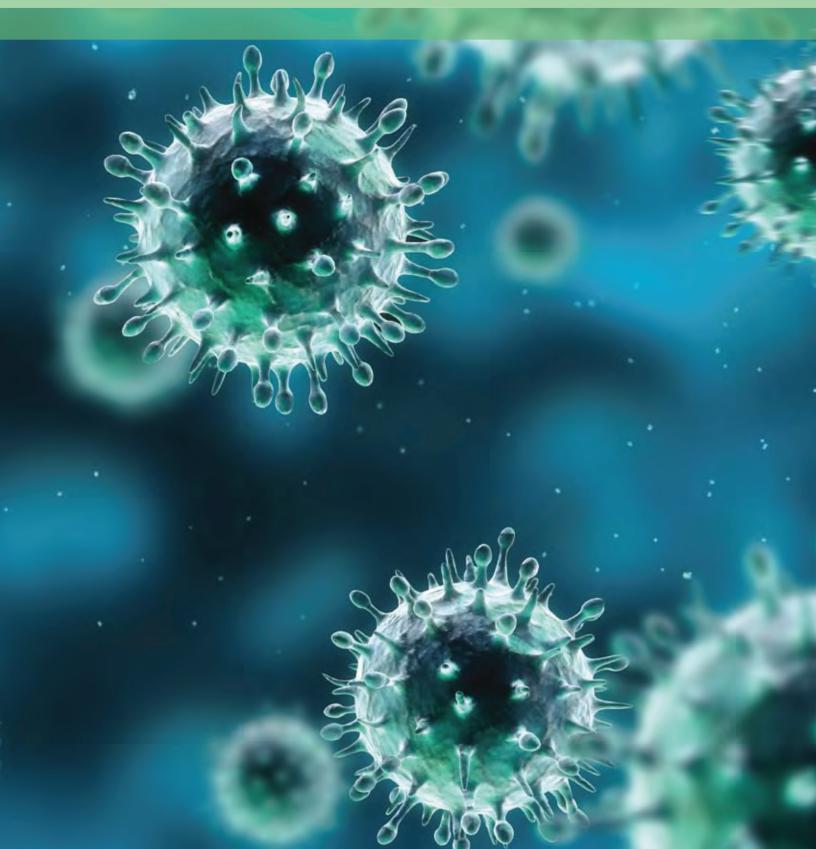
# 2011 profile

P/RMA

PHARMACEUTICAL INDUSTRY







#### Research and Development (R&D)

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

#### **Development Costs**

Cost to develop a drug

 $2005 = $1.3 \text{ billion}^2$ 

2001 = \$802 million<sup>3</sup>

1987 = \$318 million<sup>3</sup>

1975 = \$138 million<sup>3</sup>

Cost to develop a biologic
 2005 = \$1.2 billion<sup>4</sup>

#### **R&D Spending**

Year	PhRMA members <sup>5</sup>	Total industry <sup>6</sup>
2010	\$49.4 billion (est.)	\$67.4 billion (est.)
2009	\$46.4 billion	\$65.9 billion
2008	\$47.4 billion	\$63.7 billion
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 2010<sup>7</sup>

Domestic R&D as a percentage of domestic sales = 20.5%

Total R&D

as a percentage of total sales = 17.0%

### Economic Impact of the Biopharmaceutical Sector<sup>8</sup>

Direct jobs = 655,025 in 2008 (most recent data)

Total jobs (including indirect and induced jobs)

= 3.1 million in 2008 (most recent data)

#### **Approvals**

- Drugs and biologics approved in 2000–2010 = 333<sup>9</sup>
- In the 28 years since the Orphan Drug Act was established, more than 360 orphan drugs have been approved.<sup>10</sup>
- Only 2 of 10 marketed drugs return revenues that match or exceed R&D costs.<sup>11</sup>

#### **Medicines in Development**

 $2010 = 3,050 \text{ compounds}^{12}$ 

 $2001 = 2,040 \text{ compounds}^{13}$ 

#### **Value of Medicines**

- Cancer: Since 1980, life expectancy for cancer patients has increased about 3 years, and 83% of those gains are attributable to new treatments, including medicines.<sup>14</sup> Another study found that medicines specifically account for 50% to 60% of increases in survival rates since 1975.<sup>15</sup>
- Cardiovascular Disease: According to a 2010 statistics update by the American Heart Association (AHA), death rates for cardiovascular disease fell a dramatic 28% between 1997 and 2007.<sup>16</sup>
- HIV/AIDS: Since the approval of the antiretroviral treatments in 1995, the U.S. AIDS death rate has dropped by more than 75%.<sup>17</sup>

#### **Sales**

Generic share of market<sup>18</sup>
 2000 = 49%
 2010 = 78%

See inside back cover for endnotes.



