



Current Status of Safety of the U.S. Prescription Drug Distribution System

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INTRODUCTION & BACKGROUND

The U.S. Pharmaceutical Drug Distribution System

As a result of the heightened focus on preventing counterfeit prescription drugs including legislative proposals to mandate track and trace for prescription drugs, the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), and their members seek a better understanding of the prevalence of counterfeit prescription drugs in the US pharmaceutical supply chain, and a realistic assessment of the cost implications of implementing a track and trace system for prescription drugs.

Proposed legislative mandates around counterfeit prescription drugs may have significant impacts to pharmacy operations and result in increased operating costs. As providers of pharmacy services affected by the proposed technology solution, NACDS and NCPA solicited Accenture to undertake a reliable, defensible study that examines the safety and security of the U.S. pharmaceutical supply chain and the implications from track and trace proposals for prescription drugs. Another objective of this study was to research and review the U.S. prescription drug distribution system including how drug distribution purchasing practices have changed to enhance the security of the drug distribution supply chain since 2003, in response to highly publicized reports of counterfeit Lipitor, Procrit, and other drugs. This study aimed to accurately determine the frequency and magnitude of counterfeit drug occurrences in the US while weighing the cost effects and outcomes of increased governmental legislative and regulatory mandates.

The Food and Drug Administration (FDA) acknowledges that drug counterfeiting in the U.S. drug distribution system is rare, due in part to current regulatory measures regarding pharmaceutical production and penalties for counterfeiters. The agency also does not believe that incidents of counterfeit drugs entering the standard US prescription drug distribution chain have increased significantly in recent years. Although the FDA assures American consumers that the US prescription drug supply is secure, and that their medicines are safe and effective, they advocate a proactive approach using technology to prevent counterfeit prescription drugs.¹

FDA supports a track and trace technology approach to combat the potential for counterfeit prescription drugs through the application of Radio Frequency Identification (RFID) tags or other taggants such as two dimensional barcodes (“2D barcodes”) to drug product packages. RFID and 2D barcode tags would include unique individual serial numbers on each pharmaceutical drug product, allowing them to be tracked and traced through the prescription drug distribution chain. The FDA contends that the implementation of a track and trace system might help to protect the supply chain from the risk of counterfeit prescription drugs by allowing for drug authentication across the levels of the prescription drug distribution supply chain.

The Food and Drug Administration (FDA), members of the U.S. Congress, and others are currently considering options to enhance the security of the U.S. prescription drug distribution supply chain including legislation to address the potential for counterfeit prescription drugs. Last year, Congress assigned FDA the task of developing standards for a technological approach to prevent the potential for counterfeit prescription drugs in the U.S. prescription drug distribution supply chain pursuant to federal legislation enacted in 2007.

“On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, sub-potent, substandard, adulterated, misbranded, or expired drugs. [This] directs the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. [This also] states that the standards developed under 505D “shall address promising technologies, which may include--(A) radio-frequency identification; (B) nanotechnology; (C) encryption technologies; and (D) other track and trace or authentication technologies”²

¹ U.S. Food and Drug Administration. “Combating Counterfeit Drugs” February 2004; and See <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>.

² U.S. Food and Drug Administration. “Technologies for Prescription Drug Identification” 20 March, 2008. P 1-2.

Significant recent changes to state laws and regulations have played an important role in enhancing the security of the U.S. drug prescription distribution supply chain. States have enacted laws and regulations to add comprehensive requirements for licensure of wholesale drug distributors and to require statements showing the wholesale distribution history (commonly called “pedigrees”) for prescription drugs distributed outside the safety of the “normal distribution channel”³. The stringent state laws for licensure of wholesale drug distributors work to prevent illegitimate wholesale drug distributors from becoming licensed by states and distributing drugs. These laws have moved towards stronger, uniform, and comprehensive wholesale distributor licensure regulation by adding requirements such as criminal background checks, qualified designated representatives for each facility, surety bonds for payment of penalties, mandatory inspections, and enhanced civil and criminal penalties for violations including distribution of counterfeit drugs. Florida and Nevada were among the first to strengthen their laws and regulations. For example, Florida’s law, among other requirements, mandates that wholesale drug distributors located in the state and those doing business in the state provide extensive background information and undergo criminal background checks, and added significant criminal fines and possible imprisonment. Since the Florida and Nevada laws were enacted, more than half of US states have followed by enacting laws for stronger wholesale drug distributor licensure requirements and most have also acted to require pedigrees for drugs distributed outside of the “normal distribution channel.”

³ The normal distribution channel is the distribution of prescription drugs from the manufacturer through wholesale distributors to pharmacy distribution centers and pharmacies. About 20 states have enacted laws that recognize the normal distribution channel as exempt from requirements to pass a “pedigree.” See Appendix B for a diagrammatic representation of the normal distribution channel.

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EXECUTIVE SUMMARY

It is well-documented that incidents of counterfeit drugs have been on the rise *globally* since 2002; however reports of counterfeit drug occurrence in the US prescription drug distribution system continue to be scarce. Following two widely-publicized incidents of counterfeit Lipitor and Procrit in 2003 and 2004, reports of counterfeit prescription drugs have been rare, due in part to laws and regulations governing purchasing and distribution practices. With national prescription volume in the billions, occurrences of counterfeit prescription drugs are rare events. Motivated by a changing economy and by concerns for their patients' safety, pharmacies have moved toward a trend of self-regulation in some instances, making operational or procedural changes to enhance the security of their distribution systems, and to enhance assurance that they are providing patients with authentic prescription drugs. Since 2005, changes in the way that manufacturers, wholesalers, and pharmacies obtain and purchase prescription drugs may be responsible for the low number of reported counterfeit incidents in the United States.

Media and Literature Analysis

While media coverage of counterfeit prescription drug incidents globally has been extensive over the last five years, press reports involving counterfeit drugs in the US pharmaceutical supply chain are scarce. All reported incidents identified in our press research occurred during or prior to 2004. All subsequent news coverage of counterfeit prescription drugs in the US prescription drug market has involved preemptive identification and removal of potential counterfeits before the prescription drugs reached the consumer. Media reports of a movement toward voluntary self-regulation on the part of manufacturers, wholesalers, and pharmacy retailers, however, emerged as a trend throughout the press coverage over the last five years. These reports show that across the prescription drug distribution system, participants have and are increasing their efforts to ensure the security of the prescription drug distribution supply chain to maintain the safety of the prescription drugs which they buy and sell.

Pharmacy Surveys

Reports from NACDS and NCPA pharmacy members are consistent with the media reports. Surveyed members disclosed two incidents of counterfeit prescription drugs across all respondents, and both incidents occurred during or prior to 2004. Many pharmacies have taken a number of steps to help to secure the safety of prescription drug products including a move toward self-regulation, changes in the way that they obtain and purchase prescription drugs, and placing increased pressure on their suppliers through changes in their contracts. Across the board, pharmacies are moving away from relying on secondary markets, and many are requiring direct-from-manufacturer purchase of their distribution partners and wholesalers. Confidence in the US market and in particular their purchasing and distribution safeguards were high amongst pharmacies interviewed.

Cost Implications and Status Assessment of Track and Trace Systems

If a federally mandated track and trace program were to be implemented by retail pharmacy, the cost associated with complying with this program would be significant. As part of this study, a Cost Model was developed to determine these expected costs when implementing the hardware/software, infrastructure, and implementation/labor resources for a "track and trace" system. Four cost models were constructed to represent the typical "large," "medium," and "small" chain pharmacy, and an "independent" pharmacy and to provide a realistic comparison between the groups. Among the many assumptions outlined in Section 2, *Cost Model: Estimating the Cost of Implementing Track and Trace Technology*, the "track and trace" system would be fully implemented in the first year of a seven year timeframe.

A "large" chain, consisting of 14 distribution facilities and 4,000 pharmacies, would incur a total cumulative cost of \$1,307,797,800, a "medium" chain would face a \$46,643,421 total cumulative cost for 1 distribution facility and 100 pharmacies. The typical "small" chain would experience a total cumulative cost of \$3,853,894 with no distribution facilities and 15 pharmacies, while an "independent" pharmacy with no distribution facilities and 2 pharmacies, would incur a total cumulative cost of \$472,275. The table below shows a summary of the first year expenses, broken down by site costs.

Based on our analysis, the potential cost of complying with a federally mandated track and trace program would be between about \$84,000 to over \$110,000 per pharmacy in the first year alone for hardware, software, infrastructure, and implementation/labor expenses. This amount is nearly 2% of a retail pharmacy's total annual pharmacy sales which is significant in an industry which averages an annual net profit of about 3%. This high cost is driven by the fact that retail pharmacy is at the end of the supply chain and must be prepared to be interoperable with all the technology choices made by others in the supply chain. A significant segment of potential costs is related to additional labor resources required to handle serialized product in normal and exception scenarios. In addition to a lofty price tag, there are other cost considerations that need to be taken into account for a 100% compliant implementation of track and trace, such as costs for operational improvements to deter higher costs, the need for a uniform data carrier standard, and the lack of a unified track and trace model among all industry segments and trading partners.

	Per Pharmacy Data Center Costs	Per Distribution Facility Costs	Per Pharmacy Store Costs
Large	\$6,133,305	\$2,881,181	\$112,129
Medium	\$2,288,265	\$2,752,771	\$103,939
Small	\$99,900	-	\$90,399
Independent	\$33,300	-	\$84,102

Furthermore, the ability to move forward with implementation of a track and trace system on a large scale will not be in place for many years. Such implementation will involve many key and unknown factors. Among these are the challenges of versatility and costs within pharmaceutical operations for the different types of RFID and 2D serialized barcode hardware, operational processes that must be considered while leaving internal pharmacy operations intact to receive drug products and provide dispensing services to patients, high labor costs with 2D barcodes, the different data exchange models for serialized information required for compliance, the processing and transmission of information, and a host of other issues.

Our findings across this study have echoed a consistent theme. Pharmacy providers have taken steps to tighten up their prescription drug distribution chains and acknowledge the continued need for vigilance. This includes but is not limited to continuing to improve their methods for purchasing and obtaining drugs, and strengthening their supplier relationships. The reported incidents of counterfeit drugs in the US show that these items have been in most instances obtained illegally via illegitimate, unregulated Internet-based entities, or via gray market diverting, re-importing, or repackaging.

It is important to note that the recently reported incidents of prescription drug counterfeits were identified and removed from distribution. It is also important to note that changes made to purchasing and distribution processes have been kept relatively invisible to the consumer. Proposed track and trace mandate legislation – in its current form – presents substantial cost considerations to retail pharmacies. The survey findings show that pharmacy providers have taken practical steps to enhance the security of prescription drug distribution supply chain.

Assessment of Counterfeit Drug Prevalence in Media and Literature

*"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients, or with insufficient active ingredients."*⁴

Key Findings

There have been well-documented cases of counterfeit drugs in the US from 2002-2004, however reported incidents of prescription counterfeit drugs have fallen off sharply as prescription drug distribution system stakeholders began changing their practices for obtaining and purchasing prescription drugs to enhance the security. Overall, media findings of counterfeit drugs are largely occurring abroad; those in the US are almost exclusively in the domain of unregulated, illegal Internet-based entities, and the gray market diverting, re-importing, and repackaging.

