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SENATE JOINT RESOLUTION NO. 397

Offered January 10, 2007

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Requesting the Department of Medical Assistance Services to collect data on the current costs of insulin and human growth hormones to the Commonwealth's Medicaid program. Report.

Patron—Whipple

Referred to Committee on Rules

WHEREAS, biologics are a new class of drugs that include standard single molecule drugs as well as antibodies and vaccines and are mostly produced using cell culture. Approximately $10 billion in biologic therapies are set to expire by 2010. The average price of a traditional drug is about $2 per day, while the average cost is $45 per day, with Medicaid accounting for about 19 percent of federal government drug expenditures; and

WHEREAS, biologics are a major driver of increasing prescription drug costs. For the first time, five of the 20 top selling drugs in 2005 were biologics. At least three new blockbusters are expected to join that list. A typical course of three of the top biotech pharmaceuticals, Neupogen, Epogen and IntronA, cost patients $23,098, $10,348 and $5,850, respectively, each year. As evidenced by these examples alone, generic competition for biotech pharmaceuticals has the potential to offer consumers dramatic and substantial savings while lowering Virginia's healthcare bill; and

WHEREAS, the science to create affordable generic biotech drugs exists today and is being done in other countries. Raw materials are available today for many biogeneric products, including insulin, GCSF, epoetin, and interferons. In many countries around the world, competitive biotech products are already marketed and approved. In such countries, countless patients already benefit from competition; and

WHEREAS, timely competition will ensure continued innovation in biotech drugs. It is critical to preserve the incentives for innovation that drive the development of new biologics, but there is need to provide a balance of competition to those drugs off-patent in order to keep America's biotech innovators strong and growing; and

WHEREAS, a Citizens' Petition was submitted to the Federal Drug Administration (FDA) in August 2006 requesting that the FDA use its statutory and regulatory authority to issue guidelines that will facilitate the availability of more affordable, therapeutically equivalent versions of insulin and human growth hormone (HGH); and

WHEREAS, Americans spend approximately $1.5 billion on insulin products to treat diabetes and approximately $433 million on HGH, which is used to treat a variety of conditions, including growth deficiencies in children and adults, chronic renal insufficiency, and AIDS wasting syndrome; and

WHEREAS, the FDA has repeatedly and publicly indicated that guidance on the approval process for generic insulin and HGH would be forthcoming. This guidance would provide generic pharmaceutical manufacturers with the criteria for demonstrating equivalence of generic versions of insulin and HGH. However, it appears that issuance of appropriate regulatory requirements for these products has come to a standstill resulting in our citizens and taxpayers to continue to shoulder the burden for excessive costs since no generic version of either of these products is available. Insulin and HGH have relatively simple biologic structures with a long history of safe use and a wealth of data available about these products; and

WHEREAS, while such guidance unnecessarily languishes in the United States, the European Medicines Agency (EMEA) adopted final guidelines on quality and nonclinical and clinical issues regarding similar biological medicinal products in December 2003 and a general regulatory guideline on such products in September 2005. The EMEA also issued final product-specific guidance documents on similar biologic medicine products (including one for insulin) in February 2006; and

WHEREAS, in 2004, national Medicaid expenditures for insulin alone were approximately $500 million; and

WHEREAS, according to the Centers for Disease Control and Prevention, the Commonwealth of Virginia has one of the largest populations of patients diagnosed with diabetes in the nation; and

WHEREAS, on average, African Americans are 2.4 times as likely as whites to have diabetes. The highest incidence of diabetes in African Americans occurs between the ages of 65 and 75. African American women are especially affected. When adjusted for age, African American women are more likely than non-Hispanic whites, African American men, or Hispanics to be diagnosed with diabetes. African Americans with diabetes are more likely to experience complications of diabetes. Diabetic

retinopathy, an eye disease, is 19 percent more common in African American men than White men. Amputations of lower extremities (legs and feet) are also more common in African Americans with diabetes; and

WHEREAS, as of 2002, 2 million Hispanics 20 years and older, about 8.2 percent of the population, have diabetes. Diabetes is more prevalent in older Hispanics, with the highest rates in Hispanics 65 and older. On average, Hispanics are 1.5 times as likely as whites to have diabetes. Mexican Americans, the largest Hispanic subgroup, are more than twice as likely to have diagnosed diabetes than non-Hispanic Whites in the United States. And in 2002, the death rate from diabetes in Hispanics was 60 percent higher than the death rate of non-Hispanic Whites. In 2001, Hispanics of all races experienced more age-adjusted years of potential life lost before age 75 years than non-Hispanic Whites for diabetes; and

WHEREAS, diabetes is the fifth leading cause of death in the Asian American and Pacific Islander population; and

WHEREAS, HGH is one of the most expensive prescription regimes, costing a patient upwards of $30,000 a year. Annual sales of HGH in the United States are estimated to exceed $700 million. HGH costs are increasing as the number of growth deficiency-related cases continues to rise and as the FDA approves new uses for HGH; and

WHEREAS, as usage and the subsequent expenses increase, the financial impact of the availability of generic, substitutable versions of insulin, HGH, and other biologics would be dramatic to the State and its citizens. For example, if only one-third of patients using insulin began using a generic, and if it were priced at a modest 10 percent discount, payers would save $17 million annually. With a discount of 30 percent, which is more typical of the generic market, again with only one-third of patients using the generic, annual savings would exceed $50 million. If all Medicaid patients began using generic insulin at a 30 percent discount relative to current brand prices, the savings would exceed $150 million annually; and

WHEREAS, the cost savings that generic drugs provide to the Commonwealth could be provided through biogenerics if made available to patients in need of insulin for the treatment of diabetes and in need of human growth hormones for the treatment of common growth deficiencies; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Medical Assistance Services be requested to collect data on the current costs of insulin and human growth hormones to the Commonwealth's Medicaid program.

In collecting the data, the Department of Medical Assistance Services shall consider the number of patients who need such medication and the potential Medicaid cost savings.

Technical assistance shall be provided to the Department of Medical Assistance Services by the State Department of Health. All agencies of the Commonwealth shall provide assistance to the Department of Medical Assistance Services in collecting the information, upon request.

The Department of Medical Assistance Services shall submit to the Division of Legislative Automated Systems an executive summary and the data collected on the current costs of insulin and human growth hormones to the Commonwealth's Medicaid program no later than the first day of the 2008 Regular Session of the General Assembly. The Department of Medical Assistance Services also shall transmit a copy of the executive summary and data collected on the current costs of insulin and human growth hormones to the Commonwealth's Medicaid program to the United States Food and Drug Administration requesting it to issue guidelines to facilitate the production of generic biologics to treat diabetes and other diseases. The executive summary shall be submitted for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website. ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle> ldtitle>