



March 18, 2011

The Honorable John Boehner
Speaker, U.S. House of Representatives
Washington, D.C. 20515

The Honorable Harry Reid
Majority Leader, United States Senate
Washington, D.C. 20510

The Honorable Jack Lew
Director, Office of Management and Budget
The White House
Washington, D.C. 20503

Subject: Protecting Funding for FDA Office of Generic Drugs in Final 2011 Budget

Dear Mr. Speaker, Leader Reid and Director Lew:

On behalf of the Generic Pharmaceutical Association (GPhA), I am writing to ask that you please do all you can to protect funding for the FDA Office of Generic Drugs (OGD) as a budget for the remaining months of the 2011 Federal fiscal year is developed. GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 75 percent of the prescriptions dispensed in the U.S. but account for only 25 percent of the total prescription drug spending.

It is critical that OGD continues to review and approve generic medications in a timely manner. GPhA and its membership are concerned that any reductions to FDA's budget could significantly impair the ability of the agency to approve generics at a time when billions of dollars in brand name medications are coming off patent. The current median time for the FDA to approve a generic drug application continues to increase and is now approximately 30 months. To put this delay in perspective, FDA is required to review applications within 6 months. This excessive backlog has already delayed the availability of new generic medications and reduced competition.

Further reductions to the OGD budget would worsen this situation and likely increase approval times given that over 2,000 applications are pending at FDA. In fact, according to the FDA, 365 pending applications are for the first lower-cost generic version of a brand name drug on the market. The delay in getting these new generics to market means that more expensive brand name drugs are being used in lieu of lower-cost generics. For example, the average cost of a Medicaid brand prescription is about \$200, while that of a generic is about \$20 – one-tenth less.

Investing funds in the OGD pays significant dividends for public and private payers in the form of millions of dollars in reduced prescription drug costs. In fact, according to an IMS Health study released last year, generic drugs have saved the health care system \$824 billion over the past 10 years in reduced prescription drug costs. This includes important Federal and state health care programs, including Medicare, Medicaid and TRICARE. Reducing generic availability through reductions to OGD funding will needlessly increase costs in these programs.

We are working with the FDA and Congress this year on the development of a generic drug user fee program. This program will provide private sector funds to supplement Federal appropriations to help reduce the backlog of generic drug applications, and to assure the more timely approval of generic medications. However, significant cuts to the OGD program at this critical time would be devastating to millions of consumers, employers and other payers that rely on the timely approval of generics to help better manage their health care costs.

We understand the difficult budget environment in which Congress is operating, but fundamentally believe that the approval of more generic medications will help the overall Federal and state budget situations. We urge you to maintain current levels of OGD funding in any final budget agreement for FY 2011. We appreciate your consideration of our views. Thank you.

Sincerely,



John M. Coster, Ph.D., R.Ph
Senior Vice President, Government Affairs

The Honorable Mitch McConnell, Senate Republican Leader
The Honorable Eric Cantor, House Majority Leader
The Honorable Nancy Pelosi, House Minority Leader
The Honorable Daniel Inouye, Chairman, Senate Appropriations Committee
The Honorable Herb Kohl, Chairman, Senate Agriculture Appropriations Committee
The Honorable Thad Cochran, Ranking Member, Senate Appropriations Committee
The Honorable Roy Blunt, Ranking Member, Senate Agriculture Appropriations Committee
The Honorable Hal Rogers, Chairman, House Appropriations Committee
The Honorable Norm Dicks, Ranking Member, House Appropriations Committee
The Honorable Jack Kingston, Chairman, House Agriculture Appropriations Committee
The Honorable Sam Farr, Ranking Member, House Agriculture Appropriations Committee