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**GPhA: Proposed Budget Highlights Need for Historic User Fee Proposals
*Expresses Concern with Lack of Increase in Appropriated Funds***

WASHINGTON, D.C. (FEB. 14, 2012) – The Generic Pharmaceutical Association (GPhA) today cited President Barack Obama’s fiscal year 2013 budget request as further evidence of the future benefits to consumers and the U.S. health care system that will be provided by the historic user fee proposals for both generic drugs and biosimilar products.

GPhA remains concerned, however, about several provisions included in the President’s proposed budget, including a ban on pro-consumer patent settlements, a failure to increase appropriated funds to the Food and Drug Administration (FDA) and an expansion of Medicaid rebates.

“The substantial increase in FDA funding shown in the President’s budget request is based almost entirely on user fee funding and is a dramatic example of the need for Congress to act promptly on these programs,” said Ralph G. Neas, President and CEO of GPhA. “By further ensuring U.S. drug safety and significantly reducing the time needed to commercialize a generic drug, the user fee programs will ensure that Americans continue to receive access to the safe and effective medicines that now save consumers and the U.S. health care system more than \$3 billion every week.”

“It is important to emphasize that the funding provided by the user fee programs is in addition to, not a substitute for, Congressional appropriations,” Neas added. “The sustainability of the U.S. health care system, including vital programs like Medicaid and Medicare, is absolutely dependent on the savings generated through the use of generic drugs. These savings can continue only if Congress sufficiently funds the FDA to assure timely approvals of new generic drugs.”

Unfortunately, the President’s budget incorporates an ill-advised proposal that would ban patent settlements, which have demonstrably saved billions of dollars for consumers, businesses and the government. GPhA has long maintained that the use of pro-consumer patent settlements is a vital tool in providing patients with early access to safe and affordable generic medications. Banning patent settlements would delay competition, and would cut by more than a third the number of new generics that are launched prior to brand patent expiration.

GPhA also believes it would be counterproductive to increase or extend Medicaid rebates beyond what currently is paid by manufacturers. Doing so would unconstructively shift costs to other payers in the private sector and burden manufacturers that are working hard to maintain American jobs. As costs increase in the private sector, revenues would decline as employers and employees take health care deductions for higher premiums.

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 78 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending. Additional information is available at gphaonline.org.