

Supply Chain Resource Consortium

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***Future Trends
In Pharmaceutical and Biotech Distribution
White paper***

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November 4, 2005



EXECUTIVE SUMMARY

This research study was oriented primarily around the Pharmaceutical and Biotech distribution sector. We focused on the analysis of the current situation and the likely changes in this industry in the next 3 to 5 years. At the outset of the study, we developed a list of key hypotheses that served as the foundation stones for our research. These hypotheses were explored through focused interviews with over 60 subject matter experts.

Based on our exploration of these hypotheses and review of key opinion leader interviews, several key insights emerged from this situational analysis. Our interviews were carried out with multiple participants in the pharmaceutical supply chain, including manufacturers, wholesalers, chain drug stores, HMOs, pharmacies, hospitals, PBMs, 3PL's, regulators and financial analysts.

The study was performed using a process consisting of facilitated brainstorming, structured interviews, primary data collection with multiple subject matter experts and secondary research to address the following critical questions:

- What is the overall response to the new Fee for Service model proposed by the wholesalers ?
- Are there alternative distribution channels emerging that could replace/bypass the wholesalers, and how successful can they be given the complexities of the life sciences supply chain ?
- What is the likely impact on reimbursement of impending legislation in Medicare and Medicaid?
- What are the future impacts of cold chain and RFID technology on distribution in the channel?

The following key points emerged from our research.

Overall response to Fee for Service

- A diverse set of views regarding the fee for service model exists. Overall, we classified manufacturers based on their likelihood to explore other options and their perception on whether they paid a fair rate. These classifications included Stable (unlikely to change), Explorers (researching other options), Malcontents (actively engaged in discussions with 3PL's to dis-intermediate wholesale channels), and Oblivious (indifferent to the model, and unlikely to change).
- Although manufacturers in the Malcontent and Explorer groups are pursuing other options, our research suggests that downstream participants (retailers, hospitals, mail order divisions of Pharmaceutical Benefit Managers (PBMs)) are NOT open to this option, fearing deteriorated service levels, higher inventory, and higher costs.



- Manufacturers do not fully grasp the potential hidden costs of business continuity planning, accounts receivable, lost days of therapy, and lower service levels associated with alternative channels that are not robust and well-developed.

Likelihood of alternative channels

- Our research also suggests that 3PL's and manufacturers may be largely unaware of the complexities associated with the distribution channel, and have not actively engaged customers in discussing alternative options.
- A subset of wholesalers believe that manufacturers can by-pass them if they charge too high a price.

Impact of Medicare/Medicaid Legislation on the Channel

The OIG concludes that there is significant interest in changing Medicaid reimbursement for prescription drugs by aligning pharmacy reimbursement more closely with pharmacy acquisition cost. The changes proposed in the President's 2006 budget would make Medicaid reimbursement consistent with Medicare by basing reimbursement on actual sales transactions.

Once the true costs of acquisition become available and open to the public, it is highly likely that increasing pressure on wholesalers and retailers will be imminent. Unfortunately, these estimates fail to account for the significant value-added services of wholesalers and pharmacy retailers, and do not reflect a number of hidden risks associated with management of distribution channels. Some of the hidden costs and risks associated with these channels include:

- Credit risk
- Returns
- Damaged goods
- Losses on counterfeit and/or gray market goods that are discovered in the channel.
- IT infrastructure
- Distribution costs.

We also believe that state programs and private party payors will also follow. As people begin to accept higher co-pays and costs with Medicare, other parties will also follow suit. As the transparency of costs is mandated without being accompanied by an effective estimate of the hidden distribution costs, it will become imperative for wholesalers to better track and document these costs.

As the share of generics in the market increases, it is also likely that retailers will NOT be able to maintain the current margins they enjoy on generic drugs, and will be forced to accept lower reimbursements from the government. This will negatively impact their margins and



levels of service. Combined with the increasing pressure to move to 90 day scripts, retailers stand to lose revenues based on these changes.



INTRODUCTION

Today's Pharma and Bio-Tech supply chain is more complex than ever! Multiple events occurring on a daily basis are shaping the competitive and regulatory environment in which channel members operate their business. ASP regulation is changing, and non-conventional players (such as 3PLs) are threatening to dis-intermediate conventional players. Regulators are demanding that wholesalers and manufacturers reveal pricing, and are challenging the cost of pharmaceutical distribution. Market channels such as mail order, direct shipping and website pharmacies are also important competitive channels to consider.

Pharmaceutical distribution is highly complex and fragmented. Prescriptions are filled at more than 140,000 outlets in the US, but only six percent of sales are sold direct by manufacturers. The drivers for the high wholesaler market share are:

- Beginning in the early 1980s, hospitals began pushing inventory management back to the wholesalers in an effort to reduce investments in inventory and receivables
- Another driver lies in the fact that manufacturers wanted to outsource much of the distribution work to wholesalers in the 1990s and focus on their core competencies - R&D and Marketing
- Another driver for this trend was the unsatisfactory service levels provided by manufacturers during the 1990s' and which continues today!

“The manufacturers typically sought to attain a fixed sales target each quarter- and then would shut down sales once the target was achieved! We had people who needed to have prescriptions filled, and we could not purchase the drugs from the source! “ (A PBM)

Another major driver of change is the increasing share of generics that are coming into the market, as some largest branded drugs go off patent in the next three years. Although the process of manufacturing and distributing branded and generic drugs is quite similar, the design of the distribution channel might be substantially different. Many generic companies are exploring relationships with Indian & Chinese manufacturers to market their products. Generics are increasingly becoming commoditized – as one manufacturer noted: *Retailers are running reverse auctions on generic products – how much more commoditized can you get?* The share of generic drugs is likely to increase sharply in the next two to three years, which is likely to have an impact on wholesaler and retail pharmacy volumes. Depending on how reimbursements change, total volumes may increase due through increased access to medicine provided by Medicare Part D, while total revenues may increase, but profits will remain unchanged. This is driven largely by the Pharmacy Benefits Managers, who negotiate contracts directly with manufacturers and secure rebates..

