Testimony Submitted to the U.S. Senate Committee on Health, Education, Labor & Pensions

Full Committee Hearing

Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions

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Chairman Harkin, Senator Enzi, and Members of the Committee:

Thank you for the opportunity to contribute to the discussion of this important topic. Drug shortages have become of increasing concern for patients, clinicians, manufacturers and policymakers. While the issue it not entirely new, the increased number of drugs reported as being in short supply has precipitated a deeper understanding of the underlying causes of the problem, and potential remedies to prevent future shortages or alleviate their impact on patient care.

I am the Executive Director of the IMS Institute for Healthcare Informatics, which is focused on bringing objective, relevant insights and research that will accelerate the understanding and innovation critical to sound decision making and improved patient care. We have recently undertaken a study based on analysis of IMS Health data and publicly available drug shortage lists in order to bring new evidence on the products and suppliers involved, and the volume volatility occurring in the marketplace. This work has been undertaken as a public service, without industry or government sponsorship.

METHODOLOGY OF IMS ANALYSIS

The basis of our analysis is a dataset developed by the IMS Institute and based on products listed on the Current Drug Shortages Sections of websites maintained by the US Food and Drug Administration and the American Society of Health-System Pharmacists. 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.

For the 168 products, we accessed monthly volume and sales data for the five year period beginning September 2006 and ending August 2011 from IMS National Sales Perspectives. This measures volume in Standard Units and sales within the US pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. Sales amounts are based on pricing information derived from wholesaler invoices to end-users and does not include rebates and discounts commonly negotiated between end-users and manufacturers, including Medicaid rebates and 340B discounts.

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 IntrinsiQ, 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.

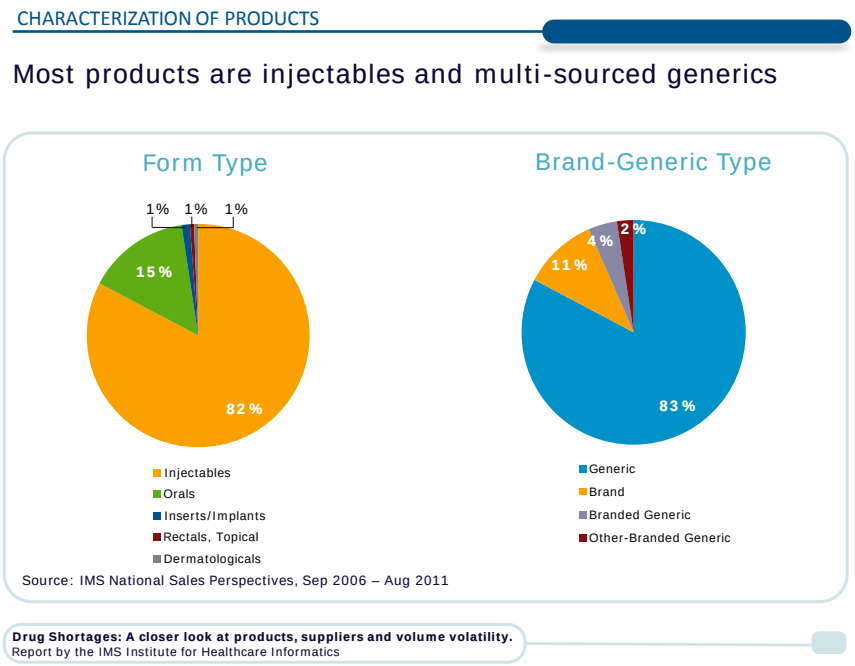
KEY FINDINGS

The key findings of our analysis relate to the characterization of the products on the shortages list; the suppliers of these products; and the volatility in supply volume for individual products.

Characterization of the products on the shortages list

Most of the 168 products included in the IMS dataset are injectables (82%) and generics (83%) (Exhibit 1). This points to the concentration of products to a segment of the market and suggests the underlying causes and solutions to drug shortages should be focused on this part of the overall pharmaceutical sector.

