

## Biologics in Perspective: The Case for Generic Biologic Drugs

**Based on U.S. sales alone, many top selling biologic drugs have recouped their manufacturer's initial investment several times over in the past six years, often within a single year.**

Spending on biologic drugs is growing nearly twice as quickly as spending on traditionally-developed "small molecule" drugs.

Overall biologic drug sales reached \$75 billion in 2007<sup>1</sup>, and it is estimated that spending on biologics will continue to increase substantially through 2012.<sup>2</sup>

**One factor driving spending on biologics is the lack of a statutory pathway to approve generic, or bio-equivalent, biologic drugs.**

Conventional drug products fall under the purview of the Federal Food, Drug, and Cosmetic Act, which has a streamlined process to approve generic drug products. However, the majority of biologics fall under the Public Health Service Act, which does not have an equivalent pathway. Therefore, biologic drug patent holders currently do not face generic competition, even though more than half of the top 20 biologics have either gone off patent or will do so by 2012.<sup>3</sup> This leaves manufacturers free to continue charging prices that are considerably higher than the prices of most non-biologic drugs. For example, Avastin, a biologic drug that is used to treat patients with advanced colon, lung or breast cancer, can cost up to \$100,000 per year.<sup>4</sup>

**There is near-universal agreement that creating a pathway for generic biologic drugs would save billions of dollars.<sup>5</sup>**

The Medicare Payment Advisory Commission (MedPAC) has clearly stated that an abbreviated biologics approval process is urgently needed because the availability of follow-on biologics will lead to increased competition, and that will improve the accuracy of Medicare's payment method and the value of Medicare spending.<sup>6</sup>

**Some manufacturers say they must protect their patents because of the costs associated**

**with biologic drug development. However, based on U.S. sales alone, many top selling biologic drugs have recouped their manufacturer's initial investment several times over in the past six years; often within a single year (see Figure 1).**

Between the rapid rise in the number of biologic drugs<sup>7</sup> and regularly expanding indications for the products that are already on the market<sup>8</sup>, biologics are quickly becoming a common treatment option. Many of the new indications are for conditions that primarily affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis. However, given the substantial out-of-pocket costs that can be associated with using biologic drugs, many patients will face impeded access until generic biologic drugs become available.

<sup>1</sup> IMS Health, "IMS Health Reports Global Biotech Sales Grew 12.5 Percent in 2007, Exceeding \$75 Billion," June 17, 2008.

<sup>2</sup> Express Scripts, "2007 Drug Trend Report," April 2008.

<sup>3</sup> E. Ehrlich and E.L. Wright, Biogenerics: What They Are, Why They Are Important, and Their Economic Value to Taxpayers and Consumers, Policy Brief, Citizens Against Government Waste, May 2, 2007.

<sup>4</sup> G. Kolata and A. Pollack, "Costly Cancer Drug Offers Hope, but Also a Dilemma," New York Times, July 6, 2008.

