quality control duties, and companies with sales of $100 million or more accounted for 83 percent of all personnel assigned to this area *(Table 16).*

Table 16: Product quality control employment, by sales group, 1973

	Average number of QC employees per company		
Sales group	**Direct**	**Indirect**	**Total**
$100 million and over	375	135	510
$30 to $100 million	59	16	75
Less than $30 million	24	7	31
Average, all firms	158	47	205

Sources: Published PMA survey reports.

SAFETY AND EFFICACY

Before a new drug can be tested in human subjects, evidence of safety and effectiveness must first be demonstrated in extensive animal studies.

Every year the pharmaceutical industry examines the effect of potential new drugs on large numbers of animals. Depending on the results of these thorough biochemical and toxicological studies, the company may submit the compound for clinical testing in humans. These tests are strictly regulated by the Food and Drug Administration (FDA).

"The objective of clinical investigation," according to FDA, "is to assess whether a drug is of value in the treatment or prophylaxis of a disease or condition, its risks or undesirable effects and the relative relationship of these assessments."[5] Drug manufacturers must notify FDA of any projected tests and have to submit periodic program

(5) *FDA Introduction to Total Drug Quality.* Washington, D.C.: Bureau of Drugs, Food and Drug Administration, HEW, November 1973, p. 53.

100 U.S. hospitals indicates that between 1940-49 and 1965-69 the percentage of acute leukemia patients who survived for one or more years increased from 5 to 37 percent. Before the advent of relevant chemotherapy 20 years ago, acute leukemia almost always proved fatal.

New and improved medicines also have contributed to sharp increases in life expectancy, which rose from 54 years in 1920 to 72 years in 1974 *(Table 15).* These added years of life, as well as significant reduction in disabilities throughout life, have added immeasurably to social welfare and economic progress.

Table 15: Life expectancies for men and women, 1920-1974

Year	Men	Women	Average
1974	68.2	75.9	71.9
1973	67.6	75.3	71.3
1972	67.4	75.2	71.2
1971	67.4	74.8	71.0
1970	67.1	74.8	70.9
1969	67.0	74.3	70.5
1968	66.6	74.0	70.2
1967	67.0	74.2	70.5
1966	66.7	73.8	70.1
1965	66.8	73.7	70.2
1960	66.6	73.1	69.7
1950	65.6	71.1	68.2
1940	60.8	65.2	62.9
1930	58.1	61.6	59.7
1920	53.6	54.6	54.1

Source: National Center for Health Statistics.

Table 13: Ten leading causes of death in the U.S., 1900 and 1975

Cause of death	Rate of death (per 100,000 persons)
1900	
Influenza and pneumonia	202.2
Tuberculosis	194.4
Gastroenteritis	142.7
Diseases of the heart	137.4
Cerebral hemorrhages and vascular lesions affecting central nervous system	106.9
Chronic nephritis	81.0
All accidents	72.3
Cancer and other malignant neoplasms	64.0
Certain diseases of early infancy	62.6
Diphtheria	40.3
1975	
Diseases of the heart	338.6
Malignant neoplasms	174.4
Cerebrovascular diseases	91.1
All accidents	46.9
Influenza and pneumonia	26.3
Diabetes mellitus	16.8
Cirrhosis of the liver	15.0
Arteriosclerosis	13.7
Certain diseases of early infancy	12.5
Suicide	12.4

Source: National Center for Health Statistics.

Table 14: Decline in the death rate from selected diseases following the introduction of pharmaceuticals, 1958 to 1974

Disease entity	Percent decline	Type of pharmaceutical
[illegible]	100	[illegible]
[illegible]	100	[illegible]
[illegible]	92	[illegible]
[illegible]	75	[illegible]
[illegible]	50	[illegible]
[illegible]	64	[illegible]
[illegible]	69	[illegible]
[illegible]	46	[illegible]
[illegible]	95	[illegible]
[illegible]	67	[illegible]
[illegible]	46	[illegible]
[illegible]	67	[illegible]

Source: National Center for Health Statistics.

