

Loss of Exclusivity



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Executive Summary

This semester, the Healthcare Distribution Alliance (HDA) Research Foundation partnered with the Rutgers Business School on a research project focused on loss of exclusivity (LOE) within the pharmaceutical industry. The Rutgers Business School Team (the RBS Team) is formed by students from the Master of Supply Chain Analytics and Master of Business Administration programs. The objective of this research project was to identify best practices and other strategies that brand drug manufacturers and other stakeholders could utilize to reduce the impact of a loss of exclusivity event. This paper will outline our findings and recommendations.

Before collecting research, we created a project plan to outline the scope and timeline of the project from start to finish. To complete this, the team separated the semester into four phases; the first of which focused on planning, the second and third focused on data collection and analysis, and the fourth and final phase focused on the compilation of research and results, delivered to the HDA Foundation in the form of a virtual presentation and white paper.

The data used to form the RBS Team recommendations were collected from various sources including: primary data collected in the form of a Google Forms survey; secondary research was conducted on available published articles on LOE; and virtual interviews of two non-profit charitable organizations.

Throughout the project, the team encountered a few challenges. Due to our limited prior knowledge of the subject matter, we were required to spend the first few



weeks of the project getting more familiarized with the pharmaceutical industry. Additionally, due to the virtual nature of this assignment, we unfortunately missed out on the benefits of face-to-face interaction. To mitigate this missed opportunity, we were diligent in attending all weekly meetings, both internally and with the HDA team and advisory committee, to keep the lines of communication open and the project moving forward.

In summary, recommendations focus on adjustments to the production methods after a loss of exclusivity event, as well as increased communication and increased focus on forecasting as the loss of exclusivity date approaches. Though we believe our recommendations will help organizations reduce the impact of a loss of exclusivity event, we fully recognize that there is no "one-size-fits-all" solution that organizations can uniformly apply. This is simply due to the fact that they each have unique available resources and capabilities. Our findings indicate that organizations which plan in advance and communicate well, however, will be in the best position to succeed.

Introduction- Overview of Pharmaceutical Supply Chain and Major Players

The pharmaceutical supply chain is very complex but essential for ensuring that prescription medications reach patients. In the U.S. prescription drugs mostly flow from manufacturer to distributor to dispenser and ultimately to patents.



Each key player plays an important role. The manufacturers bring branded and generic therapies to market. Distributors handle inventory management and provide ontime shipments of ordered products. They also play the role of financial intermediary, extending credit to providers and managing collections and payment from manufacturers along with many other value-added services. Dispensers (chain drug stores, independent pharmacies, hospitals etc.) provide patient care and dispense pharmaceutical products to the patients. All of these parties work together to ensure that drugs are manufactured and delivered to patients on time. Additional key players in the supply chain can include Pharmacy Benefit Managers (PBMs), government agencies (FDA and DEA), Group Purchasing Organizations (GPOs) and Pharmacy Services Administrative Organizations (PSAOs).

Loss of exclusivity- what it is, how it works and what it results in

When a new prescription drug is formulated, the pharmaceutical manufacturer is granted a legal patent that can last between 10 to 15 years, depending on the type of drug.¹ For a limited time, the legal rights awarded to the pharmaceutical manufacturer include the right to develop, sell, and market the drugs. Drugs face generic competition after they go off-patent. LOE requires the pharmaceutical manufacturer to relinquish control of a specific drug formulation, which is then awarded to the entire market. When

¹ Northup, Paige. "Misconceptions about Loss of Exclusivity - and Their Impact on Patients." Truveris, September 6, 2022. https://truveris.com/loss-of-exclusivity/.



a branded pharmaceutical product's patent expires, it is usually met with competition from a generic brand of that drug.² As a result, many manufacturers can sell a generic version of the same drug or employ other strategies to ensure that their sales are not adversely affected. LOE is an important part of every drug's life cycle because it allows for innovation and even improves opportunities for all.

Additionally, on most occasions, there has been a decrease in sales of branded pharmaceutical products as a result of LOE. Most people think of LOE as a phase that permanently alters brand profitability for the manufacturer who originally held the patent for a given drug. This is not always the case because competition may still be light even after the company's patent expires. Also, more than one manufacturer usually sells a generic drug after a drug is off patent, increasing the competition. Thus, due to the level of competition, the drug's price is expected to fall dramatically; however, this is not the case. Truvada, an HIV medication, is one example of a drug that has been declared to have undergone LOE. Unlike other drugs, the generic drug that was introduced to the market was 30 percent less expensive, indicating that what happens after LOE may vary. Another important variable that manufacturers use to ensure that they respond to market signals when their drug is no longer on patent is competitive intelligence.