Given these changes, it is little wonder manufacturers, wholesalers, pharmacies, hospitals, and other participants are bewildered with the array of different competitive challenges that face them! The unfortunate result is that misperceptions have been created at different



points in the supply and distribution chain, and channel participants have failed to communicate and work together to resolve the problems caused by these misperceptions.

A research study was therefore proposed to answer the following question: *What are the emerging trends that are imminent in the pharma / biotech supply chain?* This study sought to capture the current thinking and strategies from the following:

- Manufacturers (Pharma and Bio-Tech companies)
- 3PL providers (Non-Wholesaler distribution agents)
- Wholesalers (The Big Three)
- Customers (Pharmacies, Hospitals)
- Regulators
- FDA and other Government agencies

Our study addresses the following four questions:

- What is the overall response to the new Fee for Service model proposed by the wholesalers?
- Are there alternative distribution channels emerging that could replace/bypass the wholesalers, and how successful can they be given the complexities of the life sciences supply chain ?
- What is the likely impact on reimbursement of impending legislation in Medicare and Medicaid?
- What are the future impacts of cold chain and RFID technology on distribution in the channel?



METHODOLOGY

This project was completed in three phases over a six month period:

Phase 1: Development of Research Framework (May-June, 2005)

The research team met to develop an initial scope document outlining the key research questions that required analysis. A preliminary set of interviews with a focus group was conducted, and an initial set of interview participants was developed. The key questions were then organized as the basis for investigation. The steps followed included the following:

1. Determine what to include. Develop scope document based on preliminary interviews with focus group.
2. Create preliminary benchmarking assessment interview protocols, and identify existing best practice information available in Supply Chain Resource Consortium database. We drew from primary interviews as well as secondary research.

Phase 2: Data Collection – July – August, 2005.

In this phase we completed several interviews. We interviewed over 65 subject matter experts from multiple organizations. This list of interviewees represented the following groups:

Manufacturers	21
Pharmacies	5
Hospitals	3
HMO's	1
Wholesalers	5
Financial Analysts	2
Legal Experts	5
PBM's	3
3PL's	5
GPO's	5

Phase 3: Data Analysis, Preparation of Report, and Presentation of Findings – September – October, 2005.

This final report was drafted and issued to all participants who were interviewed for this study. The results are intended to provoke discussion and communication within the industry, in an effort to drive further collaboration between participants in the channel. The material from this research will also appear in a book by Dr. Handfield titled "Future Trends in the Pharmaceutical and Biotech Supply Chain". Additional details of the study and questions can be directed to Dr. Handfield at Robert_handfield@ncsu.edu.



Q: What is the industry's perception of the Fee for Service (FFS) model?

With the reduction in the opportunity to make profits based on building inventory and price inflation of drugs, wholesalers adopted a Fee For Service (FFS) model. Each wholesaler has taken a different approach to fee for service. One wholesaler seems to have a specific activity-based cost that is customized and calculated for each manufacturer that determines the fee for service, based on each manufacturer's specific characteristics:

- Sales Volume
- Line Extensions
- Special Handling requirements
- Number of Ship-To points
- Product Concentration

This move has created a great degree of turmoil in the Pharma and Bio Tech industry. In this section, we provide the Industry perception of the FFS model.

Manufacturers

In general, our research supports the notion of a diverse set of views regarding the fee for service model. Overall, we classified manufacturers based on their likelihood to explore other options and their perception on whether they paid a fair rate.

Based on these parameters, we classified manufacturers into four groups as shown below.



Types of Manufacturers

Likely to explore other options	YES	Malcontents	Explorers
	NO	Oblivious	Stable
		NO	YES

Believe they paid a fair rate

In general, manufacturers have accepted the FFS model, but may well be exploring options in the future. As for the others, the rule is that generally the larger the manufacturer, the more likely they are to resist. Smaller manufacturers are more likely to sign agreements as they have fewer options.

These are some of the comments we received from these groups of manufacturers:

Manufacturers – Stable Group

- Believe that the wholesalers provide a valuable service
- Believe the fee is appropriate
- Admit that they do not have the capabilities to run such a complicated network
- **Compliance** is the key for this group
- *“I think there might be value [in bypassing the wholesalers], and we are studying it and still in the middle of negotiations. However, I personally think that it would be too much of an effort for us”*
- *“We believe that in 5-10 years, the end user will be more of the customer, rather than the wholesaler. Ideally, we would like for the wholesaler to be an extension of the manufacturer”*
- *“I don’t know how we would be able to by-pass wholesalers – we have contracts with chains – but we ship through wholesalers. The current environment is efficient. If Pharma companies could get together and collaborate – maybe.”*

Manufacturers – Explorer Group

- A good portion of this group has signed agreements



- However, they wish to find other options to improve negotiating power in the future
- They do not have a viable structure to explore other options
- They have approached PBM's to discuss options, and are discovering that PBM's are NOT open to the idea of shipping direct.
- **Upper Management Pressure** is the key for this group
- Most "Explorers" have an exaggerated estimate of their capabilities
- They are in the discussion phase with retailers and 3PL's, with no clear strategy or idea of the total cost to deploy such an effort
- Cost is not the only consideration for this group. Issues such as risk mitigation are important to Explorers.
- *"We do go direct to the warehouse today. We would have the capability to go direct, but I am not sure if we would. However, the recent events have forced us to look at alternatives models on how to partner. There is a potential in 3-5 years that we would go direct to the consumer. Even though there is a higher cost, it is not the only issue we look at, although not an insignificant one"*

