The Effects of Cold Chain Logistics and Technology on Global Freight Distribution

By

Matthew Craig

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Dr. Jean-Paul Rodrigue
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Introduction

While Globalization has made the relative distance between two regions of the world vastly smaller, the physical separation of these same regions is still a very important reality. Phone calls, emails and videos can be transmitted in fractions of seconds to all corners of the globe, but physical objects such as a bushel of grapes, a drug or a bodily organ cannot. It takes time and coordination to efficiently move a shipment and every delay can cost money and in some cases may even cost lives. To ensure that cargo does not become damaged or compromised throughout this process, businesses in the pharmaceutical, medical and food industries are relying more and more on the cold chain technology.

The cold chain, which refers to the transportation of temperature sensitive materials along a supply chain, relies on thermal and refrigerated packaging methods and logistical planning to protect the value of a shipment. Specialization of this sort has led many companies to not only rely on the major shipping service providers such as the United Parcel Service (UPS) and FEDEX, but also more focused industry specialists such as Cavalier and World Courier who specialize themselves around the logistical expertise of international shipping and receiving. Their "ability to understand local rules, customs, and environmental conditions…" along with knowing "…the length and time of the distribution route" make them an important factor in global trade (Quinn, 15). As a result, the logistics industry is experiencing a growing level of specialization and segmentation of cold chain shipping in several potential niche markets. This fits well within the growing body of literature analyzing the emergence of global commodity chains (e.g. Gereffi and Korzeniewicz 95). Commodity chains are "… functionally integrated network of production, trade and service activities that covers all the stages in a supply chain, from the transformation of raw materials, through intermediate manufacturing stages, to the delivery of a finished good to a market" (Rodrigue 175). Among the characteristics of emerging global commodity chains is the widening separation of the function of distribution from production. Whole new segments of the distribution industry have been very active in taking advantage of the dual development of the spatial extension of supply chains supported by globalization and the significant variety of goods in circulation.

Historical and Modern Importance

While companies such as those discussed above are fairly modern expansions in the transportation industry, the refrigerated movement of temperature sensitive goods is a practice that dates back to 1797 when British fisherman used natural ice to preserve their fish stock piles (Wang & Wang 589). It was also seen in the late 1800s for the movement of food from rural farms to urban centers (Cleland, 269). Cold storage was also a key component of fresh food transmission between colonial powers and their colonies. For example, in the late 1870s and early 1880s France was starting to receive large shipments of frozen meat and mutton carcasses from South America, while Great Britain imported frozen beef from Australia and pork and other meat from New Zealand (James 947). By 1910, 600,000 tons of frozen meat was being brought into Great Britain alone (James 947).

The temperature controlled movement of pharmaceuticals and medical supplies is a much more modern transit option than the shipping of frozen food. Over the past fifty years logistical third party companies, such as World Courier in 1969 and Cavalier in 1986 began to emerge and institute new methods for successfully transporting these global commodities. Before their arrival, cold chain processes were mostly managed in house by the manufacturer (De Palma Cryoport.com). FDA restrictions and accountability measures over the stability of the cold chain forced many of these companies to rely on specialty couriers rather than completely overhauling their supply chain facilities (De Palma Cryoport.com). The value of the cold chain in the preservation of expensive vaccines and medical supplies was only beginning to be recognized when these logistical providers started to appear. In a study performed in 1995, only 32 to 48% of physicians surveyed knew of the dangers of temperature excursions to the products they were giving to patients (Seto et al CPD5). As awareness began to grow, so did the need for efficient management of the cold chain.

In today's global market, reliance on the cold chain continues to gain importance; much as it has been over the past century. Within the pharmaceutical industry for instance, the testing, production and movement of drugs relies heavily on controlled and uncompromised transfer of shipments. A large portion of the pharmaceutical products that move along the cold chain are in the experiment or developmental phase. Clinical research and trials is a major part of the industry that costs millions of dollars, but one that also experiences a failure rate of around 80% (Quinn 1). According to the Healthcare Distribution Management Association, of the close to 200 billion dollars in pharmaceutical distribution, about 10% are drugs that are temperature sensitive (Quinn 1). This makes the cold chain responsible for transporting a near 20 billion dollar investment. If these shipments should experience any unanticipated exposure to variant temperature levels, they run the risk of becoming ineffective or even harmful to patients. 'If we are going to spend all this money developing drugs, we want to get them to the customer so they are effective and safe', is what package and product testing company DDL West's technical director Karen Greene told Pharmaceutical Commerce (Heinze 1).

Temperature control in the shipment of foodstuffs is a component of the industry that has continued to rise in necessity. As more and more countries focus their primary or large portions of their export economy around food and vegetable production, the need to keep these products fresh for extended periods of time is obviously much more important than as it was in the 1800s. In 2002, an estimated 1200 billion dollars worth of food was transported by a fleet of 400,000 refrigerated containers (James 948). The uncompromised quality and safety of this food is taken for granted in today's market, despite being the main reason behind the ability to sell the food (Jol 713). The cold chain serves the function of keeping food fresh for extended periods and eliminating any doubt in the consumer's mind over the quality of the food products.

Objectives

The current global market offers a wide variety of geographical contexts and economic opportunities in which cold chains are established. The logistics industry and its cold chain components is a large and complex sector that obviously cannot be fully addressed within these lines. Therefore, the following essay will particularly focus on how the cold chain is applied to the pharmaceutical industry, one of the world's most value added industries. A great deal of the information and insights are the outcome of an internship the author spent at a major provider of cold chain services during the Spring 2007 semester[1]. Specific objectives and questions to be addressed include:

- Providing an overview of the current context in which the cold chain industry operates. Particularly, what are the primary methods to insure a temperature controlled environment in which specific packages are transported?
- Because of the inherent characteristics of the products being transported and the temperature environment and time constraints they require, what is a typical cold chain composed of and how does it operate?
- How is the reliability of the cold chain measured and assessed? This is particularly important as the cargo being transported tends to have high value and any compromise of a shipment's integrity may involve financial liability for the carrier.
- What evidence can be used to show the extent to which economic activities dependant on the cold chain have become more flexible in their site and situation choices because of reliability improvements?

[1] World Courier. As an intern in the Quality Assurance Department my responsibilities included creating status reports of pending shipments for major pharmaceutical and medical clients, downloading temperature monitors and relaying the results to the client with a detailed analysis of any problems that may have occurred during shipment, and updating flight sheets of major domestic airports with the times and regulations of each airline the company used.