² Healthcare Distribution Management Association." Loss of Exclusivity: An Inventory Management Case Study" 901 North Glebe Road, Suite 1000. Arlington, Va. 22203 (2013): 1-29



Negative Impacts of a Loss of Exclusivity Event

When LOE occurs there is, in most cases, a significant drop in demand for the branded drug because generic competition can arise and make a similar drug at a fraction of the cost. After LOE is declared, the branded drugs on the shelf are likely left to stay idle until they are returned as expired goods. If effective measures to address the LOE are not implemented, a significant loss occurs. Furthermore, when a drug goes off-patent, the drug's market share is likely to dwindle quickly because of new market entrants. One example is of a drug that lost 73 percent of its market share after two weeks of LOE.³ This is not always the case though. Market share is greatly dependent on the number of entrants in the market. If there are a lot of competitors, a company's market share for a drug will reduce but if there are not many competitors, there won't be as much of an impact.

The main issue is that the branded drug is more expensive than the generic, causing patients to switch. Despite this, the effects of LOE vary due to the brand and category of the drug. Additionally, once a drug is no longer under patent, a manufacturer does not necessarily lose the ability to command meaningful market

³ Healthcare Distribution Management Association." Loss of Exclusivity: An Inventory Management Case Study" 901 North Glebe Road, Suite 1000. Arlington, Va. 22203 (2013): 1-29



shares and profitability.⁴ Manufacturers can employ a variety of strategies to ensure that they are prepared for LOE years in advance. During this time, planning for evolution and methods for ensuring a high level of customer retention may be necessary.

Another negative effect of LOE is a decrease in profitability. More competition enters the market when the patent granted to the innovator company expires. Generic drugs are frequently manufactured at a lower cost and even sold at a lower cost than the original drug. As a result, when a branded drug goes off-patent, more generic drugs at lower prices enter the market. Because of the immense level of competition in the market, the innovator company's profitability tends to suffer as its customer base shrinks. With the loss of key customers to the competitor, the overall profit of innovator company decreases.⁵

Another negative effect of a branded drug losing its patent is a loss of market share. When a company has the exclusive right to manufacture a specific drug, they become the sole source of supply. As a result, profit is generated because patients may have no choice but to purchase the branded drug at whatever price is set. However, with LOE, patients have the option of purchasing generic drugs at a lower cost, which

⁴ Moosivand, Asiye, Ali Rajabzadeh Ghatari, and Hamid Reza Rasekh. "Supply chain challenges in pharmaceutical manufacturing companies: using qualitative system dynamics methodology." *Iranian journal of pharmaceutical research: IJPR* 18.2 (2019): 1103.: IJPR, 18(2), 1103. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706717/</u>

⁵ Reynolds;, T. F. F. G. J. (n.d.). *Loss of exclusivity: Strategies to maximize product value*. PharmExec. Retrieved January 12, 2023, from https://www.pharmexec.com/view/loss-exclusivity-strategies-maximize-product-value



has a negative impact on the innovator company. When a drug goes off patent, the sales volume decreases since the generic drugs tend to be bought at a large volume. When patients are aware that they can find a drug that performs the same function as the branded drug at a lower cost, they tend to choose generic. Consequently, the volume of drugs sold on the market tends to decrease with LOE. Another loss experienced as a result of LOE is a decrease in cash flow. With low sales of branded drugs, less cash flow is generated. Another issue is that when a drug's patent expires, there is a likelihood of a decline in total shareholder payouts.⁶

LOE is an essential and important stage for every drug, and it should happen when it is time. However, for a manufacturer, this may have negative consequences if proper precautions are not taken to ensure that post-LOE profits are not harmed. In order to adapt to shifting market conditions and company priorities, the manufacturer must also make sure that the post-LOE strategies developed over time are critically reviewed. It is crucial to plan ahead in order to safeguard medicine from the patent cliff. Thus, more targeted clients can be attracted at a reasonable cost even after the post-LOE phase. Loss of exclusivity cannot be avoided, but the harm caused by this process can be mitigated by planning in advance and implementing the best strategy.