Manufacturers – Malcontent Group

- Most of this group has signed the FFS deals
- However, they have initiated active negotiations/strategies with 3PLs to bypass wholesalers
- **Channel Control** is the key for this group
- Companies are openly challenging the FFS model, using a rationale that they are paying too much, but are often unaware of the true costs of by-passing wholesalers.
- In addition, they believe that the returns being generated through these agreements are simply being passed on to pharmacies, and not being re-invested into the channel to make it more competitive, despite the fact that wholesaler margins have decreased in line with expense efficiencies.
- *"I know XXX (a 3PL) has put their name in the hat – we talked to them about it. They are very interested, since they are already doing it with hospital groups in the metro New York area"*
- *"We have spoiled the customer to save us money and it is hard to get them to see how it is better if it is slower – do they really need same day or next day?"*
- *Will we ever get to engage with our end customers directly? Probably not. Our culture emphasizes security and brand protection. There is a potential that we could go direct in 3 - 5years. We would have the capability to go direct to stores, but I am not sure if we would. We probably would continue to have an intermediary for hospitals and pharmacies.*

Manufacturers – Oblivious Group

- Consists of small emerging players who outsource their entire distribution network to third parties
- Most of them are focused on growing the business, clinical trials, or expanding the business.



- **Business Maintenance/Expansion** is the key for this group

Retailers

Study participants from the various retail groups were relatively indifferent to the FFS model. One of the key services provided by wholesalers to retailers in the Pharma supply chain is daily delivery of product with extremely short lead times. There are players in this industry that believe that the retailers are “over-served”. However, retailers made it clear that they would refuse to accept any decrease in service levels. As one retailer we interviewed noted:

The big challenge is that we receive a wholesaler order every day. It comes in a nice gaylord, sorted by our aisles, and is easy to receive. If we were to switch to a 3PL, we now would get into large unbundled shipments from different players with different activities. Now we would have to carry safety stock on all those piles, there would be no forward DC's immediate response to stockouts, and lower service levels! Is the pharma community going to be willing to share the costs that we would incur associated with not going through wholesalers? Probably not! If I have to now incur larger safety stock carrying costs as a safeguard against lower service levels – Will you Mr. Pharma give me financial incentives that will also my incremental labor cost associated with more PO's? The big question is whether there is enough money for the pharma companies to gain enough, give us enough of an incentive, and give us something to sweeten the pot and still make a return on it. In the end, it seems it will be more costly.

Wholesalers

Wholesalers stood behind their FFS models and reiterated that the fee being charged to the manufacturers was based on a careful analysis of the various costs involved. They believed that it would be impossible for any other entity to provide the same level of service at a lower cost. Wholesalers seem to have embraced the fact that the manufacturer is the customer, and believe that it is their goal to make them happy.

Group Purchasing Organizations (GPO's)

GPO's share the belief that manufacturers are not capable of by-passing wholesalers and are generally satisfied with the level of service and cost savings provided by wholesalers to their hospital customers. However, significant potential conflict is beginning to be created by wholesalers who have allegedly “auto-substituted” their generic manufactured products for hospital-requested original products when stock-outs occur. There is also conflict created when wholesalers have attempted to “direct source” pharmaceutical products to hospitals, offering them a 2-3% savings over the GPO administration fee. In such cases, GPO's tell their clients that they are exposing themselves to undue risk, as GPO's are legitimately representing their hospital customers' best interests.

Pharmacy Benefit Managers (PBM's)



PBM's do not believe that manufacturers are capable of shipping direct. This is based on the poor service levels they have experienced from manufacturers in the past who did not go through wholesalers. They feel that in general, wholesalers represent the only viable source for reliable distribution. One quote from an individual who noted that: *The end of the year was typically the poorest service levels. Production was driven around sales numbers, not actual demand, and since manufacturers generally raised prices during the first week in January, there was no incentive to drive sales at the end of the fiscal year. So they would hold back inventory and not sell back into the channel. We fought that behavior for years – and finally decided to switch to the wholesaler model. They had better relationships with manufacturers on the buy side, and we were willing to let them do the work. However, we continue to work directly with the generics manufacturers.*



Q: What alternative channels are on the horizon?

In our opinion, there is an insufficient understanding of the complexities of the pharma/bio tech distribution supply chain. Many of the manufacturers have explored alternatives, not because they are not happy with the service, but because they fail to completely understand the complexity of the channel.

In our interviews, we discussed many of the critical services offered by wholesalers, including:

- Forecasting demand
- Inventory management systems
- Ordering systems
- PO systems (only bill for what is shipped)
- Carrying 20 or more days of inventory for pharmacies at no cost for high moving drugs
- Delivery 5X per day, 24/7, 365 days a year
- Warehouse and cost structure to ship to multiple locations
- Business continuity requirements (multiple warehouses distributed nationally)
- Credit, billing, collections
- Collecting receivables and taking on that risk
- Returns and recalls
- Providing pedigree

Again, the manufacturers in the “Stable” group were aware of these services, but the “Malcontents” or “Explorers” believed that 3PL’s were also able to offer these services.

There are three alternative channels that are being proposed as credible alternatives to the current wholesaler model:

- A 3PL model
- A consortium of smaller wholesalers replacing the larger wholesalers
- Smaller manufacturers forming a consortium to bypass the wholesalers

3PL Model

There are several 3PLs that have expressed an interest in entering the Pharma distribution market. Their offerings will be different from the wholesalers in the sense that they will not take ownership of the product. Their solutions would be oriented primarily around the actual distribution process.

