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Caterpillar Inc.

Senate Committee on Health, Education, Labor and Pensions

Follow-On Biologics

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Introduction

Chairman Kennedy, Senator Enzi and other members of the Committee, I am pleased to present testimony on behalf of Caterpillar regarding the need to establish an abbreviated, science-based regulatory pathway for the approval of biogeneric products within the Food and Drug Administration. We commend you for your swift action in holding this important hearing to begin the process, launched by the bipartisan efforts of Senators Schumer, Clinton, Stabenow, Leahy, Vitter and Collins, to apply balance and competition within the biotechnology market.

Caterpillar Background

My name is Sid Banwart. I'm vice president at Caterpillar where I have responsibility for the company's Human Services Division, which includes Compensation and Benefits.

As the world's leading manufacturer of construction and mining equipment, diesel, natural gas and turbine engines, and related services, Caterpillar employs nearly 95,000 employees worldwide, is a major U.S. manufacturer and leading exporter with some $10.5 billion of U.S.-sourced product shipped around the world in 2006.

Caterpillar is able to be a leader in the global marketplace utilizing its strong U.S. manufacturing base because we make competitive products that are known for their quality and durability. But our ability to remain a market leader depends on our success in attracting and retaining top talent. We use our benefits package to recruit the best and brightest from some of the top schools in the country and consider those new grads to be the future of Team Caterpillar.

Health Care Story

To ensure our company is well positioned in that future, we are continuing to take aggressive measures to keep our employees and retirees healthy, while managing cost. As you know, the escalation of health care costs is a top concern for U.S. business executives, and we at Caterpillar are no exception. Last year alone, we spent more than $600 million in the U.S. for comprehensive medical, dental, vision, and prescription benefits.

To manage our costs, we've taken action on both the wellness and cost sides of the equation. On the wellness front, Caterpillar has in place an award winning health promotion program, disease management systems, and our Work.Life.Solutions program to promote a balanced lifestyle. On the cost side, we've established preferred hospital groups, physician networks and a pharmacy benefit management arrangement to ensure the best possible rates and enhanced transparency in pricing.

View on Prescription Drug Marketplace

Caterpillar strongly supports a vigorous and competitive prescription drug market, one in which innovation leads to new life-saving medicines. Currently there is no opportunity for competition in the marketplace once a patent has expired on brand biotech drug products because the Food and Drug Administration (FDA) does not have clear authority to approve biogeneric products. I appear before you today to urge this Committee to find a bipartisan solution to create an appropriate regulatory route for FDA review of biogenerics. We believe the solution should grant the FDA the authority to use its discretion and scientific expertise to evaluate interchangeable and comparable biogeneric products while ensuring patient safety.

Hatch-Waxman Law

One of the most important health care laws enacted over the past 30 years was the "Drug Price Competition and Patent Term Restoration Act of 1984," commonly known as the "Hatch-Waxman" law. As Senator Hatch knows so well, this landmark legislation broke important new ground in granting FDA the authority to approve generic versions of prescription products. Hatch-Waxman also gave FDA express authority to provide an abbreviated approval process for those products deemed equivalent to the prior approved product. It is estimated that this law saves patients and payers billions per year -- and we thank you, Senator Hatch, for your leadership in this important area, as well as your recent commitment to work to pass legislation this year to spur competition within the biotechnology market.

Consumers and Purchasers Will Benefit With Greater Innovation and Greater Competition

Total spending on prescription drugs in 2006 is estimated at $213.7 billion and rising to $497.5 billion by 2016.[1] The use of biopharmaceuticals is increasing at almost twice the rate of traditional medicines – accounting last year for approximately $30 billion in U.S. sales and 12 percent of total pharmaceutical usage.[2] These medicines can and do improve the lives of millions of patients -- but without generic versions, the costs may keep needed treatments out of the hands of consumers.

Caterpillar is focused on drug issues because we expect prescription drug expenses to be the among the most significant health care cost drivers for our company in the years ahead due to an aging workforce and increased rates of utilization. For 2006,

[1] Poisal, J.A., et al, "Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact", *Health* Affairs 26, no. 2 (2007) Exhibit 6.
[2] *MedAdNews,* November 2006 .

