



CHANGING PHARMA'S PARADIGM OF WASTE

How Pharma's Demand Volatility Could
Be Costing You Millions in Material
Write-downs & Procurement

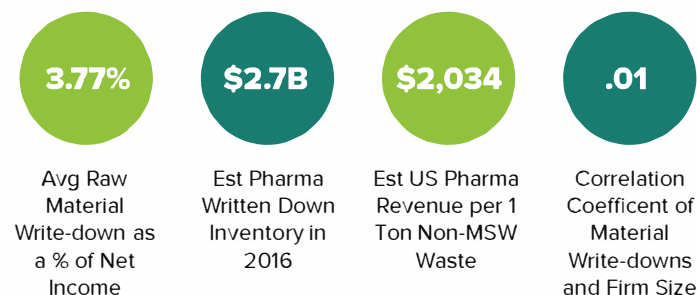
RON EGGERT | AUGUST 2018





OVERVIEW

Demand volatility is a challenge for every supply chain. It strikes at the end causing a “bullwhip effect” that becomes exponentially more impactful further back in the chain. For Pharma, the effect is strongest in manufacturing and procurement, specifically with starting raw materials and consumables. Swings in demand can cripple launches, cause stock-outs, inflate material prices, make lean planning ineffective, and cause significant write-downs of excess/obsolete materials; ultimately inflating CoGS and reducing net income. These swings can also cause inventory costs to inflate, materials to expire or become obsolete, higher disposal fees, and a larger carbon footprint. The yearly financial impacts are staggering considering Pharma's economic footprint. Twenty of Pharma's top 100 companies were sampled using 2015 & 2016 financial figures 1-2-3-4. Industry estimates for waste include:



What Do These Numbers Mean?

- 3.77% is alarmingly high and does not include capitalized consumables, equipment disposal, and similar waste
 - \$5B in net income: est \$185M in write-downs
 - \$50M in net income: est \$1.9M in write-downs
- \$2.7B is likely much lower than the real figure due to capitalizing consumable inventories for launches and other accounting practices.
- \$2,034 to one ton of industrial waste is not progressive.
- .01 correlation coefficient means this problem does not discriminate based on company size and is ubiquitous in the industry.

Industries have attempted to mitigate the bullwhip effect through many techniques and systems such as ERP, robust forecasting models, demand management, LSS tools, strategic sourcing, etc. However, life science firms still struggle to effectively address this problem as evidenced by the write-down figures. Many non-FDA regulated industries have started utilizing marketplaces and brokerage services to create circular supply chains that optimize waste by connecting buyers and sellers. Yet, Pharma and life sciences have not adopted this **waste-centric supply chain** and execute it in a manner conducive to the compliance and indemnification requirements of the industry regarding primary and secondary transactions of raw materials, equipment, consumables, spare parts, and collaborative relationships. Finished products such as APIs, intermediates, and devices are out of scope for this supply chain.

A **virtual life sciences marketplace and consortium** consortium for manufacturers, researchers, and vendors can minimize the aforementioned problems by quickly, innovatively, and transparently exchanging material information in safe and controlled environment ensuring a firm's standards for data integrity, cGMP compliance, contractual indemnification, and financial benefits are met; all by leveraging core auditing skills.

It is a call to arms among supply chain, procurement, and quality leaders to take part in a more circular, greener, and collaborative supply chain. Time is critical as global competition grows, customer and government emphasis on lowering pricing mounts⁵, and collective pressure on sustainability demands widespread action.

Let's explore the **Current** and **Future State** of this industry issue to understand why such a marketplace can begin the much-needed transition for life science companies.

BASELINE PROBLEM WHAT?

- Disposal of high-quality materials, equipment, spare parts
- Single and/or limited sources of supply
- Inability to collaborate with like-minded life sciences firms
- High CoGS due to materials write-downs
- High inventory carrying costs
- Greater business continuity risk
- High disposal costs
- Larger environmental footprint
- Stock-out of materials

WHO?

- FDA Regulated Industries, Procurement, Quality, Production, and Finance.

