

PhRMA

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2009



Key Facts

Research and Development (R&D)

- Time to develop a drug = 10 to 15 years¹

Development Costs

- Cost to develop a drug
2006 = \$1.318 billion²
2001 = \$802 million³
1987 = \$318 million³
1975 = \$138 million³
- Cost to develop a biologic
2006 = \$1.2 billion⁴

R&D Spending

Year	PhRMA members ⁵	Total industry ⁶
2008	\$50.3 billion (est.)	\$65.2 billion (est.)
2007	\$47.9 billion	\$63.2 billion
2006	\$43.4 billion	\$56.1 billion
2005	\$39.9 billion	\$51.8 billion
2004	\$37.0 billion	\$47.6 billion
2000	\$26.0 billion	not available
1990	\$8.4 billion	not available
1980	\$2.0 billion	not available

Percentage of Sales That Went to R&D in 2008⁷

Domestic R&D
As a percentage of domestic sales = 20.3%

Total R&D
As a percentage of total sales = 17.4%

Economic Impact of the Biopharmaceutical Sector⁸

Direct jobs =
686,422 in 2006 (most recent data)

Total jobs, including indirect and induced jobs =
3.2 million in 2006 (most recent data)

Approvals

- Drugs and biologics approved in 2008 = 31⁹
- In the 25 years since the *Orphan Drug Act* was established, more than 300 orphan drugs have been approved.¹⁰

Medicines in Development

2009 = 2,900 compounds¹¹

1999 = 1,800 compounds¹²

Value of Medicines

- **Cancer:** Since 1980, life expectancy for cancer patients has increased about three years, and 83% of those gains are attributable to new treatments, including medicines.¹³ Another study found that medicines specifically account for 50% to 60% of increases in survival rates since 1975.¹⁴
- **Cardiovascular Disease:** According to a 2009 statistics update by the American Heart Association (AHA), death rates for cardiovascular disease fell a dramatic 26.4% between 1999 and 2005.¹⁵ The AHA lists better control of high blood pressure and high cholesterol, and reduced tobacco use as factors in the improvement.¹⁶
- **HIV/AIDS:** Since the approval of the highly active anti-retroviral treatments (HAART) in 1995, the annual number of AIDS deaths has dropped by more than 70%.¹⁷

Sales

- Generic share of market¹⁸
2003 = 54%
2008 = 72%
- Only 2 of 10 marketed drugs ever return revenues that match or exceed R&D costs.¹⁹

See inside back cover for endnotes.

PhRMA ANNUAL MEMBERSHIP SURVEY

DEFINITIONS OF TERMS

Research and Development Expenditure Definitions

R&D Expenditures: Expenditures within PhRMA member companies' U.S. and/or foreign research laboratories plus research and development (R&D) funds contracted or granted to commercial laboratories, private practitioners, consultants, educational and nonprofit research institutions, manufacturing and other companies, or other research-performing organizations. Includes basic and applied research, as well as developmental 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. Includes the total cost incurred for all pharmaceutical R&D activities, including salaries, materials, supplies used, and a fair share of overhead, as well as the cost of developing quality control. However, it does not include the cost of routine quality control activities, capital expenditures, or any costs incurred for drug or medical R&D conducted under a grant or contract for other companies or organizations.

Domestic R&D: Expenditures within the United States by all PhRMA member companies.

- **Licensed-in:** Products for which a license is held for a compound.
- **Self-originated:** Products for which the company originates the compound.

R&D Abroad: Expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies is excluded.

Prehuman/Preclinical Testing: From synthesis to first testing in humans.

Phase 1/2/3 Clinical Testing: From first testing in designated phase to first testing in subsequent phase.

Approval Phase: From New Drug Application (NDA) submission to NDA approval.

Phase 4 Clinical Testing: Any post-marketing testing performed.

Uncategorized: Represents data for which detailed classifications were unavailable.

