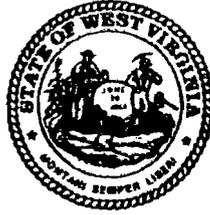


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State of West Virginia
Joe Manchin III
Governor

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Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and
Drugs
5600 Fishers Lane
Rockville, MD 20854

Dear Dr. von Eschenbach:

I am writing in strong support of other Governors' who have recently filed a Citizens Petition with your Agency respectfully requesting that the FDA issue guidance documents – without further delay -- that would clarify the approval requirements for generic versions of Insulin and Human Growth Hormone (HGH). The issuance of these guidance documents would open the door for significant savings on these important therapies for consumers across our nation.

For more than two decades, generic pharmaceuticals have offered (state here) with a mechanism to manage the high cost of providing prescription drugs for state-funded and federally mandated prescription drug programs. In addition, they have provided all of the citizens of my state with the opportunity to lower their prescription drug costs.

As a Governor, I am responsible for managing the costs that my state incurs for prescription drugs in connection with state Medicaid programs, as well as other state programs that provide a drug benefit. I am also charged with ensuring that high quality, affordable healthcare is available to all citizens of our state who are not covered by a state prescription drug benefit.

It is my understanding that your Agency 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 equivalence of generic versions of Insulin and HGH. However, it appears that issuance of appropriate regulatory requirements for these products have come to a standstill. As a result, our citizens and taxpayers continue to shoulder the burden for excessive costs since no generic version of either of these products is available.

In 2004, national Medicaid expenditures for Insulin alone were approximately \$500 million. Our state's share of this expenditure totaled \$5.4 million. It is important to recognize as well that Medicaid expenditures represent only a very small portion of total dollars spent by Insulin-dependent patients in our state.

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Based on my understanding of the issues, this excessive financial burden is unjust. Insulin, one of the early, simpler biopharmaceuticals, was historically approved for sale in the United States under the Federal Food Drug and Cosmetic Act (FFDCA). This fact should make it eligible to generic competition under the 1984 Drug Price Competition and Patent Restoration Act (Hatch/Waxman). 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 relatively simple biopharmaceutical product and many versions are no longer patent protected. If your Agency were to issue guidance in a timely manner, a lower cost generic form could rapidly begin generating savings for patients.

Similarly, HGH is one of the most expensive prescription regimes, costing 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 FDA approves new uses for HGH. The key here is that as usage and the subsequent expenses increase, our state is paying high prices for a drug product that has not been patent protected since 2003.

The financial impact of the availability of generic, substitutable versions of Insulin and HGH would be dramatic. For example, even if generic versions of Insulin were priced at a modest discount to the brand product, the savings to Medicaid patients alone would be substantial. If only one-third of patients were converted to the generic and it was priced at a modest 10% discount, payers would save \$17 million annually. A discount of 30%, more typical of the generic market, with only one-third of patients utilizing the generic, would result in savings of more than \$50 million annually. If all Medicaid patients were converted to the generic, at a 30% discount to current brand prices, the savings would exceed \$150 million annually. For our state, the savings from a generic Insulin product priced at 30% of the brand versions result in a significant savings based on our demographics.

I support the Citizens Petition recently filed by Governors from other states seeking immediate action by FDA to provide the necessary guidance to facilitate the entry of generic versions of Insulin and HGH into the marketplace. Immediate issuance of guidance that outlines the specific approval requirements for FDA-approved generic forms of Insulin and HGH would remove a significant barrier to savings for the citizens and taxpayers of West Virginia.

Sincerely yours,



Governor Joe Manchin, III