

# **The Changing Landscape of Retail and Institutional Pharmaceutical Sales**

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## **Introduction**

***“Look for companies with “economies of scale, consistent earnings, solid returns, low debt levels, and a business concept that he can understand ...”  
– Warren Buffett***

There have been a number of recent, dramatic trends in the sales of pharmaceuticals – retail-to-the-public, and wholesale-to-institutions – as well as trends in the sourcing and compounding of pharmaceuticals. These trends have been coming together over the past decade, significantly changing one of the world's largest and most profitable industries. In the process, these trends have served to open up new market niches for companies which, if they have succeeded in anticipating the market, have come to represent remarkable, often little-noticed investment opportunities.

The US population is driving the market. Currently, 12% of the population – 37.1 million Americans – are over age 65 – and this number is expected to double, to 71.5 million, by 2030. This population takes an average of 2 to 7 prescription medications each day. However, the population who are the most intensive users of pharmaceutical products – Americans over 85 – is expected to skyrocket from 6 million today to 21 million by 2050.

By 2030, 40 percent of all pharmaceutical spending by consumers will be in the “Specialty Pharma” market. This is one of a number of key factors which are driving the M&A market for Specialty Pharma companies, more than doubling in 2011 from 2010, with Specialty Pharma companies doing more than \$50 million annually shaping up to be particularly attractive acquisition candidates.

## **Retail**

***The Retail pharmaceutical market has changed almost beyond recognition in the first decade of the 21<sup>st</sup> Century – but that change is just the harbinger of dramatic transformations in pharmaceuticals, packaging and delivery techniques to come over the next decade ...***

In the beginning, there were neighborhood apothecaries – the archetypal “drug store” where hard-working pharmacists used mortar and pestle to compound individual doses of prescription and non-prescription pharmaceuticals – at least when they weren’t compounding ice cream sodas and selling a variety of general merchandise to customers who – for the most part – lived within walking distance of their establishment. Hollywood enshrined this local businessman in “Mr. Gower” in “It’s a Wonderful Life,” but for two centuries, this was the model followed throughout America.

Over time, the neighborhood drug store evolved from an individual “mom-and-pop” store into a member of one of a very few national chains. These mega-retailers: CVS (which reports that it is the largest retail pharmacy in the US), along with SavOn, Walgreens, Rite-Aid and other chain retailers – function with a team of pharmacists and assistants who dispense prescribed doses of bulk-produced prescription pharmaceuticals. These medicines were prescribed by physicians who were, in turn, courted by a panoply of “doctor detail” pharmaceutical sales reps, each representing a variety of drugs manufactured by “Big Pharma.” This trend proved so profitable that Big Box stores – Wal-Mart, K-Mart, even chain supermarkets – have all leapt into the retail prescription market.

However, over the past decade, the face of retail pharmaceutical sales has changed forever. Today, consumers have choices, and millions of consumers know that they can lower the price they pay for their medications by being careful shoppers. They can seek out lower-cost retail distributors, such as legitimate Internet pharmacies or mail-order services associated with their local retail pharmacies. Even greater savings are possible if lower-priced generics or over-the-counter formulations can be substituted for branded prescription drugs.

In today’s drastically-altered marketplace, retail prices for prescription drugs vary widely, and the savings possible from careful shopping can be substantial.

This price variance depends on where the consumer makes the purchase. According to the American Enterprise Institute, consumers can save 10 to 40 percent by shopping for the best price for brand-name prescriptions. Storefront pharmacies that have a low volume of sales are likely to have the highest prices, while large mail-order operations tend to have the lowest prices. The convenience of the local retail pharmacy typically comes at a price because of higher overhead costs and a lower ability to negotiate discounts with manufacturers.

This dynamic sea-change began with firms which specialized on providing – by mail – a relatively few and relatively tightly-focused medicines, such as those catering to Medicare-covered diabetics. This is evolving in a number of directions, from firms specializing in low-cost erectile dysfunction prescriptions to those based in Canada which offer significantly discounted prices on a wide variety of prescription drugs – many manufactured in Europe, Asia and South Africa.

In addition, the AARP is, along with serving as a non-profit advocacy group for seniors, a major drug retailer – millions of its more than 36 million of its over-age-50 members

use AARP Pharmacy Service to fill both retail and mail-order prescriptions. AARP is notably shy about reporting the exact number of members who use this service, as well as the price tag – known to be well over a billion dollars – that it rakes in by providing these services.

In addition, there is a growing U.S. specialty pharmaceuticals market, primarily comprised of more than 90 companies marketing more than 550 prescription pharmaceutical products in more than 10 therapeutic categories, such as CNS disorders, pain management, men and women’s health, rare diseases, and urology.

