

Drug Shortages: A closer look at products, suppliers and volume volatility.

November 2011



Introduction

The drug shortage problem is of increasing concern for patients, clinicians and policymakers. While the issue is not new, experts are reporting record shortages. Stakeholders are seeking a deeper understanding of what's happening and why, as well as potential remedies to ensure access for patients.

Based on analysis of IMS Health data and publicly available drug shortage lists, this report provides new, data-driven insights on the products and suppliers involved, and the volume volatility in the marketplace.

Using comprehensive, proprietary data on the drug supply chain, we were able to examine the problem from an entirely new angle.

This unique, supply-based analysis of drug shortages is intended to assist policymakers in designing appropriate solutions. Our report was developed as a public service, without industry or government sponsorship.

Murray Aitken

Executive Director

IMS Institute for Healthcare Informatics

IMS Institute for Healthcare Informatics

11 Waterview Boulevard
Parsippany, NJ 07054
USA

info@theimsinstitute.org

www.theimsinstitute.org

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APPROACH AND METHODOLOGY

The analysis included in this report is based on a proprietary dataset developed by the IMS Institute for Healthcare Informatics.

Products included in the dataset were derived from the current Drug Shortages sections of the Food and Drug Administration (FDA) and American Society of Health-System Pharmacists (ASHP) websites as of October 7, 2011.

Data selection included all strengths for the product indicated.

Our analysis resulted in a cohort of 168 products.

More detail on the approach and methodology can be found in the Appendix to this report.

Executive summary

The drug shortage problem is of increasing concern for patients, clinicians and policymakers. Stakeholders are seeking a deeper understanding of what's happening and why, as well as potential remedies to ensure access for patients.

Using IMS Health's comprehensive, proprietary data on the drug supply chain, we were able to examine the problem from an entirely new angle.

We have synthesized our research into three sections:

- 1) Characteristics of products on the drug shortages list.
- 2) Suppliers of the drugs on the shortages list.
- 3) Volume and sales of the drugs over time.

The analysis is based on the 168 drugs that were on the drug shortages list maintained by the Food and Drug Administration (FDA) and American Society of Health-System Pharmacists (ASHP) as of October 7, 2011.

INSIGHTS

The research provided the following six new insights:

Insight 1: This drug shortage problem is highly concentrated.

Generic Injectables: The drug shortage problem is almost entirely affecting generic injectable drugs, which means that the impacted patients are mostly acute care patients being treated by providers in hospitals and out-patient facilities. Of the total generic injectable market, half are on the shortages list.

Drug Classes: Two of every three drugs on the shortages list are classified in five disease areas: oncology, anti-infectives, cardiovascular, central nervous system and pain management. Oncology drugs make up the highest share of the shortages list at 16%.

Insight 2: Surprisingly, the supply of drugs on the shortages list has been stable or increased overall in the past five years.

On the whole, over the past five years, the supply of these drugs to healthcare providers – hospitals, clinics, pharmacies – has increased. Spending has also increased. In fact, for over half of the drugs on the shortages list, total supply is relatively stable or has increased over the past five years. However, there has been a dramatic decline in the total supply available for the remaining drugs on the shortages list.

Insight 3: There is significant volatility in the suppliers of the drugs, not the total volume supplied.

Although top-line volume is stable or growing, there is significant market volatility for two-thirds of the drugs, which is centered on the volatility for the suppliers of the drugs. Put another way, although the total supply has increased or been stable, the actual suppliers have not. The volume of individual suppliers has changed rapidly with market leadership switching from one supplier to another one month, and then potentially to another supplier, or back to the initial market leader a few months later.

Insight 4: The recent volatility is a new trend.

For all the listed drugs, the market is showing higher volatility in the past 12 months, compared to the previous four years. The unusually sharp swing in supply for many of the drugs on the shortages list is unprecedented compared to the experience of the previous four years.

Insight 5: The number of suppliers has fluctuated and may be one reason for the volatility.

Overall, a large number of firms supply these products. However, there have been changes to the number of companies in the past several years. Most of the drugs are

supplied by only one or two companies – over 50% of the drugs have two or fewer suppliers. If one of the suppliers is disrupted, the demand on the other suppliers skyrockets.

Insight 6: Some states are feeling the drug shortage more acutely than others.

Every state is impacted by the drug shortage problem. However, the problem varies significantly from state to state. Looking at the one-third segment of drugs that has seen significant drops, 13 states have experienced an acute decline in monthly per capita usage of more than 30%. These states are Hawaii, Arizona, Arkansas, Ohio, Massachusetts, Delaware, West Virginia, Florida, Maryland, Nevada, New Jersey, Kentucky and South Carolina.

RECOMMENDATIONS

To help the FDA, pharmacists and other stakeholders monitor drug shortages and identify new or worsening shortages the IMS Institute for Healthcare Informatics recommends that the FDA, or the industry, create an Early Warning System for drug shortages. This system should include Risk Identification, Demand Forecasting, a Volatility Index and Predictive Modeling.

CONCLUSION

The results of the study indicate the problem of drug shortages is much more complex, yet narrower, than expected. The underlying causes of the problem remain little understood and require more systematic research across the total supply chain. More rigorous monitoring and sophisticated demand forecasting may help prevent future shortages. When considering solutions, it is recommended that policymakers should focus on the market and supply chain that is most disrupted.

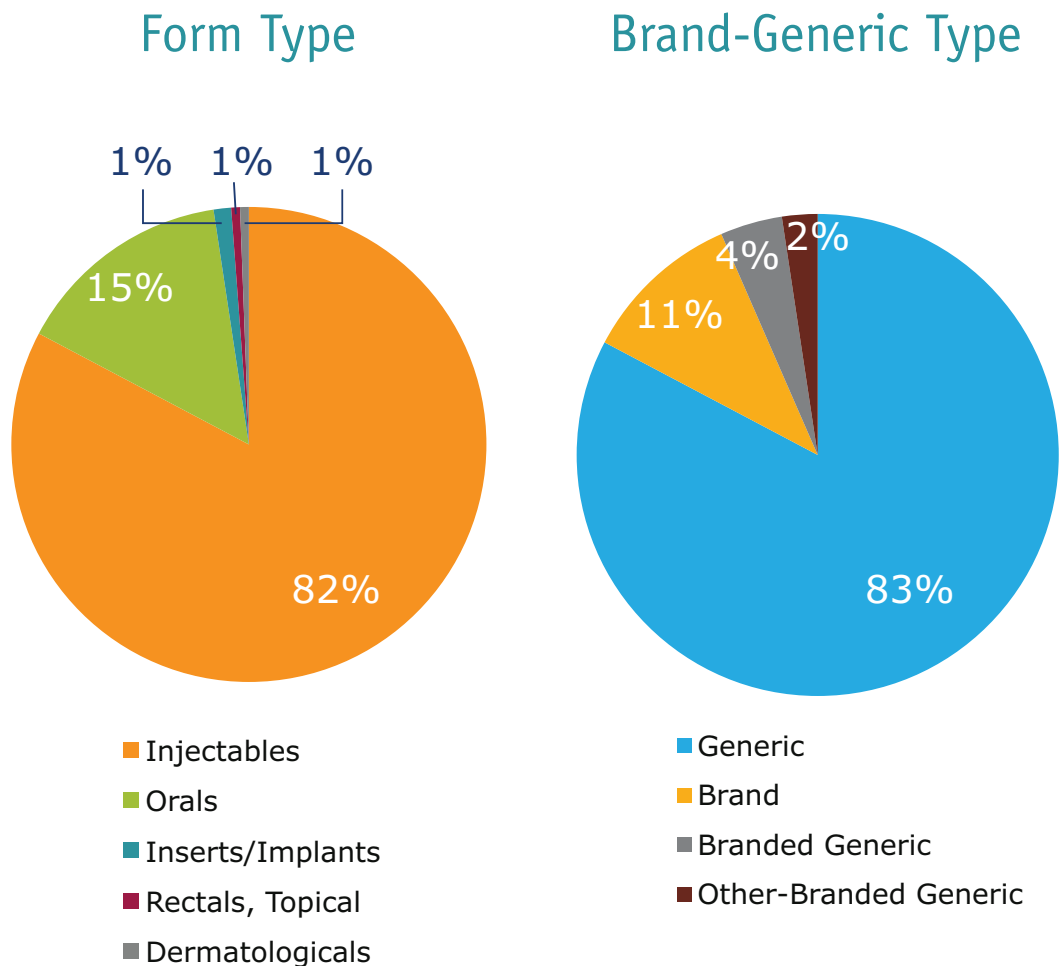
Section 1: Characterization of products on drug shortages list



HIGHLIGHTS

- Drug products on the shortages list are highly concentrated:
 - 63% are in five disease areas: oncology, anti-infectives, cardiovascular, central nervous system and pain management.
 - Over 80% are generic injectables.
 - Only 6.5% are controlled substances.
- Cancer drugs account for 28 of the 168 products, affecting nearly 550,000 patients annually.
- The shortage problem affects drug products of all ages.
 - Half came to the market before 1990.
 - 25% were introduced to the market since 2000.

Most products are injectables and multi-sourced generics



- A total of 168 products is included in the IMS database of current drug shortages based on the FDA and ASHP websites as of October 7, 2011.
- Of these 168 products, 82%, or 139 products, are sterile injectables; 15% are oral medicines; and 1% each are inserts, rectals and dermatologicals.
- In terms of the type of product, 83% or 139 products are multi-sourced generics without patent protection or other forms of market exclusivity. A further 18 products, or 11% of the total, are branded products with patent protection or another form of market exclusivity, and 4% are branded generics.
- 11 of the 168 products are classified as controlled substances under the Controlled Substances Act.

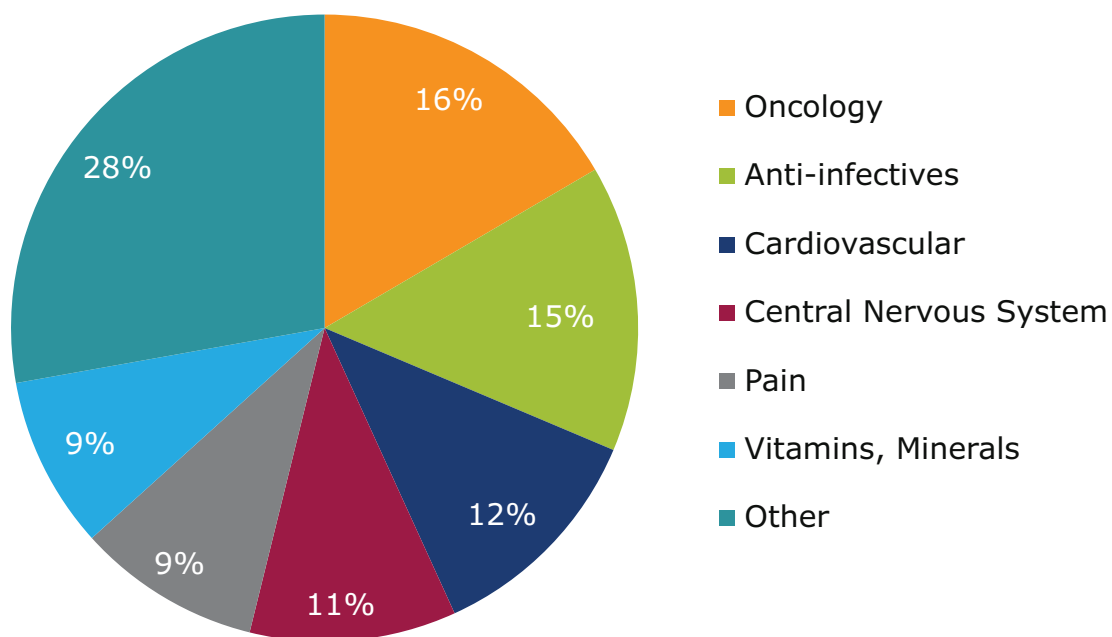
Chart notes

Based on IMS database of current drug shortages derived from FDA and ASHP websites as of October 7, 2011. Other-brand generic includes over-the-counter medicines.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

