

Drug Wholesaler Update: Industry Expert Transcript

Secondary Market Issues and Other Perspectives of the U.S.
Pharmaceutical Wholesaling Industry

Sector View: 2-NEUTRAL

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We are providing a transcript of the Lehman Brothers industry expert conference call conducted on Friday, May 27, with Dr. Adam Fein, president of Pembroke Consulting.

- Dr. Fein believes that there are ongoing attempts by drug companies to regain more control over the distribution process, based on increasing interest in understanding where the product is sold, and how many times it has been re-sold before getting to the customer.
- He suggests that the “flawed” compensation model of drug wholesalers is in the process of being changed, and believes that the recently published book on the Timothy Fagan case (from 2002) further highlights the need for greater distribution transparency. The recent announcement by CVS to stop trading with secondary wholesalers, and by CAH to stop selling to the secondary market could be outgrowths of this additional scrutiny.
- Dr. Fein’s recently published white paper suggests reduced wholesaler inventory simply shifted back to manufacturers, and has not created as much needed efficiency. He also believes that risks of drug shortages have increased with this shift.
- He notes that many FFS agreements still have some price inflation compensation (“hybrid” agreements), suggests greater regulation will be seen, and calls for re-examination of customer services and prices by wholesalers.

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Secondary Market Issues and Other Perspectives of the U.S. Pharmaceutical Wholesaling Industry

Dr. Adam Fein, Lehman Brothers sponsored Industry Expert Conference Call Summary – Friday, May 27

Larry Marsh, Lehman Brothers: Good morning everyone; I appreciate everyone tuning in for what I think will be another informative conference call.

With us today, back for the fourth time in the last five years, is Dr. Adam Fein, president of Pembroke Consulting, considered to be one of the country's leading experts on distribution industry economics.

Dr. Fein, the founder and president of Pembroke, is a noted industry expert and is the author of many industry publications including "Facing the Forces of Change: The Road to Opportunity," as well as the executive editor of the upcoming "Facing the Forces of Change Outlook."

As some of you may recall, we had Adam with us in 2002 when he discussed the coming movement and the focus around fee for service agreements well before it was discussed in other venues. I believe that this is one example of his insights on this industry.

Today he's going to be addressing several broad topics. There are three of note that we highlighted in our preview. One, ongoing company feedback around efforts by wholesalers to move to more fee for service agreements.

Two, comments on the implications of wholesalers supposedly moving out of the secondary or alternate source market, which has been most visible recently with the CVS announcement earlier this week.

And three, discussions around declining inventory trends by wholesalers and issues around further reductions that could be seen.

What we'd like to do is turn it over to Adam for some comments and then I'll ask questions. Adam?

Dr. Adam Fein, Pembroke Consulting: Thank you very much, Larry. It's a pleasure to be with you again talking about the drug wholesale industry.

As a reminder, Pembroke Consulting is a management-consulting firm. We work with companies in the health care sector, primarily manufacturers and technology companies. However, Pembroke Consulting does not make investment recommendations, in this call or otherwise. Nothing that I'm going to say today should be interpreted as an opinion by me or Pembroke on the prospects of any of the specific companies that I might mention.

Today, I want to put fee-for-service and inventory management agreements into the broad context of how the industry is changing. The emphasis on fee for service and compensation models seems odd when we consider how little wholesalers actually add to retail consumer prices. For every dollar of retail pharmacy spending in the United States,

- 70 cents goes to the manufacturer;
- 10 cents goes to the pharmacy;
- 17 cents goes to PBMs, payers, and health plans; and
- Three cents of total U.S. healthcare retail pharmacy-spending goes to the wholesalers.

In other words, the wholesale channel represents \$7 billion of a \$230 billion retail pharmacy industry.

In my opinion, the current negotiations about the format of compensation really reflect a broader attempt by manufacturers to get greater control over the distribution of their products. We are in the middle of a very significant redefinition in the role and functions of wholesalers. IMAs and fee for service are really about **control**, not just a **change in compensation**.

As I will discuss today, IMAs have rewarded wholesalers for limiting inventory, removing the temptation to generate trading profits with inventory. These agreements have also instituted a new level of monitoring of the wholesalers' activities. Manufacturers have been increasing their control over distribution in other ways, such requiring wholesalers to purchase products only from the manufacturer instead of the secondary market.

Challenges for Manufacturers

I believe that the U.S. drug distribution system is on the verge of major change due to some specific challenges facing manufacturers.

One, manufacturers are attempting to maintain pricing differences across classes of trade. Large pricing discrepancies have created arbitrage opportunities, so that products designated for one channel end up in another channel. This diversion undermines the pricing strategies of manufacturers.