3PLs claim that their costs will be lower than the fee that is currently charged by the wholesalers. In addition, they believe that the supply chain design would be simplified as by eliminating the wholesaler and playing the role of a 3PL, the DCs currently operated by the manufacturers could be eliminated.



They claim these following advantages over the wholesalers:

- Better shipment level data
- Improved Security/Drug Safety
- Easier to roll out RFID
- Increased Simplicity
- Activity Based Costing will better represent work done
- Will allow manufacturers to build direct relationships with retailers

Wholesalers on the other hand believe that 3PLs will face these problems:

- Existence of unions
- If 3PLs don't take ownership, manufacturers would be forced to retain liability for the product for a longer period
- It will be very difficult for a 3PL to take a saleable return back, and that it would probably have to be thrown away. There is no regulatory way for them to re-insert saleable products back into the supply chain, which would increase waste.
- They believe that 3PL's are not as well-positioned to deal with business continuity planning as wholesalers.
- Retailers would not accept reduced service levels
- 3PLs do not have the level of reach that wholesalers do, especially in remote areas
- Lack of relationships with retailers
- Difficulty in providing a unified ordering interface for customers
- Customers do not want to have multiple order/receipt points
- Lack the scale/size/experience of wholesalers
- Lack of ability to provide these Value Added Services
 - Returns
 - Contract Administration
 - Chargebacks
 - Demand forecasting
 - Absorbing bad loans

Here are some comments made by manufacturers about 3PLs

- Three manufacturers believe that the 3PLs could handle Pharma distribution
- Another believes that *"none of the providers have all the capabilities of a wholesaler, but believe that its only a matter of time"*
- *"A 3PL cannot replace the function of a wholesaler"*
- Another manufacturer doesn't believe that a 3PL would be the right choice as they understand their customers better than the 3PL
- Yet another manufacturer believes that although none of the 3PLs are capable of handling their distribution business independently, they would like to see an LLP model with multiple providers



All in all, considering the complexity of the distribution network and the familiarity that wholesalers have with the model, it is unlikely that 3PLs would be able to offer the same level of service at a lower price.

Consortium of Smaller Manufacturers

The likelihood of a consortium of manufacturers being formed to by-pass wholesalers is unlikely. Most of these manufacturers do not have the resources or desire to create such a network. Further, the lack of channel competency and customer knowledge suggests that such an initiative would not succeed, even if a group of renegades were to emerge.

Consortium of Smaller Wholesalers

Soon after the Big Three (Amerisource, Cardinal and McKesson) came out with their proposal to charge a fee, a few of the smaller wholesalers came out with a plan to form a consortium to try and obtain more business in a predatory manner. Their attempts have not seen much success largely because they have not offered manufacturers costs that are lower than the Big Three. Also major chains would not buy from a consortium as they cannot offer consistency in invoicing and customer service.



Q: What is the likely impact on reimbursement of impending legislation in Medicare and Medicaid?

A complex issue in the Pharma / Bio Tech supply chain is the rebate structure and pricing structure. Again, this is a highly regulated issue that is under increased scrutiny in today's market. This is especially true for reimbursements of Medicaid and Medicare.

The primary issue revolves around the calculation of estimated acquisition costs, which are shown in Figure 1. Several key terms are useful to define here:

- **Average manufacturer price (AMP):** The average unit price paid to manufacturers by wholesalers for drugs distributed to the retail class of trade minus customary prompt pay discounts. The AMP is statutorily defined and calculated from actual sales transactions. Manufacturers must report AMP to CMS quarterly for the Medicaid drug rebate program.
- **Average wholesale price (AWP):** A price published in national drug pricing compendia issued by private companies such as First Databank and Medi-Span, based on pricing information provided by manufacturers. Its calculation is not defined in statute or regulation. It is generally considered a price for retailers.
- **Estimated Acquisition Cost (EAC):** The State Medicaid agency's "best estimate" of the price generally and currently paid by providers for the drug. Within Federal parameters, each State establishes its own EAC formula in its State plan.
- **Wholesale Acquisition Cost (WAC):** A price published in national drug pricing compendia issued by private companies such as First Databank and Medi-Span. It is now statutorily defined as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.



Medicaid Drug Distribution Chain Example

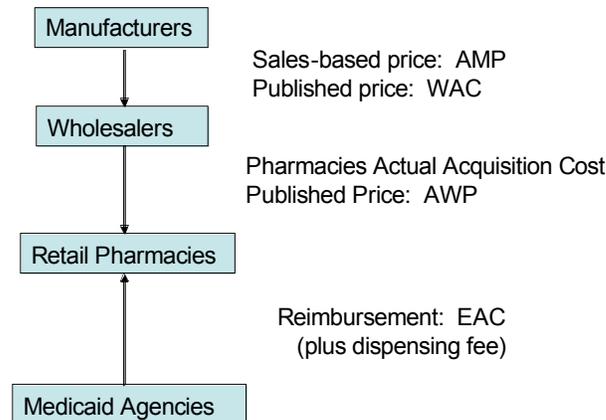


Figure 1 – Relationship of AMP, WAC, and AWP

Several key points are important here. To begin with, AWP's are not defined by law or regulation, but are compiled in drug compendia such as Medical Economics' *Red Book* and First Databank's *Blue Book*.

Second, AMP's are a statutorily defined sales-based price used in determining Medicaid drug rebates.