Caterpillar's prescription drug cost were in excess of $151 million, accounting for more than 25 percent of our health care total spend. For our company, biologics currently account for 2.9 percent of the total drugs utilized but account for 12 percent in terms of spending. Most concerning is the financial trend Caterpillar has documented with biologic products…costs have increased 45 percent since 2004. This is our single fastest growing category of health cost, and the trend is simply not sustainable.

Certainty

Caterpillar, like other U.S. manufacturers, is very concerned about the implications of our health care expenses. For business planning purposes, it is critical for us to have certainty when forecasting spending…be it for commodities such as steel or for health care benefits like prescription drugs. Currently there is no certainty in our pharmaceutical spending because we do not know when or if there will be lower cost alternatives for biopharmaceuticals. Many of the biopharmaceuticals on the market today are "off-patent" and more than $10 billion worth of biopharmaceuticals are expected to come off patent by 2010.[3] When exploring avenues to introduce competition into the marketplace, I ask Congress to clearly outline a reasonable process for early resolution of patent disputes to avoid any unintended loopholes and ensure certainty for the biogeneric marketplace.

Guiding Principles for Bipartisan Legislation

Caterpillar encourages the committee to consider five key principles as you begin to consider legislation:

1. Protect and promote fair and open competition.

[3]Engel & Novitt, LLP, "Potential Savings That Might Be Realized by the Medicare Program From Enactment of Legislation Such as The *Access to Life-Savings Medicine Act* (H.R. 6257/S. 4016) That Establishes A New cBLA Pathway For Follow-On Biologics. Table 4a. , January 2, 2007

As innovators, we respect and understand the development of innovation and need for patent protections. However, once a patent expires or is successfully challenged, biogeneric competition should be able to enter the market.

2. Provide a definitive pathway for the approval of biogenerics.

We believe there must be certainty in both timing and method of the biogeneric approval process. FDA needs the authority—to approve both comparable and interchangeable biogeneric products. Congressional deference to the FDA's expert scientific judgment is appropriate. In addition, any action should permit prescribers to substitute one biologic for another when appropriate.

3. Encourage consistent and uniform terminology.

Whether the terms are "comparable," "interchangeable," "therapeutic equivalent," or "generic" -- we want an abbreviated process that results in a "biogeneric," meaning a lower cost alternative to biologic pharmaceuticals.

4. Increase resources for the Food and Drug Administration.

In order to adequately assume these new responsibilities, the FDA will need adequate resources. We support additional resources for FDA to secure more staff to ensure the timely review of biogeneric applications and the safety of biogenerics for consumers.

5. Include the new legal authority for a biogeneric pathway in must-pass legislation this year.

We encourage Congress to move quickly to establish a regulatory pathway for the approval of biogenerics. We are confident this hearing will affirm the science for comparable and interchangeable products has arrived. Once the FDA has the

discretionary authority to begin this process, it will drive innovation that will assist in the identification of similar and substitutable methods for these off-patent products. Each day that passes without biogenerics is another day of limited options. No payer, whether individual or employer, public or private, can afford unlimited monopoly pricing. Caterpillar, therefore, is encouraged to hear reports that members are committed to including a workable pathway into the prescription drug reauthorization legislation—called PDUFA—and strongly supports you in this endeavor.

Conclusion

In conclusion, I'm pleased that the Senate HELP Committee is considering issues like biogenerics that can make a positive impact on our health care system. Thank you to all the members of this Committee who have taken an active interest in understanding the important role of the FDA to use its scientific judgment to approve biogeneric products. Chairman Kennedy and Senator Enzi, I appreciate your leadership and also that of others on the Committee who understand and have taken leadership on these issues. A bipartisan bill that empowers the FDA to use the best science to encourage innovation and biogeneric competition should be passed this year. More Americans should be given access to these important innovations -- we encourage you to support a marketplace that has fair and open competition. Thank you for this opportunity to testify today.