# **List of Tables**

# **Detailed results from the PhRMA Annual Member Survey**

R&D, PhRM	A Member	Companies
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#### TABLE 1: Domestic R&D and R&D Abroad,\* PhRMA Member Companies: 1975–2010

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad*	Annual Percentage Change	Total R&D	Annual Percentage Change
2010**	\$37,371.0	5.7%	\$12,047.4	8.7%	\$49,418.4	6.4%
2009	35,356.0	-0.6	11,085.6	-6.1	46,441.6	-2.0
2008	35,571.1	-2.8	11,812.0	4.6	47,383.1	-1.1
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	29,772.7	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
Average		11.4%		12.9%		11.7%

<sup>\*</sup>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.

<sup>\*\*</sup>Estimated.

 $<sup>\</sup>ensuremath{^{***}\text{R\&D}}$  Abroad affected by merger and acquisition activity.

#### TABLE 2: R&D as a Percentage of Sales, PhRMA Member Companies: 1975–2010

Year	Domestic R&D as a Percentage of Domestic Sales	Total R&D as a Percentage of Total Sales
2010*	20.5%	17.0%
2009	19.5	16.8
2008	19.4	16.6
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

<sup>\*</sup>Estimated.

<sup>\*\*</sup>Revised in 2007 to reflect updated data.



#### TABLE 3: Domestic R&D and R&D Abroad,\* PhRMA Member Companies: 2009

#### (dollar figures in millions)

R&D Expenditures for Human-use Pharmaceuticals	Dollars	Share
Domestic	\$34,986.7	75.3%
Abroad*	\$10,751.5	23.2%
Total Human-use R&D	\$45,738.2	98.5%
R&D Expenditures for Veterinary-use Pharmaceuticals		
Domestic	\$369.3	0.8%
Abroad*	\$334.1	0.7%
Total Vet-use R&D	\$703.4	1.5%
TOTAL R&D	\$46,441.6	100.0%

<sup>\*</sup>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.

 $\label{thm:local_problem} \textbf{Note: All figures include company-financed R\&D only. Total values may be affected by rounding.}$ 

#### TABLE 4: Domestic R&D by Source, PhRMA Member Companies: 2009

#### (dollar figures in millions)

Source	Dollars	Share
Licensed-in	\$6,339.0	17.9%
Self-originated	29,017.0	82.1
TOTAL R&D	\$35,356.0	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 Member Survey*, 2011.

#### TABLE 5: R&D by Function, PhRMA Member Companies: 2009

#### (dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	\$11,717.4	25.2%
Phase 1	3,752.9	8.1
Phase 2	7,123.7	15.3
Phase 3	16,300.1	35.1
Approval	2,046.9	4.4
Phase 4	5,302.7	11.4
Uncategorized	197.8	0.4
TOTAL R&D	\$46,441.6	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 Member Survey*, 2011.



#### TABLE 6: R&D by Geographic Area,\* PhRMA Member Companies: 2009

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Egypt	\$1.8	0.0%
South Africa	16.7	0.0
Other Africa	24.6	0.1
Americas		
United States	\$35,356.0	76.1%
Canada	444.4	1.0
Mexico	70.9	0.2
Brazil	100.9	0.2
Argentina	24.4	0.1
Venezuela	5.0	0.0
Columbia	16.5	0.0
Chile	4.3	0.0
Peru	14.8	0.0
Other Latin America	178.3	0.4
Asia-Pacific		
Japan	\$676.2	1.5%
China	124.4	0.3
India	125.1	0.3
Taiwan	18.0	0.0
South Korea	32.4	0.1
Other Asia-Pacific	345.1	0.7
Australia		
Australia and New Zealand	\$181.7	0.4%
Europe		
France	\$365.1	0.8%
Germany	583.2	1.3
Italy	210.5	0.5
Spain	223.6	0.5
United Kingdom	1,937.4	4.2
Other Western European	4,315.6	9.3
Czech Republic	97.9	0.2
Hungary	40.3	0.1
Poland	212.4	0.5
Turkey	28.7	0.1
Russia	159.6	0.3
Central and Eastern Europe (Cyprus, Estonia, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta, and other Eastern European countries and the Newly Independent States)	384.1	0.8
Middle East		
Saudi Arabia	\$2.7	0.0%
Middle East (Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, and Qatar)	118.0	0.3
Uncategorized	\$1.1	0.0%
TOTAL R&D	\$46,441.6	100.0%

<sup>\*</sup>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.

#### TABLE 7: Biologics and Biotechnology R&D, PhRMA Member Companies: 2009

(dollar figures in millions)

Туре	Dollars	Share
Biotechnology-derived Therapeutic Proteins	\$9,691.6	20.9%
Vaccines	1,161.7	2.5
Cell or Gene Therapy	250.6	0.5
All Other Biologics	1,001.8	2.2
Total Biologics/Biotechnology R&D	\$12,105.6	26.1%
Non-biologics/Biotechnology R&D	\$34,336.0	73.9%
TOTAL R&D	\$46,441.6	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 Member Survey*, 2011.



#### TABLE 8: Domestic Sales and Sales Abroad,\* PhRMA Member Companies: 1975–2010

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad*	Annual Percentage Change	Total Sales	Annual Percentage Change
2010**	\$182,610.5	0.8%	\$108,815.2	14.3%	\$291,425.8	5.5%
2009	181,116.8	-1.1	95,162.5	-7.5	276,279.3	-3.4
2008	183,167.2	-1.1	102,842.4	16.6	286,009.6	4.6
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
Average		9.8%		9.6%		9.6%

<sup>\*</sup>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.