While States must reasonably reimburse pharmacies for prescription drugs provided to Medicaid beneficiaries, they often lack access to pharmacies' actual market prices. Due to this lack of data, they rely on estimates to determine Medicaid reimbursement. Most States base their calculation of estimated acquisition costs on published average wholesale prices (AWP). These AWP's are the subject of much debate by the Office of the Inspector General, who alleges that Medicaid is paying too much for prescription drugs. Robert A. Vito, Regional Inspector General for Evaluation and Inspections, Philadelphia, commented that:

Our analysis comparing actual pharmacy acquisition costs to AWP for calendar year 1999 revealed that pharmacy acquisition costs for brand name and generic drugs were 21.8% and 65.9% below AWP, respectively . . . and that the different between actual acquisition costs and the amount the Medicaid program would have paid using the States' average estimated acquisition cost formulas was \$1.5 billion in 1999.



The OIG recently released two reports¹ that further indicate that the published prices that Medicaid uses to calculate reimbursement amounts for prescription drugs do not approximate pharmacy acquisition costs. The first report finds that for Medicaid-reimbursed drugs overall, Average Manufacturer Price (AMP – a statutorily defined sales-based price used in determining Medicaid drug rebates) was 59% lower than Average published prices such as AWP and Wholesale Acquisition Cost (WAC)

In general, States reimburse pharmacies for drugs at the lower of estimated acquisition cost (EAC) plus a dispensing fee or the pharmacy's usual and customary charge to the public. The EAC is the State's best estimate of the price generally and currently paid by providers for the drug.

Rebates are provided by manufacturers to various entities in the channel, including PBM's and wholesalers as an added incentive to buy their product. This dynamic is changing today. With increasing legislation around drug pricing, transparency is a big issue. In the past – a greater portion of rebates were kept by PBM's. Today, there is more of a migration of rebates passing through to the end payer.

One PBM we interviewed noted that:

We have adopted an above the board policy to develop an agreement pass through on all new products, so everyone knows the exact amount of the rebates coming from the manufacturer. We will now pass on 90% of the rebate to customer. We have an open-books policy that allows the payer to come in and audit our contract down to the wholesaler NDC numbers.

Another form of rebates are rebate administration fees. In order to obtain the goal of positioning their product in second tier status, rebate arrangements may be made to allow the product to be placed on a second tier instead of a third tier. This is becoming more transparent as the Office of the Inspector General is pushing for increased fraud prevention and abuse legislation.

The recent OIG study published in June 2005² contains some findings that highlight the fact that reimbursements and unbundling of WAC-based reimbursements is inevitable in Medicaid legislation (see Figure 2). The OIGA found in their audits the following key high-level results:

- At the median, AMP is 59% lower than AWP. Forty-nine States use AWP to estimate pharmacy acquisition costs. The median State EAC formula is AWP minus 12 percent. For 98 percent of Medicaid reimbursed NDC's this median State EAC formula would reimburse at a price higher than AMP.
- At the median, AMP is 25% lower than WAC.

¹ Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products (A-06-00-00023) and Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053).

² Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices, OIG, June 2005, OEI-05-05-00240, Washington, DC.



- Generic drugs exhibit the largest differences between average manufacturer price and the published prices. For generic drugs, AMP is 70% lower than the AWP at the median.
- For generic drugs, AMP is 40% lower than WAC at the median.

OIG Audit Report (June 2005)

Table 1 AMP to AWP Comparisons by Drug Category: AMP = AWP – X%			
	Median	Average	Weighted Average
Single Source Brands (3.5 NDC's)	23%	25%	24%
Multisource Brands (2.4 NDCs)	28%	40%	36%
Generics (18 NDC's)	70%	65%	74%

Source: OEI-05-05-00240 June 2005.

Figure 2 – Results of OIG Audit

Additional comparisons of OIG audits of Average Sales Price to Average Wholesaler Price add additional fuel to the fire for control and regulation of reimbursements³.

The findings of this study suggest that:

- The median percentage difference between ASP and AWP is 49% (based on 2,077 drug codes). Even when factoring in the discounted AWP most States use to calculate the estimated acquisition cost for Medicaid drugs, ASP is still substantially lower.
- The difference between ASP and AWP was greatest for generic drugs. For 704 single source brand codes, ASP is 26% below AWP at the median.

The OIG concludes that there is significant interest in changing Medicaid reimbursement for prescription drugs by aligning pharmacy reimbursement more closely with pharmacy acquisition cost. The changes proposed in the President's 2006 budget would make Medicaid reimbursement consistent with Medicare by basing reimbursement on actual sales transactions.

³ Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price, OEI-03-05-00200, June, 2005, Washington DC, Office of Inspector General.



Once the true costs of acquisition become available and open to the public, it is highly likely that increasing pressure on wholesalers will be imminent. Unfortunately, these estimates fail to account for the significant value-added services of wholesalers, and do not reflect a number of hidden risks associated with management of distribution channels. Some of the hidden costs and risks associated with these channels include:

- Credit risk
- Returns
- Damaged goods
- Losses on counterfeit and/or gray market goods that are discovered in the channel.
- IT infrastructure
- Distribution costs.
- Saleable returns
- Business continuity planning
- Avoidance of lost therapy associated with lower service costs

As the transparency of costs without an effective estimate of the hidden distribution costs associated with service continues, it will become imperative for wholesalers to better track and document these costs. The most important point to note here is that service fees have never been addressed in calculation of AMP. CMS has stated that if the service fee was a bonafide fee at fair market value and was not passed on to customer, that it could be excluded from the calculation. However, manufacturers still include the service fee in AMP, as they are not clear about this position. It is important that manufacturers consider dropping the fee from their AMP to pass value onto their customers.

