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THESIS

COST ANALYSIS FOR THE RETURN AND DISPOSAL OF EXPIRED NAVY PHARMACEUTICALS

by

Ronald J. Rundstedt

December, 1993

Principal Advisor: Katsuaki L. Terasawa

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The scope of the study was limited to the continental United States Naval Military Treatment Facilities (CONUS MTFs). Based on inferential methods in linear regression, it was determined that the dollar amount that the Navy can expect to recoup, through the return of their expired pharmaceuticals at CONUS MTFs, is over two million dollars per year. Also, after analyzing and comparing four alternatives, a conclusion was made that contracting civilian services would be the most cost effective method for the return and disposal of expired Navy pharmaceutical products.

A recommendation was made that the Navy initiate a universal policy directing the return and disposal of expired pharmaceutical products utilizing civilian services.

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Cost Analysis For The Return And
Disposal Of Expired Navy
Pharmaceuticals

by

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B.S.E.E., University of Notre Dame, 1978

Submitted in partial fulfillment
of the requirements for the degree of

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I. INTRODUCTION

A. PROBLEM STATEMENT

In the 1980s, the focus of Navy Medicine had been on the provision of quality care with less emphasis on the rigorous management of fiscal resources. There had been typically both constant dollar and real growth in each new budget, with little or no reduction, or deletion, of original line items. (Bruhn, 1992)

Now, in an era of economic downturn, the budget deficit, the collapse of the Soviet Empire, and public clamor to reap a peace dividend, there will be a continued decline in future military budgets.

To offset the current, and projected, large reductions in the budget, the Secretary of Defense has implemented cost savings initiatives that include base realignments and closures (BRAC), consolidation of commands, reduction of force levels, implementation of unit costing, and emphasis on Total Quality Leadership (TQL) (Bruhn, 1992). While some savings have been achieved, fiscal problems persist.

Throughout times of tight constraints on resources, the U.S. Department of Defense must continue to maintain its vital mission of military preparedness, as well as to execute its medical mission more effectively (Lanier, 1993).

> One of the foremost management challenges being debated among military health care leaders is how best to improve access to quality care and achieve economies, without reducing the health care benefit. Even more serious is that this challenge occurs at a time when fundamental questions are being raised about the efficacy of the organization and operation of the military's own vast and enormously complex health care system. (Lanier, 1993)

As new management methods and technologies evolve in the health care logistics management industry, military medical personnel must seize those opportunities, and exploit their potential for enhanced efficiency and improved military readiness (Blaker, 1991). "In an effort to maximize cost containment within the military budget, an often untapped source of additional revenue is the return of outdated pharmaceutical products to drug manufacturers for credit or replacement products (Capital Returns, Inc., 1993)."

B. BACKGROUND

The United States Navy Bureau of Medicine and Surgery is responsible for the operation of 33 hospitals in the United States and overseas (four of which are major multi-disciplinary teaching hospitals and four of which are family practice teaching hospitals), and 174 medical clinics and dental clinics. These are exclusive of facilities on Navy ships and in Marine Corp units. Each of these facilities handles pharmaceutical products. A by-product of normal operations is the accumulation of expired pharmaceutical products.

Currently, most Navy facilities do not return expired pharmaceutical products for cash, credit, or replacement products because it is labor and time intensive. Each line item must be cataloged by manufacturer, lot number, quantity, and purchase price. As a result, most facilities discard the expired pharmaceuticals. (Kinney, 1993)

The disposal of pharmaceuticals is subject to increasing scrutiny from local, state, and federal agencies as environmental concerns escalate. This increases the administrative burden to pharmacies and exposes Navy medicine to criticism, or potential legal problems. (Kinney, 1993)

There are companies that provide return and disposal services for hospitals and pharmacies, and charge a fee for that service. Additionally, these companies specialize in the destruction of expired pharmaceuticals and have the requisite expertise to meet local, state, and federal regulations (Kinney, 1993).

C. OBJECTIVE

One objective of this study was to quantify the dollar amount of savings that the Navy could expect if they return their expired pharmaceutical products. Another objective was to determine whether it is cost effective to contract civilian services for the return and disposal of these expired products.

D. SCOPE, LIMITATIONS, AND ASSUMPTIONS

1. Scope

Although the problem of expired pharmaceuticals is prevalent through the entire Federal Government, this study focused on the Department of the Navy. Specifically, the hospitals and clinics that are located in the continental United States (CONUS) were studied. These facilities are under the jurisdiction of the Bureau of Medicine and Surgery.

The hospitals and clinics used for data collection were selected by the Navy Surgeon General's Specialty Advisor for Pharmacy. They are a representative sample of the entire continental United States Navy health care system, and each facility had been returning their expired pharmaceuticals. Data obtained came from individual pharmacy records, civilian return company records, and Navy Health Care databases.

2. Limitations

For the purposes of this study, the following limitations were identified:

- Due to time, telephone, and logistics constraints, only continental United States Naval Medical Treatment Facilities (MTFs) were studied. Alaska, Hawaii, and overseas MTFs were not studied.
- Data was scarce because few government facilities are currently returning their expired pharmaceutical products. Also, those facilities that are returning their expired pharmaceuticals have only been doing so for a short time.

3. Assumptions

For the purposes of this study, it was assumed that:

- Naval MTFs are similar to all other medical facilities in some ways. Both are responsible for providing quality inpatient and outpatient health care, use the same or similar supplies, and provide training to physicians and other health care personnel. In addition, both must control the cost of health care as prices for supplies and equipment escalate. (Bruhn, 1992)

- Any recognized means to reduce costs, without a subsequent decline in the quality of service, are applicable to both Naval MTFs and all other medical facilities (Bruhn, 1992).

- Naval MTFs and other military medical facilities are different from civilian facilities in several ways. First, military facilities do not charge their patients for services rendered. Second, military facilities are generally smaller in size, but they generally treat more outpatients than their civilian counterparts. Third, military facilities also serve as pharmacies for active and retired military personnel and their dependents, while private sector pharmacies are largely separate and independent from medical facilities. (U.S. GAO, 1991)

E. DEFINITIONS AND ABBREVIATIONS

For the purposes of this study, the following definitions will be used:

- Ancillary Services - Those services (functions) that participate in the care of patients principally by assisting and augmenting the talents of attending physicians and dentists in diagnosing and treating human ills. Ancillary Services generally do not have primary responsibility for the management of patients. Rather, patient services are provided on the orders of cognizant physicians and dentists. Pharmacy services are an example of ancillary services.

- Authorized Medical Allowance List (AMAL) - The authorized allowances of medical equipment and consumable supplies required to accomplish health care support under combat conditions. Establishes the minimum quantities that are

to be maintained on board U.S. naval vessels at all times. (BUMEDINST 6700.13F)

- Bassinet Days - The count of total days that newborn infants occupy bassinets in MTFs that have bassinets assigned for infant use. The total count includes each day an infant occupies a bassinet at the census-taking hour (usually midnight).

  Source: HIPS.

- Catchment Area - A uniformed service MTF catchment area is defined by OASD(HA) as the five digit zip code zones whose geographic center lies within 40 miles of the center of the zip code zone in which the MTF is located. Naval Medical Clinics Commands do not have designated catchment areas, only inpatient facilities.

- Dated Drug Product - To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing. (211.137 CFR)

- Manufacturer - The functions of the ethical pharmaceutical manufacturing industry may be classified into four groups: research and development, production of medicinal chemicals, formulation of drugs into the various dosage forms (such as tablets, capsules, ointments, and injectable solutions), and marketing. Not all pharmaceutical manufacturers combine into one organization the four functional classifications, though this is the common concept. (King, 1968)

- Military Medical Treatment Facility (MTF) - A MTF is a health care facility equipped to provide various degrees of outpatient and/or inpatient care. In the Navy, this includes fixed hospitals, clinics, sickbays and land-based mobile facilities. (Standard Element Activity Reporting System (SEARS) Report)

- Naval Medical Logistics Command (MEDLOG) - Provides medical logistic and materiel management support to the Fleet, Fleet Marine Forces, and ashore medical and dental treatment facilities.

- Prime Vendor - In November 1991, Veterans Administration (VA) implemented a prime vendor program that should reduce the number of pharmaceutical products stored in selected VA warehouses and medical centers. The prime vendors are drug wholesalers that have been awarded contracts for the

warehousing and subsequent distribution of pharmaceutical products to individual medical centers. VA negotiates prices and awards contracts for products directly with the manufacturers or suppliers. The prime vendor in turn buys the products at these prices and distributes the products to the hospital. It charges a distribution fee for these inventory management and distribution services. (U. S. GAO, 1991)

- Shelf-Life - The period of time beginning with the date of manufacture/cure/assembly and terminated by a date by which the item must be used or subjected to inspection/test/restorative disposal action. For medical commodities, the term shelf-life refers only to expiration dated (potency) items. (Aguigam, 1991)

- Weighted Procedures - If the performance factors (workload) were homogenous, the cost per procedures would be simply obtained by dividing the total cost of a work center by the number of procedures performed by that work center. However, two results occur: (1) the relative costs of the various procedures performed becomes grossly distorted and (2), relative workloads become noncomparable. Hence, in order to obtain average useful cost comparison data, it is necessary to assign weighted values which reflect their relative complexities and costliness. Typically, a workload procedure is "weighted" to accurately and fairly account for the value of the resources consumed to accomplish or produce that given performance (workload) unit. The pharmacy procedures weighted values are as follows:

Pharmacy Procedures	Weighing Factors
a. Prescription	1.0
b. Clinic Issue	0.6
c. Sterile Product	2.0
d. Unit Dose	0.15
e. Bulk Issue	2.0

Prescription - Written order for a medication or device prescribed for an individual patient. A refill is counted the same as a Prescription.

Clinic Issue - A handout or prepared issue to a clinic for subsequent issue to individual patients by non-pharmacy personnel.

Sterile Product - Each parenteral bottle, bag, or syringe that is prepared by the pharmacy and is ready for administration.

Unit Dose - An individual dose.

Bulk Issue - Each line item issued to clinic wards to be used within the clinic or ward.

- Wholesaler - The wholesaler is an essential link in the channel of distribution that connects drug manufacturers with consumers. Most ethical drug products are sold to wholesalers. The wholesale druggist is also necessary to the pharmacy. The indispensability of the wholesaler is illustrated by the fact that a single large drug outlet may stock as many as 100,000 items. Most of these are purchased in small quantities. Thousands of these items are ordered one at a time. It is obviously not economically feasible for each pharmacy to attempt to deal directly with each of the thousands of manufacturers. A single wholesaler, acting as an intermediary, permits the pharmacy to handle the merchandise of thousands of manufacturers with moderate effort and expense. (King, 1968)

F. ORGANIZATION OF STUDY

Succeeding chapters of this study will focus on the following areas.

Chapter II presents information, and introduces background issues, that apply to the return and disposal of expired Navy pharmaceutical products.

Chapter III presents the methodology used in conducting the study, and the structure of the analysis.

Chapter IV presents the data and an analysis of that data.

Chapter V (1) provides a summary of the study, (2) concludes that civilian services should be used for the return and disposal of expired Navy pharmaceutical products, and (3) recommends that the Navy initiate a universal policy directing

the return and disposal of expired pharmaceutical products utilizing civilian services.

II. LITERATURE REVIEW AND BACKGROUND ISSUES

This chapter will present information, and introduce specific background issues, that apply to the return and disposal of expired Navy pharmaceutical products.

A. THE PHARMACY

According to DoD Directive 6010.13M, Medical Expense and Performance Reporting System (MEPRS) Manual:

> The pharmacy produces, preserves, stores, compounds, manufactures, packages, controls, assays, dispenses, and distributes medications (including intravenous solutions) for inpatients and outpatients. Additionally, the pharmacy plans and technically supervises all pharmaceutical activities of the medical facility; advises and makes recommendations on policies, standards, and practices; informs professional personnel of new medicinal and biological preparations; and establishes safeguards for storing and issuing poisons, narcotics, and alcoholic drugs. Other pharmacy services include the maintenance of formularies; maintenance of patient drug profiles; adding drugs to intravenous solutions; determining incompatibility in drug combinations; administering unit dose drug combinations; administering unit dose drug distribution system; and stocking floor (ward) drugs and satellite pharmacies.
>
> Pharmacy costs are in a summary account that includes all operating expenses incurred in operating and maintaining the pharmacy. Proration of nonpersonnel expenses for jointly operated or used facilities are based on work load. Proration of personnel expenses are based on time spent in each work center. The aggregate of these expenses are ultimately assigned through a stepdown process to other ancillary services and final operating expense accounts. Aggregate expenses are assigned based on the ratio of weighted procedures provided each receiving account (the work center that ordered the services or was the beneficiary of the services) to the

total weighted procedures provided by this work center. (MEPRS Manual)

By far, the largest expense in Navy MTF pharmacies is that for pharmaceutical products.

B. THE NEED - PHARMACEUTICAL PRICES ARE RISING

Pharmaceutical prices have been rising more rapidly than both medical care prices and consumer prices in general, as measured by the Consumer Price Index for medical care, and for all items (CPI - all items) (Cleeton, 1992).

> Total expenditures for drugs and sundries have grown at remarkably stable rates over the last 25 years- -average annual growth rates of drug expenditures for 5-year periods from 1965 to 1990 have not been lower than 8.1 percent nor higher than 10 percent.
>
> Prescription drug (pharmaceutical) prices have followed a different pattern than prices in general. They fell uniformly from the 1960s through the mid-1970s relative to overall price levels in the economy. From the mid-1970s through 1981, they grew at about the same rate as overall prices, and since then they have grown much more rapidly than have general prices. (Sonnefeld, 1991)

Between 1980 and 1990, while the general inflation rate was 58 percent, prescription drug price inflation was three times this -- 152 percent. In October 1991, a staff report by Senator David Pryor's Special Committee on Aging indicates that, far from being an aberration, these startling price increases are actually accelerating, reaching their highest rate of increase in a decade. (Senate, October 16, 1991)

With prices expected to continue their rapid growth, Navy health care managers must use every effort to minimize the effects of the rise.

C. AN OPPORTUNITY PROVIDED BY THE MANUFACTURERS

As stated in the Code of Federal Regulations:

> A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number, reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. (211.204 CFR)

Because of the above regulation, and in an effort to retain customers by goodwill, throughout the ethical drug industry it is common practice to accept expired pharmaceutical products for return and issue refunds, merchandise credit, or replacement products.

> Products purchased through the Federal Supply Schedule and local purchase are eligible for return in accordance with the manufacturers' policies for the commercial sector. In examining the policies of 72 of the leading drug manufacturers, ... 20 will accept outdated pharmaceuticals with no time limit, although discounting does occur depending on the age of the products. Six will accept outdates between two and five years from the date of expiration, and 36 will accept products within one year of expiration. Ten have a six month time limit.
>
> In addition to the time constraints, there are additional requirements attached to some of the policies, such as fulls only, unmarked containers, original packaging, certain products only, etc. In spite of these limitations, a systematic program for returning outdates in a timely manner will more than cover the cost of processing. (Capital Returns, Inc., 1993)

Examples of manufacturer policies are in Appendix A. These manufacturer policies present an opportunity that Navy health care managers can exploit.

D. EXPIRED PHARMACEUTICAL PRODUCTS - WHERE THEY ORIGINATE

While the problem of returned goods is not unique to the ethical drug industry, the problem is intensified because most of the products are "dated". Hospital and clinic pharmacies are required to maintain sufficient stock to service their customers. However, overstocking, and subsequent expiration, is inevitable due to variables in patient quantities, types of illnesses, and specific drug and dosage requirements. This is especially true in the larger teaching hospitals.

Teaching hospitals are distinguished by their patients' severity of illness and/or complexity of diagnosis, the comprehensiveness and/or intensity of services offered, and their institutional commitment to providing medical education (Baumgardner, 1992).

> They also maintain most of the highly specialized care units, such as trauma centers; burn units; medical, surgical, pediatric, and neonatal intensive care units (ICUs); coronary care units; transplant programs; and cancer treatment centers. Because teaching hospitals have the highest degree of control of essential support services and interdependence of units, they demand high levels of specialized pharmaceutical services. (Baumgardner, 1992)

These complex organizations generate more annual pharmacy costs per occupied bed, have a greater array of pharmaceutical products, and have a greater problem with stock expiring than non-teaching hospitals.

Rotation of stock, in any hospital or clinic pharmacy, is necessary to ensure items with the least amount of shelf-life

are used first. Due to poor management of stock, occasionally items expire that could have been used.

Additionally, in today's complex markets it is normal that some new products will not gain wide acceptance, or some older products fall out of favor. Competition from other products, dissatisfaction with performance, and patient feedback concerning adverse reactions result in physicians choosing alternatives. Expected usage may not be met, and as a result certain stocked products expire.