All of the major therapy areas have products on the list

Therapy Area
Percent of Products



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

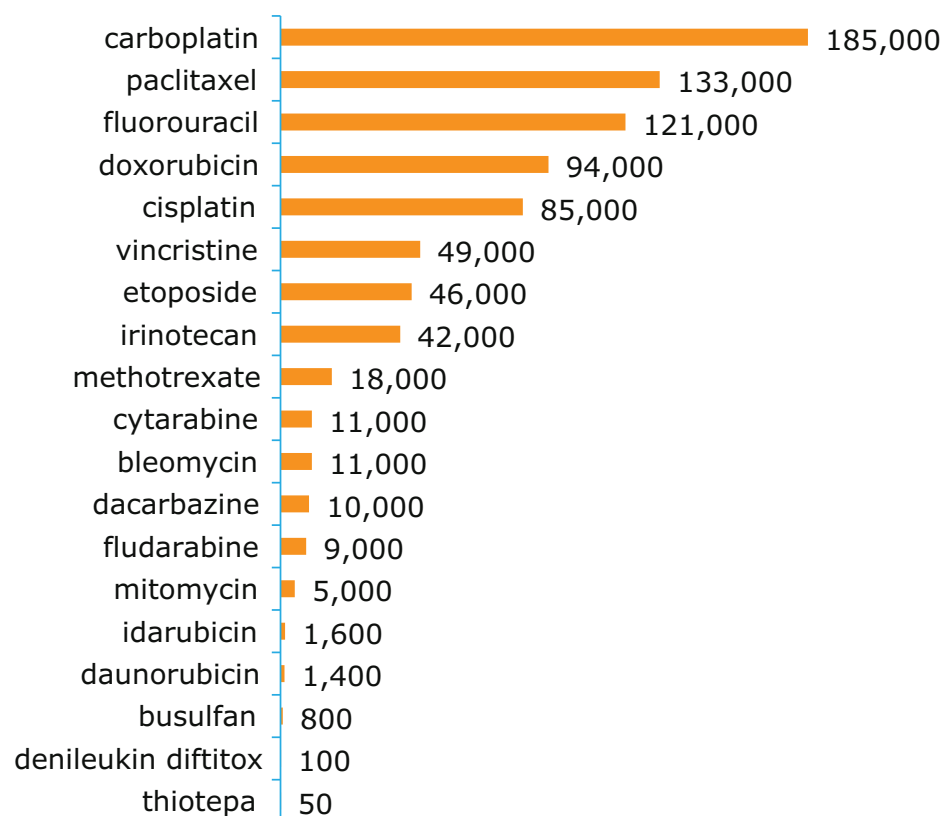
- Based on the Anatomical Therapeutic Chemical (ATC) Classification System, products included in the drug shortages list cover all of the major therapy areas.
- Five therapy areas account for 63% of the total number of products on the shortages list:
 - Oncology is the largest with 16% of products.
 - Anti-infectives are the second largest group with 15% of products.
 - ‘Other’ includes: Digestive system, Anticlotting agents, Anti-ulcerants, Allergy, Cough, Cold, Flu, Autoimmune Diseases, Hormones, Asthma/COPD, Dermatology, Reproductive and Sexual Health, and Immunosuppressants.

Chart notes

Classification of products based on customized grouping of ATC classes. See Methodology, approach and sources section for details.

550,000 cancer patients are treated with at least one molecule

Patients Treated by Oncology Product Moving Annual Total



Source: IMS Oncology Analyzer, Jun 2011

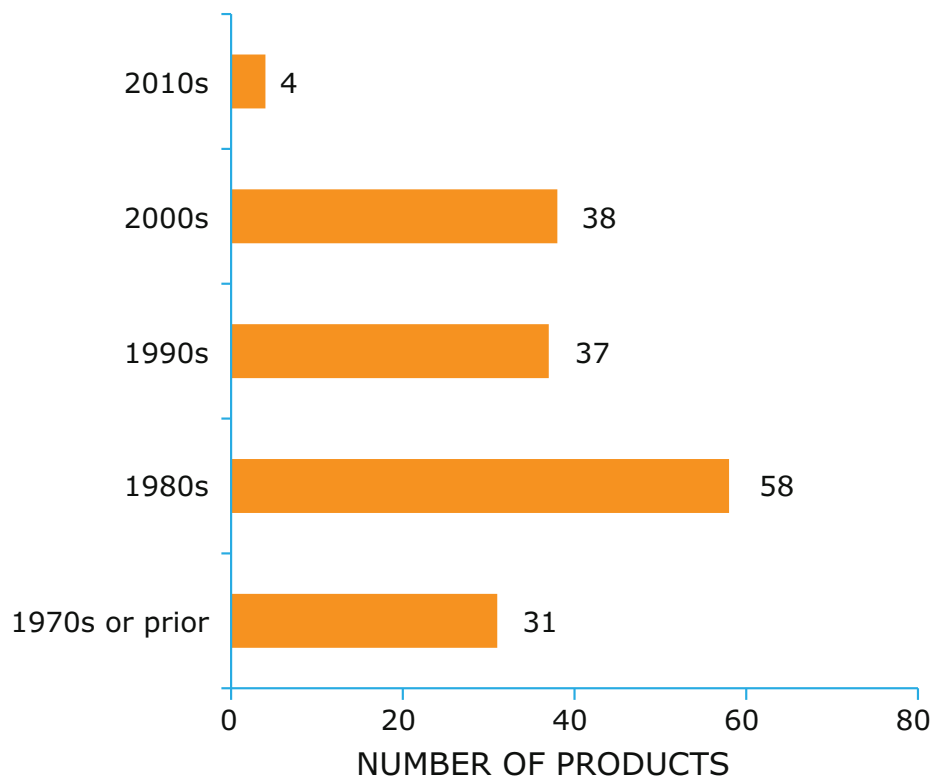
- Of the 168 products on the drug shortages list, 22 products are used in chemotherapy treatment of cancer, of which 20 are injectable.
- For these injectable oncology products, an estimated 550,000 patients received treatments during the year ending June 30, 2011, and 100,000 or more patients received carboplatin, paclitaxel or fluorouracil.

Chart notes

Patient counts are national estimates of total annual patients receiving treatment of the drug. Patients can receive one or more of the drugs listed. Patient estimates rounded to nearest thousand. Note that Doxil is included with doxorubicin for this analysis.

Listed products were introduced over several decades

Decade of Product Introduction



Source: IMS National Sales Perspectives, Sep 2006 - Aug 2011

- The mix of products on the current shortages list includes more than 30 that were introduced during each of the past two decades, the 1990s and the 2000s.
- Another 58 products were introduced in the 1980s and 31 had initial launches in 1979 or earlier.
- This analysis suggests the issue of drug shortages is affecting products of all ages.

Chart notes

Products are classified based on date of first introduction of the product form included in the shortages list.

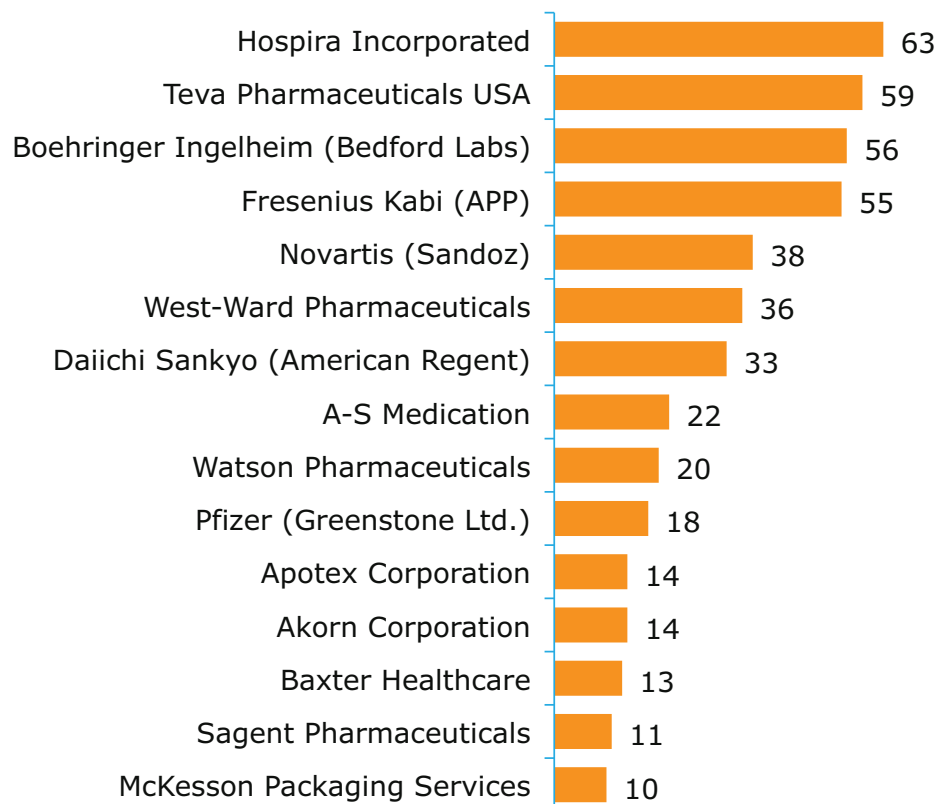
Section 2: Suppliers of products on drug shortages list



- Overall, a large number of firms supply these products, but most of the drugs are supplied by only one or two companies:
 - Over 100 suppliers involved.
 - 50 products have only one supplier.
 - Two-thirds of the drugs have three or fewer suppliers.
 - Generic drugs not on shortages list are far more likely to have multiple suppliers.
- The number of companies supplying these products has fluctuated over the last five years with an increasing number of companies no longer supplying the products on the shortages list.
- Suppliers cite production-related issues and increased demand as the top reasons for shortages, not raw material or quality issues.

