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# Key Facts

## Research and Development

- Time to develop a drug = 10-15 years<sup>1</sup>

## Development Costs

- Cost to develop a drug
  - 2006 = \$1,318 million<sup>2</sup>
  - 2001 = \$802 million<sup>3</sup>
  - 1987 = \$318 million<sup>3</sup>
  - 1975 = \$138 million<sup>3</sup>
- Cost to develop a biologic
  - 2006 = \$1.2 billion<sup>4</sup>

## R&D Spending

Year	PhRMA members <sup>6</sup>	Total industry
2007	\$44.5 billion (est.)	\$58.8 billion (est.) <sup>7</sup>
2006	\$43.4 billion	\$56.1 billion <sup>8</sup>
2005	\$39.9 billion	\$51.8 billion <sup>9</sup>
2004	\$37.0 billion	\$47.6 billion <sup>10</sup>
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 2007

Domestic R&D as a percentage of domestic sales = 18.7%<sup>5</sup>

Total R&D as a percentage of total sales = 16.4%<sup>5</sup>

## Total National Institutes of Health Funding<sup>11</sup>

(Part of this budget is allotted for developing drugs.)

- 2008 = \$28.9 billion
- 2007 = \$28.6 billion
- 2006 = \$28.5 billion

## Approvals

- Drugs approved in 2007 = 23<sup>12</sup>
- Only 2 of 10 marketed drugs ever produce revenues that match or exceed R&D costs.<sup>13</sup>
- In the 25 years since the *Orphan Drug Act* was established, more than 300 orphan drugs have been approved.<sup>14</sup>
- Average effective patent life for major pharmaceuticals in 2005 = 11 years<sup>15</sup>

## Medicines in Development<sup>16</sup>

2008 = 2,700 compounds

2003 = 2,000 compounds

## Value of Medicines

- One study found that the return on investment (ROI) for a 20% increase in adherence was substantial for disease-related costs: for every \$1 spent on ...
  - ▲ diabetes medicines → \$7.10 savings
  - ▲ cholesterol medicines → \$5.10 savings
  - ▲ blood pressure drugs → \$4 savings<sup>17</sup>
- 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.<sup>18</sup>

## Sales

- Generic share of market<sup>19</sup>
  - 2000 = 51%
  - 2007 = 67%

## Endnotes

See inside back cover.

# 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 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.

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Table 1  
Domestic R&D and R&D Abroad,\*\* PhRMA Member Companies: 1970–2007

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad**	Annual Percentage Change	Total R&D	Annual Percentage Change
2007*	\$35,394.4	2.7%	\$9,136.0	1.8%	\$44,530.4	2.5%
2006	34,467.8	11.3	8,971.3	0.9	43,439.1	9.0
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		12.2%		16.0%		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.

\*\*\*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, 2008.

Table 2  
R&D as a Percentage of Sales,  
PhRMA Member Companies: 1970-2007

Year	Domestic R&D as a Percentage of Domestic Sales	Total R&D as a Percentage of Total Sales
2007*	18.7%	16.4%
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, 2008.

Table 3  
Domestic R&D and R&D Abroad,\* PhRMA Member Companies: 2006

(Dollar figures in millions)

	2006
<b>R&amp;D Expenditures for Human-use Pharmaceuticals</b>	
Domestic	\$34,111.4
Share	78.5%
Abroad*	\$ 8,831.4
Share	20.3%
Total Human-use R&D	\$42,942.8
Share	98.9%
<b>R&amp;D Expenditures for Veterinary-use Pharmaceuticals</b>	
Domestic	\$ 356.4
Share	0.8%
Abroad*	\$ 139.9
Share	0.3%
Total Vet-use R&D	\$ 496.3
Share	1.1%
<b>TOTAL R&amp;D</b>	<b>\$43,439.1</b>
	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, 2008.

Table 4  
Domestic R&D By Type of Project,  
PhRMA Member Companies: 2006

(dollar figures in millions)

Type	Dollars	Share
Licensed-in	\$ 5,892.9	17.1%
Self-originated	24,224.1	70.3
Uncategorized	4,350.9	12.6
<b>TOTAL R&amp;D</b>	<b>\$34,467.8</b>	<b>100.0%</b>

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, 2008.

