MidMichigan
Medical Center
Midland

4005 Orchard Drive
Midland, Michigan 48670
Phone (517) 839-3000
www.midmichigan.org

July 7, 2000

5134 00 JUL 14 AM 10:23

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

To Whom It May Concern,

This letter is in response to the FDA Pharmacy Compounding Advisory Committee concept paper. I am the Director of Pharmacy for two hospitals in Michigan. One is a 280 bed teaching hospital in Midland and the other is a 50 bed hospital in Clare.

We do not do what I would consider a large volume of compounding at our hospitals and attempt to buy as much as we can pre-mixed or pre-made because, like most hospitals, they are more willing to spend money on supplies than on people. Our rule of thumb is, if we can buy it already manufactured we do. I think this is pretty much the standard of practice. Here is what we do compound.

Orally - ABH capsules, Lido Cocktail, Lopressor liquid, Lytic Cocktail, Mint Cocktail, Triplex, and Vancomycin liquid.

Topically - Acetic Acid solutions 3% and 5%, Aluminum Chloride 10%, BenzAll, Cook's, DABs, Dakins, KOH 10%, LETs, Lido 3%, Phenephrine 0.25%, MgSo4 50%, and TAC.

Ophthalmic - We make different blocks for each ophthalmologist, most are varying amounts of Lidocaine, Bupivacaine, and Wydase.

Inhalation - Pontocaine with Epi (this gets put into a nebulizer, not MDI).

Injectables - TPN and then I don't know how far reaching the FDA is planning with regard to the drugs we reconstitute. The concept paper makes this sound quite broad.

00N-1357

C1

Here are some of the things that we do to assure good practice and a pharmaceutically elegant product:

1. All employees are trained on aseptic technique upon hiring into the pharmacy and this training is based on ASHP guidelines.

2. All compounding is done in a laminar flow hood.

3. We keep a compounding log with dates, lot numbers, etc.

4. Infection Control monitors for problems (we have had zero in the past 12 years I have practiced here).

5. If there is a question of sterility we send a compounded product out for testing. This was the case with some DABs at our hospital several years back and it came back clean. It was the physician's technique that it came down to causing the infection.

6. Our hoods are inspected by an outside company every six months.

7. Hoods are cleaned after each use and thoroughly once per shift (three times per day).

Looking at the little detail provided in the concept paper on chapter 1206 of the USP, it would be very costly for our hospital to make these renovations. I would love to have a new IV room that met these specs but I don't believe there would be any clinical benefit to our patients and is an unneeded expense at a time when hospitals do not have money to throw around. If we had to send all this compounding out to a home infusion company (or some other entity that is fulfilling these rules) this would also be costly and cause a delay in therapy for our patients. I believe it would also require the entity to have a manufacturer's license, in addition to other requirements, which is costly and invites other regulations and regulatory bodies to the table.

I hope you consider carefully the clinical relevance and cost of the implementation these broad sweeping rules prior to making them final.

Professionally yours,

Joan Herbert Pharm.D.

Joan Herbert, Pharm.D.
Manager, Pharmacy Services
MidMichigan Medical Center - Midland
and Clare Campuses