Excess pharmaceutical products originate from other military specific sources:

- Base realignments and closures have produced surpluses as hospitals and clinics shut down or downsize.
- Ships departing on deployment must maintain an AMAL stocked with products that will not expire while on the deployment. Any items that do not meet this requirement will usually be given to the local MTF for their use and disposition. Likewise, ships returning from deployment will often offload unnecessary products to the local MTF, so they can be used before expiration. This practice can produce surpluses, and subsequent expirations.
- A unique function of the DoD medical care system is to provide care of its troops during wartime. To prepare for this contingency, MEDLOG Depots store additional medical supplies (called "war reserve" material) that can be used in the early stages of a conflict. When stocks of these "war reserve" materials are rotated, the depots issue them to peacetime operating MTFs. These items are closer to their expiration date, and may not be completely exhausted prior to expiration.

E. METHODS OF MANAGING EXPIRED PHARMACEUTICALS

Currently, most Navy MTFs are not returning their expired pharmaceutical products. Of the few that do, one has a

contract with a civilian return company, and the others are accomplishing the returns with internal assets.

If the expired products are not being returned, they are collected for disposal. The larger hospitals box the expired materials and send them to a centralized location for disposition. The smaller hospitals and clinics usually handle their expired materials inside the pharmacy spaces. After collection, the materials are sorted between hazardous and non-hazardous. The hazardous materials are shipped along with other hazardous hospital waste to an approved incinerator for destruction. The non-hazardous materials are usually put in dumpsters for pickup by a refuse company, which transports the waste to the local landfill.

The Navy MTFs which are performing the return functions themselves must go through a process similar to that of the civilian return companies. First, the manufacturers must be contacted to obtain their individual return policies and return forms. Expired pharmaceutical products must then be sorted/separated by manufacturer. The products are then fine sorted according to the individual manufacturer policy. Products that are returnable are inventoried, forms prepared (filled out indicating: product name, dosage form, lot number, reason for the return, expiration date, and quantity returned; examples are in Appendix B), and packed and shipped to each individual manufacturer. Refunds, credit, or replacement products are then issued to the pharmacy directly from the

manufacturer, or through their wholesaler. The products that are not returnable must be disposed of after determining hazardous and non-hazardous waste. This is illustrated in Figure 1. (Capital Returns, Inc., RX Returns, Inc., 1993)

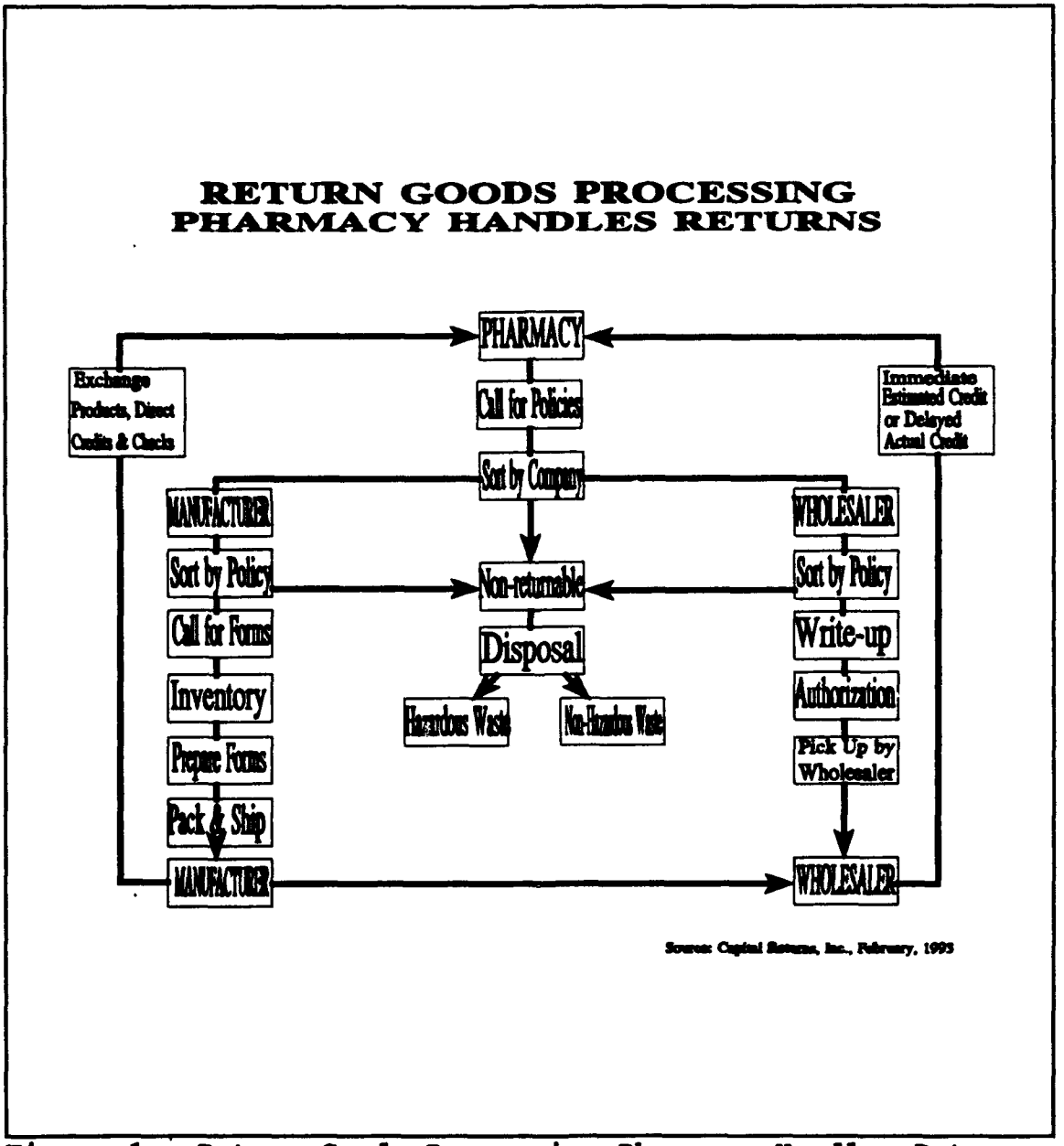


Figure 1: Return Goods Processing Pharmacy Handles Returns

When a civilian return service is used, the Navy pharmacies must gather the expired products and either box and ship them to the return company, or have them picked up directly by the return company. After that is completed, the civilian return service performs all aspects of the returns. This is illustrated in Figure 2.

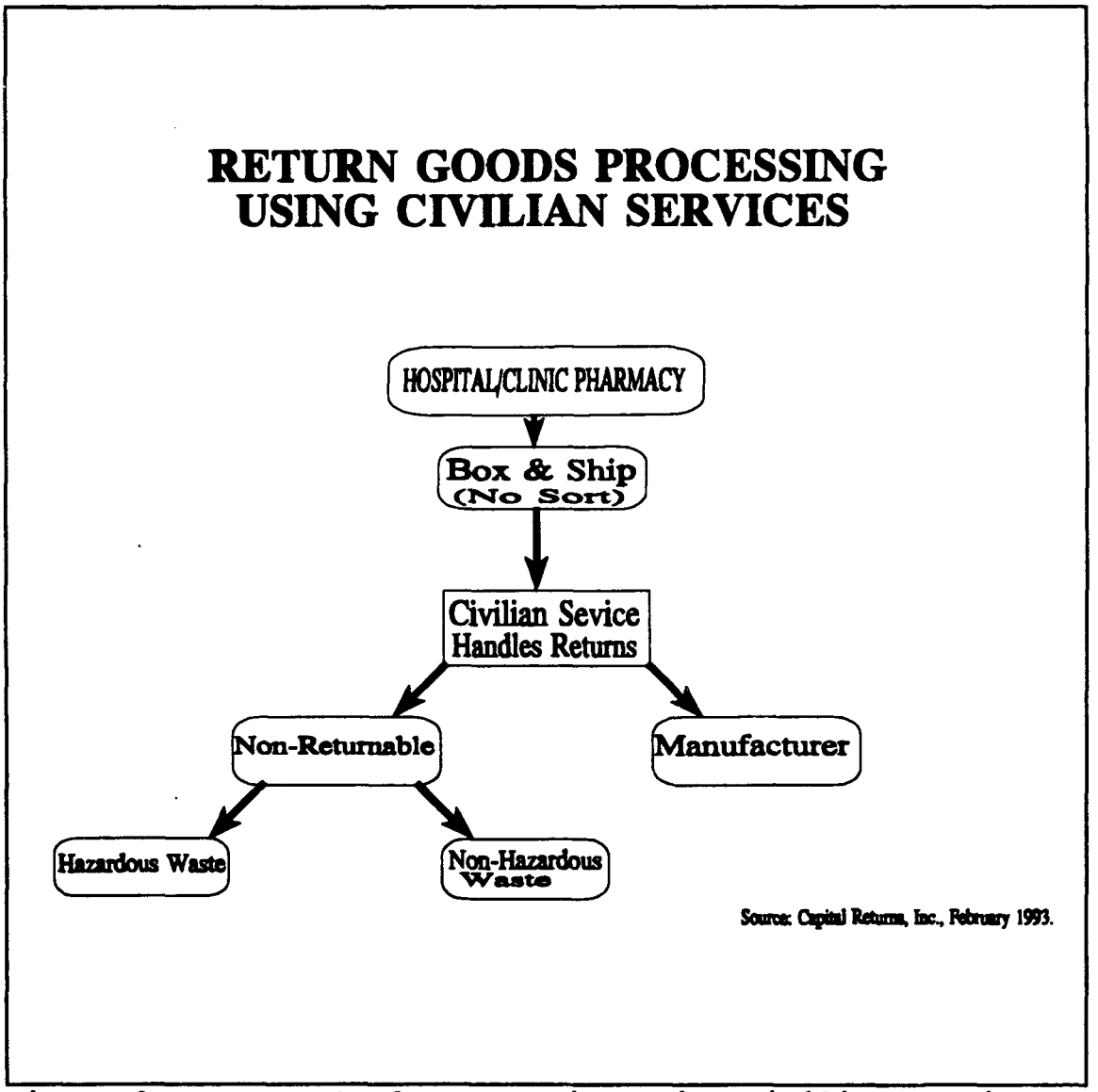


Figure 2: Return Goods Processing Using Civilian Services

F. ISSUES

There have been several issues that have emerged concerning expired pharmaceutical products.

1. Disposal

In the past, it was common to ignore the effects on the environment when disposing of pharmaceutical waste. Now, with the increase in sensitivity to the impact of all industrial waste on the environment, it becomes essential to consider how current disposal operations affect, and are perceived to affect, the air and water.

Enforcement of the Clean Air Act has resulted in the closure of many hospital incinerators, leaving pharmacies no internal method for the disposal of pharmaceutical waste. Additionally, many biomedical waste facilities are not permitted to accept pharmaceuticals, which are now designated as "special waste." "Special waste" must be incinerated at an approved site. (Capital Returns, Inc., 1993)

In addition to Federal regulations; state, local, Occupational Safety and Health Administration (OSHA), DoD, and other regulations must be followed for proper destruction of pharmaceutical products. With a continuing barrage of new regulatory requirements, significant changes must occur. The practice of pouring expired solutions down the drains, and/or flushing pills down the toilets, is finished.

2. Manufacturers' Policies

In a study of pharmaceutical returns, Joel Winterton found that:

> The pharmaceutical industry is currently under attack from a host of external influences to radically improve the manner in which returned goods are processed, accounted for, disposed of and handled.
>
> Historically, manufacturers and wholesalers have made significant efforts to automate their order entry systems and order fulfillment process. In addition, their physical distribution processes and management measurement systems are geared toward achieving high order fill rates, maximizing inventory turns and minimizing inventory carrying costs.
>
> Unfortunately, these distribution systems tend to be highly inefficient in the processing, handling, and accounting for products being moved in reverse fashion through the system. (Winterton, 1992)

This can create confusion and dissatisfaction for the hospitals and clinics who are attempting to return their expired goods. Additionally, manufacturers frequently change their return policies. Keeping a current database of the policies is extremely time and labor intensive.

3. Manufacturer Credits and Refunds

When expired pharmaceuticals are returned, the manufacturers may issue refunds, merchandise credit, or replacement products. Replacement products do not present problems with execution, but credits and refunds do.

The nature of the Navy accounting transaction cycle causes a problem with manufacturer credits. When requisitioning pharmaceuticals, an obligation (legal reservation of funds) is established and sent by the MTF's

comptroller to the appropriate Defense Accounting Office (DAO). After the DAO receives subsequent documentation from the comptroller that the pharmaceuticals have been received/accepted, the DAO pays the bill. If there are manufacturer credits from returns of expired goods, they sometimes continue to accrue. Follow-on requisitions cannot be processed using the offsetting credits to reduce the amount of the obligation. The full purchase price must be obligated by the MTF. An ensuing bill from the manufacturer will then be paid by the DAO. Due to this accounting restriction, some MTFs have had to request that the manufacturer send them a check in the amount of their accumulated credits.

Title 31, Section 3302 of the United States Code states: "... an official or agent of the Government receiving money for the Government from any source shall deposit the money in the Treasury as soon as practicable...." (31 U.S.C. 3302) Additionally, the Navy Comptroller Manual requires that proceeds from the sales of DoD excess, scrap, and surplus personal property be deposited promptly to the U.S. Treasury account. Returning expired pharmaceuticals for refunds (cash or checks) can be considered selling scrap or surplus DoD property. Depositing those proceeds in the Treasury, rather than hospital/clinic accounts, helps the Treasury's general fund. However, the regulations as written do not provide an incentive for the MTFs to pursue returning expired pharmaceuticals when they might expect refunds.

This chapter gave the backdrop in which the study was conducted. The next chapter will describe the methods used for executing the study, and the structure for the analysis.

III. METHODOLOGY

There were two distinct objectives to this study. The first was to quantify the dollar amount of savings that the Navy could expect if they return their expired pharmaceutical products. Another was to determine whether it is cost effective to contract civilian services for the return and disposal of these expired products.

A. DOLLAR AMOUNT OF NAVY RETURNS

To determine the dollar amount of expected savings, inferential methods in multiple linear regression were used. First, it was determined whether one, two, or more predictor variables were related to the dollar amount that pharmacies recouped when returning their expired pharmaceuticals, and how they were related. Then, after determining the best-fitting lines for the sample data set, those sample regression equations were used to make predictions about the population (CONUS hospitals/clinics). This yielded an estimate for the average dollars recouped per month. Multiplying by twelve gave an annual estimate for Navy returns.

To perform statistical inferences in multiple regression, it is necessary that the variables under consideration satisfy certain conditions. For multiple regression with k predictor variables, those conditions are as follows:

Assumptions for Multiple Regression Inferences

1. Population regression equation: For each set of values, $x_1, x_2, \ldots, x_k$, of the predictor variables, the mean of the corresponding population of y-values is $B_0 + B_1x_1 + \ldots + B_kx_k$. The equation

$$y = B_0 + B_1x_1 + \ldots + B_kx_k$$

is called the population regression equation.

2. Equal standard deviations: The standard deviation, σ, of the population of y-values corresponding to a particular set of values, $x_1, x_2, \ldots, x_k$, of the predictor variables is the same, regardless of $x_1, x_2, \ldots, x_k$.

3. Normality: For each set of values, $x_1, x_2, \ldots, x_k$, of the predictor variables, the corresponding population of y-values is normally distributed.

So, Assumptions 1, 2, and 3 require that there exist constants, $B_0, B_1, \ldots, B_k$, and σ, such that for each set of values, $x_1, x_2, \ldots, x_k$, of the predictor variables, the corresponding population of y-values is normally distributed with mean $B_0 + B_1x_1 + \ldots + B_kx_k$ and standard deviation σ. These assumptions are often referred to as the multiple regression model. (Weiss, 1991)

To interpret the coefficients, $B_1, B_2, \ldots, B_k$, the coefficient, B_j, of the predictor variable, x_j, represents the change in the mean of the population of y-values for every increase in x_j by one unit, with all other predictor variables held fixed. (Weiss, 1991)

When a sample regression equation is determined, $\hat{y} = b_0 + b_1x_1 + \ldots + b_kx_k$, what is obtained is the best estimate, based on the sample data, of the (unknown) population regression equation, $y = B_0 + B_1x_1 + \ldots + B_kx_k$. In fact, for each j, b_j is the best estimate of B_j. (Weiss, 1991)

The predictor variables considered for the sample regression equation were the following:

- Admissions - Comprised of the total number of patients admitted for treatment or observation in the hospital (including newborns). Patients transferred from one facility to another are included in the count of admissions at both facilities. The admission of a newborn occurs at the time of birth. Numbers are for the period: FY 91, FY 92, and the first six months of FY 93.