⁶ Zimmermann@stlouisfed.org, & Wagner, F. G. & S. (1970, January 1). Patents, data exclusivity, and the development of new drugs. The Review of Economics and Statistics. Retrieved January 12, 2023, from https://ideas.repec.org/a/tpr/restat/v104y2022i3p571-586.html



Project Scope and Deliverables

In this research project, the team helped HDA to study the possible solutions to alleviate the impact of an LOE event. The team read a case study⁷ provided to us by HDA, researched the process of LOE and learned more about the pharmaceutical supply chain which we shared with HDA during our weekly virtual meetings. A survey for committee members was created to collect information for our analysis and we scheduled one-on-one interviews with clients as necessary. Our final deliverables include a white paper that includes an in-depth report of our project, processes and recommendations and a presentation to the foundation board and subject matter experts.

Prior to commencement of the research, the team prepared a project timeline of all scheduled goals per week. This component of the project plan was important because it ensured that the team was held accountable for keeping the project moving forward. The project's timeline is very straightforward. Table 1 highlights our weekly goals, planned dates, and completion dates. In Phase I, the team started communicating with HDA and began its initial research of the subject matter. Throughout the semester, the team assessed its progress and determined that overall, the project was progressing in a timely fashion and in accordance with the schedule.

⁷ Healthcare Distribution Management Association." Loss of Exclusivity: An Inventory Management Case Study" 901 North Glebe Road, Suite 1000. Arlington, Va. 22203 (2013): 1-29



The milestones shown in Table 2 highlight the key tasks that were necessary to complete for the success of the project.

Project Timeline

Project Phase	Target Completion Date	Key Tasks	Completed Date		
I	9/10/2022	Class Intro and Product Overview	9/10/2022		
I	9/17/2022	Group Formation, Client Kick-off	9/19/2022		
I	9/24/2022	Begin Research of Pharmaceutical Supply Chain and LOE	9/24/2022		
п	10/1/2022	Finalize Project Req Doc, Timeline, Create Survey	10/01/2022		
П	10/8/2022	Research Donation Companies, Schedule Necessary 1:1 Interviews	10/19/2022		
п	10/15/2022	Complete Survey for distribution	10/13/2022		
П	10/22/2022	Mid Term Class Presentation, Receive Survey Results	10/22/2022		
ш	10/29/2022	Review Survey Results	11/04/2022		
ш	11/5/2022	Complete Analysis	11/07/2022		
Ш	11/12/2022	Agree on Identified Practices to Mitigate LOE Loss	11/14/2022		
IV	11/19/2022	Prepare Draft Presentation	11/14/2022		
IV	11/26/2022	Prepare Updated Draft Presentation	11/14/2022		
IV	12/3/2022	Dry Run Presentation	12/05/2022		
IV	12/10/2022	Final Client Presentation	12/16/2022		

Table 1: Project Timeline



Table 1 highlights the key tasks, planned dates, and completed dates. In Phase I, the team started communicating with HDA and researching online. The milestones shown in Table 2 highlights the key tasks that were necessary to complete for the success of the project

In Project Phase II, the team finalized the required documents with the HDA team. Then the team focused on designing a survey for the committee members and met with the HDA team several times to discuss and improve the survey question before distribution. The survey development took longer than expected. However, the team finalized and distributed the survey in accordance with the project timeline. While awaiting the results of the survey, the team successfully interviewed two charitable non-profit organizations and received sufficient data about the donation process and regulations.

The total number of survey responses did not meet the expected hit rate, which was challenging for the team. The group had provided two weeks for HDA members to complete the survey, but it was later determined that more time would have been beneficial. Due to the confidential nature of the survey, the team was not informed of which companies the survey was specifically distributed to. We only have data that reflect the number of respondents. Furthermore, since the questionnaire is purely voluntary, we had no control over the number of respondents or the organization type. This delayed completion of tasks during Phase III of the project slightly.

In the last phase of the project, the group divided the work and started to prepare the PowerPoint and white paper while continuing weekly check-ins. Before the final

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presentation, the team and HDA completed a dry run of the presentation. The PowerPoint was formally presented to the HDA Research Foundation Board of Directors on December 16, 2022.