Specialty pharmaceuticals are mainly prescribed by clinical specialists and target well-defined patient groups. In many cases, “specialty” products address large unmet needs that in many cases are inadequately being treated. Examples of “hot” specialty indications include but are not limited to infertility, gout, cystic fibrosis, pancreatic insufficiency, vitamin deficiencies, bipolar disorder, multiple sclerosis, and fibromyalgia. A more complete listing includes:

- |                          |                         |                         |
|--------------------------|-------------------------|-------------------------|
| - Central Nervous System | - Gastrointestinal      | - Urology               |
| - Pain Management        | - Respiratory / Allergy | - Diabetes              |
| - Dermatology            | - Women’s Health        | - Hospital & Acute Care |
| - Ophthalmics            | - Men’s Health          | - Rare Diseases         |
|                          | - Cardiovascular        |                         |

The US specialty pharmaceuticals market had an approximate value of \$21 billion in 2009, determined by the US sales of specialty pharmaceutical products.

*Drug delivery specialty pharmaceutical products* are key contributors to the US Specialty Pharma market, generating revenues of \$10.6 billion in 2009.

**IV Home Infusion:** A major trend in retail pharmaceuticals involves packaging and delivery, rather than new products. An example which has been marked for growth is the home infusion market.

**Packaging and Dispensing:** Equally significant have been the growth of packaged drug dispensers. A major issue among pharmaceuticals today is the non-compliant mistaking of drugs by individuals who have a dozen or more prescriptions, some of which (when combined) can have an impact on perception and awareness. Even without the debilitating impact of aging, individuals with one or several chronic diseases – each of which require multiple prescriptions dosed at a variety of times during the day or night – require help in sorting and dispensing their home prescription medications.

Companies which provide either the technology required for ordered home dispensing, or which come up with distinctive packaging solutions which address this same concern, are likely to become winners in the marketplace through the end of this decade and beyond.

**Non-Compliance:** Medications are only effective when taken – often, only when taken on schedule and in combination with other prescribed pharmaceuticals. To say that this can be confusing is a monumental understatement. As many as half of all Americans fail to stick to prescribed regimens of prescription drugs, and 30 percent of prescriptions written by doctors are not even filled, refilled or taken as directed. Patients with chronic diseases which require regular and multiple prescriptions are notorious for non-compliance and non-adherence – whether they forget to take their meds or choose to avoid taking them for financial or convenience reasons, the consequences of non-adherence can be dire.

The effects of medication non-adherence are far-reaching, with potentially deadly consequences for some patients and financial implications for the medical and pharmaceutical industries. Non-adherence has been likened to a chronic illness and referred to as an epidemic, with no regard for gender, race, economics or education.

According to the Wall Street Journal, studies of heart-attack patients show those who don't fill needed prescriptions have a significantly higher one-year death rate, while those who adhere to their prescriptions have better outcomes and require less care.

The New England Healthcare Institute reported that patients who don't take their medications as prescribed cost the U.S. health care system an estimated *\$290 billion in avoidable medical expenses annually*. Because 32 million Americans are prescribed three or more medications –which can lead to drug interactions and confusion over schedule and dosages – this non-compliance is easy to understand.

Out-of-pocket costs are a major reason for non-compliance, but studies show that even fully insured patients all too frequently drop or fail to start a prescribed drug. Patients worry about side effects – and those who hear TV commercials for prescription drugs that spend 45 seconds out of a 60-second message warning of risks of side-effects have good reason to do so. Yet by refusing to take prescribed drugs, they risk damaging their health while significantly increasing their cost of healthcare through lost work days, increased frequency and length of hospitalizations and other factors.

## **Sourcing and Compounding**

***Where once prescriptions medicines were individually compounded “while you wait,” today they are produced in vast lots, often outside the U.S., and distributed via channels that didn’t exist even a decade ago ...***

Some of the most significant changes in pharmaceutical marketing came to us courtesy of intervention by government – pushed, behind the scenes, by insurance companies and Medicare/Medicaid bureaucrats – that led to the legislative mandate that generic drugs be made widely available, where they could be specified by third-party payors. That they were not always as effective as the “brand name” was immaterial – as was the way that generic laws distorted pharmaceutical companies long-term per-medicine profits, forcing the price of pre-generic proprietary drugs sky-high as Big Pharma had to

rush to regain their investment over the course of years, rather than of decades, resulting in the fact that prescription drugs often have a 1,000% mark-up.

