PHARMA CI CONFERENCE & EXHIBITION USA

Drug Shortages:

Crisis and Opportunity

17th September 2013

East Brunswick, New Jersey

Harvest Moon PHARMACEUTICALS USA, INC.

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Teva Pharmaceuticals

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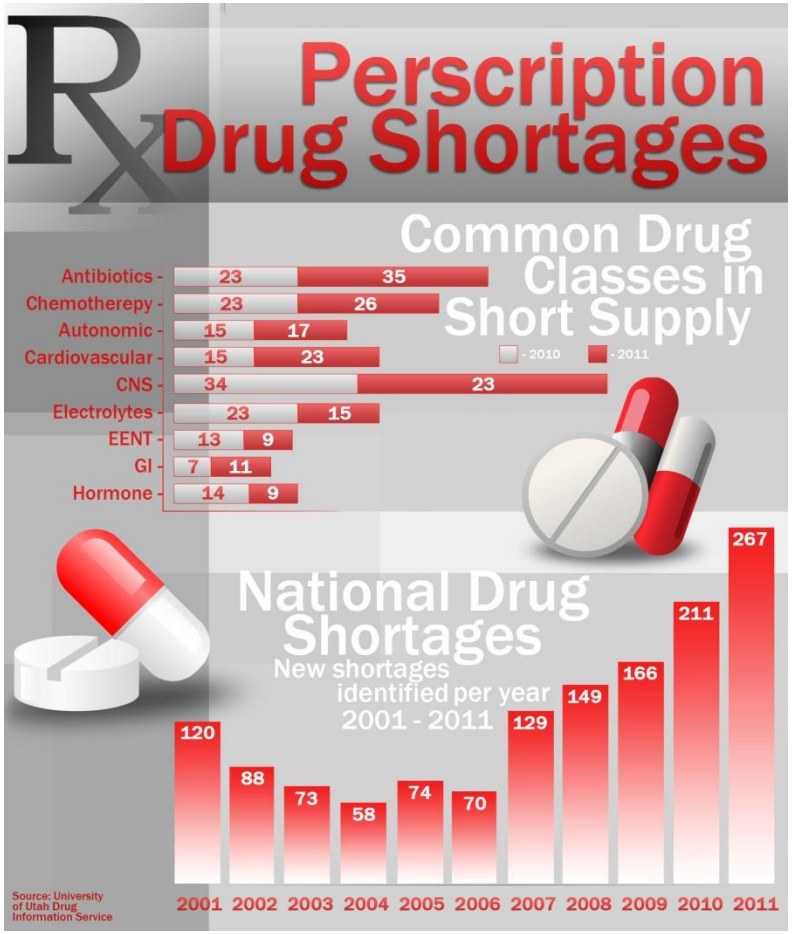
The Drug Shortage has been receiving increased attention in the last 5 years from industry, government, healthcare providers, and advocacy groups.

FDA mandated improved reporting systems and there have been legislative activity at Federal and State level.



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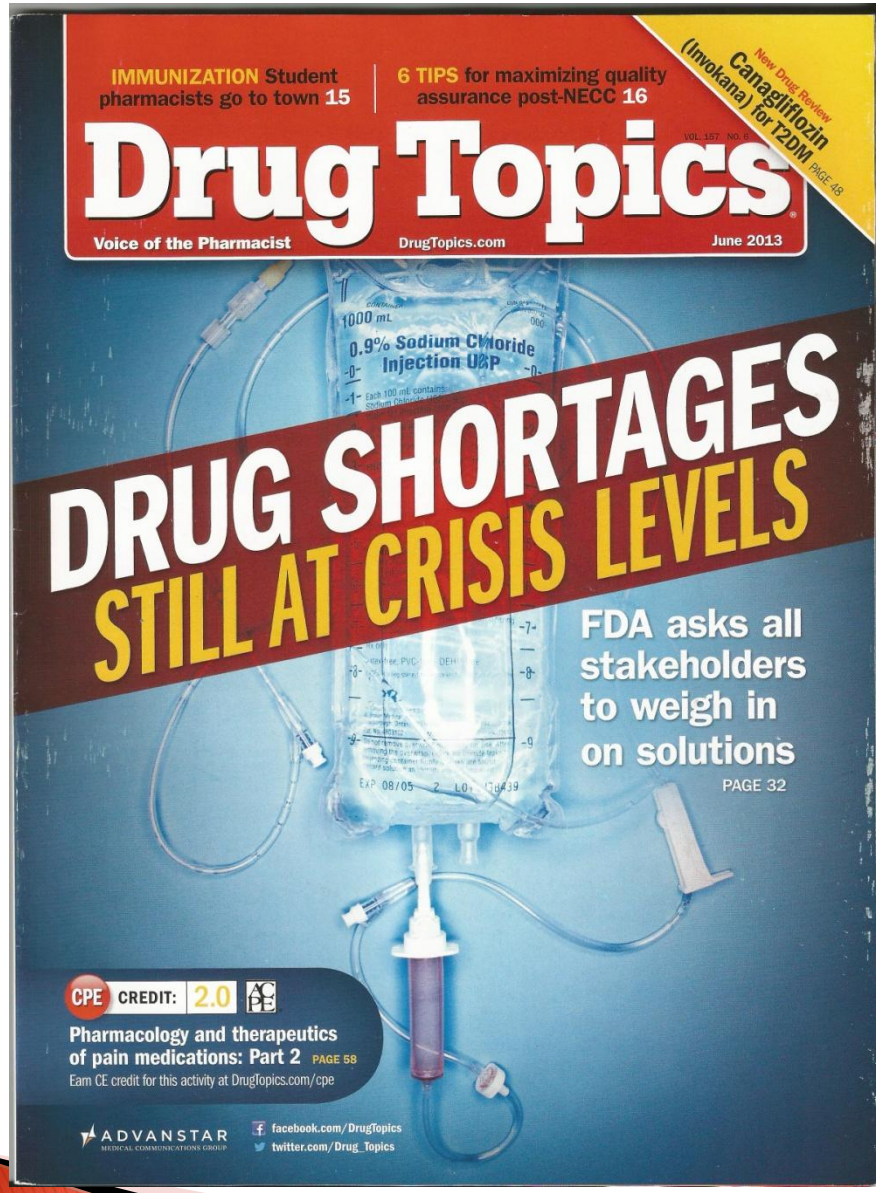

The June 2013 issue of Drug Topics magazine illustrates that this problem is

"Still at Crisis Levels"