An important finding is that since 2005 there have been numerous observable cases in which manufacturers, wholesalers, and pharmacies have changed their purchasing and distribution practices through self-regulation to help to ensure the integrity of their pharmaceutical supply chain. During that same time period, there have been no major recalls or incidents of counterfeit prescription drugs in the US pharmaceutical distribution system.

Media & Literature Analysis

The new global economy has contributed to the rise of counterfeit goods. Industries ranging from high-end fashion retail to consumer electronics have fought to prevent the spread of imitation and black-market goods, with varying degrees of success. According to estimates from the World Health Organization (WHO) and the Food and Drug Administration (FDA), sales from counterfeit drugs will reach \$75 billion (US) by 2010, with up to 10-30% of medicine being estimated as counterfeit in some countries with weak regulatory systems.⁵ This study aims to investigate the status of counterfeit prescription drugs in the U.S. pharmaceutical market.

The FDA's response to this perceived trend has been proactive, seeking to implement a national track and trace system for all prescription drugs across the supply chain using Radio-frequency Identification (RFID) technology. Many stakeholders in the US pharmaceutical distribution system maintain that the distribution network is already among the most secure in the world. However, proponents of proposed track and trace measures see track and trace as a means to help to secure the US drug distribution supply chain. The US has reported few incidents of counterfeit drugs in the primary prescription drug distribution supply chain, though there were several well-publicized examples in prior years.

One of the most widely publicized accounts of prescription counterfeit drugs made media headlines in 2003, when the FDA issued a recall on three lots of counterfeit Lipitor which had been repackaged by Med-Pro, Inc. So-called "statin" drugs are among the top-selling in the world. Also in 2003, three counterfeit lots of the anemia drug Procrit were discovered in the US, prompting a recall from the FDA. More recently, in 2005, a warning was issued regarding counterfeit lots of Lipitor, Viagra, and Evista. These incidents have led to significant changes in the supply chain distribution practices (discussed in Section 2).

The issue of potential counterfeit prescription drugs in the US drug distribution supply chain is paired with the question of *how* and at which *point* in the supply chain counterfeits get mistaken for authentic prescription drugs in the US. The two primary channels for counterfeit drugs since 2002 have been via unregulated, illegal Internet-based entities, and via the gray market.

⁴ World Health Organization. "Counterfeit Medicines." 14 November, 2006. P 1.

⁵ Birmingham Post. "Counterfeit Drugs Pose Danger." Birmingham Post 9 May, 2008. P 1.

Growth of the illegitimate Internet-based pharmaceutical market may have started following the Anthrax scares in 2002. Many consumers began stockpiling Ciprofloxacin in response to the threat of bioterrorism, frequently turning to unregulated, illegal Internet-based entities to avoid paying full price for the expensive pills. This would prove to be an early, well-documented case of prescription counterfeits via these entities, as many were receiving medicine which was counterfeited.⁶ Patients may often seek drugs via online channels for treatments that are controversial or may be stigmatized, expensive, elective, unavailable, or not prescribed to them. Although numerous US licensed pharmacies provide legitimate Internet pharmacy websites for their customers, one way in which US consumers can unknowingly expose themselves to counterfeit prescription drugs is through the use of unregulated, illegal Internet-based entities. In May of 2007, the FDA published a warning naming 24 websites were possibly involved in distributing counterfeit Xenical, Tamiflu, and Cialis.⁷

FDA has issued previous statements regarding unregulated, illegal Internet-based entities which it has determined to be sources of counterfeits, but acknowledges that stopping online prescription drug counterfeits is part of a much greater problem. The FDA's 2004 report, *Combating Counterfeit Drugs*, highlights the need for consumer education and vigilance against online counterfeits. Notwithstanding this, it is recognized many legitimate US licensed pharmacies provide legitimate Internet pharmacy websites for their customers.

The other channel which has provided a potential entryway for counterfeit prescription drugs into the US market is entities acting as secondary wholesalers⁸ through which counterfeit prescription drugs may be introduced into the US prescription drug supply chain. Activities such as repackaging and re-importing drugs have made it difficult in some instances to confirm the integrity of drugs in the US secondary market, and as a result many US pharmacies are decreasing the frequency with which they purchase through this market. Nonetheless, the legitimate secondary market can serve a valuable purpose such as matching supply with demand when pharmacies require drugs which are not readily available via primary channels.

In response to both increased threats of counterfeits and proposed government regulation, some manufacturers have already begun increasing their levels of self-regulation and assurance of the authenticity of their drug products. In 2003, in response to a recall of their drug Lipitor, US manufacturer Pfizer began piloting a new RFID pedigree program to ensure the quality of its drugs throughout the US supply chain. In 2006, then-Pfizer CEO Hank McKinnell indicated that RFID was five years from being ready for a national implementation.⁹ Boston-based biotech company Genzyme announced in May 2008 that it would also begin implementing an ePedigree system to monitor and track its entire pipeline.¹⁰ However, recently the California Board of Pharmacy recognized the need to delay of the implementation of the electronic pedigree drug tracking and tracing mandate due to concerns over effects on the drug supply chain.¹¹

One pharmacy chain publicly announced in 2005 that it would require all of its wholesalers to certify that they do not purchase any drugs from the secondary market. This was following an existing policy at the chain pharmacy that it would not deal in the secondary market at all, and was then voluntarily expanded to include its wholesalers.¹² In fact, the regularity of this practice among top manufacturers, distributors, and retailers became so widespread that secondary wholesaler RxUSA filed an anti-trust lawsuit in August 2006. The suit alleged that Authorized Distributors of Record (ADRs) were colluding to shut RxUSA out of the market by choosing not to buy from or sell to them.¹³ While new measures may present concerns for the secondary market, this illustrates activities occurring in the supply chains across the US pharmaceutical distribution system.

⁶ Rush, Mark, L.M. Villarnovo, and L. Paglia. "Combating Counterfeits." *Pharmaceutical Executive* 1 June, 2002. P 1-2

⁷ Hitti, Miranda. "FDA Warns About Fake Internet Drugs." *WebMD Medical News* 1 May, 2007. P 1.

⁸ For a discussion of secondary wholesalers, please see the FDA "prescription Drug Marketing Act – Report to Congress (2001) at <http://www.fda.gov/oc/pdma/report2001/attachmentg/3.html>.

⁹ Feemster, Ron. "FDA Raises the Stakes." *Pharmaceutical Executive*. 1 July, 2006. P 1.

¹⁰ Koroneos, George. "Genzyme Launches Digital Assault on Counterfeiters." *Pharmaceutical Executive* 14 May, 2008. P 1-2.

¹¹ See http://www.pharmacy.ca.gov/about/e_pedigree.shtml.

¹² CVS Caremark Corporation. "CVS Takes Additional Steps." 2 May, 2005. P 1-3.

¹³ Gebhart, Fred. "Secondary Wholesaler Charges Illegal Boycott." 21 August, 2006. P 1-3.

Many other recent examples of self-regulation exist as well. On May 16 several lots of Doxil, Procrit, and Remicade were stolen while in transit to a specialty distributor. This prompted a voluntary withdrawal of all the lots associated with the theft, to prevent the drugs' resale.¹⁴

Pharmacy Surveys & Interviews

Key Findings

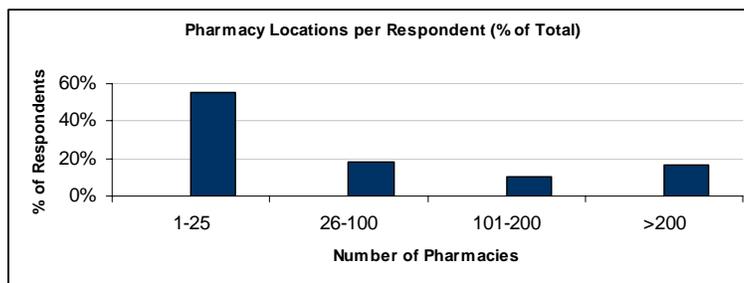
In many ways, the responses from the pharmacy surveys confirmed observable trends from the literature and media search. Pharmacies reported increasing demand for pharmaceuticals from 2002-2007, while many have changed their procurement practices over the last five years to increasingly self-regulate their purchases and ensure the authenticity of their prescription drugs. Only two incidents involving counterfeits were encountered across all respondents, both occurring before 2005.

Respondents were uniform in their emphasis on the need for rigorous practices and standards, but also uniformly opposed to additional government regulation, citing significant costs to pharmacies, redundancy with self-imposed regulation systems, and uniformly high confidence in the US drug distribution system.

Survey Discussion

Please note all statistics and figures are available in Appendix E.

Estimating the prevalence of counterfeit prescription drugs in the pharmaceutical drug distribution system is a difficult task, particularly in the United States. In an effort to better understand whether or not counterfeit prescription drugs are a legitimate threat in the US pharmaceutical prescription drug market, the project team conducted a survey of a randomly selected group of NACDS and NCPA members. The survey was intended to help to create a reasonable estimate of counterfeit occurrence in the US market.



Of the 123 surveys solicited, 54 were returned, complete and with additional commentary and observations, with a total response rate of 44%.

One survey finding is that across all respondents, *only two* personal encounters with counterfeit prescription drugs were reported. The first incident, in 2003, was the result of repackaged Lipitor bought from a large wholesaler.¹⁵ The second incident reported, in 2004, was a bottle of counterfeit Zyprexa. The drug manufacturer was contacted and the drugs were determined to be counterfeit.

Both of these incidents occurred in 2004, before pharmacies implemented significant changes in practices for obtaining and purchasing prescription drugs. All respondents indicated that they had no incidents of counterfeit prescription drugs at any point since 2005.

A broad trend observed is the change to self-regulate against the threat of counterfeit prescription drugs. Approximately 28% of respondents reported changing their purchasing habits since 2002, with many reporting that they either,

- No longer purchased from the secondary market

¹⁴ Chi, Judy. "Stolen Drugs Being Withdrawn as a Precaution." 16 May, 2008. P 1-2.

¹⁵ This is the Lipitor incident discussed in the Media and Literature section.

- Only purchased direct-from-manufacturer, or from a wholesaler who does
- Required stricter proof of pedigree requirements, or
- Some comparable increase in purchasing stringency

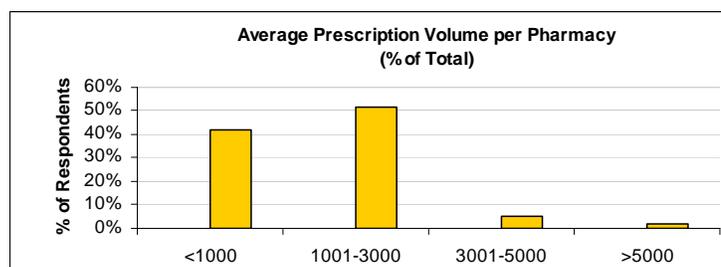
Of those who reported no change in purchasing or distribution behavior, some stated that no change was necessary, as they had always purchased directly, or had a similar method to enhance the security of their practices for obtaining or purchasing prescription drugs.

