



May 11, 2011

Dear Representative,

Medication Safety affects virtually every home in your district and across the country. It is essential that we protect families from contaminated and substandard prescription and over-the-counter medications. We hope Congress will act this year to close the gaps in our current system for regulating the drug supply chain, gaps which make all consumers vulnerable. That is why Community Catalyst, AFSCME, Alliance for Retired Americans, Consumers Union, Families USA, Medicare Rights Center, National Physicians Alliance, Our Bodies, Ourselves and U.S. PIRG strongly support HR 1483, introduced April 12 by Mr. Waxman, Mr. Dingell, Mr. Pallone and Ms. DeGette, a bill that would ensure that drugs and their ingredients imported to the U.S. are safe.

Recent alarming incidents show that the risks to the American public are growing. By mid 2008, an estimated 149 patients died after taking adulterated heparin, a blood thinner used every year by hundreds of thousands of kidney dialysis patients alone.^{1, 2, 3} Last year, poor manufacturing by Johnson & Johnson led to the recall of millions of over the counter medicines.⁴ And GlaxoSmithKline paid \$750 million to settle fines after admitting to knowingly selling millions of contaminated, adulterated, and substandard drugs manufactured in Puerto Rico.⁵

These are just a few examples of the known risks that consumers currently face. But the increasingly global nature of drug manufacturing means that more than 80 percent of active drug ingredients and bulk chemicals are now manufactured overseas.⁶ The number of drug products made at non-U.S. sites doubled between 2001 and 2008.⁷ FDA does not have the authority or resources to effectively inspect foreign suppliers of drug ingredients. Domestic plants are inspected by FDA on average every 2.5 years, while the average inspection at foreign plants is every nine years. Many Chinese or other foreign facilities may never be inspected by FDA under the current inspection schedule.⁸

An April 2010 Hart Research poll of U.S. voters indicates strong public support across party lines for reforms to improve drug safety, with 81% of Republicans, 87% of Independents, and 97% of Democrats supporting increased FDA authority to issue recalls, destroy contaminated products upon import, and inspect foreign manufacturing facilities.⁹

HR 1483 would provide FDA with new authority in these and other important areas. It allows mandatory recalls and the ability to stop importation of drugs from plants that fail safety inspections or deny access to FDA inspectors. HR 1483 also increases FDA oversight of foreign plants, and requires that industry meet new standards for adherence with current Good Manufacturing Practices (cGMP).

We urge you to support this critical legislation to protect residents in your district and across the country. More detail on the bill can be found in the attached letter from the sponsors. **For more information or to sign on as a co-sponsor, please contact Kimberlee Trzeciak in Congressman Dingell's office at 225-4071 or kimberlee.trzeciak@mail.house.gov.**

Thank you in advance for your consideration. Please do not hesitate to contact me if you have any questions.

Sincerely,



Marcia Hams
Director, Prescription Access and Quality
Community Catalyst

on behalf of

AFSCME
Alliance for Retired Americans
Community Catalyst
Consumers Union
Families USA
Medicare Rights Center
National Physicians Alliance
Our Bodies, Ourselves
U.S. PIRG

About the organizations signing this letter:

The American Federation of State, County and Municipal Employees, **AFSCME**, is a union of 1.6 million members who provide the vital services that make America happen. With members in hundreds of different occupations – from nurses to corrections officers, child care providers to sanitation workers – AFSCME advocates for fairness in the workplace, excellence in public services and prosperity and opportunity for all working families.

The four million member **Alliance for Retired Americans** brings together progressive activists to educate and mobilize retirees around local, state, and national issues. We aim to reform health care, strengthen Social Security and pensions, and improve the quality of life for current and future retirees.

Community Catalyst is a national non-profit consumer advocacy organization that collaborates with organizations in over 40 states to achieve wide-reaching federal and state health care reforms in many areas, including prescription drug access and quality.

Consumers Union, the non-profit publisher of Consumer Reports, has long been an advocate for improved safety and efficacy of pharmaceuticals. Our popular Best Buy Drugs reports, with 100,000 readers per month, provide rigorous, evidence-based, comparative-effectiveness information on a range of commonly used drugs. Our information is available to up to 10 million subscribers via *Consumer Reports* magazine, ConsumerReports.org website, ConsumerReportsHealth.org, *Consumer Reports On Health* newsletter, and *ShopSmart* magazine, and to nearly 20 million viewers of our syndicated TV news segments from CRTV.

Families USA is a national consumer advocacy organization. For over 20 years, Families USA has been advocating for access to affordable, quality health care for all Americans.

The **Medicare Rights Center** is a national, non-profit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs and public policy initiatives.

The **National Physicians Alliance** is a non-profit organization uniting physicians across medical specialties to create a genuinely inclusive, accessible, and patient-centered health care system. Refusing funding from pharmaceutical and medical device companies, the NPA believes that for too long, industry interests have outflanked the needs of patients, with negative implications for patient safety and health care affordability.

Our Bodies Ourselves provides accessible, research-based information about women's health and sexuality. We advance health and human rights within a framework of values shaped by women's voices and a commitment to self-determination and equality.

U.S. PIRG, the federation of state Public Interest Research Groups (PIRGs), stands up to powerful special interests on behalf of the American public, working to win concrete results for our health and our well-being.

¹ FDA, *Information on adverse events and heparin*, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112669>, Accessed April 29, 2011.

² Usdin, Steve. *The Heparin Story*. International Journal of Risk and Safety in Medicine. Vo. 21, 99-103. 2009.

³ Blossom, David., Kallen, Alexander J., et al. *Outbreak of Adverse Reactions Associated with Contaminated Heparin*. NEJM December 18, 2008. 359:2674-84.

⁴ David Voreacos, Alex Nussbaum and Greg Farrell. *Johnson & Johnson's Quality Catastrophe*, Bloomberg Businessweek, March 31, 2011. http://www.businessweek.com/magazine/content/11_15/b4223064555570_page_4.htm.

⁵ U. S. Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant*, Oct. 26, 2010. <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>.

⁶ U.S. Government Accountability Office, *Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program*. (Publication No. GAO/HEHS-98-21) March 1998.

⁷ Woodcock, Janet. *The FDA's Response to Biogenerics, QA and Globalization. Unbranding Medicines: The Politics, Promise and Challenge of Generic Drugs*. Harvard Interfaculty Initiative on Medicines and Society. December 12, 2008.

⁸ Government Accounting Office, *Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed*, GAO-10-961, a report to the Committee on Oversight and Government Reform, House of Representatives, Sept. 2010. <http://www.gao.gov/new.items/d10961.pdf>.

⁹ Hart Research Associates. April 2010. *American Attitudes on Prescription Drug Safety*, http://www.prescriptionproject.org/tools/initiatives_resources/files/Drug-Safety-Poll-Findings-2.pdf.