This, in turn, leads to the facts behind a 60 Minutes interview of former Surgeon General Richard H. Carmona, who said “Americans pay more for brand-name prescriptions than anyone else in the world, because of the hefty price associated with the research and development of drugs.” What he didn’t add was that prices are high because pharmaceutical companies have a limited time to cover R&D costs before they are forced to release drugs for the generic market.

Then, as generics become market-accepted and market-demanded, extra-national sources of prescription pharmaceuticals became a market-reality. These medicines often came from Canada – “the price differential for brand-name drugs between the U.S. and Canada has led Americans to purchase more than US\$1 billion in drugs per year from Canadian pharmacies.”

However, while they may be sold by Canadian pharmacies, they are often actually compounded in European and Asian countries, from France, South Africa and Israel (home of Teva, the world’s largest generic drug manufacturer) to India, China and Singapore, countries which do not always maintain the high manufacturing standards imposed by the FDA, or by the Canadian and European Union’s equivalent agencies. For instance, in an article about China’s FDA head’s conviction for systemic bribe-taking, the New York Times has reported that “every year, thousands of people in China are sickened or killed because of rampant counterfeiting of food and drugs.” As foreign-compounded drugs become more available – and more prevalent – in the U.S., this kind of problem may bleed over into the American healthcare system.

Yet despite their potential drawbacks, the dramatic reduction in wholesale and retail prices will continue to outweigh safety and efficacy issues – the smart money will continue to bet on foreign-sourced and generic drugs capturing an increasing share of market into the future.

## **Wholesale and Institutional**

***Outsourcing of prescription pharmaceuticals by institutional care-givers has evolved from rare to common, and from local to decentralized national providers. As the source has moved away from the facilities, “service” has suffered in the name of lower costs and higher margins.***

There has been a strong division in the institutional market, with hospitals on one side of that equation, and skilled nursing facilities and other extended care facilities on the other side.

Hospitals, because of the short lead-time and aggressive patient turn-over, tend to maintain their pharmacies in-house, rather than outsource their prescription pharmaceutical needs. However, hospitals – while they have total control of pharmaceuticals dispensed to their patients – have not been able to make significant

inroads into the post-discharge market. This represents, at this writing, a huge potential market waiting to be tapped by a hospital partner which can come up with a solution which will allow hospitals to tap into this hugely-profitable revenue source. That solution has yet to be identified, but – in part because hospitals, facing imposed and negotiated cuts in reimbursement, are increasingly desperate for any additional revenue source – the first vendor who can deliver this market will further change the face of prescription pharmaceuticals. That investment will be as close to a “sure bet” as anything this side of a winning lottery ticket.

On the other hand, Skilled Nursing Facilities (SNFs) and other extended care facilities (ECFs) have – because of the nature of their lower-turnover patient clientele – have long outsourced their pharmaceutical services. Initially, pharmaceuticals were outsourced to local closed-door wholesale compounding and dispensing pharmacies, which specialized in high levels of customer service. However, within the past half-decade, a few large national firms have bought market share, shaving margins but sacrificing client service.

As the large national firms have further consolidated the market – two of the largest firms have only recently merged – industry insiders report that service has continued to deteriorate while prices are rising. This has opened the market to newcomers who can compete either on the basis of enhanced and responsive local service or on reduced prices – or perhaps on a different service model which will more effectively meet the operational needs of the SNFs and other ECFs.

## **The Investment Model**

***As once-reliable investment opportunities fall on hard times or prove to be less than blue chip, investment “risk” should be evaluated based on perceived market opportunity ...***

As a business – and as an investment – despite the overall economy, healthcare remains strong; according to the New York research firm CB Insights, healthcare companies received \$1.9 billion in investment during the second quarter of 2011, up 21 percent from the prior quarter and up 16 percent from the same quarter last year. There were 147 venture-backed healthcare deals in the quarter. Seed investments accounted for 5 percent of the total, up from 1 percent in the first quarter.

Specialty Pharmacy companies are being funded at a strong pace; and are using that funding to acquire local-market specialty pharmacies throughout the United States. A recent example is Echo Specialty Pharmacy Services, a New York City firm specializing in providing drug therapies for transplant, oncology and HIV/AIDS patients – all high-volume “pharmaceutical cocktail” users who require a significant number of high-ticket medicines on very tight schedules. In addition, many of these Specialty Pharma companies have been accumulating cash on their balance sheets, making them attractive M&A targets. As a result, trading and transaction multiples are up over recent historical levels, especially for small cap companies.

