FOR IMMEDIATE RELEASE
April 17, 2012
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GPhA Commends Supreme Court for Decision in Case That Threatened Generic Competition

WASHINGTON, D.C. (APRIL 17, 2012) – The Generic Pharmaceutical Association (GPhA) today applauded the U.S. Supreme Court's ruling in *Caraco Pharm. Labs, Ltd. V. Novo Nordisk A/S* — a case that threatened to eliminate a critical check on brand-name drug manufacturers' ability to block generic competition by providing FDA with misleading and overbroad descriptions of their patents.

"This ruling is a win for generic competition and, more importantly, a win for consumers," said Ralph G. Neas, President and CEO of GPhA. "We commend the Supreme Court for preventing Novo Nordisk's actions from becoming a playbook for all brands and costing consumers millions of dollars by delaying the introduction of affordable, lifesaving generic drugs."

The *Caraco* case involved the Hatch-Waxman Act's counterclaim provision, which complements "Section viii" of the act and facilitates generic competition by permitting generic drug manufacturers to market their products for FDA-approved uses not covered by any patent. When a generic drug manufacturer seeks marketing approval for only a drug's unpatented uses, Section viii allows FDA to grant a "carve-out" label that permits the generic to market the drug for those uses alone, thus avoiding litigation over patent infringement.

In the *Caraco* case, however, Novo Nordisk thwarted FDA approval by changing its "use code," a description of the patent required to be filed by the FDA. Because FDA is not institutionally equipped to question brands' use codes by reading their patents, Novo Nordisk's change prompted FDA to reject Caraco's proposed carve-out label. With this step, Novo Nordisk demonstrated a clear path for brands to circumvent Section viii — a practice that was then upheld by the U.S. Court of Appeals for the Federal Circuit. The Supreme Court's unanimous ruling overturns that decision and provides generic manufacturers with a clear judicial remedy for addressing the problem.

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.

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