



RELIANCE ON FOREIGN SOURCING IN THE HEALTHCARE AND PUBLIC HEALTH (HPH) SECTOR:

PHARMACEUTICALS, MEDICAL DEVICES, AND SURGICAL EQUIPMENT

DECEMBER 2011

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PREPARED BY

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Table of Contents

EXECUTIVE SUMMARY.....	4
I. INTRODUCTION	9
Methodology	10
II. INDUSTRY PROFILE	13
III. MANUFACTURING OPERATIONS	17
Critical Commodities List.....	17
Product Areas Manufactured	19
Manufacturing Location.....	22
Sole Manufacturers	26
IV. NON-U.S. SUPPLIERS OF CRITICAL COMPONENTS/MATERIALS/ PRODUCTS.....	30
Overview.....	30
Non-U.S. Supplier Locations	31
Internal Versus External Suppliers	34
Components, Manufacturing Materials, and Finished Products	35
Alternate Sources of Supply	40
V. MANUFACTURING CAPACITIES	44
Lead-times to Increase Production.....	44
Primary Factors Limiting an Increase in Production	48
Change in Production Through 2015.....	50
VI. SUPPLIER RELATIONSHIPS.....	52
Supplier Selection	52
Supplier Contracts.....	53
Unique Factors Considered When Purchasing/Outsourcing Outside the United States.....	55
Contract Clauses	56
Visibility into Supplier Operations	57
VII. INVENTORIES	58
Type of Inventory	58
Selection of Products for Inventory	60
VIII. SUPPLY SHORTAGES/DISRUPTIONS	61
Alternate Sources of Supply	61
Supply Shortages and Disruptions	63
Database Detailing Supply Disruptions	66

Mechanisms to Inform the Company in Case of a Supply Disruption	67
Future Risk of Supply Disruptions/Shortages.....	68
Vulnerability to Serious/Prolonged Supply Disruptions.....	69
IX. STEPS TO REDUCE FOREIGN DEPENDENCIES	71
Company Efforts to Reduce Foreign Dependencies	71
U.S. Government Regulations	72
Non-U.S. Government Regulations	73
Steps the U.S. Government Can Take to Reduce Foreign Dependency Issues	74
X. FINANCIAL HEALTH	76
Net Profit Margin.....	77
Current Ratio.....	79
Long-Term Debt to Total Asset Ratio	80
XI. FINDINGS AND RECOMMENDATIONS	83
Report Findings.....	83
Report Recommendations.....	86
APPENDIX A: THE CRITICAL COMMODITIES LIST	89
APPENDIX B: TOP PRODUCT AREAS WITH CRITICAL COMPONENTS/MATERIALS/FINISHED PRODUCTS FROM NON-U.S. SUPPLIERS	102

EXECUTIVE SUMMARY

The Department of Homeland Security (DHS), Homeland Infrastructure Threat and Risk Analysis Center requested support from the Bureau of Industry and Security's (BIS) Office of Technology Evaluation (OTE) to conduct an industrial base assessment of critical foreign sourcing in the Healthcare and Public Health (HPH) Sector. The HPH sector is one of the 18 Critical Infrastructure and Key Resources (CIKR) sectors established under the National Infrastructure Protection Plan (NIPP). Anecdotal evidence suggested that domestic manufacturers of healthcare-related products are reliant upon non-U.S. suppliers for many critical components and materials.

Under the Defense Production Act of 1950, as amended (50 U.S.C. App. Sec. 2155) and Executive Order 12656, OTE has unique authority to conduct surveys and assessments of issues vital to the U.S. industrial base. Using this authority, combined with independent research and site visits, OTE designed a sector-specific survey that was used to collect detailed information from companies in the HPH Sector.

This assessment was designed to provide data on the scope and pervasiveness of foreign dependencies within the U.S. healthcare and public health supply chain, focusing on pharmaceuticals, medical devices, and surgical equipment marketed, manufactured, and/or sold in the United States. This information will allow government and industry to monitor trends and take informed actions to mitigate potential problems caused by foreign sourcing and dependency issues.

From the thousands of potential healthcare-related products available, OTE identified 418 commodities - 290 pharmaceuticals and 128 medical devices/surgical equipment - that were deemed critical to healthcare services in various emergency scenarios in the United States. If their availability were limited or denied, it could present risks for the delivery of needed services by U.S. healthcare providers. These commodities were selected based on previous shortages/supply disruptions, interagency input, the World Health Organization's (WHO) *List of Essential Medicines*, and other sources.

A total of 161 companies participated in the study, each of which produced at least one of the 418 commodities identified in the survey for sale in the United States. Of these, 70 respondents were pharmaceutical manufacturers, 75 manufactured medical devices/surgical equipment, and 16 manufactured both. These companies accumulated \$813 billion in net sales in 2010 for all products they manufacture. Twenty-two large-sized companies represented 89.7 percent of this sales figure.

Based on survey responses, independent research, and field interviews, OTE developed the following findings:

- There is a significant amount of U.S.-based manufacturing for critical healthcare-related commodities.
- However, there is a very high degree of foreign sourcing and dependency for critical components, materials, and finished products required for U.S.-based manufacturing operations.
- In many cases, there is no U.S.-based alternate source available for the components, materials, and products supplied from companies based outside the United States.
- Foreign dependencies are not concentrated in any one country, but are widely spread across the world. For pharmaceutical products, survey respondents identified non-U.S. based suppliers for components, materials, and finished products in 47 countries; the top five countries were Italy, India, Germany, China, and France. For medical devices/surgical equipment, there were suppliers in 41 countries; the top five countries were China, Germany, Japan, Mexico, and the United Kingdom.
- Respondents are able to increase their production in varying degrees for nearly all products considered in the OTE survey when given the appropriate lead-times.
- Increases in production are primarily limited by plant space/capacity, new machinery delivery lead-times, and non-U.S. sourced raw materials shortages/availability.
- Pharmaceutical companies tend to maintain supplier contracts of a longer length than medical device/surgical equipment manufacturers.
- Total delivered cost and product availability are the primary factors companies consider when they outsource/purchase overseas.

- Eighty-one percent of survey respondents maintain an inventory of components/materials and finished products.
- Seventy percent of respondents have a list of approved alternate suppliers, although these companies may not be approved by regulatory agencies.
- Thirty percent of respondents experienced a “significant” supply shortage or disruption from 2007-2010, most commonly related to supply shortages, manufacturing quality issues, and/or delays in regulatory approvals.
- Exposure to supply disruptions is widespread, but many respondents consider it a price of doing business in the healthcare industry. In an indicative statement, one company said they “do not believe [our company] is any more vulnerable than the rest of our industry competitors.”
- Only 34 percent of respondents are taking steps to reduce their exposure to foreign sourcing and dependency issues. Many companies are finding it difficult to reduce foreign sourcing because the products they require are not available in the United States.
- While many companies maintain relationships with multiple suppliers to mitigate the risk of supply disruptions, they often are not able to do so for all the products they require due to lack of availability, cost, and regulatory requirements.
- Many respondents noted that the long lead-times to certify new suppliers with the Food and Drug Administration (FDA) and other U.S. Government agencies make it cost-prohibitive to maintain alternate or second sources of supply for critical commodities. The competitive nature of this commercial industry makes it difficult to maintain multiple and/or domestic sources when this practice may add significant costs and regulatory obligations.

Survey respondents were asked to make recommendations on ways the U.S. Government could reduce foreign dependency issues in the HPH sector. These recommendations included:

- Speeding up FDA approval times;
- Reducing the costs and clarifying the process for FDA certification of suppliers;
- Increasing enforcement of FDA regulations outside the United States;

- Streamlining transportation and importation quota issues with Customs and Border Protection (CBP), the Department of Transportation (DOT), and the Drug Enforcement Agency (DEA);
- Reforming environmental laws, particularly those related to API production; and
- Modifying the corporate tax structure to encourage domestic manufacturing.

Based on the survey findings and discussions with U.S. Government agencies and industry groups, OTE makes the following recommendations:

- DHS, HHS, FDA, and other relevant U.S. Government agencies should further examine OTE's survey data to prioritize the foreign sourcing and dependencies that could have the greatest impact on the healthcare supply chain in an emergency situation.
- These same agencies, utilizing the HPH Sector Coordinating Council and other mechanisms, should discuss with industry the concerns presented by a high reliance on non-U.S. based suppliers for such a wide range of critical pharmaceuticals and medical devices/surgical equipment and develop possible solutions.
- The FDA should continue to hold and expand public hearings and information gathering meetings with industry to review the impact of regulatory requirements, approval times, and limited government resources on the foreign sourcing and dependencies issue. Addressing these issues may help promote dual-sourcing, allow for quicker transitions to new suppliers in case of a disruption, and increase the competitiveness of U.S. companies globally.
- DHS, HHS, FDA, and other relevant U.S. Government agencies should further examine OTE's survey data to prioritize regulatory requirements and obstacles cited by respondents that could promote the establishment of domestic sources of supply for critical commodities, particularly for active pharmaceutical ingredients. Of particular note are regulatory approval times for supplier certification, environmental regulations related to API production, and transportation/importation requirements for certain commodities.
- HHS, in coordination with DHS and the Department of Commerce, should assess whether the use of Defense Production Act authorities, such as the Defense Priorities and Allocations System (DPAS), could provide the ability to rapidly expand or surge capacity

of U.S.-based pharmaceutical and medical device/surgical equipment facilities to meet demand in an emergency situation.

- U.S. industry should make renewed efforts to ensure supply chain resiliency by developing and maintaining multiple suppliers for critical components, materials, and finished products. These efforts could include development of new business strategies that give priority to domestic sources of supply, thereby reducing dependence on critical components and materials from suppliers based outside the United States. Additional steps should also be made to monitor the potential for supply disruptions before they occur.

I. INTRODUCTION

This industrial base assessment was initiated by the Bureau of Industry and Security (BIS), Office of Technology Evaluation (OTE), on behalf of the Department of Homeland Security (DHS), to identify foreign sourcing for critical products and other supply chain issues that could have a negative impact on the delivery of effective medical services in the United States. The focus of the study was on pharmaceuticals, medical devices, and surgical equipment marketed, manufactured, and/or sold in the United States. This assessment was designed to provide data on the scope and pervasiveness of foreign dependencies within the U.S. healthcare and public health supply chain. OTE also cataloged information related to the manufacture of selected pharmaceuticals and medical devices/surgical equipment that are critical to the delivery of medical services in emergency situations. Detailed information on previous supply shortages and disruptions, inventory management, and supplier contracts were also sought to provide insight into supply chain practices in the healthcare manufacturing industry.

The Department of Homeland Security (DHS), Homeland Infrastructure Threat and Risk Analysis Center requested that BIS/OTE conduct an industrial base assessment of the Healthcare and Public Health (HPH) Sector. The HPH sector is one of the 18 Critical Infrastructure and Key Resources (CIKR) sectors established under the National Infrastructure Protection Plan (NIPP). The information collected for this study supports the primary objective of the NIPP: “to strengthen national preparedness, timely response, and rapid recovery of CIKR in the event of an attack, natural disaster, or other emergency.”¹

Foreign dependencies in the HPH Sector have long been a concern from a supply chain security perspective. For many pharmaceuticals and medical devices/surgical equipment, domestic manufacturers are increasingly reliant on non-U.S. suppliers for raw materials and critical components. In addition, manufacturing operations for many of these products have moved overseas. The lack of control over materials required for manufacturing has increased the lead-times necessary to surge production in an emergency, making contingency planning difficult. Up to this point, however, the full extent of these dependencies and their potential impact on

¹ Department of Homeland Security (DHS), *National Infrastructure Protection Plan* (2009), p.1.

American healthcare services has not been fully understood. OTE has sought to provide specific detail on where products are being manufactured, which companies manufacture them, where their critical supplies are coming from, reliance on sole sources of supply, and other issues related to foreign dependencies.

METHODOLOGY

BIS/OTE performed this assessment and data collection under authority delegated to the U.S. Department of Commerce under Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. App. Sec. 2155), and Executive Order 12656. These authorities enable BIS/OTE to conduct mandatory surveys, study industries and technologies, and monitor economic and trade issues affecting the U.S. industrial base. OTE recently completed assessments of the National Aeronautics and Space Administration (NASA) industrial base, the penetration of counterfeit electronics into the U.S. defense supply chain, five-axis simultaneously controlled machine tools, and the U.S. integrated circuits industry.

Upon initiation of the assessment, OTE undertook a number of steps over several months to better understand the HPH Sector. OTE first held discussions with various industry and government groups that are familiar with the sector and issues related to foreign sourcing, including the Department of Health and Human Services (HHS), the Food & Drug Administration (FDA), the HPH Sector Coordinating Council (SCC), leading companies in the industry, and supply chain and emergency managers of numerous hospitals. These discussions highlighted the global nature of the healthcare supply chain and the prevalence of foreign sourcing and dependency issues.

From the thousands of potential healthcare-related products, OTE identified 290 pharmaceuticals and 128 medical devices/surgical equipment deemed critical to effective healthcare services in the United States. These commodities are needed in various emergency scenarios. If their availability was limited, it could present problems for U.S. healthcare providers. These commodities were selected based on previous shortages/supply disruptions, interagency

coordination, the World Health Organization's (WHO) *List of Essential Medicines*, and trade deficit analysis.

OTE designed a survey covering respondents' current business operations, which included questions on:

- Product areas manufactured;
- Critical components, manufacturing materials, and finished products supplied by companies based outside the U.S.;
- Manufacturing capacities and lead-times to increase production;
- Supplier contracts;
- Inventory levels;
- Experiences with supply shortages and disruptions;
- Government regulations that may hinder the industry's ability to maintain a secure supply chain; and
- Recommendations to reduce exposure to foreign dependencies.

OTE field tested the draft survey for accuracy and usability with a variety of government organizations along with pharmaceutical and medical device/surgical equipment manufacturers. Once comments were received and incorporated into the survey, the documents were sent to the Office of Management and Budget (OMB) for review and approval as required under the Paperwork Reduction Act.

After receiving OMB approval, OTE disseminated the survey to healthcare manufacturers identified through basic research, participation in industry groups, and international trade data. Data collected through the survey was supplemented with information gathered from site visits, discussions with industry and government experts, participation in related conferences and technical sessions, and analysis of publicly available data.

A total of 181 surveys were received, representing 161 companies.² This included 70 pharmaceutical manufacturers, 75 medical device/surgical equipment manufacturers, and 16 manufacturers of both pharmaceuticals and medical devices/surgical equipment. These companies manufactured a broad range of products; respondents manufactured a total of 868 individual pharmaceutical products and 833 medical devices/surgical equipment relevant to the survey.

² In certain cases, companies provided multiple survey responses, detailing their operations by business unit.

II. INDUSTRY PROFILE

OTE received 181 surveys, which represented 161 healthcare-related companies.³ Of these, 70 were pharmaceutical manufacturers, 75 were medical device/surgical equipment manufacturers, and 16 were manufacturers of both pharmaceuticals and medical devices/surgical equipment. In addition to their type of business operations, companies were categorized as small-, medium-, and large-sized based on average net sales from 2007 to 2010 (see Figure II-1). Survey respondents provided their net sales for their whole company or individual business units; they did not isolate sales for the products included in this survey.

Figure II-1: Company Size by Average Annual Net Sales (2007-2010)

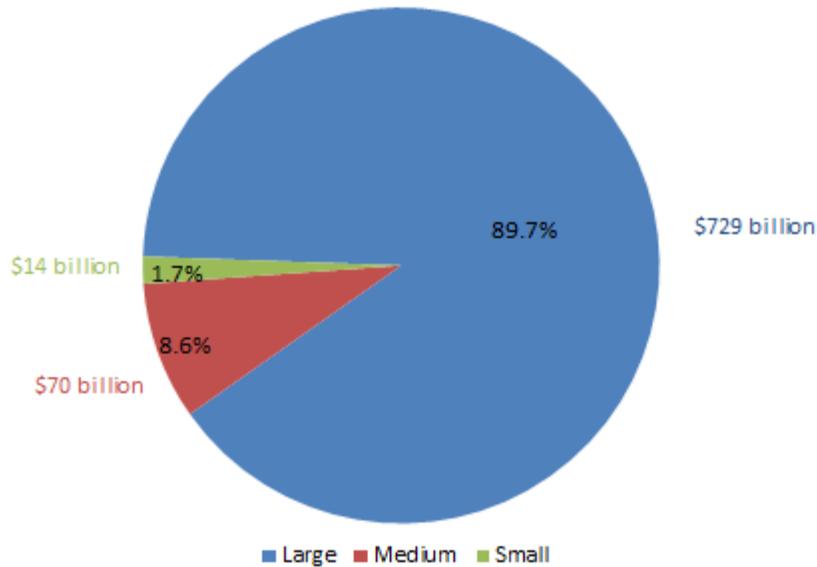
Company Size	Range of Net Sales	Business Type			Total
		Pharmaceuticals	Medical Devices/Surgical Equipment	Both Pharmaceuticals and Medical Devices/Surgical Equipment	
Small	Less than \$500 million	43	57	3	103
Medium	\$500 million - \$5 billion	16	14	6	36
Large	Greater than \$5 billion	11	4	7	22
Total		70	75	16	161

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

The distribution of small, medium, and large companies remained relatively equal across business types – pharmaceutical manufacturers, medical device/surgical equipment manufacturers, and those companies who manufacture both. Small-sized companies with average net sales of less than \$500 million per year represented 64 percent of survey respondents. When considered by sales volume, however, large companies dominate the market of pharmaceuticals and medical devices/surgical equipment considered in this study (see Figure II-2).

³ In certain cases, companies provided multiple survey responses, detailing their operations by business unit.

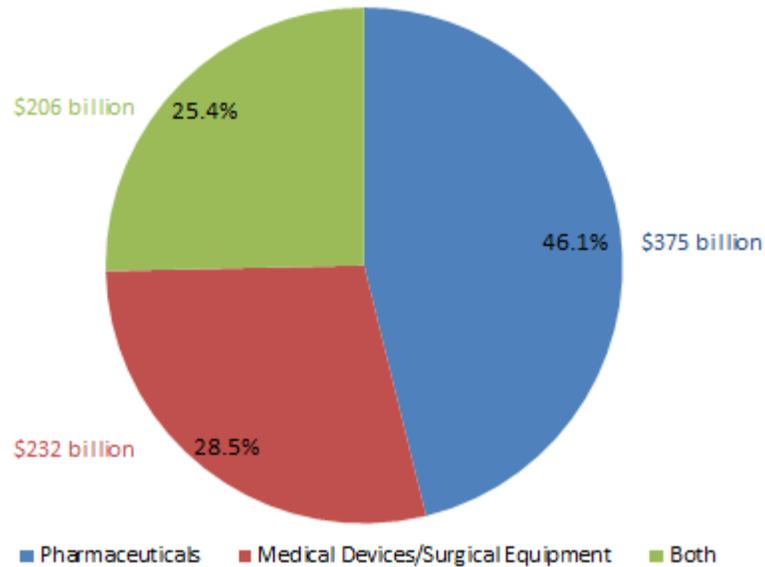
Figure II-2: Net Sales by Company Size (2010)



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

In 2010, large companies accumulated \$729 billion in net sales, comprising 89.7 percent of all survey respondents' sales. In addition, these companies offer the broadest range of pharmaceuticals and medical devices/surgical equipment related to this survey, as will be discussed later. Regardless of company size, pharmaceuticals comprised the largest portion of sales, representing nearly half of total sales dollars in 2010 (see Figure II-3). While companies that manufacture both type of products comprised only 10 percent of survey respondents, they accounted for 25.4 percent of sales in 2010.

Figure II-3: Net Sales by Business Type (2010)

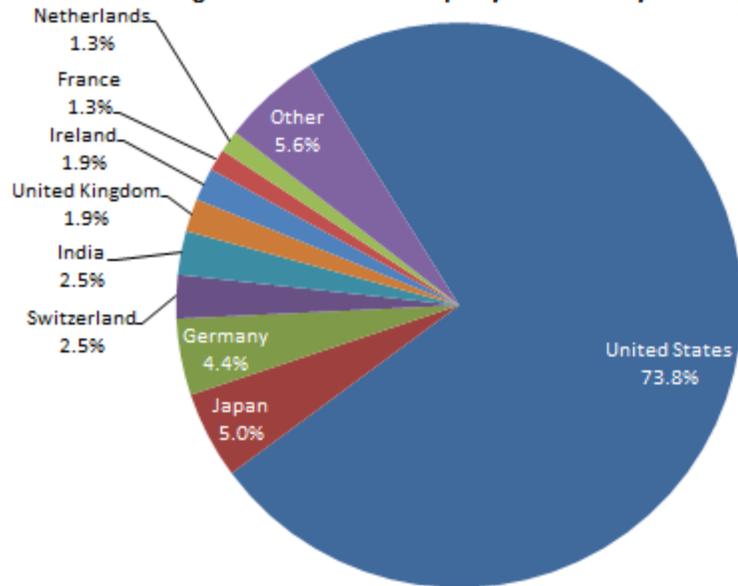


Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Most survey respondents are headquartered in the United States, although 26.2 percent of parent companies are located in other countries (see Figure II-4). In many cases, the locations of the corporate headquarters are not where healthcare-related products are manufactured (see Chapter III). The top locations outside the United States are primarily European, with Japan and India also represented. Large companies are predominately based in the United States. Only seven of the 22 large companies are headquartered outside the United States, all of which are in Europe.⁴

⁴ Two companies are headquartered in Germany and one in France, Ireland, Sweden, Switzerland, and the United Kingdom.

Figure II-4: Parent Company Location by Country



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

III. MANUFACTURING OPERATIONS

CRITICAL COMMODITIES LIST

Medical services in the United States require thousands of different pharmaceuticals and medical devices/surgical equipment. For the purpose of this assessment, OTE developed a Critical Commodities List comprised of pharmaceuticals and medical devices/surgical equipment that may be required in emergency situations, such as a national disaster or pandemic. After researching and coordinating with relevant U.S. Government agencies, 418 commodities were selected for this assessment: 290 pharmaceuticals and 128 medical devices/surgical equipment.

These 418 commodities were selected based on five major information sources. First, OTE utilized the WHO's *List of Essential Medicines*, which has been a long-standing guide to products that "satisfy the priority health care needs of the population."⁵ The WHO list is continually updated to reflect current best practices and developments, making it an excellent resource to identify commodities that are important to maintaining basic medical services. Commodities from the Centers for Disease Control and Prevention's (CDC) Targeted Countermeasures were included as well. These countermeasures are designed to treat dangerous diseases that "are easily disseminated or transmitted from person to person and result in high mortality rates."⁶ OTE also added a selection of commodities from the FDA's Drug Shortages list, which reflects some recent supply shortages and disruptions. The list also included commodities that were of particular interest to interagency partners. Finally, healthcare-related commodities were identified where the United States had a significant international trade deficit, which may be a sign of foreign dependency (see Figure III-1).

