Background

• The outsourcing facility (OF) sector has been regulated under Section 503B of the Act since 2013

• While a few firms have been operating for several years, most of the sector is comprised of relatively young companies

• As a young sector, outsourcing facilities face struggles with identity and regulatory compliance

• Outsourcing facilities serve important patient needs and this necessitates forging a clear path forward
A Simple Framework

OF Business Viability

Patient Access

Product Quality
Sources of Information for this Presentation

• The Compounding Quality Center of Excellence Landscape Study
  – Analysis of data
  – Annual surveys of OFs
  – Deloitte’s conversations with OFs and other stakeholders

• Listening sessions
OF Business Viability

Patient Access

Product Quality
## The Market

### By the Numbers: Compounding OF Market

<table>
<thead>
<tr>
<th>Number of Registered OF Facilities (As of December 2019)</th>
<th>States with OFs</th>
<th>*Size of the 503B Market</th>
<th>**Compounding Market Growth (503A and 503B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td>23</td>
<td>$2.3 - $4.6B</td>
<td>2% - 4%</td>
</tr>
</tbody>
</table>

*Methodology: CMS spending data indicate Medicare Part D spending on compounded drugs. Medicare Part D spending averages 30% of total prescription drug spending, which is the ratio applied to estimate total compounded drug spending. The GMI market report estimates 503B compounding holds a 52% market share. This is then applied to the total compounding market revenue to estimate the size of the 503B market; **Source: IBIS Report (2%), GMI Report (4%)*
Slowly Stabilizing, but Still in Flux

**Historical OF Entry / Exit Trends***

- **+ 82 entrants**
- **- 28 exits**

- **+ 46 entrants**
- **- 27 exits**

- **+ 28 entrants**
- **- 24 exits**

- **+10 entrants**
- **- 13 exits**

---

www.fda.gov
Reasons for OF Market Entry

• Good fit with business model

• Shortage drugs

• Meet customer demand/strategic partnerships
Why Do Outsourcing Facilities Exit the Market?

- Compliance issues
- Difficulties in getting established
- Outsourcing facility operations not the primary business model
- Operating as 503A
Top Business Challenges Identified by OFs

- Costs of maintaining and operating facilities, testing drug products, acquiring equipment, etc.
- Maintaining compliance with CGMP
- Recruiting skilled staff
- Keeping up with changing demand (either increases or inconsistencies)
- Availability of API and drug inputs
Top Business Challenges Identified by OFs

- Costs of maintaining and operating facilities, testing drug products, acquiring equipment, etc.
- Maintaining compliance with CGMP
- Recruiting skilled staff
- Keeping up with changing demand (either increases or inconsistencies)
- Availability of API and drug inputs
Challenges in Identifying/Acquiring API Supply

• Because most OFs are not high-volume purchasers, many must depend upon brokers for API sourcing.

• Brokers vary in quality practices and reputability. Some brokers lack transparency regarding sourcing of APIs, although this appears to be improving.

• Supply chain concerns due to high overseas production and difficulties in characterizing chain of custody.

• Resource intensive to qualify suppliers, especially when multiple suppliers are needed.
Challenges With API Suppliers

- High costs
- Inconsistent supply
- Lack of transparency
- Slow delivery
- Inconsistent quality
- Inconsistent customer service
- Consistently low quality
- Other. Please specify:

Number of Occurrences
Top Growth Opportunities Identified by OFs

• Competitive pricing
• Increasing demand
• Building and maintaining relationships with buyers
• Responding to drug shortages
• Using automation or technology
Top Growth Opportunities Identified by OFs

- Competitive pricing
- Increasing demand
- Building and maintaining relationships with buyers
- Responding to drug shortages
- Using automation or technology
Top Growth Opportunities Identified by OFs

- Competitive pricing
- Increasing demand
- Building and maintaining relationships with buyers
- Responding to drug shortages
- Using automation or technology
Trends in OF Shortage Production

Drug Shortage Production in the OF Market | January 2017 – December 2020*

Percentage of Drug Shortage Production

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7%</td>
<td>1.9%</td>
<td>8.0%</td>
<td>10.1%</td>
<td>7.6%</td>
<td>8.8%</td>
<td>17.3%</td>
<td>15.8%</td>
</tr>
</tbody>
</table>
Shortage Production Varies Across Firms

