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Comments of Community Catalyst, the American College of Physicians, the American Federation of State, County and Municipal Employees, the Bulk Pharmaceuticals Task Force, Consumers Advancing Patient Safety, Health Care for All (Massachusetts), and Our Bodies Ourselves

Concerning

**The United States Food and Drug Administration
Draft Strategic Priorities 2011-2015
“Responding to the Public Health Challenges of the 21st Century”
Administration Docket No. FDA-2010-N-0506-0001**

November 1, 2010

We are a diverse group of stakeholders, including Community Catalyst,¹ the American College of Physicians,² the American Federation of State, County and Municipal Employees (AFSCME),³ the Bulk Pharmaceuticals Task Force,⁴ Consumers Advancing Patient Safety,⁵ Health Care for All (Massachusetts),⁶ and Our Bodies Ourselves,⁷ and we jointly submit the following comments on FDA Draft Strategic Priorities 2011-2015. *We strongly support the proposed cross-cutting strategic priority 2.2 regarding strengthening the safety and integrity of the global supply chain.*

Draft Strategic Priority 2.2 recognizes the increasing threat of contamination and adulteration of medical products due to the globalization of the pharmaceutical manufacturing process, and acknowledges the importance of strengthening the global supply chain to protect all American consumers. We applaud FDA’s recognition that known cases of contaminated medications like heparin are a distress signal calling for increased FDA regulation, monitoring, and oversight.

Many problems can arise during the complex drug manufacturing and distribution system, and the results can be tragic. In 2007 and 2008, 149 patients in the U.S. died after they were given contaminated heparin, a widely used blood-thinner.⁸ The contamination is believed to be the result of the deliberate introduction of a low-cost material in place of the pure drug during the product’s manufacture in China.⁹

In 2006, diethylene glycol, a human toxicant commonly used in commercial products such as antifreeze, was labeled as glycerin, a common inactive ingredient for cold and cough syrups. Medicinal syrups contaminated with diethylene glycol in China were imported to Panama through a European broker, and at least 78 people in Panama died.¹⁰ Diethylene glycol has been associated with nine known poisoning epidemics worldwide, including 105 deaths in the U.S. in 1937. Cold and cough syrups are commonly available over-the-counter in the U.S. Strengthening the supply chain would positively impact safety of both prescription and over-the-counter medications.

The increase in volume and complexity of imported medical products presents new challenges to FDA. In 2007, Pfizer reported it sought to increase its outsourced manufacturing from 15 percent to 30 percent, primarily to Asia.¹¹ GlaxoSmithKline's outsourcing increased from 9 percent to 41 percent of costs from 2001 to 2007,¹² and AstraZeneca announced plans to outsource all Active Pharmaceutical Ingredient production to China and India.¹³ At least 80 percent of the active ingredients and bulk chemicals in U.S. prescription drugs now originate overseas, often from countries like China and India with weak enforcement of quality standards.¹⁴

Documentation and transparency throughout the manufacturing and distribution process, as well as industry commitment to ensuring manufacturing quality throughout the supply chain, is fundamental to the safety of the drug supply. While we would also support Congressional action to expand FDA authority and increase FDA resources to address the drug supply chain issue, we endorse FDA's proposed strategies as a critical foundation upon which meaningful progress can be made.

Consumer Impact and Concerns

The underlying goal of addressing the global supply chain issue is to protect all U.S. consumers, ranging from infants and children, to seniors. The impact of a drug supply chain malfunction is potentially enormous given U.S. adults and children alike have increasingly come to rely on pharmaceuticals to treat and manage of a wide variety of common, chronic and serious medical conditions.^{15, 16}

A 2006 nationwide survey found 82 percent of adults in the U.S. took at least one medication in a given week, and 29 percent reported taking five or more.¹⁷ In any given week, 56 percent of children take at least one medication, and 27 percent take two or more. Seniors continue to consume the most medications; in the 2006 study, 17 to 19 percent of people over age 65 reported taking more than ten medications per week. A Centers for Disease Control and Prevention (CDC) report for 2007-2008 also found that nine out of every ten older Americans (over 60 years old) take at least one prescription drug per month.¹⁸ Overall, the CDC reports that the percentage of Americans who took at least one prescription drug in the last month has increased by 10 percent over the last decade.

