

**DRAFT**

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# **STORAGE, DISTRIBUTION, AND DISPENSING OF MEDICAL SUPPLIES**

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Storage, Distribution and Dispensing of  
Medical Supplies

CREATE Interim Report

April 21, 2005

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## **Abstract**

The storage, distribution, and dispensing of pharmaceuticals is an important element in emergency response. The US has a well-developed non-emergency supply chain to supply pharmaceuticals. This report documents the several steps involved in the storage, distribution and dispensing of medical supplies under non-emergency conditions as well as special arrangements that have been made for emergency conditions such as in the case of bioterrorism. The report is based on interviews with personnel at hospitals, clinics, manufacturers, medical suppliers, retailers, pharmacists, emergency planners and others working on pharmaceutical matters. Problems related to the emergency supply chain as well as suggestions are noted. There are two sections to the report; the normal supply chain and the emergency supply chain.

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## Contents

<b>I. The Pharmaceutical Supply Chain.....</b>	<b>4</b>
A. Introduction.....	4
B. The product development supply chain .....	5
C. The Physical Product Supply Chain .....	6
1. Manufacturers .....	7
2. Distributors .....	8
3. Retailers .....	9
4. Secondary Market .....	10
5. Group Purchasing Organizations .....	10
D. Information systems for the supply chain .....	11
1. Product Identification.....	11
2. Bar Coding .....	11
3. Inventory Availability .....	11
4. Usage Related Information .....	12
5. Electronic Identification.....	12
E. Economics.....	13
F. Physical Logistics .....	14
<b>II. The Emergency Supply Chain .....</b>	<b>17</b>
A. Summary .....	17
B. Individual Programs & Projects.....	21
1. Strategic National Stockpile .....	21
2. Vendor Managed Inventory .....	23
3. Chempack .....	24
4. Other Related Programs.....	24
C. Problems .....	25
D. Suggestions .....	29
<b>III. Conclusion .....</b>	<b>33</b>
<b>IV. References.....</b>	<b>34</b>

# I. The Pharmaceutical Supply Chain

## A. INTRODUCTION

The pharmaceutical supply chain is relatively complex compared to the supply chains for other products, particularly when considering the fact that its product does not require the complex gathering of components from various providers and creating sub assemblies like an automobile or an airplane. Generally, the product is produced in periodic batches when necessitated by demand. Manufacturers then sell their output through wholesalers to retailers and on to the consumer or patient. Rarely does the manufacturer sell directly to retailers or the public.

The extent of use for various paths in the supply chain, in terms of sales is as follows:

<b>Distribution Channel</b>	<b>Sales, dispensed</b>
Chain Drug Stores	30%
Independent Drug Stores	19%
Hospitals	13%
Mail Order Pharmacies	11%
Food Stores	8%
Mass Merchandisers	7%
Outpatient Clinics	6%
Long Term Care	4%
Others	2%
Total	100%

Source: 1997 data, from the PROFILE OF THE PRESCRIPTION DRUG WHOLESALE INDUSTRY, Office of Policy, Planning, and Legislation, Food and Drug Administration, US Dept. of HHS, 2/12/01

Inventories tend to be relatively low. Profit margins are small for the wholesaler and retailer but larger for the manufacturer – although manufacturers have large research and marketing costs and long product development lead times.

There are two “supply chains” as people working in pharmaceutical industry operations refer to them. There is the new product development supply chain and the physical supply chain. The physical supply chain involves moving drugs and other materials from manufacturers to consumers. (See Figure 1.) There is also a supply chain creating new products. Because the industry is very research oriented and there is a constant flow of new products, this product development supply chain is of particular importance. The product development supply chain is long, taking 10 years and more for a new product to become available and the profitability of manufacturers depends on new products because older products are supplanted by less profitable generic versions.

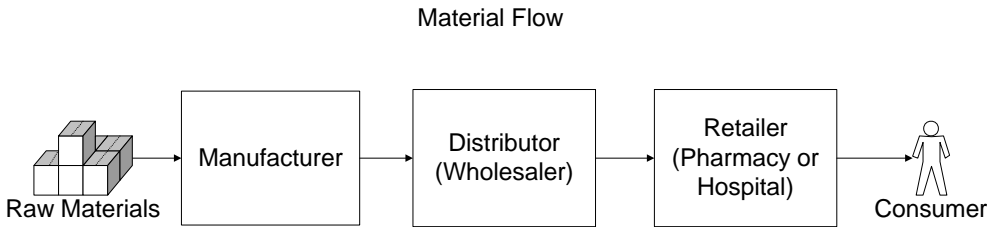


Figure 1. The Overall Physical Supply Chain

## B. THE PRODUCT DEVELOPMENT SUPPLY CHAIN

Pharmaceuticals involve extensive research and a lengthy process to secure approval from several health care authorities. This sequence can take several years, after the initial version of the product is developed. This chain of events is shown in Figure 2.

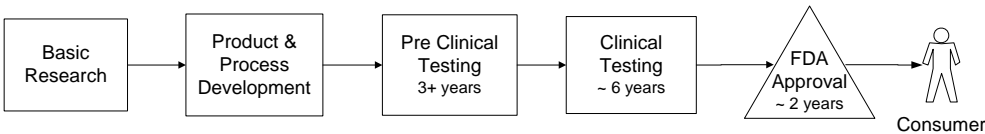


Figure 2. The Product Development Supply Chain

Each of these five steps takes considerable time. Once the basic research step supplies an idea for a new drug, the effort begins to create a useable product and a process to produce it in quantity. The pre clinical testing involves laboratory and animal studies to investigate the potential drug's biological activity vs. the targeted disease and the compound is evaluated in terms of its safety. These tests take approximately three and one-half years. If these studies are successful then clinical studies begin with human subjects. These go through various phases with increasing sizes of population. Typically about 6 years are involved to determine efficacy and identify any negative reactions. The results are then provided to the FDA for review and approval. Sometimes additional studies are required. Considerable statistical data is generated and it must be evaluated. More than two years are usually involved with the FDA before doctors can prescribe the drug although studies of long-term effects may be ongoing after the FDA makes the drug available.

The product development supply chain is undergoing considerable public review due to concerns about the length of time required and as well as its safety. There is pressure to speed up the process in order to make helpful treatments promptly available as well as a concern over recent disclosures about unsafe drugs. Many commentators on the process consider approvals too slow. For example, "new antibiotics can be a maddeningly slow and costly process — if pharmaceutical companies even bother", says Hartmut Derendorf, chairman of the department of pharmaceutics at the University of Florida

College of Pharmacy. (ref. ScienceDaily.com 3/15/05) Pfizer's Celebrex and Merck's Vioxx were recently highly publicized examples of problematic approvals. Thus, the product development supply chain may be forced to evolve in order to respond to such concerns.

### C. THE PHYSICAL PRODUCT SUPPLY CHAIN

The product supply chain involves the rapid and complex movement of a large volume of different items. A 2004 study conducted by Booz Allen Hamilton as commissioned by the Healthcare Distribution Management Association (HDMA) said: "The distribution system must efficiently serve more than 130,000 pharmacy outlets in the United States every day on demand. Pharmacy customers expect fill rates in excess of 99%, and a typical pharmacy relies on the distributor to have more than 10,000 SKUs accessible for delivery, often within 12 hours."

The supply chain involves several intermediary warehousing steps, depending on the type of retailer involved, as shown in Figure 3. The Distributor may have regional warehouses and the retailer may have warehouses to store supplies before drugs arrive at their final retail destination.

