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The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education,
Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lamar Alexander
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
835 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Alexander:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you for your bipartisan leadership in continuing to address concerns about and to improve S. 959 the "Pharmaceutical Quality, Security, and Accountability Act." The substitute amendment to S. 959, balances the need for clear oversight and greater accountability for certain compounding pharmacy practices with measures to ensure access to medically necessary treatments for patients by preserving anticipatory compounding for, among other things, emergent and urgent uses. In addition, the substitute amendment contains important provisions that provide the U.S. Food and Drug Administration (FDA) with expanded discretion to permit compounding of products when drug shortages exist.

As we communicated previously, the AMA is acutely aware of the challenge faced by Congress, the FDA, and state regulators in establishing a clear and efficient framework for oversight of compounding, particularly of those pharmacies engaged in large scale, interstate compounding. We agree that, in the wake of the New England Compounding Center tragedy, a strong public safety imperative exists to strengthen federal oversight of those compounding activities that may present a higher degree of risk to patient safety. We generally support establishing a clear distinction between regulation and oversight of compounding manufacturers (as defined in S. 959) and traditional compounders that are subject to state oversight.

We appreciate your efforts to work with the AMA and other physician organizations to include a number of provisions to ensure that this legislation does not impede patient access to medically necessary compounded products administered by physicians, as well as provisions to address concerns about access to compounded alternatives when there is a shortage of a FDA-approved marketed drug or biologic. The substitute amendment to S. 959 will enhance accountability, quality, and safety.

Sincerely,

James L. Madara, MD