Fall 2015 Student Writing Competition topic:

How is the Drug Quality & Security Act affecting the future of compounding?

Submitted by
Nasheed Shams, First Professional Year Student
Telephone number: 202-417-5909 (C)
nasheed.shams@students.acp.edu
Appalachian College of Pharmacy (ACP)
1060 Dragon Road, Oakwood, VA 24631

Faculty advisor: Quamrun Masuda, PhD, RPh
Adjunct Assistant Professor, ACP
Associate Professor, VCU School of Pharmacy
Assistant Director,
Center for Compounding Practice & Research, VCU
804-628-4548, qnmasuda@vcu.edu or qmasuda@acp.edu

Word count: 1185

How is the Drug Quality & Security Act affecting the future of compounding?

The art of compounding originates from as far back as the ancient physician-pharmacist Galen, who used vegetable and plant matters to make medications some 1500 years ago.[1] Today, compounding is the art and science of creating personalized medication to meet a patient's specific needs when products available on the market are inadequate. While the benefits of compounding are obvious, so are the risks.

In 2012, poor compounding practices at the New England Compounding Center resulted in 64 deaths and 751 cases of confirmed or suspected fungal meningitis nationwide.[2] What followed was a federal investigation of compounding pharmacies, which revealed poor regulatory conditions and gaps in oversight that were partly responsible for the outbreak. This ultimately spurred on the creation of the Drug Quality and Security Act (DQSA), which was signed into law on November 27, 2013, and has massive ramifications for huge sectors of the compounding industry.

The FDA classifies compounding pharmacies as conventional versus out-sourced or manufacturer, and subsequently identified those facilities as 503A and 503B facilities. Conventional compounding pharmacies are typically small community pharmacies which focus on making non-sterile preparations for individual patients based on prescriptions written by

[1] "A History of Pharmacy in Pictures" taken from Washington State University, 'History of Pharmacy'.
[2] "Multi-state Outbreak of Fungal Meningitis and Other Infections" : http://www.cdc.gov/hai/outbreaks/meningitis.html

providers. Conventional compounding can also include sterile admixtures prepared in hospital, based on medication orders for individual institutionalized or hospitalized patients. Irrespective of the facility type, all compounding activities must follow regulations stated in the United States Pharmacopeia, specifically addressed in general chapters USP<795> and USP<797> guidelines.[3] The Drug Quality and Security Act affected these conventional 503A facilities both positively and negatively. Compounding pharmacies now have a renewed focus on improving the quality of their compounded preparations, which ensures patient's safety and therapeutic benefit. However, they are challenged by the increased cost due to Board of Pharmacy inspection and accreditation.

The out-sourcing compounding facilities, which can produce anticipatory preparations with or without prescriptions, also faced a series of tough challenges since DQSA went into effect. According to FDA commissioner Margaret Hamburg, MD, DQSA represents a step forward in protecting Americans from unsafe drugs by creating a new pathway in which a compounder can register with FDA as an outsourcing facility.[4]

The biggest change that out-sourced compounding pharmacies have had to face in the past two years since DQSA went into effect are FDA quality-control inspections. As of December 2014, 175 facilities faced these inspections either reactively due to serious adverse events that were reported on drugs produced at those facilities or proactively, after having been targeted for screening in a risk-based model. As a result of these inspections, numerous facilities stopped

[3]An official drug compendium published annually by the nonprofit organization 'the United States Pharmacopeial Convention'

[4] "Protecting the Public from Unsafe Compounded Drug Products" Hamburg, Margaret, MD, *FDA Voice*, December 17, 2014 http://blogs.fda.gov/fdavoice/index.php/2014/12/protecting-the-public-from-unsafe-compounded-drug-products/

making sterile compounded preparations. FDA also worked with states Boards of Pharmacy to revoke or suspend licenses of those practitioners who were involved in poor compounding practice. This led to increased patient safety, but also limited options for hospitals who rely on these outsourcing facilities for compounded preparations.

Since the implementation of DQSA, hospitals and providers have been encouraged to purchase the sterile compounding services from compounding facilities that are registered with the FDA. This is challenging for many hospitals because only a small fraction of compounding pharmacies currently meet the criteria and/or are willing to bear the costs associated with registering as a 503B outsourcing facility. Additionally, because registration under current law is voluntary, most outsourcing facilities have been slow to react. It is largely up to hospitals to weigh whether the costs and limitations associated with buying the services only from approved facilities are outweighed by overall increase in safety.

But what does registration for an outsourcing facility entail?[5] For one, there are new labeling and drug event reporting requirements set forth under DQSA. In addition, these facilities must be compliant with current Good Manufacturing Practices, are subject to routine FDA inspections, and must submit detailed reports of drugs compounded at that facility to the FDA. It must be noted that if an outsourcing facility chooses not to register with the FDA as a 503B facility, but continues to produce anticipatory preparations without prescriptions, there is higher likelihood that they are non-compliant with the stricter guidelines set forth by DQSA.

[5] "Compounding Quality Act: Title I of the Drug Quality and Security Ace of 2013" : http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/

As an example of stricter guidelines, prior to DQSA, compounding pharmacies that were classified as manufacturers could follow Good Laboratory Practices Guidelines. After DQSA was passed into law, 503B pharmacies are required to follow Good Manufacturing Practice, which takes on a more rigorous approach to ensuring safety of the compounded preparations.

Compounding facility is not the only facet of compounding pharmacy that is changing as a result of DQSA. Pharmacy schools reacted strongly to DQSA by making a concerted effort to train future pharmacists in sterile compounding techniques. Compounding, long seen as an integral part of pharmacy education, had begun to fall out of favor from pharmacy education in the last ten years largely because licensing exams do not focus on compounding aptitude. In addition, the hectic work-schedule of most practicing pharmacists do not allow them to practice hands-on compounding. However, once DQSA went into effect many pharmacy schools, such as Virginia Commonwealth University, School of Pharmacy and University of South Carolina, School of Pharmacy, opened state of the art sterile compounding teaching labs to ensure future pharmacists would be prepared for the quickly changing face of compounding pharmacy.

In addition, National Association of Boards of Pharmacy (NABP) and Pharmacy Technician Certification Board (PTCB) have also responded to DQSA by adding certifications requirements for pharmacists and pharmacy technicians who are involved in compounding. Moreover, as of May 2015, NABP has partnered with United Compounding Management (UCM)[6] to administer the United Compounding and Accreditation Program (UCAP). Under UCAP, compounding

[6]"Exclusive Accreditation Program for Compounding Pharmacies" May 15, 2015, Accessed November 28, 2014 , http://ucmrx.com/exclusive-accreditation-program-for-compounding-pharmacies/

facilities will be reviewed for business and quality practices, code of conduct, and compounding specific requirements.

While only signed into law two years ago, the Drug Quality and Security Act has already begun to have massive effects on many faces of compounding pharmacy. This undoubtedly makes great strides in ensuring safety of patients receiving compounded preparations; but the law must be carefully balanced so that small outsourcing compounding facilities are not driven out of business by insurmountable costs or red-tape because ultimately, they are providing a critically necessary service.