Materials for Providing Temperature Controlled Environments

Dry Ice

The success of industries that rely on the cold chain comes down to knowing how to ship a product with temperature control adapted to the shipping circumstances. Different products require different temperature level maintenance to ensure their integrity throughout the travel process. If a shipment needs to be frozen, then an efficient way of providing a sub-zero atmosphere is to use dry ice with the packing materials. Dry ice, which is solid carbon dioxide, is about -80°C and is capable of keeping a shipment frozen for an extended period of time (WC Dry Ice 2). It is safe to use with the shipping of pharmaceuticals, dangerous goods and foodstuffs. Prices can range, but the amount of dry ice needed increases with the size and duration of the shipment. For instance, when shipping frozen food, two pounds of food traveling for two hours is going to need about two pounds of dry ice, increase the size to ten pounds, and around four pounds of dry ice will keep the shipment frozen. If the time the two pounds of food is traveling is increased to instead of four, but twenty four hours, then about eight pounds of dry ice will be needed to maintain a frozen atmosphere (Ackerman dryiceinfo.com).

TABLE 1: AVERAGE AMOUNTS OF DRY ICE FOR PACKING FROZEN GOODS IN A SINGLE WELL INSULATED CONTAINER

Weight of Frozen Food	Time In Transit			
	4 Hours	12 Hours	24 Hours	2 Days
2 LB	2 LB Dry Ice	4 LB Dry Ice	8 LB Dry Ice	16 LB Dry Ice
5 LB	3 LB Dry Ice	6 LB Dry Ice	10 LB Dry Ice	18 LB Dry Ice
10 LB	4 LB Dry Ice	8 LB Dry Ice	14 LB Dry Ice	24 LB Dry Ice
20 LB	5 LB Dry Ice	10 LB Dry Ice	20 LB Dry Ice	30 LB Dry Ice
50 LB	10 LB Dry Ice	20 LB Dry Ice	35 LB Dry Ice	50 LB Dry Ice
For each additional day add 8 to 15 pounds.				

Ackerman, www.dryiceinfo.com/shipping.htm

Some problems do exist with using dry ice to freeze shipments. First, the extreme temperature of the blocks of dry ice can burn human skin on contact, requiring the use of gloves or protective wear when handling the blocks (WC Dry Ice 2). Secondly, dry ice does not melt, instead it sublimates when it comes in contact with the air. On average, if left in the open air it will dissipate at a rate of one pound per hour (WC Dry Ice 2). Also, as it releases carbon dioxide gas it takes away from the oxygen in the air, making it unsafe to ship with live animals or to store in a poorly ventilated truck or cargo holds. Sealed containers also cannot be used to transport dry ice because the pressure created by the carbon dioxide will cause the vessel to break (WC Dry Ice 6). These issues all go into the regulation of dry ice shipments by the International Air Transport Association (IATA). They require that all parcels with dry ice be labeled as Class 9 Hazard along with having the classification code UN 1845 and the net weight of the dry ice on the outer packaging (WC Dry Ice 5). This allows customs officers and those who come in contact or handle the package to know what they are dealing with and how to process it along the transit route.

While using dry ice as a temperature control does provide an efficient way to transport frozen materials along a supply chain, the health risks and sublimation rates that characterize the substance also make monitoring the shipments a major issue. Depending on the size and the shape of the shipment, routine checks along the supply route must be performed to ensure that the dry ice has not dissipated beyond its necessary level. This requires logistical coordination at the major nodes of the cold chain. Before export, during any transfers, upon arrival and before the final delivery are all crucial parts of the supply chain where the dry ice levels must be checked. If at any of these instances the levels are found to be low or the dry ice has completely evaporated, various measures must be taken to try and maintain the integrity of the shipment. The product being shipped is a major factor, while some food stuffs or pharmaceuticals shipments have been tested and are proven to be able to handle certain temperature variations, other clinical studies or medicinal shipments may be completely ruined by even a minor temperature variation. Thawing and refreezing a product could cause irreparable damage and end up costing those involved considerable time and money (WC Dry Ice 5). Contingency plans and organization between the shipper, recipient and the travel coordinator help to limit these instances and prepare handlers on how to deal with situations where the dry ice needs to be replenished.

Being able to ensure that a shipment will remain frozen for an extended period of time comes down largely to the type of container that is used. Factors such as duration of transit, the size of the shipment and the ambient or outside temperatures experienced throughout its passage are important in deciding what type of thermal packaging is required. Two categories that classify these containers are validated and pre-qualified. Validated packages are those that have been specifically tested to transport a certain product under controlled conditions and have accomplished this consistently (WC Refrigerated Shipments 2). Pre-Qualified on the other hand, are packages that offer a specific temperature range, but are not tested for a specific product (WC Refrigerated Shipments 2). There are several different brands of each of these types of insulated boxes and each varies in capacity and validation periods. Smaller shipments can be placed in containers such as the Saf-T-Pak 310s (see Table 2). The dimensions of these packages are about fifteen inches in height, length and width and provide different substances and certifications to ensure the shipment will stay frozen. The STP 310s hold 15lbs of dry ice, and are tested to stay below 0 degrees Celsius for up to 72 hours. Bubble wrap, absorbent materials and customized envelopes provide the necessary protection for the product (WC Packaging guide 2). For slightly larger shipments, Nomadic E280s are pre-qualified to keep a shipment below -20°C for up to 72 hours. They use 25lbs of dry ice along with thermal lids and outer packaging to separate the product from the dry ice and the dry ice from the outside elements (WC Packaging guide 18). The Air Sea Bio-Transporter uses similar technology to maintain the shipments integrity, but can hold 50lbs of dry ice and keep the inner temperature below 0° C for 120 hours (WC Packaging guide 4). These are not the only packaging options available, new designs and features are continually in production to make the cold chain more efficient, but these models provide examples of how important efficient consolidation of thermal materials can be in extending transit time along the supply chain.

Table 2: Dry Ice Containers

Container	Dry Ice Capacity	Temperature Range	Time Period
Saf-T-Pak 310s	15 lbs	>0°C	72 hrs
Nomadic E280s	25 lbs	>-20°C	120 hrs
Air Sea Bio-Transporter	50 lbs	>0°C	120 hrs

Gel Packs

In pharmaceutical and medicinal shipments, large portions are classified as chilled products which means they must maintain a temperature range between 2 and 8°C. Staying within this temperature is vital to the integrity of a shipment along the supply chain. Any excursions can result in irreparable and extremely expensive damage. The common method to provide this temperature is to use Gel Packs, or packages that contain phase changing substances that can go from solid to liquid and vice versa to control an environment (WC Refrigerated Shipments 7). Depending on the shipping requirements, these packs can either start off in a frozen or refrigerated state. Along the transit process they melt to liquids, while at the same time capturing escaping energy and maintaining an internal temperature (WC Refrigerated Shipments 2). They are not dangerous to handle like dry ice and can be purchased much easier. The problems that are presented with using Gel Packs come when it is suspected that they have melted or become ambient. If a delay occurs and no replenishment protocols have been established, opening a case and replenishing the packs could spike the temperature and jeopardize the value of the shipment. Close attention must be paid to knowing when and if a shipment can be restocked.

