



July 7, 2011

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The Generic Pharmaceutical Association (GPhA) represents the manufacturers of approximately 90 percent of all generic drugs dispensed in the United States. Our products are used to fill nearly three billion prescriptions every year. We are writing today because GPhA and its members are concerned about the Administration's proposal to require drug manufacturers to pay Medicaid rebates for drugs dispensed to "dual eligible" Medicare beneficiaries and the negative impact such a policy could have on access to low cost, high quality generic pharmaceuticals in the Medicare Part D program.

Last month, the Medicare Trustees report projected that Medicare Part D costs for the first 10 years of the program (2006–2015) will be 41 percent below initial estimates—a \$300 billion savings—due primarily to higher-than-expected utilization of generic drugs. As you know, the 2003 Medicare Modernization Act does not require manufacturer rebates for the dual eligible population. As plan sponsors compete for beneficiaries, Part D plans seek to promote utilization of generic alternatives at a fraction of the cost of brand-name drugs, resulting in the enormous savings reported by the Medicare actuary. Imposing statutory rebates for the dual eligible population enrolled in Part D could dramatically reduce the impact that generic drugs have had in lowering Part D costs and would simply shift costs to those accessing medicines through the private market.

While we understand and support current proposals under consideration that exempt generic drug manufacturers from paying rebates, our concern is the adoption of policies that have the potential to shift – rather than contain – costs. The Congressional Budget Office has determined that in an effort to moderate the effect of any new rebates, pharmaceutical manufacturers would set higher "launch" prices for new drugs. We are additionally concerned that new rebates could inadvertently decrease the future availability of generic medicines due to the dampening effect each rebate would have on investment in the development of new pharmaceutical products. These types of policies preclude access to more affordable medications for all purchasers – whether they are in public programs or receive their coverage through the private sector.

As you know, generic drugs play an essential role in making health care affordable for both Medicare and Medicaid. This year, generics will enable Medicaid to meet two-thirds of its prescription drug needs while spending only one-fifth of its prescription drug budget. Clearly, generic drugs play a key role in reducing government health care costs. We urge you not to jeopardize the cost saving benefits offered by generics by putting in place a policy that could lead to fewer generic drugs. There are better policy options that would achieve federal savings in both Medicare and Medicaid by encouraging competition and reducing barriers to entry in the prescription drug market. We applaud the Administration's proposal to reduce the exclusivity period granted to manufacturers of biologic drugs. Other options for generating savings include incentivizing state Medicaid programs to raise their use of the lowest-cost multi-source drug, prohibiting states from utilizing "carve-out" policies that reduce access to generics, and collaborating with the generic drug industry to establish user fees to allow the FDA to quickly review applications for generic drugs.

The President
July 7, 2011
Page 2

We are heartened that many on Capitol Hill on both sides of the aisle agree with us that cost containment, not cost shifting, is the way to reduce the deficit and control Medicare and Medicaid spending. We believe our industry provides solutions that benefit taxpayers, beneficiaries, and the government.

Thank you for your consideration of our views on this matter. Please do not hesitate to contact us if you would like additional information concerning our positions and the vital role generic medicines play in lowering health care costs.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robert Billings". The signature is fluid and cursive, with a large initial "R" and a distinct "B".

Robert Billings
Executive Director