Note: Total values may be affected by rounding.

<sup>\*\*\*</sup>Revised in 2007 to reflect updated data.

<sup>\*\*\*\*</sup>Sales abroad affected by merger and acquisition activity.

#### TABLE 9: Sales by Geographic Area,\* PhRMA Member Companies: 2009

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Egypt	\$314.4	0.1%
South Africa	555.6	0.2
Other Africa	671.8	0.2
Americas		
United States	\$181,116.8	65.6%
Canada	6,466.5	2.3
Mexico	2,261.8	0.8
Brazil	2,988.9	1.1
Argentina	486.2	0.2
Venezuela	1,493.9	0.5
Columbia	545.3	0.2
Chile	219.2	0.1
Peru	151.1	0.1
Other Latin America	1,470.9	0.5
Asia-Pacific		
Japan	\$11,609.6	4.2%
China	2,722.1	1.0
India	638.4	0.2
Taiwan	653.7	0.2
South Korea	1,091.8	0.4
Other Asia-Pacific	2,139.6	0.8
Australia		
Australia and New Zealand	\$3,107.5	1.1%
Europe		
France	\$9,229.9	3.3%
Germany	7,410.0	2.7
Italy	6,352.4	2.3
Spain	6,243.9	2.3
United Kingdom	4,938.1	1.8
Other Western European	10,326.0	3.7
Czech Republic	646.9	0.2
Hungary	454.6	0.2
Poland	817.5	0.3
Turkey	1,412.2	0.5
Russia	1,106.5	0.4
Central and Eastern Europe (Cyprus, Estonia, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta, and other Eastern European countries and the Newly Independent States)	4,468.4	1.6
Middle East		
Saudi Arabia	\$439.3	0.2%
Middle East (Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, and Qatar)	1,728.4	0.6
Uncategorized		0.0%
TOTAL SALES	\$276,279.3	100.0%

<sup>\*</sup>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

Note: Total values may be affected by rounding.



# TABLE 10: Domestic R&D Scientific, Professional and Technical Personnel by Function, PhRMA Member Companies: 2009

Function	Personnel	Share
Prehuman/Preclinical	22,725	28.8%
Phase 1	5,748	7.3
Phase 2	10,010	12.7
Phase 3	17,622	22.3
Approval	4,179	5.3
Phase 4	8,843	11.2
Uncategorized	580	0.7
Total R&D Staff	69,707	88.3
Supported R&D Non-staff	9,243	11.7
TOTAL R&D PERSONNEL	78,950	100.0%

# endnotes

#### (continued from inside front cover)

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- <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> J. A. DiMasi and H. G. Grabowski, op. cit.
- <sup>5</sup> Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1981–2011).
- <sup>6</sup> Burrill & Co., analysis for PhRMA, 2005–2011 (includes PhRMA research associates and nonmembers); Pharmaceutical Research and Manufacturers of America, *op. cit*.
- <sup>7</sup> Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2011).
- <sup>8</sup> Archstone Consulting and R. L. Burns, The Biopharmaceutical Sector's Impact on the Economy of the United States (Fact Sheet) (Washington, DC: Archstone Consulting, LLC, 2010). Types of direct biopharmaceutical jobs in 2008 are from the U.S. Bureau of Labor Statistics, 2008 Occupational Employment Statistics (NAICS codes 3254 and 54171).
- <sup>9</sup> Pharmaceutical Research and Manufacturers of America, "New Drugs Approved" reports, (PhRMA, DC: 2001–2010); B. Silverman, "Few, But Fast and on Time: 2010 Saw Low NME Count, But Almost All Were First-Cycle Approvals and FDA Met Most User Fees," *Pink Sheet*, 73 (24 January 2011): No. 4.
- <sup>10</sup> Food and Drug Administration, Orphan Drug Designations and Approvals Database, www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm (accessed 16 February 2011).
- <sup>11</sup> J. A. Vernon, J. H. Golec, and J. A. DiMasi, "Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model," *Health Economics Letters* (2009).
- <sup>12</sup> Adis R&D Insight Database, Wolters Kluwer Health (accessed 28 February 2011).
- <sup>13</sup> Adis R&D Insight Database, Wolters Kluwer Health, customized run, December 2007.
- <sup>14</sup> E. Sun, *et al.*, "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database," *Journal of Clinical Oncology* 26, suppl. 15 (2008): Abstract 6616.
- <sup>15</sup> F. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper 10328, February 2004.
- <sup>16</sup> V. L. Roger, et al., "Heart Disease and Stroke Statistics 2011 Update: A Report from the American Heart Association," *Circulation*, published online, 15 December 2010.
- <sup>17</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Health United States, 2009 with Special Feature on Medical Technology, Table 38 (Hyattsville, MD: 2010), www.cdc.gov/nchs/data/hus/hus09.pdf.
- $^{\rm 18}\,\text{IMS}$  National Prescription Audit, February 2011.