June 13, 2013

The Honorable Tom Harkin
Chairman
Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington DC 20510-0001

The Honorable Al Franken
United States Senator
309 Hart Senate Office Building
Washington DC 20510-0001

The Honorable Lamar Alexander
Ranking Member
Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington DC 20510-0001

The Honorable Pat Roberts
United States Senator
109 Hart Senate Office Building
Washington DC 20510-0001

Dear Chairman Harkin and Senators Alexander, Roberts and Franken:

Please accept my thanks for the opportunities you have given PCCA to work directly with the Senate HELP Committee to provide our input and insights into S. 959. We appreciate both your questions and responses to our concerns. Like you, we are thoroughly committed to assuring that the practice of compounding pharmacy meets the highest quality standards.

We believe, however, that the framework of the compounding provisions of S. 959 is fatally flawed with respect to achieving its intended purpose. Though we understand that you have listened carefully, we have come to different conclusions about how to reach our shared goal. In fact, as representatives of our more than 4,000 independent community-pharmacy members, I must report that S. 959 represents a worst-case scenario for our profession, our prescribers and our patients. It will unintentionally limit, not expand, access to quality custom-compounded medications.

You have made it clear that the heart of the compounding provisions of the bill— inserting the FDA into a state-controlled profession and incorrectly assuming that FDA oversight ensures the quality and safety of compounded drugs—is not a matter of debate. With that clear position in mind, I’m writing to let you know that our organization opposes the compounding provisions in S. 959. Hanging ornamental amendments on this structure may improve the look of this bill, but will not enhance its broad acceptance by practicing pharmacists, physicians and their patients who depend upon compounding’s quality, innovation and freedom. At this juncture, we must agree to disagree.
Simply put, the pharmacy profession has decades of evidence and legal history that the FDA’s purpose is to hobble compounding pharmacy, not to encourage its growth as a profession that solves problems for prescribers and patients. The core of S. 959’s compounding provisions shifts power from the states to the FDA, enabling the agency to interfere even more substantially with our profession and the prescribers and patients who depend upon us.

As an agency both overseeing and being funded by mass manufacturers of pharmaceuticals, the FDA’s incentives are to limit or stunt the progress and expansion of compounding. These are diametrically opposed to the objectives of the pharmacy profession, which is to seek new and expanded avenues for serving prescribers and patients, many of which are manifested by filling the large and small gaps left by the companies the FDA regulates.

It is clear to us that pharmacists, physicians, veterinarians and millions of patients share our skepticism about the FDA’s proposed role in the compounding provisions of S. 959. So, as a matter of the courtesy we promised your staff, please understand that our resources now will be devoted to bringing the unintended and devastating consequences of the bill to the attention of our colleagues, prescribers and patients.

Thank you for the opportunity you provided to be heard. We expect you will hear more from advocates of personalized medicine.

Sincerely,

Jim R. Smith
President, PCCA

CC: Senate HELP Committee Members