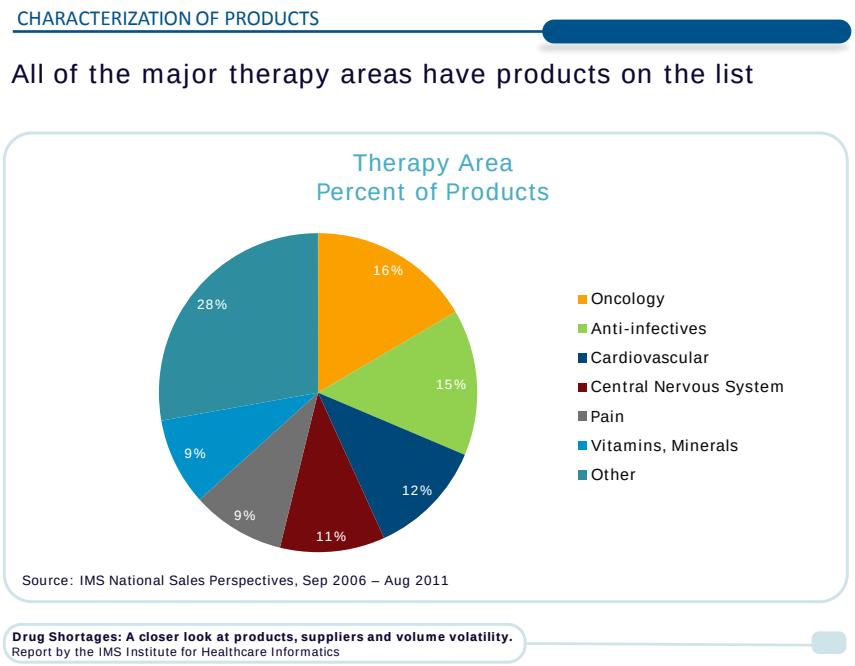
Exhibit 1



We also found that most of the products on the shortages list are used in hospital or clinic settings. For the injectables, 72% of the standard unit volume is supplied to non-federal hospitals, 16% to clinics, 3% to federal facilities, and the remaining 9% goes to retail or other channels. For the oral products, the distribution is more directed toward retail channels, accounting for 79% of the volume, and only 5% going to hospitals and 4% to clinics.

Although drug shortages are concentrated in terms of the nature of the products, they are extensive in terms of the therapy areas they are used in. In fact, the 168 products cover all of the major anatomical therapy classes used to categorize therapeutic pharmaceuticals. The largest share of products are used in oncology, representing 16% of the products; a further 15% are anti-infective products; 12% are used in to treat cardiovascular disease; 11% for central nervous system conditions; 9% for pain; a further 9% are vitamins and minerals (mostly in injectable form); and the remaining 28% cover a broad range of other therapy areas including asthma/chronic obstructive pulmonary disease and immunosuppressants (Exhibit 2).

Exhibit 2

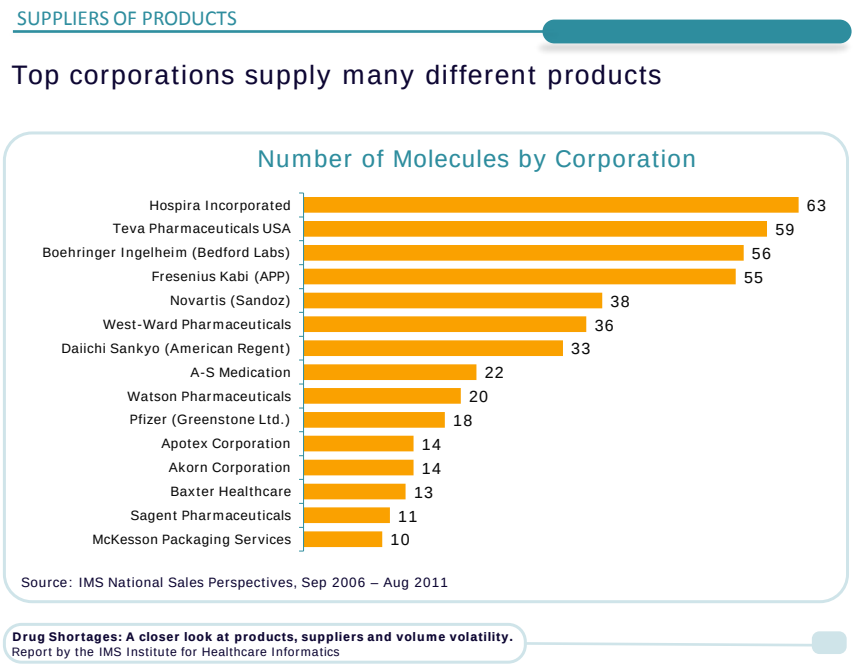


The number of patients potentially affected by drug shortages is also extensive. In the case of the 20 injectable oncology drugs on the shortages list, we estimate that 550,000 cancer patients were treated with at least one of those drugs during the past year. This therefore can represent the number of patients whose treatment could be affected by any disruption in the supply of these drugs.

Characterization of suppliers

We analyzed the firms supplying the 168 products on our shortages list over the past 5 years. In total 100 companies supplied one or more of the products on the current shortages list over the past 5 years. More recently, 98 separate companies controlled by 88 corporations were supplying these products during the three months ending August 2011. The largest generic manufacturers have multiple products (Exhibit 3).

Exhibit 3



Over time, we see a number of companies, generally supplying relatively few products, entering and leaving the marketplace. Over the past 5 years the number of corporations supplying the 168 products has fluctuated, including 13 corporations that have stopped supplying any products on the shortages list during the past two years. This movement among suppliers is one of the underlying causes of the disruption felt by pharmacists when they are no longer able to source their supplies from established manufacturers.