Two, this diversion has created avenues for counterfeit drugs to slip into the legitimate U.S. drug distribution system. I'll talk more about counterfeiting in a few minutes, but the impact on manufacturers and their brands is obviously disproportionate to the relatively low levels of counterfeit product.

Three, manufacturers are coming to grips with the fact that no wholesaler was strictly accountable for a manufacturer's product throughout the distribution system. There is a great irony here. Manufacturers are subject to intense national regulation of drug discovery, production, and, increasingly, in marketing. In contrast, once the product leaves the dock of the manufacturer, the next 30 cents of the retail pharmacy dollar has historically been, in my candid opinion, more like the Wild West.

A Flawed Compensation Model

I want to briefly summarize how we got to this point before suggesting what the future holds.

The origins and importance of investment buying to wholesalers' financial performance can be traced to changes in the market structure of the U.S. healthcare system. The last 20 years have seen the emergence of hospital buying groups, the growth of chain pharmacies at the expense of independents, and the entry of supermarkets and mass merchants into retail pharmacy. These volume buyers have demanded deep discounts from wholesalers to secure their business, leading to intense competition among the largest wholesalers.

A wholesaler compensation model evolved in which pharmaceutical manufacturers provided cash discounts and permitted investment buying as mechanisms to support the legitimate costs of distributing branded products.

Pharmaceutical manufacturers compensated their wholesalers by allowing them to purchase more products than were required to satisfy near-term sales demand. In other words, wholesalers were paid with the manufacturer's foregone profits from a price increase. Wholesalers earned as much as 40 percent of their margin from arbitrage across time – that is, buying and holding excess product inventories as drug prices rose. Another 40 percent of wholesalers' margin came from prompt payment discounts offered by manufacturers.

This situation created the deeply flawed channel compensation model that existed prior to 2002. I want to highlight four specific flaws in the model.

- 1) Wholesalers made money as speculators rather than product distributors. Eighty percent of their gross profit came from forward buying, inventory profits, trading margins, and cash discounts or rebates from suppliers.
- 2) This model supported artificially high sales levels at manufacturers. Investment buying by wholesalers allowed a drug maker to perpetually pull sales forward in time as if on a never-ending treadmill. Drug makers also avoided accounting for any distribution expenses because unrealized profits do not get reported on a financial statement.

- 3) Customers essentially got free distribution services. Healthcare customers did not have to acknowledge that product distribution added any value because they didn't have to pay up charges reflecting anything close to true economic costs. As a result, many profit-constrained hospitals built their operations around free distribution.
- 4) Thousands of small wholesalers sprung up to buy and sell the excess channel inventory in a virtually unregulated secondary market, creating opportunities for criminals to introduce counterfeit or mishandled products into the U.S. drug distribution system.

In other words, manufacturers were unable to control the actions and behavior of their product distributors. They also had some financial incentives to encourage investment buying as a significant source of wholesaler profitability. Wholesalers acted logically and legally by stocking up on inventory and trading it. Unfortunately, this system was used regularly and aggressively by criminals.

I hope everyone on this call has read a new book called *Dangerous Doses* by Katherine Eban. She was the reporter in Florida that broke the story of the secondary wholesalers that were diverting products.

If you have the book, look at the graphic on page 359 documenting the distribution path for the Epogen taken by Timothy Fagan, the Long Island teenager of "Timothy Fagan's Law" fame. Katherine Eban shows that the product was originally sold to Cardinal and AmerisourceBergen by Amgen. The wholesalers sold the product to a retail pharmacy in Florida, who sold it out the back door to a network of secondary wholesalers. The product was split up, diverted, counterfeited, stored in the back of trunks, stored in strip clubs, mislabeled, relabeled – everything you can possibly imagine. Ultimately, some of the original lot was repurchased by a regional wholesaler and then repurchased by AmerisourceBergen, who sold it to CVS, where it was dispensed to Timothy Fagan.

These activities were occurring during the time that the SEC accused Bristol-Myers Squibb of allegedly "channel stuffing" from March 2000 through December 2001. In my opinion, these developments laid the groundwork for IMAs and the manufacturers' attempt to gain greater control over the channel.

Challenge in the Channel

I released a white paper six weeks ago called "Challenge in the Channel," which is available on my company's Web site (www.PembrokeConsulting.com). This white paper examines the impact of inventory management agreements on the U.S. pharmaceutical industry and the distribution system.