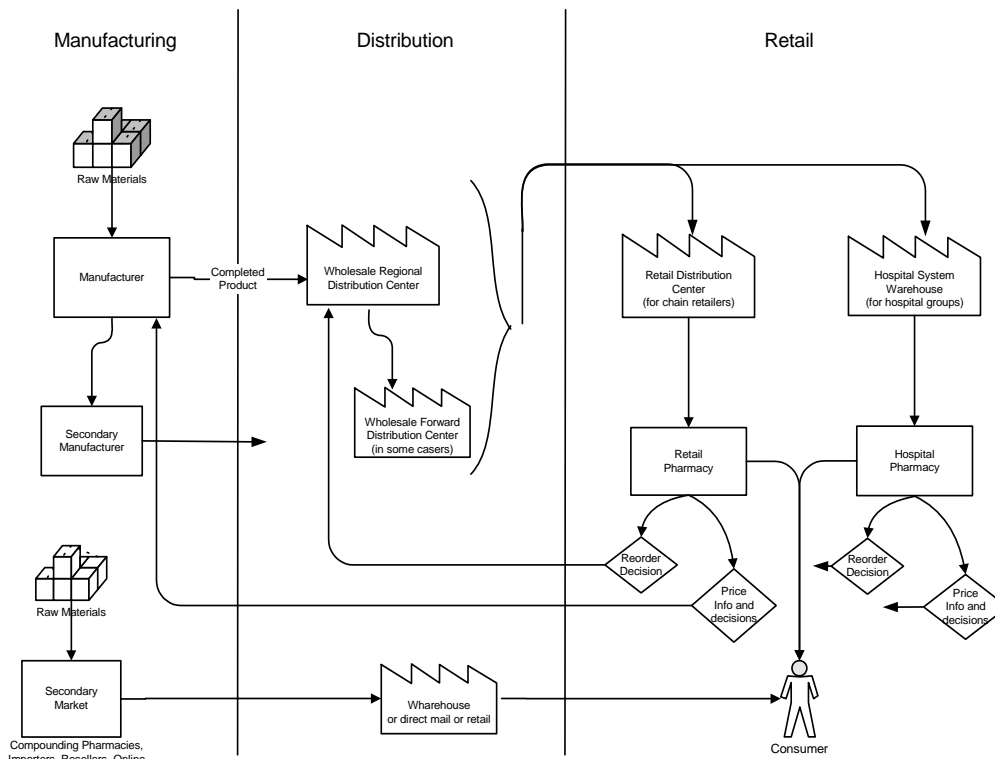


Figure 3. Three Segments of the Pharmaceutical Supply Chain

The industry is very large and a growing proportion of the total economy. The overall size of the US pharmaceutical industry has been estimated as \$230 billion in 2004. Worldwide sales in 2004 were estimated at \$550 billion. Prescription drugs are becoming an increasing share of the total health care industry. According to Richard Foster, the chief Medicare actuary, according to the Los Angeles Times “prescription drugs are predicted to be the fastest-growing sector in health care, accounting for 14.5 percent of health spending by 2014, compared to 11 percent last year”.

Different segments of the industry exhibit different profitability and growth. Manufacturers currently are reported to have operating margins of about 20% while for distributors and retailers it’s closer to 4%. Growth has been strong in all segments of the industry but profitability is much greater for the manufacturers.

Raw materials are part of the supply chain but are relatively small for this particular industry. Capital investment is relatively large with often long lead times to develop new facilities. R&D investment level is relatively large compared to other industries and often exceed 15% in the pharmaceutical industry, whereas they are usually only 2–4% in the chemical industry, for example.

**1. Manufacturers**

There are many manufacturers, however a few make up a large percentage of the total dollar volume. In the US, a considerable portion of the manufacturing is located in the Newark, New Jersey area. Eleven of the 25 largest drug companies in the world have national or global headquarters in New Jersey.

All the large manufacturing companies such as Pfizer follow the basic pharmaceutical supply chain shown in Figure 1. In terms of manufacturing, the largest companies are:

<b>Corporation</b>	<b>Rank</b>	<b>Wholesale Dollars*</b>
Pfizer	1	\$29,903
GlaxoSmithKline	2	\$18,657
Johnson & Johnson	3	\$16,028
Merck	4	\$14,137
AstraZeneca	5	\$11,275
Sanofi-Aventis	6	\$10,882
Novartis	7	\$10,482
Bristol-Myers Squibb	8	\$10,305
Abbott Labs	9	\$9,153
Amgen	10	\$8,811

\* (million) Reflects prescription data and wholesale acquisition cost prices for retail and mail order pharmacies, clinics, hospitals, long-term care and home healthcare organizations and other non-retail channels. From NDCHealth Corporation, 3/7/2005.



## 2. Distributors

Distributors manage the movement of supplies from the manufacturers to the retailers. The manufacturers do not wish to take on the responsibilities of the physical logistics and customer service involved in that aspect of the business. Probably this is a result of the high margins in manufacturing compared to the much lower margins in distribution that are typical. Manufacturers do not want to dilute their profitability rate by diversifying into distribution. Therefore, a retail pharmacy gets its supplies delivered from a distributor's warehouse. Generally, the retailer has an exclusive contract with a distributor. The retailer may negotiate prices with the manufacturer but places its purchases with the distributor. The distributor may also provide other services for the retailer, such as tracking inventory levels and providing rapid refilling of shelves, which allows the retailer to maintain low inventory levels and thereby reduce its inventory holding costs.

Distributors maintain large warehouses throughout the country. The HDMA reports that healthcare distributors warehouse more than 20,000 SKUs, including pharmaceutical products, sundry/general merchandise, health and personal care items, durable medical equipment, home health supplies, and OTC drugs. They make frequent deliveries. 57% of distributors make regular (non-emergency, non-special) deliveries to customers five days a week, 31% deliver six days a week, and 4% deliver regular orders more than once a day. This is according to the HDMA 2004 Industry Profile and Healthcare Factbook.

There are three large pharmaceutical distributors in the US, as well as many smaller ones. These supply a full line of products for independent and chain pharmacies. Other distributors exist for specialized product lines or are smaller distributors providing regional services. The "big three" are:

<b>Distributor</b>	<b>Annual Revenue</b>
McKesson	\$ 78 billion
Cardinal Health	\$ 70 billion
AmerisourceBergen	\$ 53 billion

These are large companies; Cardinal had sales of \$70 billion in 2004 but profit margins are relatively low. The industry average net profit margin over the last five years has been 1.4%. There are many smaller distributors that tend to specialize in certain products or specialized services. Also there are a few specialized distributors that provide related health care products, such as McKesson and BD that supply hospital consumables or supplies such as bandages and syringes.

The distribution industry has been plagued by financial losses and litigation related to unfair trade. The industry makes a relatively small profit margin by reselling drugs supplied and priced by manufacturers. Competition is severe. Anti trust litigation regarding price manipulation has occurred in recent years. Distributors and manufacturers were accused of manipulating financial statements. Nevertheless, the retail and

manufacturing segments of the pharmaceutical industry rely on distributors to provide customer service and logistics to move and manage its products.

Distributors are generally considered to have dealt with their so-called “accounting difficulties” but are now faced with a transition to a new business model. Wholesalers had previously earned revenue as a result of the difference between the wholesale rates at which they could buy and the rates at which they could sell to retailers. Now they are moving toward charging a fee to drug makers for distributing drugs. “Wholesalers Shift Slowly to Fee-for-Service” American Society of Health Pharmacists, from the [www.ashp.org/news/](http://www.ashp.org/news/), 4/7/05. The intent of this change is to avoid the accounting and legal problems resulting from the previous practice.

### **3. Retailers**

Pharmaceuticals are mostly dispensed by hospitals, independent pharmacies and chain pharmacies. Retailers include chains such as Walgreens, Rite-Aid, Sav-On, etc, independent & community pharmacies and mixed retailers with pharmacies (CostCo, Wal-Mart, etc.). The largest chain is Walgreens with 4,680 stores (2004) in 44 states. It is also generates the most profit. Of course, pharmaceuticals are not their only source of revenue. Walgreens reports that 63% of its sales come from pharmaceuticals. The chains generally maintain their own regional warehouses and supply chains. There are about 60,000 independent pharmacies. According to the National Association of Chain Drug Stores, NACDS Economics Department in 2003 all retail sales were \$163.9 billion of which the chains represented \$123.6 billion

<b>Retailer</b>	<b>Annual Revenue</b>
Walgreens	\$ 39 billion
CVS Corp	\$ 31 billion
Rite Aid Corp.	\$ 17 billion

Of course, other retailers such as Wal-Mart, CostCo and Target represent a large segment of retail drug sales. Wal-Mart is said to represent the third largest retail pharmacy (Business Week, 10/6/03) and grocery store chains are important sources as well.

Hospitals are another a major retail use of pharmaceuticals. They often have an outpatient retail pharmacy as well inpatient pharmacies. Hospitals generally also buy from distributors; even large chains such as Kaiser get their pharmaceuticals from a distributor. Packaging is sometimes specialized when drugs are used in a hospital setting.

Dispensing systems are increasingly common in hospitals. These automate some of the repackaging tasks. Also, hospitals are beginning to utilize bar codes as part of the dispensing process. A hand held scanner can check the bar code on a pharmaceutical, such as an IV package, scan a bar code on the patient’s chart and verify the prescription including the dosage. Even the patient may have a bar coded wristband. This can reduce the chance of errors and improve productivity. Distributors, such as Cardinal, are one of the providers of such systems as part of their consulting and material handling services.