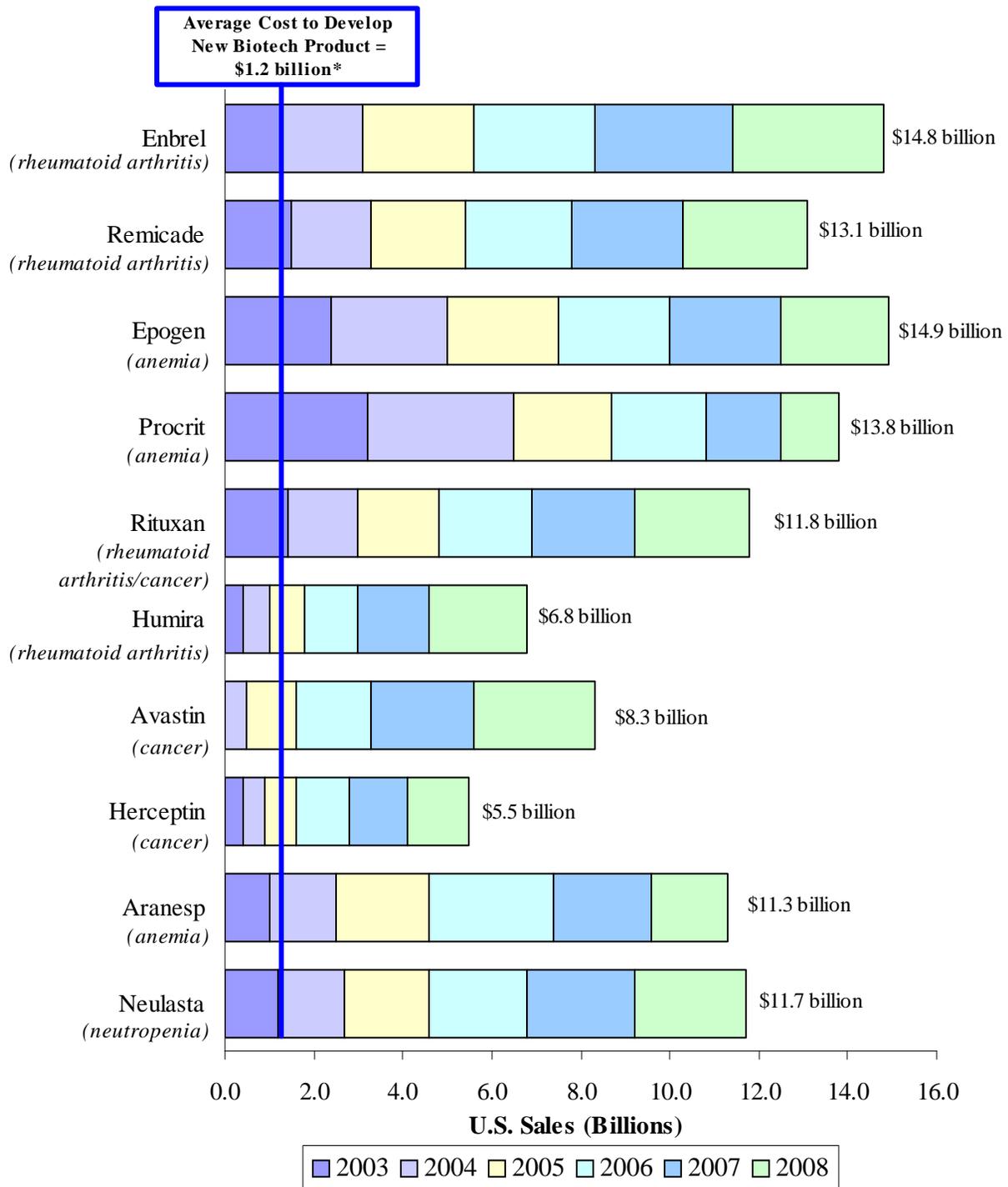
<sup>5</sup> S. Miller and J. Houts, "Potential Savings of Biogenerics in the United States," Express Scripts, February 2007; A. Ahlstrom et al., "Modeling Federal Cost Savings from Follow-on Biologics," Avalere Health, April 2007; Engel & Novitt, LLP, "Potential Savings That Might Be Realized by the Medicare Program From Enactment of Legislation Such As The Access To Life-Saving Medicine Act (H.R. 6257/S. 4016) That Establishes A New cBLA Pathway For Follow-On Biologics," PCMA, January 2, 2007.

<sup>6</sup> MedPAC, "Report to the Congress, Medicare Payment Policy (Outpatient Dialysis Services)," March 2008.

<sup>7</sup> There are now more than 250 FDA-approved biologic medicines and more than 300 in development. J. Greenwood, "The Biotechnology Industry Organization," Chain Drug Review, January 5, 2009.

<sup>8</sup> For example, Avastin, which was approved in 2004, has 23 potential additional indications under development. M. Said, C-A. Brouwers, and P. Tollman, "Continued Development of Approved Biological Drugs," The Boston Consulting Group, White Paper, December 2007.

**Figure 1: Annual and Total U.S. Sales for Top Selling<sup>1</sup> Biologic Drugs, 2003-2008**



\* Tufts Center for the Study of Drug Development, Press Release, "The cost to develop new biotech products is estimated to average \$1.2 billion," November 9, 2006.

Note: Numbers reflect annual sales in the United States; total (global) annual sales are considerably higher.

Source: AARP Public Policy Institute analysis of manufacturer financial reports and Drugs.com, "Top 200 Drugs for 2003 by U.S. Sales" and "Top 200 Drugs for 2004 by U.S. Sales." Available on the Web at: <http://www.drugs.com/>.

<sup>1</sup> Based on La Merie, "Top 20 Biologics 2008 (global sales)," March 2009.