Among the 168 products on the shortages list, we identified 86 products, or 51% of the total, that currently have two or fewer suppliers. Of those 86 products, 56 had only one supplier, and 7 had no suppliers during the three months ending August 2011 (Exhibit 4).

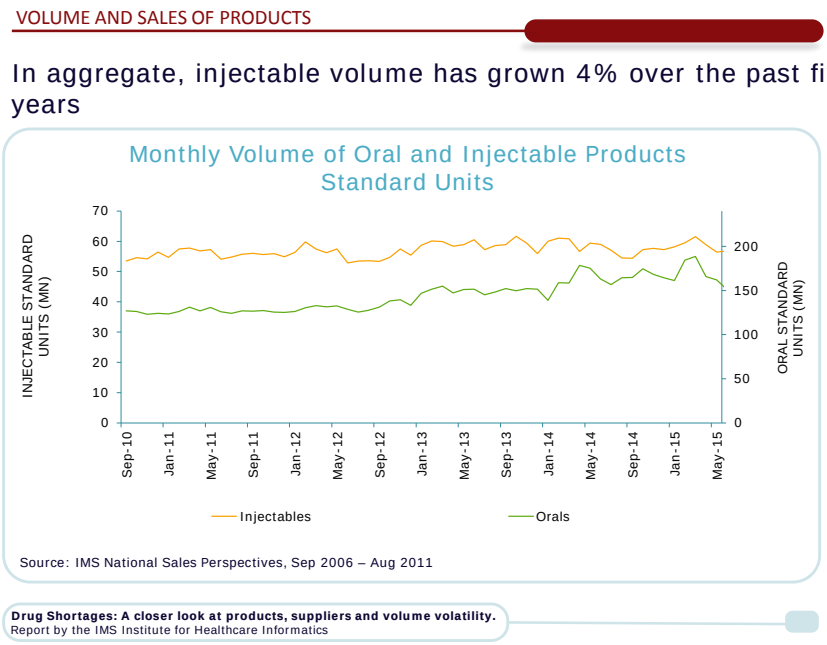
Exhibit 4

While patent protected products have single suppliers and generally do not face supply shortages, in the generics market the relatively high number of products with very few suppliers may be a contributing factor to supply disruption. In the event that one company has a temporary disruption of manufacturing capacity, it may be difficult for another company to replace that volume quickly and hence lead to a shortage.

Volatility in supply volume

The average monthly supply from wholesalers to end-user settings for the total set of 168 products has, in aggregate, increased slightly over the past 5 years. For the injectable products, the average number of standard units supplied monthly increased from 54 million in 2006 to 56 million in 201. For the smaller number of oral products, volume increased from 125 million to 157 million during the same reference period (Exhibit 5).

Exhibit 5



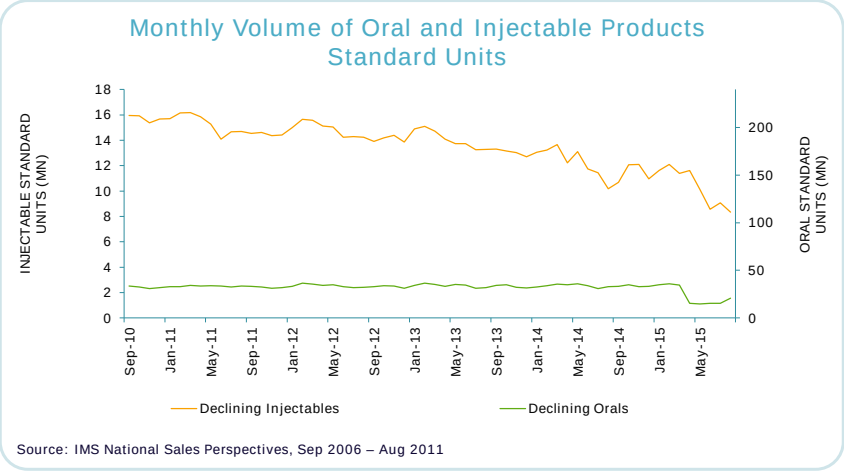
A closer examination reveals that three distinct segments exist among the drugs on the current shortages list:
a) a “declining” set of 75 products that have recent monthly supply volume of less than 80% of a base period defined as September 2006-August 2009;
b) a “stable” set of 56 products whose recent monthly supply is between 80% and 120% of the base period; and
c) a “growing” set of 31 products where monthly supply is at least 20% more than the base period.
(An additional 6 products were introduced during the five year period and not included in the above segmentation.)

In aggregate the declining segment of 75 products have seen monthly supply fall about 47% over the five year period. For the injectable products, average monthly volume has fallen from 16 million to 8 million standard units for month (Exhibit 6). Included in this segment are 12 oncology drugs, 11 anti-infectives, and 12 cardiovascular drugs, among others.

