503B Outsourcing
A Continuing Evolution

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Presented by Milton Boyer CEO – SCA Pharmaceuticals

Drug Quality & Security Act (why & what)

- Hospitals and health care systems historically compounded drugs in-house
- Outsourcing has dramatically increased in past 15-20 years
- NECC tragedy highlighted dangers of unregulated, large scale compounding
- Drug Quality and Security Act (DQSA) Signed into law on November 27, 2013
- ***New section, 503B "Outsourcing Facilities" with following requirements:***
  - *Has voluntarily registered with the FDA & compounds sterile drugs*
  - *Is not required to obtain a patient-specific prescription prior to compounding*
  - *Compounding must be done under the supervision of a licensed pharmacist subject to state licensing laws*
  - *Must comply with cGMP requirements and subject to FDA inspections*
  - *Must report which products they are compounding and any adverse events*
  - *Must pay establishment, annual fees, and reinspection fee if applicable*
  - *Is exempt from*
    - *Labeling requirements that include adequate directions for use*
    - *The approval of human drug products under drug applications (NDA or ANDA)*

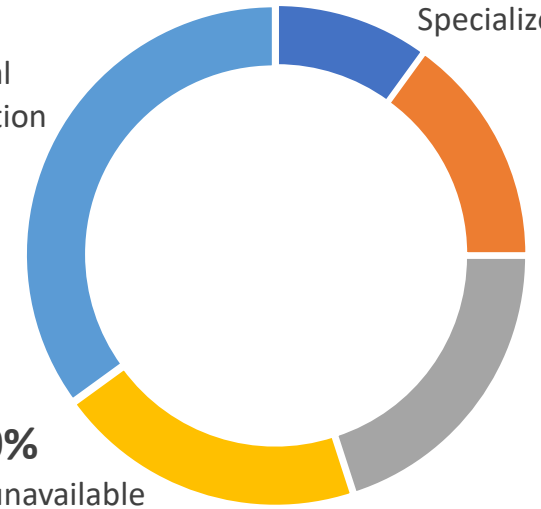
Evolution; Compounding Pharmacies to 503B Facilities

Traditonal Expectatations (prior to 2012)	• Regulated by State BOP's under USP<797> • No FDA review prior to marketing • Order to delivery less than 1 week • New Products easy to add
What Changed?	• Scale • 2012 Fungal Meningitis Outbreak (750 cases, >60 deaths) • Calls for oversight of compounding pharmacies • DQSA enacted in 2014
Current Observations	• FDA has stated it continues to observe egregious/insanitary conditions and adverse event reports associated with compounded drugs from the problematic facilities* • Enforcement Actions significantly escalated • Supply chain challenges as clients navigate changes **FDA Update on Compounding (ASHP-Mid Year 2017)*
What 's Next?	• Enforcement activities to continue to escalate • Compliance is increasing costs but ***Noncompliance*** is even more costly • Clients and manufacturers will have to transparently partner to overcome supply chain challenges

Market Size & Segmentation

- Market of $5.6B spread across more than 8,000 companies.
- 503B's typically perform:
  - Dosage alteration
  - Application alteration
  - Shortage drugs
- Pharmaceutical ingredient alteration replaces existing ingredients with alternatives to avoid allergies or adverse drug interactions
- Application alteration reformulates drugs into more convenient or tolerable forms
- Compounding unavailable products addresses supply shortages
- Dosage alteration changes strength or concentration
- 503b current market <$1.5B
  - Market penetration 15-20%

Product and Services Segmentation (2015)



35% Pharmaceutical ingredient alteration

10% Specialized animal pharmaceutical manufacturing

15% Pharmaceutical dosage alteration

20% Pharmaceutical application alteration

20% Currently unavailable pharmaceutical manufacturing

Total = $5.6B

Source: www.ibisworld.com

Drug Quality & Security Act (implications)

- Primary significance of DQSA to 503B is that it provides mechanism for oversight and regulation. Essentially, all inspections after the DQSA resulted in warning letters
- Since passage, less than 3% of 503B's have been issued an *Establishment Inspection Report* which traditionally has signaled satisfactory closure of an inspection
- Combination of demand, fragmentation and new/pending regulatory requirements are creating significant shifts in both market share and customer experience
- Although there is a tremendous amount of flux, the overall dynamic is favorable as regulatory pressure driven by both inspections and guidance is not only creating a higher barrier to entry but also driving costs up in all channels (making outsourcing more favorable). Additionally…..
  - Although the total growth is low at ~6.5% CAGR, the market remains severely underpenetrated (< 20%)
  - The market is highly fragmented with one 503b representing ~50%, the next 5 ~40% and 60+ companies share the remainder.
  - The largest company has closed two of their largest sites due to quality issues, creating a significant market share shift
  - Comparable comps in the space are few, but very favorable and based on forward looking EBITDA due to market and company growth