#### **4. Secondary Market**

In addition to the traditional physical supply chain, there is a secondary one which bypasses the traditional supply chain that is: manufacturer to distributor to pharmacy to patient. It includes Internet sites, reimportation, and compounding pharmacies. This supply chain presents a risk to the overall security of the system. “Almost all of these nontraditional sources are legitimate. These sources, however, have technological capabilities that are associated with high-quality label production—including bar codes, repackaging, and acquisition by telephone or the Internet. These capabilities have enabled unethical individuals and businesses to capitalize on the opportunity to make an enormous amount of money with little risk.” Pharmacy Times, Counterfeit Drugs and the "Secondary Market" James C. McAllister III,

#### **5. Group Purchasing Organizations**

Frequently, retailers join together to leverage their purchasing power by forming Group Purchasing Organizations. These organizations provide several services. “A group purchasing organization (GPO) is an entity that helps health care providers—such as hospitals, nursing homes and home health agencies—realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.” from the Health Industry Group Purchasing Association (HIGPA). Nearly all hospitals participate in such groups or are members of a large hospital chain that serves as its own purchasing group.

Independent pharmacies generally participate in a GPO in order to compete with the large chains. Services include information systems services as well as discounts resulting from increased purchasing volumes.

Hospitals frequently use GPO's in a central role for their supply chain. The HIGPA reports that 96% of hospitals utilize a GPO and that about 72% of all hospital purchases are made through a GPO. Thus, these organizations are very powerful in the management of supplies of all kinds, including pharmaceuticals, and should be considered in managing the emergency supply chain. Outpatient clinics play a similar role in the supply chain.

When using GPO services, or not, communication between the retailer and the manufacturer frequently occurs even though the retailer is not buying directly from the manufacturer. The manufacturer provides clinical information, product development status and also pricing specifics.

## D. INFORMATION SYSTEMS FOR THE SUPPLY CHAIN

### 1. Product Identification

Each drug is required by the Food and Drug Administration (FDA) to have an approved identification. The National Drug Code (NDC) System serves as a universal product identifier for human drugs. Each drug product is assigned a unique 10-digit, 3-segment number. This number identifies the labeler/vendor, product, and package size. The FDA assigns the first segment, the labeler code. A labeler is any firm that manufactures, repacks or distributes a drug product. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes. The firm assigns both the product and package codes. The NDC is in one of the following configurations of digits: 4-4-2, 5-3-2, or 5-4-1.

### 2. Bar Coding

“Bar codes are used in the pharmaceutical industry to identify product throughout the supply chain. Different levels of information can be carried in a barcode, including such items as National Drug Code (NDC), Lot Number, and Expiration Date. There are several different types of bar codes, and the standards for what those bar codes should look like and how they are to be used. These are the Uniform Code Council (UCC) and the Health Industry Business Communications Council (HIBCC).” Position Statement of the HDMA Guidelines for Healthcare Automated Identification that further defines recommended practices.



Figure 4. National Drug Code (NDC) and National Health Related Items Code (NHRIC) for pharmaceutical products

### 3. Inventory Availability

Pharmaceutical inventories at retailers and hospitals involve a large number of different items and a rapid turnover. This makes keeping an ongoing inventory record a challenge. Retail level operations sometimes rely on information systems provided by distributors or by a group to which the retailer belongs.

Theft can be an issue. Pharmaceuticals are often high value items in a small physical volume and therefore theft can occur. Some hospitals and many retailers find it necessary to take regular physical inventory counts to maintain an accurate measure of on-hand amounts. Daily counting is not uncommon

Inventories at the retail level tend to be related to the size of pharmacies and the mix of products. Independent and community pharmacies are often smaller and find it more difficult to minimize their inventory levels than large chains. Independent pharmacies with sales under \$1.5 million have an inventory turnover of 47 days for their entire inventory and 44 days for prescription drugs while independent pharmacies with sales over \$4 million have an inventory turnover of 33 days for their entire inventory and 27 days for prescription drugs. (ref: SCPA-Pfizer Digest 2004) At the distributor level, HDMA reports that their members have an annual average turnover of 8 (6 & 1/2 weeks). Manufacturers are said to typically average about one month's inventory on hand. From: "Wholesalers Shift Slowly to Fee-for-Service" American Society of Health Pharmacists, from the [www.ashp.org/news/](http://www.ashp.org/news/), 4/7/05.

#### **4. Usage Related Information**

When a customer (patient) purchases a pharmaceutical they often must also receive considerable information about the drug's use and warnings about various side effects. Thus, the product must be delivered with background information as well as the physical item itself. Retailers, pharmacies and hospitals, have information systems, which print out information sheets at the time the drug is dispensed.

There are several sources used pharmacy information systems. Organizations such as First DataBank provide pharmacies with online access to data on drug interactions as well as consumer information to go with prescriptions. There are over 100,000 different pharmaceuticals for which such information must be accessed as part of the dispensing process.

#### **5. Electronic Identification**

Radio frequency identification (RFID) is a way to store and retrieve product data using thin paper-like tags. The RFID tag can be attached to or incorporated into a product such as a carton of pharmaceuticals. The tags contain an antenna to receive and respond to messages.



RFID Tag

The Electronic Product Code (EPC) is a numbering scheme intended to improve on the numbering used for bar codes. The EPC is generally a 96-bit number, which can identify a specific product whereas the UPC for bar codes usually only identifies a class of products.

RFID and EPC are not generally implemented in this industry but recent studies by industry-wide groups have determined that they are both feasible and desirable. Implementation has begun to a minimal degree and will probably soon expand. Such identification will initially be at the manufacturing and distribution level by identifying pallet loads or bulk containers rather than on retail packaging. The problem with RFID use on retail packages is how to avoid obscuring instructions and other text, which already crowds the exterior of the packages.

Recently, the implementation of RFID and EPC appears to be increasing thanks to the industry realizing its benefits and the regulators signifying approval. "FDA officials recommended in February [2004] that the pharmaceutical industry should adopt the technology by the start of 2007 to help combat the proliferation of counterfeit drugs. They added that they believe RFID will also eventually produce significant savings to the drug industry through supply-chain efficiency improvements." "RFID Gets FDA Push", from FCW.Com, 11/15/04

## **E. ECONOMICS**

Drug prices, it is well known, have been increasing rapidly. In recent years prescription drug prices have been increasing more rapidly than the overall rate of inflation. Prices for the most popular brand-name medications used by older Americans increased at three times the rate of inflation last year, according to a May 25, 2004, AARP report.

Generally prices are negotiated between the retailer and the manufacturer. Often individual hospitals or smaller retailers combine their purchasing into a Group Purchasing Organization (GPO) to have stronger pricing leverage with the manufacturer.

The retailer buys pharmaceuticals from the distributor, but the price is generally set with the manufacturer. The distributor adds a markup amount or has a fee arrangement with the retailer. Prices become complicated when the manufacturer offers the distributor

special discounts. This occurs when the manufacturer wants to increase its sales figures for a particular time period. With a discount from the manufacturer, the distributor can increase its profit margin on its sales to the retailer. However, such deals have been the source of legal problems for the manufacturer as it is sometimes used as an attempt to manipulate its financial statements.

Overall, it is well known that prices are increasing as are total dollars spent on pharmaceuticals. The average annual sales per pharmacy have grown every year for the past 10 years, 250% from 1994 to 2004 according to the NCPA.

Costs for manufacturing pharmaceuticals varies between manufacturers and, of course, by type of drug. One of the largest factors is capacity utilization. Efficient manufacturers focus on careful scheduling and balancing capacity with demand. They try to minimize the variety of product produced, which helps reduce costs from changing from one product to another. This has an effect on the supply chain, since manufacturers must control demand through pricing and inventory levels.

## **F. PHYSICAL LOGISTICS**

Storage of pharmaceuticals presents certain issues. Storage must be clean and free from biological hazards. Additional requirements, particularly at the retail level include the need for clear visibility and lighting, to avoid errors. Often storage space is limited at a retail pharmacy and they must use efficient storage racking to minimize the footprint of the storage equipment. Security is needed and many organizations handling pharmaceuticals require separate locked storage for drugs that are considered illegal for certain purposes.

The pharmacy often includes workstations adjacent to storage areas to assemble drugs for individual orders (prescriptions).



Typical pharmacy workstation. Source: Herman Miller Co.

