Testimony
on behalf of the
National Association of Boards of Pharmacy

Before

House Energy and Commerce Committee
Subcommittee on Health
United States House
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Hearing on
Reforming the Drug Compounding Regulatory Framework

Presented by:

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Good afternoon Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee. I am Carmen Catizone, executive director of the National Association of Boards of Pharmacy (NABP). NABP appreciates the opportunity to appear before you again, today and provide information related to the various proposed bills concerning the regulatory framework for 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.

NABP believes that the three pending legislative proposals can provide the regulatory framework needed to protect the public health as well as identify and answer the complex questions surrounding pharmacy compounding and manufacturing. NABP supports the "Pharmaceutical Compounding Quality and Accountability Act" proposed by Senator Harkin and the United States Senate Committee on Health, Education, Labor, and Pensions (HELP). The proposed legislation addresses the critical concerns identified by the states and validated by NABP through its inspections of compounding pharmacies. 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 and manufacturing remains the responsibility of the Food and Drug Administration (FDA). NABP supports the establishment of the new category of "compounding manufacturing" regulated by FDA, and supports the clear distinction between this new category and traditional pharmacy compounding. The Senate Bill addresses and outlines all of the major areas that need to be considered in federal legislation. 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.

The House proposals identify significant areas of concern where consensus may be lacking and further clarification is required. To that extent, NABP favors modification of the key provisions of the "Verifying Authority and Legality in Drug Compounding Act of 2013" and the "Compounding Clarity Act of 2013" to coincide with the desired outcomes shared by all of the interested stakeholders and to build consensus on the remaining, unresolved issues.

We commend the authors of the House bills for their diligence and concern for patient safety and believe that their efforts provide mechanisms for moving forward on some of the more difficult

challenges of this entire issue. We must also caution that some provisions within the House bills may have the undesired effect of moving the regulatory framework in a different direction than is needed to correct the deficiencies and problems identified by the NECC tragedy. Additionally, those provisions could unwittingly create an opportunity for manufacturing to occur under the guise of compounding and even more disconcerting, cause the recognition of such activity as permissible under federal law. To some degree, passage of those provisions will surpass existing exceptions that led to the present situation and recognized need for federal legislation.

NABP agrees that there is a bona fide, but narrow, need for pharmacists to compound a limited amount of products for administration to patients. The creation of the previously referenced third category, compounding manufacturer, seems to address the needs of the majority of patients. However, NABP also understands that some stakeholders do not believe that this is an appropriate category for such activity and are seeking an approach to allow for such activity under traditional compounding and the purview of the state boards of pharmacy.

To ameliorate these concerns – specifically those of patients needing limited amounts of compounded products for direct administration in clinics, offices, and other health care settings and under restricted circumstances, NABP would support the allowance of such activity under the domain of traditional compounding provided limitations and qualifiers are in place to assure that the activities are safe and simply not a masquerade for manufacturing.

Limitations and qualifiers for traditional compounders that have been discussed with NABP and that we submit for the Subcommittee's consideration include:

1. There must be a demonstrated medical need for the compounded product.
2. The non-patient specific order must be written by the practitioner that will be administering, or is directly responsible for administering, the compounded product to the patient.
3. The total quantity provided to the clinic, office, or other health care setting cannot exceed a 10-day patient supply.
4. The compounded medication cannot be resold by the clinic, office, or other health care setting.
5. The compounded medication must be prepared in accordance with applicable USP Standards or Good Manufacturing Practices (GMP's) depending on the product, as determined by the FDA.
6. There must be a limitation on the quantity of compounded products that can be produced. Such quantity cannot exceed a certain percentage of, or some other measure of, the pharmacy's total number of prescriptions dispensed, dosage units, patient supply, or some other measurable and comparable factor.
7. The pharmacy must notify the applicable state board(s) of pharmacy and FDA of their involvement in this area in accordance with an appropriate process and time frames to be determined.
8. The FDA must have full legal access to all records of the pharmacy engaged in this activity and there can be no prohibitions on the sharing of information between the states and FDA on these activities.

NABP wants to note that these limitations and qualifiers do not erode the distinction between compounding and manufacturing provided by the three categories of activity noted in the Senate bill. They simply allow for an exception, with additional oversight, under the category of traditional compounder. NABP believes this modification is critical to maintain the present authority of the states and address one of the contributing factors to the NECC crisis, the ambiguous authority between the states and FDA. Legislation specifying that a compounding manufacturer cannot be licensed as a pharmacy must remain because it is essential to distinguishing between state-regulated compounding and FDA-regulated manufacturing. The allowance for non-patient compounded products for administration would recognize this distinction and also address one of the concerns voiced by the FDA – the need to access state-licensed pharmacy records to help determine whether such pharmacy is engaged in activities that should be overseen by FDA.

The recognition and separation of activities and authorities would apply as follows:

1. A traditional compounding pharmacy would only be engaged in patient specific compounding thus meeting the definition of compounding within the practice of pharmacy as defined by states. It would operate under the authority of the state board of pharmacy, could not license or register as a compounding manufacturer or as a manufacturer, and would be subject to all laws, regulations, requirements, records access, and inspections required by the state board of pharmacy. If the FDA had sufficient information to suspect that the pharmacy was violating federal law or engaged in manufacturing either as a manufacturer or compounding manufacturer, it could employ the enforcement means currently available to access records and gain entry into the pharmacy. Cooperation between the FDA and applicable state board(s) of pharmacy would also need to occur.
2. If the entity was operating and registered with the FDA as a manufacturer or compounding manufacturer, it would be responsible to the FDA and its laws, regulations, records access, and inspection requirements. If a state had sufficient information to indicate that the entity was violating state laws/regulations, it could employ the enforcement means currently available to the state as well as work cooperatively with the FDA.
3. If a traditional compounding pharmacy is engaged in non-patient specific compounding for administration with the limitations and qualifiers identified above, then it would be subject to the authority of both the state board of pharmacy and the FDA. As such, the pharmacy would need to license with the state as a pharmacy and comply with all of the corresponding laws, regulations, and requirements as well as complete a notification process or registration with the FDA. Such notification or registration would result in compliance with applicable federal laws and requirements and FDA access to the pharmacy's records in order to help determine if the pharmacy's activity was exceeding the boundaries of traditional compounding and instead manufacturing.

Conclusion

NABP respectfully requests that action be taken to develop and pass federal legislation to create the regulatory framework so desperately needed to address pharmacy compounding and manufacturing concerns. The opportunity to correct a serious problem and protect patients from harm is here and should not be lost. We stand ready to assist in any way we can to reach consensus provided that patient safety is not circumvented by consensus.

Thank you.