As the share of generics in the market increases, it is also likely that retailers will NOT be able to maintain the current margins they enjoy on generic drugs, and will be forced to accept lower reimbursements from the government. This will negatively impact their margins and levels of service. Combined with the increasing pressure to move to 90 day scrips, retailers stand to lose margins based on these changes.



Q: What are the trends in critical areas of the Pharma supply chain with respect to Cold Chain, RFID, and Pedigree requirements?

Pedigree and Supply Chain Security

There is no question that pedigree and security are at the top of the list at many manufacturers. This will continually drive distribution strategies in the next 3-5 years, so entities in the Pharma supply chain should continue to engage with customers, identify trends, and establish the requirements for success in this market. For example, one manufacturer we interviewed noted that:

Pedigree and securing the supply chain will be THE biggest issue in the next 3-5 years. We made a statement that required all of our direct distributors that purchase from us to ONLY buy from us, and nobody else. We have been auditing our customers for the last 6 months to see if they are holding to that agreement and complying. We have established in the last 3 months a supply chain security taskforce exploring 5 or 6 components. We have established a legislative component exploring where pedigree is going to go, and what are other areas that pharmacies are looking at. We have also established a technology component, exploring RFID, overt, covert, and partnering to look at front and reverse logistics to ensure a secure supply chain to ensure customer gets their products every time.

A hospital pharmacist also agreed that pedigree is an important issue. This individual emphasized that hospital pharmacists are under the greatest pressure to keep drugs in stock, especially as hospitals are often the last resort for patients that are ill and are refused service by physicians' offices. Theft and pilferage is also much more common in hospitals, as documented in the book "Dangerous Doses". As such, hospital pharmacists are in some cases tempted to resort to secondary wholesalers and unreliable sources of drugs that mysteriously are advertised on fax machines and internet websites and email. This has driven increased scrutiny, and has become a major issue for hospital pharmacists.

I think pedigree is a big issue. Incentive for counterfeiting is higher on high ticket items. I wouldn't anticipate that pedigree would be an issue for the 80% of drugs that are high volume and low cost. But there is already a trend in some cases for some of the high ticket items having specialized distribution systems, because there is a supply scarcity issue, or an FDA-directed issue, to be high potential targets for counterfeiting. It is very likely that a target for counterfeiters are high unit cost items going through an alternative distribution system to be targeted for pedigree requirements. I could see that happening. It will be a while before we get to a point where the drugs will be tagged and transferred using RFID! But in the next several years, the high unit cost items will go to some controlled access distribution chain.



There is no doubt that pedigree will continue to be an escalating issue in the years ahead. We interviewed an FDA regulator who was an expert in this field, and he shared his views on the importance of pedigree from the FDA's perspective:

Pedigree is something that would be very useful in the cold chain and other channels to track product and provide assurance that it is an authentic product. We don't believe that paper is the way to go, but believe that technology is on the horizon that will eliminate paper. Instead of applying the 1987 law, we decided to stay that law, and allow this technology to come on line and do the same thing. Instead of putting paper into the cold chain system, which would be unbearable, we did an update to that report, which in turn opened a lot more cases of counterfeit product being put into the chain. We are not sure why this occurred, as it could be a Hawthorn effect. We will know more as we do an update, and see how the system is reacting to new pedigree requirements.

Counterfeit Protection and RFID

From a regulatory perspective, the FDA has clearly indicated that they hope RFID will be the "silver bullet" that will address counterfeiting and pedigree concerns. If RFID were truly to become a fully embraced technology, this would be a great way to improve security in the channel. However, we are convinced there are a lot of impediments. The history of the barcode (which did not establish a global standard until 2005) suggests that the FDA cannot force people to adopt RFID universally. Florida has a pedigree law, and California has one that would force pedigree by 2008. The rest of the states are going through various stages – and each one will have a different set of conditions. It is probable that RFID and pedigree will be forced, just as tamper-proof packaging was forced, once the technology emerges. Many pharmaceutical companies established tamper-proof packaging to maintain consumer confidence. Today many manufacturers are actively pursuing RFID and channel control because of the control and security aspect that they believe is critical to maintain consumer confidence in their product integrity.

There are fundamentally two ways to view the RFID opportunity. One is as an authentication technology, another as a track and trace technology. If authentication is the objective, then processes would need to be altered. For example, Pfizer could put a tag on Viagra with a serialization number and only have to check it at the pharmacy warehouse. So they know what they have on their stores is product with the right pedigree.

In the track and trace approach, the approach would require that records be established at every place the product stops in an integrated network. This is a major hurdle to getting it implemented. RFID will not be widely adopted because there is an intricate Internet network that needs to be established and tags that are economically priced.

Tag makers know they need to improve accuracy. So the model that will probably emerge will be that the serialization number will be established by the pharmaceutical company, and they are the only ones that know that number. By the time a counterfeiter finds what the number was, it has already become part of the system – and it becomes hard to insert the



product into the chain. So counterfeiters are in the process of trying to hit a moving train, as they can't do it early enough in the sequence.

This authentication scenario would require that a database be maintained at each manufacturer. The IT solutions are as big an impediment as the tags. Authentication is much more reasonable than the track and trace scenario. The former area should be explored by channel partners through pilot testing and simulations, to enable leadership in this technology, not so much from a physics and hardware standpoint, but in terms of understanding impact on the channel and opportunity for value-added services. For example, manufacturers need to understand the implications for cost savings and information visibility in the channel. Our research team is also experimenting with an RFID simulation project to identify the total cost savings opportunity in the channel.