Distributors and manufacturers utilize more bulk storage solutions.



Pharmaceutical manufacturing requires specialized environments (such as cleanroom conditions), extensive tracking data (for regulators such as the FDA) and expensive equipment (stainless steel material handling machinery).



Transportation along the supply chain is mostly similar to that required for other industries. Volumes are often not large in comparison to the value of the materials transported but some transport must be refrigerated and security is important.

Repackaging is a common activity in the industry. Material may be purchased in bulk and then repackaged into more convenient sizes for the retailer or consumer. For some distributors, such as Cardinal Health, repackaging can be a major activity. The work can be highly automated or it can be manual.





A variety of sophisticated pharmacy information systems are in use at retail pharmacies and hospitals. These systems support simple tasks such as printing labels and patient instructions as well as managing inventory in an efficient manner and tracking drug interactions and contra indications.

Much of the inventory control information is similar to that used by many other industries. Pharmaceuticals require more extensive audit trail data and security. Identification of products is regulated, such as by the FDA, and various audits are required.

Inventory control systems vary by industry segment at the retail level. Large chains and hospital chains have sophisticated computer systems, which calculate the optimum reorder point and order quantity. Some rely on the distributor to determine inventory policy since the distributor does the replenishment frequently. Some independent retailers and small chains merely rely on subjective decision making as to when to re-order an item.

## II. The Emergency Supply Chain

### A. SUMMARY

The federal government has instituted several programs involving pharmaceuticals to assure preparedness in the case of a bioterrorism event or other emergency. Some of the programs predate 9/11. In addition to the federal programs, some hospitals and local governments maintain stockpiles of supplies for relatively small emergencies.

Each of the programs has a different objective, although there is an overlap in some cases. These programs supplement stocks from the traditional supply chain (see Section II above) and the normal supplies at local hospitals and other providers. There is no information regarding the adequacy of the traditional supply system to support a major emergency so these new federal systems are what are largely used for governmental bioterrorism planning.

The federal government's CDC and the US DHS provide a leadership role but many of the execution decisions appear to be the responsibility of local government. In Los Angeles, for example, the County's Emergency Management System is the primary agency. Separate EMS programs exist within the County (The City of Long Beach for example) but the County's EMS has assumed the overall leadership role.

The primary federal programs are summarized in the matrix in Figure 5.

The intent is to have a program that responds to the various possible types of events, as shown in Figure 6. Some events require a very rapid response, within few hours, while other events can be responded to with a longer wait and utilize a distribution planned for the general population over several days. Each program represents a quite different supply chain path, as described in Figure 7. The individual programs are described below.

Figure 5. Programs involving materials and supplies applicable to bioterrorism events.

	Program	Materials Supplied	Locations (2)	Distribution Methods
1	Strategic National Stockpile (SNS)	Medical Supplies, intended for biological and/or chemical threats. A delivery can be about 50 tons, delivered to a regional distribution site in 12 hours from request by Governor.	Delivered by Federal Govt. from a staged storage to one central point in a jurisdiction, such as a state or major city	Defined by local jurisdiction; multiple modes possible
2	Vendor Managed Inventory (VMI)	Varies with need. For ongoing and larger problem, used to re supply or supplement SNS, sent in 36 hours tailored to specific emergency.	Inventory held at vendor. Sent directly to local distribution centers for re distribution	Defined by local jurisdiction; multiple modes possible
3	Chempack, from CDC	Container of supplies primarily to respond to a chemical or nerve agent, held in a secure, monitored, and environmentally controlled storage container. Items have short shelf life and require rapid response when needed.	Now distributed, held locally. Stored in multiple sites within jurisdiction, often hospitals, costs subsidized by Fed. Govt.	About one hour access by hospital or other EMS workers & distributed by them.
4	Community Readiness Initiative (CRI)	Program to fund local best practices, including distribution, preparation for events such as anthrax or other type of attack. No supplies in itself.	21 US Cities funded, in LA County 200 distribution sites identified, for example	Supports specific distribution plans planning to use USPS letter carriers
5	Metropolitan Medical Response System (MMRS)	FEMA Program to support emergency preparedness, can include medical supplies and equipment	Varies by recipient site. Often inter agency teams are created within a jurisdiction under MMRS	Up to locality. Many have defined multiple distribution sites
6	Health Resources and Services Administration (HRSA)	Grants for pharmaceuticals to hospitals for emergency preparedness, including the National Bioterrorism Hospital Preparedness Program	Grants to localities, storage locations up to them. At hospitals or hospital chains such as Kaiser	Up to hospital or organization holding inventory.
7	Disaster Resource Center (DRC)	LA County locally devised program. Grant to hospitals paid for medical emergency equipment and pharmaceuticals. Mix specified by the County.	11 hospitals in LA County Kaiser's equipment at Owens & Merrill in City of Industry, 2 hr. delivery promised (1)	10 store at hospital, Kaiser at a central point
8	Hospital Inventory for emergency events	JACHO accreditation requires an inventory level for supplies and drugs for emergencies	Inventory held in hospital pharmacies and warehouses	Up to hospital holding inventory.

Federal Initiative → State → Local → Provider: → Use:

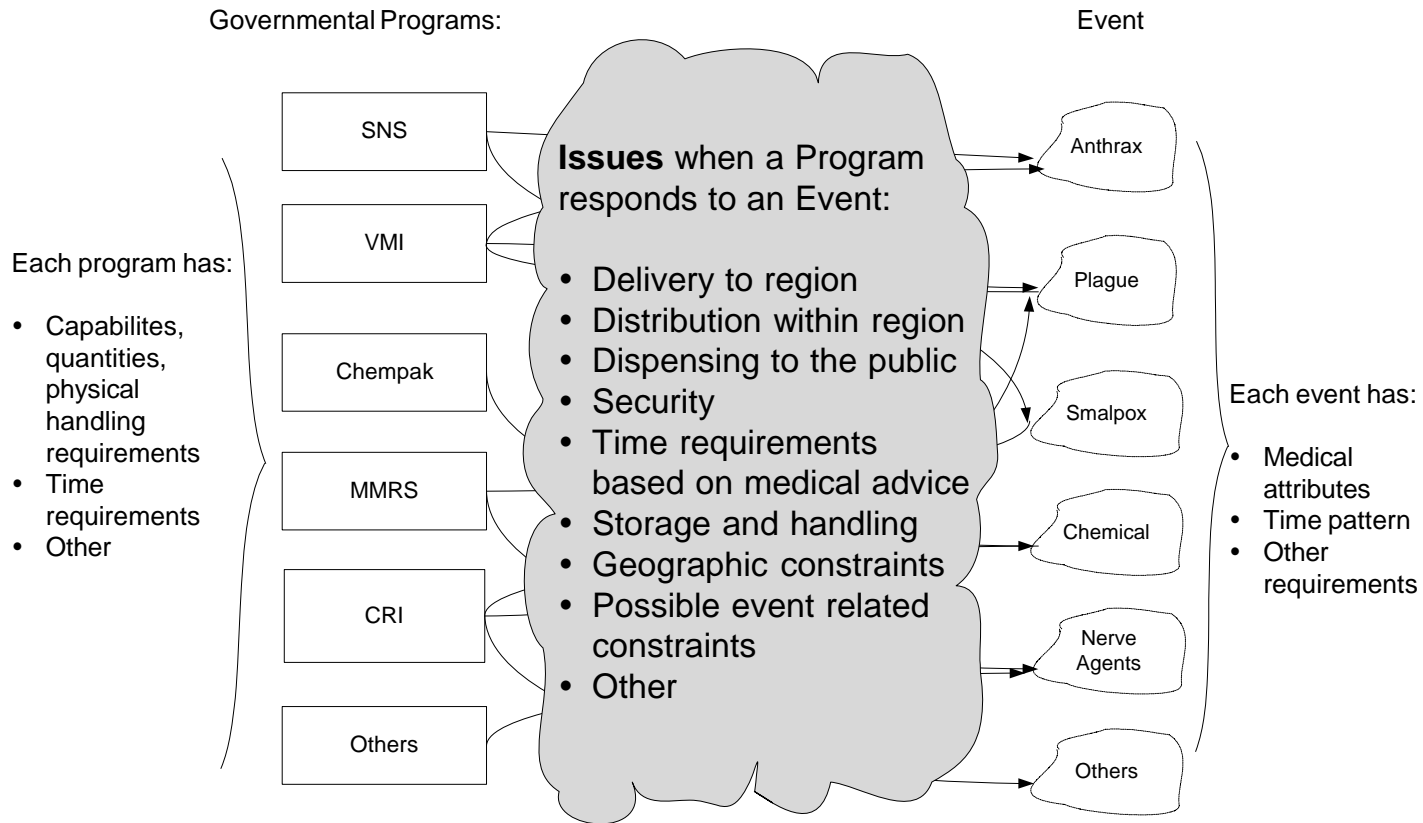


Figure 6. Relationship Between Programs and Events

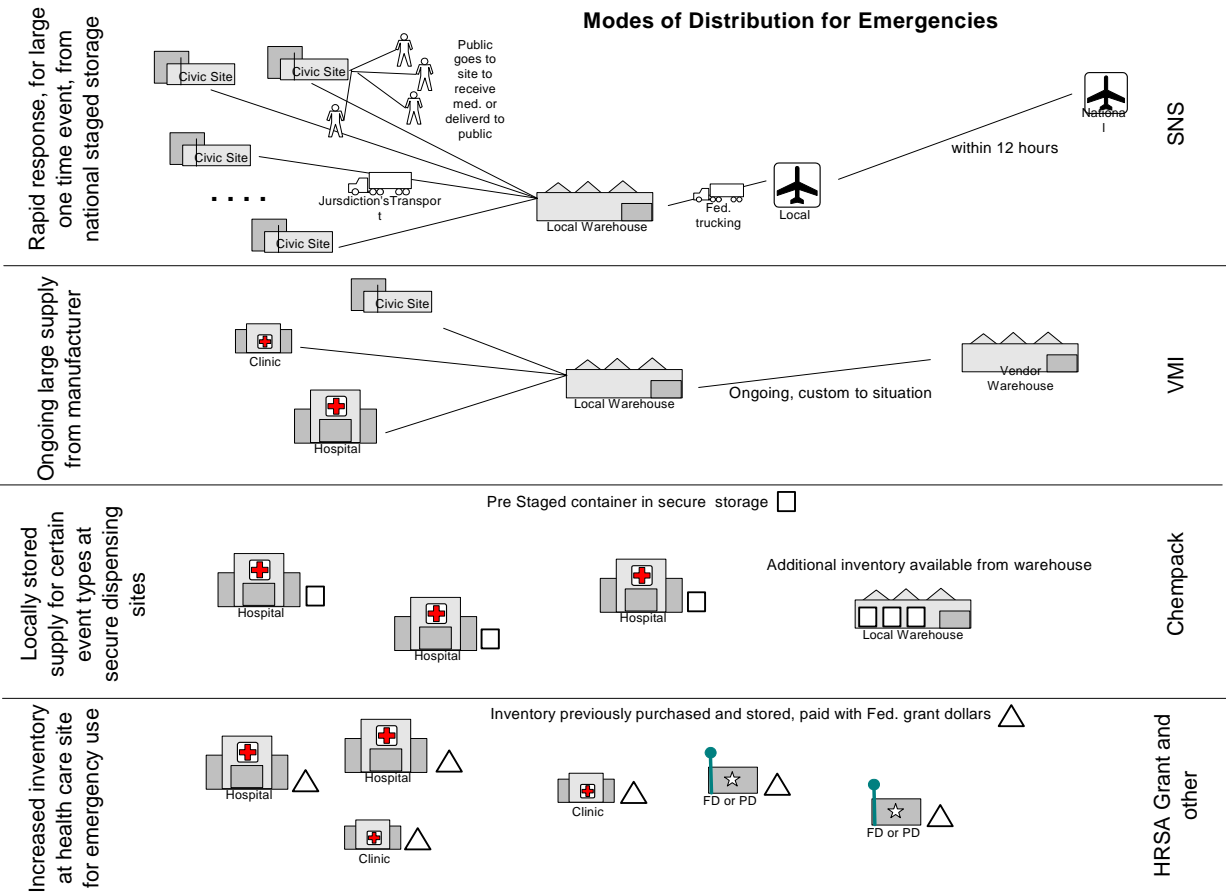


Figure 7. Emergency Supply Logistics

## **B. INDIVIDUAL PROGRAMS & PROJECTS**

Much of the preparedness for bioterrorism consists of several federal government programs to establish storage levels of pharmaceuticals and other supplies for rapid access and in sufficient quantities. The following various programs are designed to respond to differing events and with different response times. In general, a small cache can be delivered sooner than a very large one but large inventories may be needed for certain situations. Thus, there are several programs with different objectives.

Each jurisdiction has (or is in the process of) developed plans for using the materials provided by these various programs. The federal government as well as various trade and professional organizations have supplied suggested generic plans for certain programs. Some completed plans are available for other jurisdictions to use as a starting point for developing their own plans.

Sources for planning include the following:

- US Department of Homeland Security provides a variety of publications and programs See <http://www.dhs.gov/> It provides a “Lessons Learned” program which publishes examples of plans and other related planning experience. See <https://www.llis.dhs.gov/>
- The Centers for Disease Control and Prevention (CDC) is an agency of the Department of Health and Human Services and provides planning suggestions as well as the programs themselves. See <http://www.bt.cdc.gov/>
- The National Association of County and City Health Officials (NACCHO) have published guidelines, examples and held seminars on related subjects. See <http://www.naccho.org/pubs/>
- The Association for Healthcare Resource & Materials Management (AHRMM) has publishes a supply formulary for emergencies. This provides guidelines for hospital’s preparing its supply chain for a large-scale CBRDE disaster. See <http://www.ahrmm.org/ahrmm/index.jsp>

The major programs are:

### **1. Strategic National Stockpile**

The Strategic National Stockpile is intended to provide a large centralized supply that can be rapidly delivered to a local distribution site. The CDC and US DHS manage the program. State and local organizations have organized their ability to receive, distribute and dispense the supplies.

The SNS program consists of two components; “push packages” and vendor managed inventory (VMI). The push packages are large, pre positioned and ready to deploy caches of pharmaceuticals intended to respond to an ill-defined or

generic threat. Each push package contains 50 tons of anti-infective, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, surgical items, and other medical supplies. The SNS program promises to supply large volumes of pre-packaged supplies to an airport by responding to a bioterrorism event within 12 hours. The volume may seem large but still are limited with respect to possible demand. Push packs are said to contain 250k doses of antibiotics that may be small when compared to most urban or state mass prophylaxis needs.

Technical support staffing will also be provided at the same time in the form of a five-member program staff team, known as the CDC Technical Advisory Response Unit (TARU) to assist emergency workers and operate related machines if needed, such as for repackaging. Digitized inventory information in the form of a CD is promised along with the inventory itself. Some jurisdictions are developing information systems to input this inventory data.

The SNS program consists of several standard operational components but each jurisdiction must develop and implement its own detailed plan of operation. The movement of the SNS inventory consists of several components. See Figure 8.

One component of the SNS is the RSS sites (Receipt, Stage and Store). These are state selected warehouse-like locations that will receive the SNS shipment and store it as necessary. They are the locations where the SNS packages are broken down into shipments to local dispensing sites. The materials may also have to be repackaged before being sent to dispensing sites.

Dispensing Sites are the locations where the public will receive pharmaceuticals or where individuals can pick up supplies available to the public. The planning for SNS dispensing can be used for other programs as well. Generally, a POD (Point of Dispensing) site is a temporary clinic site, such as a playground or gym, where medication or vaccine can be given out in large numbers in the event of a disease outbreak or a bioterrorist event. Trained volunteers may staff the POD. The individual PODs are selected based on having attributes such as:

- ✓ Access to highways, airport, helicopter landing
- ✓ Security
- ✓ Parking
- ✓ Restrooms for 300 people
- ✓ Communications; phone, DSL, Radio, etc.

The local authorities must select the geographic location of these sites to assure rapid delivery from the RSS site and access by the public.