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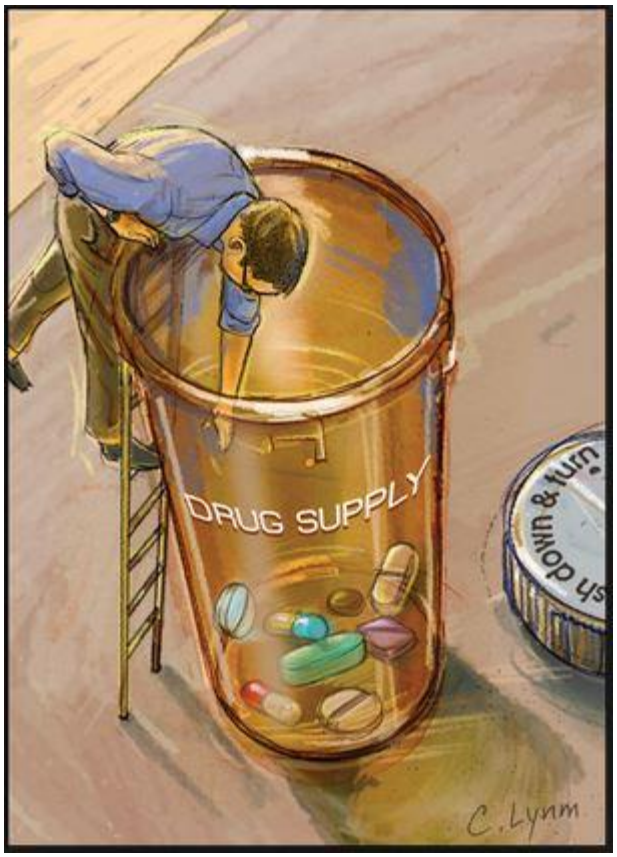
Current Statistics



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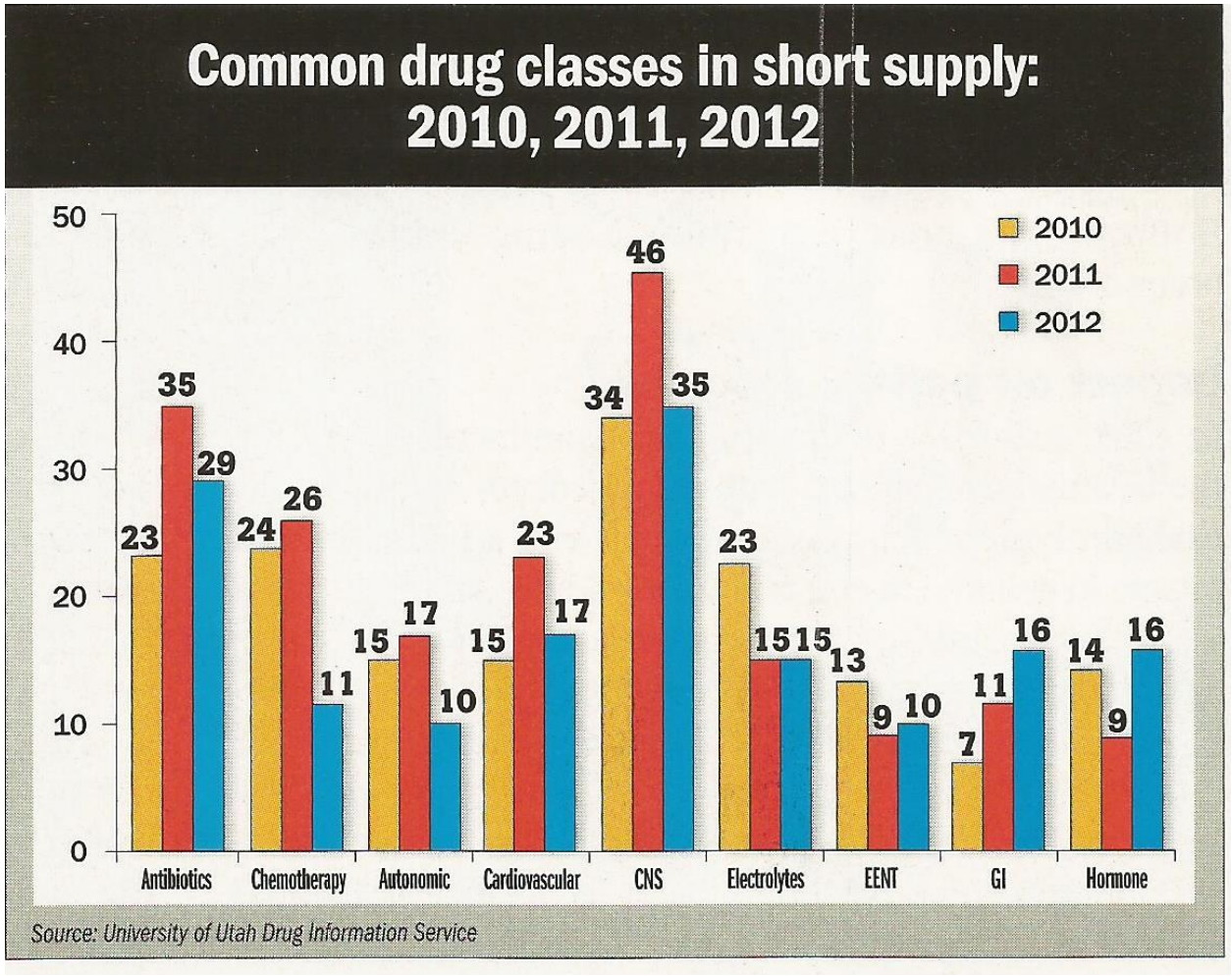

