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## BACKGROUND ON BIOLOGICS

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- FDA has approved more than 250 biotech medicines; in 2005 alone, FDA approved 39 biologic products and indications.<sup>1</sup> These products are serving more than 800 million patients worldwide.<sup>2</sup>
- There are more than 418 biologic products currently in various stages of clinical trials and development targeting more than 100 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.<sup>3</sup>
- America's pharmaceutical biotechnology industry represents one of the most successful and fastest growing segments of U.S. healthcare. In 1992, annual revenues for this industry were approximately \$8 billion. By 2003, biologics had annual revenues of \$39 billion.<sup>4</sup>
- According to IMS Health, biologic drug product sales jumped 17.1 percent in 2005, generating sales of \$52.7 billion.<sup>5</sup>
- The huge growth in biologics, or specialty drugs, is expected to reach \$90 billion by 2009.<sup>6</sup>
- According to Medco Health Solutions, one of the largest pharmacy-benefits managers, spending on biotech and specialty medicines grew 16.9 percent in 2005, much faster than the 5.4% average for traditional prescription drugs.<sup>7</sup>
- According to the Centers for Medicare and Medicaid Services (CMS), the top 2 anemia drugs, both biologics, accounted for 17% of all Medicare Part B carrier drug spending in FY 2005, and two other biologics for rheumatoid arthritis and cancer accounted for an additional 13% of all carrier spending.<sup>8</sup>

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<sup>1</sup> Biotechnology Industry Organization, *Healthcare Overview* (online at [www.bio.org/healthcare](http://www.bio.org/healthcare)) (accessed Feb. 12, 2007).

<sup>2</sup> Biotechnology Industry Organization, *Milestones 2006* (online at [/www.bio.org/speeches/pubs/milestone06/health.asp](http://www.bio.org/speeches/pubs/milestone06/health.asp)) (accessed Feb. 12, 2007)

<sup>3</sup> Pharmaceutical Research and Manufacturers of America (PhRMA), *Biotechnology Medicines in Development, 2006 Report* (online at: [www.phrma.org/files/Biotech%202006.pdf](http://www.phrma.org/files/Biotech%202006.pdf)) (accessed Feb. 13, 2007).

<sup>4</sup> Biotechnology Industry Organization (online at [www.bio.org/speeches/pubs/er/statistics.asp](http://www.bio.org/speeches/pubs/er/statistics.asp)) (accessed Feb.13, 2007).

<sup>5</sup> IMS Health, *IMS Health Reports Global Pharmaceutical Market Grew 7 Percent in 2005, to \$602 Billion* (online at: [www.imshealth.com/ims/portal/front/articleC/0.2777,6599\\_3665\\_77491316.00.html](http://www.imshealth.com/ims/portal/front/articleC/0.2777,6599_3665_77491316.00.html)) (accessed Feb. 13, 2007).

<sup>6</sup> Testimony of Mark Merritt before the Senate Special Committee on Aging (July 20, 2006) (available online at [www.pcmamet.org/newsroom/July%202006/7-20-2002/PCMA%20Final%20Senate%20Aging%207%2020%2006.pdf](http://www.pcmamet.org/newsroom/July%202006/7-20-2002/PCMA%20Final%20Senate%20Aging%207%2020%2006.pdf)) (accessed Feb. 12, 2007).

<sup>7</sup> *Opening a Path for Biotech Generics*, Philadelphia Inquirer (Sept. 19, 2006) (available online at [www.philly.com/mld/philly/business/15551714.htm](http://www.philly.com/mld/philly/business/15551714.htm)) (accessed Feb. 13, 2007).

<sup>8</sup> Kuhn, Director CMM, Testimony before the House Subcommittee on Health of the Committee on Ways and Means (July 13, 2006). (available at: <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5108>) (accessed on Feb. 13, 2007).

- The five largest Medicare Part B drug expenditures are all for biotech medicines regulated as biologics. (These expenditures are for drugs administered in doctor's offices in FY 2005, not for drugs administered in hospital clinics or outpatient centers):

<u>Drugs (indication)</u>	<u>FY '05 Medicare Spending</u>
▪ Epogen (anemia)	\$1,750,000,000
▪ Aranesp (anemia)	\$850,000,000
▪ Procrit (anemia)	\$776,000,000
▪ Remicade (rheumatoid arthritis, other inflammatory disorders)	\$541,000,000
▪ Neulasta (anemia)	\$524,000,000 <sup>9</sup>

- In FY 2005, the biggest drug expenditure for CMS was \$2 billion on Epogen, a biologic for anemia.<sup>10</sup> This is roughly the same amount as FDA's total proposed budget for FY 2008.<sup>11</sup>
- While many biopharmaceuticals are already off-patent, more than \$10 billion worth of biopharmaceutical drugs are expected to come off patent by 2010.<sup>12</sup>
- Last year alone the cost of biologics soared 17.5 percent compared with traditional drugs, which increased 10 percent.<sup>13</sup>
- Many of these drugs cost patients tens of thousands of dollars each year — and some well over \$100,000. Avastin, already a billion-dollar-a-year drug for Genentech, may become a crucial new treatment for breast and lung cancer.<sup>14</sup> Genentech plans to charge about \$100,000 a year for the product. Out of pocket co-payment costs could easily run \$10,000-20,000 a year.<sup>15</sup> Cerezyme, a drug used to treat a genetic condition, is priced at an average of \$200,000 annually per patient.<sup>16</sup>

<sup>9</sup> *Drugmakers' Battle for Medicare Market Share*, CQ Weekly (Oct. 2, 2006) (citing Centers for Medicare and Medicaid Services).