Before a chilled product is exported, certain logistical procedures are necessary in ensuring that every requirement and precautionary measure is met. First it is important to realize what is being shipped and the hazards the product may contain. For instance, blood, urine or other bodily fluids could very well contain infectious diseases. While managing shipments of this nature demands careful handling, it is also important to expect these types of shipments to experience delays. Customs clearance on international shipments could lead to packages going past validation and requiring replenishment. These types of hindrances must be anticipated and planned for accordingly. If the gel packs can not be replenished, the package may or may not need to be put into refrigeration (WC Refrigerated Shipments 3). This comes down to knowing how sensitive a product's stability is to temperature change. Qualification tests and the monitoring of shipments allow for better judgment into how to handle these situations, but for goods considered in the clinical or experimental stage there may be no way of knowing how they will react. Next it is vital to map out the distribution route along the supply chain. What forms of transportation will be taking the shipment to which locations is the core of the logistical process. At this stage certain delays can be avoided by picking efficient entry points into other countries and coordinating exchanges between land and air travel. Customs stops with long check out times can be avoided and airlines with regulations that prevent handling hazardous content or are physically unable to service temperature controlled shipments can be averted. Each of these steps is vital to having a smooth transition along the supply chain and help to anticipate and manage any delays.

When it comes to the actual packaging of shipments with gel packs, there are several different containers that can be used to ensure the 2-8°C range is not compromised. The Nomadic E280s and the smaller Nomadic E48s are two examples that are both pre-qualified to keep the product within range (see Table 3). The E280s for example can maintain a 2° to 8° C range for 48 hours by using seven 56 ounce insulated foam bricks and six 24 ounce gel packs (WC Packaging guide 18). The E48s use eight 24 ounce and three 20 ounce gels to ensure that the package will stay within 2-8°C range for 48 hours (WC Packaging guide 21). Other standards include insulated shippers, or boxes with polystyrene or polyurethane thermal lining designed to keep refrigeration in, but are not tested to guarantee holding the necessary range (WC Pharmaceuticals 3).

More advanced packaging includes brands such as Kryotrans, Kodiak and Envirotainers. These containers possess more hardware than the other models and use advanced technology to maintain the 2-8° C range. Kryotrans for instance use heavy insulation and cooling systems from the lid to produce the refrigerated atmosphere. They also have a temperature monitor built in that can be downloaded to show the interior temperature throughout the trip (WC Pharmaceuticals 3). Kodiaks use vacuum insulated panels to stay within the temperature range, while also providing thermostats and temperature monitors that display up to the minute temperature readouts (WC Pharmaceuticals 3). The Envirotainers are battery powered cooling units that have internal fans that maintain the inner atmosphere (WC Pharmaceuticals 4). The options with these models tend to be more expensive than the simpler designs, but they do provide easier forms of monitoring the shipments and aid in limiting complications along the supply chain.

Table 3: Refrigerated Shipping Containers

Container	Temperature Control Features	Other
Nomadic E280s	6 Gel Packs and 7 Insulated Foam Bricks	Maintain 2 - 8˚C for 48 hrs
Nomadic E48s	11 Gel Packs	Maintain 2 - 8˚C for 48 hrs
Kryotrans	Lid insulation/ built in temperature monitor	Can maintain 2-8˚C or -20˚C range
Kodiak	Self Contained Refrigeration	Can maintain 2-8˚C,-55˚C or -10˚C range
Envirotainers	Battery Powered internal cooling fans	Can maintain anywhere between -20 to 20˚C. Load Capacities of 882 lbs, 3,500 lbs and 13,300 lbs depending on model.

The chilled 2 - 8˚C range is not the only environment that can be maintained through the use of gel packs. Some pharmaceutical and medical products need to stay at room temperature (10- 25˚C) during shipment, or within a controlled ambient environment (WC Packing guide 15). Despite having a larger possible temperature variety than chilled products, controlled ambient shipments face just as many obstacles and require the same logistical attention. Weather and improper packaging techniques are just two exposure obstacles that can push the package out of the desired atmosphere. As a result, over heating or freezing can occur, causing just as much damage to the controlled ambient shipment as it would to a chilled shipment. Proper supply chain planning is the best way to stop this or any cold chain anomaly from happening.

Liquid Nitrogen

Another method of controlling a shipment's temperature is by using liquid nitrogen (LN), an especially cold substance used to keep packages frozen over a long period of time. While this is an extremely effective way to control a frozen atmosphere, the substance also produces large amounts of odorless and colorless nitrogen gas that if incorrectly contained can displace all of the oxygen in an area, creating a deficient oxygen environment (Eilers 3). Exposure to this gas can cause dizziness, vomiting, unconsciousness and even death (Information Specific to Liquid Nitrogen 2003). Dry shippers, or highly insulated and durable units that provide atmospheres for different temperature extremes and prevent LN leakage, use LN to create artic environments for the transportation of pharmaceuticals and medical supplies (Eilers 1). This substance has also been used in the long term cooling and freezing of foodstuffs and high value spices (Mahajan & Goswami 77).

When transporting with liquid nitrogen, proper dangerous goods regulations must be followed. First, an inversion test should be performed where the dry shipper is placed on its side and checked for any free flowing liquid nitrogen, if any LN is seen pouring out of the shipper, then the package may not be able to transported (Eilers 4). As long as there is no free flowing LN, then the shipment does not have to be labeled as having liquid nitrogen, otherwise, the shipment label must indicate the presence of the substance (Eilers 5). When a product needs to remain in an extremely cold atmosphere for an extended period of time, LN can provide better results than dry ice, but also presents more safety hazards that must be accounted for and planned around.

Food Transportation

As with the transit of pharmaceutical and medical goods, there are also a variety of methods for the transport of food products. Land, sea and air travel all have different structures for keeping food fresh throughout the journey. Certain domestic or transnational supply chains may only require land transports, but many times ground shipments are one link in a combination of transport modes. This makes efficient transfer between land, sea or air vehicles critical for keeping food fresh. Ground and sea shipments typically follow the International Standard Organization and use either 6 or 12 meter refrigerated containers that are capable of holding up to 26 tons of food (James 948). The compatibility of the containers makes loading and unloading periods shorter and less susceptible to experiencing damage during transportation shifts. Harmful actions such as these tend to occur when transferring from a ship to a train or truck or to vans or other un-insulated vehicles (James 948). The environments in these containers are currently controlled electronically by either plugging into a generator or power source on the ship or truck, but early food shipments would cycle air from stores of wet or dry ice to keep the food refrigerated (James 948-9). Moving away from ice refrigeration has allowed for much greater distances to be traveled and has greatly increased the size of the global food market.

Another efficient mode for transporting foodstuffs is air travel. While this is a preferred form of travel for highly perishable and valuable goods due to its ability to move much faster over longer distances, it does lack the environment control and transfer ease of the ground and sea transports (James 948). Also, during the flight the cargo is stored in a 15°C – 20°C, but close to 80% of the time the package is exposed to exterior weather while waiting to be loaded onto the plane or being moved to and from the airfield (James 948). This is troubling considering the value of the food and the importance placed behind quality and freshness. In order for this form of food transport to experience growth among market users, more uncompromising strategies and regulations will have to be embraced and enacted.

