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July 29, 2013

The Honorable Tom Harkin
U.S. Senate
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Lamar Alexander
U.S. Senate
455 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Harkin, and Ranking Member Alexander,

I write on behalf of The Pew Charitable Trusts, an independent research and policy organization, to express support for S.959, The Pharmaceutical Quality, Security and Accountability Act. This bipartisan legislation will improve patient safety by meaningfully enhancing the security of the drug supply chain. This legislation will also take steps to improve federal oversight of certain aspects of pharmacy compounding.

Congress has been trying to address vulnerabilities in the U.S. pharmaceutical supply since it passed the Prescription Drug Marketing Act of 1987. S.959 is an important improvement over the status quo by ensuring there will be a national unit-level serialization and traceability system to track the movement of drugs throughout the entire supply chain in 10 years.

Congress has also long struggled with how to regulate the growing pharmacy compounding industry. This bill recognizes that the industry has changed significantly over the last several decades and attempts to mitigate the risks associated with large-scale production of sterile drugs by bringing under federal oversight any facility that produces (1) sterile products, (2) without, or in anticipation of, a prescription, and (3) sells those products into interstate commerce. This addresses certain high-risk facilities while leaving traditional pharmacy dispensing essentially untouched. The safety of compounded drugs is a critical public health issue, and the failure of the status quo is illustrated by numerous incidents, including the recent fungal meningitis outbreak that has cost so many lives. The time for Congress to act is now.

Thank you again for your bipartisan commitment to improving the safety of the U.S. drug supply by addressing gaps in both our drug distribution security system and the oversight of pharmacy compounding. We would also like to thank Senator Burr and Senator Bennet as leaders on drug supply chain security and Senator Roberts and Senator Franken as champions for the compounding provisions of the bill. We would also like to thank all of your staff for their dedication and professionalism. We applaud your efforts to date, and we look forward to continue working with you to make this legislation as strong as possible on behalf of all consumers.

Sincerely,

Allan Coukell
Senior Director, Drugs and Medical Devices
The Pew Charitable Trusts