



Follow Us on Social Media



#WCC2018VEGAS



COMPOUNDING: QUO VADIS?

Vassilios Papadopoulos, DPharm, PhD Dean and Professor, School of Pharmacy University of Southern California





HOUSEKEEPING



Cell Phones



Download the Slides



Questions



No photography, audio, or video recordings



https://education.lp3network.com/WCC2018

DISCLAIMER

DISCLAIMER: The information contained in this program, which may include treatment modalities, diagnostic and therapeutic information, and instructions related to regulatory guidelines and current standards of practice for pharmacy compounding, is FOR EDUCATIONAL PURPOSES ONLY and should not be taken as a treatment regimen, product indication, suggested treatment modality, or suggested standard of practice. NOTE TO MEDICAL OR ALLIED HEALTH PROFESSIONAL: Any treatments, therapies, or standards of practice must be fully investigated and prescribed by a duly licensed medical practitioner in accordance with accepted professional standards and compendia. Any regulatory or practice standard must be fully investigated by a licensed pharmacist in accordance with accepted professional practice standards and compendia.



VASSILIOS PAPADOPOULOS, D.Pharm, PhD, D.Sc



- Dean on the USC School of Pharmacy
- Served as executive director and chief scientific officer at the Research Institute of McGill University Health Centre in Montreal.
- Has published over 300 papers
- Elected foreign member of the National Academies of Medicine and Pharmacy in France
- Fellow of the American Association for the Advancement of Science
- Fellow of the Canadian Academy of Health Sciences



LEARNING OBJECTIVES

Looking at the future of compounding as shaped by events, rules and regulations and upcoming changes in healthcare and therapeutics.



OUTLINE

- Definition
- Benefits
- Market
- Problems
- Solutions
- Future
- Conclusions



DEFINITION

Pharmaceutical Compounding is defined as a **practice** in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to **create a medication tailored** to the needs of an individual patient.

Food and Drug Administration

Pharmacy compounding is the **art and science** of preparing personalized medications for patients. Compounded medications are made based on a practitioner's prescription in which individual ingredients are mixed together in the exact strength and dosage form required by the patient.

This method allows the compounding pharmacist to work with the patient and the prescriber to **CUSTOMIZE a medication**_to meet the patient's specific needs.

Professional Compounding Centre of America

Pharmaceutical compounding is defined as the (act) preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.

United States Pharmacopeia Convention

BENEFITS

- The purpose of pharmacy compounding has traditionally been to allow a licensed pharmacist to customize a medication for an **individual patient** whose needs cannot be met by an FDA-approved drug.
- Pharmaceutical compounding is synonymous to patient-centered services with an added value for the consumers.
- The decision to treat an individual patient with a specific compounded formula should consider the patient, their medical history, comorbidities, other medications and all other factors considered before dispensing any medication compounded or commercially available.



BENEFITS

- Compounded drugs play an important role in **healthcare** delivery.
- Compounded medicines enhance **pharmacist contribution** to developing and implementing patient therapeutic plans and provide customized medications of high pharmaceutical quality.
- Patients, pharmacists, and prescribers have increased **collaborative interactions** when involved in compounded drug use compared with routine commercial drug dispensing.
- There is the perception among compounding pharmacists that there are direct and indirect **economic cost savings** as a result of pharmaceutical compounding.
- The pharmacists feeling more empowered in their roles, with improved professional satisfaction.

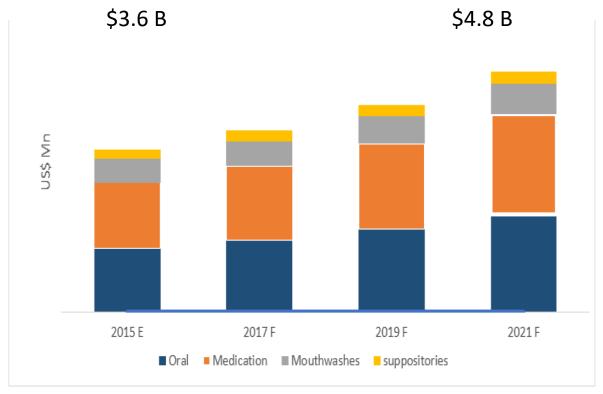
MARKET

- Compounding pharmacy is one of the **oldest forms of pharmacy**.
- Prior to the 1950s, all medications were created by compound pharmacists.
- Compounding took a lesser role when pharmaceutical companies started mass producing medicine that could treat 95% of the population.
- Since the 1980s, compounding pharmacies have grown in popularity once again. This is mainly due to drug shortages and the fact that many conventional medications cannot treat everyone due to potential side effects, allergies and sensitivities, appropriate dosage, formulation, etc.
- Today, despite increased regulation, the **future of compounding pharmacies seems positive**. The number of students who are choosing a compounding pharmacy as a career is increasing.



MARKET

US Compounding Pharmacies Market Value Share by Product, 2015-2021



Compound Annual Growth Rate of average 5.7%



MARKET

The prime driver for the compounding pharmacies market is **medicinal drought**. When the need for critical drugs are not met through commercially-available branded equivalents, compounded drugs are sought after.

