United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

Hearing on "Reforming the Drug Compounding Regulatory Framework"

Tuesday, July 16, 2013

Chairman Pitts, Vice-Chairman Burgess, Ranking Member Pallone and Members of the Subcommittee, the National Community Pharmacists Association (NCPA) greatly appreciates the opportunity to testify today and share the community pharmacy perspective on legislation addressing pharmacy compounding. NCPA represents the interests of America's community pharmacists, including the small business owners of more than 23,000 independent community pharmacies. According to a NCPA member survey, almost 86% of independent community pharmacies compound medications. Our members perform a wide variety of compounding services including hormone replacement medications, making suspensions palatable for pediatric patients, different dosage forms for patients suffering from intractable nausea and vomiting, and medications for cystic fibrosis patients, to name a few.

NCPA commends members of this Committee for taking a closer look at what actions and inactions led to the tragic NECC event. This Committee has taken the proper steps to address this tragedy by focusing on investigations into 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 Griffith for his tireless efforts to prevent a tragedy like NECC from occurring again while also making certain individuals maintain access to their essential compounded medications.

NCPA supports the approach of Rep. Griffith's discussion draft as it is not a broad expansion of FDA power over historically state-regulated pharmaceutical compounding but, to the contrary, strikes a proper balance of making certain that future tragedies are avoided while also preserving patients' access to vital compounds.

Rep. Griffith's Discussion Draft Recognizes the Importance of Compounding

Representative Griffith's discussion draft recognizes that pharmacist compounding is an integral part of the pharmacy profession and meets patients' needs in a variety of care settings. When manufactured drugs aren't an option, independent community pharmacists prepare customized medications for patients in accordance with a prescriber's prescription based on the patient's individual needs.

Rep. Griffith's Discussion Draft Preserves State Board of Pharmacy Oversight

In addition, NCPA fully supports efforts by Rep. Griffith's discussion draft to preserve state Board of Pharmacy oversight of pharmacy compounding. NCPA has always and will continue to advocate that pharmacy compounding is best regulated by the state Boards of Pharmacy while manufacturing is overseen by the FDA. Boards of Pharmacy currently oversee all aspects of pharmacy practice. If the FDA has a concern about an appropriately-licensed pharmacy, then the FDA currently has the authority to ask the state Board of Pharmacy to work with them to address the issue.

Rep. Griffith's Discussion Draft Preserves Office Use and Anticipatory Compounding

NCPA also strongly supports efforts by Rep. Griffith's discussion draft to preserve office use and anticipatory compounding where state laws allow such practices. In order to preserve access to compounds, Rep. Griffith's discussion draft acknowledges that pharmacies should not be hindered in their ability to engage in anticipatory compounding as long as it is reasonable and based on a historical pattern of prescriptions or for specific patients served by that pharmacy. In addition, NCPA supports Rep. Griffith's discussion draft's efforts to preserve the usual and customary practice of compounding for multiple patients receiving the same or similar medications at hospitals, physician offices, and other health entities.

Rep. Griffith's Discussion Draft Increases Communication between the FDA and State Boards of Pharmacy

Furthermore, NCPA strongly supports the efforts of Rep. Griffith's discussion draft in recognizing that strengthening communication between FDA and state Boards of Pharmacy is essential. NCPA believes one of the leading contributors to the NECC tragedy was the failure of the FDA to exert the existing authority it has to oversee entities going beyond pharmacy compounding. Communication and coordination between state boards of pharmacy and the FDA is imperative. Rep. Griffith's draft addresses issues such as that currently, state Boards of Pharmacy have no way of knowing whether FDA has followed up on actions previously taken against an entity. Boards do not know whether the response from an entity being inspected by the FDA addresses all concerns and is sufficient without necessary further action or whether further action is needed.

NCPA has Concerns with other Legislative Proposals

While NCPA appreciates all efforts on this very important issue, NCPA has strong concerns with other legislative proposals including:

(1) Granting FDA additional authority to create "do not compound" lists.

Contrary to Rep. Griffith's discussion draft, other legislative proposals grant FDA unrestricted authority to designate drugs or specific categories of drugs to a "do not

compound" list prohibiting these drugs from being compounded. This proposal could potentially allow FDA to prohibit compounding pharmacies from compounding hormone medications, thyroid preparations, promethazine gels, and medications to treat autism, as several examples. These "do not compound lists" would give FDA overly broad authority to regulate compounding. This would be an unnecessary expansion and overreach of FDA authority over the practice of pharmaceutical compounding while doing nothing to prevent another tragedy like NECC.

(2) *Requiring community pharmacies to notify FDA when compounding medications that are in shortage.*

While Rep. Griffith's discussion draft adequately addresses the concern that shortages of prescription drugs have tripled during the last five years and are predicted to continue to increase, other legislative proposals place burdensome FDA notification requirements on compounding pharmacies. NCPA has strong concerns with legislative proposals that purport to preserve oversight of state Boards of Pharmacy over compounding but to the contrary, mandate all compounding pharmacies trying to fill medication gaps during dire times of shortages bypass their state Board to report to the FDA. Shortages result in greater stress on the overall health care system in not only compromising the quality and safety of patient care, but also leading to both direct and indirect increased health care costs. Subjecting compounding pharmacies to over-

burdensome FDA reporting requirements during times of shortages increases the devastating impact of drug shortages while doing nothing to prevent another NECC tragedy.

(3) *Exempting pharmacies within health systems from compounding standards*.

While Rep. Griffith's discussion draft holds all compounding pharmacies to the same compounding standards so that patients have assurance that they are receiving the same quality of care regardless of whether the patient receives compounded medications from a hospital or a community pharmacy, other legislative proposals exempt all pharmacies within health systems from the proposed compounding requirements.

NECC's business growth was driven by demand from health systems because these health entities need compounded sterile products -- especially during times of drug shortages. This is alarming as a report released by the Office of Inspector General entitled, *High-Risk Compounded Sterile Preparation and Outsourcing by Hospitals That Use Them*[1], found that while hospitals plan to increase their in-house compounding, almost half of hospitals stated that cost and space limitations would be major challenges to achieve USP 797 compliance. Other hospitals in the report stated that in order to become fully compliant with USP 797, hospitals would be forced to undergo building redesign and new construction.

[1] See OEI-01-13-00150

Thus, as Congress addresses this very important issue, the intent should be to ensure **all** patients receive safe and quality compounded medications.

Conclusion

NCPA is committed to working with Members of Congress in order to make certain that a tragedy such as the New England Compounding Center does not occur in the future while also preserving patients' access to customized and safe compounded medications.

Thank you for inviting NCPA to testify and to share the viewpoints of independent community pharmacies across the country on compounding. I look forward to answering any questions that you might have.