



November 29, 2011

Chairman Fred Upton & Ranking Member Henry Waxman
U.S. House Committee on Energy and Commerce
2125 Rayburn House Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

Tens of millions of children, seniors, and other Americans rely upon prescription and over-the-counter medicines for their health. The safety and quality of drug manufacturing affects virtually every household across the country. Yet recent events affecting hundreds of millions of over-the-counter and prescription drug products are sobering reminders that ensuring the quality of drug production is critical. Both regulators and significant sectors of industry agree that increased oversight is needed to ensure patient safety and confidence in drug manufacturing. We must commit ourselves to improving FDA authority and resources to protect the public's health.

Recent high-profile events have drawn public attention to the issue of manufacturing quality in the pharmaceutical sector:

- Serious, repeated quality problems by Johnson & Johnson led to the recall of over 130 million bottles of over the counter medicines¹ causing nationwide shortages, and prompting investigations by FDA and Congress.
- GlaxoSmithKline pled guilty to criminal felony charges related to numerous manufacturing deficiencies, including mixing different drugs in the same bottle, selling drugs without the approved mix of active ingredients, selling pills with "critical defects" that reduced their effectiveness, and bacteria contamination.² As millions of U.S. patients took these defective and potentially dangerous drugs between 2001 and 2005, GSK ignored their own internal quality staff assigned to fix the problems -- a disturbing story revealed by *60 Minutes* early this year.³

These examples likely represent only the tip of the iceberg. While the FDA has discovered many safety and quality lapses by domestic manufacturers, this is likely due to the FDA's far more frequent and effective inspection of domestic sites. **However, foreign sites receive far fewer inspections, and thus most of the manufacturing problems there may go undetected.** The FDA lacks the resources and authority to adequately inspect foreign manufacturers, or to ensure their compliance with good manufacturing practices.

FDA inspects nearly all 2,500 domestic plants every two years. But 40% of medicines and more than 80 percent of active drug ingredients and bulk chemicals used to make drugs domestically are imported from approximately 3,800 foreign manufacturers in more than 150 countries.⁴ The two-fold increase in the number of foreign suppliers in the last seven years⁵ means that the FDA can inspect these 3,800 foreign sites only once every nine years.⁶ Thus **thousands of these foreign drug manufacturers have never seen a single FDA quality inspection.**

Within many of these countries (such as the largest suppliers of US drug imports, China and India⁷) regulatory oversight of manufacturing practices by local government is weak or non-existent. Foreign

suppliers have provided falsified data to the FDA, and as many as 39% of US and European drug manufacturers are misinformed about the true source of the drug ingredients they purchase.⁸

The risks of obtaining drug ingredients from unaccountable foreign suppliers were tragically illustrated in 2007 and 2008 when **numerous deaths and hundreds of adverse reactions were caused by the intentional contamination of heparin**, a blood thinner taken by hundreds of thousands of dialysis or post-operative patients every year.⁹ But despite these fatal consequences for some U.S. patients, FDA did not have sufficient authority to thoroughly investigate this Chinese supplier's records and facilities.¹⁰

Looking forward, a recent FDA report warns that economic pressure to maintain profits has driven the outsourcing of drug manufacturing to places where drug manufacturing costs 30 to 40% less. Even 'high risk' medical products such as vaccines and complex medical devices have been outsourced. These risks will increase as the dwindling number of new drugs in the development pipeline creates more pressure to outsource in order to maintain current profits from fewer drug products. And the risks of counterfeit drugs, already the leading black-market activity globally, will increase along with other potential fraud and adulteration as suppliers become more numerous and supply chains become more complex.¹¹

Industry leaders recognize these risks. Half of the pharmaceutical and life sciences executives surveyed in late 2010 saw raw materials imported from outside the U.S. as the greatest vulnerability to the supply chain, and 61% viewed contaminated or nonconforming raw materials as the top threat in the next five years.¹² The generic industry has already stepped up to the plate, agreeing to fund inspections with user fees in order to ensure public confidence in their products.¹³

And voters support reform. A poll of U.S. voters indicated strong public support across party lines. 81% of Republicans, 87% of Independents, and 97% of Democrats support increased FDA authority to issue recalls, destroy contaminated products upon import, and inspect foreign manufacturers.¹⁴

Change is needed -- regulators, the public, and regulated industry all call for it. Therefore it is critical that Congress provide the FDA with authority to ensure that the medicines we take are manufactured safely. Congress should:

- Update enforceable quality standards ensuring that manufacturers are responsible for quality controls throughout their supply chain
- Improve FDA inspections and oversight of high risk sites, especially overseas.
- Give FDA updated authority so that it can recall dangerous drugs, or destroy adulterated products at the border.

As the Chairman and Ranking Member of the House Committee on Energy and Commerce, we respectfully request that you make drug safety legislation a priority for inclusion in the upcoming reauthorization of the Prescription Drug User Fee Authorization Act (PDUFA).