⁵ World Health Organization, http://www.who.int/medicines/services/essmedicines_def/en/index.html, Accessed 21 July 2011.

⁶ Centers for Disease Control and Prevention (CDC), <http://www.cdc.gov/phin/tools/cit/index.html>, Accessed 21 July 2011.

Figure III-2: Product Areas Manufactured by Company Size

	Mean	Median
Small	4.5	2
Medium	11.9	8
Large	15.6	8
Overall	7.8	3.5

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

In the survey, the 418 commodities were listed in their generic form as “product areas.” In the case of pharmaceuticals, product areas referred to the API, usually by its globally recognized International Nonproprietary Name (INN).⁷ Product areas for medical devices/surgical equipment were selected to be general but specific enough to differentiate major product types and capabilities. See Appendix A for the full Critical Commodities List.

The product areas on the Critical Commodities List were divided into 17 product classes, with 16 based on the general type of pharmaceutical. Medical devices/surgical equipment remained in a single product class for simplicity. The list below shows the product classes with the number of product areas therein identified in parenthesis:

- | | |
|--|---|
| 1. Anesthetics (11) | 9. Antivirals (18) |
| 2. Analgesics (25) | 10. Cancer Treatments (4) |
| 3. Antibacterials (6) | 11. Cardiovasculars (17) |
| 4. Antibiotics (40) | 12. Hormones (27) |
| 5. Anticonvulsants, Sedatives,
Relaxants (35) | 13. Immunosuppressants (27) |
| 6. Anti-Inflammatories (5) | 14. Stimulants (9) |
| 7. Antileprosy (14) | 15. Vaccines (24) |
| 8. Antiprotozoals (13) | 16. Other Products (15) |
| | 17. Medical Devices/Surgical
Equipment (128) |

⁷ For more information concerning INNs, refer to <http://www.who.int/medicines/services/inn/en/>.

PRODUCT AREAS MANUFACTURED

Survey respondents were asked to identify the pharmaceuticals and medical devices/surgical equipment they manufactured, integrated/assembled, and/or sold for use in the United States. For each product area selected, companies were then asked to provide the top three company proprietary products they make and the location of manufacture. Finally, companies identified, to the best of their knowledge, whether they were the sole U.S.-based manufacturer, sole global manufacturer, or not the sole manufacturer of each product. The number of product areas each company manufactures varies by their size and type of business. Survey respondents manufactured commodities in an average of 7.8 product areas, with larger companies averaging a considerably wider range of products areas than small-sized companies (see Figure III-2).

	Mean	Median
Small	4.5	2
Medium	11.9	8
Large	15.6	8
Overall	7.8	3.5

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

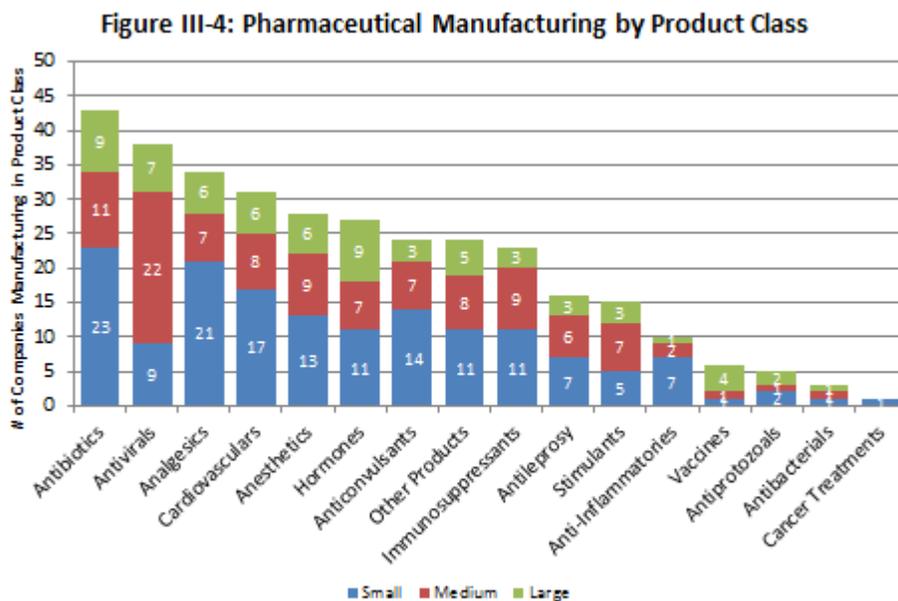
Manufacturing of product areas also varied based on the type of business. Medical device/surgical equipment manufacturers tend to manufacture fewer product lines, with companies averaging 4.2 product areas per company (see Figure III-3). Pharmaceutical companies manufacture a more diverse range of products areas per company, averaging 8.4 per company. Respondents that produce both types of products have the most diverse manufacturing operations, averaging 20.4 product areas per company.

	Mean	Median
Pharmaceuticals	8.4	6
Medical Devices/Surgical Equipment	4.2	2
Both	20.4	17.5
Overall	7.8	3.5

Source: U.S. Department of Commerce, Bureau of Industry and Security, *Impact of Foreign Sourcing on Health-Related Infrastructure*, September 2011.

Pharmaceutical companies manufacture across all 17 product classes identified in the OTE survey. Production of antibiotics is most common, with 50 percent of pharmaceutical companies manufacturing at least one product area within this product class (see Figure III-4).⁸

Manufacturing within product classes is not dominated by any particular company size, although four of six companies that produce vaccines are large-sized.



Source: U.S. Department of Commerce, Bureau of Industry and Security, *Impact of Foreign Sourcing on Health-Related Infrastructure*, September 2011.

Of the fifteen most product areas manufactured by the most companies, seven are analgesics, or painkilling pharmaceuticals. Lidocaine is the pharmaceutical product area manufactured by the

⁸ This percentage is based on the 86 companies that manufacture pharmaceuticals and those that manufacture both pharmaceuticals and medical devices/surgical equipment.

most companies. Lidocaine has numerous medical uses as a local anesthetic, such as numbing a part of the body for a procedure and relieving itching or burning of the skin (see Figure III-5).

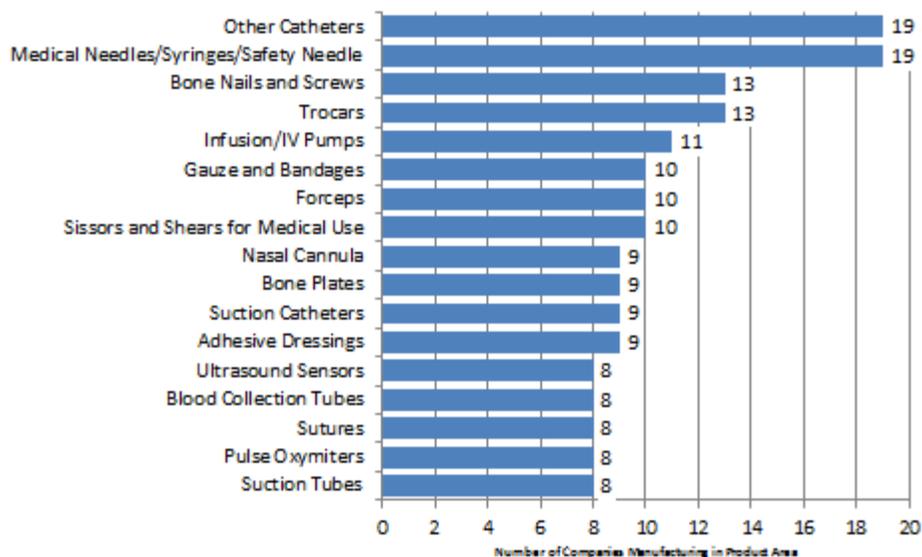
Figure III-5: Top Pharmaceutical Product Areas Manufactured

Product Area	Product Class	Number of Manufacturers
Lidocaine	Anesthetics	16
Morphine	Analgesics	12
Hydrocortisone	Immunosuppressants	12
Clindamycin	Antibiotics	12
Hydrochlorothiazide	Cardiovasculars	12
Ibuprofen	Analgesics	11
Hydrocodone	Analgesics	11
Paracetamol/Acetaminophen	Analgesics	10
Oxycodone	Analgesics	10
Promethazine	Anesthetics	10
Bacitracin	Antibiotics	10
Heparin	Other Products	10
Hydromorphone	Analgesics	9
Metronidazole	Antibiotics	9
Codeine	Analgesics	8

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

The most commonly manufactured medical devices/surgical equipment are more basic pieces of surgical equipment, such as syringes, bone nails and screws, trocars, gauze and other similar items (see Figure III-6). While numerous companies produce these items, their technical parameters or intended end-uses vary. For example, survey respondents cited 42 different proprietary types of medical needles/syringes/safety needles. More complex items, such as Magnetic Resonance Imaging (MRI) apparatus, x-ray machines, and electrocardiographs are concentrated among fewer manufacturers. Overall, catheters not specified elsewhere in the Critical Commodities List and medical needles/syringes/safety needles are the most commonly manufactured products.

Figure III-6: Top Medical Devices/Surgical Equipment Manufacturing by Product Area



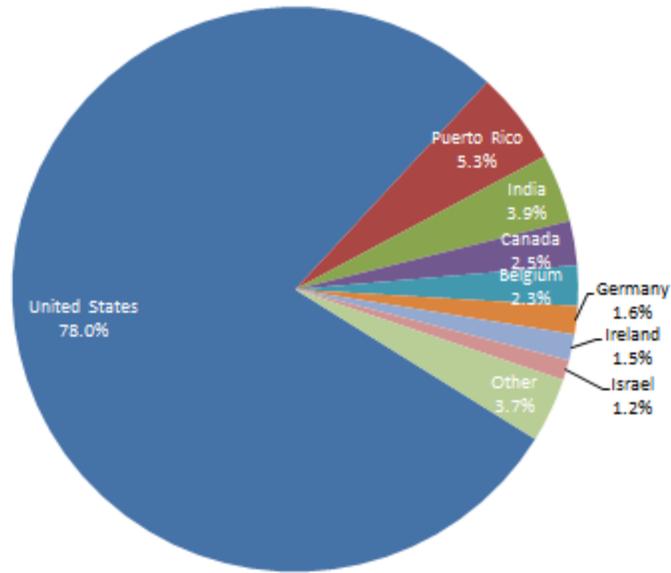
Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

MANUFACTURING LOCATION

Survey respondents were asked to provide the primary location – including the address, city, and country – where they manufacture or integrate each of their products on the Critical Commodities List. The primary location of manufacture was identified as the facility that adds the most value to the finished product. Facilities owned and operated by survey respondents that only manufacture products for sale in countries other than the U.S. were not included in this assessment.

Pharmaceuticals and medical devices/surgical equipment are predominantly manufactured in the United States. This is based on the number of product areas produced in each location, not volume. In the case of pharmaceuticals, 78.0 percent of products identified by survey respondents are manufactured in the United States (see Figure III-7).

Figure III-7: Pharmaceutical Manufacturing by Country/Territory*

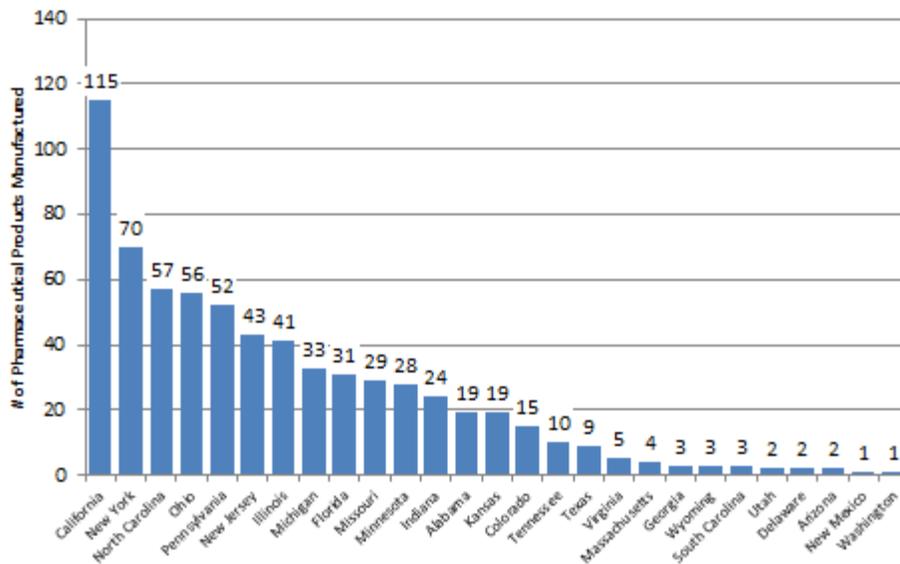


* Based on primary location of manufacture; not volume
Source: U.S. Department of Commerce, Bureau of Industry and Security,
Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Pharmaceuticals manufactured at facilities outside the United States are predominately produced in Puerto Rico, India, Canada, and countries in Europe.⁹ In total, survey respondents manufacture 868 pharmaceutical products on the Critical Commodities List at facilities they own and operate in 20 different countries. Within the United States, pharmaceutical facilities are concentrated in California, with fewer in New York, North Carolina, and Ohio (see Figure III-8). In total, respondents have manufacturing facilities in 27 states.

⁹ For the purposes of this study, Puerto Rico was considered “outside the United States.”

Figure III-8: U.S.-Based Pharmaceutical Manufacturing by State*

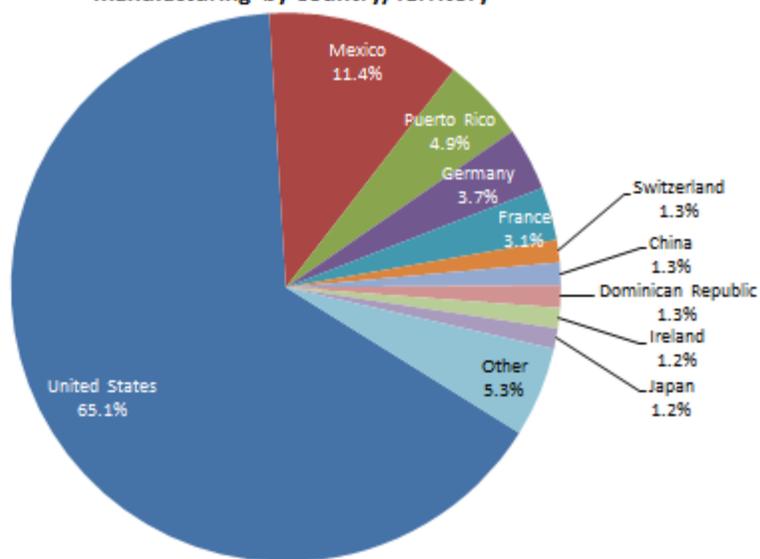


* Based on primary facility of manufacture

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Sixty-five percent of medical devices/surgical equipment identified in the OTE survey are manufactured in the United States, 12.9 percent less than pharmaceuticals. Products manufactured outside the United States are made in a slightly different group of countries than pharmaceuticals (see Figure III-9). Mexico is the most popular non-U.S. location, with Puerto Rico, Germany, and France also as significant manufacturing locations. Of particular note, China and Japan are represented at higher levels than in pharmaceuticals. In total, survey respondents manufacture medical device/surgical equipment at facilities based in 25 countries.

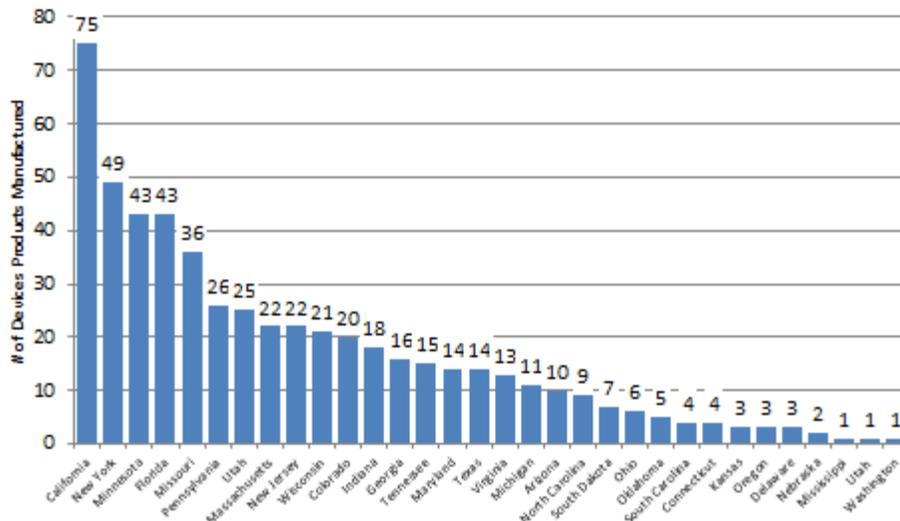
Figure III-9: Medical Device/Surgical Equipment Manufacturing by Country/Territory*



* Based on primary location of manufacture; not volume
Source: U.S. Department of Commerce, Bureau of Industry and Security,
Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Manufacturing of finished medical device/surgical equipment in the United States, like pharmaceuticals, is concentrated in California, with significant representation in New York, Minnesota, and Florida (see Figure III-10). Manufacturing facilities are located in 32 states.

Figure III-10: U.S.-Based Medical Device/Surgical Equipment Manufacturing by State*



* Based on primary facility of manufacture

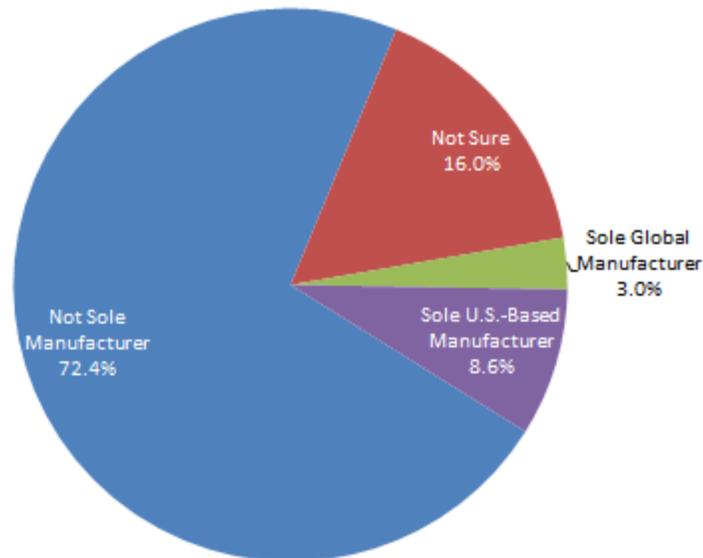
Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

SOLE MANUFACTURERS

Companies were asked to indicate whether they were the sole U.S.-based manufacturer, sole global manufacturer, or not the sole manufacturer of each product on the Critical Commodities List. Respondents were also allowed to indicate if they were not sure about their status as a sole manufacturer. Ultimately, the identification of sole manufacturing was made at the discretion of the individual survey respondents. In some cases, survey respondents had to consider whether small differences between their product and competitors’ products were significant enough to be considered a “sole source.” Of the 1,701 individual products identified by survey respondents, 75.4 percent were not unique to a particular manufacturer.

For pharmaceuticals, three percent of products are produced by a sole global manufacturer and 8.6 percent are produced by the sole U.S.-based manufacturer (see Figure III-11). Respondents were not sure about their manufacturing status for 16 percent of products.

Figure III-11: Sole Manufacturing - Pharmaceuticals



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Of the pharmaceuticals that are made by sole global manufacturers, half are manufactured by facilities in the United States. These products include three analgesics, two antibiotics, and two vaccines. The other products are manufactured in Canada, Germany, Ireland, Italy, Puerto Rico, Japan, and Norway. The pharmaceuticals produced by sole global manufacturers at facilities outside the United States are spread across the product classes included in the survey (see Figure III-12).

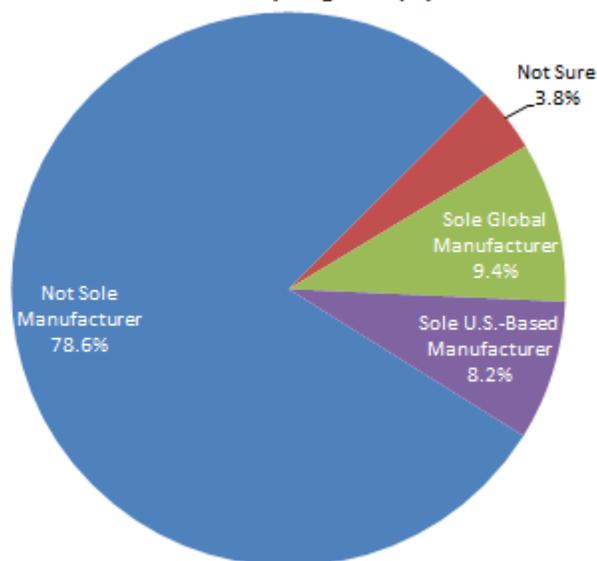
Figure III-12: Sole Global Manufacturers Outside the United States

Pharmaceuticals			
Product Area	Country of Manufacture	Product Class	# of Products
Rifampicin/Rifampin	Italy	Antileprosy	2
Insulin	Germany	Hormones	2
Cidofovir	Canada	Antivirals	1
Proguanil	Canada	Antiprotozoals	1
Phenytoin	Puerto Rico	Anticonvulsants, Sedatives, Relaxants	1
Dexamthasone	Ireland	Anti-Inflammatories	1
Flucinolone Acetonide	Ireland	Anti-Inflammatories	1
Ritonavir	Germany	Antivirals	1
Lidocaine	Japan	Anesthetics	1
Metformin	Canada	Hormones	1

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Medical device/surgical equipment manufacturers were more certain about their status as sole or not sole manufacturers; they were unsure for only 3.8 percent of product areas. Seventy-six percent of medical devices/surgical equipment product areas are not made by sole manufacturers. Nine percent of product areas were produced by sole global manufacturers (see Figure III-13).

Figure III-13: Sole Manufacturing – Medical Devices/Surgical Equipment



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Sixty-two percent of medical devices/surgical equipment produced by sole global manufacturers are located in the United States. The top product areas made by U.S.-based sole global manufacturers are bone nails and screws, influenza tests, and infusion/IV pumps. Products manufactured at facilities outside the U.S. are located in Mexico, Germany, India, and other countries, mainly in Europe.¹⁰ A wider range of medical devices/surgical equipment products are made by overseas sole global manufacturers than in the case of pharmaceuticals (see Figure III-14). Some of these products are complex medical devices, such as fetal monitors, dialysis machines, and ventilators.