Top corporations supply many different products

Number of Molecules by Corporation



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

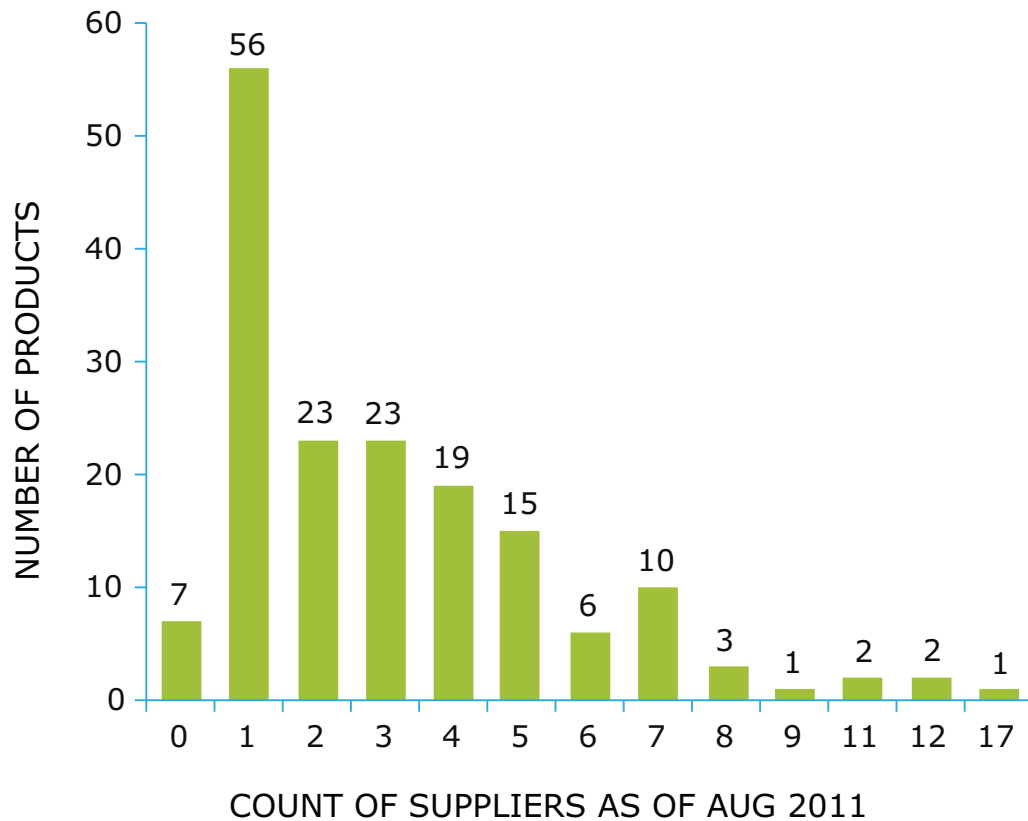
- The 168 products on the shortages list have been supplied by 98 separate companies controlled by 88 corporations during the three months ending August 2011.
- Nine of the companies, or their affiliates, have supplied 20 or more products, including Hospira, Teva, Boehringer Ingelheim and Fresenius Kabi, which supplied more than 50 products each.
- The same set of 168 products were supplied by 87 companies controlled by 77 corporations in September 2006.
- Over the past five years, the number of corporations supplying these products has fluctuated with players both entering and leaving the marketplace. In the past two years, 13 corporations have stopped supplying products on the shortages list.

Chart notes

Corporations listed include subsidiaries noted in brackets. Count includes number of products supplied by these corporations including their affiliates during the three months ending August 2011 and regardless of the volume supplied. Chart shows all corporations supplying more than 10 products.

50 products have one supplier, two-thirds have three or fewer

Number of Products by Supplier Count



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

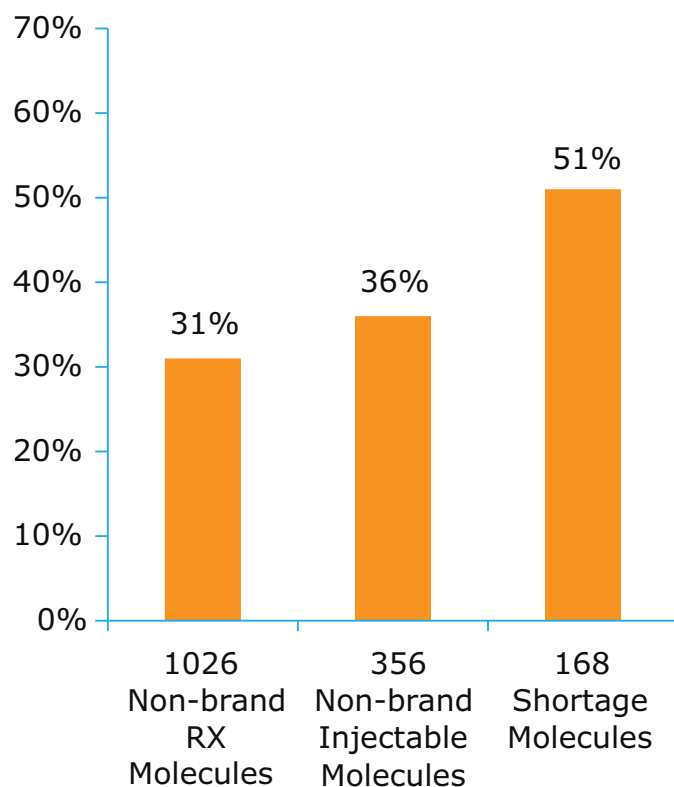
- Of the 168 products on the current shortages list, seven currently have no suppliers, while 56 products have one supplier and another 23 have two suppliers.
- In total, 51% of the products with shortages have two or fewer suppliers and two-thirds have three or fewer suppliers.

Chart notes

Analysis based on number of suppliers for each of the products recorded at any time during the three months ending August 2011.

Shortage products are more likely to have limited suppliers

Molecules with Limited Suppliers



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

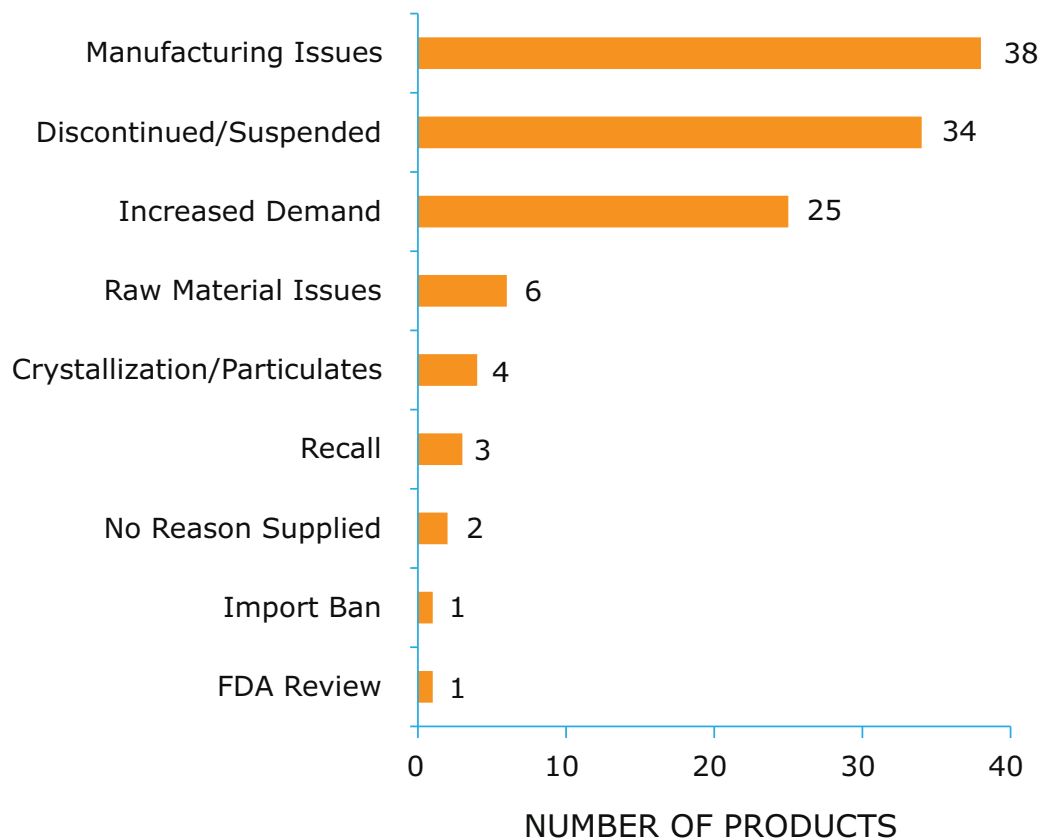
- In the overall generic pharmaceuticals market, 31% of the 1,026 molecules have two or fewer suppliers.
- By comparison, 36% of the generic injectable molecules have two or fewer suppliers.
- This increases to 51% for the 168 molecules on the current shortages list.

Chart notes

Analysis based on number of suppliers for each of the products recorded at any time during the three months ending August 2011.

Manufacturing and product supply issues are top reasons cited

Reasons for Shortage of Declining Products



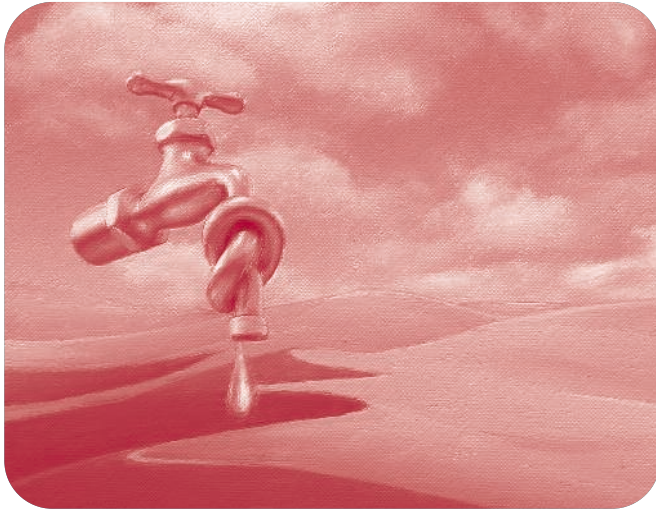
Source: American Society of Health-System Pharmacists website

- A range of reasons has been noted on the ASHP website as the cause of drug shortages. Manufacturing issues and the discontinuation or suspension of production are the most commonly cited reasons, followed by increased demand.
- Issues related to specific quality concerns such as crystallization or particulates in injectable products, or which have resulted in product recalls, were cited 7 times.
- While volume restrictions related to products licensed under the Controlled Substances Act have been mentioned in the press, only 11 of the 168 products on the current drug shortages list are designated as controlled substances.

Chart notes

Analysis based on reasons cited on the ASHP website for 75 products with declining volume in the three months ending August 2011 compared to the base period of 2006 to 2009. Multiple reasons were provided for some products.

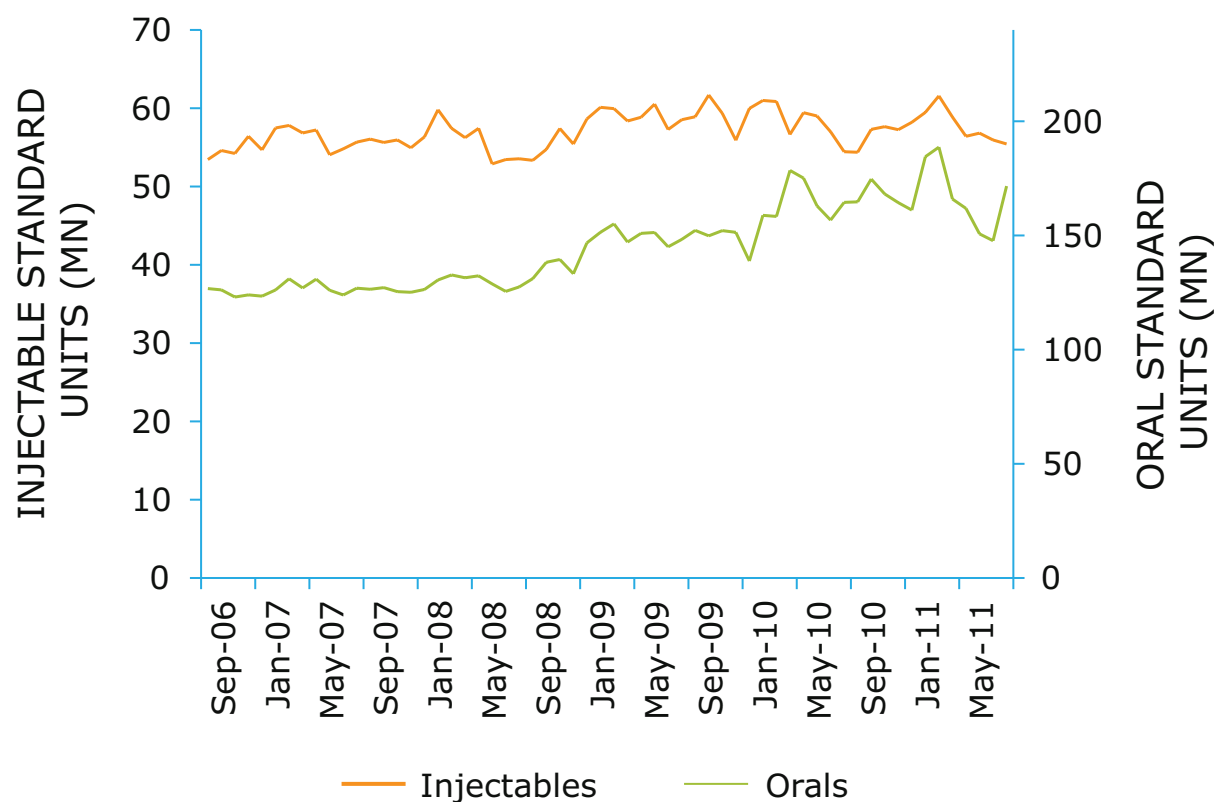
Section 3: Volume and sales of products on drug shortages list