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

Sincerely,



Marcia Hams
Director, Prescription Access and Quality
Community Catalyst

on behalf of

Action for Boston Community Development (ABCD)
AFSCME
Alliance for Retired Americans
Breast Cancer Action
California Alliance for Retired Americans (CARA)
Center for Medical Consumers
Community Catalyst
Connecticut Center for Patient Safety
Consumers Union
Families USA
Florida CHAIN
Health Law Advocates of Louisiana, Inc.
Illinois Public Interest Research Group (Illinois PIRG)
Medicare Rights Center
Mississippi Human Services Coalition
Missouri Alliance for Retired Americans
National Education Association (NEA)
National Labor Alliance of Health Care Coalitions
National Physicians Alliance
National Research Center for Women & Families / Cancer Prevention and Treatment Fund.
National Women's Health Network
New Hampshire Alliance for Retired Americans
North Carolina Justice Center's Health Access Coalition
Ohio Alliance for Retired Americans
Pennsylvania Public Interest Research Group (PennPIRG)
TeamstersCare - Teamsters Union 25 Health Services & Insurance Plan
Texas Alliance for Retired Americans
UHCAN Ohio
USAction
USPIRG
Vermont Public Interest Research Group(VPIRG)

cc: **Members of the House Committee on Energy and Commerce**

About the organizations signing this letter:

ABCD through its centrally managed programs and neighborhood network provide low-income greater Boston residents with the tools for self-help that enable them to overcome poverty, live with dignity and achieve their full potential.

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.

Breast Cancer Action carries the voices of people affected by breast cancer to inspire and compel the changes necessary to end the breast cancer epidemic.

The **California Alliance for Retired Americans (CARA)** is California's largest grassroots progressive advocacy organization representing over 900,000 seniors and their families through our 200+ affiliated community and labor retiree organizations. CARA works to improve the quality of life for seniors at the local, state and national level.

The **Center for Medical Consumers** is a New York City-based consumer advocacy organization.

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.

The **Connecticut Center for Patient Safety (CTCPS)** promotes a patient centered system that supports prevention and provides well-informed delivery of care. Today, CTCPS continues to fight for better, quality care and the protection of injured patients' rights through education, accountability, and grassroots advocacy, and now, online advocacy.

Consumers Union, the policy and advocacy division 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.

Florida CHAIN's (Community Health Action Information Network) mission is to improve the health of all Floridians by promoting sustainable access to affordable, effective health care. Our

priorities include promoting access to health care for those who are uninsured, underinsured, and supported by government programs.

Health Law Advocates of Louisiana is the only nonprofit public interest law firm in the state that is dedicated to ensuring access to quality healthcare access for low-income Louisianians, through direct client representation, systemic and impact advocacy, and consumer education.

The **Illinois Public Interest Research Group (Illinois PIRG)** is a non-profit, citizen watchdog and consumer advocacy organization.

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.

Mississippi Human Services Coalition is a state-wide network of activists and community organizations that has been working for progressive change for over 30 years. It is a major monitoring, information, and analysis group focusing on issues with particular impact on the poor in areas such as health, social services, education and civil liberties.

The **Missouri Alliance for Retired Americans** is a progressive advocacy organization representing community based advocacy groups, union retirees and individuals working together in recognition of the role played by older and retired workers in the life of the state and the nations. The members understand the importance of developing and disseminating accurate information about issues that affect them in a non-partisan manner, the need to create public policies that foster their well-being, the importance of engaging in nonpartisan voter education, registration and mobilization, and the need to maintain and increase their participation in the civic life of the State.

The **National Education Association (NEA)** is the largest professional organization and largest union in the United States with 3.2 million members. NEA represents pre-K-12 public school teachers and support professionals, faculty and staff at colleges and universities, retired educators, and students preparing to become educators.

The **National Labor Alliance of Health Care Coalitions** is a national network of labor and management health and welfare coalitions representing purchasers of health services, working together to increase value in services and benefits. Our 23 participating member coalitions provide benefits to 10 million labor union members, their families, and retirees. Our network includes Taft-Hartley funds in 29 states, including Illinois, Michigan, New Jersey, North Carolina, Ohio, and Pennsylvania.

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.

The **National Research Center for Women & Families** promotes the health and safety of women, children, and families, by using objective, research-based information to encourage new, more effective programs and policies. The Center achieves its mission by gathering and analyzing

information and translating that information into clearly presented facts and policy implications that are made widely available to the public, the media, and policy makers.