Table 5  
R&D By Function, PhRMA Member Companies: 2006

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	\$11,816.1	27.2%
Phase I	2,902.7	6.7
Phase II	5,687.4	13.1
Phase III	12,187.3	28.1
Approval	2,649.3	6.1
Phase IV	5,584.6	12.9
Uncategorized	2,611.6	6.0
<b>TOTAL R&amp;D</b>	<b>\$43,439.1</b>	<b>100.0%</b>

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, 2008.

Table 6  
R&D By Geographic Area,\* PhRMA Member Companies: 2006

(Dollar figures in millions)

Geographic Area*	Dollars	Share
<b>Africa</b>		
Africa	\$ 25.0	0.1%
<b>Americas</b>		
United States	\$34,467.8	79.3%
Canada	528.5	1.2
Mexico	32.2	0.1
Brazil	25.6	0.1
Other Latin America (Other South American, Central American, and all Caribbean nations)	85.7	0.2%
<b>Asia-Pacific</b>		
Japan	\$ 826.2	1.9%
China	32.1	0.1
India	8.7	0.0
Other Asia-Pacific	172.2	0.4
<b>Australia</b>		
Australia and New Zealand	\$ 135.2	0.3%
<b>Europe</b>		
France	\$ 424.9	1.0%
Germany	574.2	1.3
Italy	245.9	0.6
Spain	190.8	0.4
United Kingdom	2,280.4	5.2
Other Western European	2,990.0	6.9
Central and Eastern Europe (Cyprus, the Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta)	132.2	0.3
Other Eastern European (including Russia and the Newly Independent States)	125.1	0.3
<b>Middle East</b>		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey, and Qatar)	\$ 38.9	0.1%
Uncategorized	\$ 97.4	0.2%
<b>TOTAL R&amp;D</b>	<b>\$43,439.1</b>	<b>100.0%</b>

\*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, 2008.

Table 7  
 Biologics and Biotechnology R&D,  
 PhRMA Member Companies: 2006

(dollar figures in millions)

Type	Dollars	Share
Biotechnology-Derived Therapeutic Proteins	\$ 8,894.4	20.5%
Vaccines	1,121.4	2.6
Cell or Gene Therapy	64.2	0.1
All other Biologics	577.3	1.3
Total Biologics/Biotechnology R&D	10,657.3	24.5
Non-Biologics/Biotechnology R&D	30,553.4	70.3
Uncategorized R&D	2,228.3	5.1
TOTAL R&D	\$43,439.1	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, 2008.

Table 8  
Domestic Sales and Sales Abroad,\* PhRMA Member Companies: 1970–2007

(Dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad*	Annual Percentage Change	Total Sales	Annual Percentage Change
**2007	\$189,604.6	6.7%	\$81,910.8	6.6%	\$271,515.4	6.6%
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	5.9	4,633.3	19.1	11,769.0	13.6
1974	6,740.4	18.5	3,891.0	23.4	10,631.4	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		10.7%		10.3%		10.5%

\*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, 2008.

Table 9  
Sales By Geographic Area,\* PhRMA Member Companies: 2006

(Dollar figures in millions)

Geographic Area*	Dollars	Share
<b>Africa</b>		
Africa	\$ 1,081.8	0.4%
<b>Americas</b>		
United States	\$ 177,736.3	69.8%
Canada	6,239.2	2.5
Mexico	2,567.3	1.0
Brazil	1,836.2	0.7
Other Latin America (Other South American, Central American, and all Caribbean nations)	3,081.2	1.2%
<b>Asia-Pacific</b>		
Japan	\$ 8,508.8	3.3%
China	1,039.6	0.4
India	459.9	0.2
Other Asia-Pacific	3,627.7	1.4
<b>Australia</b>		
Australia and New Zealand	\$ 2,735.2	1.1%
<b>Europe</b>		
France	\$ 7,901.3	3.1%
Germany	5,672.0	2.2
Italy	5,721.7	2.2
Spain	4,762.5	1.9
United Kingdom	4,865.6	1.9
Other Western European	9,549.3	3.8
Central and Eastern Europe (Cyprus, the Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta)	3,253.3	1.3
Other Eastern European (including Russia and the Newly Independent States)	867.6	0.3
<b>Middle East</b>		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey, and Qatar)	\$ 2,158.5	0.8%
Uncategorized	\$ 941.4	0.4%
<b>TOTAL R&amp;D</b>	<b>\$ 254,606.4</b>	<b>100.0%</b>

\*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: 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, 2008.