Let me highlight a few conclusions from that paper:

- Wholesalers avoided \$4.6 billion in inventory growth due to IMAs. Since IMAs were introduced, inventories at the top three pharmaceutical wholesalers have grown only one-fifth as fast as sales. As a result, we estimate that these wholesalers have been able to avoid adding an incremental \$4.6 billion of inventories to their balance sheets in 2003 and 2004.
- The elimination of investment buying using IMAs has led to short-term sales declines for manufacturers as extra inventories are eliminated from the channel. For example, Merck estimated that its 2003 annual sales were reduced by almost \$600 million due to new inventory agreements.
- IMAs have had limited net impact on supply chain inventories. Our analyses reveal that inventory has shifted one-step up the channel back to manufacturers rather than vanishing from the supply chain. Manufacturers added nearly \$4 billion of inventories during the period when the largest three wholesalers avoided adding \$4.6 billion in incremental inventory.
- Although we lack hard data, I speculate that product flow to the secondary market has been sharply reduced, even leading Cardinal Health to shut down their trading operations in May. At the time, Cardinal stated that year to date revenues from trading were less than \$200 million per year. But a few years ago, they had indicated trading revenues of more than \$1.5 billion.

A very important feature of the new agreements is the information transparency requirements. Pharmaceutical manufacturers are also requiring order and transaction flow data to monitor wholesalers more closely. These data are reported within EDI transaction sets, referred to as 852s and 867s. Manufacturers are investing in software for real-time analysis of these commerce data to prevent the wholesalers from engaging in inappropriate ordering.

We are now at a transition point in which wholesalers claim to be signing “fee for service” agreements. My current understanding is that most agreements are actually hybrid agreements. They have a fee component but also allow wholesalers to profit from price appreciation. These agreements generally have even more stringent data transparency requirements than the original IMAs. To some extent, these agreements do not appear to be pure “fee for service” agreements.

Looking Ahead

My premise in this call has been that control is more important than compensation. This perspective leads to three conclusions that go beyond simply focusing narrowly on whether fee-for-service agreements will fully replace the lost profits from inventory investments.

One, pharmaceutical wholesalers will have to get back to a more traditional distribution business by providing value to customers and charging customers for the value being provided. This is much easier said than done. Wholesalers will find it hard to go back to the customers and say, "Guess what? We've been giving you a really great deal, but we can't make money behind the scenes anymore. So, we have to actually charge you for our services."

Naturally, customers, particularly in the institutional market, will resist paying for services that were once received for free. A senior executive with Amerinet, one of the largest group purchasing organizations (GPOs), recently stated that healthcare providers are not able to bear any increased costs due to fee-for-service arrangements between manufacturers and wholesalers.

Two, manufacturers will continue to introduce new controls on wholesaler activities. Consider the challenges of Europe, where diversion is legal and strongly encouraged by the EU regulators. Parallel trade is the practice of buying products in lower cost countries such as Spain and Greece and importing them into high cost countries such as Germany and France. For example, Pfizer has been trying to take over distribution from wholesalers in Spain, where drug prices are 50 to 60 percent below prices in the Northern European countries.

Three, wholesalers may have much lower top-line revenues in the future. Dock-to-dock warehouse sales have low or zero margin, but contribute to cash flow due to favorable timing between customer payment to the wholesaler and the wholesaler's payment to supplier. These revenues have limited effect on profits and most investors understand the impact on financial ratios.

Nevertheless, I expect chain warehouse (dock-to-dock) sales to migrate back to self-distributing chains. Retail pharmacies are under a lot of pressure and may decide – very reasonably – that they can receive large shipments for redistribution. Today, more than 30 percent of revenues at two of the three big wholesalers come from warehouse shipments to self-distributing customers such as CVS and Wal-Mart.

It's also not completely clear why wholesalers should have a role in that business going forward since they don't really need the cash flow benefits to reinvest in inventory. In fact, the wholesalers are likely to find themselves with excess warehouse space.

As I step back, I see an industry on the verge of major structural change now that inventory profits. This channel was compensated to do things that it really shouldn't have been compensated to do. The transition to more normal channel economics will make this industry look more like other wholesale distribution channels in the future.

I'm going to stop here and take some questions now, Larry.

Marsh: That's very interesting, Adam. Thank you for those comments. Let me follow up with a couple points you made.

In your paper, you referred to the relationship changing between manufacturers and wholesalers from seller/buyer to customer service provider. And then you went on to elaborate a little bit on regulated pricing.

Given the substantial margin degradation we've seen from the wholesalers in the last several years with the shrinking of inventory, would you see a more regulated customer/service provider margin being much different from what we're seeing today? And if so, how?