- On the whole, over the past five years:
 - The supply of these drugs to healthcare providers – hospitals, clinics, pharmacies – has increased.
 - Spending for these products has also increased.
 - Three distinct segments have emerged in recent months compared to the base line period of 2006-09.
- However, the market is now showing high volatility, with unusually sharp swings in supply for many of the drugs on the shortages list.
- Among the 168 drugs, three distinct supply patterns have emerged in recent months compared to 2006-09:
 - Declining: 75 drugs declined over 20% in supply.
 - Stable: 56 drugs are within 80% to 120% of historical supply levels.
 - Growing: 31 drugs have seen volume increases of over 20%.
- States vary significantly in utilization, with 13 states experiencing significant drops in supply.

In aggregate, injectable volume has grown 4% over the past five years

Monthly Volume of Oral and Injectable Products
Standard Units



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

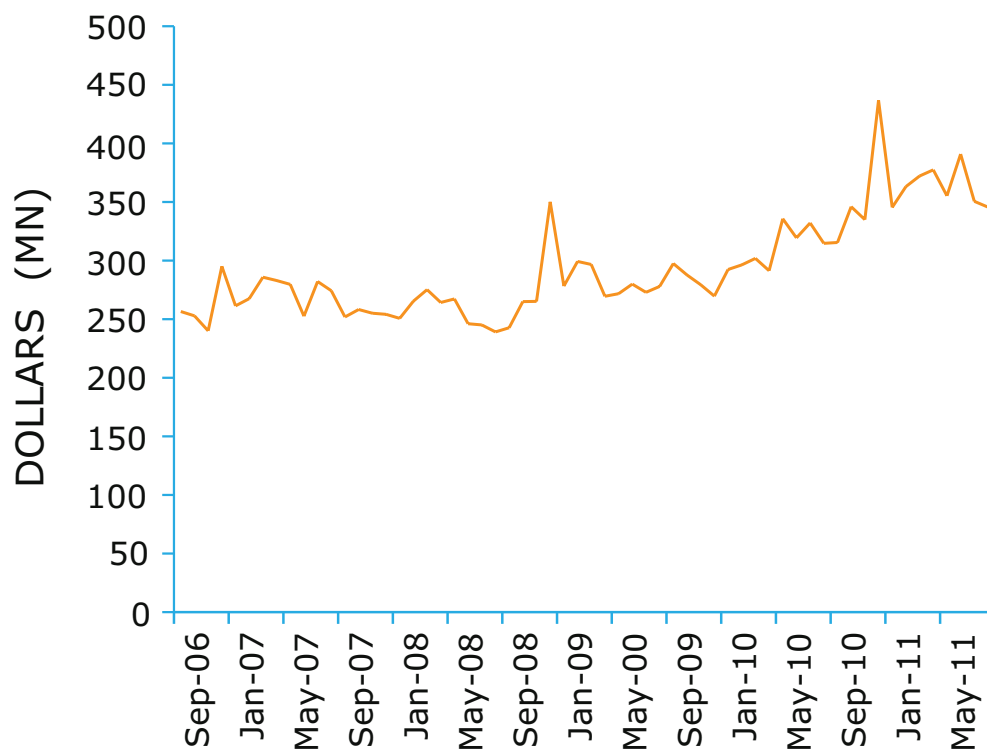
- Total volume supplied for the 168 products on the drug shortages list has increased over the past five years:
 - For injectables, the average number of Standard Units supplied has increased from 54 million to 56 million for the period ending August 2011.
 - The average number of oral Standard Units has increased from 125 million to 157 million during the same reference period.

Chart notes

Volume measured in Standard Units. Note that Standard Unit measures for injectables and orals are not directly comparable.

Dollar sales have trended upward over the past five years

Monthly Sales Value of Shortage Products (\$MN)



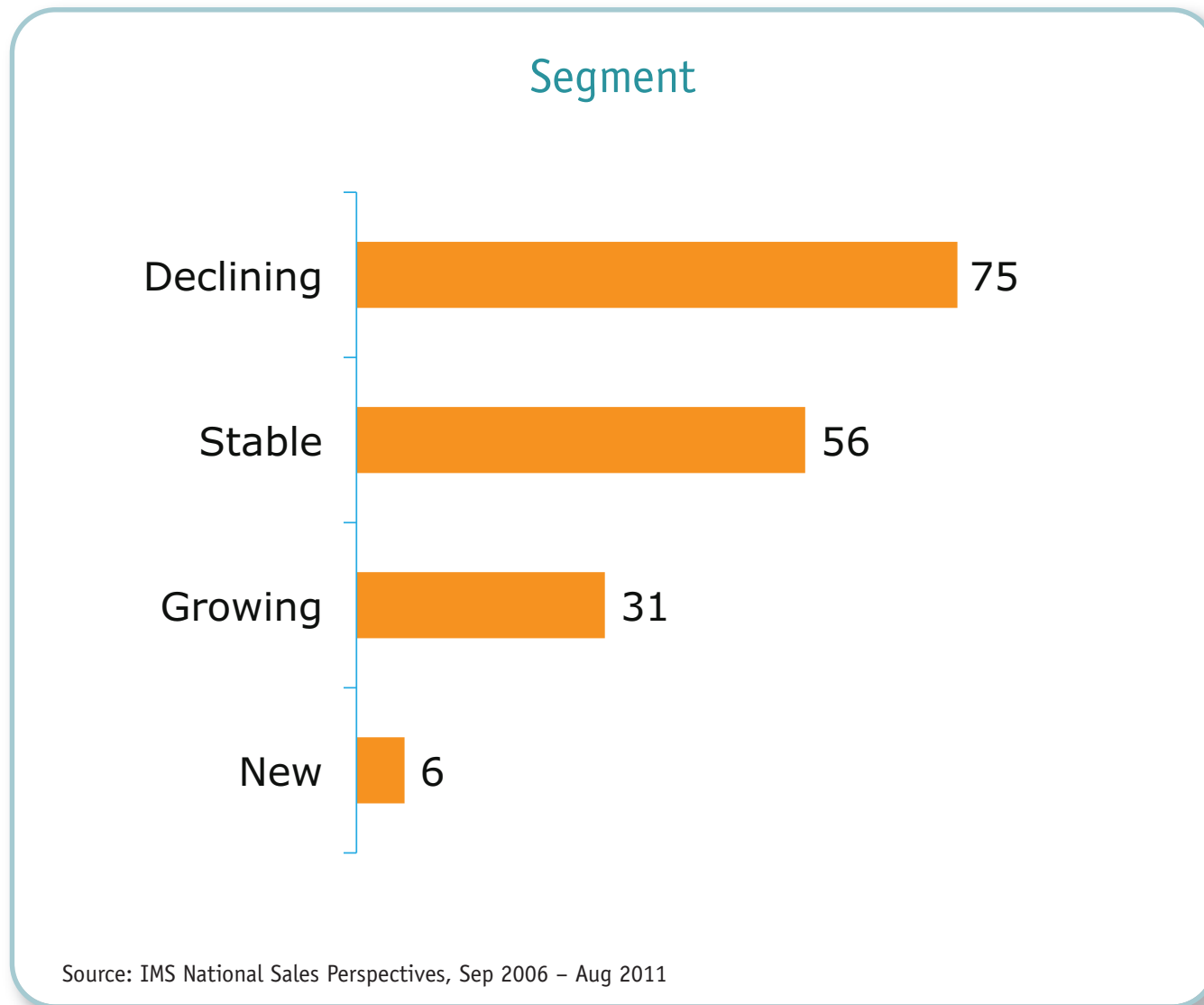
Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

- The monthly sales value of the 168 products on the shortages list has increased from about \$250 million per month in 2006 to about \$350 million per month in 2011.
- In total, the annual sales of these products was \$3.2Bn for the 12 months ending August 2007 and \$4.3Bn for the 12 months ending August 2011.

Chart notes

Sales values are derived from IMS National Sales Perspectives and reflect sales at the invoice level. Sales amounts do not reflect off-invoice discounts and rebates.

All products can be segmented by supply volume trends



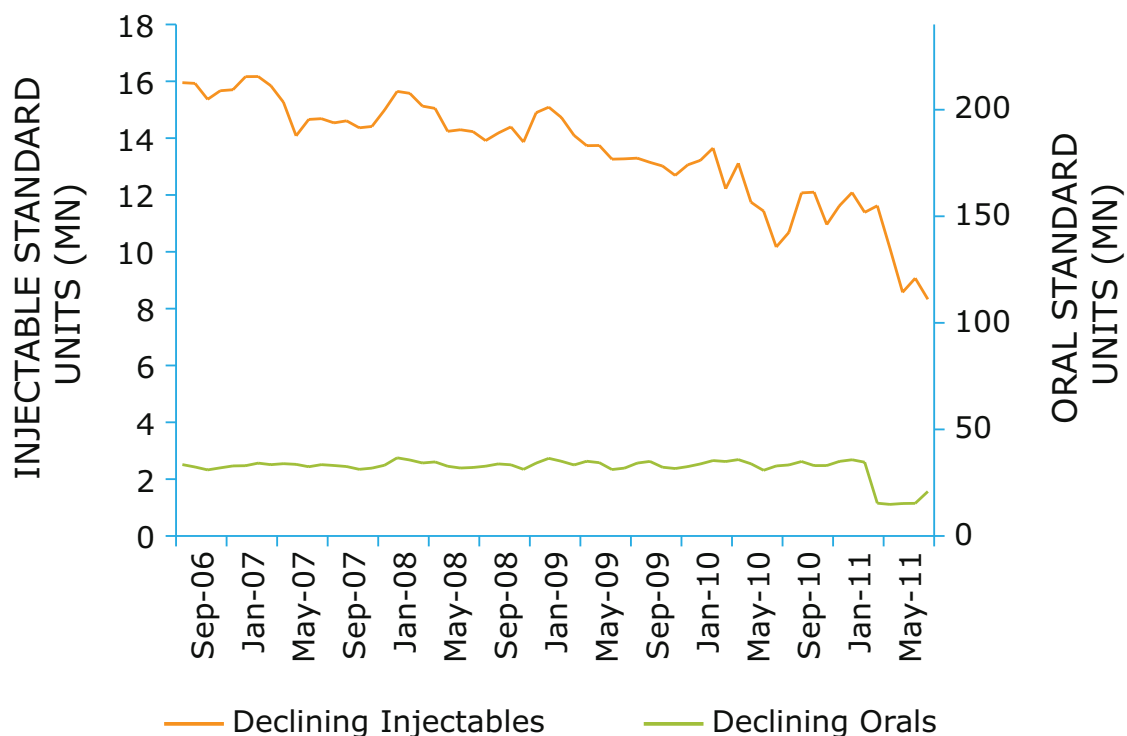
- While 168 products are on the current drug shortages list, the amount of volume change in the supply of these products over the past five years differs significantly across products. When average monthly volume supplied during the three months ending August 2011 is compared to the average monthly volume during a base period defined as September 2006–09, the following trends were observed:
 - 75 products had recent monthly supply volume of less than 80% of the base period and are classified here as “declining.”
 - 56 products had monthly supply volume between 80% and 120% of the base period and are classified as “stable.”
 - 31 products had recent monthly supply of at least 20% more than the base period and are classified as “growing.”

