
IMPORTATION

It is critical that we maintain our focus on comprehensive health reform to help all Americans access high-quality and affordable healthcare coverage. We should not pursue policies that could expose Americans to substandard drug products and potentially weaken the Food and Drug Administration (FDA) by crippling the Agency's ability to fulfill its mission in protecting public health and safety.

The Food and Drug Administration (FDA) has repeatedly said that if importation measures advocated by some members of Congress were to pass, the agency could not verify whether or not the medicines coming into U.S. borders from foreign countries are the real deal. And, former Secretaries of Health and Human Services Donna Shalala – under President Bill Clinton – and Tommy Thompson – under President George Bush – have both stated that they could not certify the safety of prescription medicines that come into the U.S. outside the current closed drug distribution system.

The worldwide counterfeit epidemic is very real and very scary. The World Health Organization has said that up to 10 percent of medicines available globally are counterfeits, posing a serious health hazard. In addition, the Center for Medicines in the Public Interest estimated that counterfeit drug sales will reach \$75 billion globally in 2010, an increase of more than 90 percent from 2005.

The alarming rate of counterfeit products being manufactured and sold around the world poses great challenges to federal agencies such as FDA and Customs and Border Protection (CBP) under the Department of Homeland Security (DHS). In fact, public statements by DHS suggest that there has been a significant increase in seizures of counterfeit imports at U.S. borders. For this reason, PhRMA believes that Congress should continue to maintain – not weaken – FDA's relatively closed drug supply system and also ensure that CBP and FDA have the resources to seize potentially dangerous and counterfeit products at our nation's borders.

It has also been reported in other countries around the world that there is a growing concern that counterfeit medicines are touching the lives of more and more of its citizens every day: the European Commission reported that it saw a 51 percent increase in counterfeit medicine seizures in the European Union in 2007 . According to the World Health

Organization, more than 30 percent of medicines in some areas with weak regulatory agencies in Latin America, South East Asia and Africa are counterfeit.

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Until comprehensive health reform moves forward to help all Americans access high-quality and affordable healthcare coverage, there are safer alternatives that can help patients access medicines:

- The Medicare prescription drug program is working and has helped more than 40 million seniors and America's disabled save on average \$1,200 a year on their medicines.
- The Partnership for Prescription Assistance (PPA) – a program spearheaded by America's pharmaceutical research companies – has helped more than 4 million uninsured and underinsured Americans access programs that provide free or nearly-free medicines. Patients can access more information about PPA by calling a toll free number, 1-888-4PPA-NOW or going online at www.pparx.org.

Visit www.buysafedrugs.info for more information about counterfeit medicines and the dangers of importation.

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