Figure III-14: Sole Global Manufacturers Outside the United States

Medical Devices/Surgical Equipment		
Product Area	Country of Manufacture	Number of Products
Fetal Monitors	India	3
Artificial Kidney/Dialysis Apparatus	Mexico	2
Medical Needles/Syringes/Safety Needle	Poland, Slovenia	2
Other Catheters	Puerto Rico	2
Sterilizers	Mexico	2
Ventilators	Sweden, Israel	2
X-Ray Apparatus Used in Medical Diagnosis	Germany, France	2
Adhesive Dressings	United Kingdom	1
Apparatus Based on Alpha, Beta, or Gamma Radiations for Medical Use	Ireland	1
Aspirators	Dominican Republic	1
Blood Collection Tubes	Denmark	1
Bone Nails and Screws	Switzerland	1
Bone Plates	France	1
Electrocardiographs	Japan	1
Electroencephalographs (EEG)	Japan	1
Endotracheal Tubes (adult and pediatric)	Mexico	1
Gauze and Bandages	United Kingdom	1
Magnetic Resonance Imaging (MRI) Apparatus	Italy	1
Oxygen Analyzers	Denmark	1
X-Ray Control Panels/Desks	Germany	1
X-Ray Generators/Producing Apparatus	Germany	1

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

¹⁰ Other countries included the United Kingdom, France, Poland, Japan, Denmark, Slovenia, Sweden, Ireland, Italy, Israel, the Dominican Republic, and Switzerland.

IV. NON-U.S. SUPPLIERS OF CRITICAL COMPONENTS/MATERIALS/PRODUCTS

Survey respondents were asked to identify any components, manufacturing materials, or finished products (herein referred to as C/M/Fs) provided by suppliers based outside the United States that they deemed critical to the final manufacture of their pharmaceutical and medical device/surgical equipment products. OTE provided sample criteria on what may constitute a critical C/M/F but allowed companies to make their own judgments. Under OTE's suggested criteria, a C/M/F may be considered critical if it:

1. Is the active ingredient;
2. Contributes 25 percent or more of value to the end product; and/or
3. Is essential to the manufacturing process, but not present in the final product.

Critical components, manufacturing materials, and finished products were linked to the product area and the proprietary names of the products in which they were required. Survey respondents provided the name, country, city, and state/province of each supplier. In addition, a distinction was made whether each non-U.S. based supplier was an internal supplier/subsidiary or an external company not linked to the respondent by ownership. Finally, companies indicated to the best of their knowledge whether an alternate U.S.-based or non-U.S. based source was available for each C/M/F provided.

OVERVIEW

Survey respondents provided details for 1,340 critical C/M/Fs from approximately 672 non-U.S. based suppliers.¹¹ Overall, 73.3 percent of companies depend on non-U.S. suppliers for at least one critical C/M/F. These companies average 11.4 critical C/M/Fs from non-U.S. suppliers required for the manufacture of products on the Critical Commodities List, with large-sized companies reliant on non-U.S. suppliers at a much higher rate than small-sized companies (see Figure IV-1).

¹¹ An attempt was made to consolidate different spellings of supplier names to identify unique responses, but there may be some degree of error.

Figure IV-1: Average Number of Critical C/M/Fs per Company

	Mean
Small	6.2
Medium	13.3
Large	25.4
Total	11.4

Source: U.S. Department of Commerce, Bureau of Industry and Security, *Impact of Foreign Sourcing on Health-Related Infrastructure*, September 2011.

Overall, medical device/surgical equipment companies rely on non-U.S. suppliers to a lesser extent than pharmaceutical manufacturers for items on the Critical Commodities List. Seventy-nine percent of manufacturers of pharmaceuticals rely on at least one C/M/F from non-U.S. suppliers compared to 63.7 percent of medical device/surgical equipment manufacturers.¹² Pharmaceutical manufacturers also average more C/M/Fs per company than their medical device/surgical equipment counterparts, 11.4 compared to 9.8.

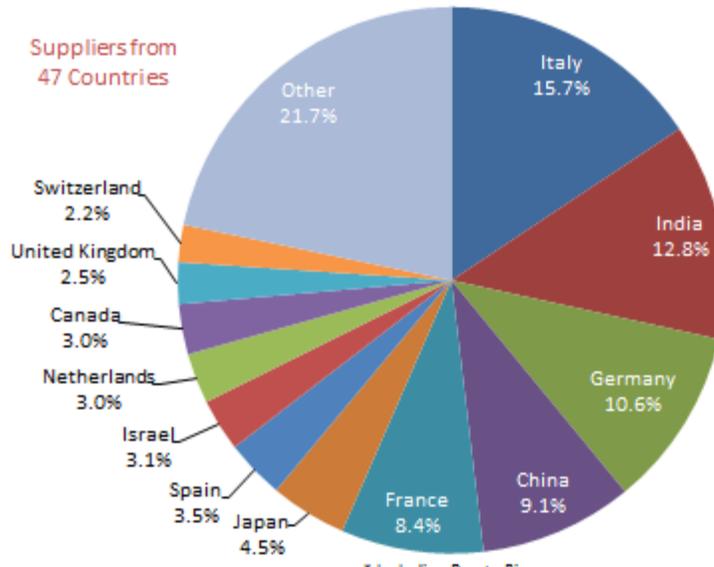
NON-U.S. SUPPLIER LOCATIONS

There were differences between the location of non-U.S. suppliers for pharmaceuticals and medical devices/surgical equipment. While Germany is the top location for non-U.S. suppliers for pharmaceuticals and medical devices/surgical equipment, it is not the leader in either product type. Suppliers located in Germany are the second most common for medical devices/surgical equipment and third most common for pharmaceuticals.

Pharmaceutical companies receive critical supplies from companies located in 47 countries, most commonly Italy, India, Germany and China (see Figure IV-2). Of these suppliers, 58.1 percent are located in Europe, followed by 11.8 percent located in East Asia, not including India.

¹² Companies that manufacture both types of products are counted in both categories.

Figure IV-2: Non-U.S. Suppliers Supporting Pharmaceutical Manufacturing by Location*

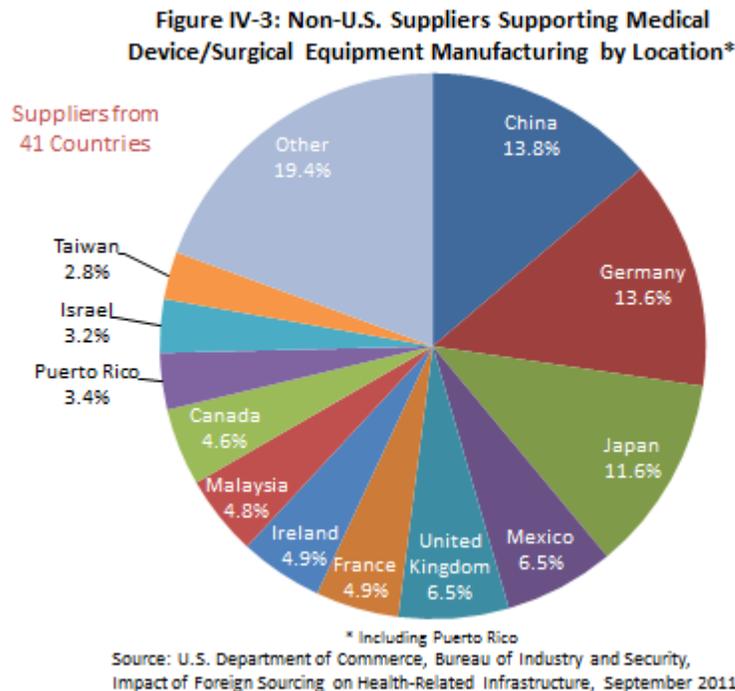


* Including Puerto Rico
 Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

While the amount of critical pharmaceutical supplies coming from Italy was unexpected, it was not found to be a statistical anomaly due to survey responses. Pharmaceutical manufacturers sourced from 41 different suppliers based in Italy for C/M/Fs used in 55 different product areas. This creates a very diverse corporate supply relationship. For example, supplies for four vaccines – Hepatitis A, Hepatitis B, Meningococcal Meningitis, and Rotovirus – are sourced from Italy. China also provides products from a diverse set of suppliers – 50 different companies for 32 product areas. While Italy and China have a diverse set of suppliers, there are also individual companies that provide a significant portion of C/M/Fs to U.S.-based manufacturers. The top three non-U.S. based companies that provide the most C/M/Fs are located in France, Italy, and India, respectively.

For medical devices/surgical equipment, non-U.S. suppliers of C/M/Fs are almost evenly split between Europe and East Asia (see Figure IV-3). Forty-one percent of these suppliers are located in Europe, while 38.4 percent are based in East Asia, excluding India. China is the most common location for non-U.S. suppliers for C/M/Fs related to medical devices/surgical equipment. Italy, the most common supplier of C/M/Fs for pharmaceuticals, only provides 1.9 percent of C/M/Fs for medical devices/surgical equipment. Similarly, while suppliers from India

constituted 12.8 percent of C/M/Fs for pharmaceuticals, only 0.2 percent of suppliers for medical devices/surgical equipment are located there.



Examining C/M/Fs from a company perspective, items used for medical devices/surgical equipment manufacturing are supplied by an even more diverse set of companies than pharmaceuticals. Fifty-one percent of non-U.S. based suppliers only provide one product for medical devices/surgical equipment, compared to 24.3 percent of suppliers for pharmaceuticals. In other words, medical device/surgical equipment manufacturers depend on a wider set of non-U.S. suppliers, often for a single component. For example, 62 of 69 suppliers from China provide only one C/M/F for medical devices/surgical equipment. Similarly, 56 different suppliers in Germany provided C/M/Fs, only 10 of which were mentioned more than once.

Overall, survey respondents rely on many suppliers for the C/M/Fs required in their manufacturing processes. Survey respondents are not heavily reliant on only one company, country, or region for their critical C/M/Fs. Instead, U.S.-based companies rely on a diverse set of foreign suppliers based in many different countries. Often times companies utilize a non-U.S. based supplier for a single critical C/M/F. Since foreign sourcing and dependencies are not

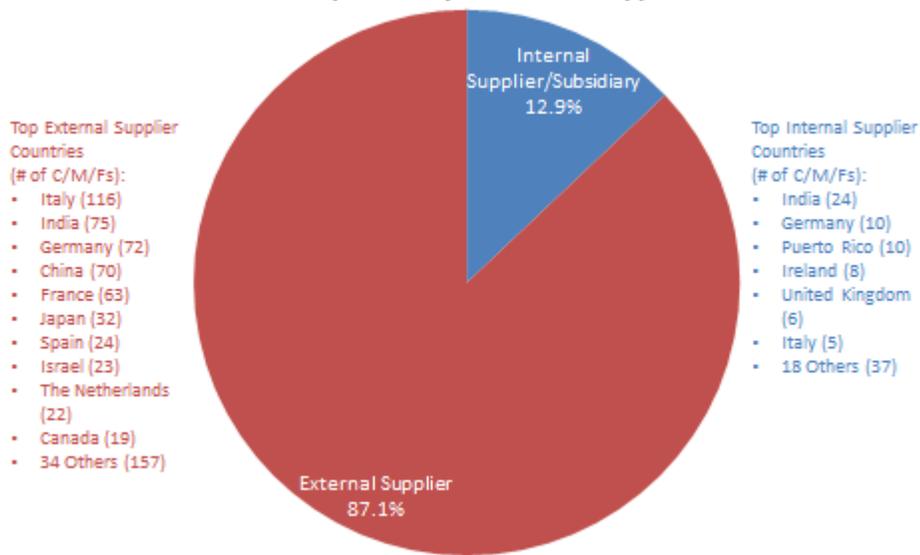
concentrated in a particular company or location, it is difficult to prioritize infrastructure protection efforts in the HPH Sector.

INTERNAL VERSUS EXTERNAL SUPPLIERS

Survey respondents were asked to identify whether their non-U.S. based suppliers were internal suppliers/subsidiaries or external suppliers not related to the company by ownership. The vast majority of critical C/M/Fs are provided by external companies rather than internal suppliers or subsidiaries.

For pharmaceuticals, only 12.9 percent of C/M/Fs are supplied by non-U.S. based internal suppliers/subsidiaries, 24.0 percent of which are located in India (see Figure IV-4). Other main internal suppliers/subsidiaries are located in Germany, Puerto Rico, Ireland, and the United Kingdom. C/M/Fs from external suppliers supporting pharmaceutical production were provided by companies in a more diverse set of countries, with Italy, India, Germany, and China as the top locations.

**Figure IV-4: Non-U.S. Suppliers to Pharmaceutical Manufacturing
- Internal/Subsidiary vs. External Supplier***

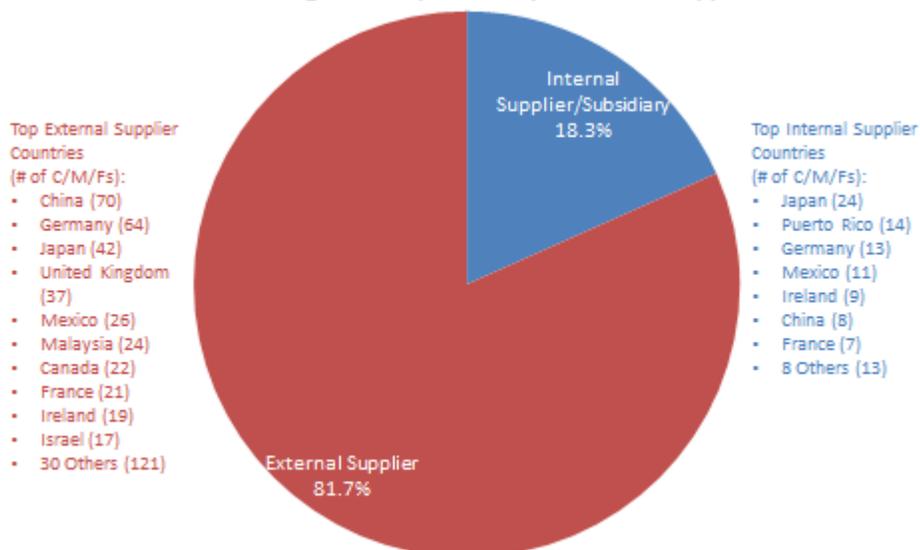


* Including Puerto Rico

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Internal suppliers/subsidiaries based outside the United States provide 16 percent of C/M/Fs for medical device/surgical equipment (see Figure IV-5). Twenty-four percent of these supplies are provided by companies located in Japan, though Puerto Rico, Germany, and Mexico are also prominent locations. External suppliers are primarily located in China, Germany, Japan, and the United Kingdom.

Figure IV-5: Non-U.S. Suppliers to Medical Device/Surgical Equipment Manufacturing - Internal/Subsidiary vs. External Supplier*



* Including Puerto Rico
 Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

COMPONENTS, MANUFACTURING MATERIALS, AND FINISHED PRODUCTS

The vast majority of C/M/Fs provided by non-U.S. suppliers for pharmaceuticals are the API for each product area. According to the Active Pharmaceutical Ingredients Committee (APIC), the API is defined as:

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to [affect] the structure and function of the body.¹³

¹³ Active Pharmaceutical Ingredients Committee, *Good Manufacturing Practices in Active Pharmaceutical Ingredients Development*, 1999. <http://apic.cefic.org/pub/5GMPDev9911.PDF>

The API is the most important material in pharmaceutical manufacturing. Dependency on non-U.S. suppliers for APIs can increase risks to supply chain security, potentially exposing companies to supply disruptions, counterfeiting issues, and quality control problems.¹⁴ Beyond APIs, some of the other foreign-sourced products used by pharmaceutical manufacturers are powders and gels for the manufacture of finished goods, resins for the purification of certain ingredients, and packaging materials.

When examined by product class, pharmaceutical manufacturers most often utilize non-U.S. based suppliers for C/M/Fs related to antibiotics, followed by hormones and analgesics. Twenty-one percent of C/M/Fs were utilized for antibiotics and 11.6 percent supported manufacturing of hormones.¹⁵ Figure IV-6 below lists the top pharmaceutical product areas that require C/M/Fs from non-U.S. based suppliers. A brief profile of some of the top product areas is also provided.

Figure IV-6: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers		
Pharmaceuticals		
Product Area	Product Class	Number of C/M/Fs
Promethazine	Anesthetics	20
Paracetamol/Acetaminophen	Analgesics	19
Insulin	Hormones	18
Imipenem	Antibiotics	17
Bacitracin	Antibiotics	17
Hydrochlorothiazide	Cardiovasculars	17
Hydrocortisone	Immunosuppressants	15
Lidocaine	Anesthetics	15
Ibuprofen	Analgesics	15
Clindamycin	Antibiotics	14

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

¹⁴ For more examples, see Food and Drug Administration (FDA) presentation on *Current Topics in Pharmacy Compounding*, 2011. <http://www.nabp.net/meetings/assets/FDA%20Update.pdf>

¹⁵ For a detailed breakdown of each product class, including the top product areas requiring C/M/Fs from non-U.S. based suppliers, see Appendix B.

Top Product Area Profiles – Pharmaceuticals:

1. Promethazine: Used to “relieve symptoms of allergic reactions...[and] relax and sedate patients before and after surgery,” among other purposes.¹⁶ In most cases, the API promethazine or promethazine hydrochloride is the C/M/F supplied from outside the United States. In 12 of 20 cases, the suppliers were based in France.
2. Paracetamol/Acetaminophen: Used “to relieve mild to moderate pain from headaches, muscle aches, menstrual periods, colds and sore throats, toothaches, backaches, and reactions to vaccinations (shots), and to reduce fever.”¹⁷ The API was the predominant C/M/F supplied for this product area. Out of 19 responses for this product area, six were supplied from China and five from India.
3. Insulin: Used to control blood sugar levels for people with diabetes. Respondents are dependent on non-U.S. suppliers for different types of resins used to purify the API, the insulin hormone itself, and in some cases, finished insulin injectors. One supplier based in Sweden was the most common source, followed by companies in Germany, Japan, and France.
4. Hydrochlorothiazide: “Used to treat high blood pressure and fluid retention caused by various conditions, including heart disease. It causes the kidneys to get rid of unneeded water and salt from the body into the urine.”¹⁸ Manufacturers predominantly rely on non-U.S. suppliers for the API. In eight of 17 cases, suppliers were based in Italy, with five from Israel and four from India.
5. Bacitracin: A “germ-killing medicine...which is used to treat infections,” usually combined with petroleum jelly to make antibiotic ointments.¹⁹ Again, manufacturers are reliant on non-U.S. suppliers for the API. In eight of 17 cases, these supplies originate in Norway, with four each from Denmark and China.

For medical devices, the most common C/M/Fs are electronic components, such as circuit boards, light emitting diodes, and integrated circuits. These electronic components are normally

¹⁶ PubMed Health, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000637/>, Accessed 8 August 2011.

¹⁷ PubMed Health, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000521/>, Accessed 8 August 2011.

¹⁸ PubMed Health, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000714/>, Accessed 8 August 2011.

¹⁹ PubMed Health, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0003176/>, Accessed 8 August 2011.

incorporated into larger medical devices such as respiration apparatus, defibrillators, and IV pumps. Manufacturers also require various molded parts and tubes for medical device production, many of which are custom made for their particular product. There is also a substantial amount of finished medical devices imported for sale in the United States. Different types of catheters are the most commonly provided finished products, though companies cited a wide range of finished devices, from blood transfusion apparatus to ventilators.

Surgical equipment is usually imported as finished products. These items, which are less expensive and complex than medical devices, are often included in larger surgical kits that are packaged in the United States. Products in these kits, such as forceps, trocars, and surgical knives, are often used once and then disposed.

Figure IV-7 lists the top medical device/surgical equipment product areas that require C/M/Fs from non-U.S. based suppliers. This is followed by a brief profile of some of the top product areas.

Figure IV-7: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Medical Devices/Surgical Equipment	
Product Area	Number of C/M/Fs
Infusion/IV Pumps	53
Defibrillators	31
Other Catheters	27
Pacemakers	22
Medical Needles/Syringes/Safety Needles	20
Sterilizers	18
Electronic Nerve Stimulation Machines	17
Oxygen Analyzers	17
Forceps	14
IV Catheters	14

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Top Product Area Profiles – Medical Devices/Surgical Equipment:

1. Infusion/IV Pumps: Designed to introduce fluids, either medications or nutrients, into a patient’s circulatory system. U.S. manufacturers require a wide range of C/M/Fs for

infusion/IV pumps, often electronic components such as LEDs, wireless cards, cables, and batteries. These companies also require various pumps and feeding sets. Twenty of the 53 C/M/Fs are from suppliers located in China.

2. Defibrillators: Used “to administer a shock and re-establish a regular heartbeat to treat sudden cardiac arrest.”²⁰ Some finished defibrillators are supplied from non-U.S. companies, but the majority of imports are electronic parts. These C/M/Fs are provided by suppliers located in a wide variety of locations, including Israel, Puerto Rico, Japan, Germany and France.
3. Catheters: Inserted into a body cavity in order to allow drainage or manipulation of surgical instruments. The catheters included under the ‘Other Catheters’ product area are those not otherwise specified in the OTE survey instrument.²¹ The finished catheter is imported in more than half the cases of non-U.S. sourcing. Other critical components or materials are stents, resins, or gauges. Non-U.S. suppliers are based in a wide range of locations, with Ireland, China, Japan, and Singapore as the top countries.
4. Pacemakers: “An implantable electronic device that delivers electrical stimulation to the heart to help regulate its beat.”²² Components from Israel and Puerto Rico are most common, with others coming from various European countries. Companies predominantly require electronic components, but there are a few cases of finished products being imported.
5. Medical Needles, Syringes, and Safety Needles: Used to inject or extract liquids to/from the body. Survey respondents import various types of finished needles and syringes. Half of these products are provided by suppliers in Japan, with fewer coming from Germany and Ireland.

²⁰ Encyclopedia of Nursing & Allied Health, <http://www.enotes.com/nursing-encyclopedia/defibrillators-portable>, Accessed 8 August 2011.