Chart notes

Based on analysis of monthly volume levels since September 2006 for each molecule.

In the declining segment, volume has fallen substantially

Monthly Volume of Oral and Injectable Products Standard Units



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

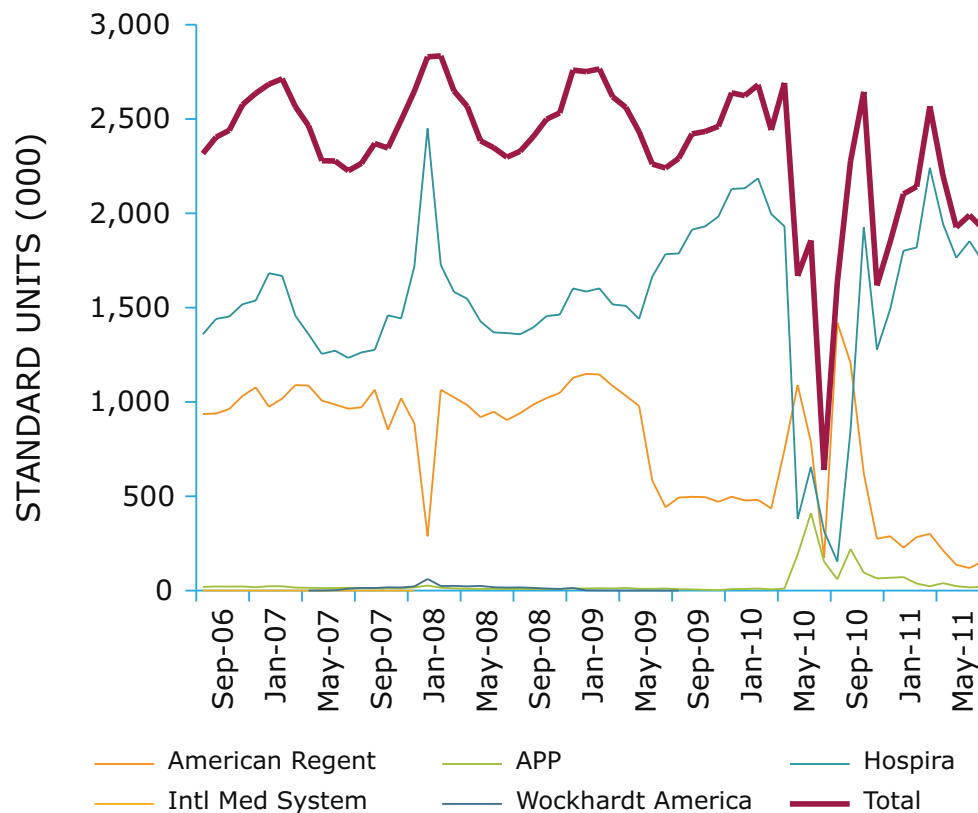
- For those 75 products with declining volume, monthly supply has fallen about 47% over the five-year period.
- For injectables, the average number of Standard Units supplied has decreased from 16 million to 8 million for the period ending August 2011.
- The average number of oral Standard Units has decreased from 34 million to 21 million during the same reference period, due mainly to a single product.
- The sales value of these 75 products was \$727Mn for the 12 months ending August 2011, compared to \$1.1Bn for the period ending August 2007.

Chart notes

Volume measured in Standard Units. Note that Standard Units measures for injectables and orals are not directly comparable.

Example: furosemide injectable has declined more than 20%

Monthly Volume of Furosemide Injectable Standard Units



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

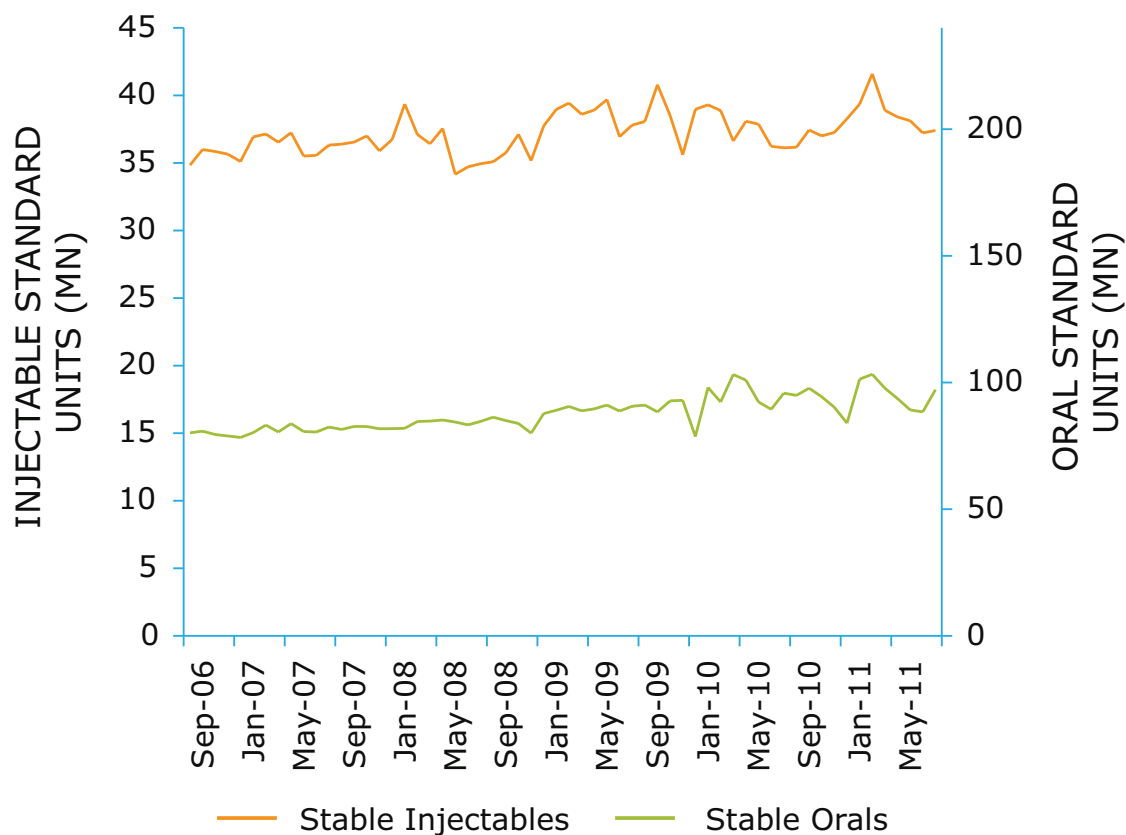
- In the case of injectable furosemide, used in the treatment of congestive heart failure and edema, volume averaged about 2.5 million Standard Units per month between September 2006 and May 2010. Since then, monthly total volume supplied has been volatile, and in the three months ending August 2011 average volume was 22% lower than the baseline period of September 2006–August 2009.
- The five suppliers of furosemide tracked by the IMS National Sales Perspectives database have been even more volatile in their monthly supply, which ASHP attributes to a combination of temporary suspension of manufacturing, discontinuation of production and increased demand.

Chart notes

Volume analysis expressed in Standard Units and derived from IMS National Sales Perspectives. Comments regarding actions of individual suppliers sourced from ASHP website.

Stable products total volume is up about 10% in past five years

Monthly Volume of Oral and Injectable Products Standard Units



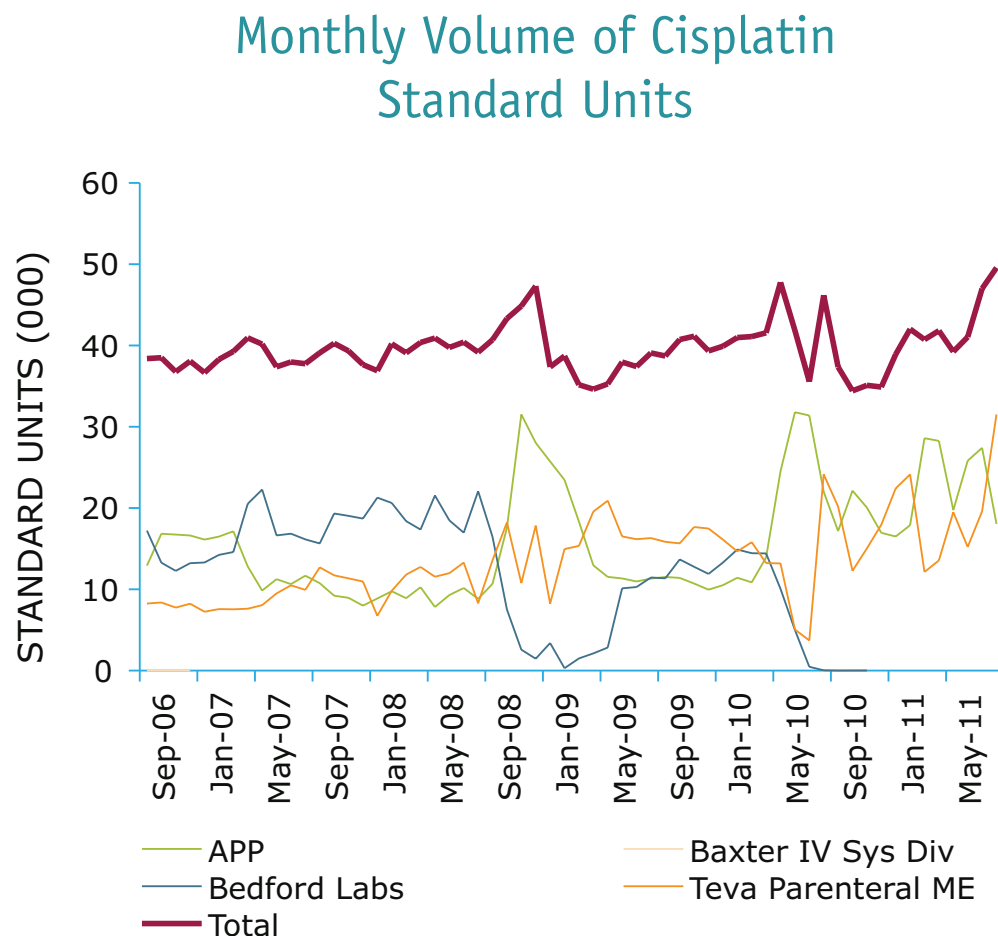
Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

- The 56 products included in the “stable” segment have, in aggregate, gradually increased monthly supply over the past five years by about 10%.
- Fluctuations in monthly supply volume of 10% to 15% are routinely observed for both the injectable and oral products.

