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28 May 2004



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HHS Task Force on Drug Importation
United States Department of Health & Human Services

To: Members of the Task Force:

As President of the American Academy of Pharmaceutical Physicians, I am writing you to state the Academy's strong position on importation and reimportation of drugs.

Let me first begin by stating that the AAPP is the sole organization in the United States that comprises a membership of Pharmaceutical Physicians (MD or the equivalent degree). Our physicians adhere to the Code of Ethics for the Practice of Pharmaceutical Medicine and they are committed to the mission of enhancing the proficiency of pharmaceutical physicians, promoting the profession of pharmaceutical medicine at all times, protecting the safety and welfare of patients and study subjects.

In 2003, the Academy wrote to the Conferees following a letter in the early summer from Speaker Hastert regarding our opposition to HR 2427, the Pharmaceutical Manufacturing Access Act. The Academy endorsed and adopted the position of the American Medical Association (AMA) as the official position of the Academy regarding reimportation and shares the AMA's serious concerns about this issue that may ultimately affect millions of lives.

In keeping with our Statement on Drug Pricing, AAPP is committed to availability of affordable but reliable medicines for all Americans. We believe that despite the allegedly lower prices, medications that are the subject of reimportation or parallel importation cannot be protected or assured for quality or integrity.

The American Academy of Pharmaceutical Physicians contends that the discussion confuses drug safety and drug pricing and that the critical issue, which is not being addressed, is patient safety. The Task Force is well aware that drugs that are distributed in the USA must meet the appropriately high standards of the FDA. While many other countries have similar standards to those in the USA, such countries have varied standards for the importation of drugs into their country, making the issue of second and third country importation considerably more complex than it first appears. We are not aware of any foreign governments that have expressed a willingness to certify the safety of medicine for export to the USA or any other country.

Accordingly, the AAPP continues to contend that we cannot support *carte blanche* legislation that allows the importation of drugs from other countries. Our stance will not change if it can be verified that drugs imported to the USA are subjected to the same scrutiny and high standards that the public has the right to expect, as at present. The USA has already developed a reasonable balance between the opposing forces of protection for intellectual property (which fosters innovation and the discovery of new drugs) and the availability of less expensive generic drugs.

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American Academy of Pharmaceutical Physicians

To ignore patient safety in the pursuit of lower drug pricing, we believe, is unethical. It is clear that, at present, the appropriate safeguards cannot be implemented and therefore the Academy opposes the importation of drugs into this country outside the normal distribution channels that are subject to our current high standards of regulation.

Drug pricing issues must be viewed as secondary to those relating to patient and product safety.

As "The Voice of Physicians Engaged in Pharmaceutical Medicine," we accept our responsibility as experts in the field to educate and inform other healthcare professionals, policy makers, reimbursement agencies, the public, and our patients about the appropriate use of today's drugs, their equitable provision, and their true value. As noted earlier, without question, we are devoted to the protection and welfare of patients and study subjects.

We strongly urge consideration of the public well being, namely, patient safety, as top priority. Importation or reimportation of drugs without the scrutiny of the FDA puts the public at serious risk because drug quality and integrity cannot be assured.

Thank you for the opportunity to again state AAPP's position on this important issue. Please do not hesitate to have your staff contact our Medical Director, Dr. Joan L. Drucker in the National Office of AAPP at (919) 355 – 1004, or me if you have any questions about our organization, our medical specialty, or our position on this most critical topic.

Sincerely,

John D Irvin, MD, PhD

John D. Irvin, MD, PhD
President & Chairman of the Board

Cc: Members of the AAPP Executive Committee

Joan L. Drucker, MD, CPI
Medical Director

(919) 355-1004



American Academy of Pharmaceutical Physicians
The Voice of Physicians Engaged in Pharmaceutical Medicine

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