

06-8405



CHRISTINE O. GREGOIRE  
Governor

STATE OF WASHINGTON  
OFFICE OF THE GOVERNOR

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October 23, 2006

Andrew C. von Eschenbach, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. von Eschenbach:

I write in strong support of other governors who are petitioning for definitive Food and Drug Administration (FDA) guidance documents for the manufacture of generic versions of Insulin and Human Growth Hormone (HGH). This prompt action by the FDA would result in significant savings for states and consumers nationwide.

I am responsible for managing Washington State's prescription drug costs for Medicaid and other state programs that offer a drug benefit. I am also charged with ensuring that high quality, affordable health care is available to state citizens not covered by these programs. For over two decades, generic pharmaceuticals have offered our state a mechanism to manage the high costs of prescription drugs for state-funded and federally-mandated prescription drug programs. The availability of generics for Insulin and HGH would enable the states, and all citizens, greater potential to lower prescription drug costs.

The number of people being treated for diabetes continues to increase, and is expected to reach about 17.4 million by 2020, requiring attendant costs of \$192 billion. We also anticipate that the number of growth deficiency-related cases will continue to increase, as well as FDA approving more uses for HGH in the future. This means higher prices for Insulin and HGH, drug products that are no longer patent protected and that are eligible for generic competition.

In 2004, national Medicaid expenditures for Insulin alone were approximately \$500 million. Washington State's share of this expenditure totaled \$10.3 million. In 2005, we spent \$12.9 million on Insulin. It is important to also recognize that Medicaid expenditures represent only a very small portion of total dollars spent by Insulin-dependent patients throughout Washington State.

It is my understanding that the FDA has repeatedly and publicly indicated that guidance on the approval process for Insulin and HGH would be forthcoming. By issuing guidance, generic pharmaceutical manufacturers have the criteria they need to demonstrate equivalency of generic versions of these products. This, in turn, will lower prescription drug costs for patients and the unjust, excessive financial burden that the states now shoulder.

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I respectfully ask that you move quickly to issue the necessary guidance documents for Insulin and HGH, both products that are so critical to meeting the health care needs of our citizens.

Sincerely,

A handwritten signature in black ink, reading "Christine O. Gregoire". The signature is written in a cursive, flowing style with a large initial "C".

Christine O. Gregoire  
Governor