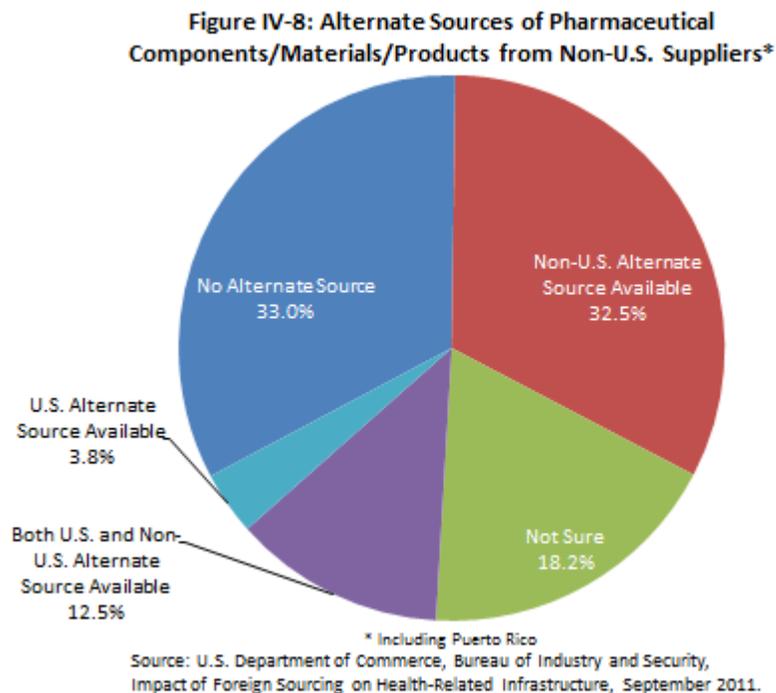
²¹ Catheters with their own product area included IV catheters, adult central venous catheters, pediatric central venous catheters, Swan-Ganz catheters, and suction catheters.

²² Encyclopedia of Nursing & Allied Health, <http://www.enotes.com/nursing-encyclopedia/pacemakers>, Accessed 8 August 2011.

ALTERNATE SOURCES OF SUPPLY

Survey respondents were asked whether alternate sources were available for C/M/Fs provided by non-U.S. based suppliers. In some cases, companies noted that they were not sure whether alternate sources were available.

For pharmaceuticals, there was no alternate sources available for 33 percent of C/M/Fs provided by non-U.S. suppliers. For 32.5 percent of C/M/Fs, a non-U.S. alternate source was available, but no source domestically (see Figure IV-8). By implication, there was no U.S.-based source for *at least* 65.5 percent of C/M/Fs identified by survey respondents.²³ For 16.3 percent of products supplied, a domestic source was available but the company chose to purchase outside the United States.



Pharmaceutical manufacturers utilized 255 C/M/Fs for which no alternate source was available in or outside the United States. These were provided by suppliers in 33 different countries, of

²³ Since respondents were not sure about alternate sources of supply for 18.2 percent of product areas, this number may be higher.

which Germany, Italy, India, and France were most common. Insulin and promethazine are the top product areas that require C/M/Fs for which there are no alternate sources available (see Figure IV-9). Seventeen of the 18 C/M/Fs used for insulin provided by suppliers in Sweden, Japan, Germany, France, and Austria did not have an alternate source available. In addition to these product areas, two vaccines for Hepatitis require C/M/Fs for which there is no alternate source available.

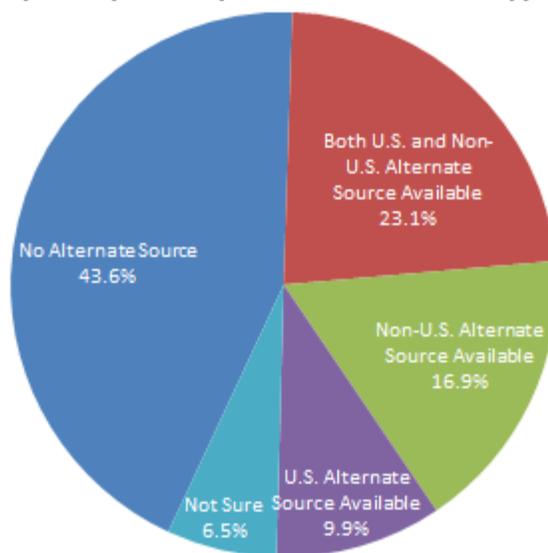
Figure IV-9: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers - With No Alternate Source Available

Pharmaceuticals		
Product Area	Countries of Supply	Number of C/M/Fs
Insulin	Sweden, Japan, Germany, France, Austria	17
Promethazine	France, United Kingdom, Switzerland, India	14
Hydrocortisone	France, China	7
Phenytoin	The Netherlands, Italy, Germany, India	6
Ciprofloxacin	Spain, India, Germany, Malta	6
Amlodipine	Spain, Malta, India	5
Bacitracin	Norway, China	5
Hepatitis A Vaccine	Germany, Japan, Italy	5
Hepatitis B Vaccine	Japan, Sweden, Germany, Italy	5
Testosterone (Androgen)	Portugal, Finland, The Netherlands	4

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

There was no alternate source available for 43.6 percent of C/M/Fs utilized for medical devices/surgical equipment (see Figure IV-10). For 16.9 percent of C/M/Fs, only a non-U.S. alternate source was available. Again, by implication, there was no U.S.-based source available for *at least* 60.5 percent of C/M/Fs identified by survey respondents. For 33 percent of products supplied, a domestic source was available but the company chose to purchase outside the United States, a higher percentage compared to pharmaceuticals.

Figure IV-10: Alternate Sources of Medical Device/Surgical Equipment Components/Materials/Products from Non-U.S. Suppliers*



* Including Puerto Rico

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

C/M/Fs to manufacture medical devices/surgical equipment that have no alternate source available in or outside the United States tend to be complex medical devices. These products are provided by suppliers based in 32 different countries, of which Germany, Japan, and China were the top locations. Defibrillators and infusion/IV pumps are the product areas with the largest number of C/M/Fs with no alternate sources (Figure IV-11). C/M/Fs required for other high value medical devices – such as oxygen analyzers, x-ray generators, electronic nerve stimulation machines, and artificial kidney/dialysis apparatus – also have no alternate source available.

Figure IV-11: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers - With No Alternate Source Available

Medical Devices/Surgical Equipment		
Product Area	Top Countries of Supply	Number of C/M/Fs
Defibrillators	Israel, Puerto Rico, United Kingdom, Germany, Japan	24
Infusion/IV Pumps	China, Israel, Taiwan, Ireland, Singapore	24
Oxygen Analyzers	United Kingdom, Switzerland, Germany, Denmark, Korea	17
Pacemakers	Israel, Switzerland, Puerto Rico, Germany, Singapore	14
Other Catheters	Ireland, Singapore, Japan, Israel, Puerto Rico	11
IV Catheters	Ireland, Japan	11
X-Ray Generators/Producing Apparatus	Germany, France, United Kingdom, Japan	10
Electronic Nerve Stimulation Machines	Korea, Taiwan, China, Australia, France	10
Sterilizers	China, Japan, Germany	9
Artificial Kidney/Dialysis Apparatus	Germany, France, The Netherlands, Mexico	9

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

V. MANUFACTURING CAPACITIES²⁴

Survey respondents identified the lead-time to increase production 50 percent and 100 percent, the primary factor that would limit such an increase for each product area, and their estimated change in production through 2015.

LEAD-TIMES TO INCREASE PRODUCTION

Survey respondents were asked to estimate the lead-time to increase their production based on the following assumptions:

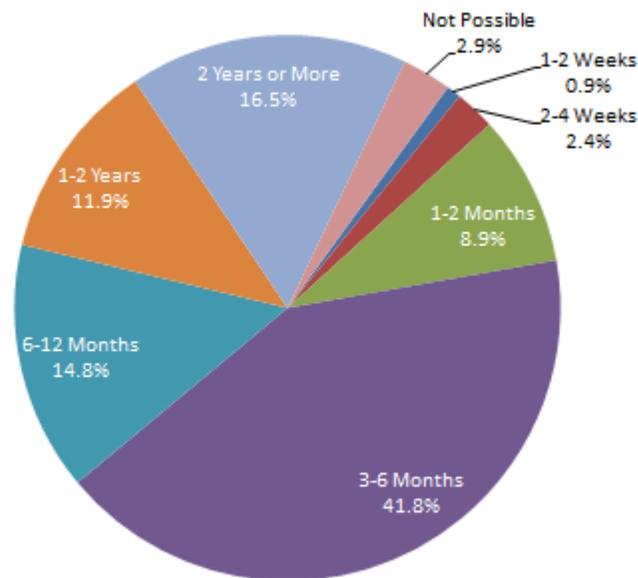
1. Existing U.S. production facilities are to be operated at maximum practical capacity (i.e. maximum number of employee shifts);
2. Labor availability reflects normal local market conditions;
3. Material availability reflects normal local market conditions;
4. Facilities operate at the maximum rate possible given technological constraints; and
5. The product area in question is given priority over other products that may use the same manufacturing resources.

Pharmaceutical manufacturers can increase their production levels by 50 percent in 3-6 months for 41.8 percent of the product areas identified in the OTE survey (see Figure V-1). Survey

²⁴ Survey respondents were also asked to estimate their company's maximum annual manufacturing capacity for 2010 for each of the product areas in which they participated. Due to differing types and sizes of doses for pharmaceuticals, companies were asked to provide their manufacturing capacity based on an estimate of the defined daily dose (DDD) for each product area. DDD is a measurement tool used by the WHO to represent the average maintenance dose per day of a drug used for its main intended purpose in adults. This measurement provides a "fixed unit of measurement independent of price and dosage form." For medical devices/surgical equipment, companies provided their maximum manufacturing capacities in units. This information was not included in this report because the data is Business Confidential.

respondents indicated that it would not be possible to increase production for 17 product areas they manufacture, including two vaccines and two types of heparin. When a specific reason was provided, most companies indicated that these product lines were being discontinued. For three product areas, however, respondents indicated that the source of the API was no longer available or “production is limited due to regulatory approval and building construction.” For those companies that would require two years or more to increase production by 50 percent, the primary delay was some combination of “product validation, equipment lead-time, and timing of regulatory approval.”

Figure V-1: Lead Time to Increase Production of Pharmaceuticals 50%

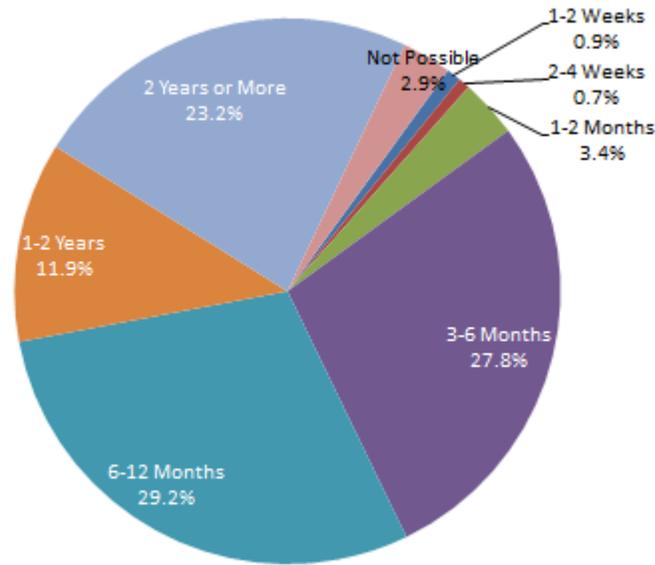


Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

On average, it will take pharmaceutical manufacturers longer to double (increase by 100 percent) production of their product areas. Most product areas would require between 3-6 months, 6-12 months, and 2 years or more (see Figure V-2). All product areas for which production can be increased 50 percent can also be doubled, but this usually requires a longer period of time. There were no additional product areas that could not have an increase in production. Eleven of the 24 vaccines listed in the OTE survey would require two or more years to double production, mainly due to plant space/capacity limitations. For the product areas requiring long lead-times, the

primary limitation is again due to some combination “product validation, equipment lead-time, and timing of regulatory approval.”

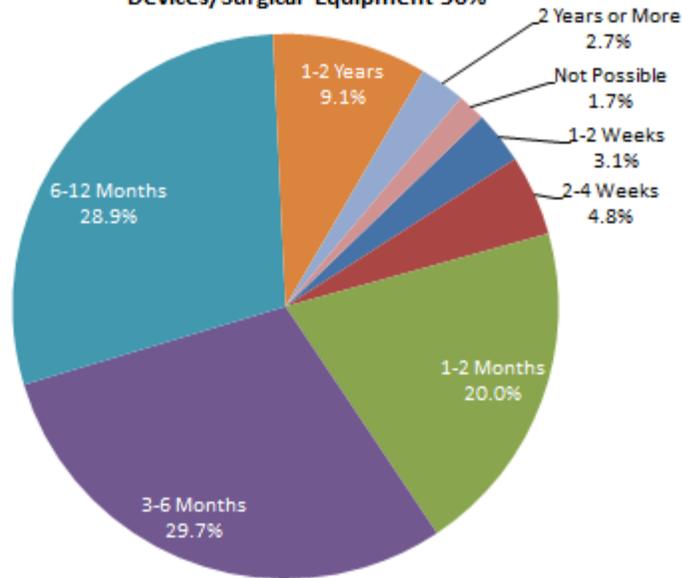
Figure V-2: Lead Time to Double Production of Pharmaceuticals



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Medical devices/surgical equipment manufacturing requires a wide range of lead-times to increase production. To increase output by 50 percent for these product areas, most companies require between 1-12 months, with 29.7 percent needing 3-6 months to do so (see Figure V-3). For eight product areas it is not possible to increase production; in two cases this is due to the product line being discontinued and in four cases it is due to plant space/capacity limitations. While it might be expected that surgical equipment – such as medical needles, gloves, and gauze – would take a shorter amount of time to surge production than medical devices, this does not appear to be the case in any consistent manner. Taking medical needles/syringes/safety needles as an example, four products will require 1-2 months to increase production 50 percent, while five will take 3-6 months, and four will take 1-2 years. In this case, the primary factor limiting production increases is new machine delivery lead-times.

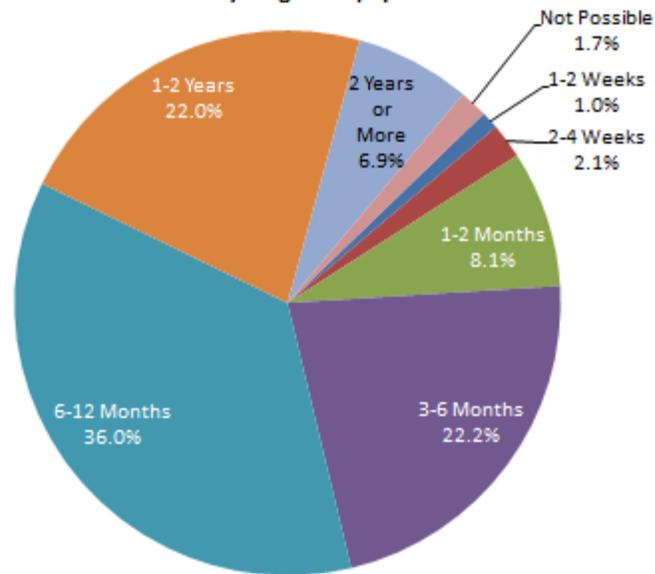
Figure V-3: Lead Time to Increase Production of Medical Devices/Surgical Equipment 50%



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Fifty-nine percent of medical devices/surgical equipment will take 3-12 months to double production (see Figure V-4). The product areas for which it was not possible to increase production by 50 percent again remain the same for a 100 percent increase. A diverse range of medical devices/surgical equipment will require long lead-times to double production. Products from bone nails and gauze to MRI apparatus and ultrasound sensors would require 1-2 years or more to double production volume. In the majority of these cases, the delays are due to new machinery delivery lead-times and plant space/capacity limitations.

Figure V-4: Lead Time to Double Production of Medical Devices/Surgical Equipment



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

PRIMARY FACTORS LIMITING AN INCREASE IN PRODUCTION

For each product area manufactured, companies were asked to indicate the primary factor that would limit an increase in production. In the aggregate, pharmaceutical manufacturers find that plant space/capacity issues are the biggest obstacles to increase their production levels (see Figure V-5). Raw materials shortages/availability from non-U.S. suppliers will limit the manufacturing of 13.9 percent of pharmaceuticals. If all factors concerning raw materials are taken together, 29.6 percent of product areas are limited by delivery delays, shortages, or availability issues. For vaccine production specifically, 21 of 27 product areas manufactured are restricted by plant space/capacity limitations. Based on these responses, pharmaceutical production is not significantly limited by access to capital or funding, but rather space, availability, and delivery issues.

In many cases, companies commented that additional regulatory approvals would be required to increase production, which would significantly extend manufacturing lead-times. For example, one company stated that an “increase in capacity would require capital facility investment and validation prior to use...[which] in turn would require approvals by FDA.” Another

pharmaceutical manufacturer noted that such an increase would require “development, filing, and approval of new production line,” which they estimate would take two to three years.

Figure V-5: Primary Factor Limiting an Increase in Production

Pharmaceuticals	
Factor	% of Total Pharmaceutical Product Areas
Plant Space/Capacity	32.0%
Non-U.S. Sourced Raw Material Shortages/Availability	13.9%
New Machinery Delivery Lead-times	10.6%
Product Validation/Regulatory Approval	9.2%
Other (Specify in Comments)	7.7%
Labor Shortages	6.0%
U.S.-Sourced Raw Material Shortages/Availability	5.0%
Delays in Delivery of Non-U.S. Sourced Raw Materials	5.0%
Products to be Replaced or Discontinued	3.4%
Delays in Delivery of U.S.-Sourced Raw Materials	3.1%
Delays in Delivery of Raw Materials (Unspecified Location)	2.6%
Dependent on Contract Manufacturers	1.4%
Access to Capital	0.2%

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Medical devices/surgical equipment are limited by new machinery delivery lead-times in 31.8 percent of product areas and plant space/capacity in 24.5 percent of product areas (see Figure V-6). Taking all factors concerning raw materials together, 25.5 percent of product areas are limited by delivery delays, shortages, or availability issues. As with pharmaceutical production, medical device/surgical equipment manufacturing is not significantly limited by access to capital or funding, but rather by space, availability, and delivery issues. Concerning production limitations, one manufacturer stated that “significant increases... would require coordination across [the] entire supply chain... due to the multiple, sequential steps in production.” Many companies echoed this sentiment, noting that numerous, highly controlled steps in the manufacturing process limit production increases for a multitude of interrelated reasons.

Figure V-6: Primary Factor Limiting an Increase in Production

Medical Devices/Surgical Equipment	
Factor	% of Total Medical Device/Surgical Equipment Product Areas
New Machinery Delivery Lead-times	31.8%
Plant Space/Capacity	24.5%
Non-U.S. Sourced Raw Material Shortages/Availability	9.2%
Labor Shortages	8.4%
U.S.-Sourced Raw Material Shortages/Availability	8.4%
Other (Specify in Comments)	6.7%
Delays in Delivery of Non-U.S. Sourced Raw Materials	3.3%
Delays in Delivery of U.S.-Sourced Raw Materials	3.1%
Access to Capital	1.9%
Delays in Delivery of Raw Materials (Unspecified Location)	1.5%
Dependent on Contract Manufacturers	0.8%
Product Validation/Regulatory Approval	0.6%
Products to be Replaced or Discontinued	0.4%

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

CHANGE IN PRODUCTION THROUGH 2015

For each product area, survey respondents indicated whether they expected their production levels to increase, decrease, or remain the same through 2015. For 67.1 percent of pharmaceutical product areas, there is no expected change in production. Increases in production are expected in 21.5 percent of product areas. Eleven percent of pharmaceuticals are estimated to have manufacturing declines. Production declines are not concentrated among pharmaceuticals in any particular product class, but antibiotics and anticonvulsants, sedatives, and relaxants are most common. Figure V-7 shows the pharmaceutical product areas with multiple companies expecting decreased production through 2015.

A small amount of respondents noted that production changes were dependent upon market demand. One manufacturer stated that “stable profitable demand justifies [our] current plant” and any increased demand could be met as needed.

Figure V-7: Product Areas with Multiple Companies Decreasing Production Through 2015

Pharmaceuticals	
Product Area	Number of Companies
Metformin	4
Clindamycin	3
Alprazolam	3
Clorazepate	2
Valproic Acid (VPA)	2
Ciclosporin	2
Erythromycin	2

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

For medical devices/surgical equipment, 65.1 percent of product areas are estimated to have production increases through 2015. The most product areas expected to have an increase in production are other types of catheters not specified in the Critical Commodity List, medical needles/syringes/safety needles, and bone plates. No change in production is expected for 28.9 percent of product areas. Only six percent of medical device/surgical equipment product areas are estimated to decline in production, most commonly infusion/IV pumps and sterilizers (see Figure V-8).

Figure V-8 Product Areas with Multiple Companies Decreasing Production Through 2015

Medical Devices/Surgical Equipment	
Product Area	Number of Companies
Infusion/IV Pumps	4
Sterilizers	3
Other Catheters	2

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

VI. SUPPLIER RELATIONSHIPS

Survey respondents were asked numerous questions about relationships with their suppliers. This information was utilized to better understand how healthcare-related companies identify, select, and interact with their suppliers, particularly with companies outside the United States.

SUPPLIER SELECTION

Companies were asked to rank the top five criteria they consider when selecting suppliers for healthcare-related components, manufacturing materials, and finished products (C/M/Fs). Their responses were aggregated and weighted based on the one through five ranking provided. There was not a significant difference in criteria between pharmaceutical and medical device/surgical equipment manufacturers. Overall, product quality/manufacturing processes were the most important criteria to companies, followed by cost and product availability (see Figure VI-1).