Food transportation is an industry that has fully adapted to the cold chain and can, despite the problems with the air transport, be considered the more solidified of the industries, particularly since a large majority of food products have a better tolerance to temporary variations of transport temperatures. As a result, small errors can be compounded without the concern of irreversible damage. The usage of refrigerated containers (reefers) has particularly helped, since they account for more than 50% of all the refrigerated cargo transported in the world. The efficiency and reliability of temperature controlled transportation has reached a point which allows the food industry to take advantage of global seasonable variations, meaning that during the winter the southern hemisphere can export perishable goods to the northern hemisphere while an opposite trade, generally of smaller scale, takes place during the summer. Countries such as Chile have substantially benefited from this and have developed an active agricultural and food transformation industry mainly servicing the North American market during the winter, but also with several niche markets such as wine (Gwynne 211).

The Setting and Organization of Cold Chains

The Product Being Transported

Successfully moving a shipment across the supply chain without suffering any setbacks or temperature anomalies becomes a more frequent accomplishment if a comprehensive logistical process is established. This means carefully calculating and preparing every precautionary measure for each phase of the supply chain. When a temperature sensitive product is being moved, it is vital to first find out specifics about the item. Certain questions must be asked before shipping, such as what the product is and if it is dangerous in any way. For example, a lab mice infected with a contagious disease or HIV positive blood require different attention then frozen produce. Other concerns include where the shipment is going and the weather forecasts for those regions. Will the shipment experience extreme cold or heat along the transport route? Will it be moving from a country in the dead of winter, to a country in the height of summer (WC Pharmaceuticals 5)? These questions lead to others such as what is the desired temperature of the shipment, what is the stability of the product to changes in temperature and are there any pre-packaging procedures that need to be preformed (WC Refrigerated Shipments 3).

Answering these questions can help to better determine the proper container and temperature control device to use. Once a temperature range is established, conditioning issues such as replenishment must be acknowledged (WC Refrigerated Shipments 3). This will allow the handler to be prepared should a delay or a depletion of freezing or refrigerating substances occur. The type of packaging also determines what forms of monitoring are available. If the shipment is not using a container with a built in temperature monitor, then one must be supplied for the shipment. These steps make both transporting a much smoother process and the defense of the integrity of a shipment easier.

Modal Choice

After all the pre-transfer questions are answered, the most efficient mode or modes of transportation must be chosen. Several key factors play into how the shipment will be moved. Distance between the origin and the final location, the size and weight of the shipment, the required exterior temperature environment and any time restrictions of the product all effect the available transportation options (Tech Report#39 17). These logistical characteristics are the difference between using land, sea or air to transfer the package. Short distances can be handled with a van or truck, while a longer trip may require an airplane or freight ship. Heavier loads may require a larger and typically slower shipping vessel, which also means factoring in more transit time. Exterior temperature also plays an important role in protecting a shipment. Shipments that need to stay in a refrigerated area or have low tolerance to heat or direct sunlight must be transported on a craft that can accommodate these needs. Vehicles need to be equipped with cooling or heating devices along with a calibrated temperature monitor (Tech Report#39 18).

Custom Procedures

Another critical point in the supply chain is clearing customs during international transit. The difficulty of this task differs depending on the geographical region. Not every customs agency operates the same way, so it is important to know where a shipment will be clearing customs and the average approval time for similar packages at that agency. A shipment that clears New York in three hours may take three days to pass through Sao Paulo. According to published clearance times, a biological, infectious or pharmaceutical package will clear customs in New York on average in six hours; Sao Paulo on the other hand takes an average of forty nine business hours (WC Official Airline Guide). Other World Cities are even more efficient, Tokyo is an average of four hours and London will clear the same shipments in under an hour (WC Official Airline Guide). If a package has a strict validation period, it is important that less proficient customs gates are avoided. This stage can become potentially damaging to a package with strict environment restrictions, so it is also essential that all the necessary import paperwork is in order and all regulations have been addressed. Providing customs agents with this information will let them know exactly what is in the package they are investigating and make it easier for them to clear the shipment. For many shipments this is the last real obstacle before delivery, so it is vital that time is not wasted while the package sits in the customs' warehouse.

The "Last Mile"

The last stage is the actual delivery of the package to the client, which in logistics is often known as the "last mile". Key considerations when arranging a delivery concern not only knowing where to go, but at what time to get there. Packages must be physically given to the recipient, not just left at the delivery location. Communicating the knowledge of any delays that would push back delivery due or being advised of the times that they are available to receive shipments are important steps to avoiding complications. Once a package clears customs, it must be picked up and transferred to the client. Trucks and vans, the primary modes of transportation for this stage, must meet the specifications necessary to transfer the package. They need to be able to block out exterior weather, have enough room to store the shipment and be capable of restraining any unnecessary movement that could damage the package during transit.

Integrity and Quality Assurance

After the package has been delivered to the client, any temperature recording devices or known temperature anomalies must be recorded and made known to the customer. The client should be made aware of how far out of range the product went, the duration of the excursion and an explanation of how it occurred. This is the step of the logistical process that creates trust and accountability. Clients are gained or lost depending on the success rates of the shipping managers. If problems or anomalies that compromise the product do occur, a concentrated and open effort to rectify the mistakes with strategies and goals aimed at eliminating them is vital to the service provider's economic success.

Some Empirical Evidence

The following studies are examples of logistical strategies that are used in the transfer of biological and pharmaceutical supplies. These studies were conducted from actual shipments that were facilitated by World Courier[2].

