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New Challenges to Emergency Management of Pharmaceutical/Healthcare Supply Chain Disruptions

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The continuity of operations in pharmaceutical/healthcare supply chains is vital to human welfare and the span and quality-of-life of patients [1]. This is particularly important when the population is confronted with a massive health problem, such as a breakout of a pandemic (e.g., a deleterious mutation of the swine flu H1N1 virus), an industrial accident (e.g., the release of a massive dose of toxic material in a dense urban area), or a terrorist high-consequence event (e.g., a massive explosion, dirty bomb, or the release of a pathogen into the environment). The continuity of operations could also be affected by data security breaches, demand variability and supply fluctuations.

A supply chain disruption occurs when supply falls severely short of supply. Such disruptions take place when either the nominal supply capacity of a business process is greatly reduced for some period of time, or a sudden surge of demand manifests itself, or both. Disruptions in pharmaceutical/healthcare contexts upset the continuity of providing for patient needs, and can have particularly severe consequences. Indeed, when other supply chains are disrupted, companies typically merely lose revenue and potential market share, whereas disruptions to pharmaceutical/healthcare supply chains can put the lives of large numbers of men, women, children and senior citizens in jeopardy. Under the all-hazard approach, DHS is tasked with handling major emergencies and disruptions regardless of cause, including natural disasters, terrorism, pandemics, etc.

Current practices and future trends in pharmaceutical industries have actually enhanced the vulnerability of their supply chains [2, 3]. First, as in other industries, outsourcing has become an important strategic issue for pharmaceutical companies due to increasing competitive pressures to reduce cost and time-to-market. In addition to outsourcing traditional non-core functions, such as manufacturing and clinical trials, pharmaceutical companies increasingly outsource upstream functions, including drug discovery, biotech R&D, and even clinical research. In fact, some companies, such as Astra Zeneca, have announced plans for 100% outsourcing within the next 10 years. Unfortunately, these outsourcing trends render pharmaceutical supply chains longer, more complex, and reduce their visibility.

Secondly, sales and distribution of pharmaceutical products depend heavily on third party distributors who fully own and control inventories once they leave the manufacturer's site. The involvement of additional parties in pharmaceutical supply chains increases their complexity and the odds of malfunction.

Third, the globalization of the pharmaceutical industry increases the risk of supply chain disruptions by adding even more complexity and geographical scope to supply chains that are already overburdened. To wit, foreign companies manufacture as much as 80% of all ingredients used by American drug makers [4]. Potential regulatory hurdles and shipping uncertainties along the distribution network, from foreign companies to drug makers, greatly complicate coordination in supply chains and are deleterious to their reliability.

The aforementioned emerging trends in pharmaceutical supply chains are giving rise to a host of new issues, challenges, and research topics that impact the management of emergencies and disruptions. These can be classified into the following two categories:

1. Pharmaceutical/Healthcare Supply Chain Resilience

Following is a list of challenges to maintaining a resilient pharmaceutical/healthcare supply chain:

- **Risk measurement and evaluation.** Analytical and/or empirical studies should be carried out to measure and evaluate the risks associated with potential partners and candidate facility locations before companies make major decisions concerning sourcing, subcontracting, inventory management or facility location.

- **Sourcing mitigation**. Recent research suggests that sourcing mitigation (e.g., dual sourcing, supply options, etc.) is increasingly favored over inventory mitigation as supplier disruptions become less frequent but longer [5]. There is a need for studies that evaluate and compare these two mitigation strategies.

- **Supplier quality assurance.** The efficacy of pharmaceuticals can be compromised in complex supply chains with a variety of storage facilities and long lead-times. Quality assurance is particularly important when managing high-consequence events with severe health implications (e.g., pandemics and releases of toxic materials and pathogens). Research on supplier evaluation that includes quality assurance under supply chain disruptions is needed.

- **Location analysis of distribution centers.** In practice, planning of distribution centers in the pharmaceutical industry has not typically included disruption as a major issue. Consequently, joint optimization of locations and sizing of distribution centers has rarely been undertaken by collaborating teams of distributors and manufacturers

aiming to minimize the negative impact of disruptions. Remedying this situation calls for the development of appropriate facility location models that consider the impacts of potential disruptions on transportation networks and distribution centers.

- **Backup facility capacity planning.** In addition to safety stocks, the availability of a level of standby capacity at each echelon of a supply chain would further increase supply chain reliability. However, increasing the standby capacity entails additional costs as well as FDA approval. This presents a new optimization problem that must trade off supply risks and additional costs subject to various constraints.