  Source: Headquarters Inpatient System (HIPS).

- Average Daily Patient Load (ADPL) - Average number of patients occupying beds per day in a fixed inpatient Medical Treatment Facility (MTF) during a given time period:

  $$\frac{\text{total \# of occupied bed days (including bassinet days)}}{\text{number of days in report period}}$$

  Source: Derived from the HIPS based on FY data.

- Average Length of Stay (ALOS) - The average number of occupied bed days for patients (including newborns) admitted to a facility during a given time period:

  $$\frac{\text{total \# of occupied bed days for patients admitted}}{\text{number of admissions during period}}$$

  Source: Derived from the HIPS based on FY data.

- Catchment Area Population Estimates - Defense Medical and Information System (DMIS) counts are developed for the Office of the Assistant Secretary of Defense (Health Affairs) OASD(HA) under contract by Vector Research, Inc. The FY 92 data are projections from the RAPS model and are based primarily on counts of eligible beneficiaries enrolled in the Defense Enrollment Eligibility Reporting System (DEERS) as of 30 September 1991, the total service POM active duty endstrength projections, projected estimates of retirees by age groups obtained from OASD(HA)/HB&P, and growth rate of paid retirees as reported by the office of the DoD Actuary, adjusted for regional migration patterns computed from historical DEERS data. The data presented are obtained for observations at a single point in time, and, therefore, may not take into account the user's knowledge of recent shifts or movement of personnel. DMIS provides population estimates by beneficiary category, sponsoring service, sex, and age

group. The DMIS methodology makes several assumptions regarding beneficiary population location which are significant to Navy and Marine Corps. Sponsors are assigned to catchment areas based on the five digit zip code of work assignment contained in the DEERS database. If the zip code of work assignment is a Fleet Post Office (FPO) zip code, active duty personnel were assigned to catchment areas based on the location of the Unit Identification Code (UIC). Dependents of active duty were allocated to catchment areas based on the five digit zip code of their residence. The population module now accounts for base realignments and closures (BRAC). User selection of project years automatically incorporates the series of modifications corresponding to the BRAC changes for the years prior to and including the selected projection year. Output reports are marked with the currently implemented version of BRAC.

Source: Defense Medical and Information System.

- Occupied bed days - Represents the count of total days that patients occupy beds (including bassinets and Alcohol Rehabilitation) in MTFs that have beds assigned for patient use. The total count includes each day a patient occupies a bed at the census-taking hour (usually midnight). Days on pass, or liberty not in excess of 72 hours, newborn infant days while occupying a bassinet, and days in the labor or delivery room are also counted as occupied bed days. In addition, an occupied bed day is credited whenever a patient is admitted and discharged on the same day, such as from same day surgery. However, days during which patients on an MTF census are subsisting out, on convalescent leave, on authorized or unauthorized leave in excess of 72 hours, or in a transient status are not counted as occupied bed days. Numbers are for the period: FY 91, FY 92, and the first six months of FY 93.

  Source: HIPS.

- Operating Beds - Accommodation in a functioning MTF that is currently set up and ready in all respects for patient care. Includes supporting space, equipment, medical material, ancillary support services, and staff to operate under normal circumstances. Excluded are transient patients' beds, incubators, bassinets, labor beds, and recovery beds.

  Source: MEDCOM 311 RT (Bed Capacity and Bed Status Report) and the Walter Reed AMC auditing department.

- Outpatient Visits - Reported for each outpatient who presents himself/herself at an MTF for medical advice, diagnosis, treatment, or complete physical examination, or who is treated or observed in his home or quarters by medical personnel. Numbers are for the period: FY 91, FY 92, and the first six months of FY 93.

  Source: Headquarters Outpatient System (HOPS).

- Pharmaceutical Funds - Money obligated during FY 91, FY 92, and the first six months of FY 93 for consumable supplies, i.e., pharmaceuticals.

  Source: Naval Standard Claimant Accounting System and the Walter Reed Army Medical Center (AMC) pharmacy.

- Pharmacy Units - The weighted number of pharmacy units for inpatients and outpatients. The number for outpatient pharmacy units includes all prescriptions and other issues which are provided to ambulatory patients, or are issued to clinics, services, etc. which support ambulatory patients. The number for inpatient pharmacy units includes all pharmacy processes which provide drug products to support inpatient prescriptions, unit dose distribution, intravenous admixture, or other systems. Numbers are for the period: FY 91, FY 92, and the first six months of FY 93.

  Source: Worldwide Outpatient Reporting System (WORS).

The y-value, or dependent variable, of the regression equation is defined as:

- Recoupment - Average dollar amount per month of refunds, merchandise credit, or replacement products that the MTF has received, or can expect to receive, from manufacturers.

  Source: For actual amounts received, individual Military Treatment Facilities.

After determining the utility of the sample regression equations, and the utility of the individual predictor variables, there was a need to predict the amount of recoupment the hospitals/clinics could expect. To determine the predicted values of recoupment for the hospitals/clinics,

their predictor-variable values were substituted into the sample regression equation:

$$\hat{y} = b_0 + b_1 x_{1p} + \ldots + b_k x_{kp}$$

The resultant predicted values were then summed up to achieve final estimates. Those estimates were averaged to produce the dollar amount per month that the Navy could expect to recoup if they return their expired pharmaceuticals.

The hospital/clinics used for this study were BUMED MTFs located in the continental United States. A summary of those facilities is in Table I. The method of data collection was via individual pharmacy records, civilian return company records, and Navy Health Care databases. Returned goods recoupment data was obtained on four Navy MTFs. Those MTFs were selected by the Navy Surgeon General's Specialty Advisor for Pharmacy. They are a representative sample of the entire continental United States Navy health care system, and each facility had been returning their expired pharmaceuticals.

One non-Navy MTF utilized during the study was Walter Reed Army Medical Center (AMC), see Table I. Due to its similarity with Navy facilities, it was chosen as an additional data source, since Navy data was scarce. Because of the limitations already noted in Chapter I, no civilian facilities were used.

Table I: PROFILE OF CONUS MTFs

FACILITY NAME	TYPE OF FACILITY	NUMBER OF BEDS FY-93
Bethesda	Major Teaching Hospital	342
Oakland		225
Portsmouth, VA		446
San Diego		393
Camp Pendleton	Family Practice Hospital	120
Charleston		181
Jacksonville		131
Pensacola		104
Bremerton	98+ Bed Hospital	109
Camp Lejeune		176
Great Lakes		136
Long Beach		113
Orlando		140
Millington	50-98 Bed Hospital	66
Newport		59
Beaufort	Below 50 Beds Hospital	49
Cherry Point		40
Corpus Christi		42
Groton		25
Lemoore		37
Oak Harbor		25
Patuxent River		20
Twentynine Palms		29
Annapolis	Clinic	None
Key West		
New Orleans		
Philadelphia		
Port Hueneme		
Portsmouth, NH		
Quantico		
Seattle		
* Walter Reed AMC	Major Teaching Hospital	570
* U.S. Army Facility		

B. COST EFFECTIVENESS OF CONTRACTING CIVILIAN SERVICES

To determine whether it is cost effective to contract civilian services for the return and disposal of expired Navy pharmaceuticals, an analysis of the following alternatives was done.

1. Navy MTFs do not return expired pharmaceuticals.
2. Individual Navy MTFs return their own expired pharmaceuticals.
3. The Navy establishes centralized locations within the Navy to process expired pharmaceuticals.
4. The Navy contracts civilian services for the return and disposal of expired pharmaceuticals.

A detailed analysis using actual costs was not possible. Since most Naval commands do not allocate all costs to final outputs, accurate and meaningful cost data was not available. Alternatively, advantages and disadvantages of each choice were discussed, and compared with the others.

This chapter outlined the methods and structure of the analysis that was used when conducting this study. The next chapter will present the data, and provide the analysis.

IV. DATA AND ANALYSIS

A. DOLLAR AMOUNT OF NAVY RETURNS

The use of multiple linear regression techniques to analyze the Navy MTFs' recoupment behavior provided a basis for analysis. This section will introduce the data and steps used in determining the sample regression equations. The sample regression equations will then be used to make predictions about the Navy's population of CONUS hospitals/clinics.

1. Sample Data Set

The sample data set, used when determining the sample regression equations, is displayed in Table II. The entire population data set is in Appendix C.

Table II: SAMPLE DATA SET

FACILITY	RECOUP-MENT	CATCH-MENT POP	BED #	ADMIS-SIONS	OCC BED DAYS	AVERAGE LOS
BETHESDA	$12,072	84,158	342	42,577	238,564	5.61
CAMP PENDLE-TON	$11,987	103,092	120	20,277	87,038	4.29
GROTON	$3,750	45,321	25	5,481	12,951	2.36
WALTER REED AMC	$74,986	274,077	789	66,293	577,365	8.71
KINGS BAY	$4,379	N/A	N/A	N/A	N/A	N/A

Table II (Continued): SAMPLE DATA SET

FACILITY	ADPL	PHARM UNITS	OUT PT VISITS	PHARM FUNDS
BETHESDA	261.58	4,420,637	1,450,099	$39,801,684
CAMP PENDLE-TON	95.44	2,089,074	1,289,171	$13,665,875
GROTON	14.20	763,189	572,920	$7,277,443
WALTER REED AMC	632.38	4,586,291	1,694,392	$44,550,000
KINGS BAY	N/A	341,340	221,045	$2,626,490

The Walter Reed numbers for admissions and occupied bed days are thirty-month estimates, based on twelve month data from FY 92. Similarly, the Walter Reed number for outpatient visits is a thirty-month estimate, based on twenty-four month data from FY 91 and FY 92. This was done due to the inability to get complete data, and so those particular numbers would be comparable with the remaining data. Because of demonstrated consistency from year-to-year, this was considered reasonable.

The Walter Reed, Camp Pendleton, and Kings Bay recoupment amounts are the result of expired goods from both pharmacy items, and items acquired from sources outside the pharmacy (ships, other MTFs, and supply inventory control points). The Bethesda and Groton recoupment amounts are the result of expired goods from only pharmacy items.

To be of benefit, regression analysis must meet certain criteria. First, a reasonable degree of causality must exist that meets economic and professional judgement. Independent predictor variables used should have some reasonable relationship with the dependent variable, Recoupment, the average dollars recouped per month. Scattergraphs and simple linear regressions for each predictor variable are contained in Appendix D. These results show that there is a positive correlation between the independent predictor variables and Recoupment. Analyzing the sample data set with simple linear regression, it can be said that Catchment Area Population is the best predictor of Recoupment, and the equation is:

RECOUPMENT = - 15354 + 0.324 CATCHMENT

As discussed below, using a single predictor variable may not always be appropriate, and multiple variables should be analyzed.

a. Catchment Area Population Estimates

It can be expected that the larger the catchment area population, the greater the amount of patients that will receive service provided by the MTF, and the greater the possibility for recoupment. However, catchment area populations may not be homogeneous because demographics are different throughout the country. One area may include a large percent of retirees needing more pharmaceutical

services, whereas another area may have a younger active duty population requiring fewer services. In addition, Naval Medical Clinics Commands do not have designated catchment area populations.

b. Number of Beds

Presumably, the more beds a hospital has, the more care it provides, and the greater the recoupment. There still may be variables, such as whether or not the beds are filled, what patient types are occupying those beds, and there is the fact that clinics do not have beds.

c. Admissions

Generally, the more patients that are admitted into a MTF, the more services that are required, and the greater the recoupment. However, the types of patients admitted will affect the amount of pharmacy services required.

d. Occupied Bed Days

The greater the amount of beds that are filled and the longer the beds are filled, the more services can be expected, and the greater the recoupment. Again, it depends on the types of patients occupying those beds, and their requirements.

e. ALOS and ADPL

Both of these are based on other predictor variables (admissions, occupied bed days), and should be highly correlated with those variables.

f. Pharmacy Units

As the amount of weighted pharmacy units increases, the amount of recoupment should increase. Weighted procedures, which are used for the pharmacy, reflect the relative complexity and costliness of the services, not the pharmaceuticals. It is possible to have a complex procedure for an inexpensive item.

g. Outpatient Visits

With more outpatient visits, pharmacy services could be expected to increase, and recoupment should follow. But, the outpatients might require inexpensive pharmaceuticals, or possibly none at all.

h. Pharmacy Funds

One would expect that the more a pharmacy spends on pharmaceuticals, the greater the recoupment. Each pharmacy is issued an operating budget. The management of that budget, and the management of the pharmacy inventory, are factors that can influence the amount of recoupment.

2. Multiple Linear Regression Analysis

Multiple linear regressions were performed for the following situations:

- Using only the sample hospitals (Walter Reed, Bethesda, Camp Pendleton, and Groton)
- Using the hospitals, and the sample clinic (Walter Reed, Bethesda, Camp Pendleton, Groton and Kings Bay)

The best of the results, for all the possible combinations, are reported in Appendix E. A constant observation was that the Walter Reed data had a large influence in obtaining the regression equations.

While attempting to use the best multiple regression equation to predict the amount of expected recoupment, by inserting the population data into the equation, two obstacles were encountered.

1. Some individual hospital predictions came up negative, and others did not seem reasonable, see Table III.
2. Because the regression equation was derived from the situation that examined only the sample data from the hospitals, the regression equation involved Occupied Bed Days. Therefore, since clinics do not have Occupied Bed Days, it could not be used directly to make predictions for the clinics.

Although the results in Table III may not have been what was expected for each individual hospital, the "Total Value of Recoupment Estimate (V)," **was** expected. In a study of returned goods done on wholesale distribution centers, the data showed returned goods constitute approximately 3.75% of the average wholesaler's gross sales (Benfield, 1993). Since MTF pharmacies are end users, their percentage should be less than 3.75%, possibly one or two percent. The Total Value of Recoupment Estimate in Table III equates to one percent of the total monthly amount of the hospital pharmacy funds expended; which is in the expected range.

Table IV: RECOUPMENT ESTIMATES USING REGRESSION EQUATION

Regression Equation	RECOUPMENT = 9646 + 0.200 OCC BED DAYS - 0.00113 PHARMACY FUNDS		
HOSPITAL	**OCC BED DAYS**	**PHARMACY FUNDS**	**RECOUPMENT ESTIMATE**
BEAUFORT	26,410	$5,244,011	$9,002
BETHESDA	238,564	$39,801,684	$12,383
BREMERTON	55,030	$10,219,829	$9,104
CAMP LEJEUNE	87,283	$13,979,389	$11,306
CAMP PENDLETON	87,038	$13,665,875	$11,611
CHARLESTON	87,451	$16,071,320	$8,976
CHERRY POINT	14,816	$4,646,899	$7,358
CORPUS CHRISTI	26,980	$7,004,585	$7,127
GREAT LAKES	67,318	$11,700,403	$9,888
GROTON	12,951	$7,277,443	$4,013
JACKSONVILLE	66,504	$25,404,966	-$5,761
LEMOORE	7,808	$3,611,752	$7,126
LONG BEACH	69,293	$11,482,808	$10,529
MILLINGTON	27,661	$8,802,869	$5,231
NEWPORT	32,589	$6,845,467	$8,428
OAK HARBOR	12,338	$3,851,387	$7,762
OAKLAND	135,968	$28,235,566	$4,933
ORLANDO	58,545	$18,492,954	$458
PATUXENT RIVER	5,935	$2,863,899	$7,597
PENSACOLA	57,108	$19,913,887	-$1,435
PORTSMOUTH, VA	269,627	$67,653,899	-$12,878
SAN DIEGO	318,204	$62,913,269	$2,195
TWENTYNINE PALMS	11,620	$2,380,477	$9,280
TOTAL VALUE OF RECOUPMENT ESTIMATE (V)			$134,233

Because of the noted difficulties, it was decided to use a **set** of regression equations for predicting:

Regressions = {$Regression_1$, $Regression_2$, ... $Regression_5$}

Also, additional regressions were obtained, after removing the influential Walter Reed data. The best of those results are reported in Appendix F.

From all of the regressions that were done, the best five were selected based on their statistical significance. Those regression equations, and their corresponding Total Values of Recoupment Estimates, are summarized in Table IV.

