July 31, 2013

The Honorable Tom Harkin
U.S. Senate
Washington, D.C. 20510

The Honorable Lamar Alexander
U.S. Senate
Washington, D.C. 20510

Dear Chairman Harkin and Ranking Member Alexander:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, and the Children’s Hospital Association, representing more than 220 children’s hospitals nationwide, we write to thank you for S. 959, the Pharmaceutical Quality, Security, and Accountability Act, specifically title I of the substitute amendment. We believe this legislation will give the Food and Drug Administration (FDA) additional tools it needs to ensure the safety of the compounded products pediatricians give their patients.

Pharmaceutical compounding for pediatric patients is a critical component of the care pediatric providers give their patients. Countless numbers of children would have no other treatment option if it were not for pharmaceutical compounding. Medications commercially manufactured for adults are often not available for children or may be packaged in doses too large or too strong to be given to children and must be divided into smaller doses or diluted. Children’s medications must typically be preservative-free and often must be converted from solid to liquid for children too young to swallow a pill. We are grateful that you and your staff have worked diligently for months to ensure that the legislation strikes the right balance between safety and access for pediatric populations.

The substitute amendment attempts to protect and preserve traditional compounding while creating a framework for compounding manufacturers that will require such manufacturers to register with the FDA and be subject to FDA inspections. We believe that this added FDA oversight will give pediatric providers greater confidence in the safety of the products they give their patients.

Of particular note, we thank you for including the health system exception which treats hospital pharmacies such as children’s hospital pharmacies as traditional compounders, preserving the current oversight framework in place today of state boards of pharmacy, accreditation organizations, and the Centers for Medicare and Medicaid Services. This provision is essential for maintaining pediatric providers’ ability to repackage, compound, dilute, divide down and otherwise provide care for pediatric patients, while increasing the oversight of compounding manufacturers. Children’s hospitals, perhaps significantly more often than adult institutions, must rely on compounding for the children under their care on a routine basis.
We remain deeply concerned about the impact drug shortages continue to have on children. There are greater pressures to rely on compounding as a result of new and persistent drug shortages. We appreciate that the legislation contains provisions intended to protect against exacerbating drug shortages and join you in the hope and expectation that the legislation will not make an already untenable situation worse. Pediatric providers have faced one drug shortage crisis after another in recent years. We encourage Congress and federal agencies to work together to find a more permanent solution on drug shortages.

We look forward to working with you to advance the legislation. Thank you for your dedication to the health and well-being of children.

Sincerely,

Thomas K. McInerny, MD, FAAP
President
American Academy of Pediatrics

Jim Kaufman
Vice President, Public Policy
Children’s Hospital Association

cc The Honorable Al Franken
The Honorable Pat Roberts