With specific regard to current habits for obtaining or purchasing prescription drugs, 90% of pharmacies reported using large-scale wholesalers as one of their primary sources, followed by direct-from-manufacturer (31%). Only 12% of pharmacies reported doing any business with the secondary market, and among these were reports that the secondary market was only used if the distributor could confirm the pedigree of the drugs. In addition, 83% of respondents reported using two distributors or less, with 0% reporting more than five.

As a possible result of increasingly stringent self-regulation, current confidence levels in the US supply chain and US government regulation are uniformly high. Related to confidence in their own purchasing practices, 100% of pharmacists expressed *High* or *Very High* levels of confidence that the drugs they receive are not counterfeit. In addition, 98% had *High* or *Very High* levels of confidence that their *supplier* would inform them of a risk of counterfeit drugs in the supply chain. The remaining 2% selected *Neutral*. While we had no expected results for these questions, the answers provided were consistent with all other observations in this study.

Survey results also indicate that satisfaction with current levels of government regulation was high, with 88% ranking it as *Adequate* or better. Of those reporting dissatisfaction with the current system, none were in favor of greater amounts of regulation, but expressed concerns with costs which would be placed on either the pharmacy or their patients. Many suggested requiring pedigrees of internet, international, and secondary suppliers, outside of the standard retail pharmaceutical supply chain and noted that controls over wholesalers and manufacturers enhanced the security at a reasonable cost.

These observations gain significance in light of the increasing prescription volumes reported. The theme is consistent with reports from the FDA, and demand for pharmaceuticals is indeed rising. Average total volume of prescriptions across all respondents rose 39% from 2002 to 2007. Among pharmacies, 96% were estimated to handle 3000 prescriptions per week or less.



Survey results provided visibility into pharmacist perceptions of which prescription drugs had the potential for counterfeit susceptibility, which were consistent with our findings from media research. Respondents were provided with the following list of drug types:

- Cholesterol medication
- Antidepressants
- Blood pressure
- Antibiotics
- Lifestyle drugs
- High-value Injectables
- AIDS medications
- CII painkillers
- CIII painkillers
- Anxiety/Sleep medications
- Other (please list)

They were then asked to assess their susceptibility to counterfeiting. Many respondents answered *Don't Know* (31% for any given drug), followed closely by the *No Problem* response with an additional average of 25%.

Drugs assigned risk levels of 3 out of 5 or greater (3 being *Moderate Risk* and 5 being *Severe Problem*) by participants were lifestyle drugs (61%), cholesterol medication (41%), and high-value injectables (39%). These assessments were consistent with what we found in our media search, as these three categories correspond most closely with drugs which had the best-publicized incidents of counterfeit since 2002. Lifestyle drugs such as Viagra and Cialis are a perennial favorite among unregulated, illegal Internet-based entities, while the FDA issued mass warnings in 2003 for both the cholesterol drug Lipitor and the injectable anemia drug Procrit.

In summary, there were many observable trends that all point towards increasingly stringent self-policing and high degrees of confidence in the current US pharmaceutical distribution system.

SECTION 2 – Implementing Track & Trace Technology- Cost Implications, Industry Readiness Status & Changes to Distribution Practices

Assessing Recent Changes in the U.S. Pharmaceutical Supply Chain: Interviews with NACDS and NCPA Members

Key Findings

As a supplement to the literature search and member survey, the project team conducted a short verbal phone questionnaire with NACDS and NCPA members. The purpose of these interviews was to explore changes made by pharmacies to their prescription drug distribution system for obtaining and purchasing prescription drugs over the last five years. The interview explored how the pharmaceutical drug distribution chain has evolved recently in order to assess market need and readiness for a track and trace solution. Several observations were brought to light by the verbal supply chain interview. Across the board responses indicated strong supplier relationships, and increased pressure to have wholesalers purchase directly from manufacturers. Of those participants who did change their mode of obtaining or purchasing prescription drugs, some were prompted by concerns over counterfeit prescription drugs and others made adjustments for economic reasons. These cost effective operational adjustments often doubled as safeguards in the supply chain. All participants reported high levels of confidence in their suppliers, and while most acknowledged a need to always be vigilant, none reported tangible concerns about counterfeit prescription drugs in the US prescription drug market.

Interview Discussion

Fourteen pharmacy groups were interviewed, representing the broad range of company compositions, from single location independent pharmacies to large national chains. Of the 14 companies interviewed, four had a single retail pharmacy location, and one independent company served as a pharmacy services provider with no attached retail location. Three interviewees had between 100 and 300 pharmacy locations, one of which was exclusively a regional pharmacy chain, another with pharmacy locations housed in long term care facilities; three participants had between 500 and 900 locations in their chain; the remainder of respondents represented larger national chains. Yearly prescription volume across respondents varied from approximately 36,000 in an independent pharmacy chain to many millions of prescriptions in a large retail pharmacy chain.

Participants' processes for obtaining and purchasing prescription drugs varied as widely as their prescription volume. Many of the larger pharmacy chains purchased or obtained prescription drugs through several different avenues, including company-owned distribution centers, large-scale wholesalers, and direct-from-manufacturer. A trend among large chains was to work with a single wholesaler purchasing directly from a manufacturer or to buy directly from a manufacturer to the pharmacy distribution center. Several respondents indicated that they managed brand and generic products through distinct but related processes. All generic products are bought directly from a manufacturer; brand drugs were either purchased directly from a manufacturer or purchased from a wholesaler who bought directly from a manufacturer. Many respondents indicated that the manufacturer had the ability to ship product directly to a retail location on an exception basis. Of the nine

medium to large size chains interviewed, none of the respondents worked with an independent buying group, purchased drugs online, or bought through a secondary market, and all but one were aware of their wholesalers purchasing practices from manufacturers or other accredited wholesalers.

A trend among the smaller pharmacy chains was to work with one or more wholesalers. Of the five pharmacies interviewed in this group, four work with one or more wholesaler. Of the pharmacies that buy through a wholesaler, only two knew whether or not the wholesaler purchased directly from a manufacturer, but assumed that to be the case.

Many members reported no change at all to their supply chain but, but highlighted instead measures that have always been in place to help to make sure that end customers are receiving safe and effective prescription drugs. One participant indicated that they didn't make any adjustments to their purchasing and distribution practices due to concerns of counterfeit drugs because they had never had a reported incident of counterfeit *and* because their supply chain has been kept as simple and straightforward as possible, with a minimum amount of handoffs. Another participant indicated no change in purchasing practices, but added in the caveat that they had always been extremely conservative across their supply chain. "If we had been buying into opportunity buys to begin with, we would have had to change our process, but we've always been away from that."

Other pharmacies, reporting no significant change to purchasing processes or distribution operations, instead called attention to increased pressure on their suppliers through contractual obligations to enhance security of the supply chain. One pharmacy indicated that while they did not make specific changes to their internal processes, they implemented a policy to only do business with wholesalers who purchased directly from a manufacturer. Across the survey, companies are relying on their wholesalers as partners to enhance the security of the supply chain. One respondent, when asked if recent regulation on wholesale licensure or product pedigree had changed their distribution practices, indicated that at this point their wholesalers managed this process for them. Another respondent, when asked about how confident they were in their supply source, replied that the burden was now on the supplier.

Smaller pharmacies echoed this sentiment. All independent pharmacies and small pharmacy chains interviewed reported no change to their purchasing or distribution practices as a result of fear of counterfeit drugs, but did indicate that they had high confidence levels in their large wholesalers and that they were aware of changes in their wholesaler practices, including purchasing directly from the manufacturer.

Several organizations did report making adjustments to their supply chain, although not all of them credited fear of counterfeit drugs as the main motivator for their changes. One pharmacy attributed changes in the economy as the driver of changes in their supply chain. Leveraging against a single wholesaler was beneficial to the company as a whole; protecting against the risk of counterfeit drugs was an added benefit. Five years ago, one organization indicated that they bought 90% directly from a variety of vendors but that the economy has forced them to move toward purchasing from a single wholesaler.

Of those reporting changes to their supply chain over the last several years, changes made were similar across companies. One company reported developing a corporate policy around procurement requiring purchases to either be made directly from a manufacturer or through an accredited wholesaler purchasing directly from a manufacturer. Another company reported adopting a similar policy. Five years ago they were buying product from distributors and other wholesalers offering the best price advantage or a buying opportunity that could decrease costs. This type of practice is now off the table. The company no longer purchases from secondary wholesalers unless they can provide one stop pedigree that says that the product was purchased directly from the manufacturer, and these secondary wholesalers are only used to avoid stock outs which accounts for less than 1% of their business. Another company reported changing their business model from consignment based inventory to company owned inventory resulting in a more secure supply chain. Previously their inventory was all consignment. Recently the company moved to a business model in which they own their own inventory. Encouraged by pedigree regulation, but chiefly motivated by getting product to the store as efficiently as possible, they have moved to a policy of purchasing straight from a wholesaler.

Changes made across the distribution system have been kept transparent at the retail locations. All fourteen respondents reported no change to the way that prescription drugs were handled or dispensed at retail locations because of fears of counterfeit drugs. Pharmacies indicated that they were engaging in practices in the supply chain and "behind the scenes" so

that there are no questions about authenticity of product. One pharmacist also pointed out that pharmacists always screen what comes in carefully and that they've always been cognizant of labels coming in and continue to be so.

When asked if changes to laws and regulations to increase requirements for wholesale drug distributor licensure and to require pedigrees for prescription drugs distributed outside of the normal distribution channel impacted their prescription drug distribution practices, most respondents answered, 'no'. Only chains with company owned distribution centers acknowledged a legislative impact. The changes in wholesale licensure requirements have made it so that chains operating their own distribution facilities require wholesale drug distributor licenses. Some states have higher levels of qualification and include certification of wholesale drug distributors from a third party entity. One member company chose to get certification across its pharmacy distribution centers, even in states where certification was not required because they found it the "right thing" to do for their supply chain. Another member adjusted its distribution programs in certain states in response to increased licensing fees and strict regulations. One participant indicated that while the licensing process is a strain on the warehousing business, with high expense and no returns, they'll do whatever it takes to comply, adding that they were hopeful that states would soon be consistent in their wholesale distributor licensure requirements to keep costs down for both retailers and manufacturers. Smaller chains indicated no impact and pointed again to a shift of responsibility to the wholesaler to manage and adjust to legislative changes.

We asked member companies how confident they were in their standard supplier in both our survey and our questionnaire. Across the board, all respondents expressed a high level of confidence that the prescription drugs they receive are not counterfeit, "as close to 100% as you can get" and all respondents indicated that if a counterfeit prescription drug were to make it into the supply chain, their supplier would notify them immediately. Many respondents indicated that it was difficult to say 'I think there is a problem' when there has been no evidence of a problem.

