

sterile compounding pharmacies believed they were *not* manufacturers, but pharmacies producing sterile drugs for doctors and patients. In my estimation, approximately 75% of all of their orders were for sterile, injectable drugs for patients “for office use” (i.e., scoliosis centers, medical facilities, etc.), and the remaining 25% were for sterile drugs tied to specific patient prescriptions.

Their receipt and inventory processes were all very similar. Supplier orders were received from the transport carrier in the morning, with the APIs and compounding ingredients unloaded from the truck and placed directly into inventory. Since all four happened to be PCCA members, they assumed that the received material was tested and packed in a sterile environment. I did witness other compounds being placed into a sterile inventory location that were bought from local sources (inert ingredients) and assumed to be sterile as well.

At two of the compounding pharmacies, I was present early enough to witness the arrival of the compounding pharmacists. These pharmacists would get ready for the day, and then proceed to sort their “to dos” into three parts: emergency orders to be filled right away for patients either directly through a physician or through a medical center, the rest of the direct patient orders, and the office use orders to replenish medical center inventories. I was able to observe the intensity of the pharmacists as they filled the emergency orders from behind glass windows.

At all times, there appeared to be great care to observe the rules for a sterile environment. For two compounding pharmacies, other on-duty pharmacists spot-checked the compounded drugs for quality and accuracy of the formulation. It was reassuring to see the dedication of these pharmacists to helping people/patients in need.

## The Complication

In the United States, there are approximately 7,500 compounding pharmacies, with approximately 3,000 of these compounding pharmacies making sterile products.<sup>3</sup> My sampling of four compounding centers is a small sample, but it does illuminate the complexity of the safety and security issue.

It is apparent that pharmacists are focused on patient (and office) order fill. All four compounding pharmacies spoke about and focused on a sterile environment. However, I received a variety of opinions on what constituted a sterile environment. Thanks to my nephew Jeff, who