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BEFORE THE
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

HEARING ON
SAFE AND AFFORDABLE BIOTECH DRUGS:
THE NEED FOR A GENERIC PATHWAY

March 26, 2007

Good Morning Chairman Waxman, Ranking Member Davis and Members of the Committee.

I am Jonah Houts, Senior Analyst at Express Scripts, and I am pleased to be here today to discuss the issue of biogenerics from the perspective of a leading Pharmacy Benefit Management Company. Express Scripts would like to thank the Chairman for his leadership in introducing this historical legislation which we believe will fundamentally improve health outcomes by giving patients access to lower-cost biologic alternatives.

Express Scripts monitors prescription drug trends and expenditures for 1600 clients including large, self-insured employers, government payers, unions and health insurance companies.

I want to talk about three basic issues today:

- First, I want to talk about the trend of specialty drug spend, especially biologic agents.
- Second, I would like to describe the tools utilized by Pharmacy Benefit Managers to control the increasing cost of prescription drugs.
- Third, I want to describe how we would apply these tools to biogenerics and the potential benefit to patients, plan sponsors and the government.

I. Trends in Specialty Spend

Spending on pharmaceuticals now represents 11% of total health care spend. Within the pharmaceuticals are specialty drugs, which are mostly the high priced biologic agents being discussed today. In 2006, spending on specialty drugs was \$54 billion, representing 20% of the pharmaceutical spend. The spend for specialty drugs will almost double by 2010, increasing to \$99 billion. This rate of increase is the second highest in the health care field, exceeded only by diagnostic imaging tests.

II. Tools of the PBM

Express Scripts represents 1600 clients, including employers, unions, governments, and managed health plans. In total, we are managing the pharmacy benefit for over 50 million individuals. Our mission is to make the use of prescription drugs safer and more affordable. To this end, we have developed sophisticated tools, such as formularies, tiered copayments, step therapies and drug utilization management programs to name a few. These tools promote the most clinically sound and cost effective use of pharmaceuticals.

One of the most potent tools we have is the promotion of generic medications. These therapies are time tested, and thus are clinically effective, and have well characterized safety profiles. The additional advantage is that they are the most affordable for patients and plan sponsors. For these reasons, patients achieve higher compliance rates with these therapies. Utilizing these programs, our company has an industry leading generic fill rate of 60%.

When a particular drug comes off patent and can be filled with a generic, that fill rate climbs to 96%. An example of this would be when simvastatin came onto the market as a generic version of Zocor.

Where there is considerable patient monitoring needed, such as the case of anti-convulsant drugs, what we call a narrow therapeutic index, physician prescribing patterns are more cautious and we see a generic fill rate of 83%.

These switch rates are based on empirical drug spend data.

It is important to recognize that all of our programs for promoting the use of generics or less expensive branded medications are reviewed by our external Pharmacy and Therapeutics committee. This committee is made up of both specialty and general medicine doctors and pharmacists who are not employees of Express Scripts.

III. How We Would Apply These Tools to Biogenerics

As we have stated, spend on biologic agents is increasing at an alarming rate. This legislation will establish a pathway at the FDA for companies to bring to market generic versions of these important medications. The PBMs have the tools to assist patients in switching to the more cost effective biogenerics. In fact, our switching tools will be even more effective in this market because of the limited number of patients, scripts, specialty physicians and the potential enormous savings. Our plan sponsors will be very motivated to have us pursue each and every savings opportunity.

Regardless if the FDA deems a product as interchangeable or just comparable, we will be quite effective at working with the prescribing physician to aid patients in receiving the most cost effective and clinically appropriate therapy.

To use a non-biologic example, Express Scripts' P&T committee reviewed the potency of drugs called statins to determine the degree that they lowered LDL or "bad" cholesterol. ESI concluded that three statins were in the "high-potency" category.

In this case, statin A had a much higher price than statin B and we educated consumers and physicians about the lower cost alternative brand product. We successfully moved 49% of market share to the preferred brand product within 6 months, and the outcomes for the patients are equally successful.

At the same time, statin B's product went generic. At that time Express Scripts moved 96% of market share to the preferred generic agent within 3 months, resulting in \$126 million of savings for our clients in the area of anti-cholesterol drugs alone.

Biologics are the fastest growing segment of drug spend and there are 400 to 700 biologics in the pipeline. While they have remained a relatively small percentage of prescriptions, they account for a large portion of spend which is growing. The average cost per day of a biopharmaceutical is \$45 compared with \$2 per day for a traditional medicine. In the traditional drug market, generic medications decrease prices 60-90% on branded oral-solid medications. The range of savings associated with the FDA's ability to approve biogeneric products remains unclear, largely because of interchangeability or comparability, but what is clear is that each study looking at this issue finds savings in the billions for the federal government.

This historic legislation will allow patients, payers, physicians and PBMs to work together to make these wonderful therapies more readily available, with improved health outcomes and tremendous savings.