



Testimony of the Generic Pharmaceutical Association on the Proposed Free Trade Agreement with Republic of Korea

March 14, 2006

Good morning. I am Shawn Brown, Director of Policy for the Generic Pharmaceutical Association. On behalf of GPhA and our members, I would like to thank the Office of the United States Trade Representative (USTR) and the interagency Trade Policy Staff Committee (TPSC) for the opportunity to share our views on the prospect of a free trade agreement between the U.S. and the Republic of Korea.

Today, 56% of all prescriptions in the U.S. are filled with generic medicines, yet they account for only 13% of the total expenditures on prescription drugs. GPhA is the sole association representing this sector of the pharmaceutical industry.

GPhA strongly supports a balance between fostering pharmaceutical innovation and ensuring access to affordable medicine. The strength of a pharmaceutical market depends on the security of intellectual property and the protection of the incentive to innovate new products. Of equal importance to a nation's health and the effectiveness of its pharmaceutical market is the cultivation of a robust generic industry able to provide affordable access to essential medicines. In free trade agreements, as with U.S. law, these interests must be balanced to provide the greatest benefit to the health of America and to our partners in trade.

FTAs should export the U.S. balance of pharmaceutical innovation and access to affordable medicine in order to ensure the same prosperity as that enjoyed by the U.S. However, recent FTAs and those currently being negotiated are contrary to or exceed U.S. law. GPhA recommends the following revisions be included in a U.S. FTA template for Korea:

- With respect to Patent Extensions, in contrast to U.S. law FTAs require no limit to the length of a patent extension; the U.S. limits patent extensions to 5 years and caps them at 14 years after the date of a drug's approval.
- Another area for revision would be Market Exclusivity. The market exclusivity provisions in the FTAs are excessively broad, excluding "same or *similar*" products from the market and requiring "at least" five years rather than a maximum of 5 years, like in the U.S.
- Like the U.S., FTAs also would grant 3 years of market exclusivity for new conditions of use—but under the FTAs, the exclusivity would apply to the "products" rather than the "new conditions of use" of the drug product. This would delay generic approval even for off-patent uses of a drug. And the FTAs also have no requirement

that such use be based on “new clinical information that is essential to its approval” as required in the U.S.

- Next, the “Bolar” Provision should be made mandatory. U.S. law requires that generic drug manufacturers be allowed to conduct research on a product during its patent life without infringing the patent. This essential provision is not required by any FTAs.
- Also, mandatory Best Mode should be included. U.S. law requires disclosure of the best method of practicing an invention. This promotes efficient use of scientific resources by eliminating redundant studies and research. The vast majority of FTAs exclude best mode, and no FTAs require it.
- Finally, Patent Linkage: the FTAs, as in the U.S., link the approval of a generic drug to the expiration of patents on the brand drug. But unlike the U.S., the FTAs provide:
 - no means to challenge questionable patents;
 - no incentive for the early resolution of patent disputes; and
 - no limit on the types of brand patents that can be listed for a drug product.

The absence of such measures creates de facto patent extensions by allowing questionable patents to delay approval of generic medicines.

U.S. taxpayers and consumers pay the highest prices in the world for their medicines and foot the majority of the bill for funding innovation. To ease this burden, President Bush’s administration aims to increase global sharing of research and development (R&D) costs. The USTR is charged with reducing foreign price controls on pharmaceuticals, but without free trade agreements that foster generic competition, such a goal is untenable.

The U.S. is approaching negotiations with the Republic of Korea. In the interest of promoting the health of both nations, GPhA implores the USTR to be mindful of the importance of balancing access and innovation.

Thank you for your time and attention and I will be happy to take questions or respond to any comments.