

public knowledge. The other pharmacy owner said she hopes all inspections become public knowledge because we are all human and mistakes can happen. The real test is how a compounding pharmacy responds to inspection findings and fixes the issues once they have been identified through proper policies and procedures.

Regarding the NECC, inspections were not necessarily the problem but enforcement was a big problem. Neither the FDA nor the state agencies took action when it was apparent action was necessary. As such, compounding pharmacies and manufacturers are now wondering which agencies (federal and state) can and will take action when violations occur. They also need to know the penalties for violations, up to and including the closure of their facilities. Another big issue was the absence of governance and leadership with the NECC. Unfortunately, governance and leadership cannot be regulated. Let's take a look at both in terms of the Drug Quality and Security Act.

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## GOVERNANCE AND LEADERSHIP

My definition of *governance* for compounding pharmacies is to conduct the actions and affairs of their companies, which includes the processes, procedures, and expectations regarding patient care, compliance to all federal and state laws and regulations, financial risk, and the culture-based setting of incentives. These incentives can be positive or negative, depending on the behavior and actions of the leaders. I would expect the governing board (most likely a board of directors) to set a commitment to quality for compounded medicines for patients, including a continuous quality improvement process that allows for systemic learning for the compounding pharmacy. This continuous quality improvement process should embrace both the compounding pharmacy's customers and suppliers, and be embedded into the compounding pharmacy's strategic plan.

My definition of *leadership* for compounding pharmacies is the actions of the senior executives to develop the vision, strategic plan, and operating plan for their companies within the boundaries set by the board of directors. Leadership should include the operating objectives, goals, and operating strategies that align with the board's expectations regarding patient care, compliance to all federal and state laws and regulations, the management of risk, and the implementation of incentives and penalties for