

November 1, 2012

## An Open Letter to College Pharmacy's Valued Healthcare Practitioners and Patients

In light of the recent media coverage pertaining to the safety, quality, and compliance standards within compounding pharmacies, I would like to reassure our valued healthcare practitioners and patients that College Pharmacy has the right people, processes, procedures, and licensing in place to provide safe, quality, and consistent sterile and non-sterile preparations.

Unfortunately, some of the media stories that are being generated fail to illustrate the dynamic role of custom compounding, the existing federal and state regulations, and the industry best practice standards that are in place to ensure safety and efficacy.

In addition, College Pharmacy has been erroneously mentioned in a small number of articles due to actions of the former owner, prior to 2008. It should be noted that College Pharmacy has never had any quality or safety issues related to custom compounding.

Our history helps us grow. In January 2008, College Pharmacy was sold to an Employee Stock Ownership Plan (ESOP): the former owner has absolutely no connection or involvement with the new operation. A board of directors was established, a trustee named, and new management was put in place to assure continued compliance and growth. We looked at every area and found ways to improve our already high standards. The College Pharmacy of today should not be compared to the College Pharmacy that existed prior to 2008.

Standards and regulations. There have been recent questions about how compounding pharmacies are regulated. Much of the recent media coverage fails to accurately illustrate the federal and state regulatory process. The International Academy of Compounding Pharmacists recently released the following clarification:

- **All compounding pharmacists and pharmacies are subject to governmental oversight by three distinct regulatory bodies:** their individual State Boards of Pharmacy for adherence to practice requirements, the Food & Drug Administration (FDA) for the integrity of the drugs and Active Pharmaceutical Ingredients (APIs) which they order, store and use; and, by the Drug Enforcement Administration (DEA) for their handling of controlled substances used in the preparation of compounded medications.
- In addition to government regulation, adherence to United States Pharmacopeia USP <797> standards for the compounding of sterile medications is expected. USP <797> is a national standard for the processing, testing, and verification of any medication prepared for administration to patients. These standards are included as a requirement in many state regulations in addition to being a professional standard.

So, where does College Pharmacy stand in regards to standards, regulations, compliance:

- We meet and strive to exceed regulations established by our State Board of Pharmacy, the FDA, and the DEA.
- We strictly follow USP 797 standards for sterile and USP 795 standards for non-sterile compounding.
- Our compounded sterile preparations are tested for potency, sterility, endotoxin and fungus.
- Our compounded non-sterile preparations are tested for potency and stability .
- We currently ship our preparations to 48 States and many foreign countries, and we are fully licensed in and in good standing in all States which require licensing.
- We have Standard Operating Procedures for all compounding and non-compounding activities.
- All prescriptions go through a multi-check system to ensure compliance with all required laws, regulations and standards.
- We have quality improvement practices in place to assure that we are continuously improving our people, processes and preparations.

- All compounding is fully documented to guarantee that we are fully compliant.
- All testing labs which we utilize are fully registered and licensed, and we have an extensive testing program in place.
- We purchase all legend pharmaceutical ingredients and controlled substances from FDA and DEA licensed suppliers.
- Upon receiving our chemical ingredients from our suppliers, Certificates of Analysis are checked, verified, and entered into our database to ensure compliance.
- All ingredients are properly stored to ensure potency and stability.
- All temperature and light sensitive preparations are shipped and packaged appropriately.
- Our licensed pharmacists and pharmacy technicians go through extensive training in the preparation, quality control, and quality assurance of compounded formulations.

An estimated 30 to 40 million prescriptions are custom compounded each year. Not including the most recent issue with New England Compounding Center, the Food and Drug Administration has recorded about 200 “adverse events” linked to compounded products since 1990. Please remember, the nature of custom compounding, the technical aspects, and the multi-level regulations are not easily translated into the media stories that are circulating.

College Pharmacy has been providing quality compounded preparations and superior customer service for 38 years. We are proud to work with 1000s of satisfied practitioners and patients a year. The industry has evolved and grown, and we have grown with it. I am very proud of what we do every day and our accomplishments.

I welcome any questions about College Pharmacy, our history, our leadership, and our compounding practices. I can be reached directly at (719) 955-1463 or via email at [jerry@collegepharmacy.com](mailto:jerry@collegepharmacy.com)

Sincerely,

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