<sup>10</sup> Government Accountability Office, *Report to the Chairman, Committee on Ways and Means, House of Representatives: End-Stage Renal Disease Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility* (Nov. 2006) (online at: [www.gao.gov/new.items/d0777.pdf](http://www.gao.gov/new.items/d0777.pdf)) (accessed Feb. 13, 2007).

<sup>11</sup> Office of Management and Budget, *Budget of the U.S. Government*, (Feb. 2007) (online at: [www.whitehouse.gov/omb/budget/fy2008](http://www.whitehouse.gov/omb/budget/fy2008)).

<sup>12</sup> *Opening a Path for Biotech Generics*, Philadelphia Inquirer, (Sept. 19, 2006) (online at [www.philly.com/mld/philly/business/15551714.htm](http://www.philly.com/mld/philly/business/15551714.htm)).

<sup>13</sup> Testimony of Mark Merritt, *supra* note 6.

<sup>14</sup> *A Cancer Drug Shows Promise, at a Price That Many Can't Pay*, New York Times (Feb. 15, 2006) (online at: [www.nytimes.com/2006/02/15/business/15drug.html?ex=1297659600&en=bc6aaaf25acffa44&ei=5088](http://www.nytimes.com/2006/02/15/business/15drug.html?ex=1297659600&en=bc6aaaf25acffa44&ei=5088)) (accessed Feb. 13, 2007).

<sup>15</sup> *Uncertain Miracle: A Biotech Drug Extends a Life, But at What Price?* The Wall Street Journal (Nov. 16, 2005).

<sup>16</sup> *Health Premium Hikes Tied to Costly Specialty Drugs*. Insurance Journal (Dec. 6, 2006) (online at: [www.insurancejournal.com/news/east/2006/12/06/74723.htm](http://www.insurancejournal.com/news/east/2006/12/06/74723.htm)).

- The following costs are for the drug only (not including administration supplies or infusion costs) and were calculated by one of the biggest pharmacy benefits managers at the average wholesale price. Costs to individual patients may vary based on a person's weight, dosing regimen, and indication for which the drug was prescribed.

<u>Drug (indication)</u>	<u>Monthly cost</u>
▪ Avastin (colorectal cancer)	\$5,500
▪ Iressa (lung cancer)	\$2,000
▪ Tarceva (lung cancer)	\$2,500

<u>Drug (indication)</u>	<u>Annual cost</u>
▪ Enbrel (rheumatoid arthritis, other inflammatory disorders)	\$17,000-\$25,000
▪ Gleevec (leukemia)	\$28,500-\$58,000 <sup>17</sup>
▪ Remicade (rheumatoid arthritis, other inflammatory disorders)	\$12,000-\$20,000 <sup>18</sup>

## TRADITIONAL GENERIC DRUGS

- Since the 1984 passage the Drug Price Competition & Patent Term Restoration Act — commonly known as Hatch-Waxman — which established the generic drug approval system in the United States, American consumers have saved billions of dollars on prescription drugs as a result of generic competition. These drugs provide the same safety and efficacy as the brand product, but at a savings of as much as 80%.<sup>19</sup>
- According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.<sup>20</sup>
- In 2004, the average price of a generic prescription drug was \$28.71. The average price of a brand name prescription drug was \$95.54.<sup>21</sup>
- Generic traditional drugs represent 56% of the total prescriptions dispensed in the United States, but only 13% of all dollars spent on prescription drugs. In 2005, U.S. brand pharmaceutical sales for 2005 were \$229.5 billion, compared to \$22.3 billion in U.S. generic pharmaceutical sales.<sup>22</sup>

<sup>17</sup> *Opening a Path for Biotech Generics*, *supra* note 7.

<sup>18</sup> *Id*; *Clearing the Record*, Philadelphia Inquirer (Oct. 24, 2006) (correcting annual cost figure for Remicade) (available online at [www.philly.com/mld/inquirer/news/local/corrections/15832564.htm](http://www.philly.com/mld/inquirer/news/local/corrections/15832564.htm)).

<sup>19</sup> *Generic Drugmakers Await End of Patents: The Generic Drug Industry Will be Buoyed as 75 Brand-name Prescription Drugs Lose Their Patent Protections*, Knight-Ridder (May 2, 2006).

<sup>20</sup> Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998).

<sup>21</sup> Generic Pharmaceutical Association, *FAQs Generics: Lower Cost* (online at [www.gphaonline.org/AM/Template.cfm?Section=FAQs&Template=CM/HTMLDisplay.cfm&ContentID=2497](http://www.gphaonline.org/AM/Template.cfm?Section=FAQs&Template=CM/HTMLDisplay.cfm&ContentID=2497)) (accessed February 13, 2007).

<sup>22</sup> Generic Pharmaceutical Association, *Statistics: Our Industry* (available at [www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm](http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm)) (accessed February 13, 2007).