Milestones Completed

Milestones	Planned Dates	Actual Dates
Prepared Draft Project Req Doc	9/26/2022	9/23/2022
Prepared Project Timeline	9/26/2022	9/27/2022
Fully Executed Project Req Doc	9/30/2022	9/28/2022
Survey Questions Approval	10/7/2022	10/6/2022
1:1 Interview with Americares	10/7/2022	10/12/2022
Schedule Interviews	10/7/2022	10/12/2022
Create Survey in Google Forms	10/14/2022	10/13/2022
Distribute the Survey to the members	10/17/2022	10/17/2022
Interviewed with Americares	10/19/2022	10/19/2022
Started receiving survey responses	10/20/2022	10/20/2022
Midterm Presentation	10/22/2022	10/22/2022
Set Interview with Dispensary of Hope	11/4/2022	11/4/2022
Interview with Dispensary of Hope	11/4/2022	11/4/2022
Finish Collecting Survey Result	11/4/2022	11/4/2022
Survey Result Analysis	11/7/2022	11/7/2022
Started to draft the white paper	11/13/2022	11/13/2022
Agreed on Identified Practices to Mitigate LOE Loss	11/14/2022	11/14/2022

Table 2: Milestones



Sep Sep 11	Sep 18 Sep 25	Oct 2	Oct 9	Oct 16	Oct 23	Oct 30	Nov 6	Nov Nov 13	Nov 20	Nov	27	Dec 4	Dec 11	Dec 18	Dec 25	Jan 1	Jan 8	Jan Jan 15
-	Prepared	Draft F	Project R	eq Doc														
	Prep	ared Pr	oject Tir	meline														
	🔲 Full	у Ехесі	uted Pro	ject Rec	Doc													
							Onli	ne Resea	rch									
			Case	Study I	Review													
		D	evelop (Questior	ns for Su	rvey												
			Survey (Questior	ns Appro	val												
			Sc	hedule I	nterviev	vs												
			C	reate Su	urvey in	Google	Forms											
				Distr	ibute the	e Survey	to the	member	S									
				1:1	Intervie	w with /	America	res										
					Midterr	n Prese	ntation											
							Set Inte	rview wi	th Dispe	nsar	y of	Hope						
							Finish C	ollecting	g Survey	Res	ult							
							Surv	ey Resu	lt Analys	is								
							Intervie	w with D	ispensa	ry of	Нор	e						
														Writing	the Whi	te Pape	r	
											Pe	rparing	g the Fin	al Powe	rPoint			
								Agre	ed on Id	entifi	ied F	Practice	es to Mi	tigate L(DE Loss			
														Final Pre	esentatio	n to the	e Client	
														Finish a	and Subr	nit the	White Pa	aper

Table 3: The Gannt chart

This Gaant chart illustrates the project timeline and any overlap of tasks completed. Our project process is relatively straightforward. The communication within our group and with the HDA team was efficient and smooth, so we incurred no delays to the overall project. However, scheduling interviews was challenging. The reason for this is that we did not know who and when to meet at the beginning of the project. With deeper communication with HDA and a deeper understanding of LOE, the group was able to get directions for what to expect during the interviews. The overall interview process, though successful, took longer than originally anticipated.



Research Insights- Surveys

In order to give HDA more appropriate recommendations to better manage inventory approaching its loss of exclusivity date, we created and distributed a survey. We split the survey into three sections: one for distributors, one for manufacturers, and one for pharmacies and retailers. The questions for all three sections were focused on inventory management and the respective industry player's methods for inventory management. A small sample of the questions we included in the survey were:

- What are your average days on hand inventory?
- What is your initial production methodology?
 - Make-to-Stock or Make-to-Order?"
- If you are made aware of drugs facing LOE, how far in advance are you given notice?"

The team coordinated with the HDA Research Foundation to send the survey on our behalf. While we were expecting a greater number of responses, we believe the quality of responses and the size of some of the responders made for better quality responses. Some of the responses we received from our survey were very surprising to us. One surprising response was that one of the four manufacturers we surveyed did not communicate an LOE date with distributors. Of the remaining three manufacturers who responded, one manufacturer communicated the LOE date to distributors with less than six weeks remaining, and the other two manufacturers communicated the LOE date with more than 16 weeks remaining (See Exhibit 1). We particularly found the two manufacturers that either do not communicate the LOE date at all or give the date with



less than six weeks remaining to be extraordinary as constant communication between distributors and manufacturers, especially about something as vital as an LOE date, is paramount to having stable inventory.

Of the four manufacturers that originally employed a make-to-stock strategy (push strategy- make product based on the forecast, not actual demand), two respondents indicated they move to a make-to-order strategy when LOE nears (pull strategy-make product based on actual orders, not forecast) (Exhibit 2). We found this to be surprising because we had initially inferred that as the exclusivity period diminishes, all manufacturers would want to reduce their risk of having surplus inventory. Once exclusivity expires, generic competition can create similar drugs at much lower prices, drastically reducing the demand for branded drugs. A make-to-stock strategy relies on accurate demand forecasts, and while the forecast may be accurate during the exclusivity period, it may not be after. We had inferred that all manufacturers would switch strategies, but that was not the case.

