



**A Coalition of 14 Medical Societies Representing  
more than 200,000 Specialty Physicians in the United States**

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John D. Barnes, Chair  
jbarnes@aad.org  
(202) 842-3555

Gordon Wheeler, Vice-Chair  
gwheeler@acep.org  
(202) 728-0610

May 12, 2004

The Honorable Vice Admiral Richard H. Carmona, MD, MPH, FACP  
U.S. Surgeon General  
Department of Health and Human Services  
Chair, Task Force on Drug Importation  
Division of Dockets Management  
Docket No. 2004N-0115  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

Dear Surgeon General Carmona and Members of the Task Force:

Thank you for offering health care providers the opportunity to comment on the important public policy issue of prescription drug importation. My name is Karen Collishaw and I am Vice President for Science and Advocacy at the American College of Cardiology.

I am here today representing the Alliance of Specialty Medicine. Founded in 2001, the Alliance brings together 14 medical specialty societies representing over 200,000 physicians throughout the United States. The Alliance is dedicated to being a strong voice for specialty medicine and the patients who need access to specialty care. We are pleased to be part of this forum as patient advocates to discuss prescription drug importation and the health, safety, and welfare of our patients.

The escalating cost of many prescription drugs affects the most vulnerable patients - the elderly, the uninsured, and those with chronic health conditions - who are most in need of timely, appropriate and affordable healthcare. As is widely known, these patients often present with advanced and co-morbid conditions, leading to complex decision-making for physicians. Unfortunately, this decision-making process must include consideration of whether the patient can afford the most appropriate drug, or in many cases, multiple drugs, for treatment. The effectiveness of any disease management regimen will be seriously reduced if a patient skips doses to stretch medication or is forced to make the difficult decision not to fill a prescription because of a lack of financial resources.

You will not be surprised to hear that the Alliance is most concerned that our nation's prescription drug importation policy be designed to provide a safe and reliable source of these medications for patients. There are undoubtedly many safety and procedural issues associated with prescription drug importation that must be addressed by the Food and Drug Administration (FDA) and other relevant agencies. The Alliance supports the necessary authority and funding for these agencies to design and implement a monitoring system with controls to ensure the safety of imported drugs, consistent with the provisions of current law. Specifically, the safeguards in any and all importation policies must ensure that prescription drugs brought into our country are safe and effective for their intended use.

As you know, there are always opportunities for prescription errors, whether in the United States or any other country. No system can be guaranteed one hundred percent effective and sanitized against human error. However, the protections specified in current law on this subject, in addition to innovations such as bar coding and tamper resistant packaging, should help to reduce the risks to patients for drug importation.

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American Academy of Dermatology Association • American Association of Neurological Surgeons/Congress of Neurological Surgeons  
American Association of Orthopaedic Surgeons • American College of Cardiology • American College of Emergency Physicians  
American College of Obstetricians and Gynecologists • American College of Radiology Association  
American Gastroenterological Association • American Society for Clinical Pathology  
American Society for Therapeutic Radiology and Oncology • American Society of Cataract & Refractive Surgery  
American Urological Association • National Association of Spine Specialists • Society of Thoracic Surgeons

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The Alliance recognizes that prescription drug importation is not the solution to address all problems that patients have with access to care. For many of us here today, saving a few dollars on a prescription may seem insignificant...but for patients on fixed incomes, it is significant. Importation of prescription drugs, done safely, may be a step in the direction of reducing cost barriers and providing much-needed financial relief for patients.

On behalf of the Alliance, thank you for the opportunity to share our views.

Sincerely,

Karen Collishaw  
Vice President, Science and Advocacy  
American College of Cardiology

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