WHERE & WHEN?

- Commercial & clinical production, R&D, sourcing/purchasing, production planning, quality testing, etc.
- Volatile demand periods, e.g., product intro growth, decline, seasonality, economic uncertainty, and unforeseen events.

HOW DO WE KNOW IT'S THERE?

- We physically see it taking place, and it's in our data.

TRIPLE BOTTOM LINE IMPACT

Financial

Vendors/ Sellers

- Higher write-downs/offers and 3rd party disposal fees

Buyers

- Lost sales – stock-outs
- Inflated market value of materials & supplier expedition fees
- High SS cost due to bullwhip effect

Environment

- Greater contribution to global warming through landfill addition, incineration, inactivation, and energy consumption.
- Noncompliance with ISO 14000 & 9000 and B-Corp Status

Society

- Lost community trust - high environment and consumer costs
- Less Innovation, collaboration, and supply chain optimization

Current State

External Solutions

A plethora of techniques are employed to mitigate, prepare for, respond to, and recover from the bullwhip effect, which is one of the leading causes of write-downs and waste. However, such efforts are predicated on:

BULLWHIP INFLUENCES

FORECAST ACCURACY

SUPPLIER RELIABILITY

PROCESS VARIABILITY

EXTERNAL ENVIRONMENT

While not fruitless, attempts to mitigate the above external influences are extremely unpredictable and have never solved pharma's write-down, inefficiency, stock-out, and environmental problems.

Internal Solutions

The next effort involves reducing obsolescence by making use of materials within the firm. Typically, interplant demand is the only outlet to optimize surplus earmarked for a reserve/write-down. Even this involves many of the same regulatory compliance, quality, and economic challenges. Facilitating this takes time, resources, and does not inherently have a broad network to utilize.

Environmental Solutions

FDA industries, like most others, make attempts to reuse, recycle, and convert to energy where applicable. However, they're unable to conduct these activities for perishable, expiring, and/or consumable materials.

Undesirable Solutions

Unfortunately, third-party disposal (frequently landfill) is typically the first and most popular option as perishable, expiring, and complex materials are generally unable to be reused or recycled. These disposals come in many forms to include responsible landfills, incineration, inactivation, etc.

Overall

Industries spend much capital and resources to reduce write-downs in an environment where the bullwhip effect reigns supreme. Mitigations to this effect are attempted but only partially successful or sustainable.

REFINED PROBLEM

There is no clear market leader that helps organizations optimize waste, collaborate to reduce it and market more quality materials to more firms whether for research, manufacturing, or donations. This marketplace must be regulated and all participants properly vetted and authenticated. Accounts must be created to enable companies to post materials and request for information/quotes. Additionally, this marketplace must facilitate collaborative relationships between companies that help them reduce supply chain costs. It must quickly, economically, compliantly, and legally facilitate those exchanges. Lack of this market leader may have enabled the waste problem as seen today.

Contemporary Operating Environment

- o Constant pressure from global competition, increasing customer and governmental demand on price, more regulatory scrutiny, and a relentless societal pursuit of sustainability are starting to erode what were once high margins for Pharma⁶.
- o Regulators are cooperative and open to solutions.
- o Exchanges and consortiums are not typically leveraged in Pharma.
- o Pharma continues to struggle with the bullwhip effect.

BARRIERS

COMPLIANCE

It is the responsibility of the industry to provide customers with quality, safe, and efficacious products. However, there is a misperception that high-quality cGMP compliant materials, parts, and equipment cannot be sourced from aftermarket exchanges and consortiums.

LIABILITY

Contractual agreements with suppliers have clauses to resolve issues dealing with poor quality. There is a misperception that these agreements cannot be effectively implemented within the marketplace.

CONFIDENCE

Exchanges can be difficult due to time/effort. A sanctioned marketplace can provide the structure to make it easy.

SUSTAINABILITY

Firms have not discovered how to leverage marketplaces to reduce environmental footprint and enable industry certifications as well as community trust.