Table 10  
Domestic R&D Scientific, Professional, and Technical  
Personnel By Function, PhRMA Member Companies: 2006

Function	Personnel	Share
Prehum an/Preclinical	27,913	35.0%
Phase I	4,242	5.3
Phase II	8,119	10.2
Phase III	16,921	21.2
Approval	3,625	4.5
Phase IV	8,633	10.8
Uncategorized	2,452	3.1
Total R&D Staff	71,905	90.0
Supported R&D Non-staff	7,951	10.0
<b>TOTAL R&amp;D PERSONNEL</b>	<b>79,856</b>	<b>100.0%</b>

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2008.

## Endnotes *(continued from inside front cover)*

<sup>1</sup>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; and 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.

<sup>2</sup>J. A. DiMasi and H.G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics* 28 (2007): 469–479.

<sup>3</sup>J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, *op. cit.*

<sup>4</sup>Tufts Center for the Study of Drug Development, "Average Cost to Develop a New Biotechnology Product Is \$1.2 Billion, According to the Tufts Center for the Study of Drug Development," 9 November 2006, <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69> (accessed 9 January 2007).

<sup>5</sup>Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1980–2007).

<sup>6</sup>*Ibid.*

<sup>7</sup>Burrill & Company, analysis for PhRMA, 2008. Includes PhRMA research associates and nonmembers.

<sup>8</sup>Burrill & Company, analysis for PhRMA, 2007. Includes PhRMA research associates and nonmembers.

<sup>9</sup>Burrill & Company, analysis for PhRMA, 2006. Includes PhRMA research associates and nonmembers.

<sup>10</sup>Burrill & Company, analysis for PhRMA, 2005. Includes PhRMA research associates and nonmembers.

<sup>11</sup>U.S. Department of Health and Human Services, *FY 2008 Budget in Brief* (Washington, DC: FDA, 4 October 2007) <http://www.hhs.gov/budget/08budget/2008BudgetInBrief.pdf> (accessed 5 March 2008.)

<sup>12</sup>B. Silverman, "FDA First-Cycle Approval Rate is Silver Lining in Cloud of Low NME Count," *The Pink Sheet* 70, no. 2 (14 January 2008) and B. Silverman, "Year in Review: New Biologics Total Seven in 2007, But Only Four Will See Market," *The Pink Sheet* 70, no. 3 (21 January 2008).

<sup>13</sup>J. Vernon, J. Golec, and J. DiMasi, "Drug Development Costs when Financial Risk is Measured Using the Fama-French Three Factor Model," Unpublished Working Paper, January 2008.

<sup>14</sup>U.S. Food and Drug Administration, *List of Orphan Designations and Approvals*, <http://www.fda.gov/orphan/designat/list.htm>.

<sup>15</sup>H. Grabowski and M. Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* 28 (2007) 491–502. Note: This figure includes drugs with sales over \$100 million.

<sup>16</sup>Adis R&D Insight Database, 27 February 2008, and Adis R&D Insight Database customized run, December 2005.

<sup>17</sup>M. C. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care* 43 (2005): 6, 521–530.

<sup>18</sup>MEDTAP International, *The Value of Investment in Health Care: Better Care, Better Lives—Executive Summary*, (Bethesda, MD: MEDTAP, 2003), [http://www.medtap.com/Products/HP\\_DiseaseBrochure.pdf](http://www.medtap.com/Products/HP_DiseaseBrochure.pdf) (accessed 25 February 2005).

<sup>19</sup>PhRMA Analysis of National Prescription Audit™ data from IMS Health, data through 3rd quarter of 2007.