Additionally, two of the five distributors that responded said that they base their demand forecast on a less than an 8-week period and one of the respondents base their forecast on a less than 3-week basis (See Exhibit 3). This is notable because basing a demand forecast on a relatively short amount of time can drastically skew the requirements one way or another. If a distributor bases their demand forecast on an 8-week basis and there is one week with a high increase or decrease in demand, that one week could skew the future demand forecast much more than if the demand forecast was based on a 10 or 11-week basis. The longer the time you use for your planning, the

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less effect a short-term, yet major increase or decrease in demand, has on your demand plan. A final surprising response we found was that both pharmacies that responded to our survey hold 30+ days of generic drugs in inventory (See Exhibit 4). Once a branded drug reaches LOE, other manufacturers release their own generic version of the drug, and the number of competitors and drugs on the market may increase drastically. We believe that holding 30+ days of generic drugs in inventory is surprising because a common reason to hold inventory is to hedge against scarcity. However, if there is an abundance of supply, holding inventory for long amounts of time does more harm than good. The reason why sitting on inventory does more harm than good is that inventory loses value and costs more to hold the longer it stays idle. If there is an abundance of generic drugs on the market, it would make sense to reduce the days on hand as it would be very easy to replenish stock when needed. If the drug was still in its period of exclusivity, then holding inventory would be a good idea as there are not as many options to get that drug since only one company has the right to make and sell it.

Research Insights- Interviews

As part of our research for this project, we engaged with representatives from two non-profit organizations to assess whether unexpired drug donations would be a viable solution to reducing surplus inventory after a loss of exclusivity event. We also thought that this would be a unique approach to other strategies, because in addition to improving a manufacturer's bottom line, it also provides them with the opportunity to



make a positive impact on society. The organizations that we interviewed both focus on providing access to medicines and other life-saving drugs to low-income communities and areas affected by natural disasters. Prior to these interviews, the team compiled a list of questions for these representatives to better understand their existing practices for collecting donations as well as their donation eligibility requirements. Samples of these questions included the following:

- What are the criteria for accepting product donations? Does [the non-profit organization] accept donations from parties other than the branded drug manufacturer (i.e., pharmacies and dispensaries)?
- What does the donation process look like? Does the manufacturer initiate this conversation prior to the loss of exclusivity event?
- Which changes, if any, would you like to see to the overall donation process of manufactured drugs?

Based on our discussions, we learned that though these organizations are enthusiastic about working directly with drug manufacturers, there are criteria that the donated product must fit before becoming eligible. The most significant restriction is that any product previously in the possession of retailers would not be eligible for donation, due to the risk of tampering. These products have tracing capabilities, so it is not difficult for non-profit organizations to track exactly where they have been. The second rule is that any surplus inventory at the wholesaler's warehouse would have to be returned to the manufacturer before it could be shipped to the non-profit organization. Lastly,



"hygienic" or "lifestyle" drugs that are not used to treat illness may not be suitable for donation.

In today's day and age, the concept of the "triple bottom line"⁶ is one that is becoming increasingly important, not just within the United States but around the globe. Individual consumers are becoming more conscious of which organizations they choose to support, which in turn puts pressure on these organizations to act ethically and in the interest of all stakeholders. We believe that brand drug manufacturers would benefit most from this strategy because they are more likely to participate in philanthropic activities than their generic drug manufacturing counterparts. Large brand drug manufacturers will likely have their own foundation through which they donate unused products, which means that smaller manufacturers would benefit the most from building relationships directly with the non-profit organization. The sooner this partnership is formed the better as the best time to build a working relationship is before a natural disaster occurs so that donated products are readily available for mobilization when needed.

Recommendations

After reviewing the survey responses and internal deliberation, we have come up with specific recommendations that we believe will help reduce the impact of LOE, particularly on inventory. One recommendation we have is for all manufacturers to

⁸ The "triple bottom line" references a company framework that measures a business's success in three key areas: social, environmental and financial.



switch from a make-to-stock strategy to a make-to-order strategy once LOE nears. We believe that this is the best way to hedge against unwanted inventory because by switching to make-to-order, we no longer leave anything to "chance." A demand forecast is based on many variables, such as the time of year, trend projections, current demand, etc. As the number of variables increases, there could be more variation in the forecast because there are more variables to account for. By switching to a make-to-order strategy, you take away all the variables and replace them with a given value, orders. By fulfilling orders as they arrive, you protect yourself against possible shortages or surpluses because you only make the product in the amount needed, when it is needed. A make-to-stock strategy requires a very good forecast, and while the forecast may be accurate during the exclusivity period, it may not be accurate after.