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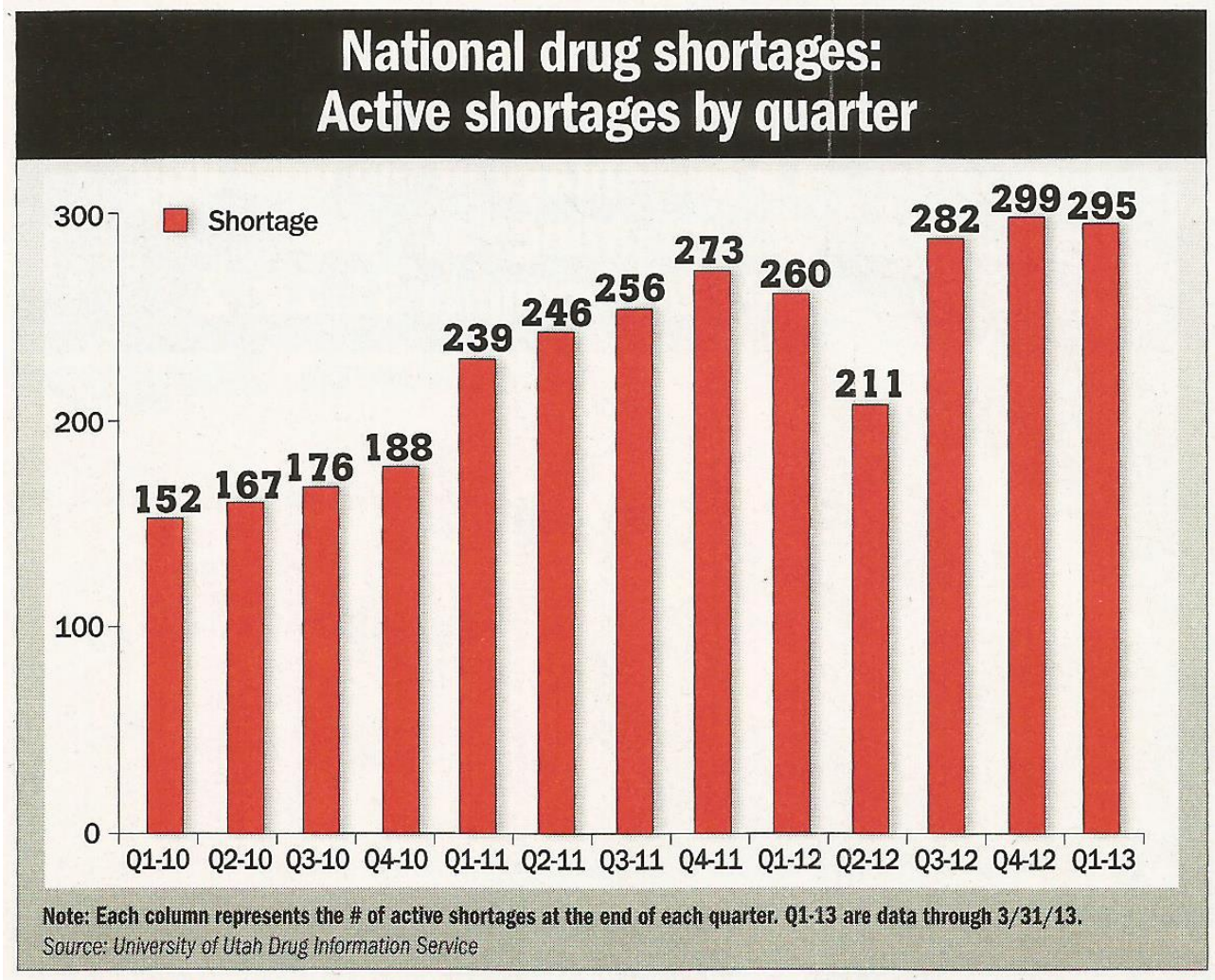

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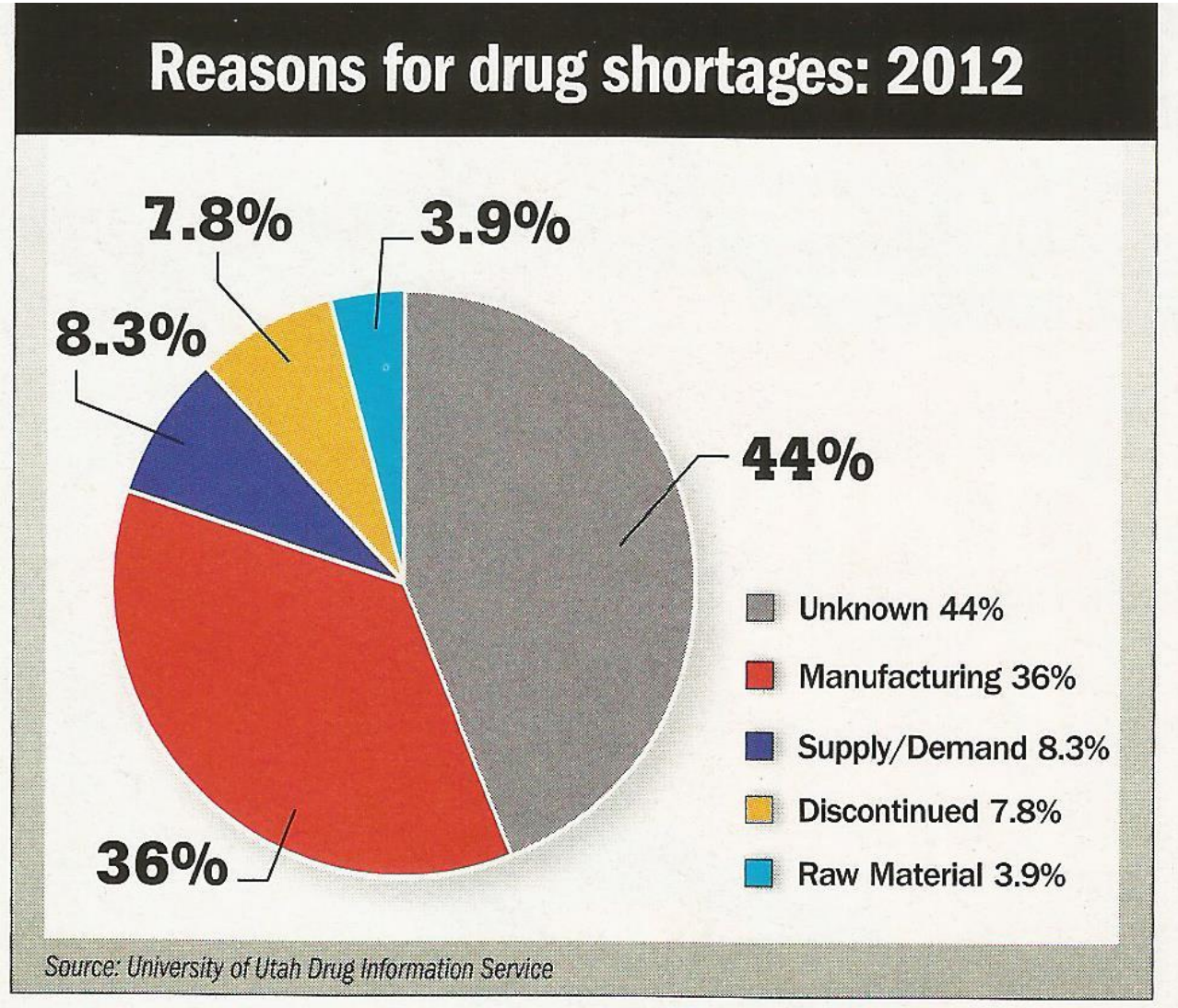

