

## **Congress debates pathway for biologic drugs**

Specialty medications represent the fastest growing part of drug spend today – comprising 25 percent of all U.S. pharmacy spend in 2008.<sup>1</sup> By 2011, industry experts project that number to increase to 30 percent, totaling \$99 billion for specialty pharmacy expenditures.<sup>2</sup>

Nowhere is the growing cost of specialty drugs felt more than by Medicare. In June, the Medicare Payment Advisory Commission (MedPAC) reported that biologics (a subset of specialty drugs for which there currently is no real generic competition) cost taxpayers about \$13 billion in 2007.<sup>3</sup> It is not surprising then that some lawmakers in the U.S. House and Senate see the introduction of generic competition as a way to reduce the cost of biologic drugs.

Rep. Henry A. Waxman (D-CA) who co-authored groundbreaking legislation in 1984 that established today's system of generic drugs, now wants to create a pathway to allow so-called "biosimilar" drugs into the biologic marketplace. To do that, he has proposed legislation to allow market exclusivity of five years for pioneer biologic drugs than would run concurrent with existing patent protections. The Pharmaceutical Research and Manufacturers of America (PhRMA), however, advocates 12- to 14-years of exclusivity as necessary to continue incentivizing pioneering research and innovation.<sup>4</sup>

Prime and the Blue Cross Blue Shield Association belong to the Coalition for a Competitive Pharmaceutical Market (CCPM) that supports the shorter, five-year exclusivity period. CCPM's diverse membership includes consumer groups, leading U.S. corporations, pharmacy benefit management companies, insurance plans and generic pharmaceutical manufacturers. According to Prime Vice President of Government Relations Jerry Steffl, "Advocates of a shorter exclusivity period have been on the offensive end of this debate." Those advocates have found support through a study issued by the Federal Trade Commission.<sup>5</sup> It details how the introduction of biosimilar drugs (sometimes called follow-on biologics) could reduce what consumers now spend on biologic drugs. It also debunked PhRMA's concern that allowing biosimilar drugs into the marketplace would severely hamper drug innovation and development.

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<sup>1</sup> Keating, Peter. "Next Frontier in Health Care: Specialty Drugs," *Smart Money*, 4 May 2009. <http://www.smartmoney.com/personal-finance/retirement/specialty-drugs-the-next-frontier-in-health-care/>, Accessed 27 July 2009.

<sup>2</sup> C. Boorady, D.L. Weinswig, and C. Tang. "Riding the Specialty Pharmacy Wave: PBMs and Drug Retailers See a Big Swell Forming," *Citi, Health Care Distribution and Technology*, 8 October 2007.

<sup>3</sup> "Biosimilars Debate Focuses on Data-Exclusivity Period Length," *Specialty Pharmacy News*, June 2009.

<sup>4</sup> Pharmaceutical Research and Manufacturers of America: Issues/Intellectual Property, <http://www.phrma.org/issues>, Accessed 21 August 2009.

<sup>5</sup> Emerging Health Care Issues: Follow-On Biologic Drug Competition: A Federal Trade Commission Report, June 2009. <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>, Accessed 27 July 2009.

Currently, Omnitrope® , a follow-on protein used in the treatment of children with growth hormone deficiencies, is one of the only biosimilar drugs that have hit the market. The U.S. Food and Drug Administration approved Omnitrope in 2006 using a different law than what governs most biotech drugs.<sup>6</sup>

“Right now the greatest opportunities for follow-on biologics appear to be in the areas of human growth hormones, erythropoiesis-stimulating agents, multiple sclerosis drugs and rheumatoid arthritis therapies,” said Shelley Sanchez, Prime’s Senior Director of Specialty Product Development.

Industry analysts say that if the law changes to allow biosimilar drugs, the FDA can expect a lot of approval requests. Many biotech drug patents have either expired or will expire in the next five to 10 years—among them Humira®, Remicade® and Enbrel®, all used in the treatment of rheumatoid arthritis. And when that happens, industry analysts expect biosimilars will enter the market at costs 20 to 30 percent below the cost of brand products.<sup>7</sup>

Currently, health reform proposals reported out of health committees in both the House and Senate include follow-on biologic proposals that allow for 12 years of market exclusivity. According to Steffl, loopholes in the legislation could ensure an even longer period of exclusivity, which CCPM members and their allies in the White House and Congress would continue to oppose.

“Ultimately follow-on biologics is a balancing act for lawmakers – balancing the need to control escalating specialty drug reimbursement costs today, while making sure it doesn’t come at the expense of future biologic research and development,” concludes Steffl.

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<sup>6</sup> Weintraub, Arlene. “Omnitrope’s Off-Label Future,” *BusinessWeek*, 1 June 2006. [http://www.businessweek.com/technology/content/jun2006/tc20060601\\_090608.htm](http://www.businessweek.com/technology/content/jun2006/tc20060601_090608.htm). Accessed 27 July 2009.

<sup>7</sup> “When Biosimilars Reach U.S. Market, Expect Competition in RA Class,” *Specialty Pharmacy News*, July 2009.