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GPhA: FTC Position Misguided on Consumer Benefits of Patent Litigation Settlements

WASHINGTON, D.C., JULY 27, 2010 – Statement from the Generic Pharmaceutical Association (GPhA) on testimony of FTC Commissioner Jon Leibowitz before the U.S. House of Representatives Committee on the Judiciary, Subcommittee on Courts and Competition Policy.

“The FTC’s testimony fails to present the whole story regarding patent settlements. The six months of data presented by the FTC does not override the fact that over the past 10 years patent settlements have enabled dozens of first-time generics to come to market many months before patents on the counterpart brand drugs expired. For instance, settlement of the patent suit involving the anti-epileptic medication Lamictal® allowed the generic version to come to market three months prior to brand patent expiration, saving patients more than \$190 million during the early launch period.

“Yet, FTC chairman Jon Leibowitz continues to lobby Congress to pass legislation that would prohibit brand and generic manufacturers from settling costly patent litigation. Unfortunately, the FTC’s position is misguided and overlooks all the complete facts.

“Wall Street analysts, economists and court rulings continue to contradict FTC’s contention that settlements are bad for consumers. The FTC claims that settlements cost consumers \$3.5 billion a year. Yet, an independent report by Jefferies and Company, Inc. noted that they ‘don’t see how a thorough evaluation of the FTC’s analytical arguments could be convincing’ and that the FTC’s study is ‘deeply flawed, being based on improper assumptions and factual inaccuracies....’

“Another independent report from RBC Capital Markets concluded that of the 37 new generic drug launches expected in 2010 and 2011, 24 of them will be able to launch prior to patent expiration because of settlements. This will save consumers millions of dollars by speeding access to lower-cost generics.

“The FTC claims that settlements delay generics from coming to market. However, it is the patents that preclude or delay a generic from coming to market. Settlements have never resulted in delaying generic market entry past patent expiration. Winning drug patent litigation is a 50-50 proposition at best for generic companies. An analysis of 370 resolved drug patent suits from 2000 through 2009 revealed that generics were successful in just 48% of the cases that went to trial. However, adding in the cases that were settled brings the generic success rate, meaning generic launch prior to patent expiry, to 76%.

“When patents are involved, there are only 3 ways for generic drugs to come to market: (1) winning patent litigation in court; (2) settling patent litigation; or (3) waiting for a patent(s) to expire. And the FTC wants to restrict the use of one of them, leaving only a less than 50-50 prospect of winning in court, or forcing consumers to wait for patent expiration. Limiting early market entry is not pro-consumers.

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“With generics saving consumers and the health care system almost \$140 million in 2009 and \$824 billion over the last decade, it stands to reason that bringing generics to market sooner through a settlement would be pro-consumer. Consumers are looking for our government to provide them more affordable medicines, not limit their access.”

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.

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