Criteria	Weighted Percentage
Product Quality/Manufacturing Processes	28.8%
Cost	18.8%
Product Availability	13.9%
Product Effectiveness (e.g., fewer side effects, higher success rate)	10.3%
Delivery Logistics/Speed	10.2%
Sole Supplier/Unique Products	6.4%
Other	5.6%
Domestic Source	2.8%
Substitute for a Critical Product	1.6%
Product Packages (e.g., bundles of multiple products from the same supplier)	1.4%
Non-U.S. Source	0.2%

* Based on 169 unique responses

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

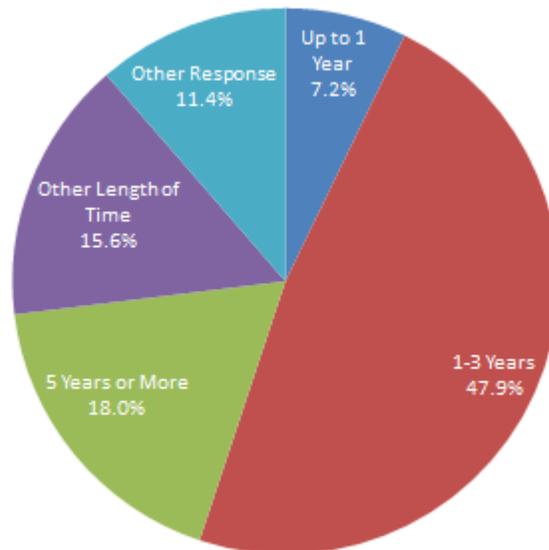
Based on these responses, the location of the supplier is only a top consideration in 3.0 percent of cases, though some consideration may be given to this issue under delivery logistics/speed. Some survey respondents noted that a combination of all the above criteria is considered to some

extent when selecting a supplier. One manufacturer noted that they “outsource when the processes are not part of our core competency...the supplier's technical expertise is primary but we also need low cost, lean manufacturing, and cost reductions.” Discussing the balance between sourcing and cost issues, another company stated that “a competitive or low price will not be a benefit if the logistics of procuring the product over shadows the price...without transportation and import costs.”

SUPPLIER CONTRACTS

Most survey respondents sign contracts with their suppliers, although the length and stipulations vary widely. Forty-eight percent of survey respondents average 1-3 year contracts and 18.0 percent average contracts of five years or more (see Figure VI-2). The average length of contracts depends upon the type of product required, regulatory restrictions, technical sophistication, and other industry considerations. As such, there were key differences between contracts made by pharmaceutical and medical device/surgical equipment companies.

Figure VI-2: Average Length of Supplier Contracts*



* Based on 167 unique responses.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Pharmaceutical companies tend to maintain longer contracts with their suppliers due to the highly regulated nature of the industry, with 25.4 percent lasting five years or more. One company explained that “a supplier must be fully vetted, qualified, approved by the FDA and audited. Therefore we do not take changing suppliers lightly.” Long-term consistency of a company’s supplier for a particular product is important in reducing costs and preventing production delays. The availability of API is also critical; some companies alter their contracts based on how many suppliers are in the market. One pharmaceutical company maintains “shorter [contract] time frames where there are multiple suppliers [and] longer time frames for sole source suppliers.” Another pharmaceutical manufacturer stated that they maintain their contracts with suppliers “until the product is discontinued or [an] alternate source is found.” In cases where there is a larger market for a required product, contracts may be subject to annual renewal based on performance or may be simple purchase orders.

Manufacturers of medical devices/surgical equipment maintain shorter contracts than their pharmaceutical counterparts, with 49.3 percent averaging 1-3 years. These companies prefer flexibility because of constantly changing technologies required for many of their products. One company said that “considering that products may get engineering and quality-related improved successors, three years is standard” for supplier contracts. Similarly, another company said they prefer not to sign contracts for longer than three years as “we are a nimble and customer driven company and we need flexibility.”

Medical device/surgical equipment companies that average contracts of five years or more tend to manufacture products that are more specialized, have longer shelf-lives, and are regulated to a greater degree. Speaking to these regulations, one company said that “the cost of changing suppliers in the medical world is very high due to validation requirements. Once we have a supplier, we tend to keep them unless they become a problem.” When supplier relationships are forged, they can extend for longer periods of time as long as the product requirements do not change irreparably. Contracts may also be “longer if they include intellectual property” to ensure that it is not compromised.

UNIQUE FACTORS CONSIDERED WHEN PURCHASING/OUTSOURCING OUTSIDE THE UNITED STATES

Beyond contracts, companies were asked what unique factors they considered when purchasing abroad or outsourcing. Based on the aggregate of responses, the primary factors companies consider are:

1. Cost;
2. Compliance with regulatory requirements;
3. Product quality;
4. Product availability;
5. Intellectual property protection; and
6. Market access.

When pharmaceutical manufacturers outsource, many consider the location of supply only with regard to how it impacts logistical costs and delivery time. One company stated that “once we have made a decision to use external suppliers, we select the most appropriate supplier based on its ability to meet our business requirements in the areas of assurance of supply, quality, service, cost, and innovation, regardless of particular geography.” Typically, as long as a source is available and meets requirements, companies will utilize it.

There are special considerations, however. Many outsource when “no other alternatives are available in the U.S.” If a required product is not available domestically, as is often the case based on the findings of this report, companies need to seek out non-U.S. based suppliers. Regulatory compliance also plays a role. Non-U.S. suppliers must be reviewed and approved to meet FDA requirements. Intellectual property protection, particularly in India and China, is also a concern for pharmaceutical companies.

Similar to pharmaceutical companies, when outsourcing, medical device/surgical equipment manufacturers primarily consider “total system cost, which will include procurement price, supply chain expenses, and inventory expense considerations.” After regulatory approval and quality have been established, suppliers are generally accepted based on total cost or access to desired markets with little consideration of domestic supply. Companies may decide to source to

a particular location, domestic or otherwise, “to provide a product sooner to the marketplace through lead-time reduction even if the purchase cost is higher.” Numerous medical device/surgical equipment manufacturers also mention seeking out supplier relationships in countries where they would like to make inroads and develop market share. In many cases, having suppliers based locally in important markets reduces lead-times and logistics costs, increasing the company’s competitiveness.

CONTRACT CLAUSES

Companies were asked if they include two types of statements in their supplier contracts designed to mitigate supply chain issues: disruption clauses and surge capacity provisions. Disruption clauses are contract provisions that impose penalties on suppliers to recoup losses in the advent of a delivery and/or service delay or interruption. Thirty-nine percent of companies utilize these clauses when they deem appropriate, with no major difference between pharmaceutical and medical device/surgical equipment manufacturers. Companies note that the particulars of these clauses vary because they are subject to negotiation. Usually these contract clauses allow for the imposition of penalties and/or permit the use of an alternate supplier when products are not delivered on time. Some contracts include *force majeure* clauses that free both parties from liability in case of an “event which could not have been reasonably avoided” as long as the party that is not meeting the contractual obligations makes “reasonable efforts” to remedy and overcome these occurrences. These unavoidable events might include a natural disaster, strike, war, or an “act of God,” among others.

Thirty-nine percent of companies also include surge capacity provisions in their supplier contracts. The provisions allow the contracting party to a) increase the quantity of products or services called for under the contract by a certain amount; and/or b) accelerate the rate of delivery established under the contract. For survey respondents, surge capacity provisions are predominantly about an increase in quantity. In most cases, these provisions call for suppliers to be able to provide anywhere from an additional 20 to 50 percent of the originally forecasted quantity of products. At times, however, the contractual obligation may only require suppliers to “use reasonable efforts to address unforeseen surges in demand, because...[they] are constrained

by long lead-time items, such as [for] certain raw materials and components.” As with disruption clauses, the inclusion of surge capacity provisions depends on the type of product supplied and what can be negotiated with the supplier.

VISIBILITY INTO SUPPLIER OPERATIONS

Companies were also asked about their knowledge of their suppliers’ business practices. Seventy-one percent of survey respondents have some degree of visibility into their suppliers’ operations and inventory. Small-sized companies are slightly less likely to have such visibility compared to larger companies. Sixty-three percent of small-sized companies have visibility as opposed to 79.5 percent of medium-sized and 92.5 percent of large-sized companies. Of the respondents that have some insight into their suppliers’ operations, 97.5 percent are aware of supplier company certifications (see Figure VI-3). Respondents are less likely to have visibility into lower levels of the supply chain, with 60.3 percent of companies able to identify the suppliers of their suppliers. Survey respondents are also less likely to have insight into their suppliers’ inventory levels and raw material supplies.

Figure VI-3: Visibility into Suppliers’ Operations and Inventory*	
Company Certifications	97.5%
Current Production Levels	75.2%
Maximum Production Capacity	66.9%
Identification of their Suppliers	60.3%
Location of their Suppliers	59.5%
Inventory Levels	56.2%
Raw Material Supplies	48.8%
* As a percent of companies that have visibility	

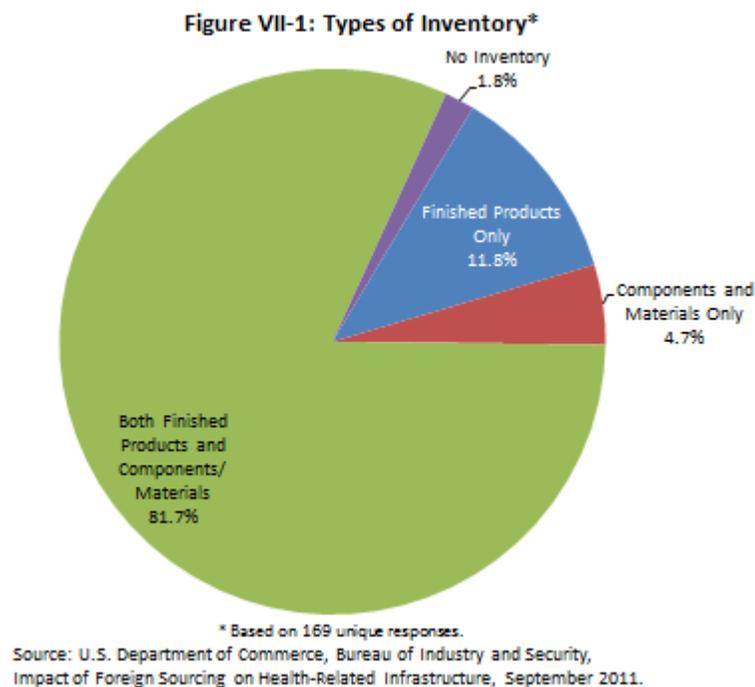
Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

VII. INVENTORIES

How companies inventory components, materials, and/or finished products is important to understanding a company's ability to successfully react to a supply chain disruption. Survey respondents were asked to detail what products, if any, they kept in inventory, the average supply level kept in inventory, and inventory selection criteria.

TYPE OF INVENTORY

Eighty-two percent of survey respondents keep inventories of components, materials, and finished products (see Figure VII-1). Twelve percent of companies have an inventory of only finished products and 4.7 percent only keep inventory of components and materials. Only 1.8 percent of companies do not keep any inventory.



Eighteen percent of pharmaceutical manufacturers maintain inventories of only finished products, higher than the 9.2 percent of medical device/surgical equipment manufacturers who

do so. Similarly, 16.5 percent of small-sized companies only inventory finished products, as opposed to 7.7 percent of medium-sized companies and no large-sized companies.

Survey respondents will typically maintain a 1-3 month supply of finished products (see Figure VII-2). Medical device/surgical equipment manufacturers keep a smaller inventory of finished products than pharmaceutical companies. Twenty-one percent of these companies maintain less than a one month supply. Overall, only 17.2 percent of survey respondents maintain more than a three month supply of finished products. There is little difference in finished product inventory levels between company sizes.

Figure VII-2: Finished Product Inventory Level by Business Type*

Inventory Level	Pharmaceuticals	Medical Devices/Surgical Equipment	Both
Less than 1 Month Supply	8.3%	21.1%	9.5%
1-3 Months Supply	62.5%	59.2%	76.2%
3-6 Months Supply	16.7%	7.9%	14.3%
6-12 Months Supply	1.4%	6.6%	0.0%
1-2 Years Supply	1.4%	1.3%	0.0%
None	9.7%	3.9%	0.0%

* Based on 169 unique responses

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

A portion of companies maintain slightly larger supplies of components and materials required for their manufacturing operations. Overall, 24.3 percent of companies maintain a 3-6 month supply of components/materials and 49.1 percent have a 1-3 month supply. Medical device/surgical equipment manufacturers generally maintain smaller supplies than pharmaceutical manufacturers (see Figure VII-3). Again, company size had no substantial impact on inventory levels.

Figure VII-3: Component/Material Inventory Level by Business Type*

Inventory Level	Pharmaceuticals	Medical Devices/Surgical Equipment	Both
Less than 1 Month Supply	6.9%	11.8%	9.5%
1-3 Months Supply	41.7%	53.9%	57.1%
3-6 Months Supply	23.6%	22.4%	33.3%
6-12 Months Supply	8.3%	2.6%	0.0%
1-2 Years Supply	1.4%	0.0%	0.0%
None	18.1%	9.2%	0.0%

* Based on 169 unique responses

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

SELECTION OF PRODUCTS FOR INVENTORY

Inventories are expensive to maintain, so companies carefully consider numerous factors when selecting certain commodities to stock over others. The most important considerations are the material lead-times from suppliers, supplier variability/risk, and current or expected market demand. One company summed up their inventory process, stating:

Critical components with long lead-times are inventoried to allow continuous production even in the event of transient supply interruptions, or to allow for switch-over to new suppliers while complying with regulatory requirements.

Another company judged their required inventory based on “how reliable demand is.” Products with significant demand variability are stocked at higher levels to ensure that the required materials are available should there be a sudden surge. Supplier risk, whether due to location, inconsistent past performance, or sole sourcing, is also an important inventory consideration. When reliant upon sole source suppliers, companies tend to keep larger inventories to mitigate the risk of a disruption. Some respondents also utilize selective inventory control practices, such as “ABC Analysis.” Under this method, inventory space is allocated based upon the relative value of a product to the company. Products are divided into A, B, and C categories, with A items being of high demand and high value and C items being the opposite.

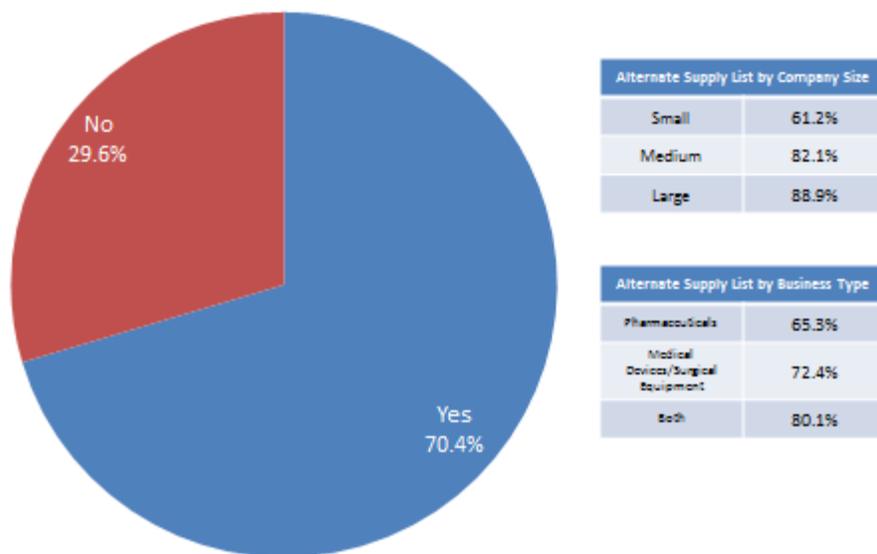
VIII. SUPPLY SHORTAGES/DISRUPTIONS

ALTERNATE SOURCES OF SUPPLY

Survey respondents were asked if they maintain a list of approved alternate supply sources for critical components, manufacturing materials, and/or finished products. Given the lack of alternate suppliers for many products on the Critical Commodities List, such a list could prove integral for ramping up production in an emergency situation. Seventy percent of companies stated that they do have a list of approved alternate suppliers (see Figure VIII-1). It is important to note, however, that this list can be for all the products that the companies produce or merely a subset.

Just over half of the small-sized companies maintain a list of approved alternate suppliers, while 88.9 percent of large-sized companies do the same. Medical device/surgical equipment manufacturers retain a list of alternate sources for products at a higher rate than pharmaceutical companies. This may correlate to the smaller supplier base for APIs than the more ubiquitous electronic devices used in medical device/surgical equipment manufacturing. While this list of suppliers may be approved by the company, it does not necessarily mean that all of these suppliers are approved by U.S. Government regulatory agencies.

Figure VIII-1: Companies With A List of Approved Alternate Supply Sources*



* Based on 169 unique responses.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

The 29.6 percent of companies that do not maintain a list of approved alternate suppliers are usually limited by product availability or regulatory approval times. One company stated that “most of our products are single-sourced due to low volume or unique technologies.” Other respondents have lists of alternate suppliers, but they are not necessarily “approved” due to long lead-times in the FDA approval process. On this point, one respondent noted that in their experience, FDA approval for new suppliers can take 2-3 years. Overall, however, respondents noted that relationships with alternate sources of supply are a balancing act:

We recognize that having a second source qualified is both a hedge against supply risk and a prudent negotiating strategy. However, we are only able to maintain a backup source...for a limited number of commodities. We have many sole source items where no second source is available and we also must weigh the cost of qualifying and maintaining multiple suppliers against the potential benefit.

In addition to maintaining a list of approved alternate suppliers, companies were asked to identify if they maintained relationships with multiple suppliers in a deliberate effort to avoid supply disruptions. Seventy percent of survey respondents attempt to alleviate disruptions through their supplier relationships. Many of these companies attempt to dual-source and are always looking to expand supplier relationships when they can. One respondent stated, “we have

been qualifying backup suppliers for critical components where it is possible. Not all items have been successfully dual-sourced yet, but it remains an objective.”

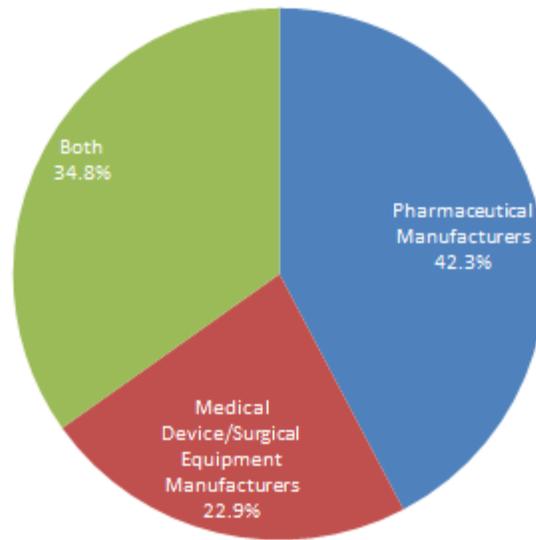
In some cases, however, respondents do not maintain multiple supplier relationships because there are no alternate sources for the materials they require. The vast majority of respondents are constrained in their ability to have multiple suppliers due to product availability, regardless of their business type.

Another company said, “it is always our goal to have redundancy for all critical suppliers; however, at any point in time we might be sole-sourced on a small number of critical components.” Most companies realize the need to maintain alternate sources, but are limited by the lack of availability and the costs required to do so.

SUPPLY SHORTAGES AND DISRUPTIONS

Companies were asked to identify their five most significant supply disruptions from U.S. and non-U.S. based suppliers for 2007 to 2010. Thirty percent of survey respondents stated that they had experienced at least one significant supply disruption or shortage of C/M/Fs. It is important to note that companies could qualify “significant” in their own terms. The type of issues encountered included general regulatory, transportation, and environmental issues. Fifty-three percent of the supply disruptions reported impacted large companies’ supply chains, with medium and small companies evenly experiencing the remaining the other half. Pharmaceutical companies experienced the most disruptions, along with companies involved with both pharmaceuticals and medical device/surgical equipment (see Figure VIII-2). The prevalence of disruptions in pharmaceuticals may be attributed to the lack of alternate U.S. and non-U.S. based suppliers for APIs.

Figure VIII-2: Supply Shortages/Disruptions by Business Type*

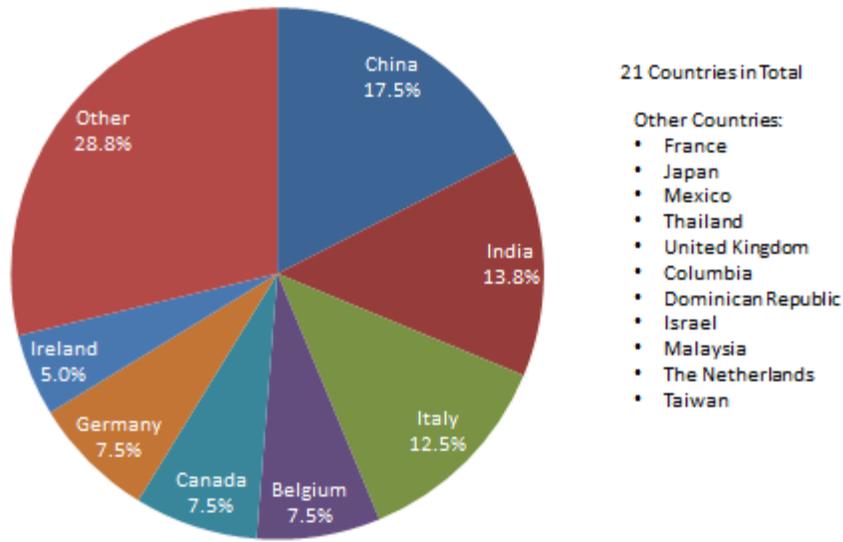


* Based on a total of 201 reported incidents.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Of all the disruptions, 60 percent were as a result of U.S. based suppliers. The 40 percent of non-U.S. based suppliers causing disruptions were based in 21 countries, with China, India, and Italy as the top locations (see Figure VIII-3). Respondents also reported the duration of supply disruptions. Both U.S. and non-U.S. based supply disruptions were approximately the same duration, averaging about 155 days.

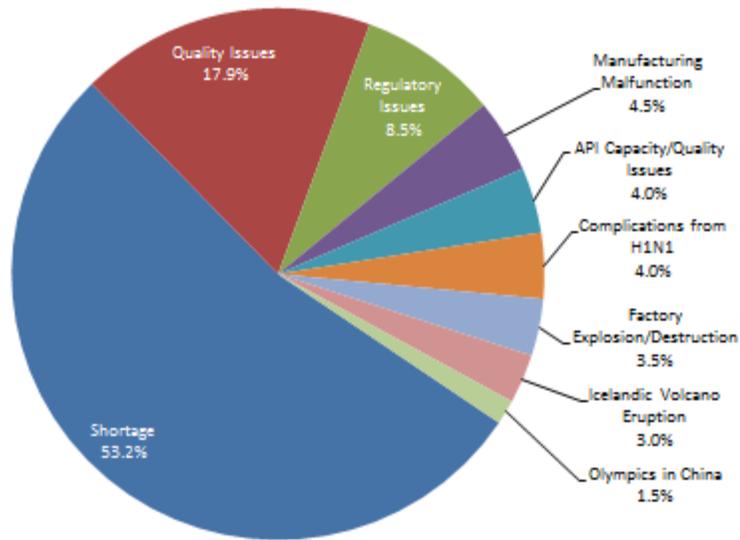
**Figure VIII-3: Non-U.S. Based Supply Shortages/
Disruptions by Country***



* Based on 80 reported incidents outside the U.S.
Source: U.S. Department of Commerce, Bureau of Industry and Security,
Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

Since survey respondents were not directed in how to qualify what they considered a “significant” disruption, OTE received a wide array of causes. Descriptions of disruptions were categorized into nine overarching categories. Fifty-three percent of supply disruptions were attributed to shortages (see Figure VIII-4). The majority of these shortages were attributed to capacity constraints or an inability to access raw materials. Quality and regulatory issues were also main factors in supply disruptions. Disruptions due to regulatory issues were the result of DEA quotas on imports or FDA approval and import bans on products and suppliers. Quality issues consisted of disruptions that were mostly the result of contaminated or defective products.