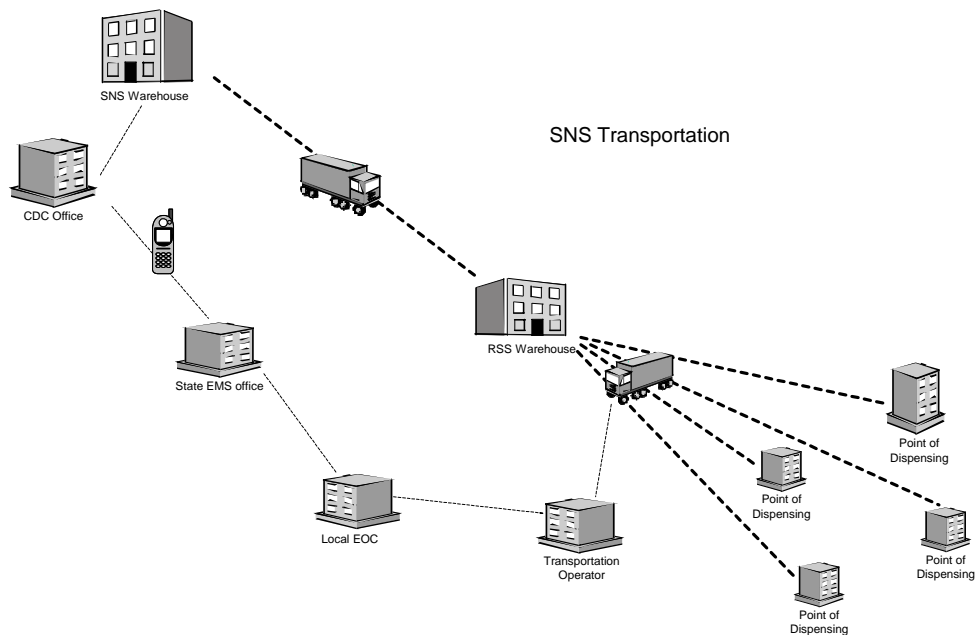


Figure 8. SNS Transportation

## 2. Vendor Managed Inventory

It is possible that the SNS initial delivery will not be sufficient to deal with the problem. Therefore ongoing demand requires additional supplies. A vendor managed inventory system (VMI) has been set up to augment SNS from vendors within 21-36 hours. By using supplies directly from vendors, governmental inventory holding costs are reduced.

The VMI pharmaceuticals are similar to those distributed in the SNS “Push” package shipments. However, they are available in potentially larger and ongoing amounts. Presumably, the VMI distribution would follow the same practices established for the initially received SNS Push packages. It appears that the VMI shipment may not include the digitized inventory information as supplied with the SNS Push Packages.

Regarding procedures for VMI materials, according to DHS: “The functions of the RSS site and the procedures for transportation of pharmaceuticals and medical supplies to dispensing sites, hospitals, and treatment sites will generally remain the same regardless of whether the SNS assets are delivered as a push package or as VMI.” per <https://www.llis.dhs.gov/>

The size of the VMI supply is dependent on the particular item needed and perhaps the inventory situation at the manufacturer. Therefore the actual quantities are uncertain at any given time.



### 3. Chempack

Certain types of bioterrorism require immediate treatment such that a program like SNS cannot be delivered on time to those affected. Chempack is a one-time project to place containers of supplies locally for very rapid response. Its primary objective is to enhance a locality's ability to respond to a chemical or nerve agent attack.

The recipients of the Chempack containers are responsible for their storage. This involves temperature control, security a connection for data access and an interruptible power supply. The recipients are reimbursed for a specific amount regarding their storage costs. The containers are sealed and are about 4 cubic yards weighing about 700 pounds.

Materials in the Chempack are included in the Shelf-Life Extension Program (SLEP) under the FDA. This permits pharmaceuticals to be utilized for a longer time than normally is available so long as the recipients follow the environmental monitoring requirements of the program. This substantially reduces the cost of the supplies buy reducing the replenishment requirements.

The fact that this project is a one-time item may mean that other efforts will have to be undertaken to continue this resource into the future.

### 4. Other Related Programs

In addition to these emergency response programs, there are several other programs that add to the overall emergency response capabilities.

#### National Disaster Medical System (DMAT)

This program sets up teams to respond to various situations. "A DMAT is a group of professional and para-professional medical personnel (supported by a cadre of logistical and administrative staff) designed to provide medical care during a disaster or other event. Each team has a sponsoring organization, such as a major medical center, public health or safety agency, non-profit, public or private organization that signs a Memorandum of Agreement (MOA) with the DHS. The DMAT sponsor organizes the team and recruits members, arranges training, and coordinates the dispatch of the team." per the Federal DHS.

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#### Emergency Operation Center (EOC)

Emergency Operations Centers are created to manage a wide variety of situations. Each jurisdiction creates what meets their particular needs. Features of an EOC generally involve pre-defined procedures and training so that the participants are able to properly do their job. Often a communications system is a key element of the EOC and it may possess a physical site. It may also be responsible for informing the public about an emergency situation.

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▲ *City Readiness Initiative (CRI)*

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“A pilot program to aid cities in increasing their capacity to deliver medicines and medical supplies during a large-scale public health emergency such as a bioterrorism attack or a nuclear accident”. The CRI program is funding a variety of efforts to improve the national ability to respond to emergency events. For example, CRI provides grants to local jurisdictions to develop plans to respond to emergencies – such a plans to distribute emergency supplies. ref. US CDC see also <http://www.bt.cdc.gov/cri/facts.asp>

▲ *Metropolitan Medical Response System (MMRS)*

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Federal grants to local “jurisdictions to focus on being prepared for terrorist events that involve radiological, nuclear, chemical, biological or explosive agents as well as epidemic disease outbreaks, large scale hazardous materials accidents and major natural disasters” ref. USDHS

▲ *Pre Positioned Equipment Program (PEP)*

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“PEP consists of standardized equipment pods that are pre positioned in selected geographic areas to permit rapid deployment to States and localities facing a major CBRNE event. In 11 planned locations Nationwide, highly specialized equipment and necessary off-the-shelf items will be stored in pods, transportable by land or air within 1 to 12 hours after help is requested. This equipment is specifically tailored to sustain and reconstitute the capabilities of local and State first responders to react to a terrorist attack or other major emergency. Through formal request and deployment procedures, the Federal Government will transfer PEP pods to specifically designated local or State officials.” Ref. Presentation by Francis R. Lepage, Lead Emergency Management Specialist, DHS Office for Domestic Preparedness, State and Local Program Management Division, Equipment Support Branch, June 25, 2003 see <ftp://www.emforum.org/pub/eiip/lc030625.doc>

▲ *Trauma Centers at Hospitals*

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While not a bioterrorism system per se, they may play a vital role because they are the system currently in use for treating patients needing immediate critical care. Several systems exist to manage these facilities on a regional basis. They are licensed at various levels of capability. About 13 exist currently in Los Angeles County, for example.

Trauma centers provide several ingredients for dealing with all sorts of emergency events, including bioterrorism. Unfortunately, they are often fully occupied responding to ongoing events in their service area. Since hospital emergency rooms and trauma centers are unprofitable for hospitals, they tend to limit their capacity and have no incentive build in much surge capacity.

## C. PROBLEMS

The new federal programs described above create a response capability better than was available a few years ago. However, some problems remain regarding the pharmaceutical supply chain for emergency events.

## 1. Information Systems

Currently, there are only limited amounts of information regarding what emergency medical supplies exist in any particular geographic area. Each institution, such as a hospital, pharmacy or EMS agency, has data on its own supplies but these sources are not tied together. Geographic area authorities, such as a county, have no way to promptly determine what pharmaceuticals exist in their service area as well as where the supplies are located or how to access them. More supplies may be available than is known. Shortages may be only due to a lack of inventory information.

Moreover, the existing pharmaceutical information systems in use at hospitals and pharmacies are not designed to serve for emergency purposes. They are primarily point of sale systems used for filling customer prescriptions or they are inventory control systems used for purchasing and accounting purposes. Data on individual drug inventories at the distributor and manufacturer level is highly proprietary and unlikely to be shared on a voluntary basis.

Some hospital groups, such as Kaiser, have begun to develop their own emergency information system so that can know what supplies they have available for various likely scenarios. However, this information development effort is fairly recent and is isolated within separate hospital systems.

## 2. Distribution Inventory Control

The CDC has delegated the distribution planning responsibility to each local authority. Local authorities have the best knowledge of their particular geographic situation – so this approach is logical. However, the CDC or DHS does not provide sufficient assistance regarding how best to organize the distribution – other than requiring a plan be done and providing limited funds to prepare such plans. Thus, the plans are very diverse in their approach and level of detail.

Based on looking at a few of the local distribution plans, they seem to be rather restricted in their scope. Perhaps because budgets for doing the plans are quite limited, the preparation of distribution plans is also minimal. Determination of optimal transportation routes under the many possible events is not simple. Also, local emergency dispensing may require considerable trained resources. Many different emergency scenarios are possible. It seems that some local authorities have decided that planning must be limited to less than the full range of possible situations. Beyond a certain level of severity, planning for a wide range of scenarios is not addressed.