Case Study 1: Successful Transfer

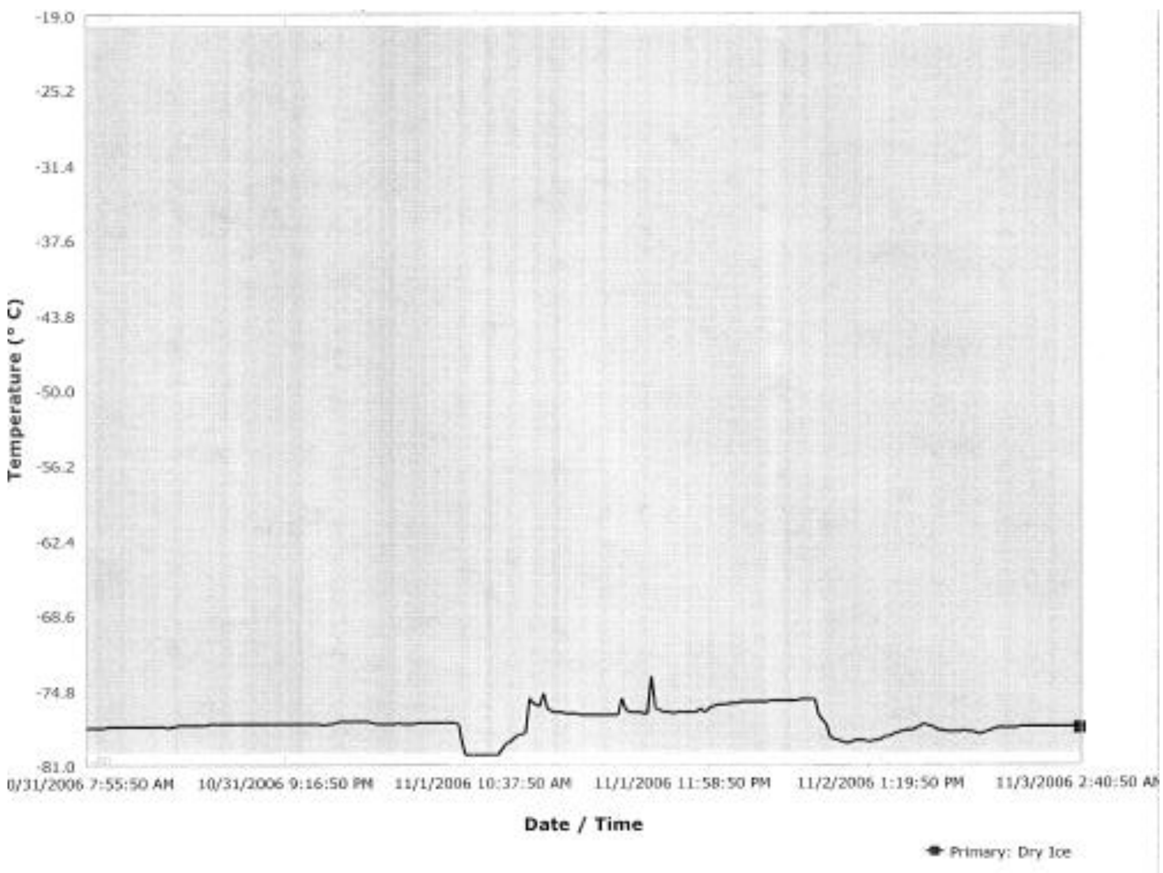
This first study is of a package that was shipped in late October/ early November of 2006. The supply chain originates in St. Petersburg, Russia on October 31, 2006 when the package containing biological samples was picked up from a medical hospital. The samples, which required a frozen environment to remain stable, needed to be transported to a major research facility in Richmond, Virginia by November 3rd for analysis. While air travel was decided on as the most efficient transport mode to move the shipment, a direct flight was not available. In order to reach Richmond, the samples would also have to first transfer flights in Frankfurt, Germany and enter the United States via Atlanta, Georgia. These extra stops posed additional obstacles to maintaining the cold chain, but were planned for and handled accordingly.

The shipment itself contained non infectious bodily fluids from a patient in St. Petersburg. Since the samples needed to remain frozen throughout their transfer, dry ice was supplied to provide the necessary atmosphere. 33 pounds of dry ice was needed for the shipment that combined with the ice weighed approximately 44 pounds. The dry ice levels were checked at each stop along the flight plan, despite the fact that the autumn exterior temperatures were not a danger in the areas the shipment passed through. In

[2] Important note: Since the evidence portrays actual commercial transactions between World Courier and its clients, confidentiality issues forbid their identification. The only information that can be disclosed concerns the type of product transported, the modal sequence used and temperature monitoring results. The exact origin and destination could not be disclosed because it could identify the clients.

Frankfurt the levels appeared low so twelve pounds of dry ice was added to the shipment. The package was checked again in Atlanta, but it was determined that the dry ice was stable and did not require further replenishment. The chart below shows that the temperature stayed well below freezing during transit. The highest temperature the shipment experienced was negative 73° C, while bottoming out at negative 80° C.

Chart 1: Temperature Variances for Case Study 1



Since this was an international flight, the shipment did have to clear customs before leaving Russia and when it entered the United States. All of the export paperwork and regulations where reviewed before the package was granted permission to leave the country. This process was avoided in Frankfurt because there was no lay over requiring the shipment to leave the airport, it simply transferred flights and left for Atlanta. Upon arriving in the United States, the package was unloaded from the plane and sent to the customs warehouse for inspection. After a five hour process where all of the necessary import paperwork and shipping regulations where reviewed, the package was approved and allowed to enter the country. Since it had been replenished in Frankfurt and packaged correctly, the sample managed to remain frozen throughout. After the package was released from customs, it was received by an agent and placed on a connecting flight to travel the approximate five hundred miles to Richmond, Virginia.

Once the plane landed in Richmond, the package was received by an agent and driven to the medical facility for testing. After the recipient had signed off on receiving the shipment, the temperature monitor inside the package was removed and turned off. Its results were then downloaded and sent out to the clients to show that at no time during transit did the integrity of the samples ever come into question. Chart 1 is a copy of those results with a line graph showing the fluctuations in temperature during the trip and the exact temperature of the shipment every fifteen minutes. By providing such an in depth report, the client can be certain that any issues with the human samples were not caused during the transport process.

