BACKGROUNDER ON BIOLOGICS

- FDA has approved more than 150 new biologics, serving more than 325 million patients.[1]

- There are more than 300 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.[2]

- America's pharmaceutical biotechnology industry represents one of the most successful and fastest growing segments of U.S. healthcare. Ten years ago, annual revenues for this industry were approximately $8 billion. Today, biologics have annual revenues that exceed $39 billion.[3]

- According to IMS Health, biologic drug product sales jumped 17.2% in 2005, to $32.8 billion.[4]

- The huge growth in biologics, or specialty drugs, is expected to reach $90 billion by 2009.[5]

- 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 percent average for traditional prescription drugs.[6]

- 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):

Drugs (indication)	FY '05 Medicare Spending
▪ Epogen (anemia)	$1,750,000,000
▪ Aranesp (anema)	$850,000,000
▪ Procrit (anemia)	$776,000,000
▪ Remicade (rheumatoid arthritis, other inflammatory disorders)	$541,000,000
▪ Neulasta (anemia)	$524,000,000[7]

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[1] Biotechnology Industry Organization, *Healthcare Overview* (online at http://www.bio.org/ healthcare) (accessed Sept. 28, 2006).

[2] *Id.*

[3] Biotechnology Industry Organization (online at http://www.bio.org/speeches/pubs/er/statistics.asp) (accessed Sept. 16, 2004).

[4] IMS Health, *IMS National Sales Perspective, February 2006* (available online at http://www.gphaonline.org/AM/ Template.cfm? Section=Media&TEMPLATE=/CM/ ContentDisplay.cfm&CONTENTID=2664) (accessed on Sept. 28, 2006).

[5] Testimony of Mark Merritt before the Senate Special Committee on Aging (July 20, 2006) (available online at http://aging.senate.gov/public/_files/hr161mm.pdf) (accessed on Sept. 28, 2006); Medco, *Drug Trend Report, 2005*.

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

[7] *Drugmakers' Battle for Medicare Market Share*, CQ Weekly, Oct. 2, 2006 (citing Centers for Medicare and Medicaid Services).

- 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.[8]

- CMS spends approximately $2 billion per year on Epogen, a biologic for anemia, its single biggest drug expense. This is roughly the same amount as FDA's total proposed budget for FY 2007.[9]

- While many biopharmaceuticals are already off-patent, more than $10 billion worth of biopharmaceutical drugs are expected to come off patent over the next five years.[10]

- The cost of biotechnology healthcare is growing faster than the economy.[11]

- Last year alone the cost of biologics soared 17.5 percent compared with traditional drugs which increased 10 percent.[12]

- 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.[13] 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. Cerezyme, a drug used to treat a genetic condition, is priced at an average of $170,000 per patient per year.[14]

- 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.

Drug (indication)	Monthly cost
Avastin (colorectal cancer)	$5,500
Iressa (lung cancer)	$2,000
Tarceva (lung cancer)	$2,500

Drug (indication)	Annual cost
Enbrel (rheumatoid arthritis, other inflammatory disorders)	$17,000-$25,000
Gleevec (leukemia)	$28,500-$58,000

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[8] Kuhn, Director CMM, Testimony before the House Subcomittee on Health of the Committee on Ways and Means, July 13, 2006.

[9] *Drugmakers' Battle for Medicare Market Share*, CQ Weekly, Oct. 2, 2006.

[10] *Opening a Path for Biotech Generics*, Philadelphia Inquirer, (Sept. 19, 2006) (available online at http://www.philly.com/mld/philly/business/15551714.htm); Wilkie, D, Can Biotech Be Generic? *The Scientist* (2004) **18**(24)**:**42.

[11] (http://www.upi.com/HealthBusiness/view.php?StoryID=20060925-113357-9165r)

[12] Testimony of Mark Merritt, *supra* note 5.

[13] *A Cancer Drug Shows Promise, at a Price That Many Can't Pay*, New York Times (Feb. 15, 2006).

[14] *Uncertain Miracle: A Biotech Drug Extends a Life, But at What Price?*, The Wall Street Journal (Nov. 16, 2005)

- Remicade (rheumatoid arthritis, other inflammatory disorders) $35,000-$66,000[15]

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%.[16]

- 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.[17]

- 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.[18]

- Generic traditional drugs represent 53% of the total prescriptions dispensed in the United States, but only 12% 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.[19]

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[15] *Opening a Path for Biotech Generics*, *supra* note 6.

[16] *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).

[17] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998).

[18] The National Association of Chain Drug Stores (Oct. 2005).

[19] GPHA website (online at http://www.gphaonline.org//AM/Template.cfm?Section=Home).