Table V: REGRESSION EQUATIONS AND RECOUPMENT VALUES

Regression Equations	**Data Source Used For Regression**	**Total Value of Recoupment Estimate (V)**
RECOUPMENT = 9646 + 0.200 OCC BED DAYS - 0.00113 PHARMACY FUNDS	Walter Reed, Bethesda, Camp Pendleton, Groton	$134,233
RECOUPMENT = 9874 + 154 BEDS - 0.00127 PHARMACY FUNDS	Walter Reed, Bethesda, Camp Pendleton, Groton	$192,412
RECOUPMENT = 2906 - 0.000940 PHARMACY FUNDS + 0.0105 PHARMACY UNITS	Bethesda, Camp Pendleton, Groton, Kings Bay	$175,556
RECOUPMENT = -15354 + 0.324 CATCHMENT AREA POPULATION	Walter Reed, Bethesda, Camp Pendleton, Groton	$243,962
RECOUPMENT = 11120 + 0.184 OCC BED DAYS - 0.00927 PHARMACY UNITS	Walter Reed, Bethesda, Camp Pendleton, Groton	$161,384

The resulting Total Values of Recoupment Estimates continued to be reasonable, so their mean was used to predict the estimated total monthly recoupment for the hospitals. The set of Total Values of Recoupment Estimates is displayed in Figure 3, along with a reference value, which is 1.5% of total monthly amount of hospital pharmacy funds expended.

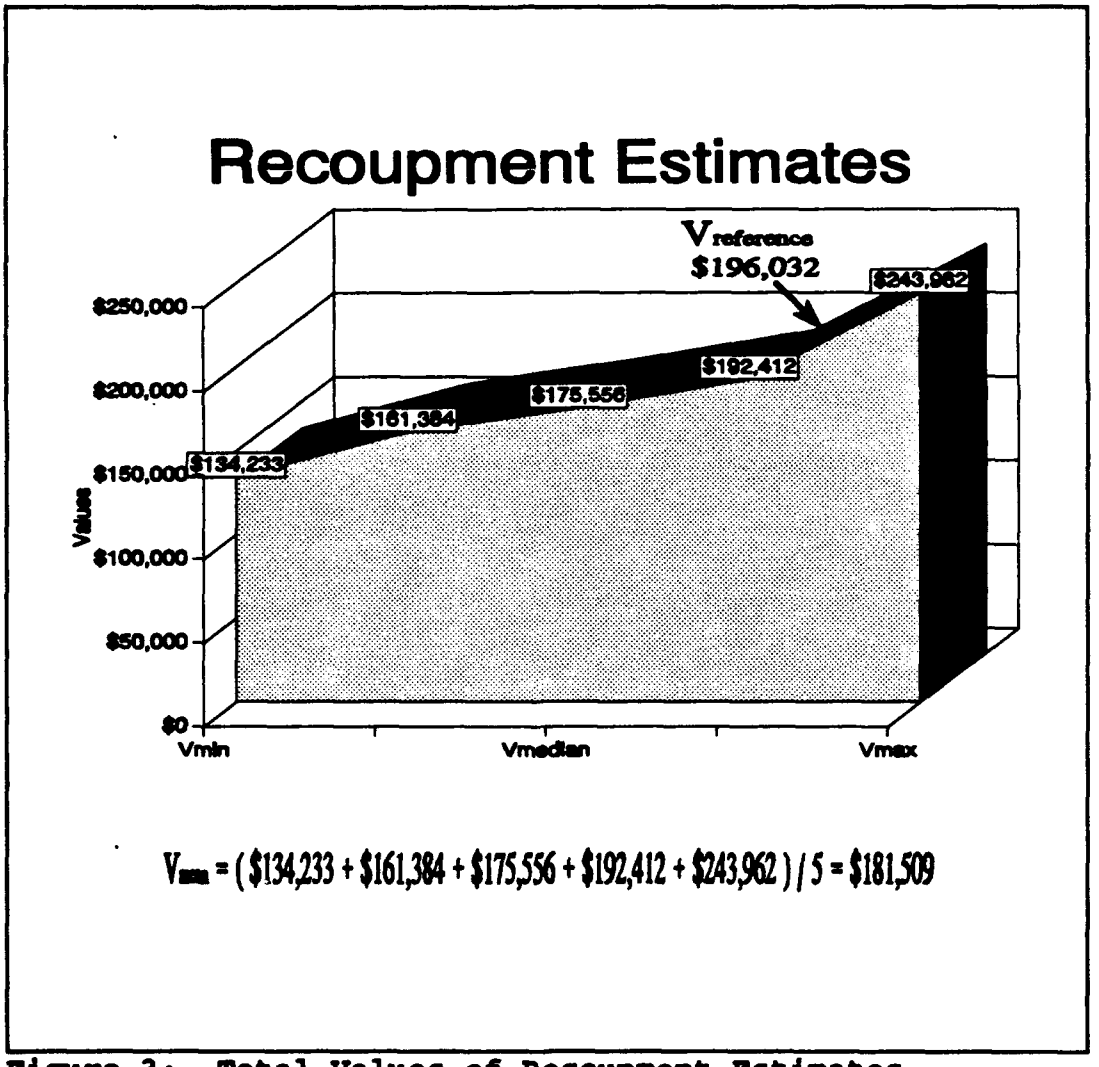


Figure 3: Total Values of Recoupment Estimates

The mean of the Total Values of Recoupment Estimates was $181,509. Dividing the mean by the aggregate average monthly amount of hospital pharmacy funds expended yielded:

$181,509 / $13,068,821 = 1.38887%

That percentage of monthly recoupment for hospitals was then applied to the aggregate monthly amount of pharmacy funds expended at the clinics to get the total clinics' estimate.

$907,607 * 1.38887% = $12,605

Finally, summing the mean total for the hospitals with the total clinics' estimate gave the complete estimate of expected recoupment per month.

$181,509 + $12,605 = $194,114 EXPECTED RECOUPMENT PER MONTH

Multiplying by twelve months gave the final annual estimate.

$194,114 PER MONTH * 12 MONTHS = $2,329,368 PER YEAR

The dollar amount that the Navy can expect to recoup through the return of their expired pharmaceuticals at CONUS MTFs is **$2,329,368 PER YEAR**.

B. COST EFFECTIVENESS OF CONTRACTING CIVILIAN SERVICES

To reach a conclusion as to the best, or most cost effective, method that should be used by the Navy when managing expired pharmaceuticals, four situations were analyzed and compared.

1. Navy MTFs Do Not Return Expired Pharmaceuticals

For most Navy MTFs this is the status quo. Accumulation of expired pharmaceuticals must be handled by the MTF personnel.

a. Disadvantages

(1) Disposal. As already mentioned in Chapter II, disposal of pharmaceutical waste has become increasingly more difficult. If the Navy processes their expired pharmaceuticals with internal assets, then each location where this is done would be considered a waste generator, and have to be licensed by the Environmental Protection Agency. All destructible items would have to be lab packed and manifested. The waste would have to be categorized and segregated by hazardous and non-hazardous. To comply with Food and Drug Administration regulations, tracking of the waste must be done. Also, regulations require a special provision of safety at facilities that handle hazardous waste, along with training programs, special twenty-four hour responders, etc. (Lehmann, 1993)

Outdated pharmaceuticals are listed as "special waste," not to be confused with red bag waste. Special waste must be incinerated at an approved site. The closure of hospital incinerators, and new regulations, have forced MTFs to contract for disposal.

> While contracted disposal is often more expensive than on-site treatment, it reduces the hospital's risk of sinking a large capital expense into a technology that may become obsolete by rapidly developing regulations and technology. Contracted disposal can also offer flexibility when waste quantities fluctuate greatly....
>
> Contracted disposal does place some increased risk on a facility in terms of accountability or responsibility for the waste. It is the responsibility of the generating facility to ensure that the ... waste contractor is running a legitimate operation which is in compliance of all applicable laws.... Legitimate ... waste contractors often offer tours of their facilities and upon completion of these tours they issue certificates to their clients. Through this process, a hospital can document that a reasonable effort was made to check the legitimacy of the contractor. While this may not relieve the hospital of ultimate responsibility for the waste, it does show the intent of the hospital to comply with applicable regulations. (Hamilton, 1992)

No matter who handles the disposal of pharmaceutical waste, there are risks for the Navy. There are social risks that are associated with the mismanagement of the disposal of pharmaceutical waste. These are mainly the poor public relations that are caused when mismanagement occurs, or even if there is a perception that there is mismanagement of pharmaceutical waste. When poor public relations are used to fuel negative feelings toward the Navy, this social risk then becomes a political risk for the Navy. (Hamilton, 1992)

> Legal risks include the violation of Federal, State, or local environmental regulations, occupational health and

> safety regulations, and legal disputes associated with waste disposal contracts. ... the wide range of locations and platforms from which the Navy conducts healthcare increases the legal risks associated with ... waste management. (Hamilton, 1992)

Through reductions in the volume of pharmaceutical waste, the Navy can minimize the risks and costs associated with the management of that waste. Pharmaceutical waste minimization can be achieved through source reduction and/or manufacturer returns.

(2) Loss of revenue. By not participating in an expired pharmaceutical return program, MTFs are foregoing the opportunity to receive manufacturer refunds. As seen earlier in this chapter, the loss of revenue can be significant. In these austere times, this is an opportunity cost that the Navy cannot continue to forfeit.

b. Advantage

(1) Increased incentive to minimize. The Navy should always have the incentive to minimize the amount of expired pharmaceuticals. Whether it is a disposal cost, or a cost to return, there will always be a cost attached to expired pharmaceuticals. This choice may give an added incentive to the Navy to decrease their expired pharmaceuticals, particularly considering the revenues foregone.

Currently, BUMED is in the process of switching all their MTFs to "Prime Vendor." This is scheduled to be

completed in FY 94. Prime Vendor has shown the ability to reduce the number of pharmaceutical products stored in MTFs. A reduction of inventory will directly decrease the amount of expired pharmaceuticals.

Newly developed inventory management systems, such as bar coding, can provide timely and accurate inventory data, help reduce replenishment errors, and help with tracking expiration dates and usage rates. As new technology evolves, and is incorporated, overordering errors and lack of stock rotation will diminish. As a result, pharmaceutical expirations previously caused by inventory management problems should decrease.

"In FY 88, the military services entered into an agreement with the Food and Drug Administration (FDA) to have expired pharmaceuticals potency tested and, if the results showed 93 percent or higher of original potency, the pharmaceuticals would be extended up to two additional years (Walters, 1993)." This Shelf-Life Extension Program, outlined in BUMEDINST 6710.62A, has the potential to decrease the amount of expired pharmaceuticals. However, its usefulness for hospitals/clinics is limited by implementation guidelines. The value of items to be tested must be $5,000 or more per National Stock Number (NSN); this may be difficult to meet. Additionally, the detailed requests for extension are not always acted on with enough lead time so replacement products can be requisitioned in time.

A drawback is that all programs that have potential to reduce the amount of expired pharmaceuticals cost money. The cost of each Shelf-Life Extension Program test is between $27,000 and $52,000. New technology inventory systems require a capital expenditure and training. The prime vendor charges a fee for their inventory management and distribution services.

2. Navy MTFs Return Their Own Expired Pharmaceuticals

This situation calls for each MTF to perform the entire return process with internal assets.

a. Disadvantages

(1) Legality. The Small Business Administration and Investment Act states:

> The essence of the American economic system of private enterprise is free competition. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and judgement be assured. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this Nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is the declared policy of the Congress that the Government should aid, counsel, assist, and protect insofar as is possible the interests of small-business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts for supplies and services for the Government be placed with small-business enterprises, and to maintain and strengthen the overall economy of the Nation. (Public Law 163, Chapter 282, Title II, Sec. 202)

The Navy is not in the business of returning expired pharmaceuticals, and is charged by Congress to protect

the interests of small-business concerns. It follows that the Navy would be perceived as wrong in pursuing an internal pharmaceutical returns program.

(2) Time and labor. As already spelled out in Chapter II, the pursuit of pharmaceutical returns is highly time and labor intensive. Tracking of manufacturer policies and tracking the returns themselves can be a full-time job. There are also the sorting, administrative paperwork, and disposal functions. Experience has shown that at small MTFs a satisfactory job can be done using two people five days each quarter. Large MTFs would require more worker-days.

Currently, some small facilities have the personnel available to perform the returns; but, even now, large facilities do not have sufficient personnel. In the future, with declining budgets, personnel manning can be expected to decrease, and the opportunity for returns to be done internally may be lost at **all** facilities.

(3) Credits and refunds. An issue that has arisen since military facilities have been returning expired pharmaceuticals is how to handle the manufacturer credits and refunds. As introduced in Chapter II, credits accumulate due to the DoD accounting procedures, and refunds must be deposited in a U.S. Treasury account, vice the MTF's account.

With the arrival of Prime Vendor, the credits problem can be alleviated by notifying all product

manufacturers to send all credit memos for the return of all creditable items to the prime vendor. The prime vendor can then act as a clearing house for the processing of all credit return memos from the various product manufacturers.

The refund issue can be dealt with by introducing and gaining approval for an exception to Title 31, Section 3302 of the United States Code. An exception can be written similarly to the law that pertains to collections from third-party payers, where the MTF collects from a third-party payer (insurance, medical service, or health plan) the reasonable costs of health care services incurred by the United States on behalf of a covered beneficiary. It states, "Amounts collected under this section from a third-party payer for the costs of health care services provided at a facility of the uniformed services shall be credited to the appropriation supporting the maintenance and operation of the facility."(10 U.S.C. 1095) Allowing the MTFs to retain the refunds would give them added incentive to pursue returning expired pharmaceuticals, even when they expect refunds.

(4) Disposal. The problems with pharmaceutical disposal have been discussed in the previous choice, and remain the same. Even if the Navy MTFs return some expired pharmaceuticals, there will still be a percentage that require disposal.

b. Advantages

(1) The Navy receives compensation. Instead of foregoing the opportunity provided by the manufacturers, in this case the Navy endeavors to recover the potential revenues of their expired pharmaceuticals. However, there is the risk that the MTFs will not secure all possible revenues. Failure to acquire and comply with all manufacturer policies, along with not being timely, may result in reduced returns.

(2) Increased incentive to minimize. This has already been discussed, and remains the same.

3. The Navy Establishes Centralized Locations Within The Navy To Process Expired Pharmaceuticals

This alternative examines the situation where the Navy starts up their own centralized program to return their expired pharmaceuticals. A program could be operated out of one location; or, two locations, one on the east coast and one on the west coast.

a. Disadvantages

(1) Start up costs. Either a new facility must be built, or an existing facility must be modified. Forklifts, tables, computers, and other property will be required. The facility must be manned, by personnel transferred or hired, and these personnel must be trained.

There will be a period of less than optimal performance as learning and data acquisition occurs. Some potential revenue will be lost during this period.

(2) Future needs. With the arrival of Prime Vendor, it is possible that the future amounts of expired Navy pharmaceuticals will not support a Navy-run facility. Therefore, it may not be cost effective to activate a facility that may be demanded for only two or three years.

(3) Legality. As discussed before, it may not be judged favorably, in the light of the Small Business Act, if the Navy creates a return business of their own.

(4) Disposal. The disposal problem has been discussed previously.

b. Advantages

(1) Economies of scale. By having centralized operations, the Navy can minimize the resources necessary to return their expired pharmaceuticals. Duplication of effort will be eliminated. Importantly, only one data base must be maintained, saving numerous work-hours. Also, there will be a single point of contact for the manufacturers, resulting in faster response and better service.

(2) Relieves MTFs. In this situation, the MTFs will just have to collect and ship their expired items. Their personnel can put more effort toward their regular duties.

(3) The Navy receives compensation. As with the previous choice, the Navy will attempt to recover the potential revenues of their expired pharmaceuticals. In this instance, the amount recovered should be greater due to increased efficiencies. Dedicated personnel, a more detailed and accurate data base, and better manufacturer relations will aid in the improvement.

(4) Allows monitoring. This alternative will allow centralized monitoring, and reporting, of the amount and status of each MTF's expired pharmaceuticals. It can be expected that the MTFs will strive to minimize their amounts, possibly encouraged by their superiors. This may become a disadvantage, if MTFs, fearing repercussions, fail to ship expired goods, resulting in lost revenue.

4. The Navy Contracts Civilian Services For The Return And Disposal Of Expired Pharmaceuticals

The Navy institutes a policy that all MTFs will return their expired pharmaceuticals through the use of civilian services. A contract could be written so one civilian return service handles all Navy returns, or each MTF could contract individually with their choice of civilian return service.

a. Disadvantages

(1) Costs of service/disposal. Civilian companies charge a fee for their service of returning expired pharmaceuticals. Depending on the contract, the fee charged

might be by weight of the goods processed, by a set percentage of the dollar amount returned, or by another method. Anyhow, the Navy does not receive the entire amount that they could realize if they had done the returns themselves.

Similarly, the civilian services charge a fee to dispose of pharmaceutical waste. Although most places in the Navy already pay for disposal of hazardous and non-hazardous waste, the fees charged by the civilian return services **could** be slightly higher.

There is also the risk that the Navy will pay more in disposal fees than the revenues that can be generated from their expired pharmaceuticals. To many of hazardous, non-returnable drugs, and not enough of revenue producing returnable drugs, could cause this situation. Figure 4 attempts to illustrate this effect.