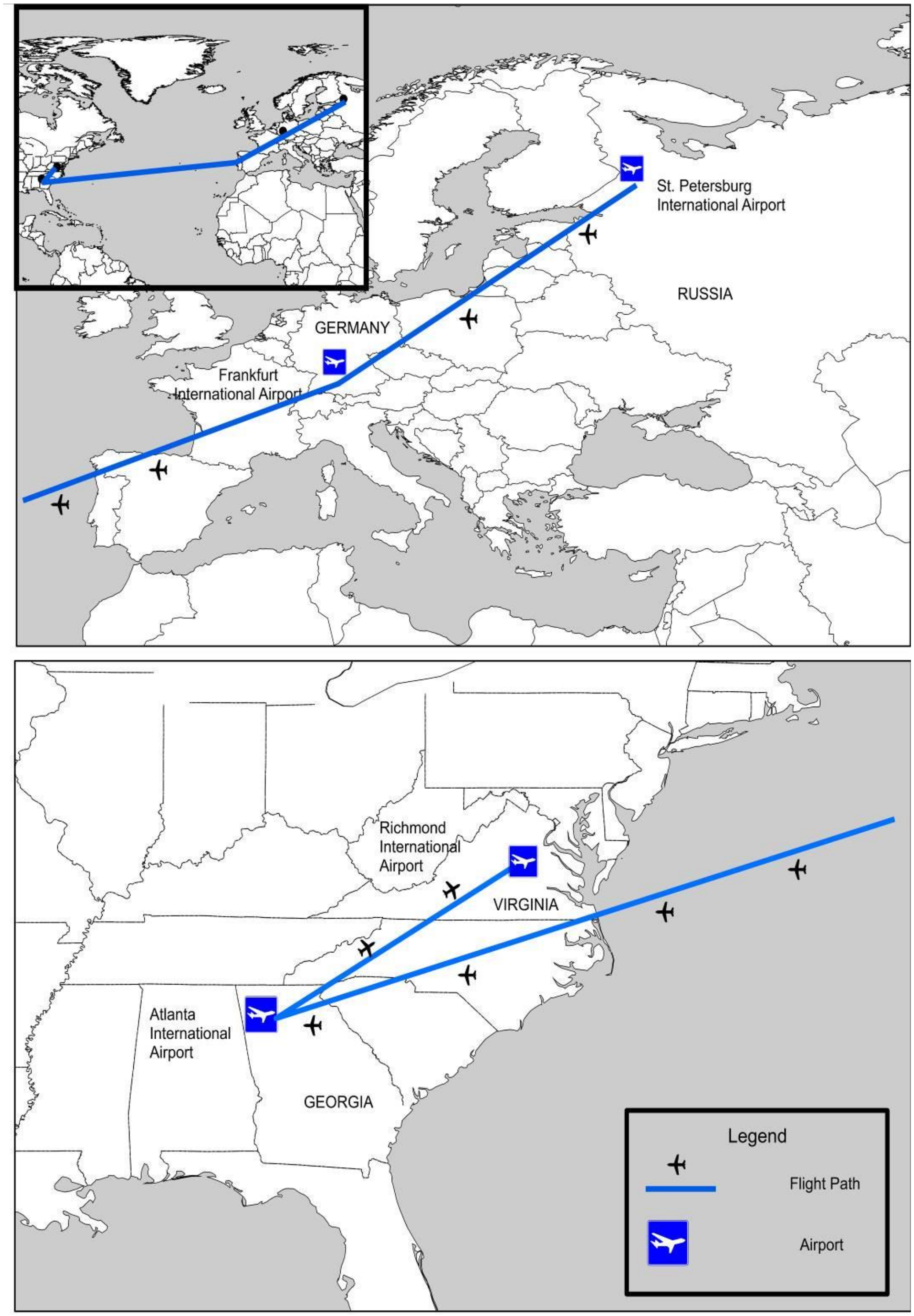


Figure 1: Transit Path

All of the important logistical factors were working together for this shipment. The required import and export paperwork was processed and submitted on time allowing for the quick scheduling of flights. Since the package was also labeled with the correct regulation stickers and notices, the time needed for the shipment to clear customs was significantly reduced. Another important factor was that the weather cooperated and did not cause any delays to the scheduled flights. This meant that the package stayed in the air and out of storage rooms where it would have been most susceptible to losing dry ice and thawing out. The periodic checks of the dry ice also helped to keep the sample frozen, but could have become more costly if the shipment suffered a significant delay at any point on the supply chain. The process was coordinated efficiently and as a result the cold chain was able to allow for this global transfer of sensitive items.

Case Study II- Compromised

This second study is of a package containing pharmaceuticals that left McPherson, Kansas on February 27, 2007 for Spokane, Washington. The shipment, which was being transferred between pharmaceutical laboratories, arrived in Spokane the following day at the expected delivery time. The shipment flew out of McPherson airport and landed in Seattle. After being unloaded from the plane, the package was then driven the roughly three hundred miles to the lab in Spokane. Throughout this process there were no recorded or significant delays to the shipment, it was ready and arrived on time, but this did not stop the shipment from going out of its temperature range.

The pharmaceuticals were shipped with the requirement that they stay in a controlled ambient atmosphere. If at any point they went out of the prescribed 15-30° C range the exploratory drugs would have been rendered useless. To accommodate these specifications, the shipper was provided with a STP 317 pack which by using eight phases change material gel packs, is validated to keep the 15-30 range for 48hrs. The shipper also had specific instructions that during transit the package not be opened for any reason and that it should not be put into refrigeration. Despite meeting all of these required specifications, the shipment, as can be seen in the chart below, still went below the 15°C line. Since none of the prerequisites were violated, a reason for the excursion had to be found through further investigation.