(Continued from p. 19)

Therapeutic Class	No. in group	No. in subgroup	Percentage
Enzymes	8		0.8%
Eye preparations	12		1.2
Fertility agents (Nonhormonal)	1		0.1
Gastrointestinal preparations	64		6.6
Antacids		9	
Antidiarrheals		4	
Antispasmodics		36	
Biliary tract therapy		2	
Enemas		2	
Enzymes—digestive		1	
Laxatives		6	
Other G.I. preparations		4	
Hematinics	15		1.5
Hemostatics	2		0.2
Hormones	83		8.5
ACTH		2	
Corticoids		31	
Anabolics (hormonal)		9	
Androgens		6	
Estrogens		20	
Progesterones		11	
Other hormones		4	
Hospital solutions	6		0.6
Muscle relaxants	34		3.5
General		14	
Parkinsonism		12	
Surgical		8	
Oxytocics	5		0.5
Parasympathomimetics	6		0.6
Psychostimulants	17		1.8
Sedatives and Hypnotics	18		1.9
Barbiturates		6	
Nonbarbiturates		12	
Thyroid therapy	8		0.8
Thyroid preparations		4	
Antithyroid preparations		4	
Vitamins and nutrients	14		1.5
Vitamins		9	
Nutrients		5	
Unclassified	17		1.8
TOTAL	**971**		**100.0%**

Source: Pharmacy Times, March 1976; (based on data from Paul de Haen, Inc.)

Anti-infectives, with a listing of 183 products, comprised the largest therapeutic class of new chemical entities. Hormones follow with 83 entities, then cardiovascular preparations, gastrointestinal preparations and ataraxics, respectively *(Table 12).*

The United States also leads as originator of new drugs in many foreign countries; for instance, the United States was responsible for the largest share of new introductions in England and Italy between 1968-1972.

Table 12: New single chemical entities introduced in U.S. market by therapeutic class, 1940-1975

Therapeutic class	No. in group	No. in subgroup	Percentage
Analgesics	30		3.1%
Migraine therapy		2	
Narcotics		13	
Nonnarcotics		15	
Analeptics	3		0.3
Antagonists and antidotes	14		1.5
Antagonists		4	
Antidiuretics		1	
Antidotes			
Antineoplastics		8	
Not specified		1	
Anesthetics	24		2.5
Inhalants		4	
Injectables		5	
Local and topical		15	
Anthelmintics	13		1.3
Anti-Arthritics (nonhormonal)	9		0.9
Anticoagulants	11		1.1
Anticonvulsants	14		1.5
Antihistamines	33		3.4
Anti-infectives	183		18.9
General		1	
Amebicides		9	
Antibacterials			
General		11	
Urinary		7	
Vaginal		7	
Antibiotics			
Broad and medium spectrum		47	
Penicillin and derivatives		29	
Topical		5	
Unclassified		2	

(Continued on p. 19)

Table 10: Drugs and medicines, patent activity
Foreign origin patents in the United States, 1963-1975

Country of origin	Number of new patents issued												
	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975
Germany	144	153	176	214	256	132	226	231	326	364	385	417	527
Japan	48	62	69	123	130	82	163	148	197	317	247	348	487
Switzerland	108	118	137	149	145	89	188	182	211	243	250	248	346
United Kingdom	82	105	113	169	119	79	121	125	95	144	129	210	271
France	66	91	79	98	84	52	111	86	107	107	121	210	253
Italy	31	48	41	47	44	23	49	41	34	61	51	73	81
Canada	23	34	32	37	31	30	31	35	41	47	47	70	81
Netherlands	38	17	33	28	36	23	37	28	31	28	37	43	57
Mexico	74	61	64	67	18	11	28	14	4	11	5	6	7
Sweden	14	4	10	21	16	12	17	17	32	28	32	36	48
Belgium	12	16	15	16	19	7	16	15	21	22	25	38	39
Denmark	4	5	6	10	11	3	6	5	9	13	7	11	16
Austria	6	5	6	10	2	6	6	4	7	12	11	14	12
Hungary	1	1	1	3	1	1	1	10	5	12	6	11	15
Australia	2	2	2	1	3	4	12	5	8	7	8	11	7
Czechoslovakia	2	3	2	2	1	4	10	1	2	10	2	5	2
U.S.S.R.	0	1	2	5	1	3	2	5	2	1	11	8	21
Israel	0	1	1	4	7	1	1	4	5	5	8	7	11
Spain	0	1	0	0	1	0	3	3	3	7	1	3	3
Poland	0	0	0	0	2	1	2	1	1	1	2	2	2
Other countries	5	9	13	15	10	11	15	15	8	22	21	26	16
Total	636	767	814	974	911	588	1093	1012	1045	1700	1483	1861	2074

Source: U.S. Patent and Trademark Office, Office of Technology Assessment and Forecast, published and unpublished data.