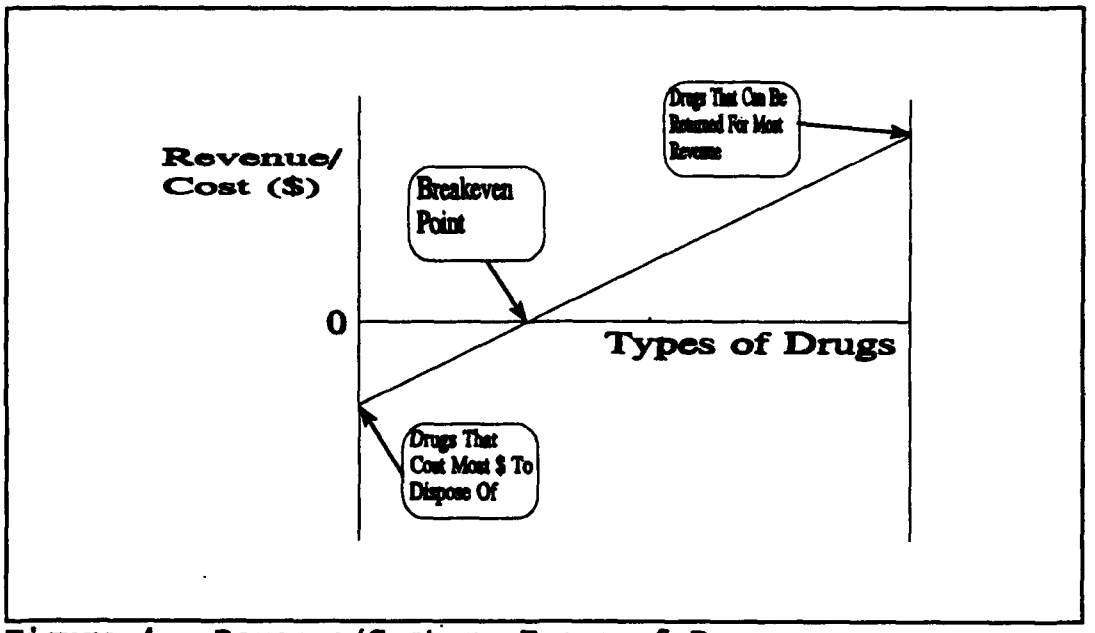


Figure 4: Revenue/Cost vs Types of Drugs

(2) Contracting and monitoring. Before awarding a contract in the Navy, bids must be solicited and evaluated. Post-award involves contract administration and monitoring. These activities, which can take considerable time and effort, are unique to this alternative.

b. Advantages

(1) Easy. Except for contracting/monitoring, this alternative is easy on the MTFs. All that is required by the MTFs is to box and ship/deliver all expired pharmaceuticals to the civilian return service. The civilian return service handles all aspects of the returns, and sends inventory, tracking, and destruction reports to the MTFs.

(2) Maximum returns. Using civilian return services, the Navy can expect maximum returns. The civilian services have been in business for a length of time, and, through their learning curve, and access to necessary information, should be able to optimize the amount of returns.

(3) Disposal. Allowing the civilian services to dispose of the outdated pharmaceutical waste will lessen the work for the Navy, and help ensure responsible destruction. Also, special waste handling procedures and training will not have to be implemented.

The Navy needs a new strategy to handle expired pharmaceuticals. They can continue with their current status, but there is an opportunity to increase revenues through the

return of **all** expired goods, and this opportunity should not be missed.

Of the two choices where the Navy uses internal assets to process returns, clearly using centralized locations is superior. Less resources are involved, and more revenues can be expected.

That leads to the decision between using centralized Navy facilities, or contracting civilian services, to do the returns. The Navy should not venture into an enterprise that may not be legal, nor cost effective. Although there are costs involved with contracting civilian services for the returns and disposal, those costs will be more than covered by the revenues generated by the returns. Therefore, the Navy's strategy should embrace the alternative of contracting civilian services for the return and disposal of their expired pharmaceuticals. How to implement that selection is beyond the scope of this thesis.

This chapter presented the data and analysis. The next chapter will provide a summary of this study, and recommendations.

V. SUMMARY AND RECOMMENDATIONS

A. SUMMARY

This study was conducted to determine: (1) the dollar amount of savings that the Navy could expect if they return their expired pharmaceutical products, and (2) whether it is cost effective to contract civilian services for the return and disposal of these expired products.

The first chapter introduced the problem. It emphasized that, as military budgets continue to decline, military health care personnel must exploit new management methods in an effort to maximize efficiency and cost containment. A proposed potential source of additional revenue was the return of outdated pharmaceutical products to drug manufacturers for refund, credit, or replacement products.

The review of literature presented background information pertaining to the return and disposal of expired pharmaceuticals. It showed that the dramatic rise in pharmaceutical prices, and the returned goods opportunity provided by the manufacturers, give a focus for cost containment efforts. A discussion of where the Navy's expired pharmaceuticals originate, and the various methods of managing expired pharmaceuticals, was done. Additionally, three important concerns were introduced: pharmaceutical disposal,

changing manufacturers' policies, and the handling of manufacturer credits and refunds.

Inferential methods in linear regression were used to quantify the dollar amount of savings that the Navy could expect if they return their expired pharmaceuticals. The scope of the study was limited to the Navy's CONUS MTF's. Difficulties were encountered due to scarcity of data. Analysis found that sample data from one hospital had significant influence when obtaining the regression equations. Results from the regressions lead to some individual hospital estimates that were negative, and some that were not reasonable. Additionally, estimates for the Navy clinics could not be made directly using the regression equations. Ultimately, an average of the aggregate values of recoupment for the hospitals, given by the five top linear regression equations, was used to predict over two million dollars per year as the total expected recoupment at CONUS MTFs.

Finally, the advantages and disadvantages of four possible methods to manage the Navy's expired pharmaceuticals were discussed. A comparison of the four yielded the conclusion that the best, or most cost effective, method is to contract civilian services for the return and disposal of the Navy's expired pharmaceuticals.

B. RECOMMENDATIONS

Based on the findings of this study, the following recommendations have been made:

- The Navy should initiate a universal program for the return of it's expired pharmaceuticals.
- The Navy should contract civilian services for the return and disposal of their expired pharmaceuticals.
- Contracts should be written to ensure manufacturer credits are sent to the MTFs' prime vendor.
- The Navy should propose legislation that will allow the MTFs to retain their manufacturer refunds.

While doing this study, it became apparent that the Navy can truly benefit through the return of it's expired pharmaceuticals. The Navy must be proactive, and initiate a universal policy directing the return and disposal of expired pharmaceutical products utilizing civilian services. This action will aid in controlling Navy health care costs in the future.

RETURNS

Lederle will, in its sole discretion and judgment, consider all justifiable requests for exchange or credit. Lederle will, providing the conditions stated below are met, issue credits to direct accounts and only exchange merchandise with nondirect accounts. Such return requests will be subject to home office approval and to the conditions noted below.

Conditions

Requests for credit must be made on Lederle's Return Goods Memorandum form which may be obtained from the Distribution Center servicing the customer or the local sales representative.

Returns will be evaluated at the actual purchase price of the quantity being returned.

All merchandise to be returned, unless otherwise directed, must be shipped prepaid to the Central Return Center located at the following address: Lederle Laboratories Division, American Cyanamid Company, Attn: Central Returns Dept., 1100 East Business Center Dr., Mt. Prospect IL 60056.

Lederle representatives are not authorized to remove or transport merchandise that is to be returned from any place of business.

Credit for outdated opened packages of less than original unit of sale, will be prorated down to the nearest half package.

Lederle reserves the right to destroy without credit, exchange or return to the customer, any returned merchandise which in its judgment is not returnable under the limitations set forth below.

Nonreturnable

Merchandise expressly sold on a nonreturnable basis or which has been involved in a fire sale, sacrifice sale or bankruptcy sale or has been, in the judgment of Lederle, subjected to improper storage conditions.

Products damaged by fire, smoke, heat or water resulting from a fire or other casualty occurrence or insurable hazard.

Products that have been deleted from the price list for a period of one year or more or dated products which are outdated more than one year beyond the expiration date on the package.

Merchandise with broken seals or opened packages of less than the original unit of sale, while still in date.

Merchandise which is salable but the return of which is intended to reduce inventory temporarily.

Merchandise obtained from a V.A., Military or U.S.P.H. Depot.

Return Goods Policy 14

EXCEPT FOR THE UPJOHN PRODUCTS PURCHASED FROM THE DEPOT*

Upjohn products in original containers, partials included, may be returned by our customers for credit or exchange, transportation prepaid

Products which have expired but are returned no later than one year past the expiration date may be exchanged for an approximate dollar equivalent of any product in our catalog. No credit or exchange privilege will be extended for products received after the one-year grace period.

Credit will not be given for merchandise damaged by improper storage, fire, or from smoke or water resulting from fire

When credit is allowed, the value of the return will be based on the best catalog net price or the actual purchase price, as determined by The Upjohn Company.

An Upjohn Returned Goods Form must be completed with the information required to comply with FDA good manufacturing practices. These forms can be obtained from your Distribution Center or your Sales Representative. Returned goods cannot be processed without this form.

RETURN GOODS POLICY

All returns of Schering or Key merchandise for credit must have the prior approval of an authorized representative and be forwarded prepaid to:

Schering Corporation
1011 Morris Avenue
Union, NJ 07083
ATTN: Return Goods Department

- Credit will be allowed on unopened and undamaged packages at current Federal Supply Schedule prices as follows:
  a) Non-dated products (including discontinued packages)
     —full credit for items less than five years old
     —half credit for items five or more years old
  b) Dated products
     —full credit up to one year after expiration
     —half credit over one year after expiration
  c) Based on our judgment, packages that are partially filled or show other evidence of being opened, will receive partial credit.

RETURNED GOODS POLICY

For the Hospital Products Division of
Abbott [redacted]

A. Authorization:

AUTHORIZATION FOR RETURN MUST BE OBTAINED FROM AN ABBOTT REPRESENTATIVE OR CORPORATE CUSTOMER SERVICE (1-[redacted]). PROPER FORMS AND SHIPPING LABELS WILL BE PROVIDED TO EXPEDITE CREDIT. RETURNS MUST BE SHIPPED TO THE ASSIGNED DISTRIBUTION CENTER, FREIGHT PREPAID.

B. Ordering/Shipping Errors:

Full credit will be allowed on returns due to ordering/shipping errors under the following conditions:

1. Corporate Customer Service (1-[redacted]) is notified promptly (within 10 days of receipt of merchandise) and return authorization is requested. An *Ordering/Shipping Error Returned Goods Authorization form* and shipping labels will be sent by return mail.
2. Returns must be received at the service area distribution center within 30 days of initial shipment and be in condition for restocking without further processing. *Standard Authorized Returned Goods credit* provisions will apply for ordering/shipping error merchandise received more than 30 days after the original shipment.
3. Returns due to ordering errors must be shipped freight prepaid.

C. Authorized Returns:

All returns accepted for credit must be in condition for restocking, in full, unopened, undamaged original Abbott shipping cases, EXCEPT products which have two or more inner packages within the shipper carton. Each inner package contains a product insert, and is therefore eligible for credit upon return provided inner packages are returned full, unopened and undamaged.

Example: List 0074-4887-10 Water for Injection, 10 mL Vial, is packaged 4/25 per shipper case. Each individual inner package of 25 is eligible for return *provided products meet all other provisions of this policy.*

1. **Expiration Dated Products:**

   A maximum of 75% credit will be allowed for all expiration dated products that are returned with 6 months or more of dating remaining when received at the distribution center and are in condition for restocking. Products having less than 6 months expiration are not eligible for credit.

   a. Spinal Trays with liquid tetracaine will receive 75% credit if returned prior to expiration date in full, unopened cases, and are eligible for 50% credit consideration up to 60 days past expiration date. List numbers are as follows:

4733	4786	4796
4735	4773	4804
4784	4774	4805

   b. Emergency Syringes received up to 12 months past expiration will be accepted for credit or exchange of like products. List numbers are as follows:

1143	4266	4900	4901
4902	4903	4904	4905
4906	4908	4909	4910
4911	4913	4914	4916
4921	4923	4924	4928
4977	4978	5534	5819
6055	6058	6248	6250
6637	7887	7888	8026
8027	9166	9267	

   c. A-hydroCort™, A-methaPred®, Nitrapress®, and Erythracin® injectable products received up to 12 months past expiration will be exchanged for like products when exchanged in multiples of ten (10). No credit will be issued for these products.

   d. Liposyn® products are not eligible for return or credit except for Abbott shipping errors.

APPENDIX B - EXAMPLES OF FORMS FOR RETURNS

PLEASE PRINT CLEARLY WITH BALL POINT PEN

PHARMACEUTICAL DIVISION • ELI LILLY AND COMPANY • INDIANAPOLIS, INDIANA 46285

- THIS FORM IS AUTHORIZATION TO RETURN PHARMACEUTICALS.
- RETURN OF INDATE ITEMS REQUIRES PRIOR APPROVAL.
- ALL PRODUCTS MUST BE IN ORIGINAL LILLY OR DISTA CONTAINER.
- IF ASSISTANCE IS NEEDED, CONTACT CUSTOMER ADJUSTMENTS (317) 276-6262.
- THE LILLY/DISTA RETAIL RETURN GOODS POLICY IS LISTED ON THE BACK OF THIS FORM.

REPLACEMENT ORDER FORM

REPL. P 374081

NOTE ANY SPECIAL INSTRUCTIONS:

DO NOT COMPLETE - FOR LILLY/DISTA REPRESENTATIVE OR HOME OFFICE USE ONLY

LILLY/DISTA REF. NO.

D.E.A.

Form No.

REPRESENTATIVE'S NAME (PLEASE PRINT)

ORDER NUMBER | DATE ORDERED

DO NOT COMPLETE HOME OFFICE USE ONLY

RETURNED MATLS. DISPOSITION

DATE REC'D | NO. CTNS. | MIN TYPE 1

TRANSPORTATION CHARGES

CUSTOMER CLAIM NO.

IMPORTANT: YOUR RETURN CANNOT BE PROCESSED WITHOUT INSTRUCTIONS FOR REPLACEMENT MERCHANDISE.

Please make selections from the list below; or use the space provided for other Lilly/Dista items. List your selection in the "%" column. Also, list an item to be used to complete your order if a balance is left over after picking 1st choice.

SUGGESTED ITEMS FOR REPLACEMENT MERCHANDISE

ITEM NO.	PREF %	PKG. SIZE	ITEM DESCRIPTION
88		60	Axid®, 150 mg, PUL 3144
87		30	Axid®, 300 mg, PUL 3145
07		100	Ceclor®, 250 mg, PUL 3661
06		15	
55		ID 100	
89		100	Becotin T®, TAB 1819
51		1's	Dobutrex, 250 mg, VL 7176
59		100	Co-Pyronil 2®, PUL 3133
60		100	Crystodigin®, 0.1 mg, TAB 1769
17		100	Keflex®, 250 mg, PUL 468
16		20	
42		ID 100	
62		100 ML	Keflex®, Oral Susp., 250 mg, M-502
48		100	Keflex®, 500 mg, PUL 483
45		20	
47		ID 100	
19		1's	Kefzol®, 1.0 gm/10 ml, VL 788
21		100	Mi-Cebrin T®, TAB 1807
23		100	Nalfon®, 600 mg, TAB 1689
44		1's	Nebcin®, 80 mg/2 ml, AMP 781
61		100	Prozac®, 20 mg, PUL 3165
82		100	Keflab®, 500 mg, TAB 4143
36		1's	Tac-Tape®, M-75
37		1's	Tubocurarine Chl. 3 mg/ml, AMP 449
39		500	V-Cillin K®, 250 mg, TAB 1691
38		100	
54		100 ML	V-Cillin K® Oral Susp., 250 mg, M-143

* IN THE SPACE BELOW, LIST OTHER ITEMS DESIRED AS REPLACEMENT MERCHANDISE. (EMPTY CAPSULES, CONTROLLED SUBSTANCES, AND ITEMS REQUIRING SPECIAL HANDLING CANNOT BE SHIPPED AS REPLACEMENT ITEMS.)

PREF %	PKG. SIZE	ITEM NO.

☐ CHECK IF TRAYPAK™ IS DESIRED

INDATE AUTHORIZATION

IF INDATE PRODUCTS ARE RETURNED THEY MUST BE LISTED BELOW AND THIS FORM MUST BE SIGNED BY YOUR LILLY OR DISTA REPRESENTATIVE.