Chart notes

Volume measured in Standard Units. Note that Standard Units measures for injectables and orals are not directly comparable.

Example: cisplatin has not declined, but volumes have varied



- In the case of cisplatin, a widely used platinum-based alkylating agent used in a variety of cancer treatments, the overall volume supplied monthly has shown some volatility but in total shows a growing trend over the past five months.
- However, a significant level of volatility in supply at the individual company level is evident, including the discontinuation of production in mid-2010 by one company that had been the leading supplier of cisplatin in the 2007-08 period.

Chart notes

Volume analysis expressed in Standard Units and derived from IMS National Sales Perspectives. Comments regarding actions of individual suppliers sourced from ASHP website.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Growth products volume increase has been strong overall

Monthly Volume of Oral and Injectable Products Standard Units



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

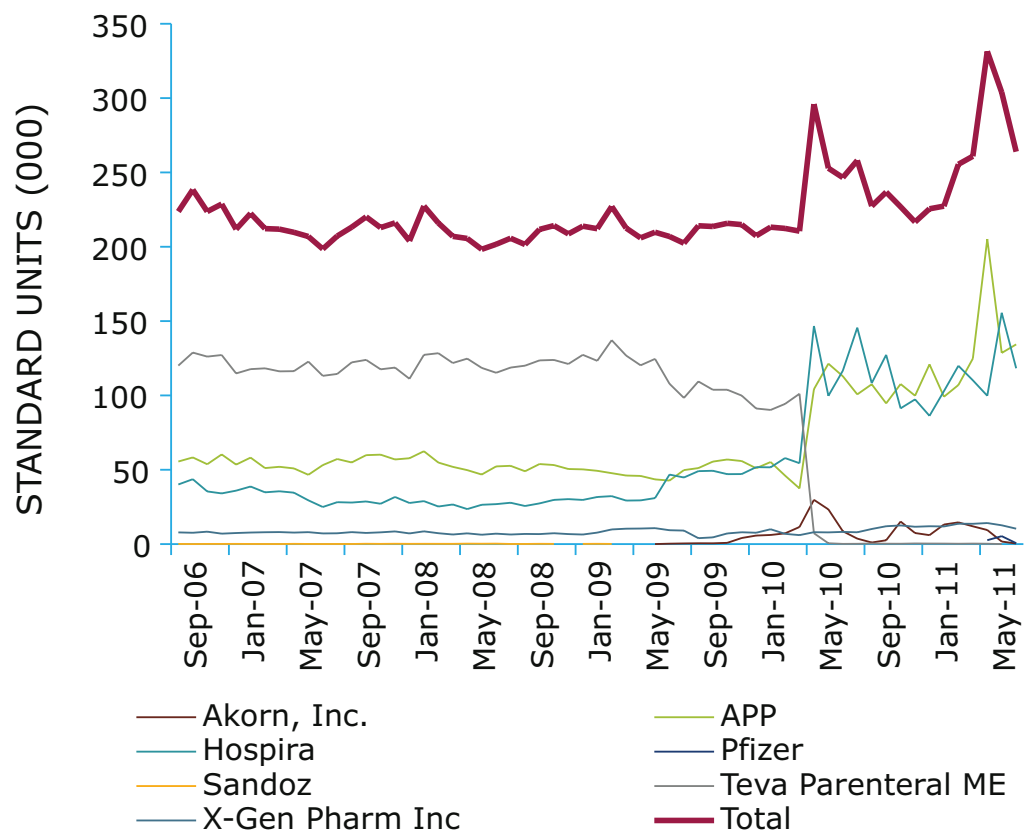
- The 31 products included in the “growth” segment have, in aggregate, increased monthly supply substantially over the past five years.
- Supply volume of the 26 injectables in this segment has increased more than three-fold since 2006.
- Monthly supply of the four orals has risen even more rapidly but is heavily influenced by calcium acetate products.

Chart notes

Volume measured in Standard Units. Note that Standard Units measures for injectables and orals are not directly comparable.

Example: tobramycin has grown in volume during 2011

Monthly Volume of Tobramycin Standard Units



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

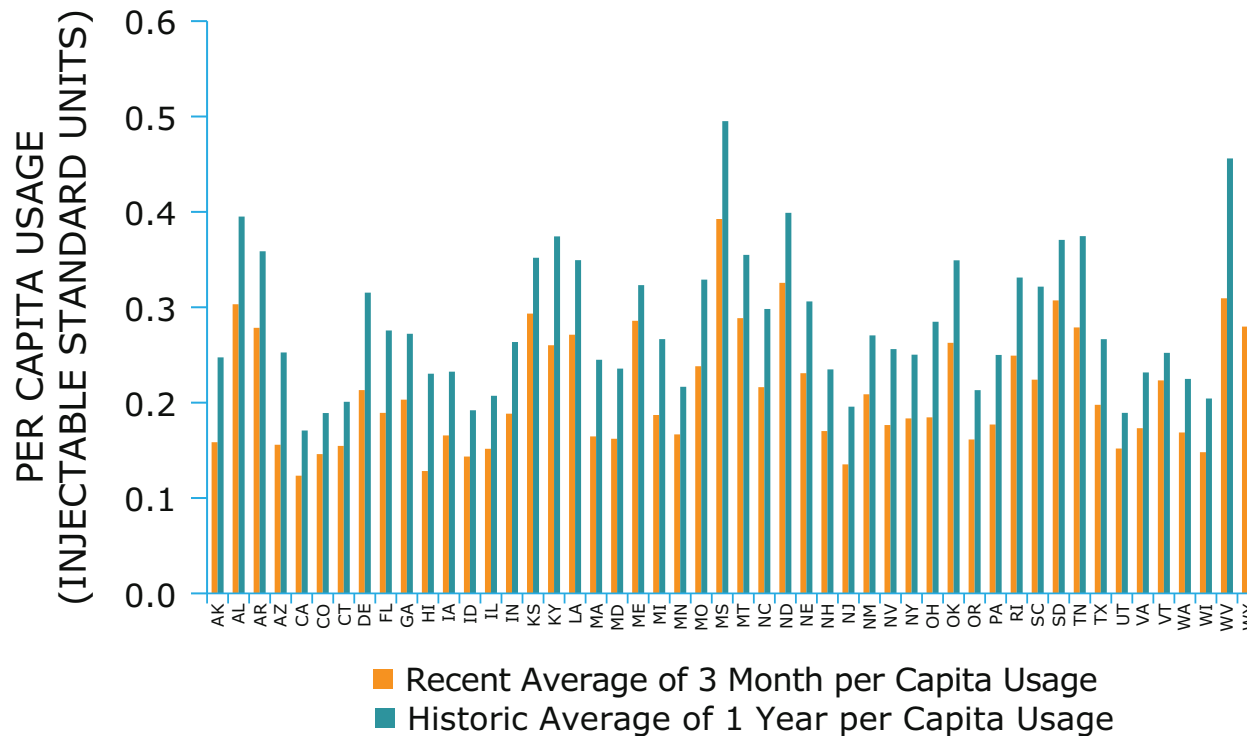
- Tobramycin is an antibiotic used to treat bacterial infections, including gram-positive infections, and is included on the ASHP current drug shortages list.
- The total monthly volume supplied through May 2010 was stable, ranging between 200,000 and 225,000 Standard Units. Since that time, volume has overall increased as it has become more volatile, and volume supplied in the three months ending August 2011 was 22% higher than the average of the three years ending August 2008.
- Of the three major suppliers in the period 2006-10, one stopped supplying in mid-2010 but the remaining two have increased their production and supply of this product.

Chart notes

Volume analysis expressed in Standard Units and derived from IMS National Sales Perspectives. Comments regarding actions of individual suppliers sourced from ASHP website.

Per capita usage of products by state varies significantly

Per Capita Volume by State for 64 Declining Injectable Products



- Of the 139 injectable products on the drug shortages list, 64 are classified as having declined in Standard Unit per capita usage by more than 20% during the three months ending August 2011 compared to the three-year base period ending August 2009. For these 64 injectable products, per capita use varies widely between states and has declined in all states in recent months.
- Average per capita usage in the 12 months ending August 2010 was highest in Mississippi, Wyoming, Alabama, North Dakota and Tennessee; and lowest in California, Utah, Colorado, Idaho and New Jersey.
- Differences in per capita usage can be due to population characteristics, concentration of high-volume treatment facilities, and regional differences in treatment patterns.

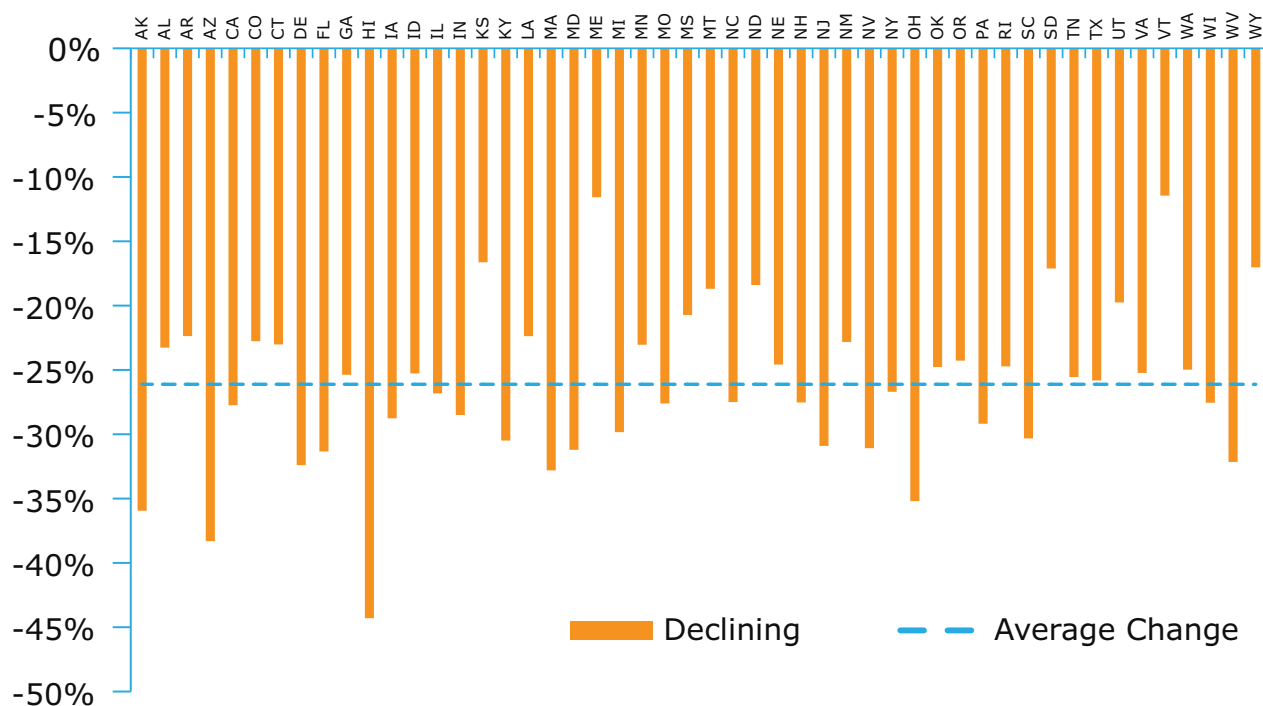
Chart notes

Analysis is based on dividing Standard Units for the 64 declining injectable products by total state population. State-level volume derived from IMS DDD. State population derived from US Census Bureau. See Appendix for details.