It seems quite possible that in the case of a bioterrorism event, authorities will be faced with a situation for which they have not planned.

### 3. Use of RFID Technology

Many industries have found that the automation provided by RFID technology improves accuracy and speed of processing information. It would seem that emergency pharmaceutical warehousing and distribution could also benefit from this technology. Since inventories such as the SNS are received from a common source, which could implement it, RFID would seem feasible to institute.

It must be recognized that RFID is not yet completely implemented in the pharmaceutical industry. This may complicate immediate implementation for emergency purposes since some drugs are not currently identified this way. In the near future, some emergency supply drugs will be available with RFID tags and some will not. Thus, RFID may have to wait until it is more universal. Still, planning of distribution information systems and procedures should take RFID into account since the industry is increasingly adopting it.

### 4. Counterfeit Drugs

The drug industry faces an increasing problem of items that enter the supply chain in a variety of ways and which are inferior and in some cases toxic. There are a number of ways in which this can occur, including:

- Imports, from a region with poor controls
- Expired drugs resold
- Reverse engineered drugs
- Bioterrorism – malicious

Because high value items are involved, various resellers could accidentally acquire such drugs. The complexity of the pharmaceutical supply chain with many intermediate steps exacerbates the problem because there are many points where counterfeit drugs can enter it. "Pharmaceuticals may be transferred up to 10 times before they get to the shelf," Ref. World Trade Magazine 11/10/04.

To combat this, the industry will likely increasingly rely on tighter contracting agreements, electronic ID tags (RFID) and other security measures. Such controls may add to the responsibilities during emergency access to pharmaceuticals. Certainly, having counterfeit drugs in the emergency supply chain must be avoided.

### 5. Vehicle Routing

Optimally routing vehicles for delivery of SNS or other emergency supply inventories can save valuable time. Apparently, some distribution plans at the local level have not taken the necessity of doing this planning into account. The EMS organizations are faced with many issues in planning their responses but budgets and staff are limited. It's generally easy to determine some route from the receiving warehouse to the dispensing site. However, the best possible route is a complex problem. Tools are available to

determine the best routing under various conditions and the use of these should be incorporated.

Problems in determining distribution routes include:

- Major roads may not be useable for a variety of reasons. Frequently urban highways are crowded at certain times of the day. An emergency situation often causes people to alter their driving patterns, such as leaving work early, which can further increase congestion.
- If many dispensing sites are involved, the distribution plans should take routes that facilitate multiple drop-off opportunities. This further complicates the routing problem.
- Many urban areas have real-time access to highway conditions. A good vehicle routing system should take into account available information on traffic delays and may need to take alternate routes that don't use major roads.

Since determining vehicle routing requires some relatively sophisticated tools, it would seem best to provide this resource nationally rather than have each local jurisdiction deal with the issue. The Federal DHS could share the software and build it in such a way to facilitate local customization and the necessary training.

## 6. Surge Capacity

Emergency hospital services and ancillary services in hospitals, such as the pharmacy, have well developed communications systems for allocating a sudden surge in demand that can be a result of various events. Accident victims are routed to only hospitals with available emergency beds and staff is called up to increase capacity. Hospitals regularly perform drills to be sure that they are ready for emergencies. However, these practices have several limitations:

- They are intended for relatively small events in comparison to what could occur from a bioterrorism event. Emergency pharmaceutical supplies are in quantities that are planned for relatively small events.
- The capacity of health care institutions is somewhat flexible. Additional space can be called into use (hallways and auditoriums), additional beds (gurneys and the floor) and health care workers assigned to duties beyond their normal ones. Thus a hospital might temporarily extend its physical capacity significantly. However, the pharmaceutical capacity has more fixed limitations. Once the drugs at a hospital have run out, there is no internal way to extend them during an emergency.
- Hospitals have agreements with local suppliers to restock their shelves when they exhaust an item but this re-supply may not be available during an emergency or it might take longer than required for the emergency patients. Hospital vendor agreements are generally not intended for re-supply during an emergency.
- Levels of care and certain standards can be relaxed if necessary to expand capacity. Similarly, the pharmacy can relax some constraints but rules such as determining when a medication is contra indicated for a patient must still be followed. Relaxing

certain rules or expiration dates can add to the available supply but must be applied selectively.

These considerations mean that defining an area's health care surge capacity is a complex problem. The potential capacity is, in reality, a variable amount rather than a single fixed number. The capacity depends on the level of the emergency and the risks the authorities are willing to take. See Figure 9. The hospital's capacity can be increased when emergency conditions occur, but only to a limited extent, particularly regarding pharmaceuticals. A problem is deciding what capacity to use when assigning patients among various providers under emergency conditions. Perhaps tools that promptly provided a picture of what choices are possible would help emergency personnel manage surge capacity.

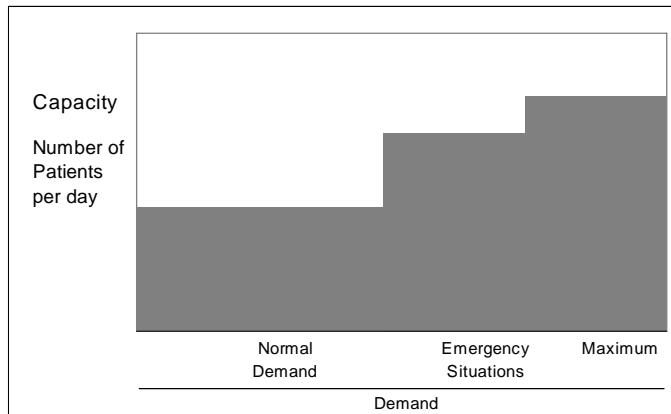


Figure 9. Emergency capacity vs. demand

#### D. SUGGESTIONS

Several solutions can be suggested to these various problems. Simply addressing them directly with consistent practices solves many of them. Also, sharing of solutions among jurisdictions seems particularly important since many of the supply chain problems apply to most geographic areas.

##### 1. Pharmaceutical Information Systems

Determining a geographic area's pharmaceutical resources is a difficult challenge. It is made easier by the fact that only a few specific drugs are applicable out of the thousands in pharmacy inventories. A costly information system is probably not justified but a limited resource could reduce the problem significantly. The cost could be minimized by selectively working with the various parties in the supply chain.

Perhaps the best approach would be to only work with those organizations that maintain large inventories. Supplies at retail pharmacies could be ignored because they are

relatively small. Thus, information should be gathered from organizations that warehouse relevant drugs, such as wholesale distributors, retail chain's warehouses and hospital chain's warehouses. The data need not be constantly accessible – only ready to be accessible at the time of an emergency event. Perhaps with RFID technology and online access, sufficient data could be made available.

Some jurisdictions are working on this inventory control information problem. One jurisdiction has a computer-based system that identifies over 70 wholesale drug distributors and over 500 communities throughout their region in order to create a monthly survey of chemical antidotes and antibiotic stockpiles. This task is not something most jurisdictions are able to mount. Solutions developed for this problem and made publicly available could make its solution feasible elsewhere.

## 2. Distribution Management

Systems to manage the distribution process have been built or are under development at certain local jurisdictions. Perhaps the best of these could be used to create a single software package, which could serve as a prototype. Thus, individual jurisdictions would have a lower development cost. The prototype would have to be customized for each locale, but it would at least begin as a system specifically designed for the emergency distribution situation. Also, greater consistency at the local level would facilitate planning at the national level. National programs, such as SNS, could organize their service to accommodate the standard information system. This would simplify such problems at the implementation of RFID.

The DHS and CDC are apparently working on an inventory tracking system, which may help in managing supplies after they are received locally. However, such a system is not currently available and local jurisdictions are currently developing their own individual software systems designed to local specifications.

## 3. Use of RFID

Moving forward supplies received under emergency conditions must not be hindered by inventory control paperwork. Technology such as RFID can expedite the process and reduce reliance on individual labor. However, such inventory control systems require advance design and implementation. Currently, they are less common in the pharmaceutical industry than in some other industries. Local authorities should incorporate RFID in RSS operations plans. This will require incorporating RFID in the specifications for systems being developed at many jurisdictions. Thoroughly testing such systems is also important since new technology often creates unexpected problems.

Probably it would be helpful to leverage national programs in this area. If DHS could provide a prototype software module to utilize RFID as well as provide specs for the pharmaceutical shipments – that would expedite the progress to automation.