X _____

(REPRESENTATIVE SIGNATURE)

GOODS BEING RETURNED. THIS IS OPTIONAL INFORMATION. FOR YOUR PROTECTION, PLEASE INSURE.

QUANTITY	PART QUAN.	PKG. SIZE	ITEM NUMBER
			1.
			2.
			3.
			4.
			5.
			6.
			7.
			8.
			9.
			10.
			11.
			12.

TOTAL NO. OF CTNS. RETURNED _____ (IF MORE THAN 1 CTN., INCLUDE A COPY OF THIS FORM IN EACH CTN.)

TRADEMARKS ARE IDENTIFIED BY THE SYMBOL ® OR ™
© DC 6075 PRINTED IN U.S.A. JAN 88 (CONTINUOUS)

ALL PRODUCTS WILL BE DESTROYED AND NO CREDIT WILL BE GIVEN FOR INELIGIBLE ITEMS (SEE REVERSE SIDE)

COPY NO. 1 (INCLUDE IN CARTON)

Bristol-Myers Squibb Company
Pharmaceutical Group

OUTDATED/UNSALABLE PRODUCT RETURN AUTHORIZATION

% Wholesaler or Direct Account Number	ATTENTION: Non-direct accounts must provide their wholesaler's information in the space provided. If not, this form will be returned to requester.	RETURN NO. 062585
Credit Issued To: (wholesaler or direct account name)	Returned By: (non-direct account name)	CUSTOMER DEA NO.
Address (wholesaler, direct account)	Address (non-direct)	CUSTOMER REFERENCE NO. (Debit Memo #, P.O. #, etc.)
City State Zip	City State Zip	TELEPHONE NO. (Requester)

To insure proper credit in accordance with our established returned goods policy, the list number, quantity, description and control number must be designated. If the item returned was purchased under a special offer, contract, bid or quantity price, the price should be indicated in the space provided.

REASON CODE	LIST NUMBER	QUANTITY	SIZE	PRODUCT DESCRIPTION	PARTIAL RETURN	CONTROL NUMBER	EXPIRATION DATE	PRICE

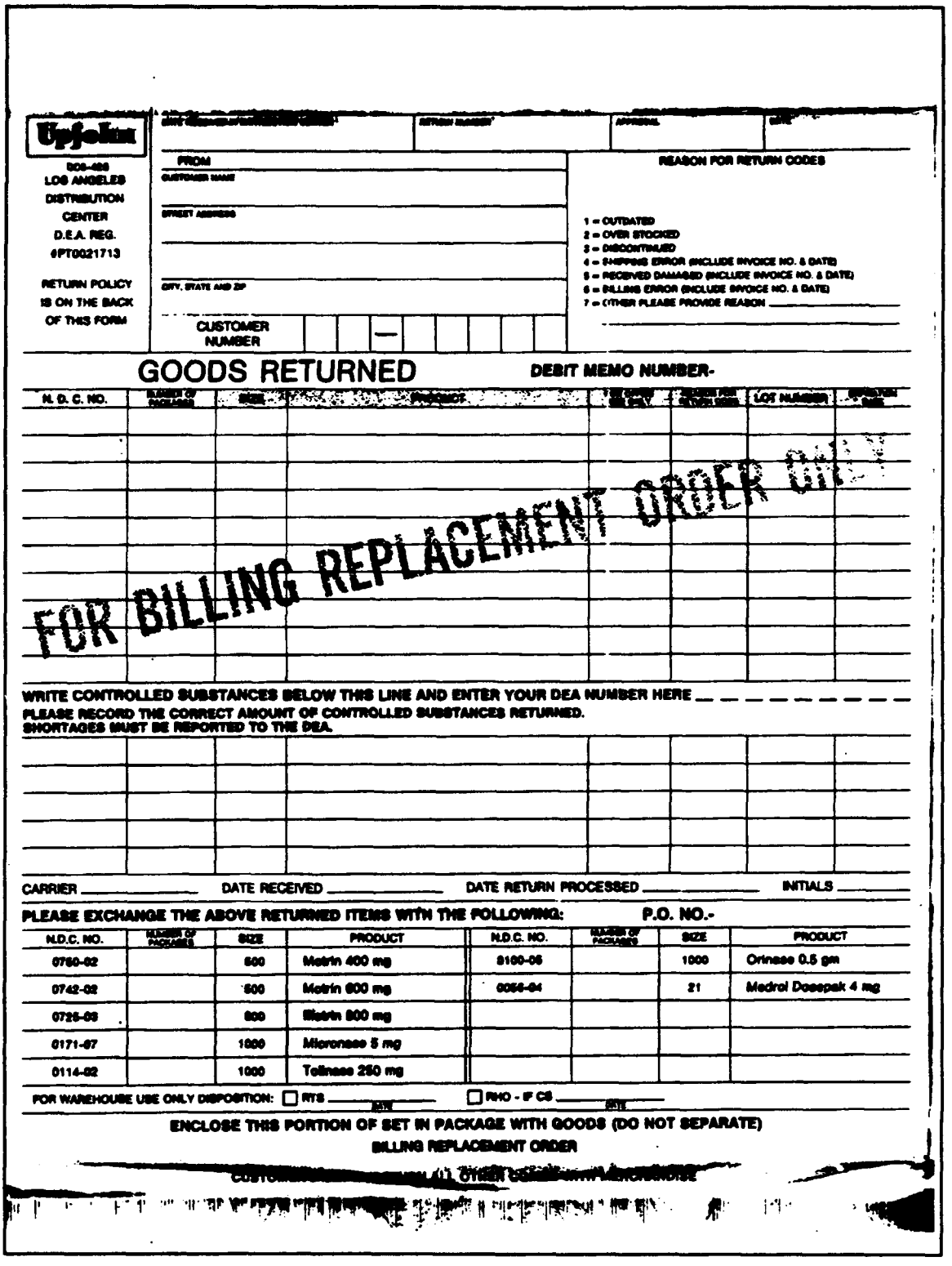
PLEASE NOTE: Credit will be based on the lower acquisition cost or current catalog cost. Bristol-Myers Squibb Company reserves the right to destroy returned goods. This form is to be used for out of date unsalable returns only. Do not use this form for the return of over stock, defective or improperly stored products.

CUSTOMER CONTACT (please print)

NO. OF CASES/UNITS	FREIGHT CHARGES	CARRIER	
APPROVED BY	CREDIT AGAINST INVOICE NO.		LITERAL

ORIGINAL - Return with product (Customer Service Copy) CANARY - Return with product (Return Goods Depot) PINK - Customer Copy

APPENDIX B (Continued)



Upjohn

909-486
LOS ANGELES
DISTRIBUTION
CENTER
D.E.A. REG.
#PT0021713

RETURN POLICY
IS ON THE BACK
OF THIS FORM

FROM
CUSTOMER NAME
STREET ADDRESS
CITY, STATE AND ZIP
CUSTOMER NUMBER

REASON FOR RETURN CODES

1 = OUTDATED
2 = OVER STOCKED
3 = DISCONTINUED
4 = SHIPPING ERROR (INCLUDE INVOICE NO. & DATE)
5 = RECEIVED DAMAGED (INCLUDE INVOICE NO. & DATE)
6 = BILLING ERROR (INCLUDE INVOICE NO. & DATE)
7 = OTHER PLEASE PROVIDE REASON

GOODS RETURNED

DEBIT MEMO NUMBER-

N. D. C. NO.	NUMBER OF PACKAGES	SIZE	PRODUCT	THE UPJOHN SEAL ONLY	REASON FOR RETURN CODE	LOT NUMBER	EXPIRATION DATE

FOR BILLING REPLACEMENT ORDER ONLY

WRITE CONTROLLED SUBSTANCES BELOW THIS LINE AND ENTER YOUR DEA NUMBER HERE _____
PLEASE RECORD THE CORRECT AMOUNT OF CONTROLLED SUBSTANCES RETURNED.
SHORTAGES MUST BE REPORTED TO THE DEA.

CARRIER _____ DATE RECEIVED _____ DATE RETURN PROCESSED _____ INITIALS _____

PLEASE EXCHANGE THE ABOVE RETURNED ITEMS WITH THE FOLLOWING: P.O. NO.-

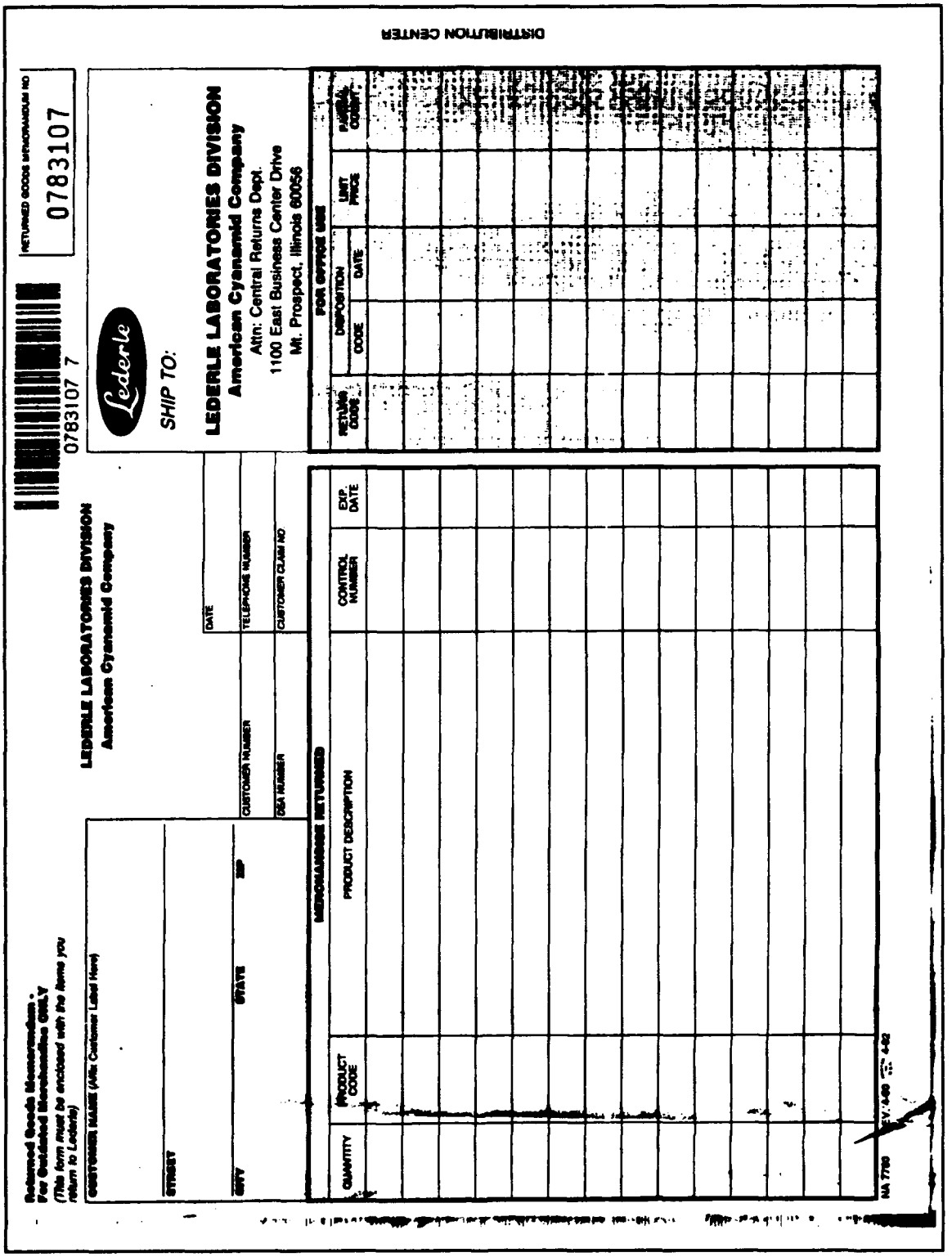
N.D.C. NO.	NUMBER OF PACKAGES	SIZE	PRODUCT	N.D.C. NO.	NUMBER OF PACKAGES	SIZE	PRODUCT
0760-02		500	Motrin 400 mg	9100-05		1000	Orinase 0.5 gm
0742-02		500	Motrin 600 mg	0056-04		21	Medrol Dosepak 4 mg
0725-03		500	Motrin 800 mg				
0171-07		1000	Micronase 5 mg				
0114-02		1000	Tolinase 250 mg				

FOR WAREHOUSE USE ONLY DISPOSITION: ☐ RTS _____ DATE ☐ RHO - IF CS _____ DATE

ENCLOSE THIS PORTION OF SET IN PACKAGE WITH GOODS (DO NOT SEPARATE)

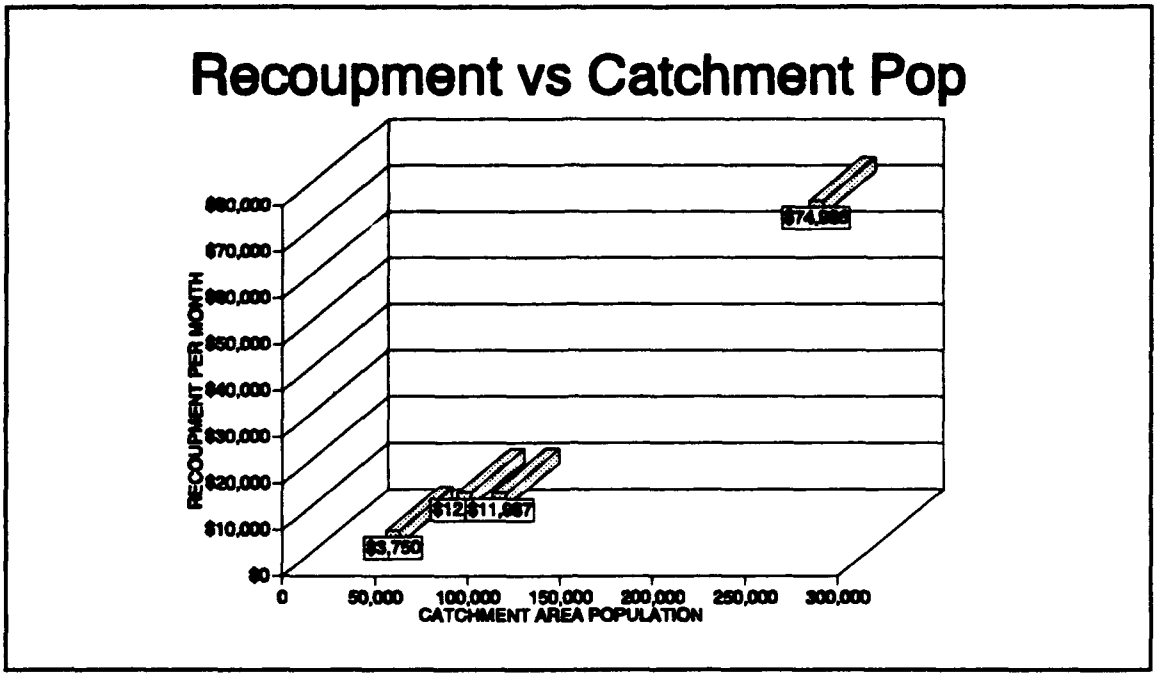
BILLING REPLACEMENT ORDER

APPENDIX B (Continued)