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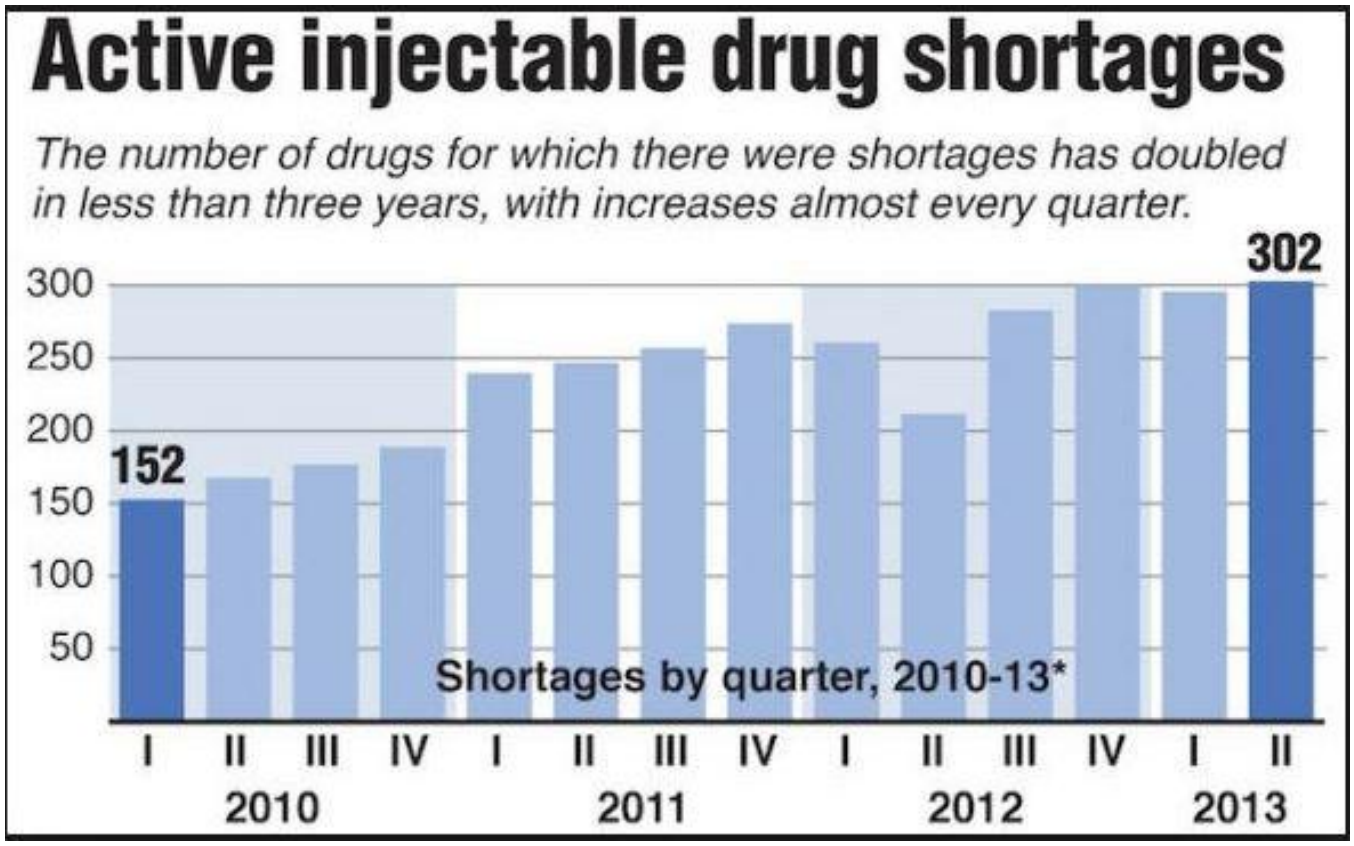

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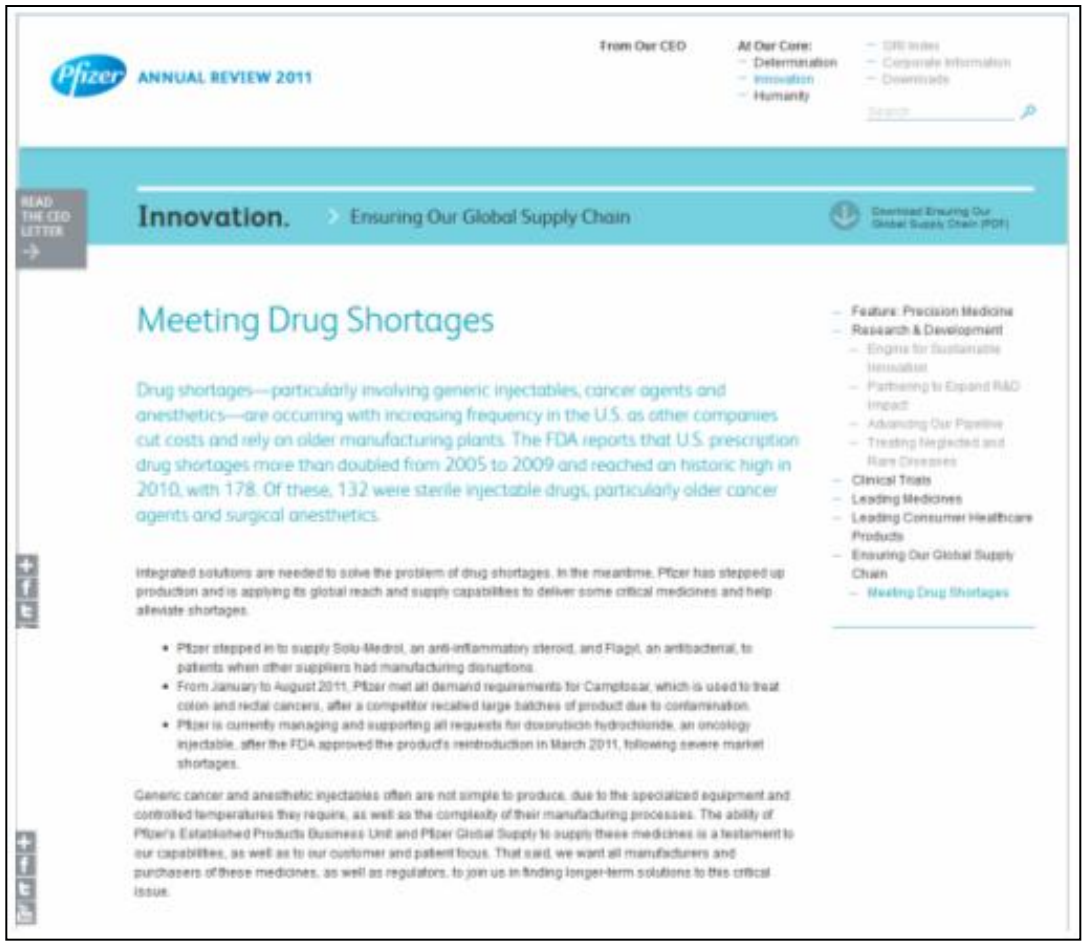
The Drug Shortage issue has become a part of Annual Reports of pharmaceutical companies



Pfizer ANNUAL REVIEW 2011

From Our CEO | At Our Core: Determination, Innovation, Humanity

READ THE CEO LETTER

Innovation. > Ensuring Our Global Supply Chain

Meeting Drug Shortages

Drug shortages—particularly involving generic injectables, cancer agents and anesthetics—are occurring with increasing frequency in the U.S. as other companies cut costs and rely on older manufacturing plants. The FDA reports that U.S. prescription drug shortages more than doubled from 2005 to 2009 and reached an historic high in 2010, with 178. Of these, 132 were sterile injectable drugs, particularly older cancer agents and surgical anesthetics.

Integrated solutions are needed to solve the problem of drug shortages. In the meantime, Pfizer has stepped up production and is applying its global reach and supply capabilities to deliver some critical medicines and help alleviate shortages.