Another recommendation we have is for distributors to increase the time period they use to create their own forecasts. As referenced in a prior section, two distributors base their order forecasts on less than an 8-week window, which we believe is too short. While basing an order forecast on short-term data is good to keep tabs on shortterm trends, the smaller the window, the bigger the effect a small period of volatility can create. For example, assume a three-day spike occurs, and one distributor creates their order forecast on a three-week basis, such as one of the distributors that responded to our survey, and one distributor creates an order forecast on a ten-week basis. While both distributors would see a three-day spike, the first distributor would see the threeday spike out of a fifteen-day sample, while the second distributor would see a threeday spike out of a seventy-day sample. Due to the difference in the amount of time

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used, the first distributor would see that there was a 20 percent hike in demand and accommodate for that change in their next forecast by drastically ordering more. On the other hand, the second distributor would only see a four percent increase in demand and realize that there may be a need for more products, but not as much of a drastic need as the first distributor. Using a large time window to create forecasts would help the company manage its inventory because a short-term hike or drop in demand would not cause as much of a bullwhip effect as using a small-time window could cause.

The final recommendation to improve inventory management is to increase communication between the parties through the use of an Inventory Management Systems (IMS). Drugs facing LOE will see a drastic reduction in demand and revenue as the price for that drug would reduce almost overnight. The best way to prepare for that day and its ramifications is through communication. Larger companies have the expertise and money to utilize software such as NetSuite and SAP. Smaller companies should invest resources into installing and using these systems. Through communication, manufacturers, distributors, and pharmacies would all be on the same page with each other regarding current inventory, future demand, costs, etc. This level of communication would make all parties work at an optimal pace because they would all be on the same page and would not have to waste time asking their partners about inventory, forecasts, or other things. They can quickly check what they need in the system and carry on. We believe that these recommendations can truly help HDA's partners improve their inventory management.



Lessons Learned and Conclusion

The topic of loss of exclusivity was a new concept to each of us and allowed us to become new "experts" on a topic from the ground up. Despite our lack of prior knowledge, we were able to apply a logical approach to our research and recommendations. Throughout the course of this semester, there have been many things we've learned, not just from the research project itself, but also from each other. As graduate students, we each bring a diverse set of insights and experiences to the table that we were able to use and apply during our discussions and analysis of the data collected. This really benefited the team in our ability to explore unique ideas. Likewise, individuals who work within the pharmaceutical industry have the same opportunity. As true experts, they are the ones who know this industry best, and they are the ones who are best equipped to overcome its challenges.

During our weekly meetings with the HDA advisory committee, one lesson that we consistently took away was the fact that the pharmaceutical industry is one that is constantly evolving. As new competition and products are introduced to the market, it's inevitable that disruption will occur in some capacity. Pharmaceutical drug manufacturers, distributors, and retailers come in all different shapes and sizes, and each of them may have a different set of resources available to them. For example, large organizations may have the tools necessary to select and implement centralized ERP systems for tracking and communication, but smaller organizations may have limited capacity and human capital available to do so. Despite these disparities, the one thing that all organizations should have in common is their capability to put together a



strategic plan during periods of uncertainty. Organizations that utilize their resources to put together an action plan will be in a much better position to succeed than organizations that do not.

The last point we'd like to highlight before concluding our paper, is the importance of communication. This has been a central theme of our project and is the best tool available to reduce the impact of a LOE event. Just as we as graduate students have unique insights, so do the experts within the pharmaceutical industry. Sharing this knowledge will benefit all stakeholders within the industry and will allow for key players to remain competitive for years to come.



Exhibits:

Exhibit 1

5) Do you communicate LOE (loss of exclusivity) date with Distributors?

4 responses



6) If you answered "Yes" to question 5, when do you communicate the LOE date?

3 responses





Exhibit 2

2) Is your initial production methodology make-to-order or make-to-stock?

4 responses



7) Do you change your production methodology (referenced in question 2) as LOE date nears?







Exhibit 3

4) What time period is your demand forecast based on?

5 responses



Exhibit 4

6) If you hold inventory, what is the average days-on-hand inventory for generic drugs?



2 responses

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