Sales Definitions

Sales: Product sales calculated as billed, free on board (FOB) plant or warehouse less cash discounts, Medicaid rebates, returns, and allowances. These include all marketing expenses except transportation costs. Also included is the sales value of products bought and resold without further processing or repackaging, as well as the dollar value of products made from the firm's own materials for other manufacturers' resale. Excluded are all royalty payments, interest, and other income.

Domestic Sales: Sales generated within the United States by all PhRMA member companies.

- **Private Sector:** Sales through regular marketing channels for end-use other than by government agency administration or distribution.
- **Public Sector:** Sales or shipments made directly to federal, state, or local government agencies, hospitals, and clinics.

Sales Abroad: Sales generated outside the United States by U.S.-owned PhRMA member companies, and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded.

- **Exports to Other Customers:** Sales to third parties only, FOB U.S. port. Excludes all intrafirm transactions, such as sales or shipments to subsidiaries or affiliates.
- **Foreign Sales:** Sales consummated in foreign countries.

R&D Employment Definitions

Scientific, Professional, and Technical Staff: Full-time employees, as well as full-time equivalents for part-time employees, whose work requires the application of R&D knowledge, skills, and scientific techniques in the life, physical, engineering, mathematical, or statistical sciences, as well as persons engaged in technical work at a level that requires knowledge in one of the above-mentioned fields. Does not include persons who have formal training in the sciences but who are not actively engaged in R&D.

Supported Scientific, Professional, and Technical Nonstaff: Persons whose work requires the application of R&D knowledge, skills, and scientific techniques in the life, physical, engineering, mathematical, or statistical sciences, as well as persons engaged in technical work at a level that requires knowledge in one of the above-mentioned fields who are supported through contracts or grants to commercial laboratories, private practitioners, consultants, educational and nonprofit research institutions, manufacturing and other companies, or other research-performing organizations located in the United States. Does not include persons who have formal training in the sciences but who are not actively engaged in R&D.



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TABLE 1

Domestic R&D and R&D Abroad,* PhRMA Member Companies: 1970–2008

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad*	Annual Percentage Change	Total R&D	Annual Percentage Change
2008**	\$38,427.8	5.0%	\$11,825.7	4.7%	\$50,253.6	4.9%
2007	36,608.4	7.8	11,294.8	25.4	47,903.1	11.5
2006	33,967.9	9.7	9,005.6	1.3	42,973.5	7.8
2005	30,969.0	4.8	8,888.9	19.1	39,857.9	7.7
2004	29,555.5	9.2	7,462.6	1.0	37,018.1	7.4
2003	27,064.9	5.5	7,388.4	37.9	34,453.3	11.1
2002	25,655.1	9.2	5,357.2	-13.9	31,012.2	4.2
2001	23,502.0	10.0	6,220.6	33.3	29,722.7	14.4
2000	21,363.7	15.7	4,667.1	10.6	26,030.8	14.7
1999	18,471.1	7.4	4,219.6	9.9	22,690.7	8.2
1998	17,127.9	11.0	3,839.0	9.9	20,966.9	10.8
1997	15,466.0	13.9	3,492.1	6.5	18,958.1	12.4
1996	13,627.1	14.8	3,278.5	-1.6	16,905.6	11.2
1995	11,874.0	7.0	3,333.5	***	15,207.4	***
1994	11,101.6	6.0	2,347.8	3.8	13,449.4	5.6
1993	10,477.1	12.5	2,262.9	5.0	12,740.0	11.1
1992	9,312.1	17.4	2,155.8	21.3	11,467.9	18.2
1991	7,928.6	16.5	1,776.8	9.9	9,705.4	15.3
1990	6,802.9	13.0	1,617.4	23.6	8,420.3	14.9
1989	6,021.4	15.0	1,308.6	0.4	7,330.0	12.1
1988	5,233.9	16.2	1,303.6	30.6	6,537.5	18.8
1987	4,504.1	16.2	998.1	15.4	5,502.2	16.1
1986	3,875.0	14.7	865.1	23.8	4,740.1	16.2
1985	3,378.7	13.3	698.9	17.2	4,077.6	13.9
1984	2,982.4	11.6	596.4	9.2	3,578.8	11.2
1983	2,671.3	17.7	546.3	8.2	3,217.6	16.0
1982	2,268.7	21.3	505.0	7.7	2,773.7	18.6
1981	1,870.4	20.7	469.1	9.7	2,339.5	18.4
1980	1,549.2	16.7	427.5	42.8	1,976.7	21.5
1979	1,327.4	13.8	299.4	25.9	1,626.8	15.9
1978	1,166.1	9.7	237.9	11.6	1,404.0	10.0
1977	1,063.0	8.1	213.1	18.2	1,276.1	9.7
1976	983.4	8.8	180.3	14.1	1,163.7	9.6
1975	903.5	13.9	158.0	7.0	1,061.5	12.8
1974	793.1	12.0	147.7	26.3	940.8	14.0
1973	708.1	8.1	116.9	64.0	825.0	13.6
1972	654.8	4.5	71.3	24.9	726.1	6.2
1971	626.7	10.7	57.1	9.2	683.8	10.6
1970	566.2	-----	52.3	-----	618.5	-----
Average		11.8%		15.5%		12.3%

