

OFFICE OF THE GOVERNOR
STATE OF MONTANA

BRIAN SCHWEITZER
GOVERNOR



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LT. GOVERNOR

1580 '06 OCT -4 P1:07

September 29, 2006

Andrew C. von Eschenbach, M.D. Acting
Commissioner
U.S. Food and Drug Administration
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.

As Governor of Montana, 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 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 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, Montana citizens and taxpayers continue to shoulder the burden for excessive costs since no generic version of either of these products is available.

Diabetes is on the rise and is a matter of great concern for our state with a high Native American. If your Agency were to issue guidance in a timely manner, a lower cost generic form could rapidly begin generating savings for patients. HGH is one of the most expensive prescription regimes, costing upwards of \$30,000 a year. A generic version would greatly help patients who require HGH.

In 2004, national Medicaid expenditures for Insulin alone were approximately \$500 million. Our state's share of this expenditure totaled \$1,300,000. 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. For our state, the savings

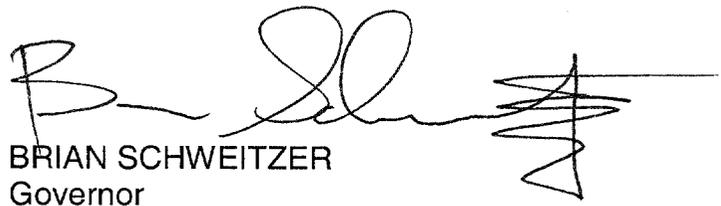
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from a generic Insulin product priced at 30% less than the brand versions result in a savings of \$390,000 to our Medicaid program.

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 (state name).

Respectfully,



BRIAN SCHWEITZER
Governor