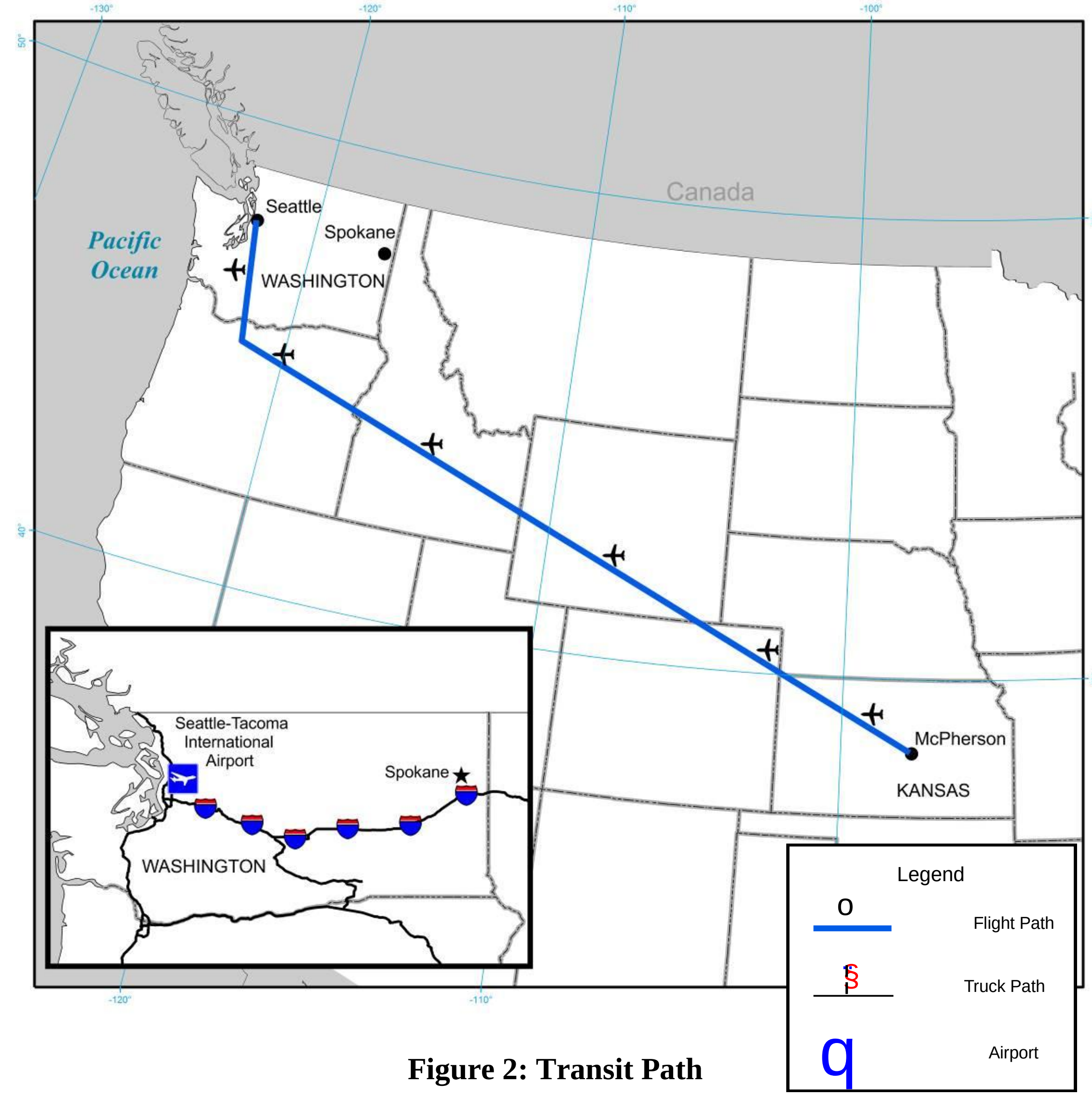


Figure 2: Transit Path

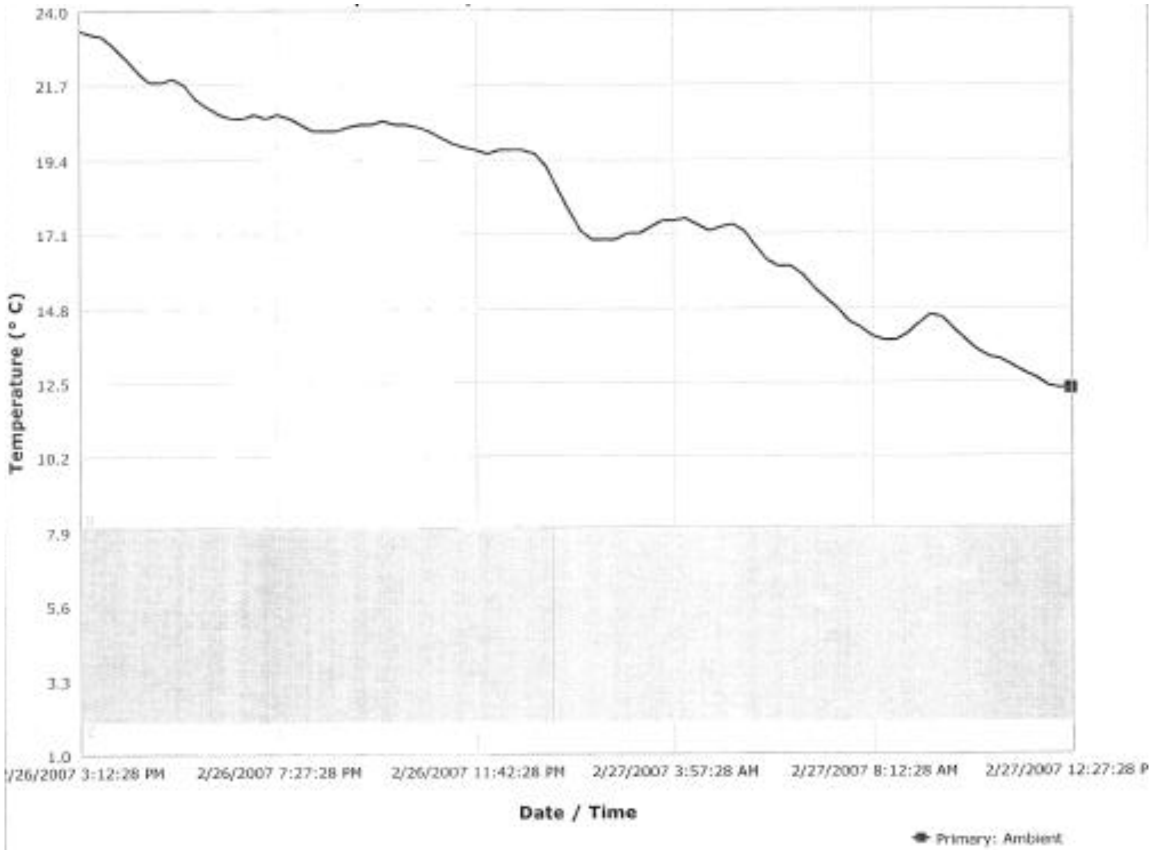


Chart 2: Temperature Variances for Case Study 2

Figure 3

The photo taken immediately after the package was delivered to the lab in Spokane offers some reason as to why the temperature results went out of range. While it is not over packed, it does not have the proper amount or spacing of the gel packs that are required to maintain the ambient temperature. The gel packs should be positioned so that there are two on top, two on the bottom and one on each side. This type of a packing design provides better insulation for the samples and keeps them separate from exterior temperature hazards. Each container comes with a packing design for the shipper to follow. If packaged incorrectly, as is the case with this shipment, the samples run the risk of being exposed to temperatures out of their specified range.

The results for this shipment, which are shown in Chart 2, show an immediate decline in temperature. While the majority of this seventeen hour trip was spent in the required range, the last five hours of transit were below 15°C. Since these five hours rendered the product useless for the company, several questions were asked as who was to blame for failing to keep the product in the proper environment. Since the courier service that organized the logistics of the supply chain followed the instructions of not opening the package and keeping it out of refrigeration, they were not faulted for the excursion. The fault fell on the shipper for not properly preparing the samples in the container before sealing it and sending it off to Spokane. Had the courier not been prepared to defend their logistical methods, they may have been required to reimburse the company or lost significant credibility in providing safe and reliable transit along the cold chain.

Problems and Challenges for Cold Chains

There are still several roadblocks in the path to improving the cold chain. Issues beyond proper packaging techniques and detailed logistical strategies continue to require the attention of companies and groups aiming to improve the chain's efficiency. One of the largest obstacles is the strengthening of supply chains to reduce waste in developing countries, in particular, the ability to provide better forms of cold storage for medical supplies and food between urban and rural regions. "The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have estimated overall wastage rates [of vaccines] in developing countries [at] around 50%" (Setia, et al 1148). In a 1993 effort to end polio in Egypt, a reported 25% of vaccines in urban clinics were wasted, while 41.5% were squandered in rural regions (Setia et al, 1148-9). Other collapses in the cold chain have led to polio outbreaks in South Africa and vaccine damage in Hungary due to extreme weather exposure (Setia et al, 1154). A study of the maintenance of hepatitis B vaccinations in Indonesia found that 75% of the costly medication shipments were exposed to potentially damaging freezing temperatures during transit (Wirkas et al 692). With the high levels of disease and national debt that plague developing nations such as these, to lose valuable resources due to holes in the cold chain is a problem with a critical social impact.