- Pfizer stepped in to supply Solu-Medrol, an anti-inflammatory steroid, and Flagyl, an antibacterial, to patients when other suppliers had manufacturing disruptions.
- From January to August 2011, Pfizer met all demand requirements for Camptosar, which is used to treat colon and rectal cancers, after a competitor recalled large batches of product due to contamination.
- Pfizer is currently managing and supporting all requests for doxorubicin hydrochloride, an oncology injectable, after the FDA approved the product's reintroduction in March 2011, following severe market shortages.

Generic cancer and anesthetic injectables often are not simple to produce, due to the specialized equipment and controlled temperatures they require, as well as the complexity of their manufacturing processes. The ability of Pfizer's Established Products Business Unit and Pfizer Global Supply to supply these medicines is a testament to our capabilities, as well as to our customer and patient focus. That said, we want all manufacturers and purchasers of these medicines, as well as regulators, to join us in finding longer-term solutions to this critical issue.

- Feature: Precision Medicine
- Research & Development
- Clinical Trials
- Leading Medicines
- Leading Consumer Healthcare Products
- Ensuring Our Global Supply Chain
  - Meeting Drug Shortages

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Some Reasons for Drug Shortages

- Manufacturing issues – FDA Warning Letters at several sterile facilities
- Economic issues based on Medicare Part B vs. Part D for hospital products
- GPOs and their current practices
- API & Drug Suppliers who exited the market
- Supply and Demand changes

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House Committee on Oversight & Government Reform

- "in a report released on June 15, 2012 by the House Committee on Oversight and Government Reform, FDA's "overzealous" inspections and enforcement actions have engendered drug shortages. In 2010, FDA issued 673 warning letters, a 42 percent increase from 2009; and in 2011, the agency issued 1,720 warning letters, a further increase of 156 percent. Scott Gottlieb, a former deputy commissioner of the FDA, echoed the House committee's conclusions in congressional testimony about the agency's enforcement excesses:

- **"Instead of calling for targeted fixes of troubled plants, the agency has often required manufacturers to undertake costly, general upgrades to facilities. As a result, in 2010, regulatory actions taken by the FDA to address these problems were involved in 42 percent of the drug shortages."** (Forbes)

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Drug Sponsors and CMOs

- If a Drug Sponsor depends on an outside CMO to manufacture its product, the risks are increased.

- J&J's Doxil, a $500M product worldwide, was manufactured at Ben Venue. The supply was disrupted in 2011 when Ben Venue had manufacturing issues. Today, Doxil is still on the drug shortage list.

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Healthcare Group Purchasing Organizations

Giant hospital group purchasing organizations (GPOs), control the purchasing of an estimated $250+ billion in drugs, devices and supplies for about 5,000 private acute care member hospitals and increasingly, non-acute care facilities.

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- In specifically exempting GPOs from the Federal Anti-Kickback Law, many healthcare providers interpreted the act as an encouragement to the expansion of GPOs. Congress did not specify any limit on contract administration fees, but required the United States Department of Health and Human Services (HHS) to monitor such fees for possible abuse – particularly with respect to fees in excess of 3.0 percent.
- In 1991, HHS promulgated safe harbor regulations, reflecting Congress' intent to permit contract administration fees and creating the additional safeguard that GPOs inform members of administrative fees in excess of 3.0 percent. Despite these safeguards, the Government Accounting Office (GAO) published a study in 2002 indicating that GPOs did not always in fact reduce the cost of supplies and equipment for hospitals, but in some cases increased these costs by as much as 37%. Further examining the practices of GPOs, the Federal Trade Commission (FTC) clarified that "safety zone thresholds do not prevent and should not be appropriately read as preventing antitrust challenges to any of the alleged anticompetitive contracting practices..." of GPOs.
- In 2002, the Senate Judiciary Committee's Antitrust Subcommittee imposed stricter standards on GPOs in healthcare, requiring the adoption of a Code of Conduct to which GPOs must subscribe.
- **Critics of GPOs charge that, as long as GPOs receive fees from the vendors they are charged with policing, the industry has anti-competitive contracting potential that should be subjected to further scrutiny and/or regulation**

GPOs and Drug Shortages

- A June 2012 report by the House Committee on Oversight and Government Reform concluded that GPOs have contributed to the current shortage of generic injectable medications because of pressures that the purchasing organizations exert on manufacturers and suppliers. “Companies that cannot produce a drug at large enough output levels to take advantage of the economies of scale—often because they lack the guaranteed source of demand that GPOs provide—will stop producing the drug or will neglect to enter the market,” the House report stated

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Are GPOs the Problem? A 2012 Whitepaper thinks so:

"The GPOs use a variety of anticompetitive, exclusionary practices that favor dominant manufacturers that can pay them the largest kickbacks, which were permitted as a result of the passage of the 1987 Medicare anti-kickback "safe harbor" exemption. These practices include, but are not limited to:

1. Exclusionary, sole source, long-term contracts;
2. Tying and bundling of product lines to give the advantage to large incumbent suppliers and discourage competition from smaller, entrepreneurial companies with fewer products;
3. Forced compliance programs that impose stiff penalties on hospitals and wholesalers if the volume of their purchases from manufacturers on contract drops below 95%, in many cases, for a particular product or product line;
4. A Byzantine system of manufacturers' rebates to large, favored distributors that ensures that only those distributors can sell to GPO-member hospitals.

These practices have created a concentrated market that excludes other existing and would-be suppliers and distributors. So increases in demand for generic drugs have resulted in shortages and surging prices, with no other suppliers able or available to fill the gap. It is no coincidence that the problem is generally limited to generics sold to healthcare facilities through GPO contracts rather than directly to consumers through retail pharmacies……"

Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage

Premier reinforces leadership role in reducing drug shortages, creating safer and healthier marketplace

Agreements with new and small suppliers aim to increase patient safety, access to drugs on FDA shortage list

For Immediate Release

Charlotte, N.C. (August 15, 2013)

The Premier healthcare alliance announced new agreements with a broader scope of generic drug manufacturers to provide drugs on the drug shortage list, including bringing new manufacturers into the generic injectable market. This is part of the alliance's ongoing commitment to solve drug shortages for American patients.

The first of these agreements is with Heritage Pharmaceuticals Inc., a subsidiary of Emcure Pharma Ltd., to offer alliance members safer and more reliable access to drugs on the Food and Drug Administration (FDA) shortage list, including:

- Cidofovir, used to treat viruses in AIDS patients. Heritage received the 2013 Healthcare Distribution Management Association best new generic product introduction of the year award for its launch of Cidofovir.
- Ondansetron, which prevents nausea and vomiting caused by surgery or cancer therapy.

Heritage also has a deep pipeline of products pending at the FDA and is working closely with the FDA to receive expedited review for approval of additional shorted drugs. Under their contracts, Premier will be able to rapidly make the products available to members at specially negotiated pricing and terms.