Respondents from smaller pharmacies also demonstrated a high level of confidence in their supplier, and little concern over counterfeit drugs in the US market in general. One pharmacist did indicate a concern over generic houses, making regular cold calls offering deals on brand names. Several pharmacists indicated general concern over counterfeit drugs on the internet or secondary market which is consistent with what we found in both our survey and in our literature search. The internet market, as one pharmacist pointed out, has a greater susceptibility to counterfeit prescription drugs because of the lack of controls in place.

When asked about their overall concern about counterfeit drugs in the marketplace, respondents were in agreement. Some respondents indicated that their confidence in their own supply chain and in changes already put into place including "changes put into place by states especially Florida" has "already tightened up [the supply chain] pretty well." One respondent pointed to changes within the last five years, indicating that the channel today is very different from that of the 90s or even earlier in this decade. This member also indicated that there hasn't been a single recall or drug alert on a counterfeit product since 2004. While no respondents revealed a concern for drugs in the US market, several indicated a general concern. "I don't think it is going to happen but it is important to continue to do the right thing and to make sure that you are doing the right thing for your patients ultimately; keeping your guard up." Respondents seemed to agree that their high level of confidence in their supply chain and in the system was directly related to a low level of reported incidents. "On a scale of one to ten, one being lightly scared, to ten being terrified, probably a one. You have to be concerned but it's important to have safety measures in place and great [supplier] relationships."

In an effort to gauge how pharmacies manage prescription drug shortage situations and to assess if they look to secondary markets should such a situation arise, we asked respondents how and where they would obtain prescription drug products in the event of a product shortage. Most respondents looked to buy directly from the manufacturer or through a primary wholesaler. Several respondents indicated that stores could purchase directly from the manufacturer and that products were drop-shipped from the manufacturer directly to the stores. Generally speaking if the manufacturer doesn't have the product, the shortage is a widespread problem.

All respondents seemed to feel very confident in their sources for prescription drugs, and none of the interview participants indicated seeking prescription drugs from secondary markets or online sources. Given the choice, several indicated that they would out of necessity need to short the patient or work with the prescriber to find an alternative over purchasing drugs of questionable origin in order to ensure their patients' safety.

In the case of generics, large chains indicated that they would look to different manufacturers if their primary manufacturer ran out. On the brand side, most would opt to purchase from the wholesaler or manufacturer until both ran out of product. Smaller chains might opt to call a colleague to obtain the prescription drug from them until they were able to get it through their wholesaler.

Interview responses called attention to the push for contractual changes to enhance security of the supply chain. One participant indicated that they thought it was a “good thing” to tighten up contractual obligations in order to protect the supply chain so that there is a high level of accountability to maintain security. Another said that open lines of communication and a constant back and forth discussion with their supplier are in place which is why they have such a high level of confidence in their source of supply. Throughout the interview many respondents emphasized their strong supplier relationships, the thoughtful considerations put into supplier contracts, and supplier authentication of prescription drug supply.

Cost Model: Estimating the Cost of Implementing Track & Trace Technology

Overview

The implementation of track and trace technology for a pharmacy Retailer brings widespread administrative, operational, and infrastructure costs. The Cost Model estimate required the development of four separate models to reflect the various sized pharmacy operations within the US. The purpose of the Cost Model was to provide a high level estimate for serialization and track and trace costs and cash flow per year for each Retailer operation based on a basic and specific set of assumptions of serialization and track and trace capabilities and processes. Input for the Cost Model parameters was derived from aggregation of information from previous Accenture market expertise and NACDS/NCPA participant information.

The Cost Model estimated total incremental costs based on line items within the infrastructure required for a complete track and trace system within the first year of implementation with extension for a number of years. Specific parameter costs included serialization track and trace hardware/software, serialization infrastructure, resources, training, and the annual maintenance necessary to implement a distribution facility, pharmacy, and a pharmacy central data center. The Cost Model also accounted for additional labor resources required to handle two-dimensional (2D) barcodes at the item level in distribution facilities and pharmacy operations. This increase in labor was governed by the percentage of 2D serialized barcodes within the Retailer supply chain for any given year in the specified timeframe. In order to implement a complete track and trace technology system, it is assumed that these requirements/components would be essential.

Below are some general assumptions used to determine the cost estimates for each size of pharmacy Retailer chain:

- Track and trace was defined as the ability to identify, or system of identifying, each unique unit-level product and identifying its location from manufacturer to the end user; "tracking" is the ability to locate an item in the supply chain and "tracing" is the ability to identify where the product has been. This system includes both changes in ownership of a drug and its physical movement
- Estimates only take into account U.S. operations and current U.S. compliance standards
- Any proposed operational efficiencies or inventory management benefits realized from RFID product in the supply chain have not been considered
- Data sharing occurs between trading partners (Hierarchical Advanced Shipping Notice (ASNs), Serialized Pedigree, Authentication, etc.)
- Concept of inference is used for the inbound receipt process in the distribution facility; items are individually picked for outbound processing at the distribution facility
- Small to independent sized chains will utilize a certified, hosted subscription-based Pedigree/Authentication service
- Infrastructure, resource, and labor costs will remain constant for each distribution facility and pharmacy and will scale linearly if multiple sites are implemented for each Cost Model

- Data Center Infrastructure costs will increase incrementally every two years to support growing infrastructure and future compliance changes
- Custom integrations/interfaces and server setup were based on the typical pharmacy Retailer technical architecture
- Training/change management, operational/technical resources, and annual maintenance costs were based on industry averages
- Annual Maintenance and labor costs for various parameters and sites are realized at an average 2.3% CPI yearly increase
- Labor cost estimates for pharmacy and distribution facility employees were gathered using the average U.S. salary for specific personnel and may differ based on the type or quantity of personnel at any particular site
- Line item cost estimates are based on industry average prices and may delineate if additional functionality/interoperability was considered
- Hardware cost estimates may decrease in the next 3-5 years
- The percentage of 2D serialized barcode in the Retailer supply chain for each Cost Model decreases within the given timeframe

Specific Considerations

A number of specific considerations were made to fully understand the scope of the cost estimates and how they were arrived at. Along with the assumptions above, hardware component options would be assessed to determine the type and quantity necessary for pharmacy distribution facilities and pharmacies. Additional labor resources would be identified for any affected operational impacts as a result of handling 2D serialized product. Also, group profiles would be setup to reflect “typical” chains in order to provide a realistic scale to compare the cost estimates.

A pharmacy distribution facility would require both RFID and 2D serialized barcode hardware. The several RFID components would be capable of scanning both the high frequency (HF) and ultra high frequency (UHF) RFID ranges to enable all tag scanning, independent of the packaging level tag placement made by upstream trading partners. The quantity of serialized barcode and RFID hardware would support distribution facility operations such as the receiving, shipping, double check, and returns processes.

A combination of RFID and 2D serialized barcode hardware would be required at the pharmacy as well. Equipment would be available to scan both HF and UHF RFID frequencies via handhelds or workstations. The quantity of the two types of hardware would support pharmacy operations such as the receiving, replenishment, point of sale, and dispensing processes.

Labor costs would be impacted by the percentage of the drug product that contains 2D barcode in the Retailer supply chain. As seen in Table 1, the percentage is assumed to decrease from the first year of implementation until the end of the timeframe.

Year	% of 2D
1	95%
2	93%
3	90%
4	87%
5	83%
6	79%
7	75%

Table 1: Annual percentage of 2D serialized barcode in Retailer supply chain

Additional labor is necessary to handle 2D barcode serialized drug product for normal operations in a pharmacy distribution facility or a pharmacy since each 2D barcode requires manual scanning, and thus packed pallets or cases must be broken and each individual item must be scanned and placed back into the containers. It is assumed that there is no inference on outbound processing in distribution facilities, which requires individual scanning for shipment orders to pharmacy sites. Pharmacies may incur a labor cost in exception scenarios where pertinent data is unavailable with received serialized shipments, and thus each item must be individually scanned as well. Serialized data may require additional input into reports or forms used for backend administrative purposes, which is represented as another cost of labor for both types of sites. The pharmacy labor resource cost was derived from the combined average U.S. salary of a Pharmacy Technician and a Pharmacist¹⁶. The distribution facility labor resource cost was derived from the combined U.S. salary of a Warehouse Worker and an Order Filler/Picker¹⁷. The specific salary changes due to location were not considered. It was assumed that 15% of a labor resource at any site would be necessary to input serialized data into reports.

¹⁶ Combined average U.S. salary of Pharmacy/Pharmacy Technician: \$74,955.

¹⁷ Combined average U.S. salary of Warehouse worker/Order Filler&Picker: \$23,670.

The “large” chain pharmacy Retailer, envisioned for purposes of comparison to NACDS/NCPA members, had total retail sales of \$18.8B annually. The implementation for this size Retailer assumed that 14 distribution facilities and 4,000 pharmacies would be enabled in the first year. This would include all site and data center infrastructure, hardware/software, resources, recurring annual maintenance, and labor impacts.

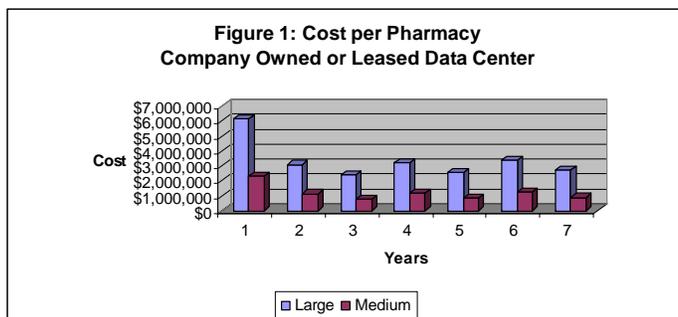
The “medium” chain pharmacy Retailer, envisioned for purposes of comparison to NACDS/NCPA members, had total retail sales of \$450M annually. The implementation for this size Retailer assumed that 1 distribution facility and 100 pharmacies would be enabled in the first year. This would include all site and data center infrastructure, hardware/software, resources, recurring annual maintenance, and labor impacts.

The “small” chain pharmacy Retailer, envisioned for purposes of comparison to NACDS/NCPA members, had total retail sales of \$60M annually. The implementation for this size Retailer assumed that no distribution facilities and 15 pharmacies would be enabled in the first year. This would include all site infrastructure, hardware/software, resources, recurring annual maintenance, and labor impacts. This would also include a hosted solution for the EPCIS/ePedigree system to replace a central Data Center.

The “independent” pharmacy Retailer, envisioned for purposes of comparison to NACDS/NCPA members, had total retail sales of \$6.5M annually. The implementation for this size Retailer assumed that no distribution facilities and 2 pharmacies would be enabled in the first year. This would include all site infrastructure, hardware/software, resources, recurring annual maintenance, and labor impacts. This would also include a hosted solution for the EPCIS/ePedigree system to replace a central Data Center.