Table 8: Drugs and medicines, patent activity, United States, 1963-1975

	Number of new patents issued												
	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975
Total Patents	1886	2273	2289	3010	2885	1995	3001	2799	2700	4144	3419	4011	4557
Originating in the United States	1250	1506	1475	2036	1974	1407	1908	1787	1655	2444	1936	2150	2483
Originating in other countries[a]	636	767	814	974	911	588	1093	1012	1045	1700	1483	1861	2074
Patents originating in the United States	1250	1506	1475	2036	1974	1407	1908	1787	1655	2444	1936	2150	2483
Owned by United States corporations	1122	1405	1357	1854	1804	1275	1755	1634	1520	2112	1736	1900	2240
Owned by United States Individuals	30	22	25	22	28	26	24	17	24	36	49	39	66
Owned by United States government	83	73	90	145	124	69	89	107	106	282	137	191	147
Foreign owned	15	6	3	15	18	37	40	29	5	14	14	20	30
Patents originating in other countries	636	767	814	974	911	588	1093	1012	1045	1700	1483	1861	2074
United States owned	122	154	189	193	185	135	239	264	185	269	231	330	352
Foreign owned	514	613	625	781	726	453	854	748	860	1431	1252	1531	1722
Foreign corporations	463	560	563	708	661	417	789	684	782	1215	1106	1368	1591
Foreign government	0	2	1	0	3	1	2	1	1	0	0	2	5
Foreign individuals	51	51	61	73	62	35	63	63	77	216	146	161	126

[a]The Patent office credits patents to the country of residence shown by the inventor on the patent application.

Table 5: New drug[a] introductions, United Kingdom and the United States, 1962-1971

	Introduced in both countries			Introduced in one country only	
	U.K. first	U.S. first	both at same time	U.K.	U.S.
Total: 180	43	55	14	27	41
Aggregate time lead for new drug (years)	129	59	0	255	66

[a]New drug is defined as a new single chemical entity, excluding vaccines and new salts.

Source: William Wardell and Louis Lasagna, *Regulations and Drug Development*, (Washington: American Enterprise Institute for Public Policy Research, 1975).

Table 6: Summary of new drug introductions in Britain and the United States, January 1972-June 1974

Category	Total drugs	Introduced in both countries		Introduced in one country only	
		U.K. first	U.S. first	U.K.	U.S.
Cardiovascular	7	1	0	5	1
Diuretic	2	1	0	1	0
Respiratory	4	3	0	1	0
Antibacterial and chemotherapeutic	17	2	4	6	5
Central nervous system	15	3	3	6	3
Anesthetic	3	2	0	0	1
Analgesics	7	0	0	7	0
Gastrointestinal	0	0	0	0	0
Total	55	12	7	26	10

Source: Wardell and Lasagna, *Regulation and Drug Development*, (Washington: American Enterprise Institute for Public Policy Research, 1975).

the total industry R&D expenditures by the number of new single chemical entities introduced. Professor David Schwartzman calculated that this amounted to $1.3 million in 1960 and rose to an average of $24.4 million for a typical new single chemical entity started in 1972.

One measure of activity in the new drug research process is the submission of drug documentation to FDA. *Table 7* shows the number of investigational (INDs), new drug (NDAs), supplemental, final printed labeling (FPLs), and abbreviated new drug (ANDAs) applications filed

NEW PRODUCT INTRODUCTIONS

In the past 35 years, 971 new single-chemical entities have been introduced in the United States. The smallest number, 9, was recorded in 1969; the largest, 65, in 1959. From 1941 to 1959 there was a fourfold increase in introductions of new single chemical entities; from 1960 to 1975 there was a threefold decrease *(Figure 4).* Two thirds of the new entities appeared before 1960. Even without the increased regulatory requirements for approvals, a decline in new product introductions would probably have occurred as industry researchers developed more sophisticated instruments and techniques for measuring safety and effectiveness and addressed more complex problems, including therapy for the more intractable diseases.

