

Should states institute a “wet lab” examination as part of the pharmacist licensing process?

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Pharmaceutical compounding has and will continue to be a necessity in our society due to the fact that it is usually prepared to meet the unique needs of individual patients. These products are prepared when commercially available drugs do not meet those needs or patients may require a drug that is currently in shortage or discontinued. Compounded drugs are able to fulfil patient's needs such as: adjustment of strength or dosage; making drugs more palatable by adding flavors; reformulating drugs to accommodate patient allergies such as gluten or dye; change of dosage forms to suitable forms unique to the patient's needs.

After the New England Compounding Center (NECC) fungal meningitis outbreak, many conversations have been had regarding ways to prevent such an adverse event from occurring again. These conversations led to enactment of the Drug Quality and Security Act (DQSA) which was signed into law by President Obama in November 2013.¹ Although DQSA is supposed to help prevent another NECC event from occurring by regulating compounding pharmacies, more can be done to increase patient safety and the quality of compounded products. These goals can be achieved by making sure that all graduating pharmacists are adequately trained in theory and practice of sterile product preparation during their education and also that their technique are assessed. Student's techniques can be assessed by instituting a "wet lab" examination as part of the pharmacist licensing process. Adoption of both didactic and laboratory course(s) by all pharmacy schools across the United States can help prepare graduates to pass this examination and be adequately trained for pharmaceutical care practice in compounding.

NAPLEX tests to assess the knowledge, skills, and judgment an individual is expected to demonstrate as an entry-level pharmacist. AREA 2 of the NAPLEX is designated to "Assess Safe and Accurate Preparation, Compounding, Dispensing and Administration of Medications and Provisions of Health Care Products;" yet many believe that current pharmacy graduates are

inadequately trained to immediately go into compounding. Loyd V. Allen and many others believe that this problem needs to be addressed and corrected at the college level.² In a study designed to find out the extent of didactic and laboratory instruction related to compounded sterile preparations (CSPs) provided by U. S. school of pharmacy; it was found that all schools included in the study included some instruction on CSPs but only 70% required students to compound on their own; 21% offered a stand-alone course on this topic, 88% taught students about U.S. Pharmacopeia chapter 797 standard for sterile compounding, however, only 13% of schools felt that their students had adequate training in compounding sterile preparations before graduation.³

Pharmacy schools should use the NAPLEX Blueprint- AREA 2 when designing their courses in order to make sure that all graduating students are competent and ready to not only pass the written test but also the wet lab. Georgia and New York are the only two states that require a wet lab as part of their licensing examination for pharmacists. Although they both require a wet lab as part of their examination they have different requirements; this highlights one of the ongoing issues in the compounding industry, lack of uniformity in regulations. In order to assess students compounding competency adequately, it is important to institute a standardized testing (USP 795 and 797) and scoring across the board. Without a standardized testing and scoring procedures, it will be very hard to institute a wet lab examination across the country that will assess the competency of all pharmacists regardless of what institution they graduated from.

As we move to a more individualized based patient-centered care, the need for pharmaceutical compounding is increasing. With this increase in demand, the need for qualified pharmacists is more important more than ever especially in the advent of the NECC

misadventure. The institution of a wet lab as part of licensing examination for pharmacists will prompt most if not all pharmacy schools across the United States to adopt classes in their curriculum that will adequately train their graduating students to be able to provide quality and safe pharmaceutical compounded products to be dispensed to patients across the country.

References

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