Results¹⁸

As can be seen in Figure 1, the majority of the costs for an \$18.8B chain are realized in the first few years after the initial full implementation of all distribution facilities and pharmacy sites in Year 1. The high quantity of total sites requires each company to build and maintain a central pharmacy Data Center¹⁹ capable of supporting a relatively large infrastructure. This included the appropriate amount of server setups for EPCIS and ePedigree systems to manage serialized authentication and pedigree data transmitted from each site. The pharmacy Data Center costs for the \$450 MM chain show that the infrastructure costs decreased as the total number of sites supported decreased. The total costs of the pharmacy Data Center reduce to half of the Year 1 costs but increase in Years 4 and 6 due to the assumed software/infrastructure upgrades for both the \$18.8B and \$450M chains. These costs were assumed to grow every two years to support future compliance regulations that would force supplementary components to be installed to satisfy new or changing requirements. The hosted EPCIS/ePedigree subscription-based service allowed minimal integration and changes to be made to existing infrastructure. The solution required a first year, one-time fee as well as annual subscription fees related to the volume of product assumed to be processed by a small to independent chain pharmacy annually.



¹⁸ All detailed line item costs by budget year can be seen in the provided attachment.

¹⁹ Data Center costs consist of Enterprise EPCIS/ePedigree systems and IT Infrastructure such as servers, firewall devices, PCs, and implementation resources. Detailed line item costs can be found in the provided attachment.

The pharmacy Data Center cost for Year 1 is different for both the \$60M chain pharmacy and \$6.5M pharmacy since this includes a size-specific initial setup fee for the hosted solution, as seen in Figure 2. For the remaining years, there is a higher annual subscription fee for the “small” chain pharmacy assumed to require about 50,000 pedigree transactions, compared to the 25,000 pedigree transactions for the “small independent” pharmacy. Compared to the \$18.8B and \$450M chains, there is no significant increase or reduction in costs after Year 1 for the small chain pharmacy and the independent pharmacy. This can be attributed to a lack of software/infrastructure upgrades since the certified hosted solution is assumed to upgrade its services to remain compliant with any future regulations.

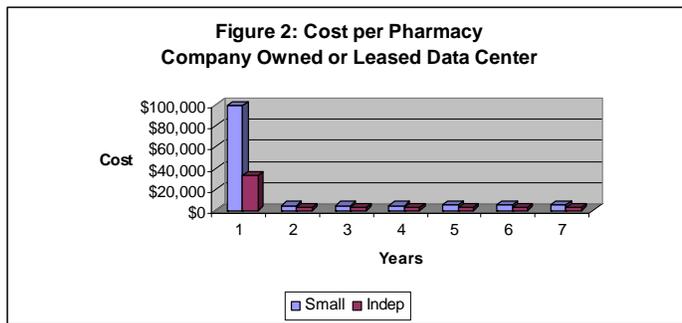
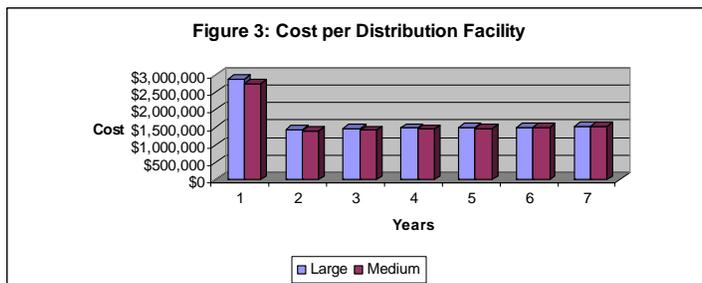


Figure 3 shows the cost per distribution facility²⁰ for the “large” and “medium” chains. For a “large” chain the cost is about \$2.9 million and is about \$2.8 million for a “medium” chain pharmacy. The data shows the cost to peak at Year 1 to enable full implementation for both chains, and gradually decrease throughout the timeframe. The infrastructure of the \$18.8B and \$450M chains include similar quantities of RFID and 2D serialized barcode hardware, although the “medium” chain requires fewer points for systems integration and thus the costs are slightly less. The number of resources needed for distribution facility operations to handle 2D serialized product is less in a “medium” chain compared to a “large” chain because there are fewer pharmacy stores supported. Operational labor resources were required to infer cases on receipt, and handle returns and double check processing.²¹ Additional labor was needed to individually scan each item for an order to a pharmacy site, since inference cannot be used at outbound processing²². Manual inputting of specific serialized data into forms or reports for administrative purposes required 15% of the average labor resource at a distribution facility.



As shown in Figure 4, throughout the given timeframe, the cost to implement each pharmacy store²³ for each of the pharmacy categories differs slightly, depending on the quantity of specific hardware required for each type of store and labor costs. The cost for a “large” chain is around \$110,000 with a “medium” chain estimate of \$100,000, a “small” chain cost of about \$90,000, and a cost of about \$80,000 for an independent pharmacy. The receipt, dispensation, and point-of-sale operations

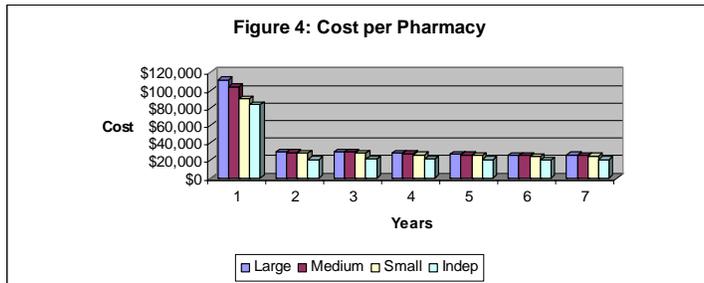
²⁰ Distribution facility costs consist of RFID/2D hardware, software, IT infrastructure, and labor. Detailed line item costs can be found in the provided attachment.

²¹ DC operational labor was based on handling 900,000 cases on the inbound with an average scan time of 10 seconds and using an average of 2,080 hours of annual labor for full-time employee (FTE).

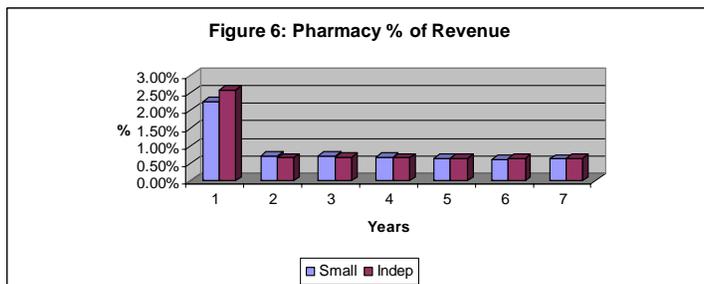
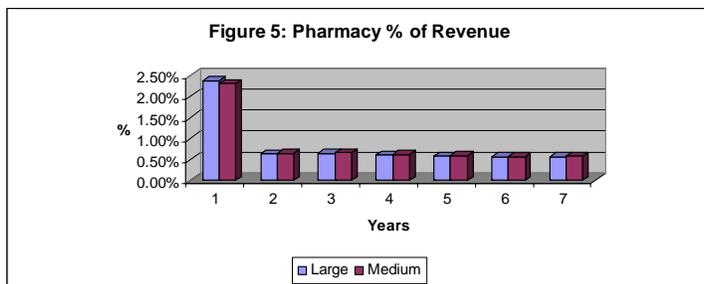
²² DC non-inferable labor was based on handling 38M units on the outbound with an average scan time of 10 seconds and using an average of 2,080 hours of annual labor for an FTE.

²³ Pharmacy costs consist of RFID/2D hardware, software, IT infrastructure, and labor. Detailed line item costs can be found in the attachment.

required supplementary labor to handle 2D serialized product²⁴. Additional labor was needed to individually scan each item for a shipment received at a pharmacy to account for exception scenarios²⁵. Manual inputting of specific serialized data into forms or reports for administrative purposes required 15% of the average labor resource at a pharmacy store. Variances in this pattern can be attributed to the assumed rise in recurring annual maintenance costs by the adjusted CPI figure throughout the seven year timeframe.



According to Figures 5 and 6, the percentage of total annual revenue allocated to the implementation of one pharmacy store is the highest for the \$6.5M “small independent” pharmacy. The high percentage of total revenue for the \$18.8B “large” chain is realized from the high average labor costs in the pharmacy. The cost for implementation was an average of 0.88% of the total annual revenue for each pharmacy store, across all four retailer operations.



Status Assessment

The implementation of a track and trace system involves many key and unknown factors that can determine the status of the pharmacy retailer industry segment for implementation of a track and trace system. A number of data exchange options are

²⁴ Pharmacy operational labor was based on handling 50,000 units for specified operations with an average scan time of 10 seconds and using an average of 2,080 hours of annual labor (13.4% of FTE in Year 1). 25,000 units were considered for a typical \$6.5M chain (6.7% of FTE in Year 1).

²⁵ Pharmacy exceptions labor was based on handling an average of 25,000 exceptions on the inbound with an average scan time of 10 seconds and using an average of 2,080 hours of annual labor (3.4% of FTE in Year 1). 12,500 exceptions were considered for a typical \$6.5M chain (1.7% of FTE in Year 1).

either currently in use or can be put into practice. In conjunction with these options are current and potential challenges that the industry may face to become fully implemented.

One of these challenges is the requirement of versatility within pharmaceutical operations. The industry must be equipped at all sites with a union of various types of RFID and 2D serialized barcode hardware. Presence of RFID or 2D products at any location within a site must be accounted for with the appropriate scanning hardware. As seen from the Cost Model, these hardware costs can be about 70% of the total implementation cost and 2% of a typical \$18.8B chain's total annual revenue in Year 1. These costs are even higher for the small to independent pharmacy chains. Furthermore, the benefits of RFID operational efficiencies and inventory management benefits are not recognized in this estimate, and thus additional software, infrastructure, resources, and annual maintenance would be required to realize these potential advantages.

There are the several operational processes that must be considered for track and trace to be successfully implemented while leaving existing internal operations intact or with minimal change. Operational challenges are seen within the high labor costs associated in dealing with serialized 2D product. An example with an exception handling scenario is if a pertinent serialized data document is not received for a shipment at a pharmacy. Considerable pharmacy labor costs are associated with scanning at the item level when the inference process cannot be utilized, as seen in the Cost Model. Additional scenarios or integrations must be developed to have the capability to retrieve necessary serialized data to deter these high costs. Operational changes may also be related to legislative changes in compliance requirements. The capability of tracking and tracing a drug product to the individual patient is assumed to have an exponential cost for full implementation. An additional five seconds to attribute each drug product to a particular patient record would cost an average of \$4,100 annually per pharmacy store, using the combined average U.S. salary of full-time Pharmacy employees and assuming that 81,668 prescriptions are filled each year. Additionally, decommissioning a shipment of drug product to several individual serialized item-level containers would require functionality to store specific serialized data in existing forms or reports. Scenarios may also need to be developed to internally track each individual serialized product in instances where there is a physical movement as opposed to just a change in financial ownership. These scenarios necessitate an increased software and infrastructure to support the additional processing as well as a number of custom interfaces and systems integrations.