*R&D Abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

**Estimated.

***R&D Abroad affected by merger and acquisition activity.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 2**R&D as a Percentage of Sales,
PhRMA Member Companies: 1970–2008**

Year	Domestic R&D as a Percentage of Domestic Sales	Total R&D as a Percentage of Total Sales
2008*	20.3%	17.4%
2007	19.8	17.5
2006	19.4	17.1
2005	18.6	16.9
2004	18.4	16.1**
2003	18.3	16.5**
2002	18.4	16.1
2001	18.0	16.7
2000	18.4	16.2
1999	18.2	15.5
1998	21.1	16.8
1997	21.6	17.1
1996	21.0	16.6
1995	20.8	16.7
1994	21.9	17.3
1993	21.6	17.0
1992	19.4	15.5
1991	17.9	14.6
1990	17.7	14.4
1989	18.4	14.8
1988	18.3	14.1
1987	17.4	13.4
1986	16.4	12.9
1985	16.3	12.9
1984	15.7	12.1
1983	15.9	11.8
1982	15.4	10.9
1981	14.8	10.0
1980	13.1	8.9
1979	12.5	8.6
1978	12.2	8.5
1977	12.4	9.0
1976	12.4	8.9
1975	12.7	9.0
1974	11.8	9.1
1973	12.5	9.3
1972	12.6	9.2
1971	12.2	9.0
1970	12.4	9.3

*Estimated.

**Revised in 2007 to reflect updated data.

SOURCE: Pharmaceutical Research and Manufacturers of America,
PhRMA Annual Membership Survey, 2009.

TABLE 3**Domestic R&D and R&D Abroad,* PhRMA Member Companies: 2007**

(dollar figures in millions)

	Dollars	Share
R&D Expenditures for Human-use Pharmaceuticals		
Domestic	\$ 36,178.3	75.5%
Abroad*	\$ 11,006.4	23.0%
Total Human-use R&D	\$ 47,184.7	98.5%
R&D Expenditures for Veterinary-use Pharmaceuticals		
Domestic	\$ 430.0	0.9%
Abroad*	\$ 288.4	0.6%
Total Vet-use R&D	\$ 718.4	1.5%
TOTAL R&D	\$ 47,903.1	100.0%

*R&D abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 4**Domestic R&D by Source, PhRMA Member Companies: 2007**

(dollar figures in millions)

Type	Dollars	Share
Licensed-in	\$ 6,294.2	17.2%
Self-originated	27,126.9	74.1
Uncategorized	3,187.3	8.7
TOTAL R&D	\$36,608.4	100.0%

Note: All figures include company-financed R&D only. Total values may be affected by rounding.
 SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 5**R&D by Function, PhRMA Member Companies: 2007**