<http://www.center4research.org/> The **Cancer Prevention and Treatment Fund** helps children and adults reduce their risks of getting all types of cancer, and assists them in choosing the safest and most effective treatments. We carefully analyze research by scientists around the world, and draw conclusions about the best strategies for preventing and treating cancer. We help keep you healthy and help you get the best medical care by making information available to doctors, patients, family members, and the public. <http://www.stopcancerfund.org/>

The **National Women's Health Network** improves the health of all women by influencing policy and supporting informed consumer health decision-making. The NWHN believes that evidence rather than profit should drive the services offered and information that is made available to women to inform their health decision making and practices. We are supported by our national membership and do not accept financial support from pharmaceutical companies, tobacco companies or medical device manufacturers.

The **New Hampshire Alliance for Retired Americans** is a grassroots voice for over 13,000 New Hampshire retirees. We bring together union and non-union retirees to speak up for Social Security, Medicare and prescription drug affordability and safety.

The **North Carolina Justice Center's Health Access Coalition (NCHAC)** works to "put people first" in an increasingly profit-driven health care system. We advocate for the expansion of publicly funded health services for low- and moderate-income families, and we provide research and analysis on the state's health care system.

The **Ohio Alliance for Retired Americans Educational Fund** is a coalition of community and union organizations working together making our affiliate members 230,000 senior voices heard on the laws, policies, community concerns and institutions that shape our lives. Our mission is to advance public policy that protects and promotes the health and economic security of older Ohioans.

The **Pennsylvania Public Interest Research Group (PennPIRG)** is a state-wide, non-partisan, non-profit consumer advocacy organization.

TeamstersCare is a Taft Hartley Health and Welfare Fund providing health benefits, including prescription drug benefits, for Teamsters Local Union 25 members, retirees and their families.

The **Texas Alliance for Retired Americans** is the grassroots voice of almost 112,000 Texans. We educate, mobilize and advocate on public policy issues that affect seniors and their loved ones at the national and state level.

UHCAN Ohio is a statewide consumer health advocacy organization working for high quality, affordable health care for all Ohioans.

USAction builds power by uniting people locally and nationally, on-the-ground and online, to win a more just and progressive America.

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.

Community Catalyst is a national non-profit advocacy organization building consumer and community leadership to transform the American health care system.
www.communitycatalyst.org

Founded in 1972, The **Vermont Public Interest Research Group (VPIRG)** is the largest nonprofit consumer and environmental advocacy organization in Vermont. VPIRG's mission is to promote the health and well-being of Vermont's people and environment by informing and mobilizing citizens across the state. For nearly four decades, VPIRG has infused public policy debates with the voices of Vermont citizens concerned about health care, the environment, consumer protection, and democracy.

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 - ² 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, available at <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>.
 - ³ 60 Minutes, *Bad Medicine: The Glaxo Case*, January 2, 2011 5:15 PM, available at <http://www.cbsnews.com/video/watch/?id=7206290n>, transcript available at <http://davidbozek.net/2011/01/20/text-of-the-60-minutes-interview-with-glaxo-smithkline-whistle-blower-cheryl-eckard/>.
 - ⁴ Autor, Deborah, FDA Deputy Commissioner for Global Regulatory Operations and Policy, Testimony before the U.S. Senate Committee on Health, Education, Labor and Pensions, Sept. 14, 2011, available at <http://www.fda.gov/NewsEvents/Testimony/ucm271073.htm>.
 - ⁵ FDA, *Pathway to Global Product Safety and Quality*, June, 2011, at 15, available at <http://www.fda.gov/AboutFDA/CentersOffices/OC/GlobalProductPathway/default.htm>.
 - ⁶ 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, available at <http://www.gao.gov/new.items/d10961.pdf>.
 - ⁷ U.S. Government Accountability Office, *Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program*, Sept. 2008, at 15, at <http://www.gao.gov/products/GAO-08-970>.
 - ⁸ Pew Health Group, *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*. July 2011, at 27, 30, and generally, available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Health/Pew_Heparin_Final_HR.pdf
 - ⁹ FDA, *Information on adverse events and heparin*, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112669>; See also Usdin, Steve, *The Heparin Story*, International Journal of Risk and Safety in Medicine. Vol. 21, 99-103. 2009.
 - ¹⁰ Mundy, Alicia, *China Never Investigated Tainted Heparin, Says Probe*, July 22, 2010, available at http://www.prescriptionproject.org/tools/initiatives_resources/files/wallstreetjournal7.21.10.pdf.
 - ¹¹ FDA, *Pathway to Global Product Safety and Quality*, supra not 5, at 18, 20, 21.
 - ¹² PwC Health Industries, *Global Supply Chain Increases Risks, Threats Drug Discovery & Development*, Oct. 27, 2010, at www.pwc.com/us/supplychainsurvey.
 - ¹³ Harris, Gardiner, *Deal in Place for Inspecting Foreign Drugs*, NY Times, August 13, 2011, available at <http://www.nytimes.com/2011/08/13/science/13drug.html>.
 - ¹⁴ 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.