The different data exchange models for the serialized information required for compliance are additional obstacles for track and trace implementation. The "push forward" model allows each industry segment to generate, store, and receive/transmit the necessary serialized hierarchy and shipping information. The processing and transmission of this information would require dedicated servers, specialty serialization software systems, and integrations between trading partners. These requirements can translate to high costs for configuration or custom installation involving legacy systems or expanding an infrastructure unfit to support such processes, as is the case for most small independent chains. EPCIS/ePedigree systems to support this type of model are already in place and being implemented by other pharmaceutical industry segments. The "individually hosted" model allows an industry segment to retrieve the necessary serialized data from established network connections with trading partners' serialization software systems and servers. This would limit the dedicated software/hardware and infrastructure requirements needed for storage, generation, and management at the Retailer industry segment, but would raise uncertainties concerning recurring maintenance, connection, and high service fees per transaction. The model would also require trusted trading partner relationships, an assessment of specific integration points, and an agreed upon third party provider solution. The "single central repository" model allows each pharmacy operation to provide and share serialized data and shipping information via a third party provider. High costs are associated with initial setup and service fees, interoperability between legacy systems, possible expansion of existing infrastructure, and custom interfaces and integration points. One provider with the capability to handle all data processing and storage for the numerous upstream trading partners for a pharmacy operation is unlikely. The strategy and technical architecture to support this type of model has been observed. However, in using a central government entity to control serialization and data exchange requirements, and ensure full cooperation between all industry segments, such a large-scale integration may not be in place for years.

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Assumptions & Methods

The primary focus of this study is to develop an overview of the safety and security of the current US prescription drug distribution system. This study will be limited exclusively to *prescription drug products* in relation to retail pharmacies and will not address over-the-counter drug products or medical devices.

Additionally, this study will be limited in scope to *counterfeit prescription drugs*. For the purposes of this study, the definition of a counterfeit medicine will be consistent with the definition provided by the World Health Organization,

“A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

As a general matter, counterfeit prescription drugs are products that (through intentional actions of counterfeiters) are not legitimate authentic drug products. This study will not investigate or address incidences of contaminated active ingredients occurring during the manufacturing process, such as the recent well-publicized 2008 case involving contamination of the active ingredient found in Heparin.

While NACDS and NCPA may be involved relative to general information regarding their member pharmacies, all primary research will be held confidential by Accenture, and only compiled findings will be presented, to assure the anonymity of respondents and to promote honesty and full disclosure of all observed incidents.

Track and trace as discussed in this study, refers to the ability to identify, or system of identifying, each unique unit-level prescription drug product through a unique numerical identifier, and its location from manufacturer to the end user; "tracking" is the ability to locate an item in the supply chain and "tracing" is the ability to identify where the product has been.

The study will address two primary questions – 1) What is the frequency and magnitude of occurrences of counterfeit prescription drugs in the US pharmaceutical supply chain, and 2) What is the estimated cost to retail pharmacies of implementing a track and trace system. This will be achieved through detailed press research, a survey of NACDS and NCPA members, a request of FDA counterfeit investigation materials, focused supply chain interviews, cost modeling, and leveraging past and current Accenture market expertise.

1) Frequency & Magnitude of Counterfeit Prescription Drugs in the U.S. Pharmaceutical Supply Chain -

Estimating prevalence of counterfeit prescription drugs in the pharmaceutical supply chain is difficult particularly in the United States. Accenture will assess the prevalence of counterfeit prescription drugs in the US pharmaceutical chain through a three-fold approach: detailed press research, a survey of NACDS and NCPA members, and a request of recent investigations and reports from the FDA.

Press Research

Accenture will perform a detailed investigation of media and literature (2002-2007) based on the assumption that most instances of prescription drug counterfeit affecting patients would be recorded in the local or national press.

Survey

The project team will conduct a survey of NACDS and NCPA members selected at random. Members will be divided into three groups: large, national chains; regional, small chains; and independents. For the national group, the team assumes that five of the top seven pharmacy operators will respond and that the top two pharmacy operators will both complete the survey. For the "regional" group, the project team will distribute surveys to 60 randomly selected members with the assumption that we will receive responses from 25 of those selected. For the "independents" group, the project team will distribute surveys to 60 randomly selected members and will anticipate that will receive 20 responses from all of those selected.

The project team will develop a short confidential 15 question survey of no more than 10-15 minutes in duration to query the respondents regarding incidences of counterfeit prescription drugs. All surveys will be provided to members via overnight shipping and all members will have the option of either returning responses using a provided overnight FedEx envelope or through a dedicated fax number to protect the anonymity of the survey. All survey responses will be collected, reviewed, and kept strictly confidential by Accenture. No personally identifying information (including company names or employee information) will be published, and all individual answers will remain strictly confidential according to research study best practices.

Food and Drug Administration (FDA) Investigations

The project team will request access to and copies of recent Food and Drug Administration (FDA) investigations (within the last five years) and reports of counterfeit prescription drugs in the US pharmaceutical distribution supply chain. The team will solicit information regarding FDA investigations of reported counterfeit occurrences and corresponding data related to these occurrences at retail pharmacies, specifically: the number of occurrences of counterfeit prescription drugs in the US pharmaceutical distribution supply chain within the last five years, the type of drugs involved in each incident, the quantity of products impacted, the point of entry into the U.S. prescription drug distribution supply chain, the level of the distribution system impacted (i.e. manufacturer, wholesaler, etc.), where the counterfeit prescription drug was discovered, and whether or not the counterfeit drug entered into retail pharmacies.

Operating on the assumption that the FDA will not be forthcoming with information, the team will also file a Freedom of Information Act request, pursuant to federal Freedom of Information Act, 5 U.S.C. § 552 . The statute requires a reply within 20 business days; however, the scope of this study will terminate prior to that time period, so any FOIA data from the FDA will likely be provided too late for inclusion in the final report. To date, the project team has still not received any response or materials from the FDA.

2) Cost of Implementing Track and Trace in Retail Pharmacies

To investigate factors related to the implementation of systems to track and trace prescription drugs in the US prescription drug chain in relation to retail pharmacies, Accenture will conduct verbal interviews with a subset of NACDS and NCPA members and will build a holistic cost model to estimate cost implications of such an implementation. Interview answers, survey responses, and cost model inputs and assumptions will form the basis of the assessment of overall industry readiness for “track and trace.”

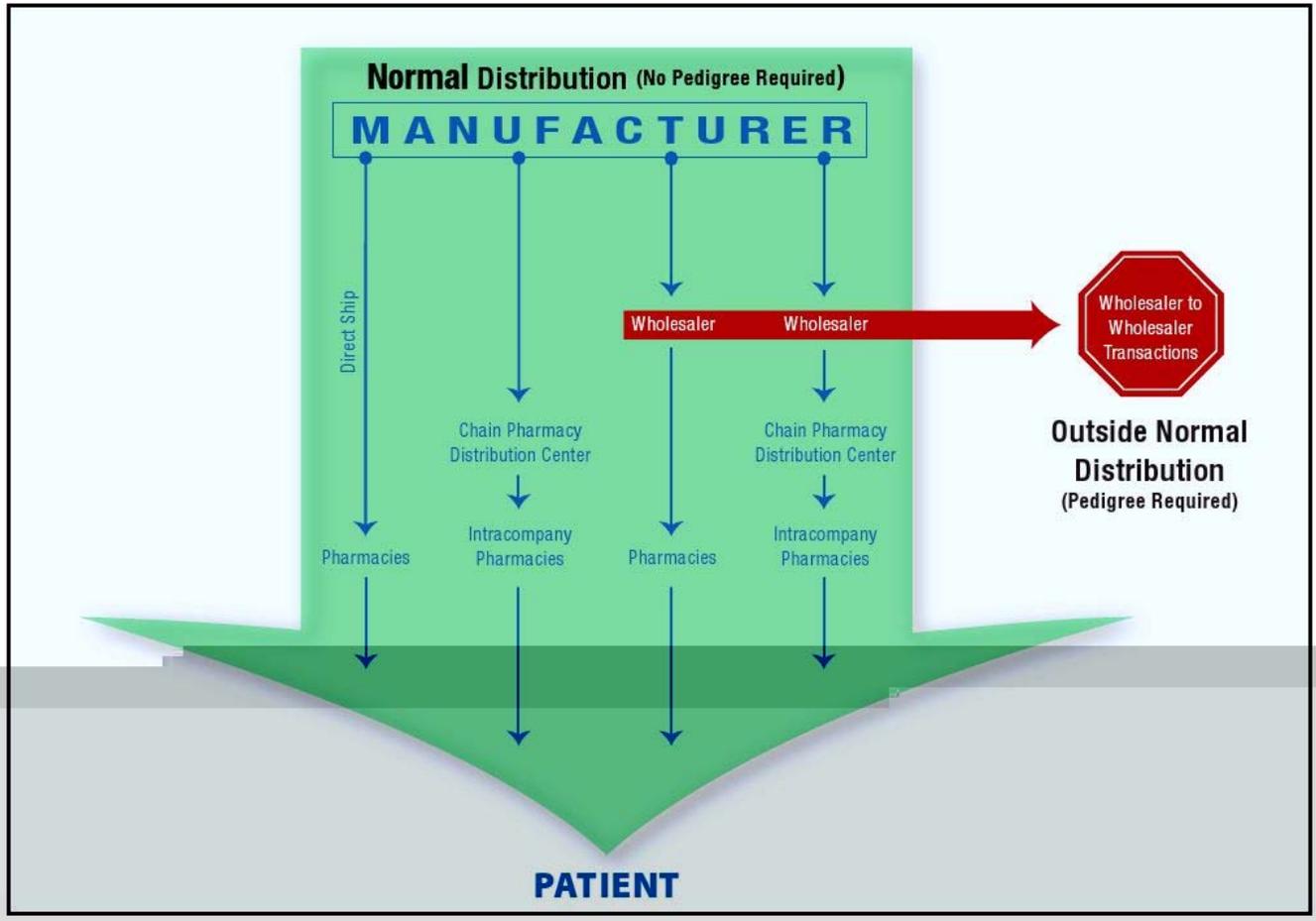
Interviews

The project team will develop a verbal interview questionnaire and will contact ten member companies provided by the NACDS and NCPA, to query companies based on the assumption that many companies have already taken action to increase the safety of their distribution system. The purpose of this interview is to explore changes made to member prescription drug distribution systems for obtaining and purchasing prescription drugs over the last five years.

Cost Model

The team will develop a cost model for implementing track and trace for a retail pharmacy. Four models will be created to assess the cost for independent pharmacies, and small, medium and large pharmacy chains. The models will reflect the “average” company in each group. The purpose of the Cost Model is to provide a high level estimate for prescription drug serialization track and trace system costs for each pharmacy category based on a basic and specific set of assumptions of serialization capabilities and processes. Input for the Cost Model parameters was derived from aggregation of information from previous Accenture engagements and NACDS/NCPA participant information. The estimate will take into account the necessary setup of serialized hardware, software, infrastructure, resources, and annual maintenance within a data center, distribution facility, and pharmacy location for each chain.