In addition, modifications in the regulatory process since the late 1950s have increased the time needed to test new drugs and to meet other requirements of the Food and Drug Administration. On the average, 10 years may elapse between the discovery of a new drug and FDA's final approval, compared to an average of approximately 2 years prior to the 1962 amendments to the Federal Food, Drug and Cosmetic Act.

The time required for approvals may delay for several years therapeutic application of a new discovery in the United States. A recent study by Drs. W.M. Wardell and L. Lasagna compared new drug introductions in the United States and the United Kingdom. Data in *Table 5* show that in the period 1962-1971 the United Kingdom was well ahead of the United States in terms of availability of new drug therapies. For example there were 159 new drugs introduced in the United Kingdom during this period versus 103 introductions in the United States. Some of these were introduced in each individual country only, some were introduced in both countries at different times and still others were introduced in both countries at the same time. Adding the lead times for those drugs first introduced in each country, the United Kingdom accumulated 376 lead time years, almost three times as much as the United States with 127 lead years. In the period January 1972 to June 1974, there was some improvement in this situation even though differences still occur especially in certain therapeutic classes, e.g., cardiovascular drugs. In spite of improvements Great Britain still leads in the absolute number of introductions, i.e., 45 versus 29 for the United States *(Table 6).*

The increase in the costs of R&D per new drug introduced is even more spectacular than the increase in time required for approvals. Because a large part of R&D expenditure cannot be allocated to specific products (e.g., basic research and the cost of development on projects which must be abandoned for reasons of inadequate effectiveness or excessive risk), it is not feasible to estimate the full R&D costs identified with the average approved product. But one can divide

Table 3: U.S. applied R&D expenditures on pharmaceuticals, by product class, 1973-1974

1974	1973	Product class	Percentage share of applied R&D dollar 1974	1973	Percent change 1973/1974
1	1	Central nervous system	18.5%	17.4%	+ 6.3
2	2	Anti-infectives	17.8	15.8	+ 12.7
3	4	Cardiovasculars	15.1	12.8	+ 18.0
4	3	Neoplasms	14.0	15.4	- 9.1
5	5	Digestive	6.2	6.0	+ 3.3
6	9	Respiratory	4.8	3.9	+ 23.1
7	8	Biologicals	4.5	4.0	+ 12.5
8	7	Dermatologicals	3.5	4.1	-14.6
9	10	Vitamins	2.1	2.0	+ 5.0
[a]	6	Diagnostics	—	5.1	—
		Other	6.1	5.8	+ 5.2
		Veterinary preparations	6.9	7.2	- 4.2
		Veterinary biologicals	.5	.5	0.0
			100.0%	100.0%	

[a]Diagnostic products were omitted in the 1974 Survey.

Source: Published PMA survey reports.

RESEARCH AND DEVELOPMENT MANPOWER

The pharmaceutical industry employed 24,092 persons in research and development in 1974. R&D scientific and professional staff accounted for more than 50 percent of the total. Technicians numbered 5,389, or 22 percent of the total, with 6,141 supporting staff comprising 25 percent *(Table 4)*.

Table 4: R&D manpower, 1974

Type of Staff	Educational level: Doctoral	MS	BA	Less than BS	Total
Scientific & professional	4,642	2,379	4,970	571	12,562
Supporting Staff	282	346	654	4,859	6,141
Technicians	3	23	307	5,056	5,389
Total	**4,927**	**2,748**	**5,931**	**10,486**	**24,092**

Sources: Published PMA survey reports.