CONFIDENCE

Trust is critical to firms. They should know that a marketplace has properly vetted members and information is available.

SPEED

Transactions should be seamless and quick. The right marketplace design can make this a reality.



ROOT CAUSE & PARADIGM SHIFT

Comfort in the status quo has enabled a culture of waste. With life science margins so high, it hasn't been a priority to solve. Additionally, there hasn't been an effective means to deal with waste. This limits the industry's ability to leverage these marketplaces. Finally, misperceived issues or liability and quality have strained innovation; all are solvable problems.

Future State

Creation of Private Virtual Life Sciences Multi-Vendor Marketplace & Consortium where researchers, manufacturers, and original-end manufacturers can create a simple storefront for their organization and transact materials, equipment, parts, and collaborative relationships in a compliant and professional environment. This marketplace uses a series of software logic that leverages auditing capabilities of buyers and sellers by making FDA required data and documentation visible and subject to ALCOA-Plus, thus enabling transactions in a fast and compliant manner. This logic then automates contracts for digital signature in a Part 11 compliant package.

Benefits

- o Avoid write-downs for surplus material/consumable stock
- o Continue production when stocked-out of materials
- o Reduce the purchase price of materials
- o Risk pool safety stock to reduce the amount required
- o Allow for leaner planning in that stock outs can be addressed
- o Allow for more responsive planning with an outlet to sell SS
- o Reduce supplier audit resources and costs
- o Reduce environmental footprint by avoiding disposal fees

VISION

- A collaborative and compliant multi-vendor marketplace is part of Pharma's normal operating practices
- Waste is not tolerated in the life sciences industry
- There is always a compliant outlet to procure and transact before and after market materials

HOW TO IMPLEMENT

Application of the following guidance, regulations, and bodies will drive exchange process and design:

- o ICH Q7 (international harmonized cGMP standards)
- o CFR Title 21 (US cGMP standards)
- o Data Integrity Draft Guidance by FDA (good doc practices)
- o WHO GMP for Pharmaceutical Products (World Health Organizations cGMP standards)
- o APIC - Good Manufacturing Practices in Active Pharmaceutical Ingredients Development, 1999.
- o APIC Supplier Qualification and Management Guidelines

Data Integrityt

Data integrity will drive how the exchange operates. All parties are encouraged to use the FDA's ALCOA-Plus system to review documents associated with transactions. This enables adherence to buyers' standards of data integrity and cGMP quality compliance.

HOW TO FIND OUT MORE

The exciting new marketplace called **RawConnect** is scheduled for initial launch Fall 2018.

FOR MORE INFORMATION:

Email : **Ron Eggert**

Visit Us : **www.rawconn.com**

Call Us : **844-383-7272**

***WE** enable a greener, more cost-efficient, and quality-driven supply chain through a collaborative life sciences marketplace.

***WE** are an emerging small business with the ultimate goal to educate, inspire, and align Pharma around a new paradigm of waste optimization and sourcing strategies.

***WE** aspire to increase medicine access around the world and decrease Pharma's overall environmental impact.

SOURCES

➤ Top 100 Pharma Companies

https://scrip.pharmaintelligence.informa.com/-/media/market-ing/scrip-100/pdf/Scrip100_LeagueTables.pdf?la=en

➤ 2016 Annual/10K Reports

GSK, Roche, Sanofi, AstraZeneca, Bayer, Astellas, CSL, Merck Group, UCB, Recordati, Ono, Daiichisankyo, Chugai-pharm, Stada, Lundbeck, Dr. Reddys, Hikma, KRK

➤ Total Pharma Revenue 2016

<http://pubs.acs.org/doi/pdfplus/10.1021/acscchemneuro.7b00253>

➤ Currency Exchange Rates 29 Jan 2018

<http://www.x-rates.com/table/?from=USD&amount=1>

➤ Pricing Pressure

<http://www.nejm.org/doi/full/10.1056/NEJMp160129>

EVERY NEW JOURNEY OF CHANGE AND INNOVATION IS FOR THEM...

THE PATIENT

