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**To:** <drugpricing@ita.doc.gov>

**Date:** 6/23/04 11:33AM

**Subject:** Submissions for MMA 2003 section 1123 study

Per the notice in the Federal Register [Federal Register: June 1, 2004 (Volume 69, Number 105)

Page 30882-30883], I submit the following documents for consideration in the study required under section 1123 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

I am willing to testify on the following topics:

- 1. The effect on pricing and innovation of drug importation from Canada and other OECD nations
- 2. The role of patents and TRIPS in drug innovation, including parallel trade (exhaustion rules) and non-patent marketing exclusivity rules (Hatch-Waxman, etc)
- 3. TRIPS Plus trade agreements, particularly the US-Australian FTA and its effect on Australia's PBS (a form of internal reference pricing with value-based economic evaluation).
- 4. State efforts to implement reference pricing.

I have attached a few of my recent articles. You need to hear from a few people who are not funded by PhRMA on these issues.

Best wishes,

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