Figure VIII-4: Causes of Supply Shortages/Disruptions*



* Based on a total of 201 reported incidents.

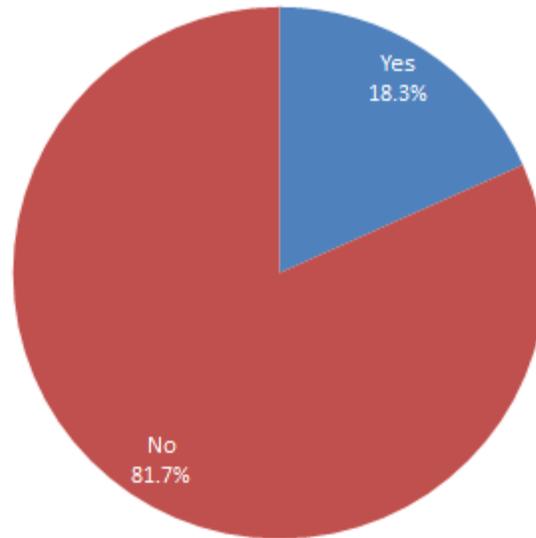
Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

DATABASE DETAILING SUPPLY DISRUPTIONS

Only 18.3 percent of survey respondents maintain a database detailing supply disruptions that occurred outside of the United States (see Figure VIII-5). For the most part, survey respondents identified open communications with suppliers as the primary way they track disruptions rather than keeping a database. One respondent stated, “we have a small number of suppliers and are in constant communication with the suppliers so we would know of any supply chain disruptions.” Multiple suppliers also noted that such a database did not “justify the expenditure of resources,” in some cases because they have not yet experienced any disruptions.

Those companies that keep a database often link it to some other tracking system, such as their shipment or inventory database. Some respondents also keep track of disruptions as part of their evaluation of supplier performance. For example, one company said it can track disruptions because their “strategic sourcing organization maintains information on supplier performance for all of our suppliers, domestic and international.” In addition, multiple companies keep weekly backorder reports, which inform them of ongoing supply delays or disruptions.

Figure VIII-5: Companies Maintaining a Database Detailing Supply Disruptions that Occur Outside the U.S.*



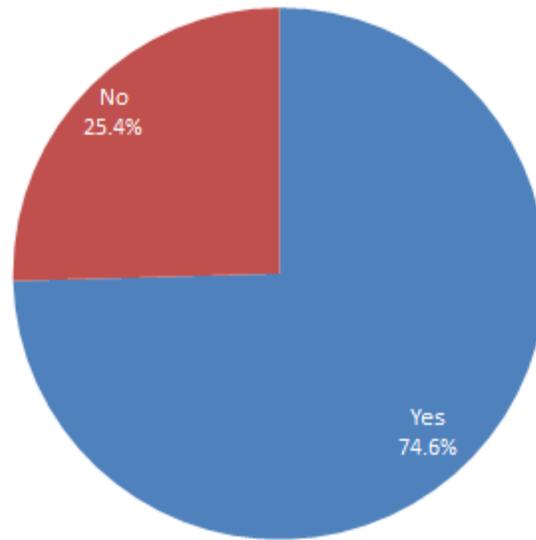
* Based on 169 unique responses.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

MECHANISMS TO INFORM THE COMPANY IN CASE OF A SUPPLY DISRUPTION

While the majority of companies do not maintain a database tracking supply disruptions, 74.6 percent of survey respondents say they have a mechanism in place to inform other parts of their organization if a disruption to their supply chain occurs outside the United States (see Figure VIII-6). Survey respondents identified formal and informal mechanisms for communicating a supply disruption. Formal means of communication were primarily “sales and operating plan[s]...and sales communication processes to inform parts of the organization about supply disruption and develop mitigation and contingency plans.” The majority of survey respondents communicated disruptions through a combination of formal and informal means, initiating contact via e-mail or phone and following up with Quality Assurance and Supply Chain Management processes to initiate contingency plans.

Figure VIII-6: Companies With a Mechanism in Place to Inform Parts of Their Organization in Case of a Non-U.S. Supply Disruption*



* Based on 169 unique responses.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

FUTURE RISK OF SUPPLY DISRUPTIONS/SHORTAGES

Survey respondents were asked if they anticipated a risk of supply disruptions or shortages for C/M/Fs produced outside the United States in the near future. Only 16.6 percent of companies foresee a risk of supply disruptions from outside of the United States. These risks were primarily due to regulatory lead-times and the availability of APIs and raw materials. Once again, companies were concerned about their ability to quickly qualify new sources of supply with the FDA, particularly for new API suppliers. One company has had trouble finding and certifying another source of their API as demand for their product has increased. Another company expects “to run out of [our product’s] API supply from [our supplier] (who discontinued several years ago) sometime in 2011; it may take up to 2 years to qualify a new source.”

Raw materials shortages and lead-times are also a major concern. Increasing demand for metals, chemicals, and oil has driven up raw material prices, which has strained supplier capacity in some circumstances. Medical device/surgical equipment manufacturers also expressed concern over increasing lead-times for electronic parts. The combination of electronic parts quickly

becoming obsolete and the long regulatory approval process has caused difficulties for many of these companies.

Numerous companies reasoned that there is no foreseeable risk in supply chains due to risk management techniques, limited exposure to foreign dependencies, and/or product availability. One company believes there is a low risk because “outside the U.S. supply chain sources are in very stable parts of the world.” Some respondents believe that their supply chain is secure because their suppliers are not located in countries with political instability. In these cases, they were most often referring to European countries.

Many companies also believe that they have sufficiently accounted for market demand, which helps them lower the risk of supply disruptions. One pharmaceutical company has taken steps to adjust their manufacturing capacity to demand and maintain “swing capacity allocated to opportunistic one-time buyers [based on] willingness to pay.” Another believes that if they lose their current supplier “there are other sources that may be qualified.” In the case of sole sources, this company maintains what they consider the “necessary” inventory.

VULNERABILITY TO SERIOUS/PROLONGED SUPPLY DISRUPTIONS

Twenty-nine percent of respondents believed their company was vulnerable to serious and/or prolonged supply chain disruptions from events or dependencies outside the United States. For pharmaceuticals, the top concern again was lack of API availability domestically. One company said, “we do not have redundant sources for the majority of our purchased product and some supply is provided from non-U.S. sources [so] we are currently vulnerable to such disruptions.” Companies may be vulnerable to supply disruptions not due to their own business practices, but simply because there is no alternate source for the materials they need.

Pharmaceutical companies that do not believe they are vulnerable either have confidence in where they source their components from, have sufficient risk mitigation strategies, or assume that disruptions are just another risk of doing business. Some companies view supplies from “allied countries” as safe from serious disruption. Other companies believe their vulnerability

stems primarily from natural disasters which they “have no control over.” After taking steps, such as maintaining inventories and seeking out alternate suppliers, many companies believe that their exposure to supply disruptions is as limited as it can be in the healthcare industry.

Medical device/surgical equipment manufacturers believe they are vulnerable primarily due to their reliance on other countries for electronic parts. The recent Japanese earthquake highlighted dependency issues for one company who said that “suppliers of semiconductors and electronic components depend on silicon, substrates and films for which Japan is a significant portion of global supply.” Even when these companies take steps to reduce their exposure to these issues, they have significant obstacles “due to the combination of intellectual property [concerns] and the costs associated with validating a second supplier.”

Those medical device/surgical equipment manufacturers that do not feel vulnerable often have contingency plans to ensure continued supply. Some commented that the parts they receive from outside the United States could be “re-sourced domestically” should the need arise. Another company believes that their actual manufacturing is safe, but expressed concern of the continuity of raw material supplies, such as titanium. As with pharmaceutical companies, however, some of these companies believe that supply disruptions are just another part of their business. One company said they “do not believe [our company] is any more vulnerable than the rest of our industry competitors.”

IX. STEPS TO REDUCE FOREIGN DEPENDENCIES

Survey respondents were asked if their company was taking steps to reduce their exposure to foreign dependency issues. In addition, they were asked to identify United States or non-U.S. Government regulations that might hinder their company's ability to maintain a secure, continuous supply chain. These regulations were detailed in depth by companies.

COMPANY EFFORTS TO REDUCE FOREIGN DEPENDENCIES

Only 33 percent of survey respondents are taking steps to reduce their exposure to foreign dependency issues. Based on company size, only 22.8 percent of small companies are taking steps, compared to 53.9 percent of medium and 44.4 percent of large companies. There was not a meaningful distinction between the number of pharmaceutical and medical device/surgical equipment manufacturers in this area. A small number of companies indicated that they were not taking action because their "foreign exposure is limited."

Pharmaceutical companies have difficulty limiting their exposure to foreign dependencies primarily because most of the APIs are produced outside the United States. In an attempt to reduce dependencies, one company said they are acting "as much as we can, however, many of the materials we use just aren't available in the U.S." Another company mentioned that "specific raw materials dictated by the FDA may only be made from foreign sources and not are able to be made here because of environmental regulations and laws." Many companies also see foreign dependencies merely as an accepted part of their business. One pharmaceutical manufacturer did not want to reduce foreign dependencies because they saw "no need to restrict business opportunities." Another company summed up their consideration of foreign suppliers, simply stating that "if outside U.S. companies are the best choice then we will stay with them."

Those pharmaceutical manufacturers that are attempting to reduce exposure to dependencies are finding dual-sources, reducing the physical distance of their supply chain, and expanding inventories for critical items. While many companies recognize that dual-sourcing reduces supply chain vulnerabilities, it is "difficult because both sources need to be exercised and it

impacts volumes...[which] can become cost prohibitive.” Another company is attempting to move production and their API to their own overseas facilities as opposed to contracting suppliers to better control their supply chain. Many companies also implement risk mitigation strategies as they continue to outsource production, identifying, although not necessarily qualifying, alternate sources of supply in case of a disruption.

Medical devices/surgical equipment manufacturers are operating under similar assumptions related to foreign dependencies. Many of these companies view foreign dependencies as just another risk. On this point, one company said, “we view all risks, domestic and international, equally important and take reasonable and necessary means to mitigate them.” As long as the required product arrives on time, on cost, and meets quality standards, the location of the supplier seems to be irrelevant to many survey respondents. Another company views the benefit of domestic suppliers from the perspective of reducing the time products take to get to their manufacturing location, but says “the cost effectiveness of U.S. sources will, however, continue to be an obstacle to moving manufacturing or suppliers onshore.”

Supplier diversification and inventory adjustments are the main ways that medical device/surgical equipment manufacturers attempt to reduce their exposure to foreign dependencies. One company is “diversifying its platform by allocating volume among more manufacturing locations, but cost pressures are indicating that sourcing will continue outside the U.S. to a significant degree.” Unlike with pharmaceuticals, it appears to be easier for medical device/surgical equipment manufacturers to maintain stockpiles or “safety stocks” to mitigate the risk of a disruption. One company advises engaging in long-term contractual agreements where possible and continual market observation to identify emerging risks.

U.S. GOVERNMENT REGULATIONS

Only 22.6 percent of survey respondents said that there are U.S. Government regulations or processes that hinder their ability to maintain a secure, continuous supply chain. Despite this low number, companies pointed to numerous regulatory issues that were common themes throughout many survey responses. FDA regulations were the primary concern for HPH

companies. Few companies complained of the regulations themselves, but rather that the “initial [product] registration, along with changes in manufacturing that require an update to the registration, make managing...supply chains much more complex.” For products that have already reached the market, FDA approval requirements for any changes to the supply chain make qualifying alternate suppliers more costly, time consuming, and difficult. One company said, “the FDA approval cycle is so incredibly long and cumbersome it is sometimes difficult to convince suppliers to do business with us on the parts we need because they have no promise of future business.” According to comments, FDA approval processes for some respondents are averaging anywhere from one to three years, hindering the ability of companies to quickly transition to alternate sources of supply should the need arise.

Transportation and import issues are also a common source of frustration for survey respondents. In some cases, delays in getting products through U.S. Customs had caused disruptions and lead to increased costs to expedite shipments. Manufacturers in this industry are highly reliant on just-in-time delivery, so these delays can cause significant disruptions in their supply chains. Even companies that are participants in the Department of Homeland Security’s Customs-Trade Partnership Against Terrorism (C-TPAT) program have found that delays of international shipments have hindered their manufacturing schedules. The Department of Transportation (DOT) also regulates the shipment of many healthcare-related products – such as radioisotopes and carcinogens – which increases requirements and logistical issues.²⁵ Numerous products are also subject to DEA quota limitations.²⁶ A few companies have encountered issues with these quotas, with one company complaining that the “national quota was maxed out by mid-year,” causing a significant supply disruption.

NON-U.S. GOVERNMENT REGULATIONS

Fewer companies believe that non-U.S. Government regulations or processes are hindering their ability to maintain a secure supply chain. Only 7.5 percent of companies identify issues with

²⁵ For more information on DOT regulations see Title 49 of the Code of Federal Regulations (C.F.R.).

²⁶ The DEA sets quotas that regulate the manufacture and importation of certain chemicals, such as ephedrine, pseudoephedrine, and phenylpropanolamine. For more information see: http://www.dea diversion.usdoj.gov/quotas/quota_apps.htm.

non-U.S. Government regulations or processes. Regulatory issues are again a primary concern; conflicting standards and requirements complicate international business operations in this industry. Lack of familiarity or clarity of regulations required by non-U.S. Government agencies are a hurdle to manufacturing and supplier relationships. In addition, one company cited a “lack of regulatory enforcement to adequately protect intellectual property” as their concern with non-U.S. Governments.

STEPS THE U.S. GOVERNMENT CAN TAKE TO REDUCE FOREIGN DEPENDENCY ISSUES

OTE also asked what steps the U.S. Government can take to reduce companies’ exposure to foreign dependency issues. The majority of company comments revolved around speeding up the FDA regulatory approval process. In addition to requesting more resources to reduce inspection times, companies want the FDA to enforce regulations more stringently outside the United States. One company called for a more even playing field, noting that “U.S. suppliers are subjected to a higher level of scrutiny compared to foreign manufacturers due to the inspection resources of the FDA being concentrated domestically.” Companies also complained that the certification of new products is too costly and confusing, which, according to one respondent, “stops most new [American] products from receiving investment/funding.” This company believes that “simplifying and clarifying product requirements would increase U.S. product development.” In addition, companies called for more FDA approval of Abbreviated New Drug Applications (ANDA) so “if one supplier of a critical material is unable to supply, manufacturers are able to go to a different source in order to fill their requirements for production and reduce costs.”²⁷

Beyond FDA approvals, survey respondents point to the lack of tax incentives and strict environmental regulations as key drivers for outsourcing in the HPH sector. Pharmaceutical companies blame environmental laws as the primary reason why most API supplies are now sourced from outside the United States. One company that relies on non-U.S. suppliers for chemicals calls for environmental regulation reform to “make manufacturing in the U.S. a

²⁷ An ADNA is an application for the certification of a generic drug that is equivalent to an existing drug product. These applications typically do not require preclinical or clinical trials, but rather demonstration of bioequivalence.

favorable option.” Survey respondents also point to corporate tax rates as a source of supply chain issues. One company explained, “as more firms outsource production to offset high labor costs and tax rates, companies that perform final assembly and test have to source more product overseas, lengthening our supply chain and introducing risk.” Numerous medical device manufacturers also specifically cite the new 2.3 percent medical device tax included in the 2010 Affordable Care Act as an incentive to outsource production. Many respondents called for tax incentives for domestic production of healthcare-related products, and some mentioned increasing regulations or imposing duties/tariffs on foreign manufacturers to protect U.S. industry.

Some product-specific advice was provided, as well. A few companies called for steps to reduce the price of oil, which has increased the cost of plastics and polymeric materials. Survey respondents also called for assistance in establishing a domestic source for some items, such as Molybdenum-99, thin film transistor panels, and APIs.

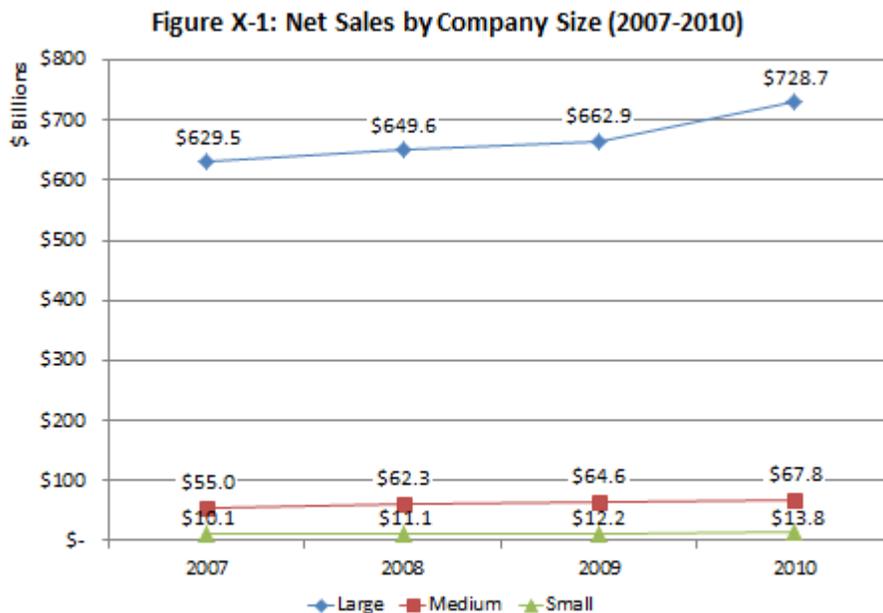
One small-sized company summed up their feelings on the state of the healthcare and public health sector by saying:

We realize today's business world is global, but it is sad to see so much of our manufacturing go off-shore and decisions being made more and more based on purchase price rather than quality. And purchase price isn't including the price of managing the off-shore source -- something that is an ever increasing expectation from the FDA and is very, very expensive.

X. FINANCIAL HEALTH

OTE asked survey respondents to provide selected financial line items from their income and balance sheets for 2007-2010. While most companies were able to provide this data, some companies, particularly medical devices/surgical equipment manufacturers, were unable to separate their healthcare-related operations from their broader corporate financial information. In addition, sales and financial information could not be isolated specifically for the products included on the Critical Commodities List in this survey. Instead, this section provides a broad overview of the general financial health of survey respondents.

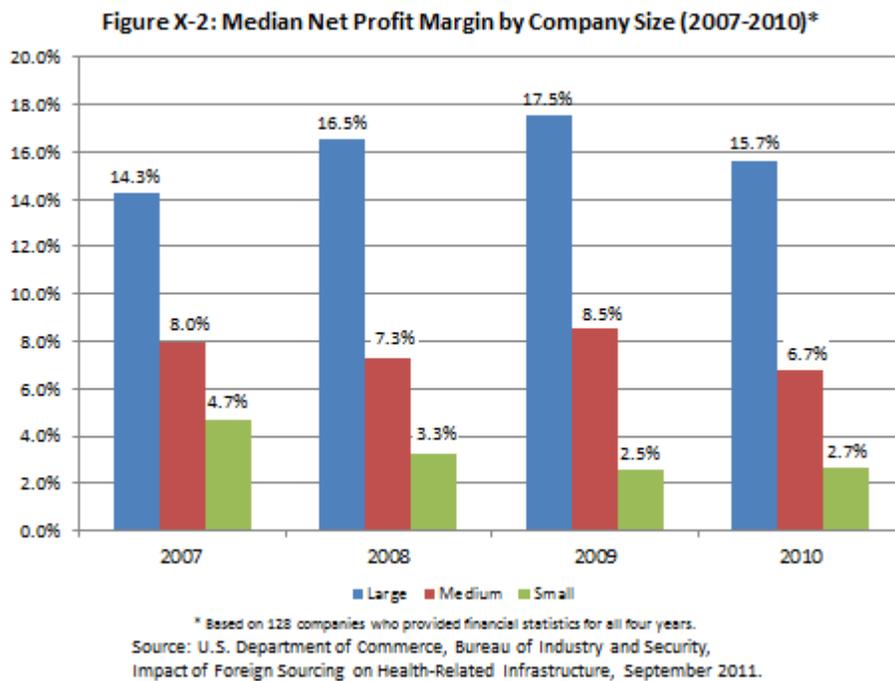
From 2007-2010, small-, medium-, and large-sized companies increased their aggregate net sales (see Figure X-1). During this period, small companies increased their aggregate net sales by 36.6 percent, medium companies by 23.3 percent, and large companies by 15.8 percent. As mentioned previously, large-sized companies represented 89.7 percent of net sales for 2010.



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

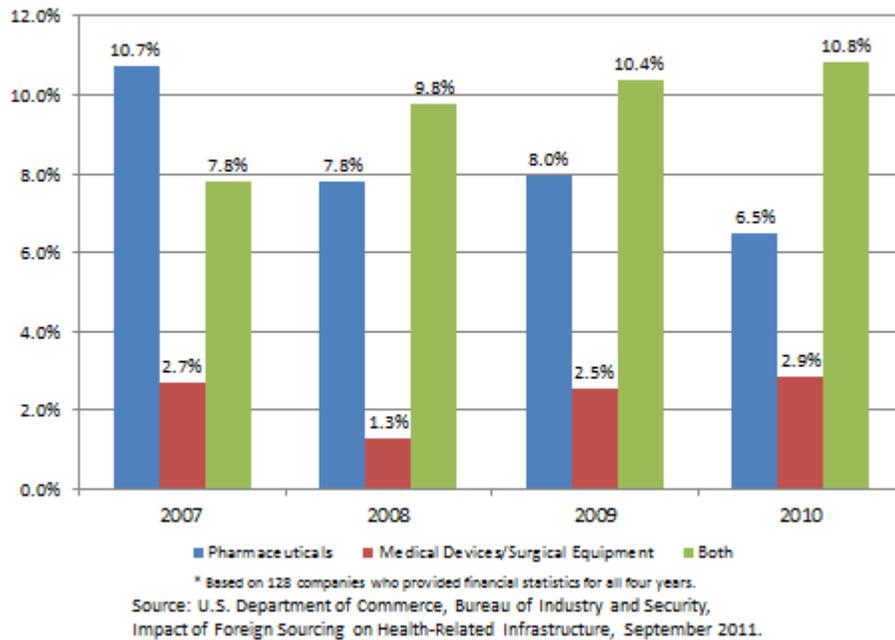
NET PROFIT MARGIN

An increase in aggregate net sales revenue does not necessarily indicate individual company profitability. An examination of median net profit margins reduces the impact of data anomalies that may skew the aggregate picture of survey respondents' viability and competitiveness. The median net profit margin was positive for all company sizes, with large-sized companies much higher than smaller companies (see Figure X-2). The median profit margin for large-sized companies increased slightly from 2007-2010, while those of small-sized and medium-sized companies decreased.



