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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.

- **Basic Research:** Domestic expenditures on research projects that represent original investigation for the advancement of scientific knowledge and that do not have specific commercial objectives, although they may be in fields that are of present or potential interest.
- **Applied Research:** Domestic expenditures on research projects that represent original investigation in discovery of new scientific knowledge and that have specific commercial objectives with respect to either products or processes.
- **Development:** Domestic expenditures on research projects that represent technical activities concerned with non-routine problems encountered in translating research findings or other general scientific knowledge into products or processes.

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 I/II/III 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 IV 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.

List of Tables

Detailed Results From the PhRMA Annual Membership Survey

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Table 1
Domestic R&D and R&D Abroad,** PhRMA Member Companies: 1970–2005

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad**	Annual Percentage Change	Total R&D	Annual Percentage Change
*2005	$31,444.2	6.4%	$7,987.1	7.0%	$39,431.3	6.5%
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	29,772.7	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		**12.2%**		**15.6%**		**12.7%**

*Estimated

**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 is 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, 2006.

Table 2
R&D as a Percentage of Sales, PhRMA Member Companies: 1970–2005

Year	Domestic R&D as a % of Domestic Sales	Total R&D as a % of Total Sales
*2005	19.2%	15.8%
2004	18.4	15.3
2003	18.3	15.7
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

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 3
Domestic R&D and R&D Abroad,* PhRMA Member Companies: 2004

(dollar figures in millions)

	2004
R&D Expenditures for Human-Use Pharmaceuticals	
Domestic	$29,273.6
Share	79.1%
Abroad*	$ 7,356.9
Share	19.9%
Total Human-Use R&D	**$36,630.5**
Share	99.0%
R&D Expenditures for Veterinary-Use Pharmaceuticals	
Domestic	$ 281.9
Share	0.8%
Abroad*	$ 105.7
Share	0.3%
Total Vet-Use R&D	**$ 387.6**
Share	1.0%
TOTAL R&D	**$37,018.1**
	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 is 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, 2006.

Table 4
R&D By Function, PhRMA Member Companies: 2004

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	$9,585.7	25.9%
Phase I	2,473.3	6.7
Phase II	3,770.4	10.2
Phase III	9,682.1	26.2
Approval	3,415.3	9.2
Phase IV	4,902.9	13.2
Uncategorized	3,188.4	8.6
TOTAL R&D	**$37,018.1**	**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, 2006.

Table 5
R&D By Geographic Area,* PhRMA Member Companies: 2004

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 24.1	0.1%
Americas		
United States	$29,555.5	79.8%
Canada	380.5	1.0
Latin America (South and Central America, Mexico and all Caribbean nations)	122.0	0.3%
Asia-Pacific		
Asia-Pacific (except Japan)	$ 94.1	0.3%
India and Pakistan	7.9	0.0
Japan	945.4	2.6
Australia		
Australia and New Zealand	$ 96.9	0.3%
Europe		
France	$ 410.2	1.1%
Germany	524.2	1.4
Italy	213.1	0.6
Spain	175.6	0.5
United Kingdom	1,947.3	5.3
Other Western Europe nations	2,251.5	6.1
Central and Eastern European nations (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia and Malta)	109.1	0.3
Other Eastern European nations (including Russia and the Newly Independent States)	35.5	0.1
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey and Qatar)	$ 35.2	0.1%
Uncategorized	$ 90.0	0.2%
TOTAL R&D	**$37,018.1**	**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 is 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, 2006.

Table 6
Domestic Sales and Sales Abroad,** PhRMA Member Companies: 1970–2005

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad**	Annual Percentage Change	Total Sales	Annual Percentage Change
*2005	$164,152.4	2.1%	$85,879.6	5.5%	$250,032.0	3.3%
2004	160,751.0	8.6	81,364.0	14.9	242,115.0	10.6
2003	148,038.6	6.4	70,782.2	31.8	218,820.8	13.5
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	5.9	4,633.3	19.1	11,769.0	13.6
1974	6,740.4	18.5	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		**10.9%**		**11.1%**		**10.8%**

*Estimated

**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.

***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, 2006.

Table 7
Sales By Geographic Area,* PhRMA Member Companies: 2004

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 944.5	0.4%
Americas		
United States	$160,751.0	66.4%
Canada	5,594.5	2.3
Latin America (South and Central America, Mexico and all Caribbean nations)	5,514.6	2.3
Asia-Pacific		
Asia-Pacific (except Japan)	$ 3,871.1	1.6%
India and Pakistan	623.0	0.3
Japan	8,885.2	3.7
Australia		
Australia and New Zealand	$ 2,939.9	1.2%
Europe		
France	$ 8,790.3	3.6%
Germany	5,969.8	2.5
Italy	6,383.3	2.6
Spain	4,712.1	1.9
United Kingdom	5,367.3	2.2
Other Western European nations	10,421.2	4.3
Central and Eastern European nations (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia and Malta)	2,272.3	0.9
Other Eastern European nations (including Russia and the Newly Independent States)	516.1	0.2
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey and Qatar)	$ 2,105.0	0.9%
Uncategorized	$ 6,453.8	2.7%
TOTAL SALES	**$242,115.0**	**100.0%**

*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.