Increasing demand for **anti-aging** products that use custom compounded drugs is a prevalent consumer-driven trend across the globe.

Innovative sub-therapeutic areas such as **bioidentical hormone replacement therapy**.

Oral medications, constituting drugs that can be swallowed, are expected to exhibit stable growth rates ranging from 4.7% to 8.4% over 2015–2021.

- Since the 2012 outbreak of fungal meningitis there have been over **200 recalls** by compounders.
- Since the enactment of Drug Quality and Security Act (DQSA) in 2013, the FDA has conducted over 500 inspections, issued 180 warnings and issued more than 70 letters referring inspectional findings to state regulatory agencies.



In general, threats to patient safety from compounded medications are mainly due to:

- i) quality, e.g., product identification, purity, stability, compatibility
- ii) the **environment**, e.g., using a segregated compounding area with specialized airflow capabilities, reducing particulate matter, practicing proper hygiene, properly cleaning of equipment and work areas
- iii) **personnel activities**, e.g., human error, familiarity with protocols, following expiration dates
- iv) the control process, e.g., process monitoring, control test post-preparation



- The safety and efficacy of most of the treatments with compounded medication are not based on randomized clinical trials establishing the safety and efficacy, but on evidence collected during years of clinical practice.
- Compounded drugs are not reviewed by the FDA or any other regulatory agency for safety, effectiveness or quality before administration to patients.
- Many compounded medicinal products are dispensed without a package insert but some pharmacists and/or formularies developed their own package inserts as pharmaceutical care is very important for a better care to the patients. Compound specific databases comprise ChEMBL, ChemSpider, PubChem, OpenPHACTS and the Orange Book with supportive information on a compound's chemistry and pharmacology.

- Reporting (are there more cases that have not been reported? Is there sufficient reporting for across states deliveries of compounded drugs?)
- Compounded medications should be distributed to meet the needs of patients whose medical needs cannot be met by an FDA-approved drug. However, scanning through the web and talking to users raised the question whether occasionally compounders and practitioners are creating a need rather than fulfilling a need.
- Compounding pharmacies have been used injudiciously by naturopaths, "integrative medicine" doctors, "functional medicine" doctors, and other providers who prescribe treatments that are not supported by credible evidence and that often involve risky administration (IV).

SOLUTIONS

- Following the 2012 outbreak of fungal meningitis we saw the birth of DQSA, the creation compounding pharmacies (503A) and outsourcing facilities (503B). Today, there are 7,500 compounding pharmacies and 70 outsourcing facilities.
- However, as noted earlier problems persist (200 recalls in 5 years).
- How does this compare with recalls of FDA-approved drugs (about a third of the drugs the FDA approved between 2001 and 2010 were involved in some kind of safety event after reaching the market and in 2014, 35 drugs were pulled off the market).



SOLUTIONS

- Do we need 7,500 compounding pharmacies?
- Do we need a better definition and oversight of the compounding pharmacy?
- Do we need more outsourcing facilities?
- Do we need more training?
- Do we need more regulation?
- Do we have the right metrics for decision making?



FUTURE

- Precision/personalized medicine is expanding.
- Pediatric population gets more attention.
- Chronic disease management.
- Pharmacology of the aging male and female.
- Rare diseases.
- Compounds vs biologics vs biosimilars.
- Cell therapy.
- 3D printed medicines and 3D bioprinting.
- New biomaterials.
- Veterinary applications.

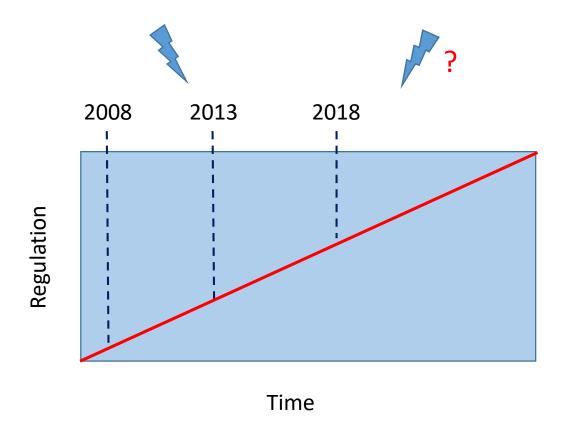


FUTURE

- Incidents (reduce errors).
- Reporting.
- Outsourcing sector vs compounding pharmacies (GMP; GLP).
- Education (PharmD programs; Certificates).
- Security issues (lessons from hacking medical devices).
- Costs.
- Drug availability.
- Reimbursement
- Regulatory and legal exposure.



CONCLUSIONS



There is a clear need for compounding, and market trends and analyses indicate that the future of this

practice/art/science is positive.

However, any major new incident might tip the balance and a healthcare issue will become a political issue. That will leave little space and time to develop a consensual among stakeholders plan that will ensure the future of compounding in delivering safe medications to patients in need.









THANK YOU FOR LISTENING

