

[sent 12-15-2011]

VIA ELECTRONIC MAIL
Honorable Brian P. Bilbray,
United States House of Representatives
2410 Rayburn HOB
Washington, DC 20510

Dear Representative Bilbray:

We are writing to commend you on your leadership in introducing the Safeguarding America's Pharmaceuticals Act of 2011, H.R. 3026, with Mr. Matheson. We agree that this vital legislation is needed to protect the American public from counterfeit and diverted drug products, which continue to enter the U.S. distribution market despite existing regulations and action by industry.

As you know, the U.S. distribution system that brings drugs from the manufacturer to the patient is extremely complex, creating opportunities for highly lucrative schemes to move stolen or counterfeit drugs into legitimate channels of distribution—and then to patients. These products may be degraded, clinically dangerous or ineffective, putting patients at risk. For example:

- Two men were convicted in 2008 for a \$6.8M scheme in which they bought medicines from Medicaid patients on the streets of New York and resold them to a wholesaler, who then sold them to pharmacies. These included drugs for treating cancer and for controlling cholesterol, as well human growth hormone. Patients were unaware that the drugs were resold and could have been stored in unsafe conditions.
- In 2009 thieves stole 129,000 bottles of insulin, which is temperature sensitive. The medicine was stored under unknown conditions before it was sold back into distribution where it reached pharmacies and ultimately patients with diabetes.
- In 2002 criminals in Florida relabeled as high dose up to 110,000 bottles of low dose Epogen™ and the generic Procrit, used by cancer and transplant patients. These counterfeit products yielded a profit of \$46M. More than 90,000 vials may have reached patients; the scheme was uncovered when several patients suffered painful side effects.
- In 2003 counterfeit Lipitor™ from Central America was illegally imported and sold into U.S. distribution.ⁱ

These types of schemes could be stopped before patients are harmed if we implemented a uniform national track and trace system to better secure drug distribution.

Drug products can pass through many hands before reaching patients, moving between large wholesalers, smaller wholesalers, large chain drugs stores or small pharmacies. Federal statute requires smaller wholesalers to maintain transaction history 'pedigrees' of the drugs they buy and sell, but wholesalers listed as "authorized distributors" by manufacturers—usually larger distributors—are exempt from this requirement. A uniform track and trace system would allow a drug's provenance to be easily verified, providing assurance that the product is legitimate.

As you know, the state of California took the lead on the “pedigree” issue in 2004 when it passed legislation spearheaded by the Board of Pharmacy, CA senior groups and Health System Pharmacists. Subsequent CA legislation delayed implementation of state requirements until 2015-17,ⁱⁱ with a proviso that it would become “inoperable” if comparable federal legislation is passed. Twenty-eight other states have also passed some form of drug pedigree law, but varying provisions make industry compliance complicated and open to abuse. Comprehensive federal legislation like H.R. 3026 would ensure consistency, as well as meet the California legislature’s deadline and goals.

We support the establishment of a national system to permit the authentication of drugs as they travel through distribution, and we see the Safeguarding America’s Pharmaceuticals Act of 2011 as a key reform to establish such a system. Specifically, we support:

- Requiring manufacturers to place a unique identification number on each package of drugs (the smallest salable unit) bought and sold in the United States.
- Establishing an electronic tracking system to allow companies to verify the authenticity of the drugs they buy and sell, and requiring every entity that receives a drug during distribution to perform such authentication.
- Strengthening national guidelines for state wholesaler licensure standards.

We believe federal action is required now to ensure the safety and quality of the U.S. drug supply through a uniform track and trace system.

We ask that you continue to press your colleagues in the House and Senate to enact Safeguarding America’s Pharmaceuticals Act of 2011, H.R. 3026.

Thank you for your leadership, and please do not hesitate to call on us for support.

Sincerely,



Marcia Hams
Director, Prescription Access and Quality
Community Catalyst
Community Catalyst
On behalf of:

Berkeley-East Bay Gray Panthers
California Alliance of Retired Americans (CARA)
California Citizens for Health Freedom
California Public Interest Research Group (CALPIRG)
Community Catalyst
Congress of California Seniors
Gray Panthers Association of California Networks

cc: **Members of the California House delegation**

ⁱ *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*. Pew Prescription Project/Pew Health Group. 2011. See pgs. 74, 75, 76 and 79 for sources and more information on these examples and others.

ⁱⁱ http://www.pharmacy.ca.gov/about/e_pedigree_laws.shtml Accessed October 29, 2011