Source: IMS DDD, Sep 2009 - Aug 2011; US Census Bureau

The per capita change also varies significantly nationally

Change in Per Capita Usage by State for 64 Declining Injectable Products



- The average decline in monthly per capita usage between the 12 months ending August 2010 and the three months ending August 2011 for the 64 injectable products included in this analysis was 26%.
- Thirteen states, led by Hawaii, Arizona, Arkansas and Ohio, had declines in excess of 30% between the two time periods. Maine and Vermont had the smallest decline in per capita usage though this still exceeded 10%.

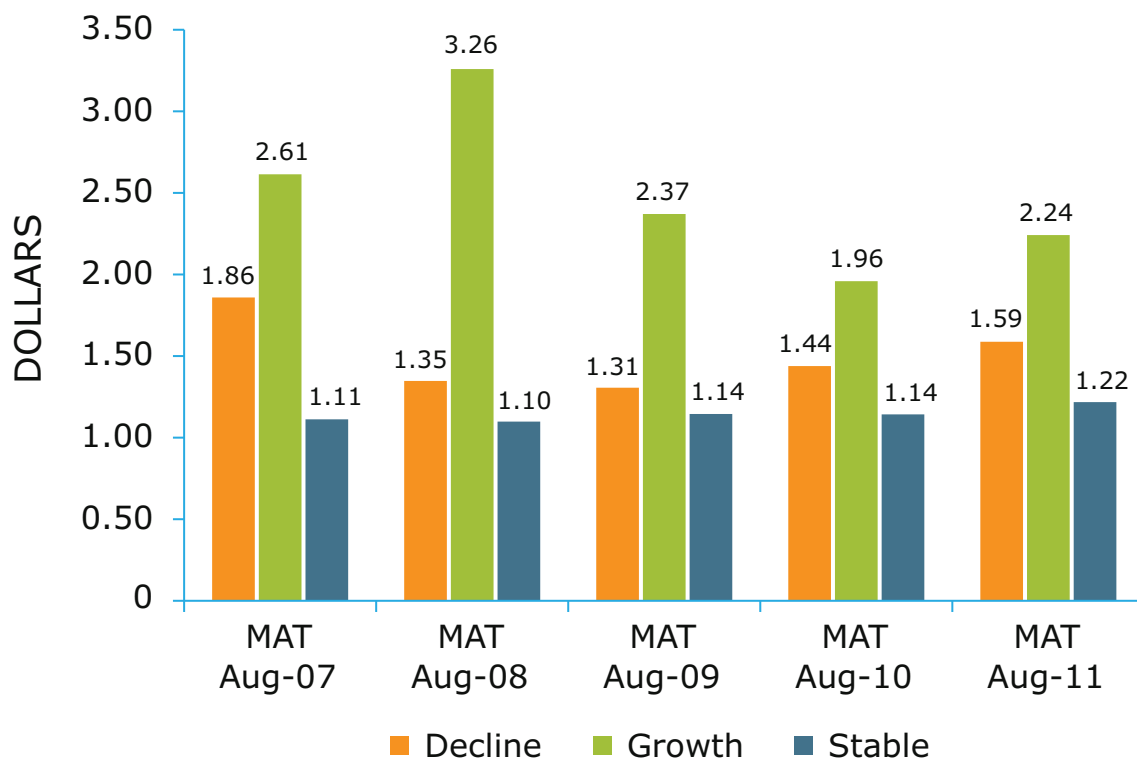
Chart notes

Analysis is based on dividing Standard Units for the 64 declining injectable products by total state population. State-level volume derived from IMS DDD. State population derived from US Census Bureau. See Appendix for details.

Source: IMS DDD, Sep 2011 - Aug 2011; US Census Bureau

Average price per Standard Unit is not consistent

Average Price per Standard Unit by Segment



- The average annual price per Standard Unit for products included in the drug shortages list varies significantly across the segments but does not appear to be changing in a consistent way.
- A small number of products with substantial change in pricing can distort these averages.
- Net prices, including rebates and discounts, are not publicly available and are not reflected in these analyses, which are based on invoice prices.

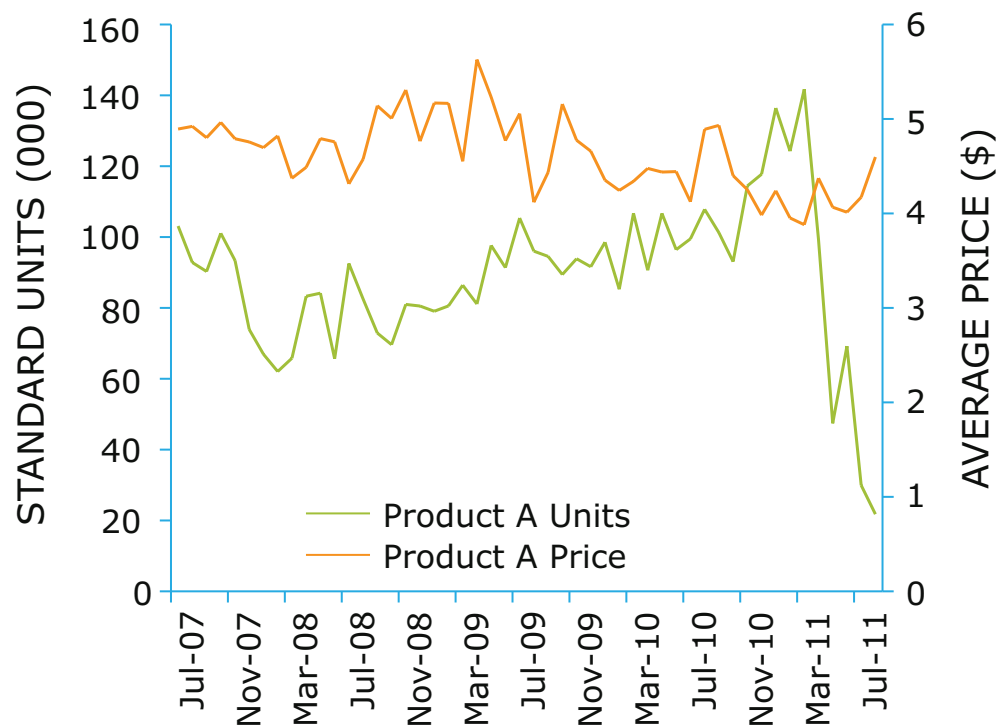
Chart notes

Sales values are derived from IMS National Sales Perspectives and reflect sales at the invoice level. Sales amounts do not reflect off-invoice discounts and rebates. MAT = Moving Annual Total.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Example: Product A pricing remains steady as volumes decline

Monthly Product A Injectable
Volume and Price Change



- For individual products, pricing levels generally trend down or reflect modest levels of price increase.
- In this example of a product with a substantial decline in volume during 2011, prices have not changed significantly since the supply disruption.
- Pricing flexibility by suppliers may be constrained by long-term purchase contracts, although in many cases companies have multiple contracts staggered throughout the year, which provides some ability to adjust pricing to market conditions.

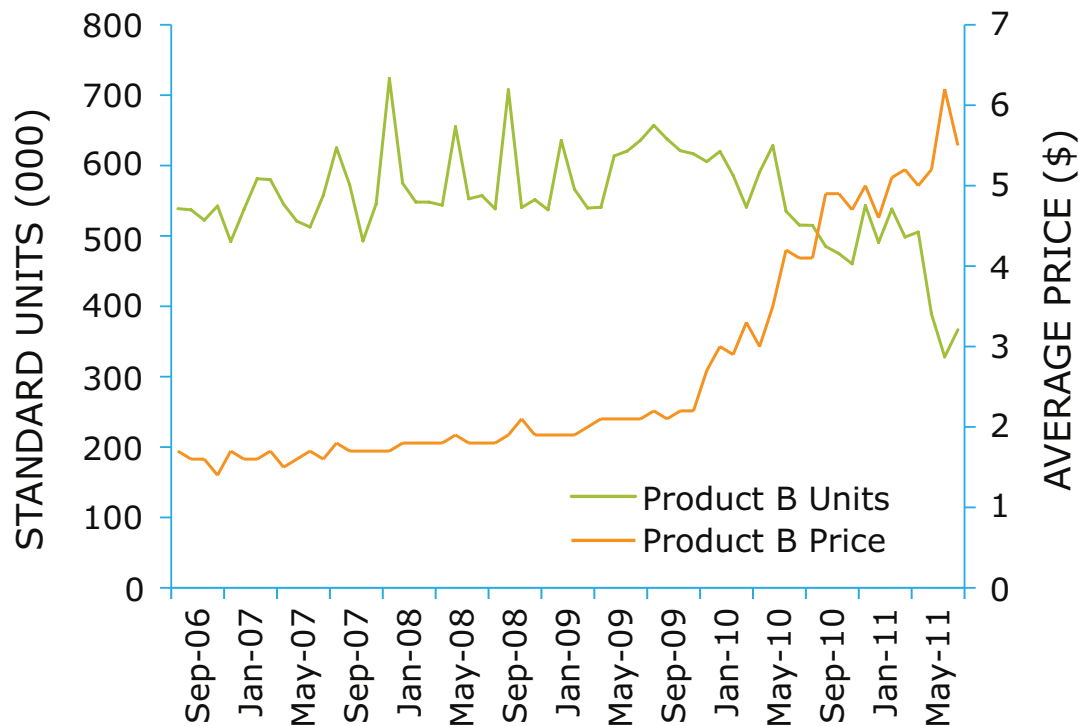
Chart notes

Pricing is derived from sales dollars divided by Standard Units.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Example: Product B price levels grow as volumes decline

Monthly Product B Injectable
Volume and Price Change



- In this case, the product also has reduced volume in recent months, while a substantial price increase beginning in 2010 has occurred.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2010

Chart notes

Pricing is derived from sales dollars divided by Standard Units.

Recommendations



RECOMMENDATION: EARLY WARNING SYSTEM FOR DRUG SHORTAGES

To help the FDA, pharmacists and other stakeholders monitor drug shortages and identify new or worsening shortages the IMS Institute for Healthcare Informatics recommends that the FDA or the industry create an Early Warning System for drug shortages.

The Early Warning System should include:

- 1. Risk Identification:** Systematically identify the high-risk sectors of the generics market. Identify all the low-cost, technically challenging and critical medicines – whether or not they are currently on shortage lists.
- 2. Demand Forecasting:** Continuously forecast the long-term demand for low-cost, technically challenging and critical medicines. Adjust forecasts based on such factors as demand trends, new medications, changes in clinical guidelines, practice patterns, care delivery changes and needs of clinical trials.
- 3. Volatility Index:** A quantitative measure to systematically track and report month-to-month changes in the volume of drugs supplied to hospitals, clinics and retail pharmacies.

Volatility in supply – whether national, regional, by individual supplier, or for specific drug molecules – is a sentinel of problems in meeting demand and instability or dramatic change in the supply chain. Volatility itself can seriously exacerbate problems in meeting demand, encourage overstocking, disrupt patient therapies and facilitate short-term price manipulation by a few suppliers.

- 4. Predictive Modeling:** With the wealth of data available, predictive modeling techniques could be applied to anticipate shortages or supply disruptions for critically important medications at the national and regional levels. As data accumulate and measures are improved, the model can tightly focus interventions on those specific parts of the market and supply chain genuinely needing attention.

Other tools would augment the Early Warning System, including self-reporting of demand and supply disruptions by pharmacies, wholesalers, group purchasing organizations and drug manufacturers.

