

STORAGE, DISTRIBUTION, AND DISPENSING OF MEDICAL SUPPLIES

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CREATE REPORT
Under FEMA Grant EMW-2004-GR-0112

April 21 , 2005



**Center for Risk and Economic Analysis of Terrorism Events
University of Southern California
Los Angeles, California**



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.

Acknowledgment

This research was supported by the United States Department of Homeland Security through the Center for Risk and Economic Analysis of Terrorism Events (CREATE), grant number EMW-2004-GR-0112. However, any opinions, findings, and conclusions or recommendations in this document are those of the authors and do not necessarily reflect views of the U.S. Department of Homeland Security.

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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:

Distribution Channel	Sales, dispensed
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.

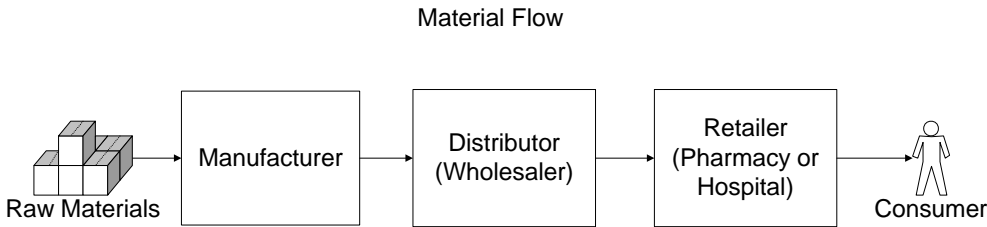


Figure 1. The Overall Physical Supply Chain

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.

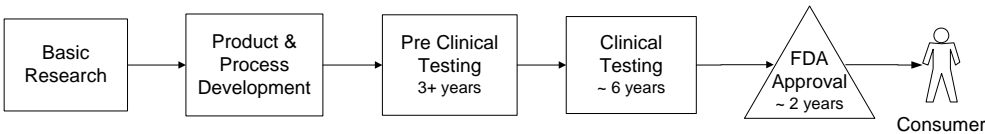


Figure 2. The Product Development Supply Chain

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 pharmaceuticals 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.

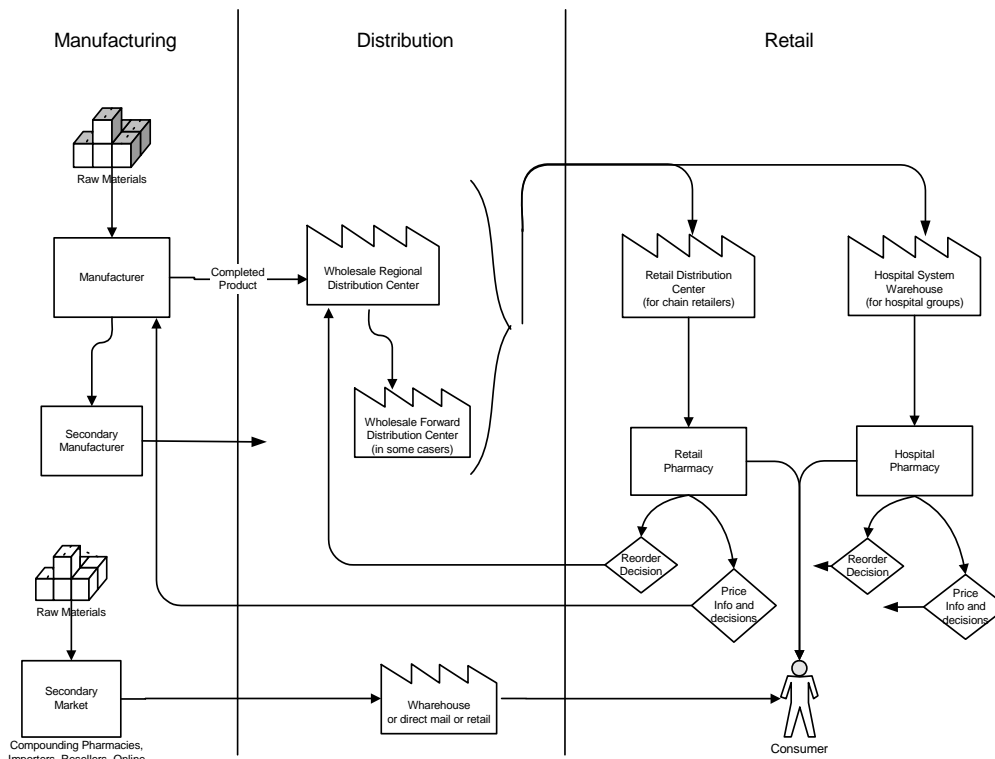


Figure 3. Three Segments of the Pharmaceutical Supply Chain

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:

Corporation	Rank	Wholesale Dollars*
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.