Dr. Fein: As you know, it's very difficult to determine precisely how a wholesaler earns its margins. For the sake of argument, let's assume that wholesalers add three percent to retail pharmacy price, which translates into a seven to eight billion dollar market for wholesale distribution services as currently provided.

Unfortunately, we really have no way to determine if that is an appropriate expenditure to distribute products from manufacturers to the 140,000 dispensing points around the country. Is that too high? Is that too low? No one knows.

The HDMA study from last fall argued that manufacturers would incur billions of dollars to replicate the exact same service levels that we have now. But large pharmacy chains have highly sophisticated logistics operations. The top ten pharmacy retailers now dispense more than 70 percent of all retail prescriptions in the United States. Yet the cost of distribution has been zero to these customers, so we do not yet know how much "wholesaler service" they truly are willing to pay for.

Marsh: The second question from me, you talked about the fee for service model as really paying for that service in the purest sense. We have heard and you discussed many of the fee for service agreements being signed are more hybrid models with an important component of compensation still being inflation based.

Do you feel that that's a non-sustainable model? Especially given the underlying inflation that's ongoing in the pharmaceutical industry. And are there any examples that you can point to in other industries, the U.S. where a pure fee for service model is accepted as a model.

Dr. Fein: To me, the core question for manufacturers is straightforward: "Do I want my channel to be compensated for performing services in support of my business strategy? Or do I want them to make money hoping the prices go up?"

In other industries, a distributor's sell-side margin comes from both manufacturers and customers. Manufacturers set prices or provide buy-side incentives that allow a distributor

to earn a "fair" margin, while distributors provide value add that customers recognize and are willing to pay for.

The dynamics of the healthcare industry have created an unstable situation in which powerful customers have successfully demanded that the cost of a wholesaler's service be deleted from the price. Manufacturers have been responsible for almost all of a wholesaler's profit margin on product distribution. As we know, the manufacturers got these services without having to acknowledge any costs of distribution.

One of the most controversial recommendations in my Challenge in the Channel paper was that controlled investment buying should be allowed to gradually return as a source of wholesaler profit. My understanding is that many current manufacturer-wholesaler agreements are essentially following my recommendation. Many agreements include fees as well as allow for inventory profits related to price appreciation.

As a counterpoint, consider the drug wholesale model in South Africa. Briefly, a group of manufacturers set up an independent distribution service company to distribute their products. Subsequent changes in South African health policy forced these pharmaceutical manufacturers to divest the company to a third party logistics company.

This type of example appears very difficult in the U.S. market, yet supply chain companies such as UPS and FedEx are attempting to enter the wholesale market with this type of pure fee-based distribution model.

Marsh: And then just maybe one final point from my perspective. You address in your white paper this issue that some of these inventory costs are being borne by manufacturers that may actually be a less efficient vehicle to carry those costs.

I think you also addressed that if taken to an extreme we could run into issues of product shortages. Is that still a concern of yours? And wouldn't that mitigate some of the potential ongoing pressure on inventory in the channel?

Dr. Fein: My suggestion that service levels could be affected by IMAs is highly controversial. At the aggregate level, manufacturers are holding additional inventories in response to reduced channel inventory. If manufacturers can consistently maintain the same service levels with direct distribution as wholesalers, then this shift of inventory would have no apparent impact on patients, providers, or pharmacies.

This assumption is highly questionable given the current capabilities and distribution networks of most manufacturers. Pharmacy channels remain complex, with prescriptions dispensed at more than 140,000 outlets. Only six percent of sales are sold directly by manufacturers. The greatest impact would be felt by healthcare customers that are currently served primarily by wholesalers, such as independent pharmacies, nursing homes, and hospitals.

My concern appears to be theoretical at this point. I don't have direct evidence that drug shortages have occurred because of IMAs. But if manufacturers cannot effectively accommodate smaller customers, then we could see stock outs, shortages, or discretionary allocations. This would open the back door to the secondary market.

As I recommend in my white paper, I believe that manufacturers and wholesalers must work together to study the impact of inventory agreements on availability and access.

Marsh: And is that one of the manifestations of why there has been additional scrutiny around the secondary market, do you think?

Dr. Fein: It's one factor. We are learning more every day about problems with the secondary market. I believe anyone who reads the book *Dangerous Doses* would immediately stop purchasing from the secondary market, as CVS recently announced. Frankly, I was surprised by the extent of criminal activity in the secondary market that *Dangerous Doses* documents.

The secondary market is also being squeezed by new licensing requirements being set up at the state level, although the regulations vary widely. The Healthcare Distributors Management Association recently changed its membership requirements and eliminated many members who may have been secondary wholesalers. The Big Three (AmerisourceBergen, Cardinal Health, & McKesson Corp) all had extensive trading operations, which are now being shut down or reorganized.