Methodology, approach and sources

The analysis included in this report is based on a proprietary dataset developed by the IMS Institute for Healthcare Informatics as follows:

PRODUCT SELECTION

Products included in the dataset were reviewed and based on the Current Drug Shortages sections of websites maintained by the FDA (<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>) and ASHP (<http://www.ashp.org/DrugShortages/Current/>). Information related to products and molecules was accessed on October 7, 2011, resulting in an initial list of 197 unique products. Of these products, 11 are considered to be widely available, and a further 18 are products unable to be uniquely identified in the IMS databases, leaving 168 products in the final dataset.

DATA SELECTION

For each product in the dataset, all strengths were included for the forms of the product indicated on the FDA or ASHP website. Monthly volume in Standard Units for each supplier of the product for the period beginning September 2006 and ending August 2011 was extracted from IMS National Sales Perspectives. Pricing information was also derived from IMS National Sales Perspectives for the same period and reflects invoice prices charged to end-user channels; it does not reflect off-invoice discounts or rebates.

Additional information related to distribution channel, therapy class using the Anatomical Therapeutic Chemical (ATC) Classification System, and

characterization of the product as a brand, generic or branded generic was also included and derived from IMS National Sales Perspectives. For oncology products, patient counts by tumor site and regimen were sourced from IntrinsicQ, a unit of AmerisourceBergen Specialty Group, via IMS Oncology Analyzer, for the period of June 2006–June 2011.

Regional volume usage was derived from IMS Drug Distribution Data (DDD) for the period of September 2007 to August 2011.

THERAPY CLASSES ARE DEFINED AS:

Oncologics - A4A, L1 & L2 & Revlimid, and V3D; Anti-infectives - J1A, J1C, J1D, J1E, J1F, J1G, J1K, J1L, J1X, J2A, J4A, J5B, and J7; Central Nervous System - N3A, N4A, N5A, N6B, N7E, and N7X; Pain - M1A, M3A, M3B, N1A, N1B, N2A, and N2B; Cardiovascular - C1A, C1B, C1C, C1E, C1X, C2A, C3A, C4A, C6A, and C8A & C8B; Vitamins/Minerals - A11, A12, A13, and B3X. All other therapy classes have been defined in the "All Other" category.

APPROACH

Key analyses were performed on the total cohort of 168 products in order to determine overall characteristics of those products classified by the FDA or ASHP as currently in shortage. Additional analyses were performed on subsets of products defined, based on the level of change in monthly supply during the period June 2011 through August 2011, when compared to the average monthly volume supplied from September 2006 through August 2009.

NOTES ON SOURCES

IMS National Sales Perspective (NSP)TM measures spending within the US pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. It is the only source to report 100 percent coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices.

IMS DDDTM provides spending on pharmaceutical products down to the ZIP code level for retail stores and outlet level for non-retail outlets. It measures the types of products the pharmacies and outlets are purchasing through wholesalers, as well as directly from the pharmaceutical manufacturer.

IMS Oncology AnalyzerTM provides a complete perspective of cancer patient care from diagnosis onward, facilitating critical research in areas such as product adoption, dosing, market sizing and off-label use.

Molecules Included in Declining Segment

THERAPY AREA	MOLECULE	CHANGE	THERAPY AREA	MOLECULE	CHANGE	
Anti-infectives	capreomycin	-70%	Central Nervous System	aripiprazole	-98%	
	cefaclor suspension	-100%		fluphenazine	-44%	
	fluconazole	-29%		fosphenytoin	-41%	
	foscarnet	-100%		magnesium	-55%	
	ganciclovir	-100%		phenytoin	-26%	
	isoniazid	-30%		rotigotine	-100%	
	kanamycin	-100%		valproic acid	-47%	
	MMR&V vaccine live	-100%		Oncology	bleomycin	-47%
	rifampin	-34%			busulfan	-95%
	sulfamethoxazole	-78%			cytarabine	-21%
	ticarcillin	-65%			daunorubicin	-77%
	Cardiovascular	alprostadil			-99%	denileukin diftitox
caffeine - injectable		-100%	fludarabine		-31%	
clevidipine		-33%	idarubicin		-43%	
digoxin		-30%	irinotecan		-28%	
dopamine - injectable		-44%	leuprolide		-55%	
furosemide		-22%	liposomal doxorubicin		-57%	
ibuprofen - injectable		-100%	prochlorperazine	-61%		
methyldopate		-100%	thiotepa	-59%		
nitroglycerin		-24%				
norepinephrine		-96%				
papaverine		-29%				
procainamide		-26%				

Percent change represents average monthly volume for three months ending August 2011 compared to average monthly volume for period September 2006 to August 2009.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2010

Molecules Included in Declining Segment

THERAPY AREA	MOLECULE	CHANGE	THERAPY AREA	MOLECULE	CHANGE	
Pain	bupivacaine	-60%	Other	aminophylline	-40%	
	buprenorphine	-99%		atropine	-36%	
	butorphanol	-48%		azathioprine	-89%	
	choline	-100%		bisacodyl	-35%	
	droperidol	-35%		cyclosporine	-29%	
	etomidate	-64%		dipyridamole	-64%	
	nalbuphine	-28%		ethiodized oil	-100%	
	sufentanil	-36%		gold sodium thiomalate	-94%	
	vecuronium	-48%		levothyroxine	-99%	
	Vitamins, Minerals	calcitriol - injectable		-55%	methoxsalen	-99%
		leucovorin		-22%	methylprednisolone	-50%
multivitamins - injectable		-92%		metoclopramide	-32%	
selenium		-59%		opium - paregoric	-99%	
vitamin A - injectable		-100%		phentolamine	-95%	
				phenylephrine	-28%	
				promethazine	-43%	
				protamine	-38%	
				terbutaline	-31%	
				ticlopidine	-47%	

Percent change represents average monthly volume for three months ending August 2011 compared to average monthly volume for period September 2006 to August 2009.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2010

Molecules Included in Growth Segment

THERAPY AREA	MOLECULE	CHANGE	THERAPY AREA	MOLECULE	CHANGE
Anti-infectives	doxycycline	22%	Other	agalsidase beta	130%
	primaquine	45%		deferoxamine	28%
	tobramycin	22%		dexamethasone	51%
	vaccine varicella	131%		imiglucerase	67%
Cardiovascular	esmolol	39%		octreotide	21%
	nicardipine	39%		phenylacetic acid	24%
Central Nervous System	methylphenidate	52%		ranitidine - injectable	59%
Oncology	fluorouracil	34%		sodium chloride	1474%
	ondansetron	116%		testosterone	166%
	paclitaxel	22%		thyroid stimulating hormone	22%
	scopolamine	33%			
	tretinoin	123%			
Pain	rocuronium	45%			
Vitamins, Minerals	calcium ace	46%			
	chromium	23%			
	copper	128%			
	cyanocobalamin	47%			
	hydroxocobalamin	98%			
	levoleucovorin	182%			
	manganese	57%			
	zinc	23%			

Percent change represents average monthly volume for three months ending August 2011 compared to average monthly volume for period September 2006 to August 2009.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2010

Molecules Included in Stable Segment

THERAPY AREA	MOLECULE	CHANGE	THERAPY AREA	MOLECULE	CHANGE	
Anti-infectives	acyclovir	13%	Oncology <i>continued</i>	etoposide	9%	
	amikacin	-9%		granisetron	-14%	
	amphotericin b	-18%		mesna	24%	
	ampicillin	-11%		methotrexate	-5%	
	azithromycin	-18%		mitomycin	18%	
	cefotaxime	-2%		vincristine	-9%	
	cefpodoxime proxetil	-4%		Pain	acetaminophen	-13%
	gentamicin	0%			fentanyl	-2%
	vancomycin	2%			ketorolac	3%
Cardiovascular	amiodarone	-4%	propofol	19%		
	diltiazem	-4%	Vitamins, Minerals	sulfur	10%	
	hydralazine	15%		Other	aminocaproic acid	-11%
	labetalol - injectable	-19%	calcium cl		15%	
	metoprolol - injectable	-6%	cilostazol	14%		
Central Nervous System	diazepam	0%	desmopressin	-5%		
	glycopyrrolate	-4%	diphenhydramine	8%		
	haloperidol	-1%	epinephrine	-20%		
	hydroxyzine	-20%	famotidine	-7%		
	lorazepam	-9%	gonadotropin chorionic	-10%		
	midazolam	-1%	heparin	16%		
	naloxone	-15%	leflunomide	19%		
	phenobarbital	15%	methylene blue	-3%		
	thiothixene	-12%	metronidazole	11%		
Oncology	capecitabine	3%	nystatin	6%		
	carboplatin	-3%	sodium bicarb - injectable	-3%		
	cisplatin	18%	sodium thiosulfate	17%		
	dacarbazine	-3%	sucralfate	3%		
	doxorubicin	-10%	vasopressin	0%		

Percent change represents average monthly volume for three months ending August 2011 compared to average monthly volume for period September 2006 to August 2009.

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2010

Per capita change in usage by state for declining injectable products

STATE	AVERAGE Sep 2009 - Aug 2010	AVERAGE Jun 2011 - Aug 2011	CHANGE IN VOLUME	STATE	AVERAGE Sep 2009 - Aug 2010	AVERAGE Jun 2011 - Aug 2011	CHANGE IN VOLUME
AK	0.25	0.16	-35.9%	MT	0.35	0.29	-18.7%
AL	0.40	0.30	-23.3%	NC	0.30	0.22	-27.5%
AR	0.36	0.28	-22.4%	ND	0.40	0.33	-18.4%
AZ	0.25	0.16	-38.3%	NE	0.31	0.23	-24.6%
CA	0.17	0.12	-27.7%	NH	0.23	0.17	-27.5%
CO	0.19	0.15	-22.8%	NJ	0.20	0.14	-30.9%
CT	0.20	0.15	-23.0%	NM	0.27	0.21	-22.8%
DE	0.32	0.21	-32.4%	NV	0.26	0.18	-31.1%
FL	0.28	0.19	-31.3%	NY	0.25	0.18	-26.7%
GA	0.27	0.20	-25.4%	OH	0.28	0.18	-35.2%
HI	0.23	0.13	-44.3%	OK	0.35	0.26	-24.8%
IA	0.23	0.17	-28.8%	OR	0.21	0.16	-24.3%
ID	0.19	0.14	-25.3%	PA	0.25	0.18	-29.2%
IL	0.21	0.15	-26.8%	RI	0.33	0.25	-24.7%
IN	0.26	0.19	-28.5%	SC	0.32	0.22	-30.3%
KS	0.35	0.29	-16.6%	SD	0.37	0.31	-17.1%
KY	0.37	0.26	-30.5%	TN	0.37	0.28	-25.6%
LA	0.35	0.27	-22.4%	TX	0.27	0.20	-25.8%
MA	0.24	0.16	-32.8%	UT	0.19	0.15	-19.8%
MD	0.24	0.16	-31.2%	VA	0.23	0.17	-25.2%
ME	0.32	0.29	-11.6%	VT	0.25	0.22	-11.4%
MI	0.27	0.19	-29.8%	WA	0.22	0.17	-25.0%
MN	0.22	0.17	-23.0%	WI	0.20	0.15	-27.6%
MO	0.33	0.24	-27.6%	WV	0.46	0.31	-32.2%
MS	0.50	0.39	-20.7%	WY	0.34	0.28	-17.0%

Analysis is based on dividing Standard Units for the 64 declining injectable products by total state population. State population derived from US Census Bureau.

Source: IMS DDD, Sep 2009 – Aug 2011

About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care.

With access to IMS's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS information and expertise to support the advancement of evidence-based healthcare around the world.

RESEARCH AGENDA

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

Demonstrating the effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

GUIDING PRINCIPLES

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.