

Congress of the United States

Washington, DC 20515

October 17, 2003

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

As you prepare for your trip to Australia scheduled for October 22-23, we are writing about an aspect of the U.S.-Australia Free Trade Agreement (FTA) that is of concern to us. Specifically, we want to ensure that the FTA does not weaken Australia's ability to evaluate the comparative effectiveness of pharmaceuticals, which in turn could hinder efforts to establish similar programs in the U.S.

The Pharmaceutical Benefits Scheme (PBS) is the Australian Government's system for providing prescription drug coverage for its population. One of the innovative features of the system is that it provides a mechanism for evaluating the relative cost effectiveness of drugs covered by the system. Its Pharmaceutical Benefits Advisory Committee, which consists of medical specialists, general practitioners, a pharmacist and a consumer representative, evaluates whether a drug is safe, effective and cost-effective in comparison with other available treatments. The reviews are largely based on the clinical and economic evidence provided by pharmaceutical manufacturers.

We believe that the United States should also establish an independent source of information on the comparative effectiveness and cost effectiveness of pharmaceuticals. We are cosponsors of the Prescription Drug Comparative Effectiveness Act (H.R. 2356). Our legislation would require the National Institutes of Health (NIH) to conduct research, and the Agency for Healthcare Research and Quality (AHRQ) to perform studies, on the comparative effectiveness and cost effectiveness of drugs that account for high levels of expenditures or use by individuals in federally funded health programs. Having NIH and AHRQ make this information available and accessible would be invaluable to clinicians, physicians and patients. The approach also has the potential to reduce our nation's prescription drug expenditures, by enabling doctors to make better informed prescribing decisions.

We raise this concern about the Australian Pharmaceutical Benefits Scheme because U.S. trade officials have suggested that the PBS could be subject to negotiation under the FTA.¹ In addition, the U.S. trade association for brand name drug makers

¹ Comments by Under Secretary of Commerce Grant Aldonas in "US wants reform of 'unfair' PBS," *Australian Financial Review*, August 12, 2003; comments by Assistant U.S. Trade Representative Ralph Ives in "U.S. wants Australia to modify its cheap drugs scheme as part of trade deal," *bmj.com*, March 29, 2003.

(PhRMA) has repeatedly petitioned the U.S. Trade Representative to target the Australian PBS as an alleged unfair trade practice.²

By their nature, trade agreements compel reciprocal treatment of policies and regulations. Thus, we are concerned that inclusion of any provision in the U.S.-Australia FTA that targets the Australian Government's ability to evaluate drug cost effectiveness under the PBS would have a chilling effect on efforts to establish similar mechanisms in the U.S. At worst, the existence of such a provision in the FTA could enable domestic legal challenges to the kinds of programs we seek to establish under H.R. 2356.

Therefore, as you prepare to discuss the U.S.-Australia Free Trade Agreement (FTA), we ask that you indicate to the Australians that the U.S. has no interest in negotiating any changes to the Australian Pharmaceutical Benefits Scheme that would hamper its ability to conduct and review comparative effectiveness and cost effectiveness studies on pharmaceuticals.

Thank you in advance for your consideration of this request.

Sincerely,



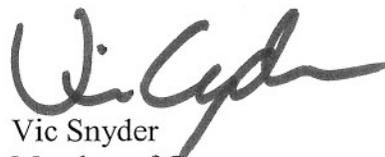
Tom Allen
Member of Congress



Jo Ann Emerson
Member of Congress



Doug Bereuter
Member of Congress



Vic Snyder
Member of Congress



Marion Berry
Member of Congress



Henry Waxman
Member of Congress



Zach Wamp
Member of Congress

² PhRMA's Special 301 submission to USTR for 2003 (and prior years), under Australia, Market Access Barriers