Distribution Channels



Appendix C – Accenture Prescription Drug Distribution Questionnaire

Thank you for participating in the Accenture Pharmaceutical Prescription Drug Distribution survey. This survey is conducted as one part of a study that Accenture is undertaking on behalf of the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA).

This questionnaire is designed to identify the frequency and magnitude of users' encounters with counterfeit prescription drugs in the U.S. pharmaceutical drug distribution system over the last five years.

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." [Source: World Health Organization]

As a general matter, counterfeit prescription drugs are products that (through intentional actions of counterfeiters) are not legitimate authentic drug products. However, the recent incident of contaminated Heparin would not be included in this survey as that involved contamination of the active ingredient through faulty manufacturing processes.

Please note: All survey responses will be collected, reviewed, and kept strictly confidential by Accenture. The NACDS and NCPA will not have access to your individual response. No personally identifying information (including company names or employee information) will be published, and all individual answers will remain strictly confidential according to research study best practices. Please answer each question to the best of your knowledge.

Estimated time required: 10-15 minutes

Company Background

- 1) Please indicate the number of pharmacy locations in your company:
 - a) 1-25
 - b) 26 -100
 - c) 101-200
 - d) >200

- 2) What would you estimate *your* weekly prescription volume to be for an average store?
 - a) <1000
 - b) 1001-3000
 - c) 3001-5000
 - d) >5000

- 3) Over the last five years, 2002-2007, please indicate the total prescriptions filled by your *company*, per year.
 - a) 2002 _____
 - b) 2003 _____
 - c) 2004 _____
 - d) 2005 _____
 - e) 2006 _____

f) 2007 _____

4) Please describe your current process of obtaining or purchasing prescription drugs (please select all that apply):

- a) ___ Company Owned Distribution Center
- b) ___ Large scale wholesaler
- c) ___ Direct from manufacturer
- d) ___ Secondary market
- e) ___ Regional wholesaler
- f) ___ Independent Buying Group
- g) ___ Other _____(please specify)

5) Does your company have a distribution center or warehouse servicing your pharmacy locations?

- a) Yes
- b) No

If yes, please indicate the number of distribution centers/warehouses in your company that store and provide prescription drugs:

- a) 1-2
- b) 3-5
- c) 6-7
- d) 8-10
- e) 11+
- f) N/A

6) How many wholesalers do you currently use?

- a) 1-2
- b) 3-5
- c) 6-7
- d) 8-10
- e) 11+
- f) N/A

7) Do you currently use an independent buying group to service your pharmacy locations?

- a) Yes
- b) No

Market Environment

8) How many times in the last five years, 2002-2007, have you or your company reported an occurrence of a counterfeit drug product to the FDA or other authorities? If you reported the same incident to more than one authority, please count each incident only once.

- a) 2002 _____
- b) 2003 _____
- c) 2004 _____
- d) 2005 _____
- e) 2006 _____
- f) 2007 _____

Please take a moment to provide additional clarifying details/comments regarding any of the incidents above:

9) Have you changed the way that you purchase prescription drugs over the last five years because of your concerns about counterfeit prescription drugs?

- a) Yes
- b) No

If “yes,” how have you changed your habits over the last five years? i.e., do you only purchase directly from a manufacturer, do you only purchase from wholesalers who purchase directly from a manufacturer? Have any other changes been made? Please explain:

10) How would you describe the current level of government regulation of the pharmaceutical distribution system?

- a) Excellent
- b) Above average
- c) Adequate
- d) Below Average
- e) Needs improvement

Please provide the reasoning for your response:

11) How much confidence do you have that the prescription drugs you receive are not counterfeit?

- a) Very High Level of Confidence
- b) High Level of Confidence

- c) Neutral
- d) Very Little Confidence
- e) No Confidence Whatsoever

12) How much confidence do you have that your wholesaler/distributor/supplier will notify you of counterfeit drugs in the system?

- a) Very High Level of Confidence
- b) High Level of Confidence
- c) Neutral
- d) Very Little Confidence
- e) No Confidence Whatsoever

13) Please rate your overall perception of which specific drugs have been most susceptible to counterfeit from 2002-2007.

	No Problem					<	Severe Problem					Don't Know
a. Cholesterol Medication	1	2	3	4	5							0
b. Antidepressants	1	2	3	4	5							0
c. Blood Pressure	1	2	3	4	5							0
d. Antibiotics	1	2	3	4	5							0
e. Lifestyle Drugs	1	2	3	4	5							0
f. High-Value Injectables	1	2	3	4	5							0
g. AIDS Medications	1	2	3	4	5							0
<i>Controlled Substances:</i>												
h. CII Painkillers	1	2	3	4	5							0
i. CIII	1	2	3	4	5							0
j. Anxiety/Sleep Medications	1	2	3	4	5							0
<i>Other (please list):</i>												
k. _____	1	2	3	4	5							0
l. _____	1	2	3	4	5							0

14) Do you have any specific concerns, or areas in your current system of obtaining prescription drugs (prescription drug distribution system) which you feel merit immediate attention in this study? Please describe in the space below:

15) Additional Comments/Concerns:

Appendix D – Accenture Prescription Drug Focus Interviews

Thank you for participating in the Accenture Pharmaceutical Prescription Drug Interview regarding supply chain drug distribution practices. This interview is being conducted as one part of a study that Accenture is undertaking on behalf of the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA).

The purpose of this interview is to explore changes made to your prescription drug distribution system for obtaining and purchasing prescription drugs over the last five years. We are conducting this interview as a supplement to the written survey we distributed previously.

As a general matter, counterfeit prescription drugs are products that (through intentional actions of counterfeiters) are not legitimate authentic drug products. However, the recent incident of contaminated Heparin would not be included in this survey as that involved contamination of the active ingredient through faulty manufacturing processes.

We have provided you with general questions and topics that we will cover during the course of the oral interview. All interview responses will be kept strictly confidential by Accenture. The NACDS and NCPA will not have access to your individual responses. No personally identifying information (including company names or employee information) will be published or shared, and all individual answers will remain strictly confidential according to research study best practices. Please answer each question to the best of your knowledge.

Estimated time required: 10-15 minutes

1. Please describe your company:

- Number of pharmacy locations in your company?
- Weekly prescription volume for an average pharmacy location?
- Total yearly prescription volume?

2. Please describe your current process of obtaining or purchasing prescription drugs?

- Company Owned Distribution Center, Large scale wholesaler, direct form manufacturer, secondary market, regional wholesaler, independent buying group, other?
- Number of distribution centers/warehouses in your company that store and provide prescription drugs to your pharmacies (if applicable)?
- Do you purchase directly from drug manufacturers?
- Number of wholesalers you currently use (if applicable)?
- Do you purchase from wholesalers that buy directly from drug manufacturers?
- Do you use an independent buying group to service your pharmacy locations?

3. Have you changed the way that you purchase prescription drugs over the last five years because of your concerns about counterfeit prescription drugs?

- If “yes,” how have you changed your habits over the last five years? i.e., do you only purchase directly from a manufacturer, do you only purchase from wholesalers who purchase directly from a manufacturer? Have you implemented contractual commitments with your suppliers? Have you changed your quality control requirements?

- Have any other changes been made?
 - Please describe any specific changes you have made to your supply chain in the last five years
4. Have you changed the way that you handle or dispense prescription drugs at your retail locations because of your concerns about counterfeit prescription drugs?
 5. Many states have changed their laws and regulations to increase requirements for wholesale drug distributor licensure and to require pedigrees for prescription drugs distributed outside the normal distribution channel. Have these changes had an impact on your prescription drug distribution practices?
 6. How confident are you in your usual supply source?
 - How much confidence do you have that the prescription drugs you receive are not counterfeit?
 - Do you have any specific concerns about supply sources which you feel need attention? If so, please describe.
 - How much confidence do you have in the system that your supplier uses to notify you of counterfeit drugs in the system?
 - How concerned are you about counterfeit drugs in the market place?
 7. If you ever have a shortage of a product, how and where do you obtain the prescription drug products? Do you have any concerns about these alternate sources that you do not have with your usual supply source?
 8. Are you aware of any supplier auditing programs or have you participated in any supplier auditing programs involving practices for dispensing of prescription drug products received from the supplier?

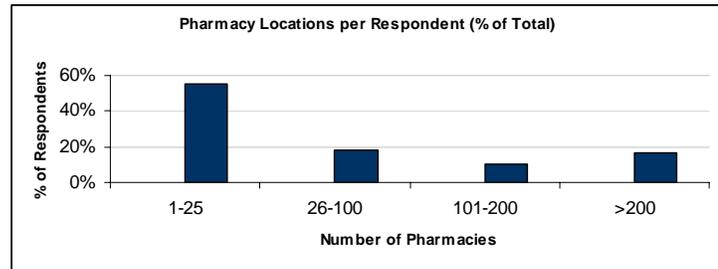
Appendix E – Survey Data Summaries

Please Note: In the interest of preserving respondents' anonymity, all essay-format responses have been held confidential to Accenture. All other response data is provided in its entirety.

NACDS & NCPA Survey

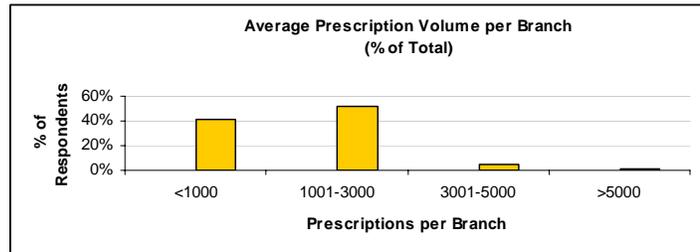
1) Please indicate the number of pharmacy locations in your company:

Answer Options	Response Percent	Response Count
1-25	55.0%	33
26-100	18.3%	11
101-200	10.0%	6
>200	16.7%	10
Answered question		60
Skipped question		0



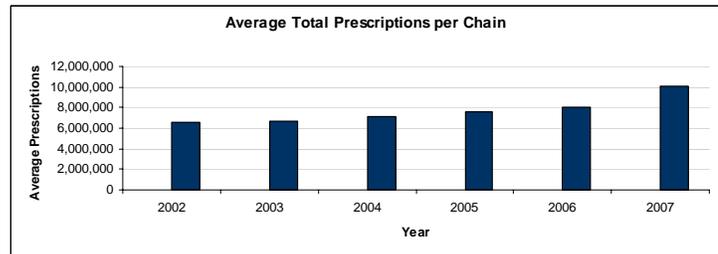
2) What would you estimate your weekly prescription volume to be for an average store?

Answer Options	Response Percent	Response Count
<1000	41.7%	25
1001-3000	51.7%	31
3001-5000	5.0%	3
>5000	1.7%	1
Answered question		60
Skipped question		0



3) Over the last five years, 2002-2007, please indicate the total prescriptions filled by your company, per year.