Many prescription medications are crucial for preventing and treating illness and helping to avoid more costly health problems.¹⁹ We support the prevention-based model FDA is proposing to provide safe prescription and over-the-counter medications to consumers.

A recent poll commissioned by the Pew Prescription Project found most Americans have confidence in the safety of drugs manufactured in the United States.²⁰ However, the same poll found a majority of Americans has concerns about the safety of drugs manufactured overseas. These concerns underscore the importance of strengthening weak regulatory structures in developing nations where drug manufacturing increasingly occurs.

American consumers need to be confident that when they choose a prescription or over-the-counter medication, the product purchased or dispensed at their pharmacy is not contaminated, contains the correct amount of Active Pharmaceutical Ingredients, and has been properly stored. For these reasons, we support FDA's proactive plan to prevent future harm to consumers.

Health Care Provider Perspective

Health care providers are among the stakeholders affected by the drug supply chain issue. Providers want to ensure their patients receive necessary drugs and want patients to comply with prescribed drug therapy and treatment plans. Not only could actual contamination in the drug supply jeopardize patient health, but credible fears of contamination could jeopardize patient health if patients and providers interrupt treatment due to uncertainty around safety.

Pharmacists, the last institutional safeguard of the prescription drug delivery system, also rely on a safe drug supply chain to help patients make the best use of their medications. All of their efforts to help improve medication use and advance patient care are compromised if medication integrity is questionable.²¹ We support the FDA's priority of improving the global supply chain to support the health care delivery system and the work of health care providers.

Drug Component Manufacturer Perspective

The manufacturing industry also has a vested interest in drug safety and improvements to the global pharmaceutical supply chain. Some manufacturing groups have expressed support for FDA working with a global alliance of regulators to ensure that Active Pharmaceutical Ingredient production follows good manufacturing practices. This would include ensuring foreign facilities operate under comparable standards to U.S. manufacturers so public health risks are minimized.²²

Regardless of whether ingredients originate in the U.S. or overseas, the production of all drug components should comply with standardized good manufacturing procedures. Of all possible consumer goods, medications should not be subjected to manufacturing short-cuts or high-risk cost savers. Enforceable global supply chain standards will facilitate production of high-quality products. We encourage FDA to adopt its proposed strategic priority to ensure that product supply chains are monitored throughout the product life cycle and to help ensure good manufacturing processes are always used.

Conclusion

We agree with FDA that Americans expect and deserve a safe drug supply. We wholeheartedly support FDA's proposal to strengthen the safety and integrity of the global supply chain to provide protection to U.S. consumers who rely on medications of all types,

whether they be for the common cold, a chronic disease such as diabetes, or a life-threatening condition such as cancer. Concerns about pharmaceutical treatment choices, side-effects and other clinical issues are complex enough for patients and providers without the added complication that products could be contaminated or adulterated.

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¹ Community Catalyst is a national non-profit health care advocacy organization based in Boston.
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² The American College of Physicians is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 130,000 internal medicine physicians (internists),

related subspecialists, and medical students. Internists specialize in the prevention, detection, and treatment of illness in adults. www.acponline.org

³ The American Federation of State, County and Municipal Employees (AFSCME) is the largest union in the AFL-CIO with 1.6 million members who provide the vital services that make America happen and advocate for prosperity and opportunity for all working families.

⁴ The Bulk Pharmaceuticals Task Force is an industry trade organization for U.S. manufacturers of active pharmaceutical ingredients (APIs), their intermediates and excipients. Created in 2002 as an affiliate organization with the Society of Chemical Manufacturers and Affiliates, its primary objective is to seek clarification of current regulatory requirements and to interact with government agencies on emerging issues that may impact SOCMA members.

⁵ Consumers Advancing Patient Safety (CAPS) is a consumer-led non-profit organization formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. CAPS is committed to exploring and contributing to wisdom and experience that consumers can offer to patient safety research, education of both consumers and providers, reporting of bad outcomes and near misses, development and implementation of solutions that can prevent harm, and policy making that will help create healthcare systems that are safe, compassionate and just.

