



**Testimony Before the Interagency Trade Policy Staff Committee on the
Proposed Free Trade Agreement with Malaysia: Generic Pharmaceutical Association**

May 3, 2006

Good morning. I am Kathleen Jaeger, President and CEO of 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 Malaysia.

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 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 Malaysia:

- With respect to Patent Extensions, in contrast to U.S. law, FTAs do not limit such extensions to New Chemical Entities (NCEs), nor do they require any 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—but under the FTAs, the exclusivity would apply to the "same or similar *products*" rather than the "new conditions of use" of the drug product studied. This would broaden the exclusivity to delay generic approval even for off-patent uses of the same drug and

related drug products. And the FTAs also have no requirement that the new 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, the concept of Linkage must be carefully examined. To date the FTAs link the approval of a generic drug to the expiration of patents on the brand drug which provides the brand pharmaceutical sector with an extra level of IP protection that no other industry enjoys. But unlike the U.S.:
 - the FTAs fail to limit the types of brand patents that can block generic competition; without these limitations the brand companies can misuse patents to needlessly block generic competition;
 - the FTAs provide no means to challenge questionable patents nor their applicability in the linkage system; and
 - they provide no incentive for the early resolution of patent disputes which need to run concurrently with the review and approval of the generic application.

As we have learned in the U.S., prior to the Medicare Modernization Act (MMA), the absence of these measures allows brand companies to exploit unintended loopholes to extend product monopolies to the detriment of consumers. It is our understanding that Malaysia is currently implementing an informal linkage system—one that lacks the necessary generic access provisions to prevent brand company abuses.

In fact, in Malaysia, generic manufacturers are effectively required to perform and submit a patent search when seeking approval, yet no apparent regulatory framework or guidance is provided to indicate precisely which patents trigger notification requirements. Furthermore, there appears to be no method for delisting questionable patents from the system. Although there are means to challenge questionable patents, the process can take up to 10 years; in contrast, patent challenges in the U.S. take an average of 2 years. With no viable and timely mechanism for challenging patents, abuses of the patent system are unfettered. Finally, to encourage efficiency, patent challenges in the U.S. run concurrently with the regulatory approval system. We advise USTR to negotiate for similar efficiency in the Malaysian FTA to prevent dilatory litigation and de facto patent



extensions. Should the U.S. decide to continue to promote linkage through the FTAs, it would be remiss not to include essential generic access measures. The strength of the U.S. pharmaceutical industry is founded on the careful balance of access and innovation within its intellectual property and drug regulatory systems.

President Bush's administration has set the admirable goal of increasing global sharing of research and development (R&D) costs. Accordingly, the administration has undertaken efforts to eliminate foreign price controls on pharmaceuticals. GPhA is supportive of this initiative as it will foster robust generic competition. Yet, free trade agreements that do not include the necessary generic access provisions undermine this laudable goal and are contrary to sound global health policy.

In the interest of promoting the health of both nations, GPhA implores the USTR to be mindful of the importance of balancing pharmaceutical access and innovation.

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