September 4, 2013

Chairman Fred Upton
Chairman
Energy and Commerce Committee
US House of Representatives
2125 Rayburn HOB
Washington, DC 20515

Henry A. Waxman
Ranking Member
Energy and Commerce Committee
US House of Representatives
2322A Rayburn HOB
Washington, DC 20515

Chairman Upton and Ranking Member Waxman:

The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. Independent community pharmacies dispense approximately 40% of the nation’s retail prescription drugs, and almost 86% of independent community pharmacies compound. These independent community pharmacies perform a wide variety of compounding services including hormone replacement medications, flavoring medications for pediatric patients, progesterone suppositories to prevent miscarriages, and medications for cystic fibrosis patients, to name a few.

Last fall the tragic practices and events surrounding the New England Compounding Center (NECC) were uncovered and our thoughts and prayers continue to be with the family and friends of the victims of the horrific meningitis outbreak. We certainly understand and appreciate the federal government's desire to prevent a tragedy like this from occurring again. That is why we have, and will continue to, work with the House and Senate as they consider legislative proposals to change current laws surrounding drug compounding.

Compounding is the backbone of pharmacy practice and for many decades independent community pharmacists have provided millions of adults, children, and animals with access to safe, effective and affordable medications through compounding services. When manufactured drugs aren’t an option, state licensed pharmacists prepare customized medications for patients in accordance with a doctor's prescription based on the patient's individual needs. Compounding can help bridge the gaps during times of drug shortages. Drug shortages have nearly tripled, according to the FDA, and their impact can be devastating.

NCPA commends members of the House Energy and Commerce Committee for taking a closer look at what actions and inactions led to the tragic NECC event. The Committee has taken the proper steps to address this tragedy by investigating what steps should have been taken and oversight to ensure that the appropriate regulatory bodies are exercising their full authority. NCPA also is grateful to Congressman Morgan Griffith for his tireless efforts to prevent a tragedy like NECC from occurring again while also making certain individuals maintain access to their vital compounded medications. It is essential that in addressing this tragedy and preventing future
tragedies, that Congress does not act in a manner that interferes with the triad relationship of patient-physician-pharmacist, and prevents patients from obtaining their necessary compounded medications.

While NCPA supports the efforts by the House Energy and Commerce Committee to investigate the actions and inactions leading to this tragedy, NCPA is very concerned with the broad overreach of FDA authority within the Senate compounding legislation, the *Pharmaceutical Compounding Quality and Accountability Act* (S. 959). We believe the Senate legislation would create unnecessary federal regulatory burdens, hamper independent community pharmacies from providing medications to patients with unique health needs, and far exceeds a targeted approach to prevent another tragedy such as NECC.

S. 959 would broaden FDA authority by requiring pharmacies to report directly to the FDA when they are compounding medications to alleviate a drug shortage. During the H1NI outbreak several years ago, when Tamiflu was in short supply, independent pharmacies utilized their compounding expertise to fill the void. As drug shortages continue to skyrocket with no relief in sight, Congress must make certain that patients receive medication in a timely manner, not create further delays by adding additional bureaucracy.

Furthermore, by allowing the FDA to unilaterally create a “do not compound” list, it could potentially be used to prevent compounding of hormone medications, thyroid preparations, promethazine gels, and medications to treat autism, as several examples. Thus, the Senate legislation grants FDA overly broad authority and impedes patient access to vital medications instead of directly addressing the issues that led to the meningitis outbreak caused by NECC.

Despite the good intentions of S. 959, the legislation falls short in protecting the public against another NECC tragedy as well as protecting beneficiary access to vital compounded medications. As the unintended consequences of the compounding provisions in S. 959 on pharmacy compounding have largely been unaddressed, NCPA cannot support S. 959 in its current form.

Therefore, as an alternative to S. 959, NCPA strongly supports the discussion draft in the House of Representatives circulated by Mr. Griffith. His draft rightfully maintains state board of pharmacy oversight of traditional compounding pharmacies while strengthening badly need two-way communications between the FDA and state boards of pharmacy. State boards of pharmacy have traditionally exercised oversight over the practice of pharmacy and are best suited to continue this role. The House draft also preserves a pharmacy’s ability to engage in anticipatory compounding so long as it is reasonable and based on historical patterns. The House discussion draft also preserves the usual and customary practice of compounding for multiple patients receiving the same or similar medications at hospitals, physician offices, and other health entities, which are additional areas where S. 959 misses the mark.

Our independent pharmacies provide a needed service in compounding medications and have a long history of protecting patient safety while preserving patient access to vital medicines.
medications. While NCPA cannot support S. 959 in its current form, NCPA supports the Griffith discussion draft in the House as a workable solution that appropriately addresses the issues that led to the NECC tragedy.

NCPA looks forward to working with Congress to preserve access to vital compounded medications while best addressing the practices surrounding the NECC tragedy. Please contact NCPA Senior Vice President Government Affairs, Steve Pfister at (703) 683-8200.

Sincerely,

B. Douglas Hoey, CEO National Community Pharmacists Association