However, while Specialty Pharma is soaring in terms of business generated and M&A activities, Big Pharma has been facing major challenges to sustained growth for well-documented reasons, including:

1. Mega-sized revenue bases
2. Major product patent expiries
3. A more aggressive and better capitalized generic drug industry
4. Thin mid- and late-stage pipelines resulting from low R&D productivity

In the near term, smart money is looking not so much for companies with new formulations – that remains a multi-million-dollar crap shoot – but in those which can address specific problems facing today’s marketplace. For instance, any company which can effectively address non-compliance, either at the retail or the institutional level – which can help individuals stay healthier by taking even the most confusing “cocktails” of prescription drugs – has a remarkable opportunity to become the next run-away bestseller in the pharmaceutical hit parade.

## **Pharmaceutical Industry – Run the Numbers**

*With the Baby Boomers entering the plus-65 market at a rate of 10,000 per day – a rate that will continue for decades to come – pharmaceutical retailing and wholesaling operations are, pure and simple, reliable cash-generating operations – money machines with few working parts to break down ...*

If ever there was an industry that was destined, by virtue of demographics, to grow now and in the foreseeable future – on out to 2050 or later – it is the pharmaceutical industry. Not just Big Pharma with their multi-billion-dollar breakthrough prescription medicines, but also those firms which can more effectively serve the retail or institutional markets, providing solutions to rampant (and deadly) non-compliance or skyrocketing retail costs.

In Q4 of 2011, Credit Suisse reported that this market segment continued to outperform the S&P year-to-date, and projects that, through 2020, sector growth of 5-7% or more per year is expected for at least the next eight years; despite flat international economies, this savvy organization has just pushed its market projections upward. It also reports that this market segment’s resiliency to threats is potentially far better than appreciated by the markets at this time.

The Specialty Pharmaceutical Market is particularly attractive to investors. For instance, according to a confidential report by Bourne Partners, there are three main categories of Specialty Pharma companies:

- Branded original manufacturers
- Branded generics companies
- Drug delivery and reformulation companies

Specialty Pharma companies, Bourne reported, market products within a defined therapeutic area with a small, focused sales force. In order to avoid direct competition with big Pharma, Specialty Pharma companies typically target areas of limited competitive activity. For example, reformulation, repackaging and subsequent brand development are key strategies utilized by Specialty Pharma.

## **The National Market**

***Pharmaceutical demand continues to trend upward while cost pressures squeeze providers to find more cost-effective sources of supply ...***

One wildcard in the healthcare market generally is healthcare reform; however, for the Pharma market, this offers nothing but upward trends.

The volume benefits of healthcare reform based on expanded coverage to 32 million new lives are clear – this could add \$11 billion dollars annually to the prescription drug market. Innovations in delivery of this huge influx of demand create bold new markets for those willing to embrace alternatives to the traditional corner drug store.

However, the numbers show that there are unmet demands, and waste in the system which could be addressed by innovative packaging or other practical solutions. According to the national Council on Patient Information and Education, as reported in the Wall Street Journal:

- Even before healthcare reform dramatically increases the market, 32 million Americans take three or more medications daily
- Nearly 75% of Americans report not always taking their medications as prescribed
- Almost 30% of Americans stop taking their medicine before it runs out
- Only about half of patients with high blood pressure take their prescribed doses of drugs
- Non-Adherence is linked to 125,000 deaths per year, and poor adherence costs between \$177 billion and \$290 billion annually, depending on the source and methodology of the study

## **Conclusion**

***While the investment market remains volatile to a remarkable degree, there remain solid, reliable and attractive investments available to those who actively seek opportunity ...***

It is hard to imagine someone over the age of 40 who doesn't regularly take some kind of prescribed medication. Our society, our culture, our collective lifestyle – all of these factors mitigate toward the kinds of chronic health problems best solved or ameliorated by prescription medications. Big Pharma – and more specialized Specialty Pharma – companies continue to come up with medical solutions for what were, at one point, not even problems. Yet with effective and aggressive marketing and promotion, prescriptions which are “solutions in search of a problem” are nonetheless becoming profitable – often hugely profitable.

At the same time, as individuals age – and our society is aging as never before, and will continue to do so at least through 2050 – they become more dependent on pharmaceuticals, and more challenged by the difficulties of remembering and complying with those prescribed drug regimens. Here indeed is a problem in search of a solution – both at the institutional level and at the consumer retail level. Whether it involves dispensing devices or pre-packaged ready-doses, there is a market eager to enrich companies which come up with real, effective solutions.

With damage measured in hundreds of thousands of lives lost and hundreds of billions of dollars in lost costs, the solutions will be rewarded. Savvy investors continue to sift the opportunities, looking for that golden nugget in the pan of gravel.

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