

Biologistics Security: Implications for Market Growth, Transportation and Logistics

A proposal submitted to the
FedEx Institute of Technology in
Collaboration with the Intermodal Freight
Transportation Institute
The University of Memphis

Submitted by the Sparks Bureau of Business and Economic Research with
the Intermodal Freight Transportation Institute
The University of Memphis
October 15, 2015

PROJECT TITLE:

Biologistics Security: Implications for Market Growth, Transportation and Logistics

PURPOSE:

The purpose of this proposal is two-fold—

1. To present an overview of the current security issues associated with the shipment of life sciences products, dual-purpose elements, vaccines, pathogens, “gain of function” substance sharing among research laboratories, and high value pharmaceuticals. Product security risks associated with theft, terrorism and mishandling of biological shipments is on the rise. The cost of shipping is directly associated with the increase in product linked liability risk and the reputational risks for companies along the supply chain. The increasing problem of theft, manipulation and resale of biological products is a global issue associated with controlling security at every stage of the supply chain.
2. To develop an organization and operation plan for a “Center for Biologistic Product Protection and Security Research” —a research, education and training partnership between the Intermodal Freight Transportation Institute and the Sparks Bureau of Business and Economic Research.

RESEARCH JUSTIFICATION:

Two primary factors support the need for research in this area. First, the anticipated growth in the need for life sciences products, high value pharmaceuticals, and designer drugs will increase shipments and the risk associated with the shipments. The cost of providing secure shipping paths will rise exponentially as the shipments increase and the threats of bio-terrorism and theft increase. Second, recent high profile and serious lapses in the physical security of regulated products from government and research labs, and high-value pharmaceutical thefts has created new challenges in the handling of biologic products safely and securely.

1. Market Growth:

Aging populations, the global growth of chronic and lifestyle diseases, emerging-market expansion, and treatment and technology advances are expected to spur life sciences sector growth long into the future and significantly change the life sciences product demand and delivery systems that exist today. It is becoming evident that the life sciences sector is being transformed with increasingly sophisticated products with individualized shipping requirements. A dynamic clinical, regulatory, and business landscape is requiring that pharmaceutical, biotechnology, and medical technology companies adopt delivery systems that support safety and security concerns. Those delivery systems involve the education and training of personnel all along the length of the supply chain. In addition to these trends concerning the bio logistics industry, the growth of e-

commerce has spurred the need for additional research as personalized home delivery programs are becoming more common and a growth trend for carriers.

2. Public Safety and Security:

A changing risk environment for life sciences products and research elements has resulted in a number of high profile safety and security breaches in the last decade most recently the anthrax breach in July 2015. In that case, the CDC reported anthrax errors involving 575 shipments. Immediately, carriers began to limit pathogen agents they would handle, a serious setback to infectious disease research. The risk associated with mishandling biologic product shipments can be enormous and mistakes can negatively impact the reputation of companies along the supply chain. As a result, shippers must be compensated not only for the cost of shipments but the total range of risks involved in handling highly valued and dangerous products. Cost increases will occur as the risk associated with shipping increase. Weak or incomplete security fosters high-profile incidents and increases the need for product security, personnel education and increased transparency. Public controversy, highly visible risks and rising costs associated with the supply chain is a barrier to the growth of the biologistics industry.

The growth of security concerns and associated costs is being driven, in large part, by expanded consumer access to health care and life sciences products in the United States and the movement of biological shipments around the world. Specialty drugs (cancer treatments, Hepatitis C treatment and other emerging drugs) that warrant premium prices also provide lucrative opportunities for theft and resale. (Deloitte, *Global life sciences Outlook: Adapting in an Era of Transition*, 2015.)

THEORITICAL BASIS:

Transportation costs rise as the risk associated with shipping any product increases. Rising costs have to be absorbed by the consumer or the provider or both. While transportation costs may be a small percentage of total costs, the spread to biologicistic product shipments around the world increases as the threat associated with theft, terrorism and product manipulation increases.

RESEARCH METHODOLOGY:

--By reviewing current literature, this research will provide an overview of current practices in the protection and security of life sciences products. Education and training practices related to door-to-door transport of dangerous or high value products will be examined.

--A catalog of resource materials—including databases pertinent to the current topic—will be compiled.

--Based on the overview findings, the report will recommend an organizational and operational framework for a “Center for Biologic Product Protection and Security Research.”

RESEARCH QUESTIONS:

1. Are there reliable data sources available regarding the protection and security of life sciences products?
2. What are the current data sources regarding the protection and security of life sciences products?
3. What is the current cost of providing security for life sciences products?
4. How are those shipping costs determined?
5. What are the primary companies that provide security for life sciences products?
6. Where are these companies located, what do they do, what are their personnel practices, what has been their experience in the protection and security of life sciences products?
7. What are the primary sources of the demand for the protection and security of life sciences products?
8. Does a taxonomy for products requiring hands-on security exist?
9. Can security requirements be reliably assigned to these products?
10. What is the status of existing research, education and training centers, where are they located, how are they staffed and what do they do?
11. What are the current technological advancements and trends for the safe and secure transit of these products?
12. Do research gaps exist, and how can they be remedied?

ANTICIPATED CONTRIBUTION TO THEORY AND PRACTICE:

The global movement of biologic products of all types is increasingly important. As the industry grows, the security of the biologic supply chain (especially shipping) is paramount to the successful movement of goods and services. Reducing the cost and risk of handling these products is an essential step in making businesses more profitable and reducing consumer costs.

