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Before the

UNITED STATES HOUSE OF REPRESENTATIVES
ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

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Biosimilar Medicines Policy

Good Morning Chairman Pallone, Ranking Member Deal and other distinguished Members of the Committee.

I am Doctor Ed Weisbart, Chief Medical Officer 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 and committee for their consideration of this historic policy issue which we believe will fundamentally improve health outcomes by giving patients access to lower-cost biologic alternatives.

Express Scripts is one of the nation's largest pharmacy benefit managers. We monitor prescription drug trends and expenditures for 1600 clients including large, self-insured employers, government payers, unions and health insurance companies with over 50 million lives. We work every day on behalf of our clients and their patients to make prescription drugs safer and more affordable. It should come as no surprise given the dramatic rise in the cost of biotech pharmaceuticals that our clients look to us for advice on how to manage this ever-increasing biotech drug spend. In fact, they have been demanding action to make these therapies more affordable.

In my testimony today, I want to make three basic points:

- First, specialty drug spend, especially biologic agents, is growing at an alarming rate;

- Second, pharmacy benefit managers have developed many tools to manage the increasing cost of prescription drugs; and

- Third, 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. As spend for non-specialty pharmaceuticals has slowed to single-digit growth, specialty drug spend increased 21% in 2006.[1]

[1] *Express Scripts, Inc., 2006 Drug Trend Report, www.express-scripts.com/ourcompany/news/outcomesconference*

In 2006, spending on specialty drugs was $54 Billion, representing 20% of the pharmaceutical spend. In 2010, spend for specialty drugs will almost double to $99 billion. This rate of increase is the second highest in health care field, exceeded only by diagnostic imaging tests.

II. Tools of PBMs

As I said, Express Scripts represents 1600 clients, managing the pharmacy benefit for over 50 million individuals. 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, proven to be clinically effective, and have well characterized safety profiles. One additional key advantage is that they are the most affordable option for patients and plan sponsors. For these reasons, patients achieve higher compliance rates with these therapies. Utilizing these programs, our company leads the industry in filling as many as 60.3% of all prescriptions with generic drugs.

When a particular drug comes off patent and can be filled with a generic, that fill rate climbs to about 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 in preventing transplant rejections, what we call a narrow therapeutic index, physician prescribing patterns are more cautious and we see a generic fill rate of 83%.

These generic fill 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 independent self-governing committee is made up of both primary care and sub-specialty physicians and pharmacists, none of whom are employed by Express Scripts.

III. How We Would Apply PBM Tools to Biogenerics

As we have stated, the money spent on biologic agents is increasing at an alarming rate. This legislation will allow for a pathway at FDA for

companies to bring to market generic versions of these important medications. PBMs have the tools to assist patients in transitioning to the more cost-effective biogenerics. In fact, our transitioning tools will be even more effective in this market because of the limited numbers of patients, prescriptions and treating physicians, and the potential enormous savings. Our plan sponsors will be very motivated to have us pursue each and every savings opportunity.

Regardless of whether 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 receive 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. Our independent P&T Committee concluded that three statins were in the "high-potency" category.

In this case, statin A had a much higher price than statin B. So, 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. And, Express Scripts simultaneously moved 96% of market share to the preferred generic agent within three months, resulting in $230 million of savings since January of 2006 in the area of anti-cholesterol drugs alone.

While they have remained a relatively small percentage of prescriptions, biologics are the single, largest segment of drug spend, with an additional 400 to 700 biologics in the pipeline. 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% as compared to branded oral-solid medications.

Many studies—including a detailed one by Express Scripts—have sought to demonstrate the potential savings associated with the FDA's ability to approve biogeneric products. What is clear about each of these studies is that the federal government—as well as all payors—stands to find savings in the billions of dollars.

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

Mr. Chairman and Members of the Committee, thank you for allowing me to testify before the Committee on this important issue. I would be happy to answer any questions you may have.