SJ0048SAM001

AMENDMENT TO SENATE JOINT RESOLUTION 48

AMENDMENT NO. ___. Amend Senate Joint Resolution 48 by replacing everything after the heading with the following:

"WHEREAS, With approximately $16 billion in biologic drug patents set to expire next year, the average price of a traditional drug is about $45, while the average cost of a biologic can be about 4 times as much, and with Medicaid accounting for about 19% of federal government drug expenditures, the 110th United States Congress will be considering legislation to authorize a regulatory pathway at the federal Food and Drug Administration (FDA) for the determination and approval of safe comparable versions of biologic drugs that are expected to produce the same clinical results as the innovator product; and

WHEREAS, Biologics are a major driver of increasing prescription drug costs; for the first time, 5 of the 20

top-selling drugs in 2005 were made by biotech companies; additional competition for biotech pharmaceuticals has the potential to offer consumers real savings, while also lowering America's healthcare bill; and

WHEREAS, Illinois spends nearly $200 million for 61 biologics under its Medicaid pharmacy benefits and Part D wrap around programs and an estimated 12% of its drug benefits on biologics for State employees and retirees; and

WHEREAS, The science to create safe comparable biotech drugs exists today in other countries; raw materials are available today for many comparable protein products including insulin, GCSF, epoetin, interferons, and others; in many countries around the world, competitive biotech products are already available to consumers; in these countries, patients have access to safe comparable biological products and receive cost savings from additional competition; and

WHEREAS, Significant investment is made by biotech drug developers in intellectual property, and appropriate intellectual property protection and the ability to recoup their investment and make a fair profit is needed; however, as has been proven under the Drug Price Competition and Patent Restoration Act of 1984, competition fuels innovation; competition from safe comparable biologics will ensure

continued innovation in biotech drugs; it is critical to preserve the incentives for innovation that drive the development of new biologics, recognizing that data exclusivity and patents work together to create the environment to support investments in discovering new biologics in order to keep this country's biotech innovators strong and growing; and

WHEREAS, A Citizens Petition was submitted to the 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 versions of insulin and human growth hormone (HGH); and

WHEREAS, American patients currently 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 insulin and HGH would be forthcoming; this guidance would provide generic pharmaceutical manufacturers with the criteria for demonstrating safety and efficiency of comparable 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 costs because no comparable version of either of these products is available; insulin and HGH have less complex biologic structures with a long history of safe use and a wealth of data available about the innovator versions of those products; and

WHEREAS, While such guidance unnecessarily languishes in the United States, the European Medicines Agency (EMEA) has adopted final guidelines on quality, non-clinical 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; insulin was historically approved for sale in the United States under the Federal Food Drug and Cosmetic Act; this fact should make it eligible to generic competition under the Drug Price Competition and Patent Restoration Act of 1984; diabetes is on the rise, and, if current population and diagnosis rates continue as projected, the number of people with diabetes could

reach 17.4 million by 2020 with attendant costs rising to an estimated $192 billion; insulin is a less complex biopharmaceutical product and many versions are no longer patent protected; if the FDA were to issue guidance in a timely manner and approve a lower cost, safe, comparable form of insulin, patients could begin realizing savings; and

WHEREAS, On average, African-Americans are 2.4 times as likely to have diabetes as Caucasians; the highest incidence of diabetes in African-Americans occurs between 65 and 75 years of age; African-American women are especially affected; when adjusted for age, African-American women are more likely to be diagnosed with diabetes than non-Hispanic Caucasians, African-American men, or Hispanics; African-Americans with diabetes are more likely to experience complications of diabetes; diabetic retinopathy, an eye disease, is 19% more common in African-American men than Caucasian men; amputations of lower extremities are also more common in African-Americans with diabetes; and

WHEREAS, As of 2002, 2 million Hispanic adults age 20 years and older and about 8.2% 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 to have diabetes as Caucasians; Mexican-Americans, the largest Hispanic subgroup, are more

than twice as likely to have diagnosed diabetes than non-Hispanic Caucasians; in 2002, the death rate from diabetes in Hispanics was 60% higher than the death rate of non-Hispanic Caucasians; in 2001, Hispanics of all races experienced more age-adjusted years of potential life lost before age 75 years than non-Hispanic Caucasians for diabetes; and

WHEREAS, HGH is one of the most expensive prescription regimes, costing a patient upwards of $30,000 a year; HGH has annual sales in the United States that are estimated to be more than $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; as usage and the subsequent expenses increase, Illinois is paying more for a drug product that has not been patent protected since 2003; and

WHEREAS, With the availability of safe comparable versions of insulin, HGH, and other biologics there will be savings to the State and its citizens; for example, if only one-third of patients using insulin were converted to a comparable insulin product and it was priced at a modest 10% discount, payers would save $17 million annually; a discount of 30%, more typical of the small molecule generic market, with only one-third of patients utilizing the small molecule generic, would result in savings of more than $50 million annually; if all Medicaid patients were converted to the small molecule

generic, at a 30% discount to current brand prices, the savings would exceed $150 million annually; and

WHEREAS, For more than 2 decades, generic pharmaceuticals have offered our State with a mechanism to manage the high cost of providing prescription drugs for State-funded and federally mandated prescription drug programs; at the same time, generic drugs have provided all of the citizens of Illinois with the opportunity to lower their prescription drug costs; therefore, be it

RESOLVED, BY THE SENATE OF THE NINETY-FIFTH GENERAL ASSEMBLY OF THE STATE OF ILLINOIS, THE HOUSE OF REPRESENTATIVES CONCURRING HEREIN, that we urge the members of the 110th United States Congress and the President of the United States to enact legislation that establishes a regulatory pathway authorizing the FDA to approve, when appropriate, abbreviated applications for comparable biological products that are expected to produce the same clinical results as the innovator product and are deemed by the FDA to be safe and effective; and be it further

RESOLVED, That the FDA be authorized to approve applications for safe comparable biologics in a manner that is determined to be in the best interests of patients; and be it further

RESOLVED, That the FDA promptly promulgate guidance for the specific approval requirements for forms of insulin and HGH; the issuance of these guidances would open the door for potential savings on these important therapies for consumers across our nation; and be it further

RESOLVED, That the FDA also commit to working with drug companies developing such products and to expediting the process so that these products may be approved and made available to patients as quickly as possible; and be it further

RESOLVED, That any new regulatory pathway for safe comparable protein products contain appropriate incentives for new biological products; and be it further

RESOLVED, That we strongly concur with those Governors who filed the Citizens Petition or sent letters of support for the Citizens Petition to the FDA on this issue; and be it further

RESOLVED, That we also strongly support the twenty Governors who have sent a letter encouraging Congress to authorize the FDA to provide a pathway for safe comparable biologics; and be it further

RESOLVED, That we and the Governor have a responsibility for managing the costs that the State incurs for prescription

drugs in connection with our State Medicaid program, as well as other State programs such as State employees and State retirees that provide a drug benefit; we are also charged with ensuring that high quality, affordable healthcare that provides safe and effective care is available to all citizens of our State; and be it further

RESOLVED, That suitable copies of this Resolution be provided to the Commissioner of the FDA, the Speaker the United States House of Representatives, the Minority Leader of the United States House of Representatives, the Majority Leader of the United States Senate, the Minority Leader of the United States Senate, and each member of the Illinois congressional delegation.".