Enhanced Cold Chain

Control of storage and transportation temperatures is a major factor in maintaining the quality of medicinal products in the supply chain. Increasing international trade in medicines (for example parallel import/export of insulin) together with the growth of the biotechnology industry, has resulted in an increasing reliance on the distribution chain for many companies with international operations as well as major pharma companies. For example, some medicine products, such as vaccines, are rendered ineffective or can even be potentially harmful if they are not stored and transported at the correct temperature. The threat of bioterrorism has highlighted the need for safe transportation of vaccines using secure, tamper-proof systems. The UK and US military have both recently demonstrated an interest in secure shippers and are currently carrying out their own validation tests. With the increase in cross-border movements of pharmaceuticals, theft is a significant potential problem and packaging specialists are now using computer technology 'event loggers' and reinforced outer casing to make containers resistant to unauthorized access.

In developing a temperature profile(s) used to design a shipping container or system, a complete analysis of the distribution process flow is required. Distributors should "walk through" their system to the extent possible to gain a better understanding of what happens to the freight. Each step should be analyzed to provide the shipper with a very clear expectation of the time/temperature relationship throughout the distribution process. This understanding will allow for the development of a temperature profile that will be used to design and challenge a package or system through the qualification process and will therefore provide the shipper with a high degree of assurance that his merchandise can be shipped to its final destination, while minimizing the risk associated with loss of product as a result of deviations in temperature and/or humidity during transit. It is impossible to develop a temperature profile that will represent every shipment you make, but do develop a profile that is a representative challenge of the distribution process to minimize the risk of temperature deviations.



Customized Therapeutic Distribution

A major opportunity that exists today is the movement towards improving compliance to patients, and offering Therapeutic management services tied to track and trace technologies. Therapeutics requires that manufacturers create “boutique” drugs and formularies that are customized to patient requirements. In the future, the healthcare transaction model would begin by segmentation of patients based on clinical trials, into different categories based on initial testing and diagnosis of which therapies would work best for specific individuals. A patient seeking treatment would be tested and segmented into a category of treatment, and the physician would then recommend the therapy best suited to the individual’s particular condition, including their recommended dosage, etc. That individual might not even receive reimbursement for their PBM for alternative therapies based on this diagnosis. The supply chain participants would then play an important role in creating specific “boutique” customized therapies to align with individual requirements, genetic characteristics, etc. In this manner, a truly customized set of therapies that is most effective would evolve. Follow-on technologies would then be used to ensure compliance to these requirements.

Compliance

This discussion reveals another important opportunity for supply chain participants to explore, which is how to offer services that promote compliance to prescribed therapeutics. Compliance curves suggest that most people stop taking medicines that are proven to be therapeutically effective. Thus, a significant value proposition not satisfied is how to promote compliance, ensure that patients are taking their medicine. This would also provide a valuable service to manufacturers, in the form of increased revenues, and increased channel loyalty.

As Medicare and Medicaid become a reality, retailers are going to be looking at other sources of revenue other than dispensing fees. Compliance management and pharmacy services will become an important service offering in this channel where there is money to be made. There is definitely room for collaboration between manufacturers, wholesalers and pharmacies in compliance and persistency programs, and the pharmacies are in an excellent position to be able to drive this. The manufacturers are unlikely to be able to drive this. The wholesalers also have an opportunity to provide outsourced services to pharmacies on such programs, to ensure that people take their meds!

The problems begin when the patient first receives the scrip from the physician. One retailer we spoke with noted that 15-25% of prescriptions are never filled. Even if they are filled, the fall off on compliance is substantial. A patient who takes the medication 80% of the time on a daily dose med is at the high end of compliance. Programs that could be put together to increase that initial fill rate by 10% would promote improved treatment for the patient, as well as improved revenue for the pharmacy, wholesale channel, and manufacturer!

There are many electronic alternatives that have not yet been explored. For example, companies are exploring the possibility of creating a system to send a text message to a cell phone to a patient on a daily drug – reminding you to take your meds today. If the patient is



paying two dollars a day for the drug— that is the kind of thing that would improve market share and avoid the wrath of the government (it is good for the patient).

One retailer and expert in the area of compliance noted the following.

In the e-prescribing area, no one has explored whether a scrip is filled in the first place. For example, if a patient's cholesterol is at 250, the physician will write a prescription for Lipitor. The patient then comes back in 30 days and their cholesterol is still at 250. So the physician will automatically assume that "I picked the wrong drug or dose." But the patient may not have had it filled in the first place! With e-prescribing, the physician would be able to quickly perform a trace revealing that the scrip was sent to CVS and the patient never picked it up! Or that the patient received a 90 day supply on March 1 and hasn't had a refill and it is August.

