

August 1, 2013

The Honorable Tom Harkin, Chairman  
731 Hart Senate Office Building  
Washington, DC 20510

The Honorable Al Franken  
309 Hart Senate Office Building  
Washington, DC 20510

The Honorable Lamar Alexander, Ranking Member  
455 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Barbara Mikulski  
503 Hart Senate Office Building  
Washington, DC 20510

The Honorable Pat Roberts  
109 Hart Senate Office Building  
Washington, DC 20510

The Honorable Elizabeth Warren  
317 Hart Senate Office Building  
Washington, DC 20510

Dear Chairman Harkin, Ranking Member Alexander, and Senators Roberts, Franken, Mikulski and Warren:

The organizations listed below are writing in support of S. 959, the “Pharmaceutical Quality, Security, and Accountability Act” of 2013. This bipartisan legislation will address the regulatory gaps that exist with respect to sterile compounding and help prevent a tragedy such as the meningitis outbreak of 2012 from occurring in the future. In addition, it will protect the public health by ensuring that compounding entities who operate in a manner more closely resembling manufacturing will be regulated and inspected by the Food and Drug Administration (FDA).

S. 959 would create a new category of registration through the FDA for commercial compounding outsourcers now referred to as compounding manufacturers. We believe this will close the regulatory gap and jurisdictional uncertainty between the FDA and state boards of pharmacy while maintaining state oversight of the practice of pharmacy, which includes traditional pharmacy compounding.

We firmly believe this bipartisan legislation adequately reflects recent shifts in the pharmaceutical marketplace that have spurred an evolution of a new type of drug entity that prepares sterile compounded products as a service to customers who administer them to patients, rather than a traditional pharmacy compounder who prepares sterile compounded products pursuant to a prescription, or in limited quantities for anticipatory use. In addition, we are grateful the Committee recognized the valuable role that traditional compounding pharmacies play in patient care, and that the bill keeps traditional compounding pharmacies under state board of pharmacy purview.

We thank you for your leadership in addressing the regulatory gaps in non-patient specific sterile compounding and ensuring that entities preparing sterile products and introducing them into interstate commerce are properly inspected by and accountable to the FDA. We look forward to working with you and the full Congress to pass this critical legislation.

Sincerely,