Marsh: Let me stop there and turn it over to the operator and see if there are any questions to be addressed.

Q&A

Question: I was just wondering if you could comment on the cash discount component of the compensation model. How do you see that evolving over the near term? And do you see any risks with that 2% cash discount?

Dr. Fein: The prompt pay discount has been a mainstay of wholesaler compensation. In my opinion, it is a non-transparent, non-accountable compensation model and ripe for change.

One, it's difficult to determine exactly how much prompt pay contributes to a wholesaler's profit margin, as the details are never fully disclosed. I assume it contributes 175 to 200 basis points to gross margin, on average.

Two, payment term discounts allow manufacturers to perpetuate the fiction that distribution is free. In a pure fee-for-service world, the cash discount really should migrate to a fee. In fact, I've heard talk that some manufacturers in Canada are thinking about changing the cash discount structure.

Manufacturers are starting to recognize that they can use fee structures to leverage their influence and change wholesaler behavior. A cash discount provides no leverage and no influence.

Question: That gets to a second question from me. We've heard a little bit about some selective price increases for the customers from some of the wholesalers. Cardinal has talked about rationalizing their inventory in their health and beauty aids business.

I was just interested in your perspective on the ability of the wholesalers to raise prices to customers. And what interests do you think they actually have in raising prices to customers?

Dr. Fein: Actually, I think the shift will force the wholesalers to run their businesses like distributors in other industries rather than simply raise prices.

Large distributors in all industries are focusing on customer profitability. Understanding internal cost structure and the customer's true service needs is vital to a wholesaler-distributor's ability to properly develop and price service offerings. Here's a rule of thumb that I often cite. For a typical wholesaler-distributor, about 200% of operating profits come from the top 20% of customers, 60% of their customers essentially break even, the remaining 20% are minus 100% of operating profits.

So rather than raising prices or increasing up charges, drug wholesalers may simply have to align their services with what customers are actually willing to pay for. Today, we really don't know what the ideal drug distribution should look like because inventory profits have subsidized excess warehousing and distribution capacity.

It's an old law of economics: When price is zero, demand is infinite. Drug wholesalers are famous for top notch service levels, but perhaps wholesalers have been over servicing customers beyond genuine need, willingness to pay, or customer profitability. The realignment will require back-to-basics wholesale distribution operational strategies. This is a culture shift for top management at these companies.

Question: Can you reconcile the views that you've just laid out which are very interesting, as to what the wholesalers are saying publicly with regard to the change in the distribution model. And specifically the IMAs which sounds more like everything's on track and things are going well.

Second, the comments on regulation, any thoughts about how we're going to see that. Thanks.

Dr. Fein: The wholesalers have been accurate in the sense that agreements are being signed and the agreements have worked – inventory has come out of the channel.

To me, the bigger strategic question comes down to the future impact of control. If you believe that the agreements are more about control than compensation, then what is the next step of control going to be?

At this point, I am only speculating about regulation, although having a patchwork of state regulations does not seem to benefit anyone, including the Big Three wholesalers. I presume that HDMA will be forced to acknowledge this reality sooner or later. On the political front, Congressman Steve Israel (D:New York) has put forward Timothy Fagan's Law, but there is not significant momentum around that legislation yet.

Another potential issue is the re-importation requirement that is baked into the Medicare reform bill. Last December, the Secretary of Health and Human Services released a very thorough and balanced report looking at the importation issue. The existence and prevalence of secondary market activity in the U.S. wholesale system was identified as a barrier to safe importation.

I don't know if anyone has put the pieces of the puzzle together, but the distribution system is getting under control thanks to IMAs and controls that tighten the gaps to the secondary market. But perhaps the next administration would combine the improved security with the political will to push for re-importation.

Question: One final topic that I would like you to address. I think you quoted some class action lawyer suggesting some big potential liability of wholesalers. It seems that this is hyperbole, given what seems to be focus by many of these companies to have pedigree representation backed buying only certain products back from manufacturers. Would you agree, or no?

Dr. Fein: My understanding – and I'm not a legal expert – is the potential risks have to do more with prior practices. Manufacturers have enforced discipline on the channel, so fewer problems are occurring today. By the way, I'm not talking about ancient history – I'm thinking about the past three to five years.

Marsh: Very interesting. Well let me stop there and thank Dr. Fein for being with us again this year. As always, you have provided good perspectives for us to ponder as we continue to try to judge trends in the ongoing evolution of the pharmaceutical wholesaling business.

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