Answer Options	Response Average	Response Total	Response Count
2002	6,526,536	365,486,007	56
2003	6,640,215	378,492,252	57
2004	7,106,890	405,092,727	57
2005	7,539,428	429,747,382	57
2006	8,004,596	464,266,537	58
2007	10,056,940	583,302,616	58
Answered question			58
Skipped question			2



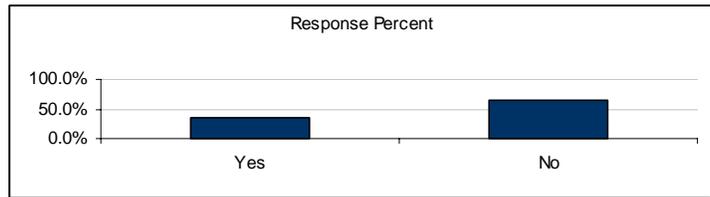
4) Please describe your current process of obtaining or purchasing prescription drugs (select all that apply).

Answer Options	Response %	Response Count
Company-owned distribution center	25.9%	15
Large-scale wholesaler	89.7%	52
Direct from manufacturer	31.0%	18
Secondary market	12.1%	7
Regional wholesaler	25.9%	15
Independent buying group	6.9%	4
Other (please specify)		1
Answered question		58
Skipped question		2



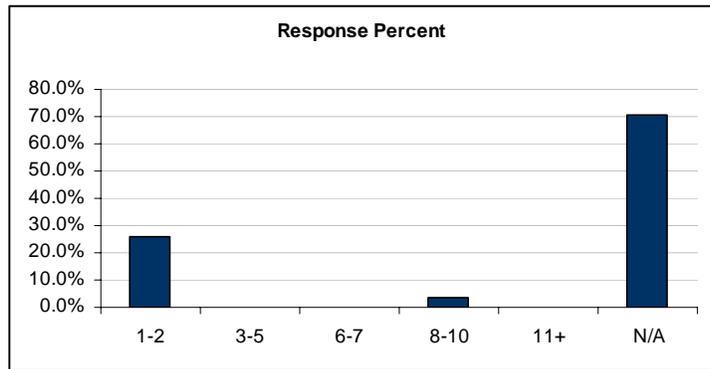
5) Does your company have a distribution center or warehouse servicing your pharmacy locations?

Answer Options	Response Percent	Response Count
Yes	33.9%	20
No	66.1%	39
Answered question		59
Skipped question		1



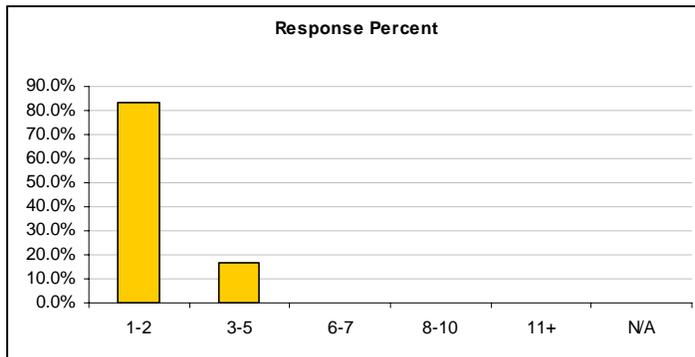
...If yes, please indicate the number of distribution centers/warehouses in your company that store and provide prescription drugs.

Answer Options	Response Percent	Response Count
1-2	25.9%	15
3-5	0.0%	0
6-7	0.0%	0
8-10	3.4%	2
11+	0.0%	0
N/A	70.7%	41
Answered question		58
Skipped question		2



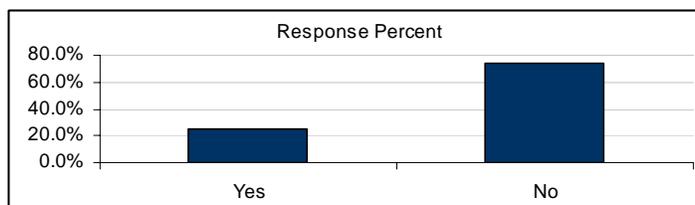
6) How many wholesalers do you currently use?

Answer Options	Response Percent	Response Count
1-2	83.1%	49
3-5	16.9%	10
6-7	0.0%	0
8-10	0.0%	0
11+	0.0%	0
N/A	0.0%	0
Answered question		59
Skipped question		1



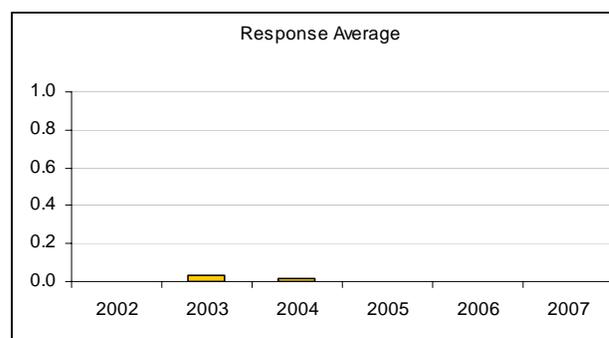
7) Do you currently use an independent buying group to service your pharmacy locations?

Answer Options	Response Percent	Response Count
Yes	25.4%	15
No	74.6%	44
Answered question		59
Skipped question		1



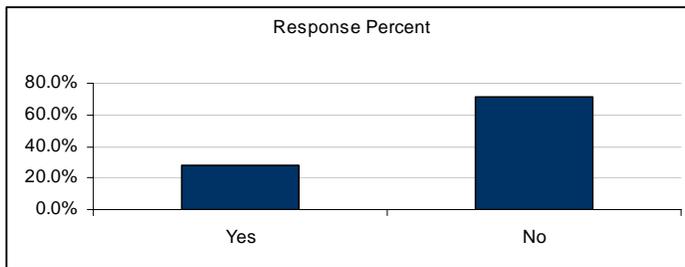
8) How many times in the last five years, 2002-2007, have you or your company reported an occurrence of a counterfeit drug product to the FDA or other authorities? If you reported the same incident to more than one authority, please count each incident only once.

Answer Options	Response Average	Response Total	Response Count
2002	0.000	0	59
2003	0.033	2	60
2004	0.017	1	59
2005	0.000	0	59
2006	0.000	0	59
2007	0.000	0	59
Answered question			60
Skipped question			0



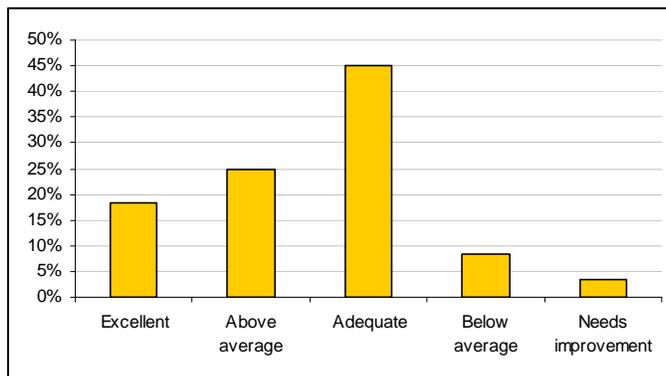
9) Have you changed the way that you purchase prescription drugs of the last five years because of your concerns about counterfeit drugs?

Answer Options	Response Percent	Response Count
Yes	28.3%	17
No	71.7%	43
If "yes,"how have you changed your habits over the last five years?		
		18
Answered question		
		60
Skipped question		
		0



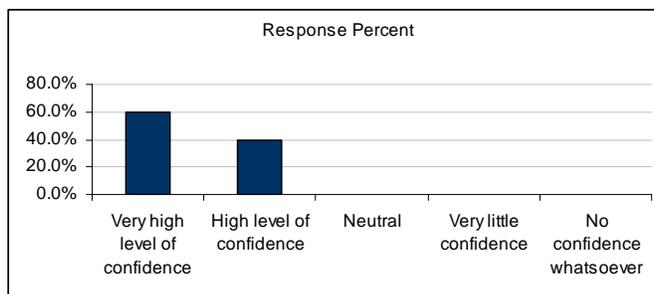
10) How would you describe the current level of government regulation of the pharmaceutical distribution system?

Answer Options	Response Percent	Response Count
Excellent	18.3%	11
Above average	25.0%	15
Adequate	45.0%	27
Below average	8.3%	5
Needs improvement	3.3%	2
Please provide the reasoning for your response:		
		33
Answered question		
		60
Skipped question		
		0



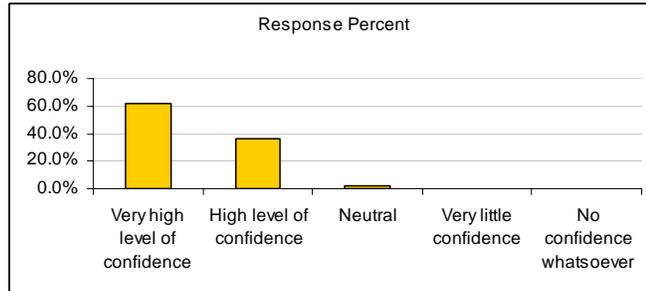
11) How much confidence do you have that the prescription drugs you receive are not counterfeit?

Answer Options	Response Percent	Response Count
Very high level of confidence	60.0%	36
High level of confidence	40.0%	24
Neutral	0.0%	0
Very little confidence	0.0%	0
No confidence whatsoever	0.0%	0
Answered question		
		60
Skipped question		
		0



12) How much confidence do you have that your wholesaler, distributor, or supplier will notify you of counterfeit drugs in the system?

Answer Options	Response Percent	Response Count
Very high level of confidence	61.7%	37
High level of confidence	36.7%	22
Neutral	1.7%	1
Very little confidence	0.0%	0
No confidence whatsoever	0.0%	0
Answered question		60
Skipped question		0



13) Please rate your overall perception of which specific drugs have been most susceptible to counterfeit from 2002-2007

Answer Options	1	2	3	4	5	0	Response Count	Number	Response	Please specify "Other" drugs
Cholesterol medication	13	9	14	10	0	14	60	1	5/28/2008	Glucose Blood test strips
Antidepressants	19	10	6	2	2	21	60	2	5/28/2008	Generics
Blood pressure	21	11	3	2	0	23	60	3	5/28/2008	Diabetic strips
Antibiotics	23	7	6	3	0	21	60	4	6/3/2008	Antipsychotics (Zyprexa)
Lifestyle drugs	6	4	13	16	7	14	60	5	6/3/2008	Lanoxin (generic)
High-value injectibles	7	8	6	12	5	22	60	6	6/3/2008	Anti-Diabetics
AIDS medications	12	6	6	12	0	24	60	7	6/3/2008	Diabetic Strips
CII painkillers	15	9	9	7	2	18	60			
CIII	14	8	11	7	0	20	60			
Anxiety/Sleep medications	14	6	15	5	1	19	60			
Other (1)	1	0	2	4	0	50	57			
Other (2)	0	0	0	0	0	52	52			
Please specify "Other" drugs							7			
Answered question							60			
Skipped question							0			

Appendix F – Pharmacy Cost Models

Please Note: Due to the large size of Appendix F, all cost models associated with this analysis have been provided as an Excel attachment.