**FOR IMMEDIATE RELEASE**
February 14, 2011

CONTACT: Bob Billings 202-249-7100

GPhA Statement on Administration's FY 2012 Budget Request

# GPhA Rejects Proposal to Ban Settlements Based on Grossly Flawed Economic Analysis

**WASHINGTON, DC (FEBRUARY 14, 2011)** – The Generic Pharmaceutical Association (GPhA), which represents the world's leading generic drug manufacturers and suppliers, issued the following statement in response to President Obama's FY 2012 Budget Request that incorporates a proposal to ban pharmaceutical patent settlements between brand and generic drug companies:

"GPhA is concerned that the President's budget incorporates a proposal that would ban patent settlements, a misguided public health policy initiative that has repeatedly failed to receive Congressional support in separate and frequent legislative attempts at passage. The Administration's proposal purports that such a ban would save $8.8 billion over the next 10 years. GPhA believes that this economic assumption is fatally flawed.

"An August 2010 analysis conducted by Jonathan Orszag, former Director of the Office of Policy and Strategic Planning and member of President Clinton's National Economic Council, concluded that the Congressional Budget Office (CBO) used faulty assumptions to support the estimate of savings. Those faulty assumptions included the positions that: (1) banning settlements would accelerate generic competition; (2) banning settlements would save money; and (3) the Federal Trade Commission (FTC) needs additional authority to police settlements and reject anti-competitive deals. Also, the CBO analysis ignored the cost savings that continues to be generated from the pro-competitive, pro-consumer patent settlements that already have created savings and competition.

"It is important to note that the FTC already has the authority to review and reject any patent settlement, and that its challenges to the validity of settlements has been consistently and soundly rejected by the Courts. And it is important to note that patent settlements have never prevented competition beyond the patent expiry, and generally have resulted in the early, date-certain introduction of generics years earlier than would otherwise have been possible.

"Congress should reject this initiative, and instead concentrate efforts on those initiatives that would continue to dramatically reduce prescription drug spending; namely, promoting the increased utilization of generics for federal and state government funded health care programs and accelerating the approval of more affordable generics by increasing funding for the Office of Generic Drugs."

**Editors: GPhA Statements on other provisions in the FY2012 Budget Request:**

Shortened Period for Biological Exclusivity: "GPhA applauds the President for urging that the exclusivity period for branded biologics be reduced to seven years. There is no question that a 12-

year exclusivity period would provide unwarranted monopolies for brand biopharmaceuticals, which would delay the savings that could result from the earlier introduction of biogenerics."

Establishment of Generic Drug User Fees: "GPhA has long supported a workable and meaningful generic drug user fee program. This means implementing a holistic program with appropriate performance goals to assure the timely approval of generic drugs. The Office of Generic Drugs cannot keep pace with its workload without additional resources. GPhA is delighted that the President included generic drug user fees in his budget request and we are anxious to work with the Agency to make user fees a reality."

– 30 –

*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 consume just 22 percent of the total drug spending. Additional information is available at gphaonline.org.*