COMMUNITY IMPACT:

Biosafety concerns will be allayed by knowledge-based information regarding the protection and security of life sciences products as well as personnel practices associated with public safety.

This project will contribute to public assurances that risky and high value life science agents are not a threat to the community but can be securely, efficiently, safely and cost effectively transported with proper care and systems to monitor the delivery process.

The public wants assurances that life sciences products are risk-free and that the protection and security of life sciences products as well as personnel practices associated with public safety are maintained.

TIMELINE AND BUDGET:

The report will be completed by April of 2016. The project cost will be \$20,000. The Sparks Bureau will be the lead research unit and will work closely with IFTI to complete the work outlined.

DATA COLLECTION:

A literature review and an industry survey will be the primary source of data collection. Follow up conversations with selective partners will create a dialogue of future opportunities and solutions that are widely accepted as industry practices.

COLLABORATION WITH INDUSTRY:

Industry partners will be identified and surveyed regarding their views on issues related to shipping biologic products.

- Overnight delivery companies
- Transportation companies
- Trucking companies
- Shippers that deal with direct consumer deliveries
- Pharmaceutical companies
- Logistic Accelerator companies

COMMUNITY AND GOVERNMENT PARTNERS (based on current and previous relationships):

- FBI
- Cargo Theft Task Force
- TDOT
- Tennessee Department of Homeland Security
- Shelby County Government

--City of Memphis

CAPACITY STATEMENT:

A combined effort of SBBER and IFTI at the University of Memphis will be a great partnership to utilize their expertise in working on this project. Both organizations have had success in engaging the private and public sector in various research projects, outreach, studies and surveys to enhance the University's reach within this region. Additionally, both organizations have brought national exposure to the University by the work they have competed on the various projects.

The mission of the SBBER is to conduct economic and labor market research and service activities that complement the teaching, research, and public service missions of the Fogelman College of Business & Economics at the University of Memphis. The objective of the SBBER is to maintain its status as one of the nation's largest and most successful applied research, technical assistance, and outreach divisions of a college of business. The SBBER staff conducts research related to economic, demographic, and business issues that impact Tennessee and the surrounding Mid-South states.

The Bureau employs professional and support staff members that include Ph.D./Ed.D. Economists and researchers, Masters-level research associates and IT professionals, graduate students, and student workers. The SBBER is also home to three associated research centers: the Center for Manpower Studies, the Center for Real Estate Research, and the Applied Information Technology Center.

Haskel D. "Hack" Harrison, Ed. D--Dr. Harrison is an Educator and Associate Research Professor of Applied Public Sector Research and Evaluation, and Senior Researcher, in the Sparks Bureau of Business and Economic Research, Fogelman College of Business and Economics, University of Memphis and will be the PI for this project.

Dr. Harrison has over 40 years of experience conducting, directing and managing a variety of research and evaluation projects. He has produced over 50 research reports and monographs, has published 30 articles and editorials in refereed journals or by invitation, and has presented at dozens of conferences and professional association meetings.

For the past three years, Dr. Harrison has conducted studies on labor market supply and demand issues in the trucking industry to include labor market projections, productivity, compensation, long-term employment trends, and the impact of regulation on a variety of transportation sectors. These investigations resulted in the publication of two reports for the Intermodal Freight Transportation Institute, University of Memphis --*Examining Driver Turnover and Retention in the Trucking Industry* and *The Labor Market Impacts of Compliance, Safety, and Accountability (CSA) on the Trucking Industry: Supply and Demand Issues for the Future*.

The Intermodal Freight Transportation Institute has experience in addressing critical issues affecting the planning, design and operation of the nation's intermodal freight

transportation systems. Their work is nationally recognized in linking people to solutions in freight and logistics through research, education and technology transfer activities.

Dan Pallme is the Senior Associate Director of the Intermodal Freight Transportation Institute (IFTI) at the University of Memphis. He received his Bachelors from the University of Memphis and Masters degree from the University of Denver. He spent his entire career focused in the transportation sector. During his undergraduate years, he worked at Federal Express (Air) working a variety of positions while he focused on graduating. Upon graduating from Memphis, he went to work for Yellow Freight System (LTL) in their management trainee program. He worked for Yellow Freight System in various capacities and moved to several locations in their network. In 1990, he started in the intermodal industry at Union Pacific (rail) as a general supervisor. He finished his career with the Union Pacific Railroad in several management positions at a few locations. From 2004 to June 2011, he was Director of Business Development at Comtrak Logistics. He was responsible for all the revenue associated with the company. During that timeframe, Comtrak Logistics grew from 15 to 25 terminals. Comtrak Logistics (now Hub Group Trucking) developed into one of the largest nationally drayage providers specializing in intermodal in the country. Mr. Pallme will be the industry expert for this project and will work with Dr. Harrison as the research team.

The combined centers of SBBER and IFTI bring a wealth and depth of knowledge and experience to the University of Memphis. An internal University of Memphis collaborative effort between IFTI and SBBER bringing in real solutions to this issue will put the University at the forefront in the area of biologistics. Memphis with a city of the highest percentage of population involved in the transportation sector, it would only be a natural decision for the University of Memphis to lead the way on this subject. With the expertise housed at both of the centers and the industry contacts, we should be poised for positive international exposure to the field of biologistics.