Testimony

on behalf of the
National Association of Boards of Pharmacy

to the

House Energy and Commerce Committee
United States House
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presented by:

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Good morning Chairman Pitts, Ranking Member Pallone, and members of the Committee. I am Elizabeth Scott Russell, Government Affairs Manager for the National Association of Boards of Pharmacy (NABP). NABP appreciates the opportunity to appear before you today and provide information related to pharmacy compounding.

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 the New England Compounding Center (NECC) was also occurring at other facilities in other states. To date, NABP has inspected approximately 165 pharmacies across the states and will continue our inspections until all of Iowa's approximately 600 nonresident pharmacies are inspected.

NABP is also in discussions about similar inspection programs with a number of other states and has plans to establish an e-Profile for each pharmacy in the United States. These e-Profiles will include verifications of licensure, disciplinary checks, and verification that a timely and robust inspection has occurred for each pharmacy, including those performing sterile and non-sterile compounding. The information in the e-Profiles for pharmacies will be sent proactively to boards for use in making licensure and registration determinations for nonresident pharmacies.

In the event that a board of pharmacy has been unable to perform a timely or robust inspection, NABP will conduct an inspection on behalf of the states to ensure relevant laws and pharmacy practice standards are being met. In addition, once an inspection has been completed, NABP will make all publicly available documents, including inspection reports and disciplinary actions, available at no cost to consumers, boards, and Food and Drug Administration (FDA) through a user-friendly and searchable console.

NABP supports the legislation proposed by the United States Senate Committee on Health, Education, Labor, and Pensions (HELP), with some minor modifications. The proposed legislation addresses the critical concerns identified by the states and validated by NABP through its inspections of compounding pharmacies. We welcome the Senate legislation's clarifications to the regulatory uncertainties that currently exist – uncertainties that were a primary factor 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

As provided in the proposed Senate legislation, NABP agrees that the regulation of the practice of pharmacy, which includes traditional pharmacy compounding, remains the responsibility of the state boards of pharmacy. NABP supports the establishment of the new category of "compounding manufacturing" regulated by FDA, and the clear distinction between this new category and traditional pharmacy 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, specifically, the ambiguous authority between the states and FDA. The provision of the proposed legislation that specifies a compounding manufacturer cannot be licensed as a pharmacy is essential to distinguishing between 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 or registration, it will be more difficult to separate the two enterprises and could 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, however, about allowing 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, FDA will have access to all documents and records concerning these activities. Authorizing FDA access to pharmacy records could create jurisdictional conflicts with the states and impede the states from investigating or prosecuting a case because 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.

Intrastate Exemption from Definition of Compounding Manufacturer

NABP discussed with the Senate HELP Committee concern with the proposed exemption for intrastate distribution of non-patient-specific sterile compounded products. We understand the logic of establishing a delineation point to more readily identify and regulate large-scale operations that conceivably pose more risk to patients than smaller operations. However, as we explained to the Senate HELP Committee, it is our finding that non-patient-specific, sterile prepared products distributed within a state bear the same risk levels to patients as products that are introduced into interstate commerce. The differentiation between intrastate and interstate activities to define a compounding manufacturer could create patient safety concerns by allowing large-scale intrastate entities to avoid federal regulation. We indicated to the Senate HELP

Committee that although this is a critical concern for the states, NABP would support the proposed legislation absent this revision, if our concern is noted and the situation monitored for any additional future action that may be necessary.

Conclusion

As stated earlier in our statement, NABP supports the proposed Senate legislation, as it addresses the safe preparation of medications and products for patients and aligns well with the approaches suggested and recommended by the states. NABP supports legislation that 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 while maintaining the necessary protections. NABP appreciates this opportunity for input and is available to discuss our comments and any legislative solution in greater detail.

Thank you.