To combat losses in the food trade economy, countries like India, Singapore and the Philippines are stressing the importance of refrigeration facilities and cold chain logistics. In India, measures are being taken to advance the cold chain for the 134.5 million tons of food they produce. More refrigeration centers and better supply routes are needed to update the current services that only accommodate about 13% of their food and vegetable production (Cold is Hot 1). In August of 2006, Singapore recognized that inefficiencies in their supply chain were costing them and began to draft new plans to better manage the movement and handling of their vegetable stock (Xinhua News 2006). Reports from within the country claimed that close to 40% of goods going from rural farms to supermarket shelves are ruined in transit, while new temperature controlled shipping options are estimated to lower the number to 5% (Channel News Asia 2006). Similarly, the Philippines have invested 11.3 million dollars in building cold chain facilities in three cities on the Mindanao Island (Asia Pulse 2006). Vegetable producers on the island stand to see significant gains from the advancements. The aim of each of these nations is that strengthening the cold chain in their country will secure the future success of their food trade industries.

Another area of particular concern for shippers is the proper transportation of hazardous goods. Since the attacks of 9/11 and the heightened security concerns of countries combating terrorism, the transfer of shipments containing potentially hazardous goods has fallen under greater government scrutiny (Clark 2006). The movement of materials classified as dangerous is vital to the biopharm and medical industries, but complications or accidents that occur during transit can be both costly and illegal. According to the Department of Transportation, Pipeline and Hazardous Materials Safety Administration, committing a violation of Hazmat policies that causes damage or creates an unsafe environment can carry both civil and criminal penalties that can reach fines up to 500,000 dollars and 10 years in prison (Clark 2006). A result of these regulations is that companies and handlers are held accountable for not only training themselves for the safe transfer of these goods, but also preparing the supply chain for any occurrence that may be destructive to the environments the shipment passes through. With Hazmats, making sure the product is not compromised during transit is only half of the mission, preventing a disaster is just as critical.

Current and Future Innovations

As the pharmaceutical and food industry companies that rely on cold chain transportation for their economic livelihoods move into the future, new technological advancements and inter-industry cooperation seminars aimed at strengthening every link in the supply chain will continue to emerge. One growing technological improvement to the supply chain is radio frequency identification (Refrigerated Transportation 2006) or the use of identification tags that provide up to the minute reports of where a shipment is located anywhere in the world (Murphy-Hoye et al 46). The use of a tracking device such as these offers the prospect of being able to provide total accountability and service control while a shipment is moving through the supply chain. Any delays or location questions will be able to be answered immediately, making logistical pre-planning much easier. RFID technology also reduces the amount of labor hours needed for tasks associated with accounting for and recording stock piles of inventory (Murphy-Hoye et al 46). The tracking system also offers better protection against potential counterfeit drugs infiltrating the pharmaceutical market (Basta 1).

Another technological advancement that has the ability to greatly alter the analysis and storage of information related to the cold chain are geographical information systems (GIS). This digital mapping program has the capability to produce various visualizations of data entered into its database. Category, physical, topographical and interactive maps are just some of the output that GIS programs can create. One example of using this technology to improve tasks linked to the cold chain can be seen in the study presented on June 29 at the 2005 Post International Food and Agribusiness Management Association Workshop by Burton E. Swanson and his team members. In their report (Swanson et al), they looked at horticultural exports in Upper Egypt and the locations of cold chain facilities to the various agricultural regions. By using GIS they were first able to create maps showing the physical locations of the country's cold chain centers. Then were able to generate visual representations of the data sets for the sales and volume of the nation's major crops and by utilizing different shades of color, show the largest crop concentrations around Egypt. With this information, the team displayed where new cold chain facilities are most needed and generated a plan of how to supply the country with the new technology. A study of this nature is just the tip of the iceberg, GIS also offers the ability to create visual outputs of supply chains and label potential or frequent areas of delay or difficulty during transit. These maps can then be used to provide the best logistical strategies available and produce data that saves both time and money.

Another popular way to educate and share logistical knowledge is by holding industry related conferences where representatives from all facets of cold chain related companies meet to discuss ideas and advocate for new technologies. In late January of 2007, a conference entitled "Advanced Cold Chain Management & Distribution for the Regulated Industry" was held in San Diego and featured several presentations related to the industry (PR Newswire 2007). Sensitech, a company that specializes in cold chain visibility solutions such as temperature monitors and readouts, presented an interactive workshop at the conference entitled "Implementing Good Cold Chain Management

Practices for Shipping and Thermal Mapping Studies" (PR Newswire 2007). This was just one of the presentations given over the two day conference that also focused on issues such as efficiency, cost reduction and regulatory fulfillment strategies (PR Newswire 2007). A similar effort was conducted in the food industry during March of 2007 with the formation of Global Cold Chain Alliance. This group features the partnership of the International Association of Refrigerated Warehouses, the World Food Logistics Organization and the International Association for Cold Storage Construction (Hudson 38). The main objective of this organization, similar to the conference mentioned above is to discuss and share logistical practices and trends, government and economic issues and various opportunities for investment (Hudson 38). Cooperative efforts like this are ways to not only spread awareness about prominent issues, but also serve as stages to present and sell new technologies and strategies aimed at improving the industry.

Conclusion

The size and economic potential of the pharmaceutical, bioscience and foodstuff industries is the core reason behind the success of logistical service providers and cold chain experts. The evidence shows that the demand for cold chain services is growing and that the segments relying on these services are getting increasingly diverse and extended in terms of their geography. It can also be concluded with a reasonable level of confidence that the global behavior of activities relying on the cold chain is changing rapidly. For example, biological samples can be brought in from Russia to a major medical facility in the United States in a reliable and efficient manner (case study 1), favoring a spatial concentration and a specialization of niche medical analysis activities. If a cold chain was not present, the investigation of these samples may either have not taken place, would have been less precise and certainly would have been more expensive. For the pharmaceutical industry, increasing transport expenses, since shipping through a cold chain is much more expensive than by conventional means, are more than compensated by the resulting increases in productivity. Even if the second case study showed a compromised shipment, this is actually a rare event. The shipment took place between two laboratories each specializing on specific aspects of the pharmaceutical commodity chain. From the observed volume and frequency of shipments between these laboratories, it can be inferred that the cold chain supports their respective specialization. This essay has focused on specific segments linked with the pharmaceutical and biological industries and inferring their behavior to other cold chain dependent activities cannot at this point be substantiated.

The number of new complications and eroding obstacles to the many facets of the supply chain will continue to grow along with the industry. Combating these problems and formulated cost efficient and practical solutions will fall into the hands of individuals with firm understandings of logistical planning and the geographic themes that compose their strategies. Beyond being able to read a map and point out a region, successful logistic managers will need to understand difference between the relative and physical distance of points along the supply chain. Knowledge of the strengths and weaknesses of transportation routes such as shipping lanes, gateway cities, highway supply lines and air corridors are also vital to properly planning a shipment's transit path. An understanding of industry related technology, such as GIS mapping and temperature monitoring devices, and how to effectively apply information derived from these to the logistical strategies is another important advancement skill. The cold chain is a business, the financial figures and market importance make this clear, but for every business professional and investor that backs the cold chain, more and more experts that keep shipments moving will be required to strengthen the chain. Moving a bushel of grapes, expensive drugs or a kidney transplant may produce profits, but it won't make it to its final destination without the logistical planning of an industry professional.

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