Note: Total values may be affected by rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 8
Domestic Sales and Sales Abroad* By End Use and Customer, PhRMA Member Companies: 2004

(dollar figures in millions)

	Human Use	Vet Use	Total
To Private Sector	$ 135,687.4	$ 1,080.9	$ 136,768.3
To Public Sector	21,878.3	873.6	22,751.9
Uncategorized	1,230.8	–	1,230.8
Total Domestic Sales	**$ 158,796.5**	**$ 1,954.5**	**$ 160,751.0**
Exports	$ 301.2	$ 46.7	$ 347.9
Foreign Sales	78,237.9	2,205.2	80,443.1
Uncategorized	573.0	–	573.0
Total Sales Abroad*	**$ 79,112.1**	**$ 2,251.9**	**$ 81,364.0**
Total Sales	**$ 237,908.6**	**$ 4,206.4**	**$ 242,115.0**

*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.

Note: Total values may be affected by rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 9
Domestic R&D Scientific, Professional and Technical Personnel By Function, PhRMA Member Companies: 2004

Function	Personnel	Share
Prehuman/Preclinical	28,838	35.3%
Phase I	5,981	7.3
Phase II	7,955	9.7
Phase III	15,839	19.4
Approval	5,116	6.3
Phase IV	11,681	14.3
Uncategorized	1,770	2.2
Total R&D Staff	**77,180**	**94.5**
Supported R&D Nonstaff	4,516	5.5
TOTAL R&D PERSONNEL	**81,696**	**100.0%**

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Key Facts

Research and Development

Developing a drug requires time and money. It takes an average of 10–15 years to develop a new medicine.[1] And, the costs continue to rise.

R&D Spending

Investment in R&D has increased dramatically in the past 25 years.

R&D Spending — 1980-2005

Year	PhRMA Members (in billions)	Total Industry (in billions)
2005	$39.4 (est.)	$51.3 (est.)[2]
2004	$37.0	$47.6[3]
2000	$26.0	not available
1990	$8.4	not available
1980	$2.0	not available

Total National Institutes of Health budget

Part of this budget is allotted for developing drugs.

- 2005 = $28.6 billion[4]
- 2004 = $28 billion[5]

Percentage of sales that went to R&D in 2005

- **19.2 percent** (est.) — Domestic R&D as a percent of domestic sales
- **15.8 percent** (est.) — Total R&D as a percent of total sales

Development Costs

As regulatory requirements become more stringent and the amount of information needed grows, the cost to develop a drug continues to go up.

Average Cost to Develop One Drug

Year	Cost (in millions)
2000	$800[6]
1987	$318
1975	$138

Drug Approvals

- The FDA approved **28** new drugs in 2005.[7, 8]
- Only **3 of 10** marketed drugs ever produce revenues that match or exceed R&D costs.[9]
- In the past decade (1995-2005), **over 160** orphan drugs have been approved.[10]
- The average *effective* patent life for pharmaceuticals is **11.5 years.**[11]

Value of Medicines

- New medicines generated **40 percent** of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000.[12]
- For every dollar spent on newer medicines in place of older medicines, total health care spending is reduced by **$6.17.**[13] In addition, every additional dollar spent on health care in the United States over the past 20 years has produced health gains worth **$2.40 to $3.00.**[14]

Prescription Medicine Sales

- A total of **3.6 billion** prescriptions were filled in the United States between October 2004 and September 2005.[15]
- In July 2005, the ratio of generic/brand share of market by volume (weighted average) was **54/46**. In 2006, it is estimated to be **58/42.**[16]

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[2] Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2006 (includes PhRMA research associates and nonmembers).

[3] *Ibid.*

[4] U.S. Department of Health and Human Services, National Institutes of Health, *Summary of the FY 2007 President's Budget* (Bethesda, MD: NIH, 6 February 2006), http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf (16 February 2006).

[5] U.S. Department of Health and Human Services, National Institutes of Health, *Summary of the FY 2006 President's Budget* (Bethesda, MD: NIH, 7 February 2005), http://www.nih.gov/news/budget/FY2006presbudget.pdf (2 February 2006).

[6] J. A. DiMasi, R. W. Hansen and H. G. Grabowski, *op. cit.*

[7] "New Molecular Entities Approved in 1005," *The Pink Sheet* 68, no. 2 (9 January 2006) 29-30.

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