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CONTACT: Steve Arnoff  
202-249-7113

## **New Study Shows Pharmaceutical Patent Settlements Netted \$25.5 Billion in Savings for U.S. Health System**

WASHINGTON, D.C. – Generic pharmaceuticals launched prior to patent expiration due to a patent settlement helped the U.S. health system save \$25.5 billion from 2005-2012 and brought generic medicines to market on average 81 months sooner than patent expiry, according to a new analysis conducted for the Generic Pharmaceutical Association (GPhA) by the IMS Institute for Healthcare Informatics. An additional \$61.7 billion will be saved if the current level of savings continues through to patent expiry for each molecule analyzed, the study projects.

“For years, opponents of pharmaceutical patent settlements with consideration have stated that settlements create a cost for consumers, the government and others. This new analysis provides the most current, complete and transparent estimate of the impact of patent settlements on health costs, and it shows that the opposite is true,” said Ralph G. Neas, President and CEO of the Generic Pharmaceutical Association. “In particular, the new analysis estimates that patent settlements – including those with consideration – have led to billions in savings. For example, the settlement involving Lipitor alone will save \$22 billion over the next four years. This is critical for lawmakers to understand, because any further restrictions on settlements will put these savings at risk.”

The study analyzed a set of 33 molecules subject to patent settlements between 2005 and 2012 and measured the savings resulting from lower cost generics entering the market in advance of the each molecule’s patent expiration date as recorded in the FDA’s Orange Book. In addition, arithmetic modeling was used to estimate the proportion of patent settlements with consideration to derive estimated savings.

Key findings include:

- Generic pharmaceuticals launched prior to patent expiry as a result of a patent settlement reduced drug costs by \$25.5 billion from 2005-2012.
- The Federal government benefits from almost one-third (\$8.3 billion) of these savings.
- Savings from patent settlements with consideration, those at issue in the Court and legislation, would be between \$11.8 and \$13.6 billion if these settlements are typical of all settlements.
- The Federal government’s share of such savings would be between \$3.8 and \$4.4 billion.

Other findings:

- In addition to the \$25.5 billion saved by patent settlements from 2005 to 2012, the study projects an additional \$61.7 billion saved if the current level of savings continues through to patent expiry for each molecule analyzed. That equates to more than \$87 billion in savings from settlements.
- The study also looked at the savings that would have been negated if patent settlements

had not been an available course of action. Applying the success rate of 48%, derived from a separate Royal Bank of Canada analysis of patent challenges from 2000-2009, the IMS Institute found that realized (from 2005-2012) and projected (from 2013 until each molecule's patent expiry) savings of \$87 billion would have been reduced by nearly half, to only \$45 billion.

"Recent IMS Institute and Department of Labor studies have shown the first decline in drug expenditures in 55 years. We believe generic medicines, including those that come to market through settlements and settlements with consideration, have contributed to this historic success," said Neas.

Slides from the July 9, 2013 presentation are available here:

<http://www.gphaonline.org/gpha-media/gpha-resources/impact-of-patent-settlements-on-drug-costs-estimation-of-savings-ppt>

View the full report: <http://www.gphaonline.org/gpha-media/gpha-resources/impact-of-patent-settlements-on-drug-costs-estimation-of-savings>

GPhA reports, statements, fact sheets, legal briefs and related materials on patent settlements are available at: [www.settlementssave.org](http://www.settlementssave.org).

*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 80 percent of the prescriptions dispensed in the U.S. but consume just 27 percent of the total drug spending. Additional information is available at [gphaonline.org](http://gphaonline.org).*

Generic Pharmaceutical Association - 777 Sixth Street, NW, Suite 510 - Washington, D.C. 20001