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HOUSE JOINT RESOLUTION NO. 713

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Rules
on January 31, 2007)

(Patron Prior to Substitute—Delegate O'Bannon)

Requesting the Department of Medical Assistance Services to confer with the U.S. Food and Drug Administration on the implementation of certain guidelines relating to the costs of Insulin and human growth hormones for the Commonwealth's Medicaid program. Report.

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, and approximately $10 billion in patents for biologic therapies are set to expire by 2010; and

WHEREAS, the average price of a traditional drug is about $2 per day, while the average cost of a biologic drug is $45 per day, with Medicaid accounting for about 19 percent of federal government drug expenditures; and

WHEREAS, biologics are a major force in increasing the costs of prescription drugs, and five of the 20 top-selling drugs in 2005 were biologics, and at least three new blockbusters are expected to be added to the list; and

WHEREAS, generic competition for biotech pharmaceuticals has the potential to offer consumers dramatic and substantial savings while lowering Virginia's health care costs; and

WHEREAS, the raw materials for many biogeneric products, including Insulin, are available today, and the science to create affordable generic biotech drugs also exists, and in many other countries competitive biotech products are marketed and approved, and countless patients already benefit from such competition; and

WHEREAS, while competition promotes continued innovation in biotech drugs and preserving incentives for innovation is critical to fostering the development of new biologics, providing balanced competition between off-patent drugs and America's biotech innovators will help ensure the continued strength and growth of this vital industry; and

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

WHEREAS, in 2004, national Medicaid expenditures for Insulin alone were approximately $500 million; 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; and 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, according to the Centers for Disease Control and Prevention, Virginia has one of the largest populations of patients diagnosed with diabetes in the nation; and

WHEREAS, African Americans are 2.4 times as likely as whites to have diabetes, with the highest incidence of diabetes in African Americans occurring between ages 65 and 75, and when adjusted for age, African American women are more likely than non-Hispanic whites, African American men, or Hispanics to be diagnosed with diabetes; and

WHEREAS, African Americans with diabetes are more likely to experience complications of diabetes, including diabetic retinopathy, an eye disease, which is 19 percent more common in African American men than in white men, and amputations of lower extremities (legs and feet); and

WHEREAS, according to health data in 2002, two million Hispanics 20 years and older, about 8.2 percent of the population, have diabetes, and diabetes is more prevalent in older Hispanics, with the highest rates in Hispanics 65 and older; and

WHEREAS, 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; 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 in 2002, the death rate from diabetes in Hispanics was 60 percent higher than the death rate of non-Hispanic whites; and

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

WHEREAS, a Citizens' Petition was submitted to the U.S. 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; and

WHEREAS, Insulin and HGH have relatively simple biologic structures with a long history of safe use and a wealth of data are available concerning these products, and FDA guidelines would provide criteria to generic pharmaceutical manufacturers for demonstrating equivalence of generic versions of Insulin and HGH; and

WHEREAS, although the FDA has repeatedly and publicly indicated that guidance on the approval process for generic Insulin and HGH would be forthcoming, appropriate regulatory requirements for these products have not been issued; and

WHEREAS, without FDA guidelines and absent the availability of generic versions of Insulin and HGH, Virginia's citizens and taxpayers continue to shoulder the burden of excessive costs for these drugs; 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, a general regulatory guideline on such products in September 2005, and has issued final product-specific guidance documents on similar biologic medicine products (including one for Insulin) in February 2006; 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 Department of Medical Assistance Services be requested to confer with the U.S. Food and Drug Administration on the implementation of certain guidelines relating to the costs of Insulin and human growth hormones for the Commonwealth's Medicaid program.

The Department of Medical Assistance Services shall (i) collect data on the current costs of Insulin and human growth hormones to the Commonwealth's Medicaid program, (ii) consider the number of patients who need such medication, (iii) if possible, determine the potential Medicaid cost savings to Virginia resulting from the implementation of FDA guidelines; and (iv) confer with the U.S. Food and Drug Administration regarding the release of FDA guidelines relating to generic versions of Insulin and human growth hormones to provide potential cost savings in Virginia.

The Department of Medical Assistance Services shall submit to the Division of Legislative Automated Systems an executive summary and report of its progress in meeting the requests of this resolution no later than the first day of the 2008 Regular Session of the General Assembly. The executive summary and report 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.