FACILITY	CATCHMENT POPULATION	BEDS	ADMISSIONS	OCC BED DAYS	ALOS	ADPL	PHARMACY UNITS	OUT PT VISITS	PHARMACY FUNDS	RECOUPMENT PER MONTH	TOTAL RECOUPMENT	# OF MONTHS
BEAUFORT	24,567	49	6,320	26,410	4.18	28.96	916,707	758,253	$5,244,011			
BETHESDA	84,158	342	42,557	236,564	5.61	261.58	4,420,637	1,450,099	$39,801,684	$12,072	$48,287	4
BREMERTON	50,537	109	14,026	55,030	3.92	60.34	1,301,097	1,114,744	$10,219,629			
CAMP LEJEUNE	91,542	176	21,008	87,263	4.15	95.71	2,111,697	1,155,819	$13,979,389			
CAMP PENDLETON	103,092	120	20,277	87,036	4.29	95.44	2,069,074	1,269,171	$13,665,675	$11,997	$59,984	5
CHARLESTON	100,527	181	24,400	87,451	3.58	95.89	1,878,967	953,635	$16,071,320			
CHERRY POINT	31,390	40	6,102	14,816	2.43	16.25	704,283	437,172	$4,646,899			
CORPUS CHRISTI	27,925	42	4,356	26,980	6.19	29.58	1,031,747	369,766	$7,004,585			
GREAT LAKES	64,907	136	9,840	67,316	6.84	73.81	1,629,830	929,192	$11,700,403			
GROTON	45,321	25	5,481	12,951	2.36	14.20	763,189	572,920	$7,277,443	$3,780	$45,000	12
JACKSONVILLE	126,369	131	22,576	66,504	2.95	72.92	2,761,820	1,308,992	$25,404,966			
LEMOORE	22,682	37	3,855	7,806	2.03	8.56	599,038	326,727	$3,611,752			
LONG BEACH	136,516	113	7,924	69,293	8.74	75.96	1,419,974	564,116	$11,462,606			
MILLINGTON	37,612	66	7,725	27,661	3.58	30.33	1,060,700	529,963	$6,602,669			
NEWPORT	32,669	59	4,475	32,589	7.28	35.73	631,343	436,392	$5,645,467			
OAK HARBOR	24,333	25	5,672	12,338	2.18	13.53	590,632	343,040	$3,851,367			
OAKLAND	99,502	225	26,617	135,966	4.75	149.09	2,826,669	1,265,660	$26,235,566			
ORLANDO	77,069	140	12,976	58,545	4.51	64.19	2,017,569	1,007,485	$18,492,954			
PATUXENT RIVER	13,231	20	2,923	5,935	2.03	6.51	427,045	225,497	$2,663,699			
PENSACOLA	65,720	104	14,599	57,108	3.91	62.62	2,412,010	943,290	$19,913,867			
PORTSMOUTH, VA	266,949	446	65,361	269,627	4.13	295.64	6,735,097	3,199,421	$67,653,699			
SAN DIEGO	260,302	393	70,950	318,204	4.48	348.91	6,597,662	2,723,347	$62,913,269			
TWENTYNINE PALMS	15,735	29	5,709	11,620	2.04	12.74	526,232	291,539	$2,360,477			
WALTER REED AMC	274,077	769	66,293	577,365	8.71	632.38	4,586,291	1,694,392	$44,550,000	$74,995	$899,935	12
ANNAPOLIS							362,841	362,821	$3,523,173			
KEY WEST							197,958	100,590	$1,187,366			
KINGS BAY							341,940	222,045	$2,626,490	$4,379	$74,446	17
NEW ORLEANS							389,296	114,428	$1,951,256			
PHILADELPHIA							531,742	554,969	$5,765,297			
PORT HUENEME							342,353	290,479	$2,919,447			
PORTSMOUTH, NH							402,412	162,178	$3,468,945			
QUANTICO							440,931	364,919	$3,619,445			
SEATTLE							172,409	63,846	$1,968,772			

APPENDIX D - SCATTERGRAPHS AND SIMPLE LINEAR REGRESSIONS



Using all hospitals (Walter Reed, Bethesda, Camp Pendleton, Groton), the regression equation is:

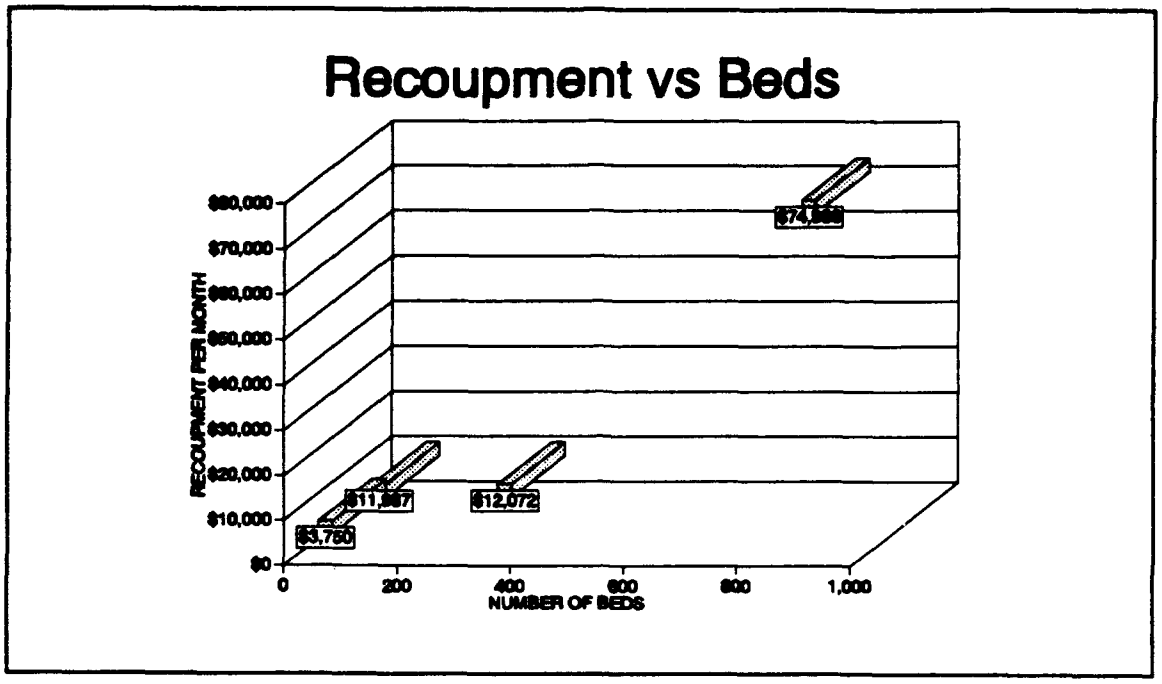
RECOUPMENT = - 15354 + 0.324 CATCHMENT

Predictor	Coef	Stdev	t-ratio	p
Constant	-15354	4760	-3.23	0.084
CATCHMENT	0.32411	0.03090	10.49	0.009

s = 5416 R-sq = 98.2% R-sq(adj) = 97.3%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	3226018560	3226018560	109.99	0.009
Error	2	58662456	29331228		
Total	3	3284680960			



Using all hospitals, the regression equation is:

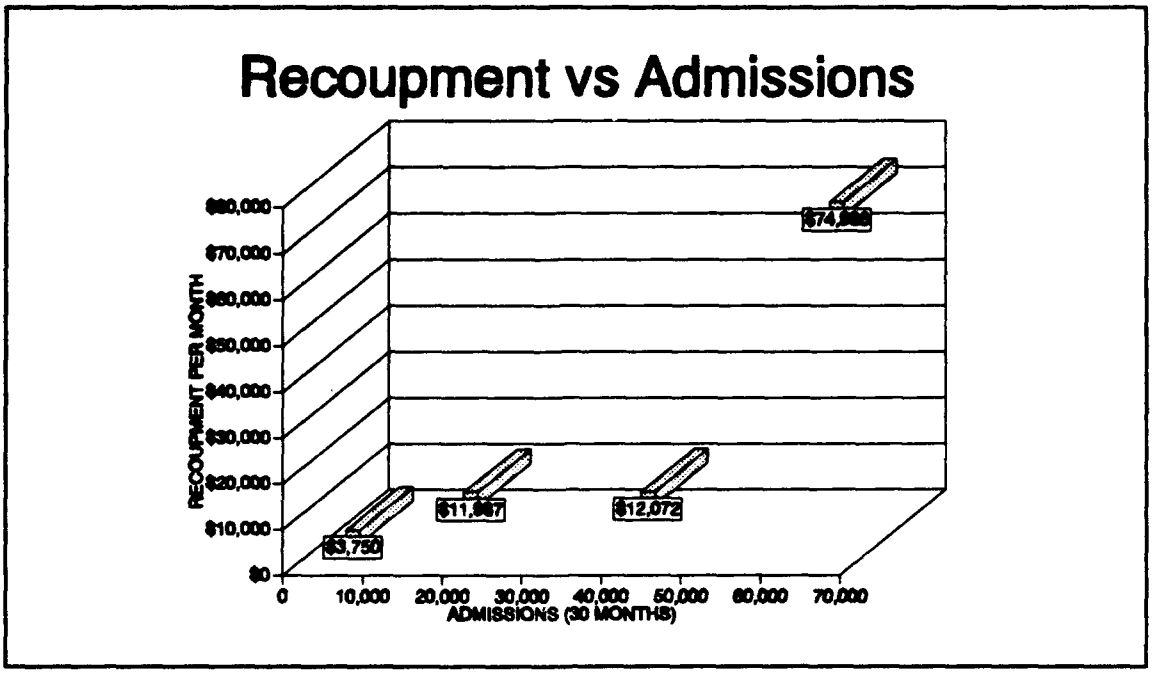
RECOUPMENT = - 3710 + 92.2 BEDS

Predictor	Coef	Stdev	t-ratio	p
Constant	-3710	9486	-0.39	0.733
BEDS	92.19	21.84	4.22	0.052

s = 12875 R-sq = 89.9% R-sq(adj) = 84.9%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	2953162496	2953162496	17.82	0.052
Error	2	331518624	165759312		
Total	3	3284681216			



Using all hospitals, the regression equation is:

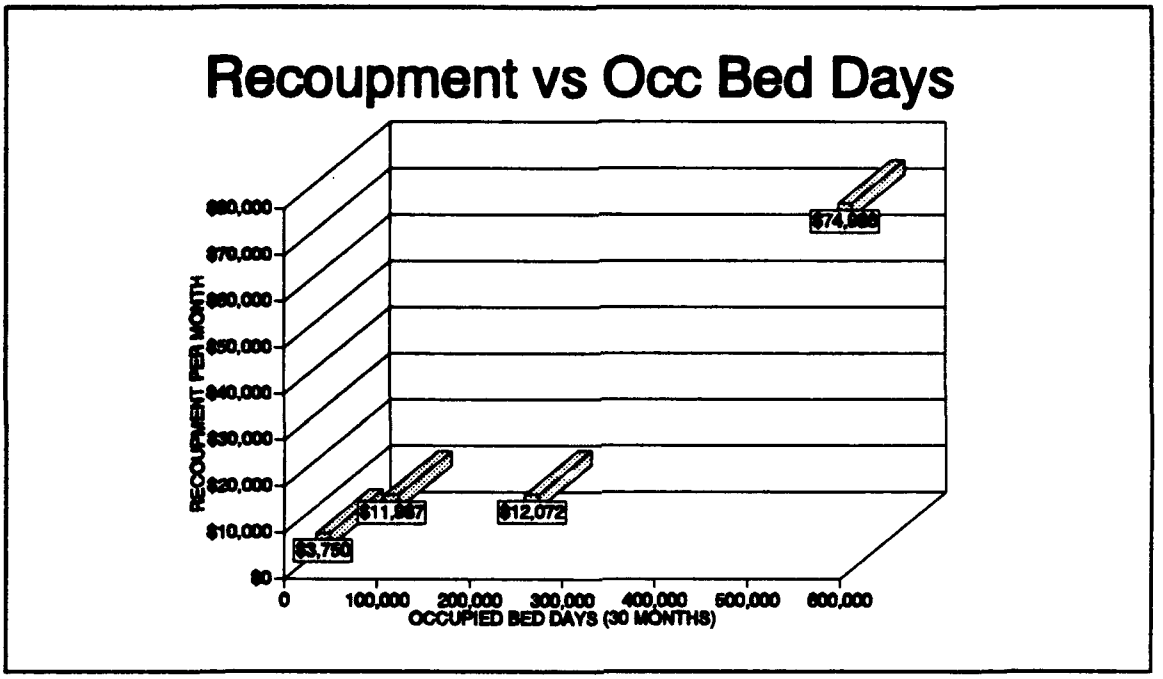
RECOUPMENT = - 10686 + 1.08 ADMISSIONS

Predictor	Coef	Stdev	t-ratio	p
Constant	-10686	17825	-0.60	0.610
ADMISSIONS	1.0812	0.4373	2.47	0.132

s = 20120 R-sq = 75.4% R-sq(adj) = 63.0%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	2475034112	2475034112	6.11	0.132
Error	2	809646912	404823456		
Total	3	3284680960			



Using all hospitals, the regression equation is:

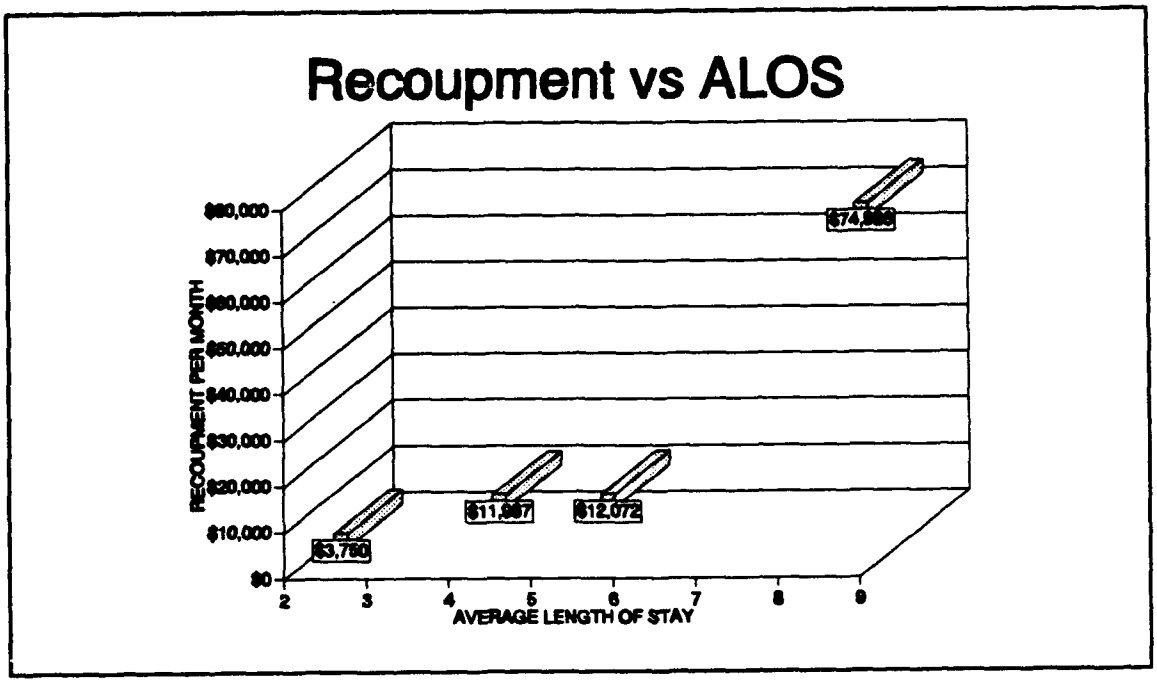
RECOUPMENT = - 3159 + 0.126 OCCUPIED BED DAYS

Predictor	Coef	Stdev	t-ratio	p
Constant	-3159	8819	-0.36	0.754
OCCBDAYS	0.12603	0.02796	4.51	0.046

s = 12131 R-sq = 91.0% R-sq(adj) = 86.6%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	2990367744	2990367744	20.32	0.046
Error	2	294313280	147156640		
Total	3	3284680960			



Using all hospitals, the regression equation is:

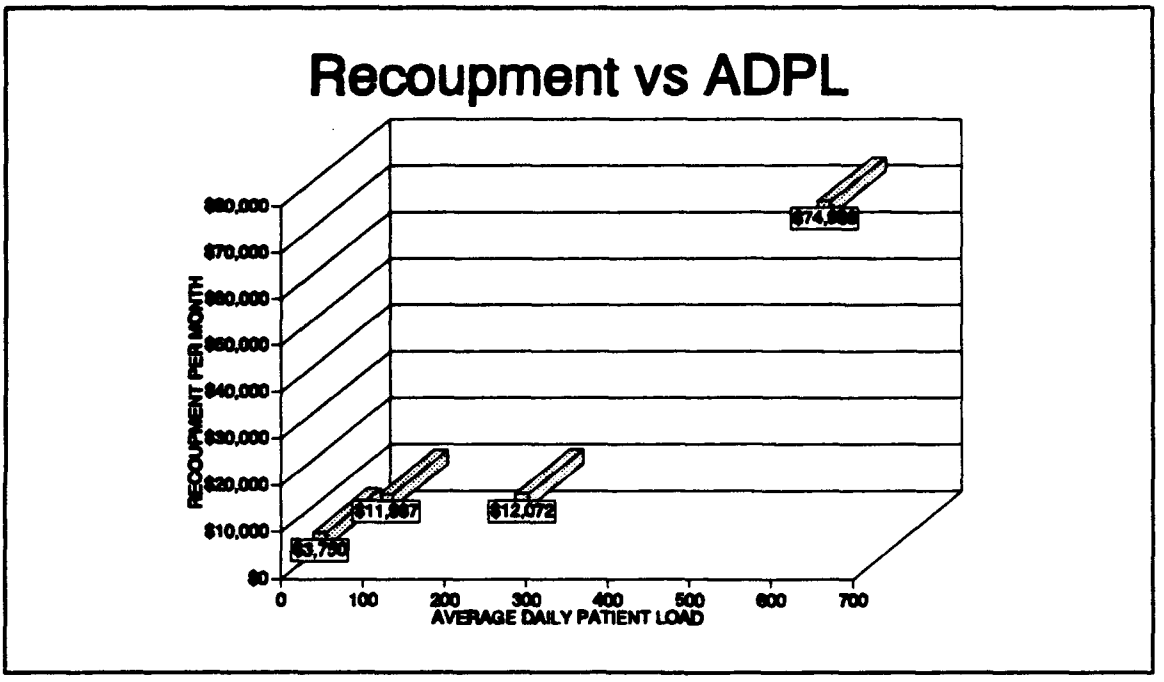
RECOUPMENT = - 33711 + 11332 ALOS

Predictor	Coef	Stdev	t-ratio	p
Constant	-33711	20359	-1.66	0.240
ALOS	11332	3553	3.19	0.086

s = 16428 R-sq = 83.6% R-sq(adj) = 75.4%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	2744939264	2744939264	10.17	0.086
Error	2	539741760	269870880		
Total	3	3284680960			