⁶ Health Care for All (HCFA) is a Massachusetts-based, nationally recognized non-profit organization dedicated to making affordable and quality health care available to everyone. HCFA's work combines policy analysis, information and referrals, public education, legislative advocacy and community organizing in an integrated approach aimed at building a grassroots movement for health care reform. www.hcfama.org

⁷ Our Bodies Ourselves, also known as the Boston Women's Health Book Collective, is a nonprofit, public interest women's health education, advocacy, and consulting organization. www.ourbodiesourselves.org

⁸ The number of reported deaths is from www.fda.gov/Cder/drug/infopage/heparin/adverse_events.htm and includes only patients with symptoms consistent with those caused by the contaminant. This represents a marked increase in deaths over the previous year, but some reports may have been stimulated by public awareness, and causality cannot be determined precisely.

⁹ Staff Testimony, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. U.S. House of Representatives. Hearing on "The Heparin Disaster: Chinese Counterfeits and American Failures" April 29, 2008.

¹⁰ Rentz, E. Danielle. World Health Organization: "Outbreak of Acute Renal Failure in 2006: A Case-Control Study." 2010. <http://www.who.int/bulletin/volumes/86/10/07-049965/en/print.html>. Accessed October 25, 2010.

¹¹ Goldstein, Jacob. Pfizer Aims to Outsource More Manufacturing. *Wall Street Journal* Health Blog. November 30, 2007. <http://blogs.wsj.com/health/2007/11/30/pfizer-aims-to-outsource-more-manufacturing/tab/article/>. Accessed October 25, 2010.

¹² Barnes, Kristy. GSK to strip down through outsourcing and offshoring. *Drugresearcher.com*. October 26, 2007. <http://www.outsourcing-pharma.com/Contract-Manufacturing/GSK-to-strip-down-through-outsourcing-and-offshoring>. Accessed October 25, 2010.

¹³ Jarvis, Lisa M. AstraZeneca Leaves Manufacturing: British firm looks to China for its pharmaceutical chemical production needs. *Chemical & Engineering News*. Volume 85, Number 31, July 30, 2007. <http://pubs.acs.org/cen/business/85/8531bus3.html>. Accessed October 25, 2010.

¹⁴ U.S. Government Accountability Office. (1998, March). "Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program." (Publication No. GAO/HEHS-98-21).

¹⁵ Patterns of Medication Use in the United States 2006: A Report from the Slone Survey Slone Epidemiology Center. Boston University.

¹⁶ Vernacchio, L. Medication Use Among Children < 12 Years Of Age In The United States: Results From The Slone Survey. *Pediatrics*. 2009;124(2):446-454.

¹⁷ Patterns of Medication Use in the United States 2006: A Report from the Slone Survey Slone Epidemiology Center. Boston University.

¹⁸ Gu Q, Dillon CF, Burt VL. Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008. NCHS data brief, no 42. Hyattsville, MD: National Center for Health Statistics. 2010.

¹⁹ American College of Physicians. Improving FDA Regulation of Prescription Drugs. Philadelphia: American College of Physicians; 2009: Policy Monograph.

²⁰ Americans on Prescription Drug Safety, April 2010, Hart Research/POS for Pew Prescription Project. http://www.prescriptionproject.org/tools/initiatives_resources/files/Drug-Safety-Poll-Findings-2.pdf. Accessed October 25, 2010.

²¹ American Pharmacists Association Issue Brief, “Counterfeit Medications: Protecting Our Nation’s Medication Supply.” March 2009. <https://www.aphanet.org/AM/Template.cfm?Section=Home2&CONTENTID=20007&TEMPLATE=/CM/ContentDisplay.cfm>. Accessed October 25, 2010.

²² Society of Chemical Manufacturers & Affiliates Press Release, “SOCMA’s Bulk Pharmaceutical Task Force Supports Senate Drug Safety Bill: Measures Increase Protection of Drug Supply Chain.” August 4, 2010. <http://www.socma.com/PressRoom/index.cfm?subSec=3&sub=71&articleID=2557>. Accessed October 25, 2010.