Value Proposition - Insourced Versus Outsourced

503B compounding pharmacy is a highly regulated industry that compounds and packages ready-to-use pharmaceuticals for a hospital environment

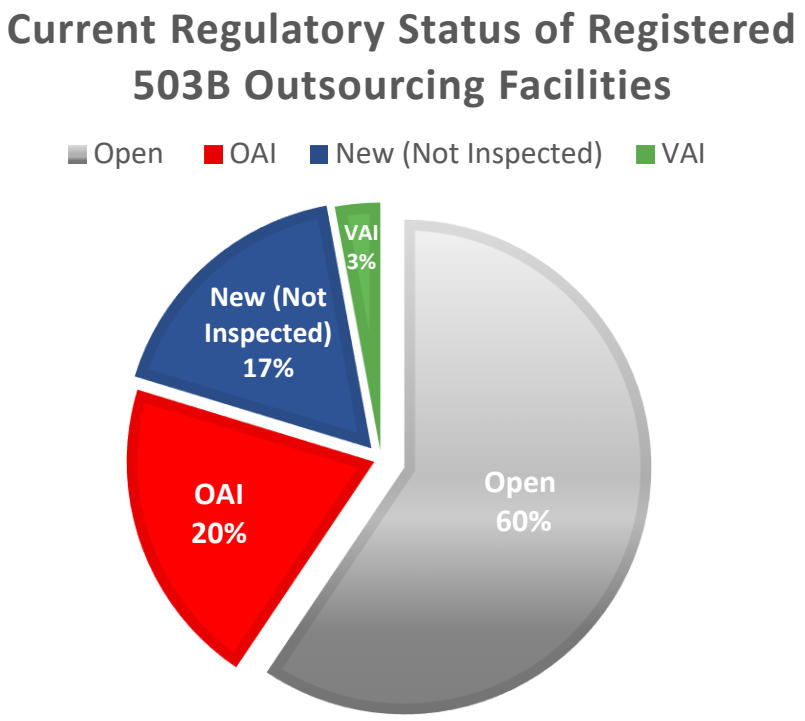
Acute Care Pharmacy Concerns	Outsourcing Solutions
USP <797> compliance	Applicable cGMPs & USP <797> compliance
Capital expenses for clean rooms, hoods, etc.	State of the art clean rooms, hoods, and equipment
Trained personnel & staffing issues	Fully staffed with trained pharm techs
Fixed costs	Variable costs based on usage
24 hour expiry	Stability studies and longer dating
Environmental monitoring and testing	Fully staffed Quality Assurance departments
Basic labeling capabilities	Enhanced custom labeling
Waste	Inventory management & less waste
Must order multiple items & supplies	Easy ordering of ready-to-use items

Challenges

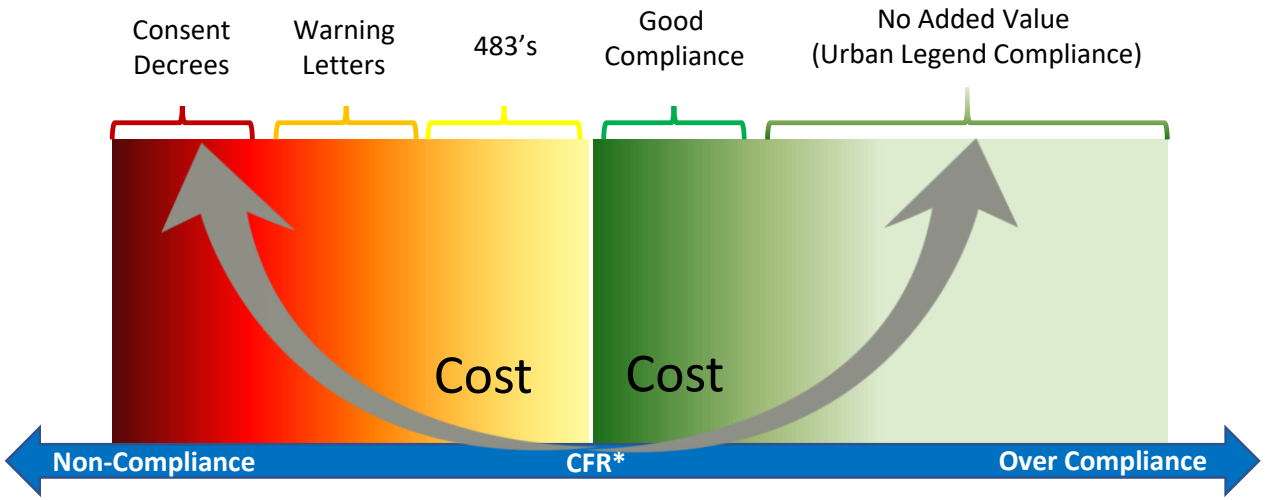
- Prior to passage of the DQSA, current Outsourcing Firms had to comply with USP <797> and the GMP requirements in 21 CFR 210 & 211 are significantly more stringent than USP <797>
  - Many companies have struggled to make transition
- Industry guidance developed for 503B's to comply with the standards remains in draft form and the FDA has a stated policy of discretionary enforcement
- Although industry reports suggest compounding/outsourcing market is a multi-billion dollar component of supply chain, almost 100% of inspected firms are in formal Official Action Indicated (OAI) or a pending status