In addition to Heritage, Premier has signed contracts with a number of emerging suppliers that are investing in the development and production of shorted generic injectables.

"The Premier alliance is determined to lead the effort to solve our nation's drug shortage problem to benefit care providers and the patients they serve," said Michael J. Alkire, Premier's chief operating officer. "We're aggressively exploring all opportunities to bring high-quality suppliers with the capacity to produce shorted drugs to the market. Through our scale, experience and expertise, we're able to assist smaller suppliers and those new to the generic injectable market by adding their products to our contracts and making the FDA aware of these alternate sources."

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How are Doctors and Hospitals Coping?

What can they do to find additional supplies of critical drugs for their patients when their traditional sources have no product available?

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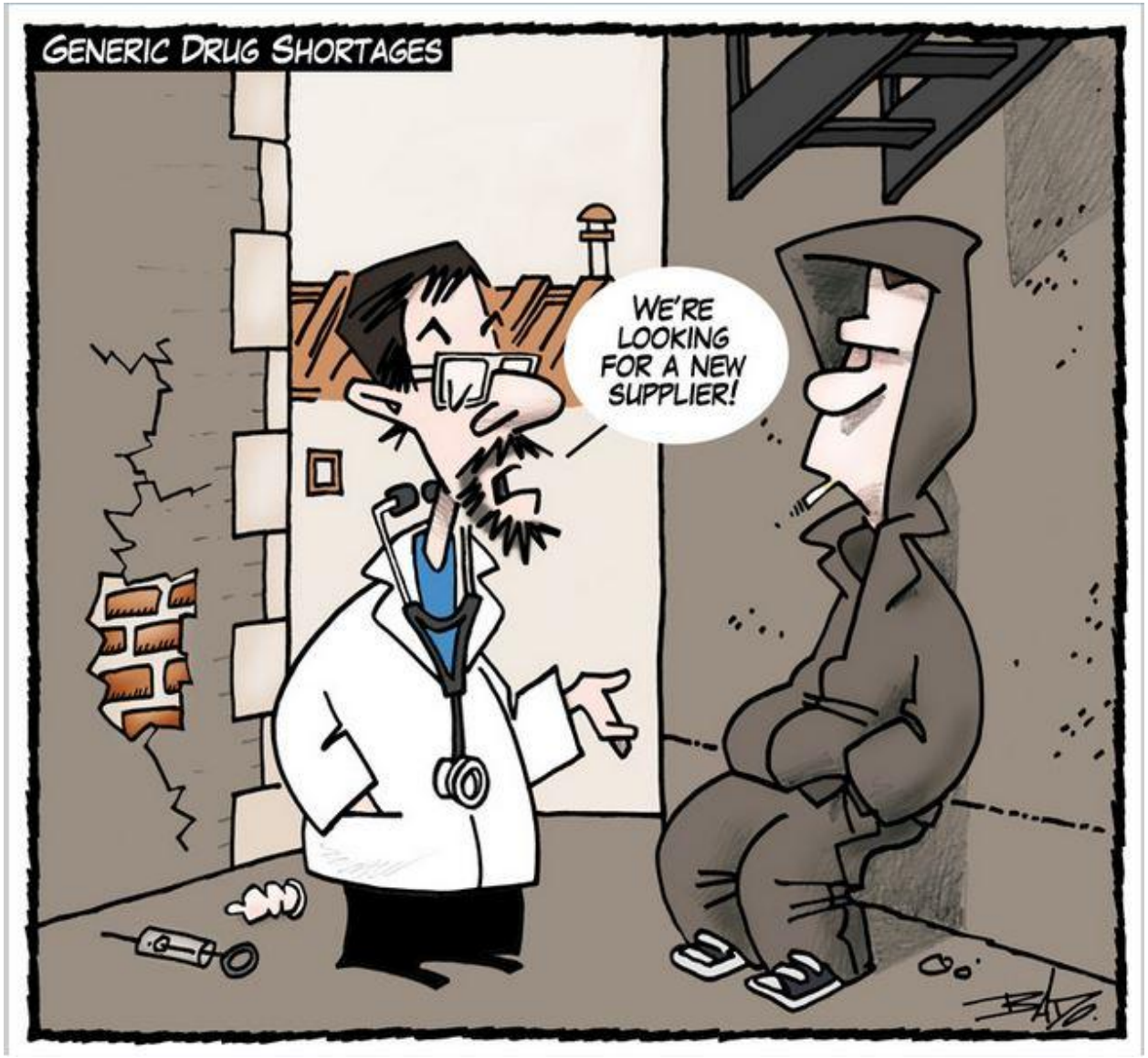

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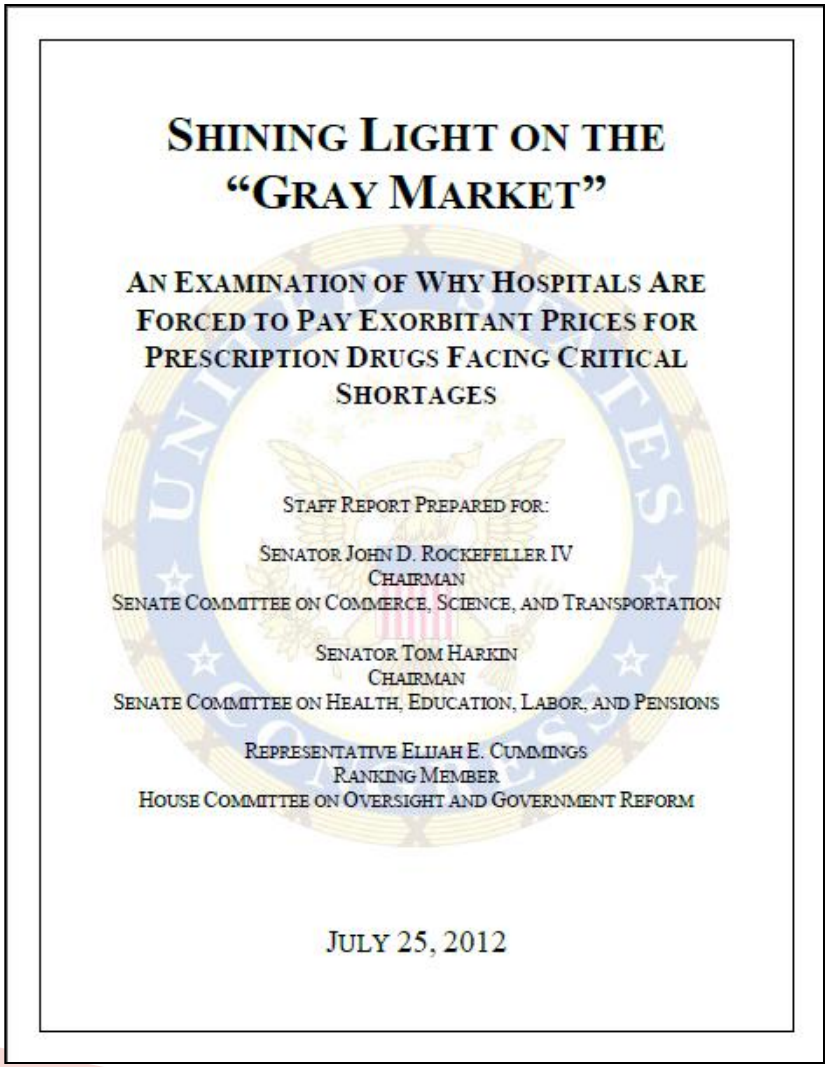
The Gray Market:



SHINING LIGHT ON THE "GRAY MARKET"

AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES

STAFF REPORT PREPARED FOR:

SENATOR JOHN D. ROCKEFELLER IV
CHAIRMAN
SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

SENATOR TOM HARKIN
CHAIRMAN
SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

REPRESENTATIVE ELIJAH E. CUMMINGS
RANKING MEMBER
HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

JULY 25, 2012

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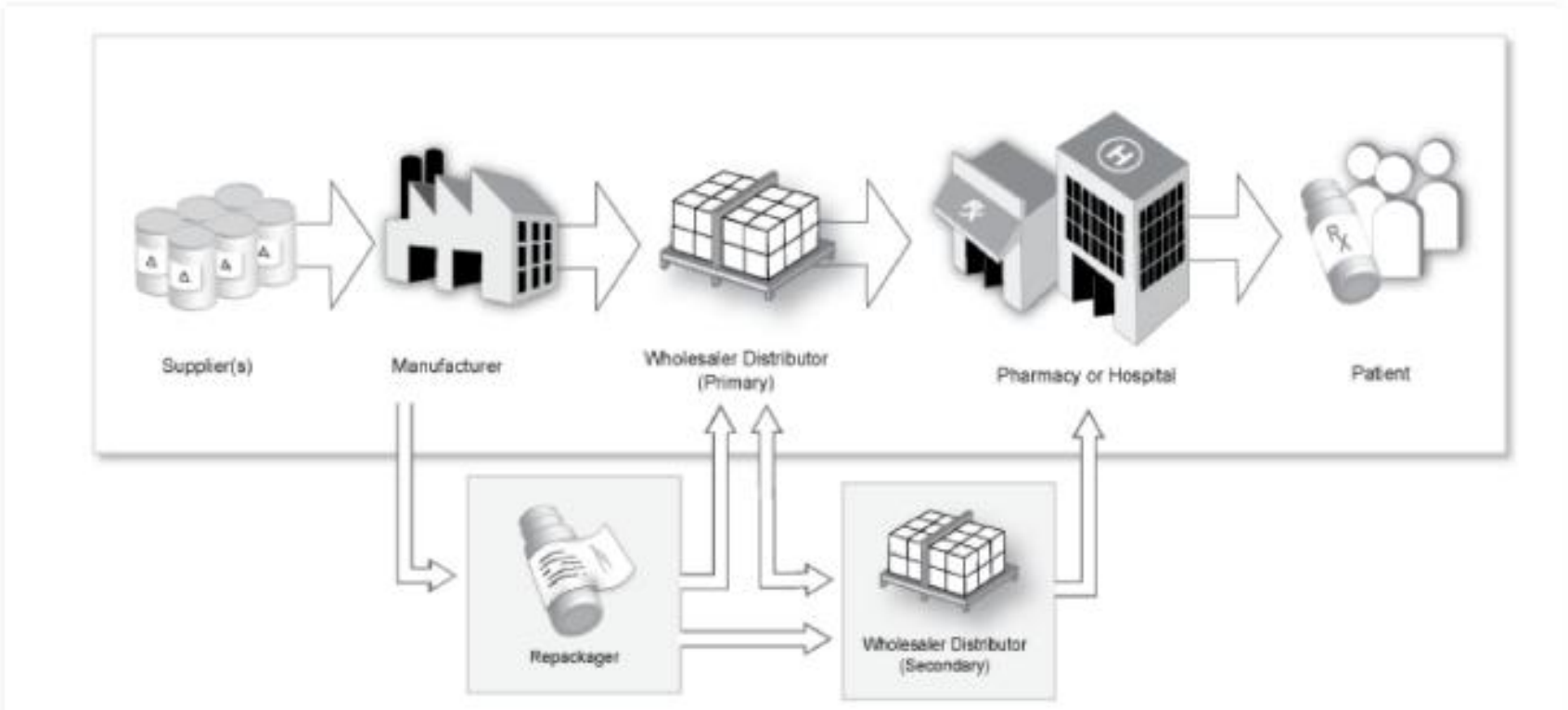
Normal Supply Chain for Drug Products



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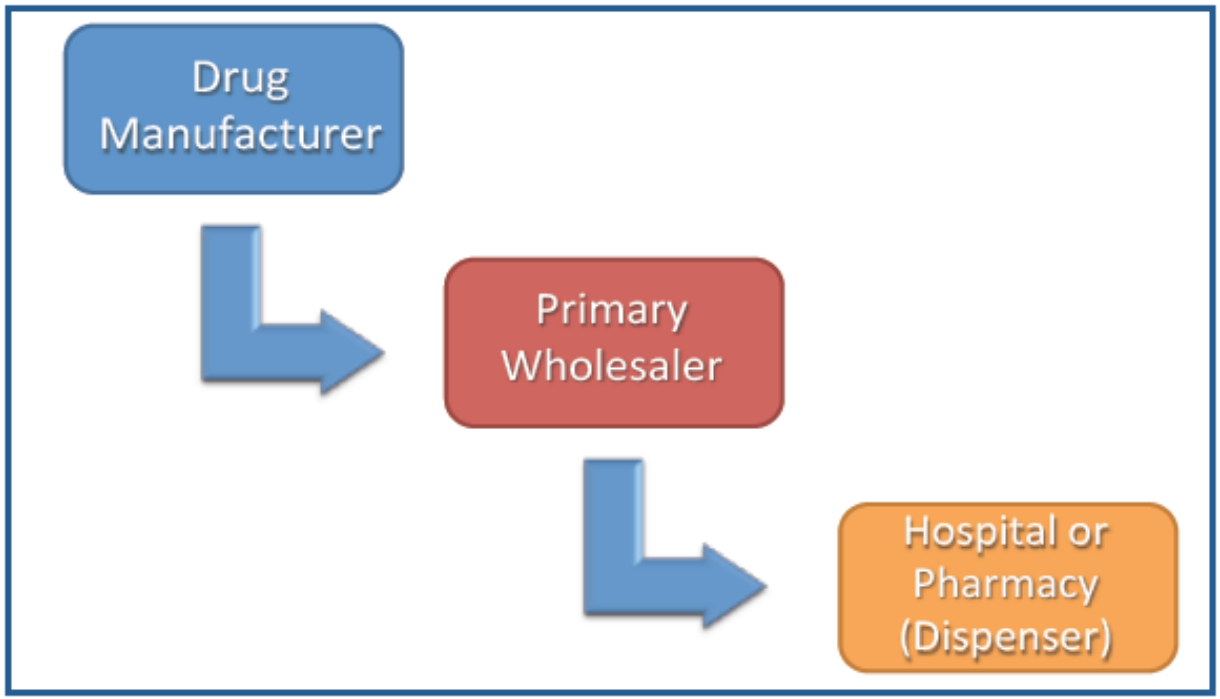
Commonly Understood Distribution Supply Chain