Exhibit 6

VOLUME AND SALES OF PRODUCTS

In the declining segment, volume has fallen substantially



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

Drug Shortages: A closer look at products, suppliers and volume volatility.
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For the remaining 55% of products in the stable or growing segments, the total volume has not declined, but there may be volatility among the suppliers of the individual products. For example, cisplatin - a widely used platinum-based alkylating agent used in treating about 85,000 patients for a variety of cancer treatments in the past year - has had some volatility in total monthly supply volume, but overall shows a growing volume trend over time. 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 (Exhibit 7). This level of volatility reflects disruption throughout the supply chain which ultimately affects providers and patients.

Exhibit 7
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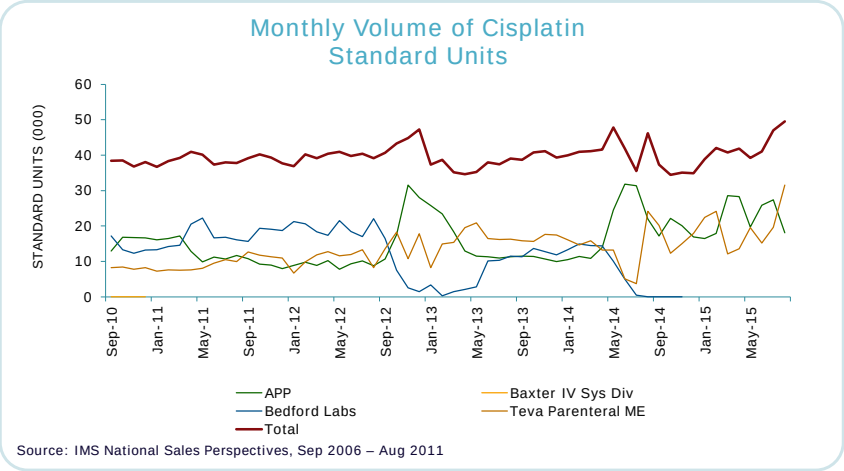
VOLUME AND SALES OF PRODUCTS

Example: cisplatin has not declined, but volumes have varied



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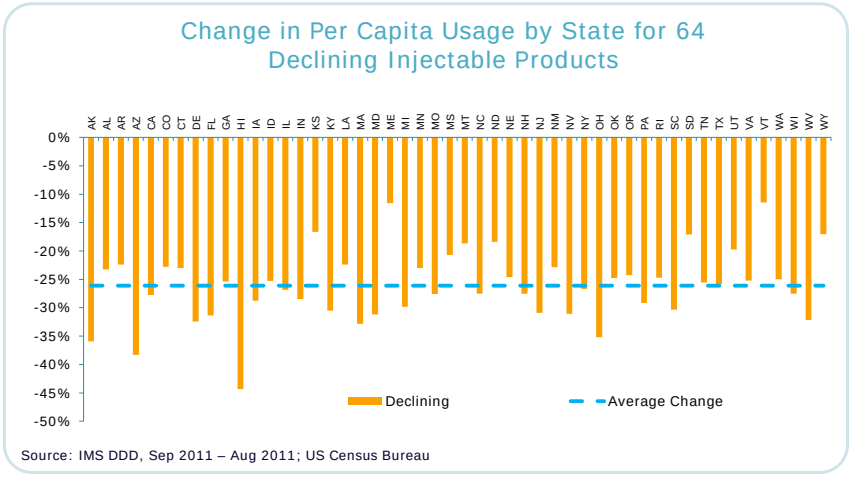
Across the 50 states we see varying levels of volatility in the supply of products on the shortage list. For example, for the 64 injectable products included in the declining segment, the average decline in monthly per capita use between the 12 months ending August 2010 and the three months ending August 2011 was 26%. Thirteen states had declines in excess of 30% between the two time periods, suggesting a significant disruption to patient care in a short time period (Exhibit 8).

Exhibit 8

VOLUME AND SALES OF PRODUCTS

The per capita change also varies significantly nationally



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RECOMMENDATIONS

Our analysis provides new insights - based on granular information – about the characterization of the products on current drug shortages lists, the suppliers of those products and a deeper, industry-wide understanding of the volume dynamics and volatility for individual molecules and suppliers of those molecules. Our perspective on recommendations is focused on how existing information and analytical approaches can be applied to preventing or alleviating the affects of shortages going forward. Specifically, we believe that an Early Warning System for drug shortages created by the FDA or the industry can be a critical tool to help the regulator, pharmacists and other stakeholders predict, monitor or mitigate the impact of supply disruptions on the healthcare system.

Specifically, the Early Warning system should include the following elements:

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.

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

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We are grateful for the opportunity to present our perspective to this Committee and look forward to discussion of the potential solutions.