According to FDA Commissioner Margaret Hamburg, the agency’s ability to take action against large-scale entities that exceed the bounds of traditional pharmacy compounding and pose risks to patients has been hampered by ambiguities in the Food, Drug and Cosmetic Act (FDCA). While claiming they were exempt from FDA oversight, NECC had long ago ceased operating as a traditional compounding pharmacy and were clearly engaged in illegal drug manufacturing.

To clarify FDA’s authority, the Compounding Clarity Act replaces section 503A of the FDCA with a new regulatory framework for traditional compounding pharmacies. The legislation removes the constitutional concerns about advertising that were raised in court cases that created ambiguities that the agency had cited.

The Compounding Clarity Act protects traditional pharmacies by clarifying FDA's role in regulating compounding. Under the legislation, traditional pharmacies will continue to remain under the jurisdiction of state boards of pharmacy and remain exempt from FDA's manufacturing authority. The bill protects access to the customized, compounded medications that patients need. Chiefly, all compounding must be done pursuant to a patient-specific prescription, while allowing for anticipatory compounding based on a preexisting relationship with a patient or doctor. Recognizing a need for uniform quality, the legislation also establishes an enforceable safety standard for all compounded drugs.

The legislation also maintains the important practice of office use where drugs can be dispensed to hospitals, doctors' offices, and other healthcare settings to administer before an identified patient is known. However, once these compounded drugs are administered to a patient, a prescription or patient name must be reconciled back to the pharmacy within 7 days. The legislation also draws a volume limitation on the practice that both protects public health, while maintaining patient access to these drugs, especially in border regions.

Given the concerns that FDA received numerous complaints from state boards about NECC and failed to act on them or alert other concerned state boards, the Compounding Clarity Act requires the timely implementation of a notification system to allow for meaningful communication with the state boards of pharmacy; submissions of concerns relating to the products and practices of compounding pharmacies; and facilitation of appropriate inspections and/or enforcement actions from the FDA.

Finally, the legislation clarifies FDA’s authority over the large-scale compounding entities, or outsourcing facilities, by outlining new federal requirements. Outsourcing facilities are compounding entities that exceed the legislation’s volume limitations and would now be subject to annual registration; reporting and listing of the drugs they compound; labeling; adverse event reporting; inspections and user fees.