

India or China or Australia? Can the pedigree start with PCCA's receipt of APIs and compounding ingredients? PCCA already has a pedigree system as required by the state of Florida. Will this be sufficient, or will the Drug Quality and Security Act be changed? For now, we will have to wait for this item to be determined by the FDA. PCCA will have to be prepared to initiate the pedigree necessary to comply with the upcoming track and trace requirements if compounded drugs are not exempted. This should not be a big problem since they have a similar program to satisfy the state of Florida.

Compounding Pharmacy Order Fill

Member pharmacists place specific orders to PCCA for the APIs and compounding ingredients to make the compounded drugs needed by their patients. PCCA performs its order-fill activities and ships the material to its member customers. The PCCA process, from supplier approval to customer ship, is tightly controlled under cGMP guidelines. Continuous testing is done throughout the process to ensure the safety and security of drug compounds.

PCCA receives the orders from its member pharmacies, fills them, and most of the time ships the product within 24 hours of receipt of the order. There is a significant amount of interaction between PCCA and its member pharmacies on both orders and consultation regarding formulations. In fact, PCCA averages over 3,000 inquiries per day to its consultants from its member pharmacies.

The process from patient demand to shipment to the compounding pharmacy meets/exceeds the known requirements under the Drug Quality and Safety Act provisions. Why is this important? It is important because PCCA's market share with their independent pharmacy members is over 50%. If the intent of the lawmakers passing H.R. 3204 into law as the Drug Quality and Security Act was in part to secure the compounding pharmacy supply chain, they are over halfway there, from patient order demand to APIs and compounding ingredients, thanks to PCCA.

FROM APIS AND COMPOUNDING INGREDIENTS TO COMPOUNDED MEDICINES

During my research for this book, I had the pleasure of visiting four sterile compounding pharmacies in two states. All four owners expressed interest in remaining anonymous. In all four cases, the owners of these