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	\$ 13,087.4	27.3%
Phase 1	3,547.7	7.4
Phase 2	6,251.0	13.0
Phase 3	13,664.7	28.5
Approval	2,413.8	5.0
Phase 4	6,439.9	13.4
Uncategorized	2,498.6	5.2
TOTAL R&D	\$ 47,903.1	100.0%

Note: All figures include company-financed R&D only. Total values may be affected by rounding.
 SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 6

R&D by Geographic Area,* PhRMA Member Companies: 2007

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	\$ 28.6	0.1%
Americas		
United States	\$36,608.4	76.4%
Canada	612.4	1.3
Mexico	63.0	0.1
Brazil	81.2	0.2
Other Latin America (Other South American, Central American, and all Caribbean nations)	217.9	0.5%
Asia-Pacific		
Japan	\$ 954.2	2.0%
China	62.9	0.1
India	33.3	0.1
Other Asia-Pacific	191.8	0.4
Australia		
Australia and New Zealand	\$ 161.0	0.3%
Europe		
France	\$ 521.8	1.1%
Germany	714.7	1.5
Italy	240.1	0.5
Spain	235.5	0.5
United Kingdom	2,892.9	6.0
Other Western European	3,568.6	7.4
Turkey	39.0	0.1
Russia	40.1	0.1
Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States)	481.8	1.0
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar)	\$ 29.7	0.1%
Uncategorized	\$ 124.2	0.3%
TOTAL R&D	\$ 47,903.1	100.0%

*R&D abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 7**Biologics and Biotechnology R&D,
PhRMA Member Companies: 2007**

(dollar figures in millions)

Type	Dollars	Share
Biotechnology-derived Therapeutic Proteins	\$10,075.7	21.0%
Vaccines	1,159.9	2.4
Cell or Gene Therapy	95.3	0.2
All Other Biologics	796.5	1.7
Total Biologics/Biotechnology R&D	12,127.4	25.3
Non-biologics/Biotechnology R&D	32,178.3	67.2
Uncategorized R&D	3,597.4	7.5
TOTAL R&D	\$ 47,903.1	100.0%

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 8

Domestic Sales and Sales Abroad,* PhRMA Member Companies: 1970–2008

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad*	Annual Percentage Change	Total Sales	Annual Percentage Change
2008**	\$189,260.5	2.2%	\$99,025.0	12.3%	\$288,285.5	5.4%
2007	185,209.2	4.2	88,213.4	14.8	273,422.6	7.4
2006	177,736.3	7.0	76,870.2	10.0	254,606.4	7.9
2005	166,155.5	3.4	69,881.0	0.1	236,036.5	2.4
2004***	160,751.0	8.6	69,806.9	14.6	230,557.9	10.3
2003***	148,038.6	6.4	60,914.4	13.4	208,953.0	8.4
2002	139,136.4	6.4	53,697.4	12.1	192,833.8	8.0
2001	130,715.9	12.8	47,886.9	5.9	178,602.8	10.9
2000	115,881.8	14.2	45,199.5	1.6	161,081.3	10.4
1999	101,461.8	24.8	44,496.6	2.7	145,958.4	17.1
1998	81,289.2	13.3	43,320.1	10.8	124,609.4	12.4
1997	71,761.9	10.8	39,086.2	6.1	110,848.1	9.1
1996	64,741.4	13.3	36,838.7	8.7	101,580.1	11.6
1995	57,145.5	12.6	33,893.5	****	91,039.0	****
1994	50,740.4	4.4	26,870.7	1.5	77,611.1	3.4
1993	48,590.9	1.0	26,467.3	2.8	75,058.2	1.7
1992	48,095.5	8.6	25,744.2	15.8	73,839.7	11.0
1991	44,304.5	15.1	22,231.1	12.1	66,535.6	14.1
1990	38,486.7	17.7	19,838.3	18.0	58,325.0	17.8
1989	32,706.6	14.4	16,817.9	-4.7	49,524.5	7.1
1988	28,582.6	10.4	17,649.3	17.1	46,231.9	12.9
1987	25,879.1	9.4	15,068.4	15.6	40,947.5	11.6
1986	23,658.8	14.1	13,030.5	19.9	36,689.3	16.1
1985	20,742.5	9.0	10,872.3	4.0	31,614.8	7.3
1984	19,026.1	13.2	10,450.9	0.4	29,477.0	8.3
1983	16,805.0	14.0	10,411.2	-2.4	27,216.2	7.1
1982	14,743.9	16.4	10,667.4	0.1	25,411.3	9.0
1981	12,665.0	7.4	10,658.3	1.4	23,323.3	4.6
1980	11,788.6	10.7	10,515.4	26.9	22,304.0	17.8
1979	10,651.3	11.2	8,287.8	21.0	18,939.1	15.3
1978	9,580.5	12.0	6,850.4	22.2	16,430.9	16.1
1977	8,550.4	7.5	5,605.0	10.2	14,155.4	8.6
1976	7,951.0	11.4	5,084.3	9.7	13,035.3	10.8
1975	7,135.7	10.3	4,633.3	19.1	11,769.0	13.6
1974	6,740.4	13.8	3,891.0	23.4	10,361.4	17.2
1973	5,686.5	9.1	3,152.5	15.9	8,839.0	11.5
1972	5,210.1	1.3	2,720.2	10.6	7,930.3	4.3
1971	5,144.9	13.0	2,459.7	18.0	7,604.6	14.6
1970	4,552.5	-----	2,084.0	-----	6,636.5	-----
Average		10.4%		10.6%		10.4%