Based on business type, companies that manufacture pharmaceuticals or both types of products had much higher median net profit margins than those who solely manufacture medical devices/surgical equipment (see Figure X-3). For pharmaceutical companies, however, the median net profit margin decreased from 10.7 percent to 6.5 percent during this period. Companies that manufacture both types of products had their median net profit margin increase from 7.8 percent to 10.8 percent, while medical device/surgical equipment margins remained roughly the same.

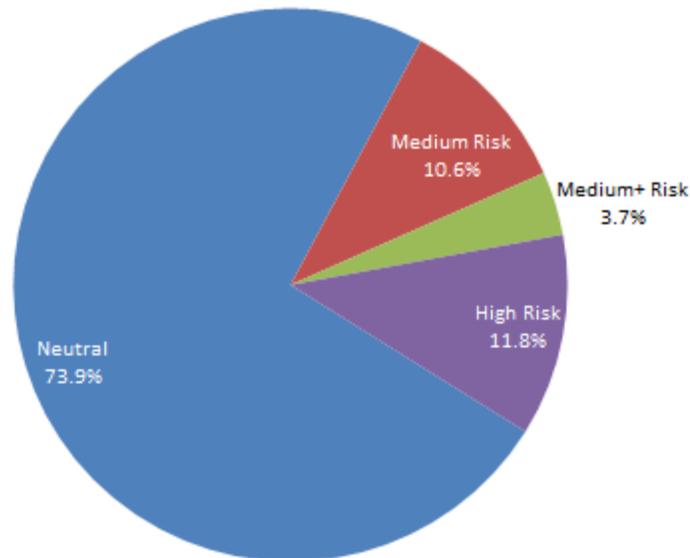
Figure X-3: Median Net Profit Margin by Company Type (2007-2010)*



A company-by-company analysis of net profit margins allows for a general measure of long-term viability and competitiveness. For the purposes of this study, a company that has four consecutive years of negative net profit margins can be said to have a high risk long-term outlook. Companies with three consecutive years of negative net profit margins are considered to be a medium+ risk, and two years are at medium risk.

Based on these criteria, 19 companies are at high risk, 16 of which are small-sized and three are medium-sized. Five high risk companies manufacture pharmaceuticals, 13 produce medical devices/surgical equipment and one produces both types of products (see Figure X-4).

Figure X-4: Respondent Financial Risk



Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

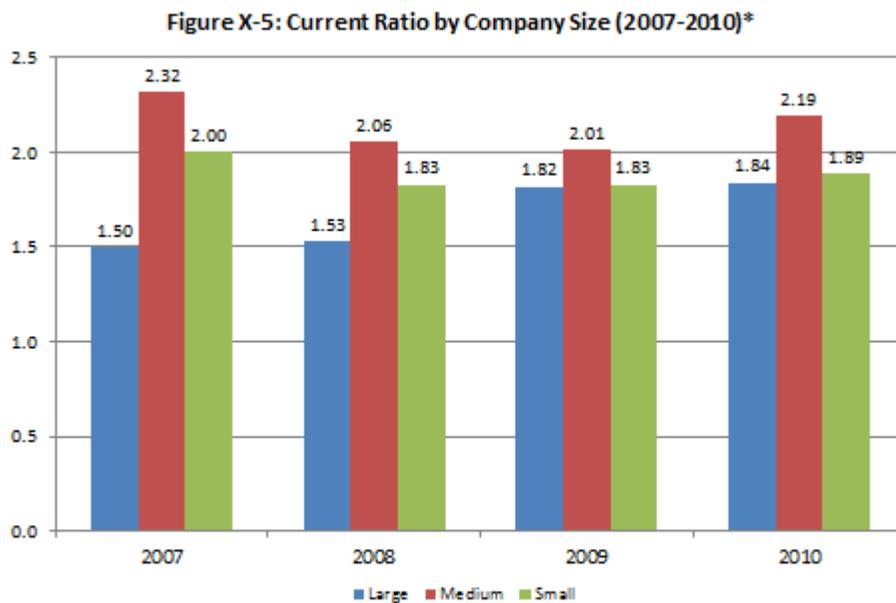
Those companies that are deemed to be at high financial risk manufacture in 93 product areas identified in the OTE survey. For pharmaceuticals, these companies predominantly manufacture antibiotics, such as bacitracin, gentamicin, and erythromycin. These companies also produce different types of cyanide treatments. For medical devices/surgical equipment, at risk companies mainly produce surgical equipment, such as bone nails/screws, medical needles, and mallets/hammers.

CURRENT RATIO

The current ratio measures how effective companies are at meeting their short-term debt obligations. This ratio is established by dividing total current assets by total current liabilities. OTE compared median current ratios for survey respondents to industry-wide benchmarks provided by the U.S. Census Bureau. Corporations manufacturing “Pharmaceuticals and Medicines” under North American Industry Classification System (NAICS) code 3254 had a current ratio of 1.42 in 2010. Pharmaceutical manufacturers who participated in this survey had a median current ratio of 1.89 in 2010, indicating that they faced a lower burden from short-term liabilities than the overall industry.

Manufacturers of medical devices/surgical equipment primarily fall under NAICS 339 for “Miscellaneous Manufacturing.” The 2010 current ratio for these companies was 2.16. For medical device/surgical equipment survey respondents, the ratio was lower at 1.92. Companies that manufacture both had a median current ratio of 1.78. Although this is lower than the industry total, it is difficult to compare accurately due to the lack of detail in the benchmark.

Based on company size, small and medium companies had a decreasing current ratio during the survey period. Small companies went from a median of 2.00 in 2007 to 1.89 in 2010. Medium companies had a similar drop from 2.32 to 2.19. Large companies saw a significant median increase from 1.50 in 2007 to 1.84 in 2010 (see Figure X-5).



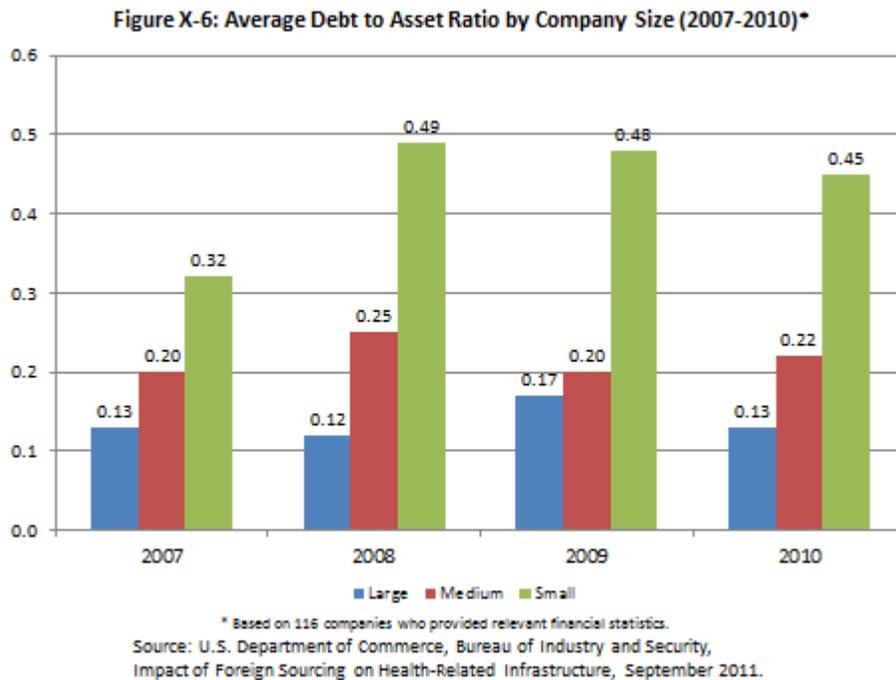
* Based on 133 companies who provided relevant financial statistics.
 Source: U.S. Department of Commerce, Bureau of Industry and Security,
 Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

LONG-TERM DEBT TO TOTAL ASSET RATIO

The debt-to-asset ratio indicates how much of a company’s total assets are financed through debt. In other words, it indicates “how much a company is reliant on borrowing to finance its

operations.”²⁸ If a company has \$10,000 in debt and \$100,000 in assets, it has a debt ratio of .10. This means that for every asset dollar, the company has 10 cents in debt, a relatively healthy percentage.

As an aggregate, survey respondents’ long-term debt has deteriorated slightly on an annual basis, with an increase in the total debt to total assets from 0.26 in 2007 to 0.35 in 2010. There is a significant difference in long-term debt between company sizes and business types, however. For this period, large- and medium-sized companies had a relatively consistent debt to asset ratio, while small companies saw a significant increase (see Figure X-6). Small companies’ debt-to-asset ratio jumped from 0.32 in 2007 to 0.45 in 2010.

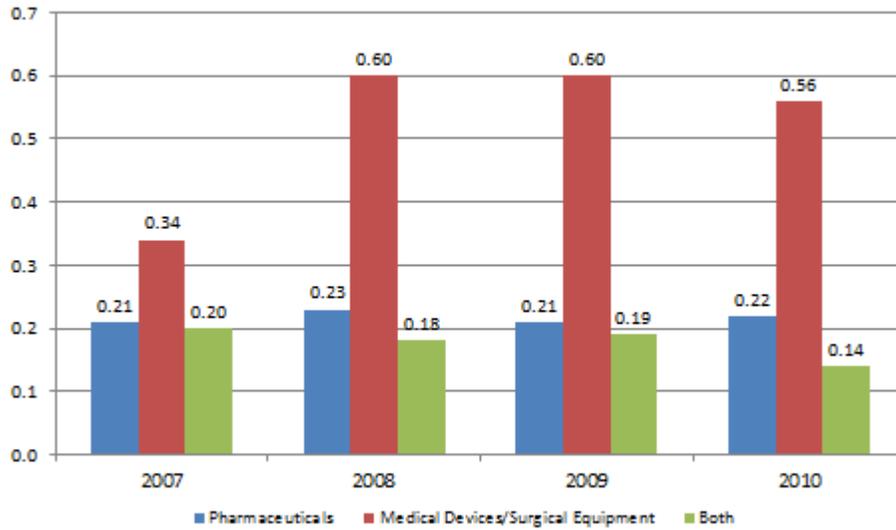


Medical devices/surgical equipment manufacturers have, on average, a much higher debt-to-asset ratio than other survey respondents. These companies increased from 0.34 in 2007 to 0.56 in 2010 (see Figure X-7). Pharmaceutical manufacturers remained relatively consistent during the

²⁸ Keeffe, Philip, “Business Ratios are Indicators of Company Health,” <http://www.suite101.com/content/business-ratios-are-indicators-of-company-health-a241254>.

survey period. Manufacturers of both types of products actually reduced their debt compared to their assets, falling from 0.20 in 2007 to 0.14 in 2010.

Figure X-7: Average Debt to Asset Ratio by Company Type (2007-2010)*



* Based on 116 companies who provided relevant financial statistics.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Impact of Foreign Sourcing on Health-Related Infrastructure, September 2011.

XI. FINDINGS AND RECOMMENDATIONS

REPORT FINDINGS

There is a significant amount of U.S.-based manufacturing for critical healthcare-related commodities. Survey respondents produced 1,701 individual products (868 pharmaceuticals and 833 medical devices/surgical equipment) within the product areas identified in the OTE survey, the majority of which were manufactured in the United States.

There is, however, a very high degree of foreign sourcing and dependency for components, materials, and finished products. Seventy-three percent of respondents relied on non-U.S. based suppliers for at least one component, material, or product that they deemed ‘critical’ to their manufacturing operations. Survey respondents identified 1,340 critical components, manufacturing materials, and finished products for which they rely on suppliers based outside the United States. In many cases, these suppliers are the sole global source.

There is no alternate U.S.-based supplier for 63.4 percent of components, materials, and finished products provided by non-U.S. companies. The imports supporting pharmaceutical manufacturing were predominantly the API, the most important part of a drug. Imports supporting medical devices/surgical equipment were primarily electronic components, such as semiconductors, circuit boards, wires, and video displays.

Foreign sources are not concentrated in any one country, but are widely spread across the world. Survey respondents identified non-U.S. based suppliers for pharmaceutical components, materials, and products in 47 countries; most were located in Italy, India, Germany, China, and France. Medical device/surgical equipment suppliers were identified in 41 countries, most commonly in China, Germany, Japan, Mexico, and the United Kingdom. In most cases, respondents rely on multiple suppliers for several different components in each of these countries rather than a single company.

Respondents are able to increase their production in varying degrees for nearly all products in the OTE survey, when given the appropriate lead-times. Pharmaceuticals most commonly require a 3-6 month lead-time to increase production 50 percent. Medical devices/surgical equipment require a wider range of lead-times to increase production 50 percent. These products most commonly require between 3 and 12 months to do so.

Survey respondents most commonly require more plant space/capacity to increase their production. For pharmaceuticals, plant space/capacity and non-U.S. sourced raw material shortages/availability are the primary factors limiting a production increase. Medical device/surgical equipment manufacturers are limited by delivery lead-times of new machinery and plant space/capacity.

Pharmaceutical companies tend to maintain longer supplier contracts than medical device/surgical equipment manufacturers. Regulatory requirements and the limited availability of API force pharmaceutical companies to pursue long-term contracts in many cases. Medical device/surgical equipment manufacturers may maintain shorter contracts due to the constantly changing technology required to produce their products. Overall, 47.9 percent of survey respondents have contracts with suppliers for an average length of 1-3 years.

Total cost and product availability are the primary factors companies consider when they outsource/purchase overseas. Many pharmaceutical and medical device/surgical equipment manufacturers select suppliers that offer the best combination of purchase cost, quality, and logistics, regardless of their location. In other cases, companies pursued suppliers outside the United States because they believed no domestic alternatives were available for the products they required.

Eighty-one percent of survey respondents maintain an inventory of components/materials and finished products. Companies most commonly maintain a 1-3 month supply of finished products and a 1-6 month supply of components/materials. Inventory levels were relatively consistent between pharmaceutical and medical device/surgical equipment manufacturers.

Seventy percent of respondents have a list of approved alternate suppliers, although these companies may not have been officially reviewed by regulatory agencies such as the FDA. The FDA approval process requires a significant investment of time and money, which limits the extent to which respondents maintain alternate suppliers.

Significant supply disruptions were primarily due to supply shortages, manufacturing quality issues, and delays in regulatory approvals. Twenty-nine percent of survey respondents experienced a “significant” supply disruption or shortage from 2007-2010. Disruptions outside the United States most commonly occurred in China, India, and Italy. The average length of these supply disruptions was 155 days.

Exposure to supply disruptions is widespread, but many respondents consider it a cost of doing business in the healthcare industry. Both pharmaceutical and medical device/surgical equipment manufacturers expressed concern because many of the components and materials they require are procured exclusively from non-U.S. based suppliers. Some manufacturers viewed supply disruptions and dependency issues as an assumed cost of doing business in the industry. While they recognize the industry’s exposure to significant disruptions, some companies believe that they are no worse off than any of their other competitors. In addition, although many respondents have complex risk management procedures to reduce their exposure to supply chain issues, dependency on suppliers outside the United States is not often seen as a primary concern.

Only 34 percent of respondents are taking steps to reduce their exposure to foreign sourcing and dependency issues. While some companies have limited exposure to these issues, many more are finding it difficult to reduce foreign sourcing because the products they require are not available in the United States. This is particularly true regarding the API required for pharmaceutical manufacturing. In some cases, companies are attempting to develop dual-sources, reduce lead-times, diversify the location of their suppliers, and expand product inventories, but this can be cost prohibitive to do for all aspects of their business.

Many companies mitigate the risk of supply disruptions by maintaining relationships with multiple suppliers, but it is not feasible to do so for all of the products they require. This is in large part due to a lack of alternate sources of supply or product availability. Alternatively, it is sometimes cost prohibitive to actively maintain multiple sources of supply for a company's manufacturing operations. In addition, many companies found it too time consuming and costly to certify alternate sources of supply with U.S. regulatory agencies.

The long lead-times to certify new suppliers with the FDA and other U.S. Government agencies make ensuring supply chain continuity difficult. Should a supply disruption occur, companies cannot quickly transition to a new domestic or non-U.S. supplier in order to continue production. The competitive nature of this commercial industry makes it difficult to maintain multiple suppliers and/or domestic sources. These strategies may present significant costs and regulatory obligations for industry.

Survey respondents made several recommendations to the U.S. Government to reduce foreign dependency issues in the HPH sector:

- Speeding up FDA approval times;
- Reducing the costs and clarifying the process for FDA certification of suppliers;
- Increasing enforcement of FDA regulations outside the United States;
- Streamlining transportation and importation quota issues with Customs and Border Protection (CBP), the Department of Transportation (DOT), and the Drug Enforcement Agency (DEA);
- Reforming environmental laws, particularly related to API production; and
- Modifying the corporate tax structure to encourage domestic manufacturing.

REPORT RECOMMENDATIONS

Based on the survey findings and discussions with U.S. Government agencies and industry groups, OTE makes the following recommendations:

- DHS, HHS, FDA, and other relevant U.S. Government agencies should further examine OTE's survey data to prioritize the foreign sourcing and dependencies that could have the greatest impact on the healthcare supply chain in an emergency situation.

- These same agencies, utilizing the HPH Sector Coordinating Council and other mechanisms, should discuss with industry the concerns presented by a high reliance on non-U.S. based suppliers for such a wide range of critical pharmaceuticals and medical devices/surgical equipment and develop possible solutions.
- The FDA should continue to hold and expand public hearings and information gathering meetings with industry to review the impact of regulatory requirements, approval times, and limited government resources on the foreign sourcing and dependencies issue. Addressing these issues may help promote dual-sourcing, allow for quicker transitions to new suppliers in case of a disruption, and increase the competitiveness of U.S. companies globally.
- DHS, HHS, FDA, and other relevant U.S. Government agencies should further examine OTE's survey data to prioritize regulatory requirements and obstacles cited by respondents that could promote the establishment of domestic sources of supply for critical commodities, particularly for active pharmaceutical ingredients. Of particular note are regulatory approval times for supplier certification, environmental regulations related to API production, and transportation/importation requirements for certain commodities.
- HHS, in coordination with DHS and the Department of Commerce, should assess whether the use of Defense Production Act authorities, such as the Defense Priorities and Allocations System (DPAS), could provide the ability to rapidly expand or surge capacity of U.S.-based pharmaceutical and medical device/surgical equipment facilities to meet demand in an emergency situation.
- U.S. industry should make renewed efforts to ensure supply chain resiliency by developing and maintaining multiple suppliers for critical components, materials, and finished products. These efforts could include development of new business strategies that give priority to domestic sources of supply, thereby reducing dependence on critical components and materials from suppliers based outside the United States. Additional steps should also be made to monitor the potential for supply disruptions before they occur.

- Any actions taken by the U.S. Government to enhance the security of the U.S. HPH supply chain must factor in the potential impact these measures have on individual company finances and market viability.