#### 4. Counterfeit Drugs

While incidence of counterfeit drugs is not likely, information systems can further reduce their probability. RSS and other facilities could have access to FDA or other sources that provide warnings about such drugs. RFID technology can also help in this regard.

#### 5. Vehicle routing

Access to software to assist in the complex task of vehicle routing will often be necessary in larger urban environments. Organizations such as the CREATE center are developing such tools. Larger shipping companies have been using vehicle routing systems for years and software providers have relevant software products. Each version deals with differing degrees of complexity, such as the ability to accommodate multi-stop trips.

To make them effective, however, local agencies and RSS sites must have used them in advance and understand how to implement them under changing conditions. In the case of an emergency event, transportation routes may be different than under normal conditions. In such cases, the routing software must be informed of the new conditions and the users of the tools must be able to understand how to promptly implement them.

#### 6. Surge Capacity

Limitations on surge capacity may present untenable problems for very large events. However, the demand resulting from a particular event must be met in the best possible way. Therefore, emergency managers must know what pharmaceuticals are available. Often the amounts will vary over time. With longer waits – more supplies become available.

Emergency plans should take into account the quantities of particular pharmaceuticals that are available, how to get them for use in terms of an ongoing event, in what situation they are applicable and how much time it will likely take to gather the supplies. Thus, over time, after an emergency event, the amounts of available supplies can grow but emergency management must know this relationship in detail. In addition to the planned receipt of SNS/VMI items the local authorities could draw on local supplies from retailers and distributors as well as possible increases to manufactured quantities. See Figure 10. The quantity of supply coming from Chempack, SNS and local supplies are fixed but VMI and additional manufactured supplies will grow over time.



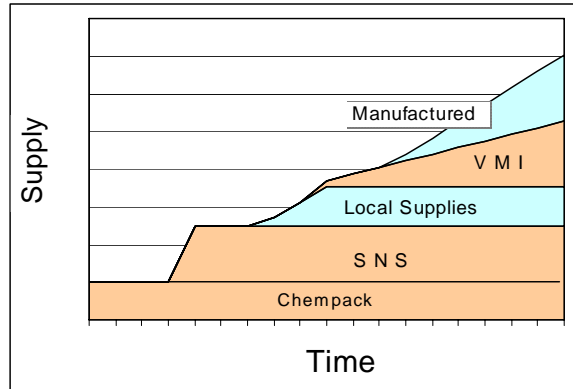


Figure 10. Emergency pharmaceutical supply vs. time

The cost of the emergency pharmaceutical supplies might be reduced by an interchange with local inventories. Some items may be moved from the emergency inventory into the traditional supply chain before their useful life has expired so that they can be consumed locally. This would reduce costs since supplies left in the emergency supply chain may otherwise have their useful life expire before they are used. Drawing on inventories outside the jurisdiction could also extend the surge capacity – if the other jurisdiction does not require the supply itself. See Figure 11.

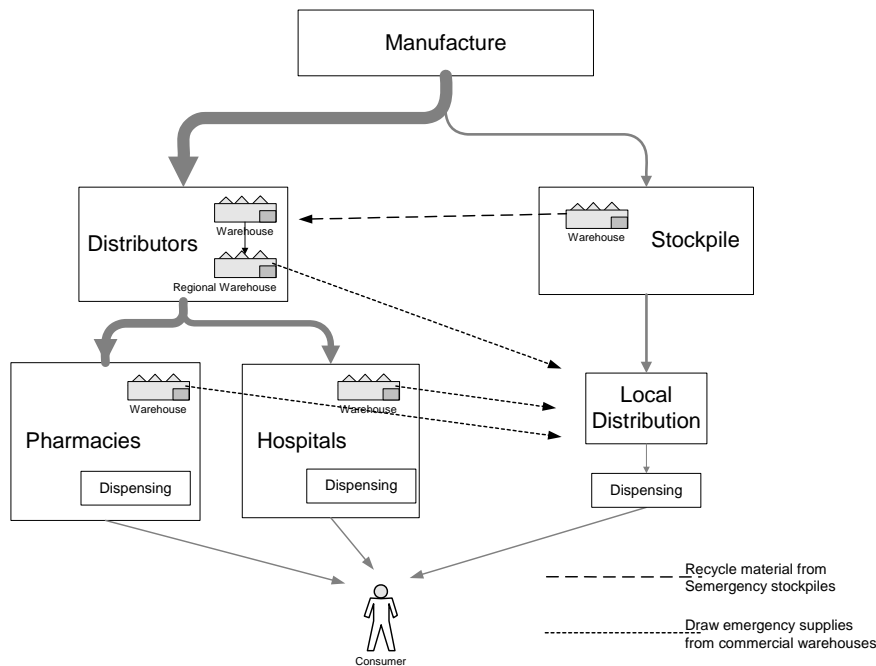


Figure 11. Integrated Emergency and Traditional Supply

### **III. Conclusion**

The availability of an adequate level of pharmaceuticals is an absolutely necessary component of terrorism response. Planning for emergency supplies should leverage the existing traditional pharmaceutical supply chain since emergency supply chains are small in comparison.

The current technology used in managing the traditional supply chain should be incorporated into the emergency system to maximize its effectiveness. The challenge is to assure that sufficient supplies are available as promptly as needed. In order to do so, a modern inventory information and management system is required along with access to all the potential supply.

## IV. References

1. Burns, Lawton R., The Health Care Value Chain, New York, John Wiley, 2002.
2. NCPA-Pfizer Digest 2004, National Community Pharmacists Association. It is a summary of financial and demographic information of independent community pharmacies in the United States.
3. Integrity of the Pharmaceutical Supply Chain, HIGPA, Health Industry Group Purchasing Association, February, 2004
4. Bioterrorism Readiness Report, Los Angeles County Department of Health Services, March, 2004
5. Various publications from the Department of Homeland Security were used for this report that describe various programs in detail including:
  - 00-SNS Overview.pdf, Strategic National Stockpile: Overview
  - 03 - SNS Transporting Materials.pdf. Strategic National Stockpile Distribution
  - CDC - NPS Version 9.pdf. Receiving, Distributing and Dispensing the Strategic National Stockpile
  - chempack-attachj.pdf, CDC Chempack Program Description

Links (regarding specific emergency programs):

1. DMAT: <http://oep-ndms.dhhs.gov/dmat.html>
2. NDMS (the National Disaster Medical System): <http://oep-ndms.dhhs.gov/index.html>
3. SNS: <http://www.bt.cdc.gov/stockpile/>
4. VMI: <http://www.bt.cdc.gov/stockpile/>
5. Chempack:  
<http://www.bt.cdc.gov/planning/continuationguidance/docs/chempack-attachj.doc>
6. CRI: <http://www.bt.cdc.gov/cr/facts.asp>
7. MMRS: <http://training.fema.gov/emiweb/IEMC/mmrs.asp>
8. HRSA:  
<http://www.hrsa.gov/bioterrorism/preparationandplanning/index.htm>
9. DRC (Los Angeles, CA):  
<http://www.ladhs.org/ems/disaster/Year2DisasterResourceCenterAmendment.pdf>
10. JCAHO: <http://www.jcaho.org/>
11. HIGPA: <http://www.higpa.org/>
12. State of California, Emergency Preparedness Office:  
<http://www.dhs.ca.gov/ps/ddwem/environmental/epo/epoindex.htm>
13. County of Los Angeles, Emergency Medical Services Agency,  
<http://www.ladhs.org/ems/index.htm>

Links (general information sources used for this report):

1. US Department of Homeland Security: <http://www.dhs.gov/>
2. HDMA, Healthcare Distribution Management Association, <http://www.healthcaredistribution.org/>
3. National Association of Chain Drug Stores: <http://www.nacds.org/>
4. Pharmaceutical Supply Chains: <http://www.pharmaceuticalsupplychain.com/index.html>
5. Lessons Learned (related to homeland security): <https://www.llis.dhs.gov/>
6. RFID policy at the FDA: [http://www.fda.gov/oc/initiatives/counterfeit/rfid\\_cpg.html](http://www.fda.gov/oc/initiatives/counterfeit/rfid_cpg.html)
7. Association for Healthcare Resource & Materials Management (AHRMM): <http://www.ahrmm.org/ahrmm/index.jsp>
8. National Association of County and City Health Officials (NACCHO): <http://www.naccho.org/pubs/>
9. CDC bioterrorism planning materials: <http://www.bt.cdc.gov/>
10. American Society of Health-System Pharmacists: <http://www.ashp.org/>