Using all hospitals, the regression equation is:

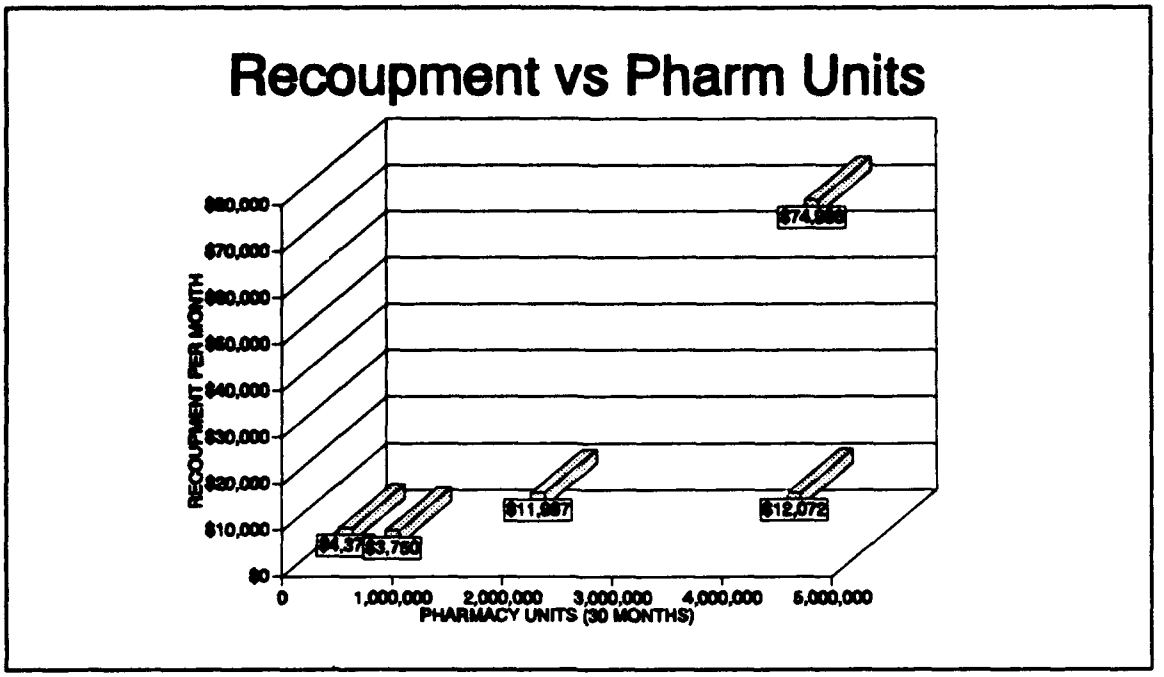
RECOUPMENT = - 3168 + 115 ADPL

Predictor	Coef	Stdev	t-ratio	p
Constant	-3168	8834	-0.36	0.754
ADPL	115.05	25.56	4.50	0.046

s = 12148 R-sq = 91.0% R-sq(adj) = 86.5%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	2989519616	2989519616	20.26	0.046
Error	2	295161408	147580704		
Total	3	3284680960			



Using all hospitals and Kings Bay clinic, the regression equation is:

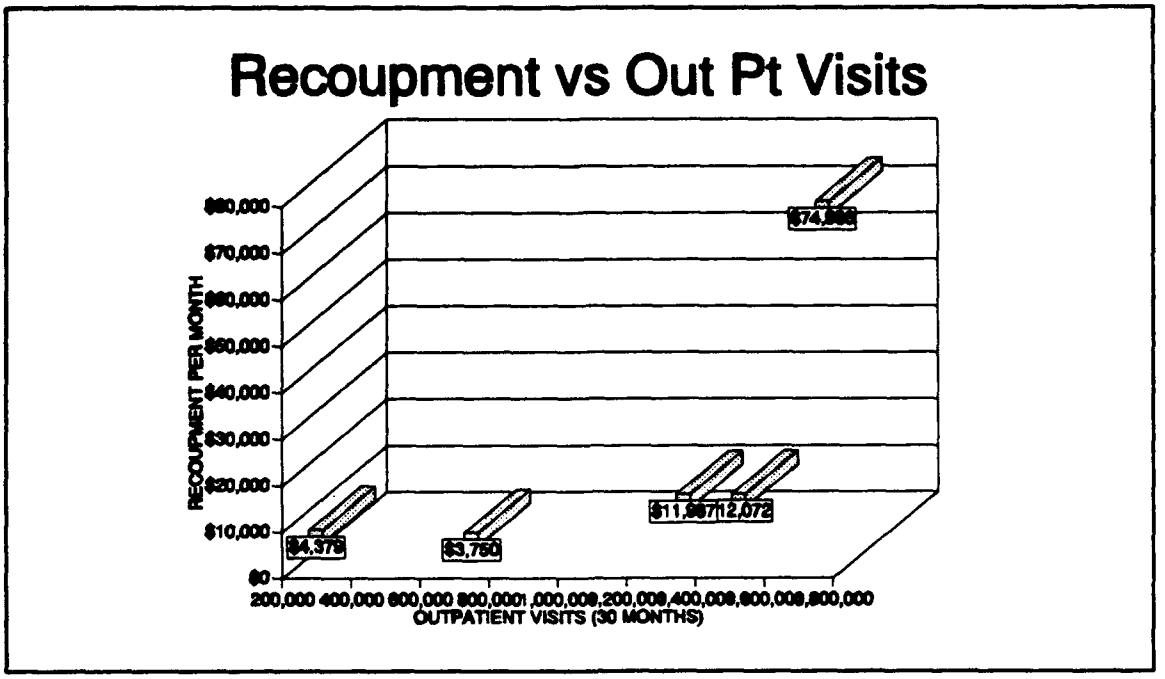
RECOUPMENT = - 3965 + 0.0104 PHARMACY UNITS

Predictor	Coef	Stdev	t-ratio	p
Constant	-3965	19235	-0.21	0.850
UNITS	0.010409	0.006367	1.63	0.201

s = 25360 R-sq = 47.1% R-sq(adj) = 29.5%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	1718946688	1718946688	2.67	0.201
Error	3	1929359744	643119936		
Total	4	3648306432			



Using all hospitals and Kings Bay clinic, the regression equation is:

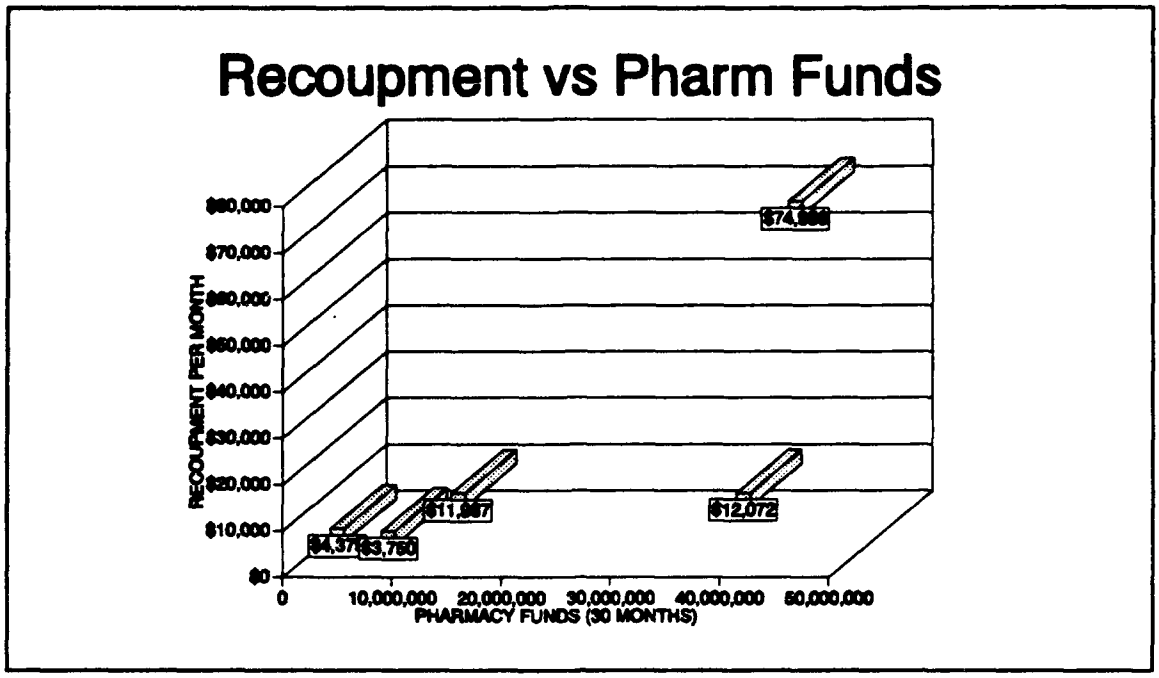
RECOUPMENT = - 13113 + 0.0330 OUTPATIENT VISITS

Predictor	Coef	Stdev	t-ratio	p
Constant	-13113	24359	-0.54	0.628
OUTVSTS	0.03304	0.02057	1.61	0.207

s = 25569 R-sq = 46.2% R-sq(adj) = 28.3%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	1686913408	1686913408	2.58	0.207
Error	3	1961393024	653797696		
Total	4	3648306432			



Using all hospitals and Kings Bay clinic, the regression equation is:

RECOUPMENT = - 3408 + 0.00115 PHARMACY FUNDS

Predictor	Coef	Stdev	t-ratio	p
Constant	-3408	16956	-0.20	0.854
FUNDS	0.0011510	0.0006138	1.88	0.157

s = 23662 R-sq = 54.0% R-sq(adj) = 38.6%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	1968672128	1968672128	3.52	0.157
Error	3	1679634304	559878080		
Total	4	3648306432			

APPENDIX E - MULTIPLE LINEAR REGRESSIONS

Using just hospitals (Walter Reed, Bethesda, Camp Pendleton, and Groton), the regression equation is:

RECOUPMENT = 9646 - 0.00113 PHARMACY FUNDS + 0.200 OCC BED DAYS

Predictor	Coef	Stdev	t-ratio	p
Constant	9645.5	454.0	21.25	0.030
FUNDS	-0.00112913	0.00002891	-39.06	0.016
OCCBDAYS	0.200352	0.002145	93.39	0.007

s = 433.5 R-sq = 100.0% R-sq(adj) = 100.0%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	2	3284493056	1642246528	8740.38	0.008
Error	1	187892	187892		
Total	3	3284680960			

SOURCE	DF	SEQ SS
FUNDS	1	1645710720
OCCBDAYS	1	1638782336

Unusual Observations

Obs.	FUNDS	RECOUP	Fit	Stdev.Fit	Residual	St.Resid
1	44550000	74986	75019	432	-33	-1.00 X
2	39801684	12072	12100	433	-28	-1.00 X

X denotes an obs. whose X value gives it large influence.

Using just hospitals (Walter Reed, Bethesda, Camp Pendleton, and Groton), the regression equation is:

RECOUPMENT = 9874 - 0.00127 PHARMACY FUNDS + 154 BEDS

Predictor	Coef	Stdev	t-ratio	p
Constant	9874	1264	7.81	0.081
FUNDS	-0.00126704	0.00008400	-15.08	0.042
BEDS	154.163	4.589	33.60	0.019

s = 1204 R-sq = 100.0% R-sq(adj) = 99.9%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	2	3283230208	1641615104	1131.59	0.021
Error	1	1450717	1450717		
Total	3	3284680960			

SOURCE	DF	SEQ SS
FUNDS	1	1645710720
BEDS	1	1637519616

Unusual Observations

Obs.	FUNDS	RECOUP	Fit	Stdev.Fit	Residual	St.Resid
1	44550000	74986	75062	1202	-76	-1.00 X
2	39801684	12072	12167	1201	-95	-1.00 X

X denotes an obs. whose X value gives it large influence.

Using just hospitals (Walter Reed, Bethesda, Camp Pendleton, and Groton), the regression equation is:

RECOUPMENT = 11120 - 0.00927 PHARMACY UNITS + 0.184 OCC BED DAYS

Predictor	Coef	Stdev	t-ratio	p
Constant	11120	6007	1.85	0.315
UNITS	-0.009270	0.003020	-3.07	0.201
OCCBDAYS	0.18410	0.02241	8.22	0.077

s = 5247 R-sq = 99.2% R-sq(adj) = 97.5%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	2	3257152768	1628576384	59.16	0.092
Error	1	27528220	27528220		
Total	3	3284680960			

SOURCE	DF	SEQ SS
UNITS	1	1399133312
OCCBDAYS	1	1858019456

Unusual Observations

Obs.	UNITS	RECOUP	Fit	Stdev.Fit	Residual	St.Resid
1	4586291	74986	74897	5246	89	1.00 X

X denotes an obs. whose X value gives it large influence.

Using all hospitals and the one clinic (Walter Reed, Bethesda, Camp Pendleton, Groton, and Kings Bay), the regression equation is:

RECOUPMENT = - 16901 + 0.00833 PHARMACY FUNDS + 0.0832 OUTPATIENT VISITS - 0.0937 PHARMACY UNITS

Predictor	Coef	Stdev	t-ratio	p
Constant	-16901	27077	-0.62	0.645
FUNDS	0.008334	0.005780	1.44	0.386
OUTVSTS	0.08320	0.07343	1.13	0.460
UNITS	-0.09366	0.07136	-1.31	0.414

s = 24754 R-sq = 83.2% R-sq(adj) = 32.8%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	3	3035525376	1011841792	1.65	0.507
Error	1	612781056	612781056		
Total	4	3648306432			

SOURCE	DF	SEQ SS
FUNDS	1	1968672128
OUTVSTS	1	11317578
UNITS	1	1055535680

Using all the hospitals and the one clinic (Walter Reed, Bethesda, Camp Pendleton, Groton, and Kings Bay), the regression equation is:

RECOUPMENT = 3337 + 0.00410 PHARMACY FUNDS - 0.0289 PHARMACY UNITS

Predictor	Coef	Stdev	t-ratio	p
Constant	3337	21749	0.15	0.892
FUNDS	0.004101	0.004713	0.87	0.476
UNITS	-0.02885	0.04561	-0.63	0.592

s = 26453 R-sq = 61.6% R-sq(adj) = 23.3%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	2	2248735232	1124367616	1.61	0.384
Error	2	1399571200	699785600		
Total	4	3648306432			

SOURCE	DF	SEQ SS
FUNDS	1	1968672128
UNITS	1	280063168

APPENDIX F - REGRESSIONS WITHOUT WALTER REED DATA

Using only three hospitals (Bethesda, Camp Pendleton, and Groton), the regression equation is:

RECOUPMENT = - 1880 + 0.0101 OUTPATIENT VISITS

Predictor	Coef	Stdev	t-ratio	p
Constant	-1880	1956	-0.96	0.512
OUTVSTS	0.010099	0.001674	6.03	0.105

s = 1106 R-sq = 97.3% R-sq(adj) = 94.7%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	1	44481224	44481224	36.39	0.105
Error	1	1222467	1222467		
Total	2	45703692			

Using three hospitals and the one clinic (Bethesda, Camp Pendleton, Groton, and Kings Bay), the regression equation is:

RECOUPMENT = 2906 + 0.0105 PHARMACY UNITS -0.000940 PHARMACY FUNDS

Predictor	Coef	Stdev	t-ratio	p
Constant	2906.1	406.9	7.14	0.089
UNITS	0.0105244	0.0009998	10.53	0.060
FUNDS	-0.0009401	0.0001105	-8.50	0.075

s = 494.9 R-sq = 99.6% R-sq(adj) = 98.8%

Analysis of Variance

SOURCE	DF	SS	MS	F	p
Regression	2	63397740	31698870	129.43	0.062
Error	1	244917	244917		
Total	3	63642656			

SOURCE	DF	SEQ SS
UNITS	1	45684688
FUNDS	1	17713054

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