



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Steven C. Anderson, IOM, CAE
President & Chief Executive Officer

November 14, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

As Congress continues to investigate the tragedies surrounding the recent meningitis outbreak, the National Association of Chain Drug Stores (NACDS) would like to share our perspectives on pharmacy compounding and the critical, life-saving benefits that it provides. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over \$1 trillion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.81 trillion, equal to 12 percent of GDP.

The type of compounding tied to the recent meningitis outbreak, sterile compounding, is a much smaller subset of compounding, and sterile compounding must be performed in very controlled settings. Sterile compounding is not the kind of compounding that is typically available to a patient who walks into a chain pharmacy to fill a prescription.

Compounding services are the only source of critical medications for millions of patients with unique health needs. For these patients, there are no commercially manufactured preparations available. Through compounding, pursuant to a prescription, pharmacies provide these patients with personalized medications. Frequently, these types of personalized medications meet the needs of patients who are allergic to a dye or other ingredient, or need a different strength or dosage form from what is commercially available. Sometimes, however, compounding is also necessary to help provide critical medications in the event of a prescription drug shortage. For example, chain pharmacists helped to meet the need for liquid Tamiflu during the 2009 H1N1 flu outbreak through their ability to compound the liquid product from Tamiflu capsules – and at the request of FDA.

Prescription compounding has been a traditional function of the practice of pharmacy ever since the beginning of the profession. For many years, compounding was synonymous with the practice of pharmacy. Although compounding is not as widespread as it once was, compounding continues to be an integral function of pharmacy practice.

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Pharmacists are trained to prepare compounded medications and are tested on this competency. State boards of pharmacy license pharmacies after ensuring, among other things, that they have the proper tools and equipment to compound prescription products. State boards of pharmacy regularly inspect pharmacies, including their compounding practices.

FDA has compliance guidelines for pharmacy compounding. NACDS supports FDA and the state boards of pharmacy working together to identify sites that violate FDA's compounding compliance guidelines. We further support FDA and the state boards of pharmacy working together to investigate any questionable practices so that compounding is regulated appropriately and in the best interest of patients.

We would welcome the opportunity to discuss with you the importance of pharmacy compounding in meeting individual patients' health care needs. Please do not hesitate to contact Tom O'Donnell, Vice President, Federal Government Affairs, at (703) 837-4216 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, IOM, CAE
President and CEO