*Sales Abroad includes sales generated outside the United States by U.S.-owned PhRMA member companies and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic sales, however, includes sales generated within the United States by all PhRMA member companies.

**Estimated.

***Revised in 2007 to reflect updated data.

****Sales Abroad affected by merger and acquisition activity.

Note: Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 9

Sales by Geographic Area,* PhRMA Member Companies: 2007

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	\$ 1,246.6	0.5%
Americas		
United States	\$185,209.2	67.7%
Canada	6,693.0	2.4
Mexico	2,987.1	1.1
Brazil	2,438.7	0.9
Latin America (Other South American, Central American, and all Caribbean nations)	3,463.6	1.3%
Asia-Pacific		
Japan	\$ 9,089.4	3.3%
China	1,586.0	0.6
India	589.4	0.2
Other Asia-Pacific	4,348.6	1.6
Australia		
Australia and New Zealand	\$ 3,284.2	1.2%
Europe		
France	\$ 8,923.3	3.3%
Germany	6,774.4	2.5
Italy	6,206.6	2.3
Spain	5,567.0	2.0
United Kingdom	5,607.4	2.1
Other Western European	10,584.7	3.9
Turkey	1,449.6	0.5
Russia	925.2	0.3
Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States)	3,755.5	1.4
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar)	\$ 1,643.7	0.6%
Uncategorized	\$ 1,049.6	0.4%
TOTAL SALES	\$273,422.6	100.0%

*Sales Abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic sales, however, includes sales generated within the United States by all PhRMA member companies.

Note: Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey, 2009*.

TABLE 10**Domestic R&D Scientific, Professional and Technical Personnel
by Function, PhRMA Member Companies: 2007**

Function	Personnel	Share
Prehuman/Preclinical	30,023	31.1%
Phase 1	6,117	6.3
Phase 2	10,098	10.5
Phase 3	18,579	19.3
Approval	4,108	4.3
Phase 4	13,332	13.8
Uncategorized	3,613	3.7
Total R&D Staff	85,870	89.0
Supported R&D Non-staff	10,616	11.0
TOTAL R&D PERSONNEL	96,486	100.0%

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

ENDNOTES (continued from inside front cover)

- ¹ J. A. DiMasi, "New Drug Development in U.S. 1963–1999," *Clinical Pharmacology & Therapeutics* 69, no. 5 (2001): 286–296; M. Dickson and J. P. Gagnon, "Key Factors in the Rising Cost of New Drug Discovery and Development," *Nature Reviews Drug Discovery* 3 (May 2004): 417–429; J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151–185.
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