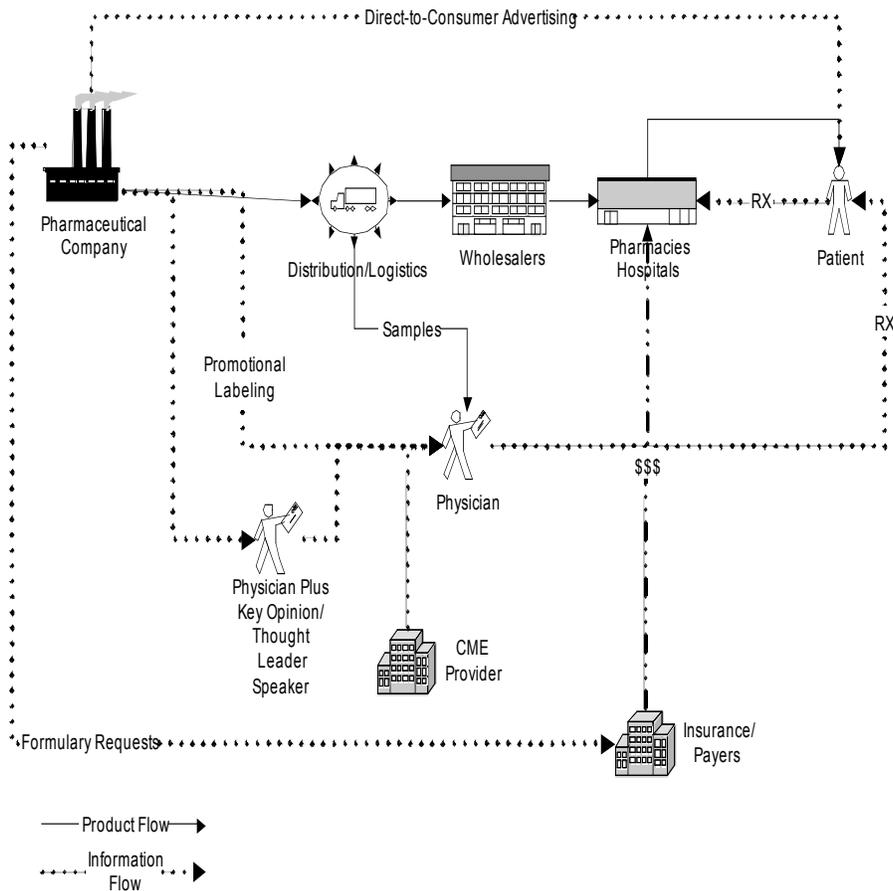
Today what happens is the doctor assumes they have prescribed a non-optimal therapeutic, and just assume the drug was taken the way it was ordered. In the field, that is often not the case. Pharmacies today have the information, but they are not mining it. Scripts are not collected electronically, and manufacturers certainly do not have that information. There is major room in the pharmaceutical sector to get around the current safe harbor regulations to encourage eprescribing. This would entail getting the doctor wired, the pharmacy wired, getting the patient more involved and tied together. The single biggest key is to get doctors wired – they are hesitant, and it interferes with their current workflow – but there is change. Younger doctors understand technology, and are willing to do different things.



Summary and Implications

The trends towards managed care, dis-intermediation, compliance, RFID, pedigree, and therapeutic medicine will significantly change the look and feel of the Pharma Distribution channel, based on the new set of relationships and transactions that occur. Channel design will need to be changed significantly, and a much more “hands on” approach to cross-functional channel design will be required to integrate product and demand realization strategies. Customer intimacy must begin with all parties clearly communicating and understanding customer needs, through interaction with prescribers, patients, and payors. Finally, partnerships between manufacturers and channel partners will be needed to design channels that deliver optimal value to the customer through customized delivery.

Today, the pharmaceutical and biotech supply chain can best be described as a “fragmented” system of participants. There is a need for a clear model of collaboration and communication within the channel. While the focus in the past has been negotiating over fees charged for distribution, the real issue is how to make the “pie bigger” through improvements in technology and customer service. A focused discussion around how to better deliver value to customers is needed, with companies sharing their strategic plans and finding ways to complement each other. In this manner, the “pharmaceutical/biotech supply chain of the future” can evolve.





Such a model would take inventory out of the channel, and respond much more in an integrated “on-demand” model. Data integration would be key, so that retailers would have access to a single integrated data model, and forecasting is an integrated planning tool that is customer-facing and real-time. All participants would work together to eliminate stockouts, while promoting patient compliance and therapeutic benefits. Such a model will require that all of the participants shown in the above figure work together to share information, engage in joint planning activities, and identify exceptions and problems in the supply chain to combat counterfeiting and diversion.

We would be happy to discuss the results of this research and our vision for this new model at your convenience.

Researcher Bios

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Robert B. Handfield is the Bank of America University Distinguished Professor of Supply Chain Management at North Carolina State University, and Director of the Supply Chain Resource Consortium (<http://scrc.ncsu.edu>). He is a world-renowned researcher and consultant in supply chain management, new product development, and global logistics. Handfield is actively engaged in working with a number of manufacturers, providers, retailers, and wholesalers as a strategic consultant to create best-in-class strategies and optimal supply chain configurations for improving the quality of health care in this country.

Handfield's research focuses on benchmarking best practices in supply chain business processes. He has written several research reports for the Center for Advanced Purchasing (CAPS), and has published research in journals such as the *Sloan Management Review*, *California Management Review*, *Journal of Operations Management*, *Decision Science*, *Journal of Supply Chain Management*, *Journal of Business Logistics*, and *IEEE Transactions in Engineering Management*.

Handfield serves as Editor-in-Chief of the *Journal of Operations Management*, and serves on the Editorial Board of the *Supply Chain Management Review*, *Decision Sciences* and the *Journal of Supply Chain Management*. He is the author of several best-selling books on strategic sourcing and supply chain management, including the recently published books *Supply Market Intelligence* (2005) and *Supply Chain Re-Design* (2002), *Purchasing and Supply Chain Management* (2004), and *Introduction to Supply Chain Management*. Handfield has been interviewed for articles in leading periodicals such as the *Wall Street Journal*, *CIO Insights*, *Purchasing* and *Optimize*.

He is a frequent speaker at professional conferences, and has extensive consulting experience with a number of Fortune 500 companies, including Bank of America, Home Depot Lyondell Chemical, Boston Scientific, Englehard, Shell, Caterpillar, Federal Express, Duke Energy, Microsoft, Milliken, John Deere, General Motors, Colgate Palmolive, Union Pacific, GlaxoSmithKline, Suncor Energy, American Airlines, and many others.

Vel Dhinagaravel

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