Testimony

on behalf of the
National Association of Boards of Pharmacy

to the

Senate Health, Education, Labor, & Pensions Committee
United States Senate
May 9, 2013

presented by:

Carmen Catizone, M.S., RPh, DPh,
Executive Director
National Association of Boards of Pharmacy

Good morning Chairman Harkin, Ranking Member Alexander, and Committee members. I am Carmen Catizone, executive director of the National Association of Boards of Pharmacy (NABP). NABP thanks you for the opportunity to appear today and comment on the bipartisan *Draft Proposal on Pharmaceutical Compounding*. NABP commends the Senate HELP Committee for its diligence on this issue and the thoughtful approach taken in the draft proposal.

NABP is the impartial organization founded in 1904 whose members are the state agencies that regulate the practice of pharmacy. NABP supports the state boards of pharmacy by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP also helps state boards of pharmacy to ensure the public's health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs.

Following the tragic meningitis outbreak caused by contaminated injectable drugs, several states implemented compounding pharmacy inspections or conducted surveys of pharmacies, focusing especially on those engaged in sterile compounding. As part of the NABP Compounding Action Plan that was developed in November 2012 and implemented in December 2012, NABP partnered with the Iowa Board of Pharmacy and other states to begin conducting inspections of all nonresident pharmacies delivering compounded drugs into Iowa. Our initial inspections confirmed that what occurred at NECC was also occurring at other facilities in other states. To date, NABP has inspected approximately 150 pharmacies across the states and will continue our inspections until all of Iowa's approximately 600 non-resident pharmacies are inspected. In addition to the inspection program with Iowa, NABP recently executed an agreement with the State of New Jersey to assist with the inspection of in-state compounding pharmacies and the prosecution of any pharmacy or individual illegally engaged in the practice of compounding. Four other states have legislation pending or are in the process of designating NABP to conduct or assist with inspections of pharmacies for, or in their states.

The states thank the Committee for the proposed legislation that addresses the critical concerns identified by the states and validated by NABP and its inspections of compounding pharmacies. As such, we welcome the clarifications provided by the proposed legislation to the regulatory uncertainties that currently exist and were one of the primary factors leading to the recent meningitis tragedy. Most importantly, the clarifications provide the needed distinction between compounding and manufacturing and provide a safe and equitable environment for both compounding and manufacturing to occur in the best interest of the patient.

Authority of the States

NABP supports a clear separation of "compounding manufacturing" from traditional pharmacy practice and compounding. Although we would prefer that "compounding" not be included in the proposed designation because of the inference to traditional compounding and the confusion that could result, we understand that some terminology must be employed that describes the activity being regulated.

The separation of compounding from manufacturing is also critical to maintain the present authority of the states and address one of the contributing factors to the NECC crisis, ambiguous

authority between the states and the Food and Drug Administration (FDA). The provision of the proposed legislation that specifies a compounding manufacturer cannot be licensed as a pharmacy is essential to distinguishing from state-regulated compounding and FDA regulated manufacturing. Our experience, and most recently our inspections of compounding pharmacies, affirms the importance of this prohibition in clarifying what activities fall under federal jurisdiction (FDA) and what entities can engage in compounding and operate under state jurisdiction (state boards of pharmacy).

If a compounding manufacturer is allowed to hold dual licensure/registration, it will be more difficult to separate the two enterprises and will provide a veil for unscrupulous entities to obfuscate their activities. NABP supports FDA receiving authority to access any and all documents and records required for the oversight and regulation of compounding manufacturers. We are concerned about allowing the FDA access to pharmacy records for activities that are regulated by the states. If an entity is manufacturing or compound manufacturing, then under the proposed legislation and current authority, the FDA will have access to all documents and records concerning these activities. Authorizing the FDA access to pharmacy records could create jurisdictional conflicts with the states and impede the states from investigating or prosecuting a case because the FDA has seized evidence or information needed by the state(s). What is needed in lieu of allowing such access is increased communication between the states and FDA.

NABP is collecting and maintaining data on the compounding pharmacies identified by the Iowa Board as well as those indicated by other boards of pharmacy. Our electronic data base of e-Profiles for pharmacies is being expanded and enriched to include all pharmacies licensed or registered in the US by state boards of pharmacy and comparable state agencies. Data collected from the boards and the inspection reports provided by the states and through NABP's activities with, or on behalf of the states, will be stored in an NABP Pharmacy e-Profile, allowing us to disseminate pertinent information among state boards and the FDA. States are now able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The e-Profiles for Pharmacies will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, the FDA, and to the public for their use in selecting an appropriate pharmacy.

Transition Period to Ensure Uninterrupted Patient Care and Necessary Exceptions

Equally tantamount to the recognition of state authority is the need to ensure an appropriate transition period with the states as well as to recognize exceptions for activities such as the preparation of radiopharmaceuticals. An appropriate transition period is needed so states will have sufficient time to alert pharmacists and other practitioners and ensure that patient care is continued and not halted by new requirements that may no longer allow certain activities that were previously permitted under state laws. One such example is the compounding "for office use" that is currently allowed in some states. It is our understanding that the proposed legislation addresses this concept in different provisions and that overall the classification of such activities is a state matter when the products prepared are distributed intra-state and a federal matter when the products prepared are distributed in interstate commerce. If the proposed legislation is

adopted and these distinctions are correct and implemented, states will need some time to make the adjustments in state laws in order to ensure uninterrupted patient care and close any regulatory gaps that might result.

Intra-state Exemption from Definition of Compounding Manufacturer

NABP is also concerned with the exemption of the intra-state distribution of non-patient-specific sterile compounded products. We support the logic of establishing a delineation point in order to more readily identify and regulate large-scale operations that conceivably pose more risk to patients than smaller operations. However, it is our finding that non-patient-specific, sterile prepared products distributed intra-state bear the same risk levels to patients as products that are introduced into interstate commerce. In fact, some intra-state operations are as large and larger than interstate distributors of products and therefore the volume of products distributed, and the associated risk, can be equal to or greater than the interstate distribution of similar products. The differentiation between intra-state and interstate activities to define a compounding manufacturer could create patient safety concerns by unintentionally creating a safe haven for entities and individuals engaging in intra-state activities who have the intent to simply avoid the different and federal-based requirements for interstate activities.

We ask the Committee to reconsider this provision and instead include the preparation of non-patient-specific, sterile prepared products for intra-state activities as a defining component of a compounding manufacturer and within the scope of authority of the FDA.

Conclusion

As stated earlier in our statement, the other provisions of the proposed legislation that address the safe preparation of medications and products for patients align well with the approaches suggested and recommended by the states. The legislation proposed by the Committee demonstrates the hard work conducted to understand a complex area of pharmacy practice that is necessary to ensure that patients receive the appropriate medications but must also be regulated effectively. The legislation distinguishes between compounding and manufacturing, defines a new category of manufacturing that balances effective regulation with reality, and carefully constructs allowances and prohibitions on the scope and activities of a compounding manufacturer in order to meet patient needs with the necessary protections. NABP appreciates this opportunity for input and is available to discuss our comments and the proposed legislation in greater detail.

Thank you.