Regulatory Status Changing the 503b Landscape

- The number of companies registering as 503B outsourcing facilities is not increasing (only 71 after the passage of the DQSA 69 as of 04/2018) One possible explanation is unclear regulatory status
- A review of the latest enforcement actions show the industry (as a whole) is not GMP compliant
  - Only two firms have received an EIR (VAI Status)
  - 20% are in OAI status and 17% waiting inspection
  - 60% of the industry pending/waiting classification
  - Largest provider ceased operations in primary facility
- The cGMP bar is difficult for pharmacies that are used to USP 797 compliance
- Further supports the opportunity for cGMP compliance facilities



Non-Compliance is Costly

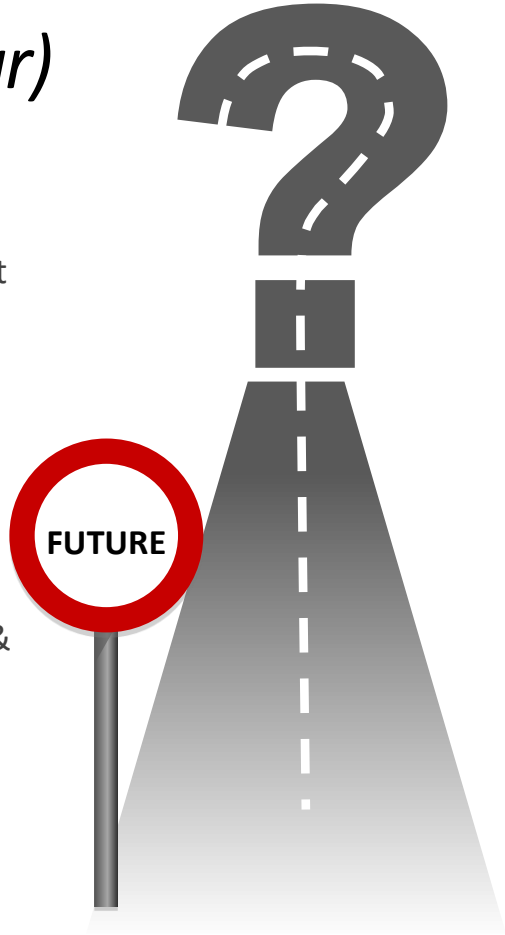


*Code of Federal Regulations – establishes what is to be done but not how to do it

The continuing lesson for FDA-regulated companies is that the FDA is fully-engaged, and highly-focused, on enforcement activities. Movement from 483 to Warning Letter and beyond is much swifter than in past years and a new paradigm to navigate for 503B outsourcing facilities. Understanding the environment suggests non compliance has a huge negative impact on your business' bottom line and greatly impacts product availability to the market.

Crystal Ball *(future is not completely clear)*

- Still appears to be some "runway" for full compliance
  - By the end of 2018 firms will be expected to have sterility, endotoxin, EM data, potency and stability data to support labeled BUD for each lot of material
  - Those that do not will not survive, creating more opportunity for compliant companies
- Combination of shifting market share and low penetration presents significant upside potential in the space
- Market is ripe for consolidation
- Ability to market without ANDA/NDA approval equals fast time to market & ROI
- Rapid Growth means valuations are based more on projected EBITDA than TTM
  - Currently trending at 9-12X forward looking EBITDA
- Overall 503b's are moving towards an integral part of the hospital drug supply chain and the future for the companies investing in cGMP facilities is bright.



Final Thoughts