Percentage of each OFs Production Volume that are Drug Shortage Products

- **25%** of OFs have 20% or more of their production volume encompassing shortage drugs.
- **33%** of OFs do not produce any drug shortage products.
Top Growth Opportunities Identified by OFs

• Competitive pricing
• Increasing demand
• Building and maintaining relationships with buyers
• Responding to drug shortages
• Using automation or technology
Automation Technology

• Approximately 60% of OFs claim to utilize automation technologies (based on survey data)

• Most technologies center around filling and packaging/labeling

• Firms not utilizing automation technology cite cost and lack of scale
Impact of Regulation

• All regulated industries are impacted by regulation—financially and otherwise.

• As a newly regulated industry, there is greater policy flux than with established industries as FDA continues to develop new policies.

• OFs are a young industry with mostly smaller companies. Firms can be more heavily influenced by policy changes due to being smaller in size.

• While public health and patient safety are always our foremost priorities, FDA is also mindful of the interplay between policy development and OF sector operations.

• OFs also cite that the differing regulatory models among states continue to be a challenge.
Product Quality
Quality—Motivating Factors

• In general, OFs are motivated to include quality practices/quality culture within their firms

• In addition to patient safety, OFs cite standardization, reliability, and customer satisfaction as motivators

• OFs also cite that purchasers tend to place more value on OFs that have more robust quality practices

• Risks of reputational harm and regulatory consequences also cited as motivators
Quality—Challenges

• Broad variability among OFs regarding quality practices and level of implementation

• Based on survey, 60% of OFs referenced utilization of SOPs to deal with quality failures, and 33% indicated use of a quality unit
Compliance Challenges

• Compliance is an ongoing challenge, especially within the realm of CGMP

• Some OFs express a lack of clarity in reference to FDA expectations regarding 483 and Warning Letter responses

• OFs indicate FDA delays in timeliness of inspection closeouts, responses to submissions (e.g., 483 responses, Warning Letter responses)

• Some OFs indicate difficulties with understanding areas of FDA policy
A Glimmer of Improvement

Inspection Classification Breakdown by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>OAI</th>
<th>VAI</th>
<th>NAI</th>
<th>#N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-2015</td>
<td>61%</td>
<td>27%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>2016-2018</td>
<td>50%</td>
<td>44%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>2019-2020</td>
<td>53%</td>
<td>35%</td>
<td>6%</td>
<td></td>
</tr>
</tbody>
</table>

n= 135 inspections*
Patient Access
Who are the Customers?

- Hospital(s) / Medical Center(s)
- Physician Office(s)
- Clinic(s)
- Health System(s) / Integrated Delivery Network(s)
- Other
- Nursing home(s)
Hospital Systems

• Large batch, standardized products (especially true for larger hospitals/hospital systems)

• Products that are beyond the compounding/production capabilities of in-house pharmacies

• Longer beyond use dates for products compared to in-house or 503A pharmacy
Physician’s Offices/Clinics

- Smaller portfolio of specialized products
- Office stock
- Niche products for specialized use (ophthalmology, dermatology)
Are GPOs Involved?

- Up to 45% of OFs (per survey) work with GPOs
- Typically true of larger OFs
- Hospitals and health systems utilize GPOs to assist in vetting OFs
Potential Product-Specific Areas of Demand Per Hospitals and Providers

- Shortage drugs
- Ready to use formulations
- Small-batch, niche products
Key Takeaways

• OFs are young but growing and while there are difficulties, there are viable areas for business growth.

• Quality/compliance continues to be a pain point, but is showing signs of slight improvement and firms are motivated to improve quality.

• There is demand for OF products from diverse areas, most of which should be viable in the long-term. OFs indicate demand is growing.
The Future Involves All Stakeholders

Outsourcing Facilities

Medical Facilities

Physician Offices

GPOs

Hospitals

Health Systems

OF Business Viability

Industry Organizations

Pharmacy Organizations

Patient Access

Product Quality

API Suppliers

FDA

State Regulators
How Do We Get to the Center?

- OF Business Viability
- Patient Access
- Product Quality