BASIC AND APPLIED RESEARCH

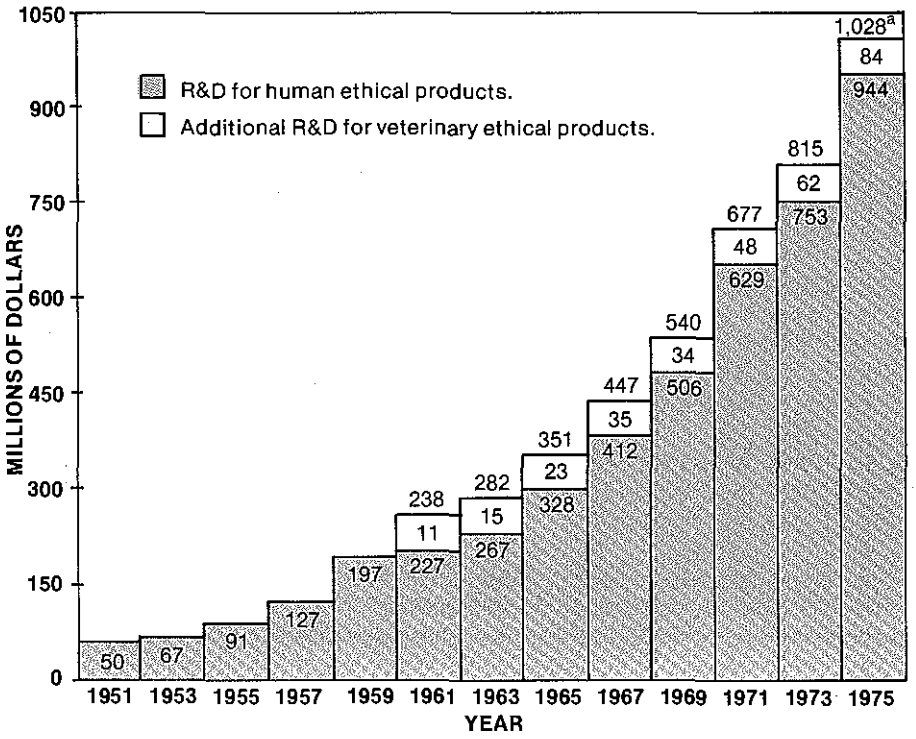
The National Science Foundation (NSF) customarily divides research outlays into Basic, Applied and Developmental categories.

By definition, *basic* research is conducted without specific commercial objectives, but is directed toward advancing scientific knowledge that is necessary before applied research and development can begin. *Applied* research, on the other hand, as defined by the National Science Foundation, has specific commercial objectives with respect to either products or processes. As one might expect, most private industry research expenditures support applied research and development.

Even though the expenditures for basic research have risen, the share of total R&D represented by basic research has declined under the impact of stricter regulatory requirements, which cause the "development" component of R&D to rise disproportionately. The pharmaceutical industry, however, leads all other U.S. industries in the proportion of research funds allocated to basic research; further, approximately 95 percent of those funds spent on basic research are company funds. The bulk (over 90 percent) of government support of basic research in industry goes to other types of manufacturing. The total spent for basic research in all industry in 1974 was $683 million, including government and private funds; this constitutes about three percent of the $22 billion total spent for R&D by industry in 1974. The share of R&D spent on basic research is significantly higher in pharmaceuticals (12 percent) than in other industries surveyed. *Table 2* illustrates this, with statistics from the National Science Foundation.

Most of applied R&D (65 percent in 1974), according to PMA data, is allocated to the search for drugs to treat central nervous system diseases, infections, neoplasms and cardiovascular problems *(Table 3).* These four categories have led in applied R&D for many years; changes occur primarily within each category. A comparison of 1974 and 1973 rankings shows that central nervous system and anti-infective drugs retained first and second places, respectively. A decline of 9.1 percent in R&D expenditures for neoplasm therapy and an increase of 18.0 percent in the cardiovascular category led to an exchange of place in the rankings of these two product classes.

Figure 1. Research and development expenditures for ethical products 1951-1975 (odd numbered years)



[a]Budgeted.
Sources: Published PMA survey reports.

This decrease reflected the net effect of a reduced rate of growth in the domestic R&D effort and substantial increases in R&D expenditures abroad. Inflationary pressures on R&D costs also appear to have made it increasingly difficult for smaller firms to expand research programs. The ratio of 11.7 percent for 1974 indicates what may be a resumption of the historical levels.

Additional factors also will have a considerable impact on future growth, including an increased awareness of the importance of health care and the health needs of an aging population. These are certain to intensify demand for pharmaceuticals and to expand the need for devices and diagnostic products. Further, the Medicare and Medicaid programs introduced in the mid 1960s may well become the forerunners of a national health insurance program. The sweeping changes that would result from the passage of such a plan are bound to have a far-reaching effect on the industry, as well as all other sectors of the health care system.

The information that follows deals with ethical pharmaceuticals, medical devices and diagnostic products. Medical device and diagnostic product data will be found in Section X; other sections deal with ethical pharmaceuticals. The medical device and diagnostic product industries are relatively new and not fully defined, and comprehensive information on production, distribution and consumption is not readily available. PMA began collecting these data from its members in 1973; the latest available statistics are reported in Section X.

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