APPENDIX A

THE CRITICAL COMMODITIES LIST

A. Anesthetics

1. Atropine/Atropine Sulfate
2. Bupivacaine
3. Halothane
4. Ketamine
5. Lidocaine
6. Nitrous Oxide
7. Pancuronium Bromide
8. Promethazine
9. Propofol
10. Thiopental/Pentothal
11. Thiopentone Sodium

B. Analgesics

1. Acetylsalicylic Acid (Aspirin)
2. Allopurinol
3. Aminophenazone
4. Azathioprine
5. Buprenorphine
6. Carbamazepine
7. Chloroquine
8. Cinchonine
9. Codeine
10. Dihydrocodeine
11. Etorphine
12. Hydrocodone
13. Hydromorphone
14. Ibuprofen
15. Levorphanol
16. Methotrexate
17. Morphine

18. Nicomorphine
19. Oxycodone
20. Oxymorphone
21. Paracetamol/Acetaminophen
22. Penicillamine
23. Pholcodine
24. Quinine
25. Thebacon

C. Antibacterials

1. Furazolidone
2. Sulferamerazine
3. Sulphadiazine
4. Sulphapyridine
5. Sulphathiazole
6. Sulphathiourea

D. Antibiotics

1. Actinomycins
2. Amoxicillin
3. Ampicillin
4. Azithromycin
5. Aztreonam
6. Bacitracin
7. Benzylpenicillin (Penicillin G)
8. Cefalexin
9. Cefazolin
10. Cefixime
11. Cefotaxime
12. Ceftazidime
13. Ceftriaxone
14. Chloramphenicol
15. Ciprofloxacin
16. Clarithromycin
17. Clindamycin
18. Cloxacillin

19. Doripenem
20. Doxycycline
21. Erythromycin
22. Gentamicin
23. Gramicidines
24. Imipenem
25. Levofloxacin
26. Metronidazole
27. Minocycline
28. Nitrofurantoin
29. Phenoxymethylpenicillin
30. Procaine Benzylpenicillin
31. Sarkomycin
32. Spectinomycin
33. Streptomycin
34. Talampicillin
35. Tetracycline
36. Thiamphenicol
37. Trimethoprim
38. Tyrocidin
39. Vancomycin
40. Zanamivir

E. Anticonvulsants, Sedatives, Relaxants

1. Alprazolam
2. Atracurium Besylate
3. Camazepam
4. Chlordiazepoxide
5. Clonazepam
6. Clorazepate
7. Delorazepam
8. Diazepam
9. Estazolam
10. Ethosuximide
11. Ethyl Loflazepate

12. Fludiazepam
13. Flunitrazepam
14. Flurazepam
15. Halazepam
16. Lorazepam
17. Lormetazepam
18. Mazindol
19. Medazepam
20. Midazolam
21. Nimetazepam
22. Nitrazepam
23. Nordazepam
24. Oxazepam
25. Phenobarbital
26. Phenytoin
27. Pinazepam
28. Pralidoxime/Pralidoxime Chloride
29. Prazepam
30. Pyrovalerone
31. Temazepam
32. Tetrazepam
33. Triazolam
34. Valproic Acid (VPA)
35. Vecuronium Bromide

F. Anti-Inflammatories

1. Dexamthasone
2. Flucinolone Acetonide
3. Indometacin/Indomethacin
4. Rutoside/Rutin
5. Tolmetin

G. Antileprosy

1. Amikacin
2. Capreomycin
3. Clofazimine

4. Cycloserine
5. Dapsone
6. Ethambutol
7. Ethionamide
8. Isoniazid
9. Kanamycin
10. Ofloxacin
11. P-Aminosalicylic Acid
12. Pyrazinamide
13. Rifabutin
14. Rifampicin/Rifampin

H. Antiprotozoals

1. Amodiaquine
2. Artemether
3. Benznidazole
4. Diloxanide
5. Eflornithine
6. Mefloquine
7. Nicarbazin
8. Nifurtimox
9. Paramomycin
10. Pentamidine
11. Primaquine
12. Proguanil
13. Pyrimethamine

I. Antivirals

1. Abacavir (ABC)
2. Acyclovir
3. Amantadine
4. Atazanavir
5. Cidofovir
6. Didanosine (ddl)
7. Efavirenz (EFV or EFZ)
8. Indinavir (DIV)

9. Lamivudine (3TC)
10. Nevirapine (NVP)
11. Oseltamivir (aka Tamiflu)
12. Ribavirin
13. Rimantadine
14. Ritonavir
15. Saquinavir (SQV)
16. Stavudine (d4T)
17. Tenofovir Disoproxil Fumarate (TDF)
18. Zidovudine (ZDV or AZT)

J. Cancer Treatments

1. Folinic Acid/Leucovorin
2. Thiotepa
3. Valrubicin
4. Vinblastine Sulfate

K. Cardiovasculars

1. Amiodarone
2. Amlodipine
3. Arrolol
4. Atenolol
5. Digoxin
6. Dopamine
7. Enalapril
8. Furosemide
9. Glyceryl Trinitrate
10. Hydralazine Hydrochloride
11. Hydrochlorothiazide
12. Isosorbide Dinitrate
13. Mexiletine
14. Sarpogrelate
15. Simvastatin
16. Streptokinase
17. Verapamil

L. Hormones

1. Aglepristone
2. Estradiol
3. Estriol
4. Estrone
5. Ethinyl Estradiol
6. Fludrocortisone
7. Glibenclamide
8. Granulocyte-Colony Stimulating
Factor (G-CSF)
9. Insulin
10. Levonorgestrel
11. Levothyroxine
12. Liothyronine
13. Medroxyprogesterone Acetate
14. Mestranol
15. Metformin
16. Norethisterone
17. Onapristone
18. Pegvisomant
19. Potassium Iodide
20. Pregnandiol
21. Progesterone
22. Propylthiouracil
23. Rathyronine
24. Somatotropin
25. Somatrem
26. Somenopor
27. Testosterone (Androgen)

M. Immunosuppressants

1. Aldosterone
2. Asparaginase
3. Bleomycin
4. Calcium Folate
5. Carboplatin

6. Chlorambucil
7. Ciclosporin
8. Cortisone
9. Cortodoxone
10. Cyclophosphamide
11. Cytarabine
12. Dactinomycin
13. Darcabazine
14. Daunorubicin
15. Etoposide
16. Fluorouracil
17. Hydrocortisone
18. Hydrooxycarbamide
19. Ifosfamide
20. Mercaptopurine
21. Mesna
22. Prednisolone
23. Prednisone
24. Procarbazine
25. Tamoxifen
26. Vinblastine
27. Vincristine

N. Stimulants

1. Aminorex
2. Brotizolam
3. Clotiazepam
4. Ephedrine
5. Epinephrine (Adrenaline)
6. Fenethylamine
7. Norepinephrine
8. Pseudoephedrine
9. Racepinephrine

O. Vaccines

1. Anthrax Treatments (Immune Globulin Injection, Raxibacumab, etc.)

2. BCG Vaccine
3. Cholera Vaccine
4. Diphtheria Vaccine
5. Haemophilus Influenzae Type B Vaccine
6. Hepatitis A Vaccine
7. Hepatitis B Vaccine
8. Japanese Encephalitis Vaccine
9. Measles Vaccine
10. Meningococcal Meningitis Vaccine
11. Modified Vaccinia Ankara (MVA)
12. Mumps Vaccine
13. Pertussis Vaccine
14. Pneumococcal Vaccine
15. Poliomyelitis Vaccine
16. Rabies Vaccine
17. Rotavirus Vaccine
18. Rubella Vaccine
19. Smallpox Vaccine
20. Tetanus Vaccine
21. Typhoid Vaccine
22. Vaccinia Immune Globulin (VIG)
23. Varicella Vaccine
24. Yellow Fever Vaccine

P. Other Products

1. Acridine
2. Botulinum Toxin(s)
3. Cyanide Treatments - Amyl Nitrate
4. Cyanide Treatments - Hydroxocobalamin
5. Cyanide Treatments - Sodium Nitrate
6. Cyanide Treatments - Sodium Thiosulfate
7. Diethylene Triamine Pentaacetic Acid (DTPA)/Pentetic Acid
8. Granisetron
9. Heparin
10. Imipramine

11. Lysine
12. Probenecid
13. Prussian Blue
14. Technetium Generators or other equipment for the processing of radioisotopes
15. Thiopen

Q. Medical Devices/Surgical Equipment

1. Adhesive Dressings
2. Aerosol Therapy Apparatus
3. Anaesthesia Units
4. Anaesthetic Apparatus
5. Anti-Radiation Protective Suits
6. Apnea Monitors
7. Apparatus Based on Alpha, Beta, or Gamma Radiations for Medical Use
8. Argon Enhanced Coagulation Units
9. Artificial Kidney/Dialysis Apparatus
10. Artificial Respiration Apparatus
11. Aspirators
12. Auriscopes
13. Blood Collection Tubes
14. Blood Pressure Measuring Equipment
15. Blood Transfusion Apparatus
16. Bone Nails and Screws
17. Bone Plates
18. Bronchoscopes
19. Capnographs
20. Cardioscopes
21. IV Catheters
22. Adult Central Venous Catheters
23. Pediatric Central Venous Catheters
24. Swan-Ganz Catheters
25. Suction Catheters
26. Other Catheters
27. Cauteries
28. Cephalometers

29. Crutches
30. Cutaneous Dressings
31. Defibrillators
32. Dilators
33. Electrocardiographs
34. Electroencephalographs (EEG)
35. Electronic Nerve Stimulation Machines
36. Electrosphygmographs
37. Electrotonographs
38. Endoscopes
39. Endotracheal Tubes (adult and pediatric)
40. Fetal Monitors
41. Forceps
42. Gas Masks
43. Gastrosopes
44. Gauze and Bandages
45. Gouges
46. Hyperbaric Chambers
47. Hysterectomy Instruments
48. Infant Incubators
49. Influenza Tests
50. Infusion/IV Pumps
51. Intubation Tubes
52. Keratometer
53. Kidney Dishes
54. Lancets
55. Laparoscopic Insufflators
56. Laryngoscope
57. Laryngoscope Handle and Blade (Intubating)
58. Lensometer
59. Liquid Dressings
60. Lithotripsy Instruments
61. Lytic Bacteriophages
62. Magnetic Resonance Imaging (MRI) Apparatus

63. Mallets and Hammers for Medical Use
64. Medical Needles/Syringes/Safety Needle
65. Mirrors and Reflectors for Medical Use
66. Nasal Cannula
67. Nasogastric Tube (adult and pediatric)
68. Nebulisers
69. Oesophagoscopes
70. Oropharyngeal Airway
71. Oscillometers
72. Oxygen Analyzers
73. Oxygen Tents
74. Oxygen Therapy Apparatus
75. Ozone Therapy Apparatus
76. Pacemakers
77. Parts for Pacemakers
78. Pelvimeters
79. Phonocardiographs
80. Protective Screens/Shields for X-Ray Facilities
81. Pulse Oximeters
82. Pyrometers
83. Radiotherapy Apparatus
84. Respirators
85. Respiratory Pumps and Filters
86. Resuscitator Bag Valves and Masks
87. Pulmonary Resuscitators
88. Oxygen Resuscitators
89. Retractors
90. Rheocardiographs
91. Saws and Scrapers for Medical Use
92. Sissors and Shears for Medical Use
93. Spatulae
94. Specula
95. Sphygmomanometers
96. Spinal Needles

- 97. Spirometers
- 98. Splints
- 99. Sterilizers
- 100. Stethoscopes
- 101. Stomach Pumps
- 102. Suction Pumps
- 103. Suction Tubes
- 104. Surgical Gloves
- 105. Surgical Gowns
- 106. Surgical Knives and Scalpels
- 107. Surgical Masks
- 108. Surgical Staplers
- 109. Suture Clips
- 110. Sutures
- 111. Tensiometers
- 112. Thermometers
- 113. Tourniquets
- 114. Tracheal Tubes
- 115. Trocars
- 116. Trusses
- 117. Ultrasound Sensors
- 118. Ultra-Violet or Infra-Red Apparatus for Medical Use
- 119. Urethrotomes
- 120. Vaginal Retractors/Speculums
- 121. Venous Cannula
- 122. Ventilator Circuits
- 123. Ventilators
- 124. Wire Guides
- 125. X-Ray Apparatus Used in Medical Diagnosis
- 126. X-Ray Control Panels/Desks
- 127. X-Ray Generators/Producing Apparatus
- 128. X-Ray Screens

APPENDIX B

TOP PRODUCT AREAS WITH CRITICAL COMPONENTS/MATERIALS/FINISHED PRODUCTS FROM NON-U.S. SUPPLIERS

Figure B-1: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Antibiotics	
Product Area	Number of C/M/Fs
Bacitracin	17
Imipenem	17
Clindamycin	14
Ciprofloxacin	13
Doxycycline	12
Trimethoprim	9
Metronidazole	8
Ampicillin	7
Ceftriaxone	6
Clarithromycin	6

Figure B-2: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Hormones	
Product Area	Number of C/M/Fs
Insulin	18
Ethinyl Estradiol	9
Metformin	8
Somatotropin	7
Estradiol	6
Levonorgestrel	6
Testosterone (Androgen)	6
Norethisterone	5
Pegvisomant	4
Levothyroxine	4

Figure B-3: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Analgesics	
Product Area	Number of C/M/Fs
Paracetamol/Acetaminophen	19
Ibuprofen	15
Acetylsalicylic Acid (Aspirin)	7
Allopurinol	6
Methotrexate	5
Hydrocodone	5
Carbamazepine	4
Oxycodone	4
Codeine	4
Morphine	3

Figure B-4: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Anticonvulsants, Sedatives, Relaxants	
Product Area	Number of C/M/Fs
Valproic Acid (VPA)	12
Alprazolam	10
Phenytoin	7
Lorazepam	6
Phenobarbital	5
Midazolam	5
Ethosuximide	5
Diazepam	5
Temazepam	4
Clorazepate	4

Figure B-5: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Cardiovasculars	
Product Area	Number of C/M/Fs
Hydrochlorothiazide	17
Amlodipine	10
Atenolol	7
Simvastatin	6
Amiodarone	6
Isosorbide Dinitrate	5
Verapamil	5
Digoxin	5
Furosemide	4
Enalapril	3

Figure B-6: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Anesthetics	
Product Area	Number of C/M/Fs
Promethazine	20
Lidocaine	15
Atropine/Atropine Sulfate	9
Ketamine	6
Bupivacaine	3

Figure B-7: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Antivirals	
Product Area	Number of C/M/Fs
Atazanavir	7
Acyclovir	6
Amantadine	6
Indinavir (DIV)	6
Ritonavir	4

Figure B-8: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Vaccines	
Product Area	Number of C/M/Fs
Hepatitis A Vaccine	5
Hepatitis B Vaccine	5
Varicella Vaccine	4
Pneumococcal Vaccine	2
Meningococcal Meningitis Vaccine	2

Figure B-9: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Other Products	
Product Area	Number of C/M/Fs
Heparin	10
Technetium Generators or other equipment for the processing of radioisotopes	9
Granisetron	6
Imipramine	4
Probenecid	3

Figure B-10: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Anti-Inflammatories	
Product Area	Number of C/M/Fs
Dexamthasone	9
Flucinolone Acetonide	8
Indometacin/Indomethacin	4

Figure B-11: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Antileprosy	
Product Area	Number of C/M/Fs
Rifampicin/Rifampin	5
Ofloxacin	3
Capreomycin	3
Amikacin	2
Rifabutin	1

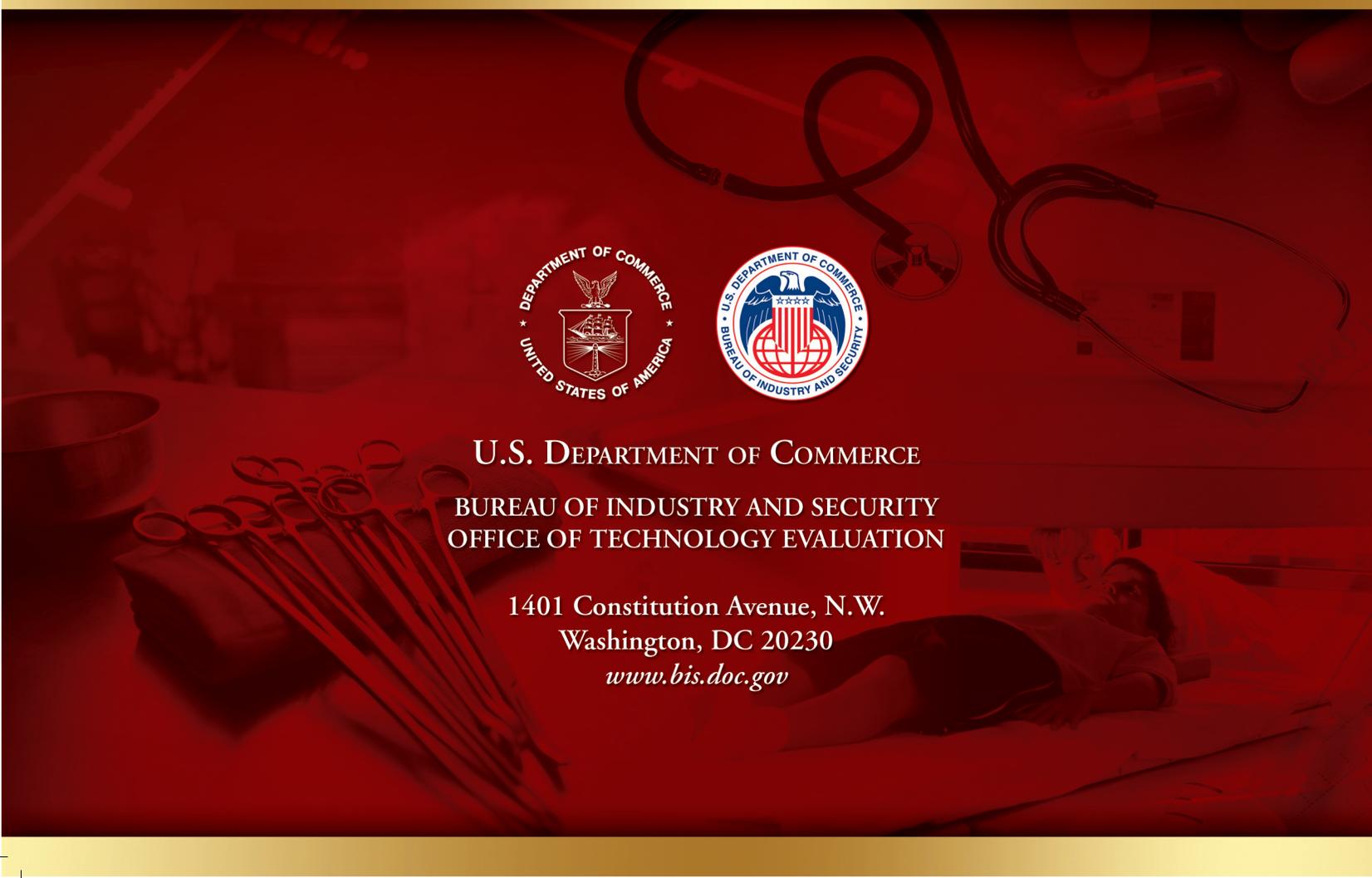
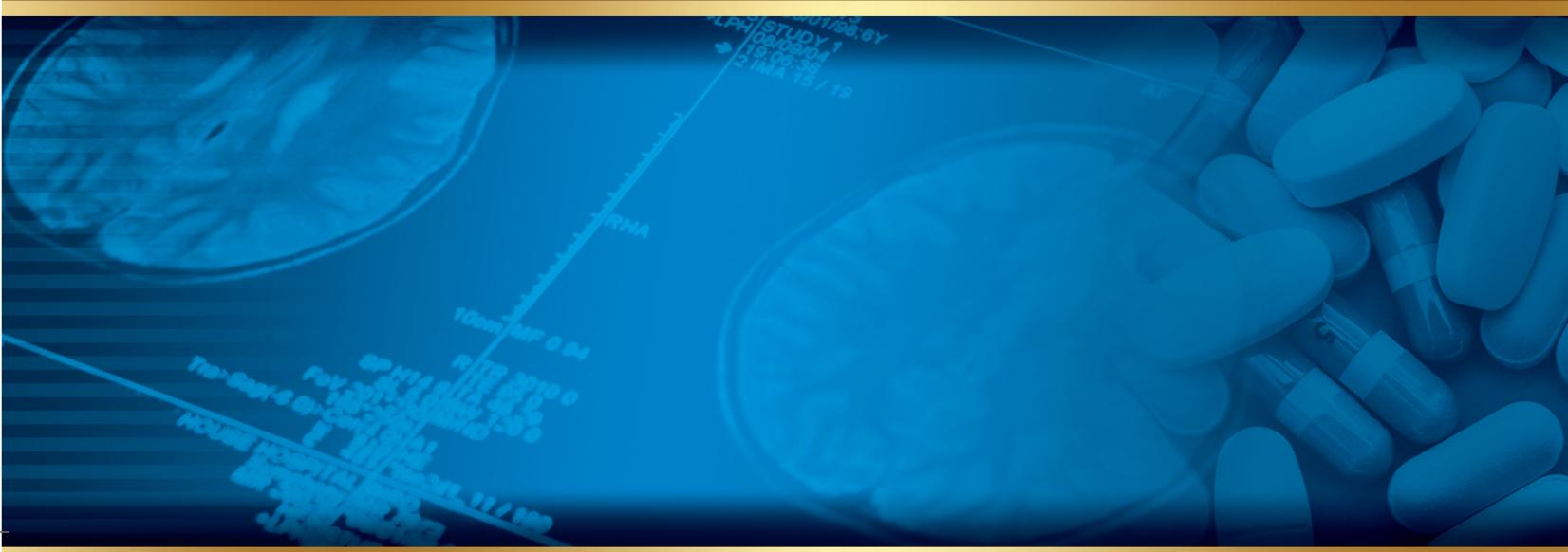
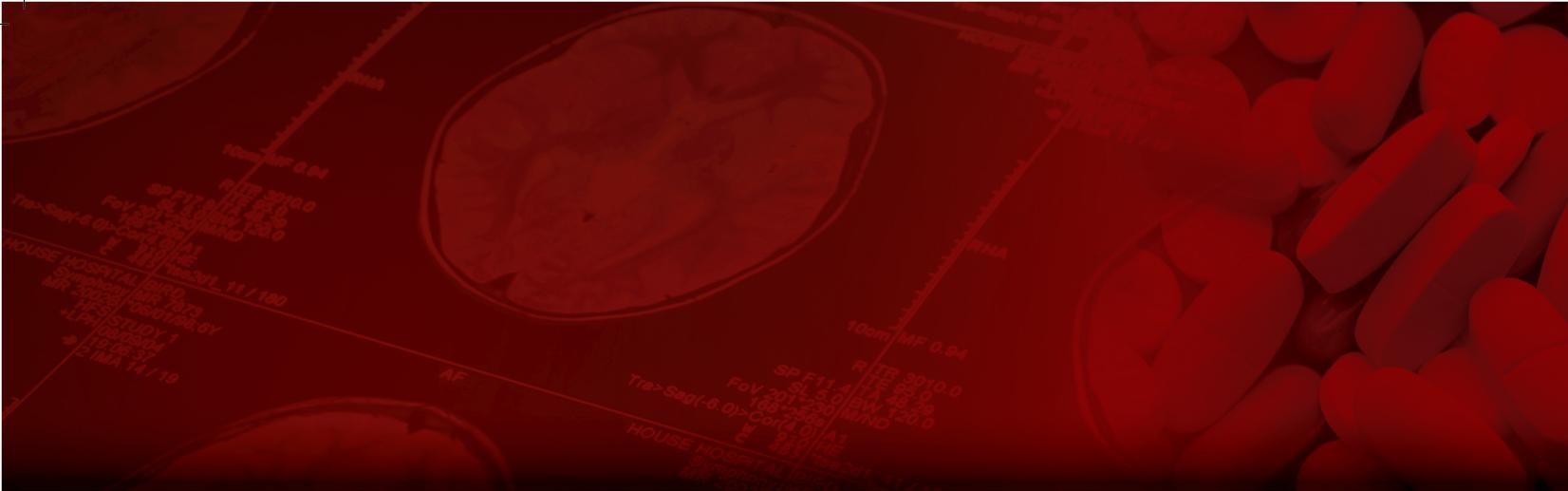
Figure B-12: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Stimulants	
Product Area	Number of C/M/Fs
Pseudoephedrine	6
Ephedrine	3
Epinephrine (Adrenaline)	3
Norepinephrine	1

Figure B-13: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Antiprotozoals	
Product Area	Number of C/M/Fs
Mefloquine	3
Proguanil	1

Figure B-14: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Cancer Treatments	
Product Area	Number of C/M/Fs
Folinic Acid/Leucovorin	1
Vinblastine Sulfate	1
Thiotepa	1

Figure B-15: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Antibacterials	
Product Area	Number of C/M/Fs
Sulphadiazine	2

Figure B-16: Top Product Areas With Critical Components/Materials/Products From Non-U.S. Suppliers	
Medical Devices/Surgical Equipment	
Product Area	Number of C/M/Fs
Infusion/IV Pumps	53
Defibrillators	31
Other Catheters	27
Pacemakers	22
Medical Needles/Syringes/Safety Needles	20
Sterilizers	18
Electronic Nerve Stimulation Machines	17
Oxygen Analyzers	17
Forceps	14
IV Catheters	14



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