- **Economic impact of port disruptions.** The bulk of imported pharmaceuticals as well as raw material and intermediate compounds arrive in the U.S. via maritime ports. Disruptions of port operations can have a severe detrimental effect on pharmaceutical supply chains, since limited shelf life and storage requirements of many pharmaceuticals can affect their medicinal efficacy. Thus, management of port disruptions must plan for alternate maritime transportation routes and take into account the increased lead times stemming from the rerouting of cargo vessels.

- **Continuous quality management.** Chemical compounds for pharmaceutical products are provided by suppliers dispersed across multiple regions [6]. Small pharmaceutical companies often partner with contract manufacturers to produce their pharmaceutical products, and many parties contribute to product safety. Preventive and emergency procedures have to be developed for assuring raw material quality and final product safety. Multiple parties have to collaborate with one another on product safety issues in order to reduce quality disruption risks in the supply chain.

- **Disruptions** at **contract manufacturers.** The general approach to enhancing the reliability of the manufacturing echelon in a supply chain is to construct a portfolio of manufacturing sources, including contract manufacturing and in-house manufacturing. This issue is of particular importance to the pharmaceutical industry in view of its increasing reliance on outsourcing, and the specific time constraints and quality requirements of many drugs. Consequently, managing disruptions at contract manufacturers calls for entering into a business relationship with a set of alternate contract manufacturers.

2. Response and Recovery from Pharmaceutical/Healthcare Supply Chain Emergencies and Disruptions

Following is a list of issues pertaining to response and recovery actions in the wake of an emergency or significant disruption of a pharmaceutical/healthcare supply chain:

- **Dynamic demand estimation and forecasting**. The course of an infection process (e.g., a pandemic, such as a virulent swine flu) will strongly influence decision

making. In such cases, accurate forecasts of the demand (for vaccines and drugs) to treat severely ill patients are essential to controlling the outbreak. Epidemiological studies are needed to model the spread of infection in time and space (using population density data across geographical regions) in order to forecast demand for pharmaceuticals. Such models will likely make use of additional parameters, such as seasonal weather conditions, specific social network structures, etc.

- **Dynamic allocation of resource**. The outbreak of a pandemic would dramatically increase demand in pharmaceutical (including hoarding), thereby creating supply chain disruptions. Given limited amount of resources, we need to determine where and how much to distribute them to different infected areas (with different number of infected people and density, etc.). Is it better to proportionally allocate resources to different areas (might be politically correct) or maybe it is better to make sure we control the possible spread of virus from the largest infected areas? Given that we have forecasts on the future supply of resources and demands in the future, the dynamic version of this problem is even more complex and interesting.

- **Inventory positioning for short shelf-life products.** In general, adequate safety stocks can protect a supply chain against potential disruptions, and improve customer service levels. However, in the pharmaceutical industry, pharmaceuticals have a limited shelf life, with many drugs having a short expiration date. This fact imposes severe constraints on safety stock management, thereby increasing management complexity. In addition, stock visibility is often hampered when third-party distributors control substantial inventories. Research is needed on effective inventory positioning (locations and quantities) as well as ways to enhance supply chain visibility, in order to support optimal response to the emergency/disruption management problems.

- **Information sharing and collaboration.** Information sharing and collaboration among all supply chain echelons, such as suppliers, contract manufacturers and pharmaceutical companies, are critical to managing recovery processes from supply chain disruptions. Information sharing is especially critical in first-response activities following a high-consequence event. Consequently, incentive policies, and mechanisms as well as business models for information sharing and collaboration among all supply chain echelons should be studied and designed.

- **Developing business models for minimizing counterfeiting.** In recent years, pharmaceutical supply chains have been attacked by increasingly sophisticated criminals who divert, counterfeit and adulterate patient medications. As compared to other industries, the pharmaceutical industry is under severe pressure to further enhance supply chain security, while simultaneously reducing costs and maintaining service levels. The industry also faces a growing challenge in the form of an expanding plethora of state regulatory requirements, as well as new challenges

stemming from unregulated Internet drug sales and personal importation. Counterfeiting attacks many elements of the chains, from packaging centers, shipping, Internet sales, and distribution networks. Any disruption of the chain can create a tremendous opportunity for counterfeiters who step in to fill pent-up demand with bogus or substandard pharmaceuticals, thereby imperiling patient health. There is a pressing need to develop cooperative business models, where supply chain partners work together to minimize counterfeiting opportunities. Published academic research on tackling such issues is essentially nil.

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