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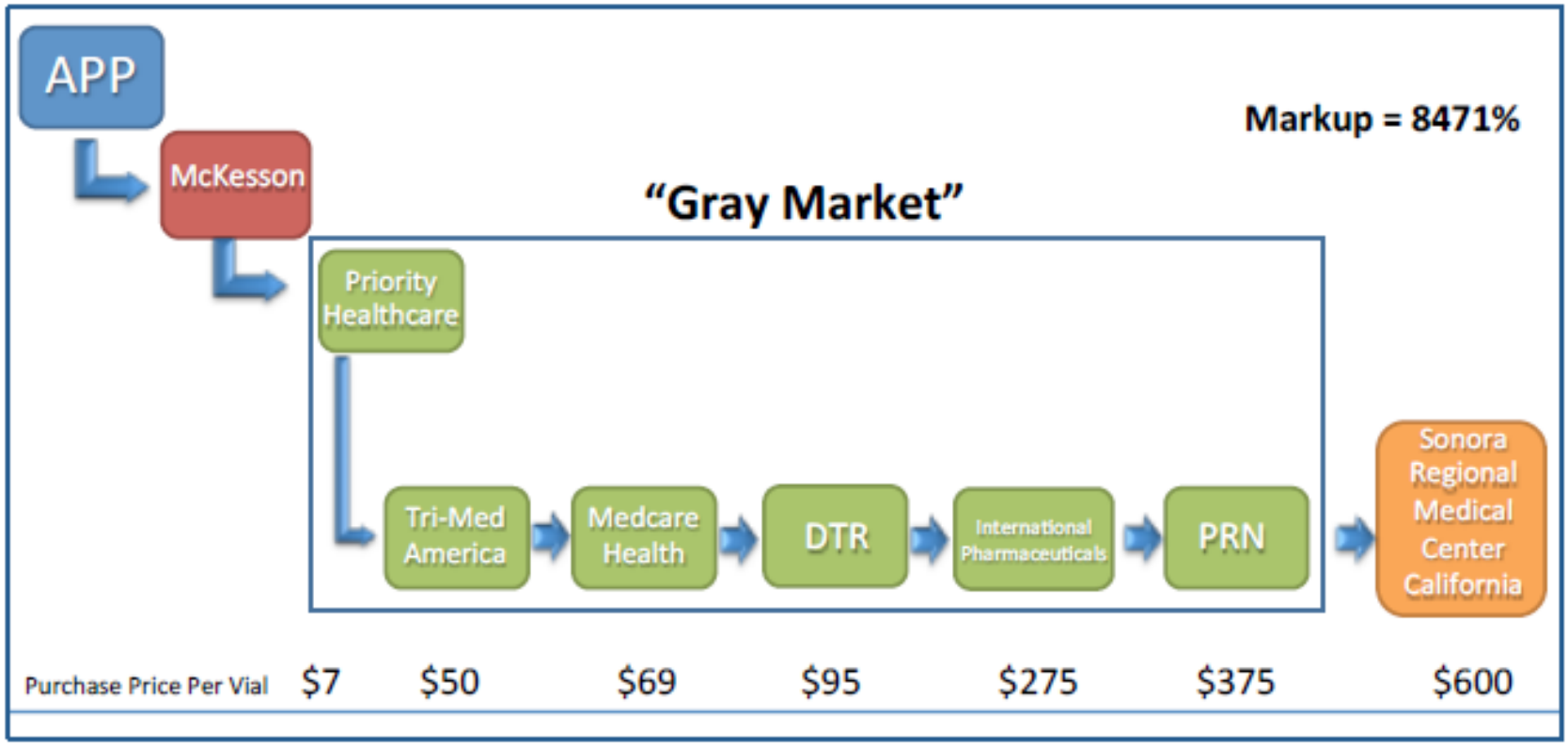

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Exhibit I
"Gray Market" Drug Distribution Shipment
25 Vials of Fluorouracil 2.5g/50mL

Drugs in the Gray Market: 9/23/11 – 9/27/11

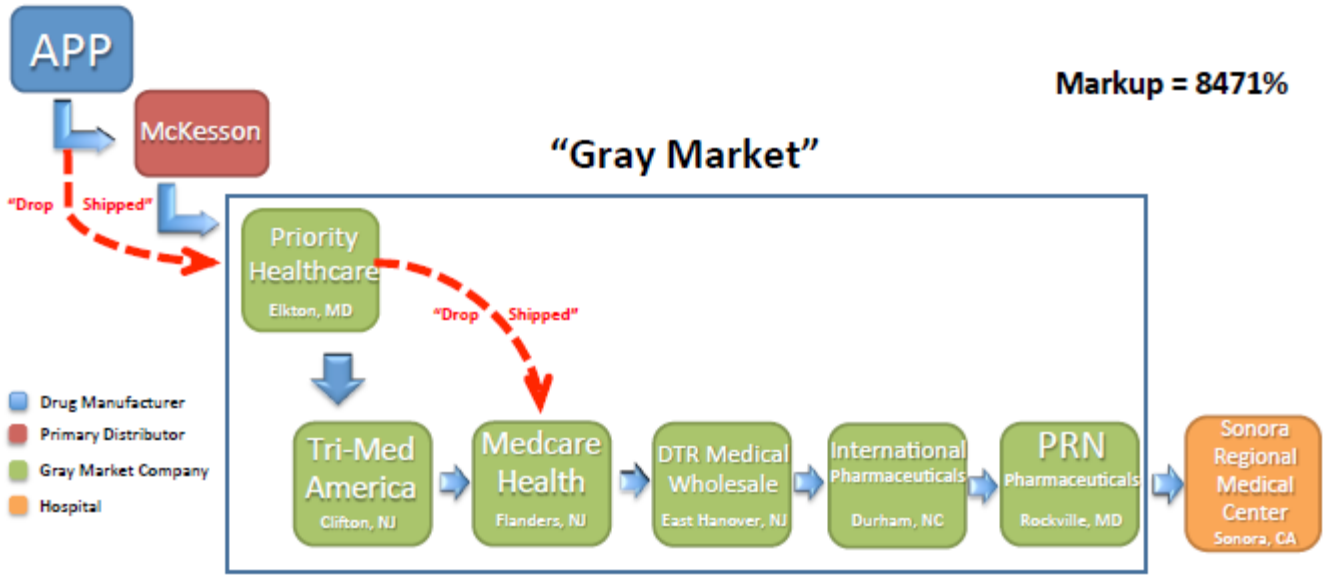

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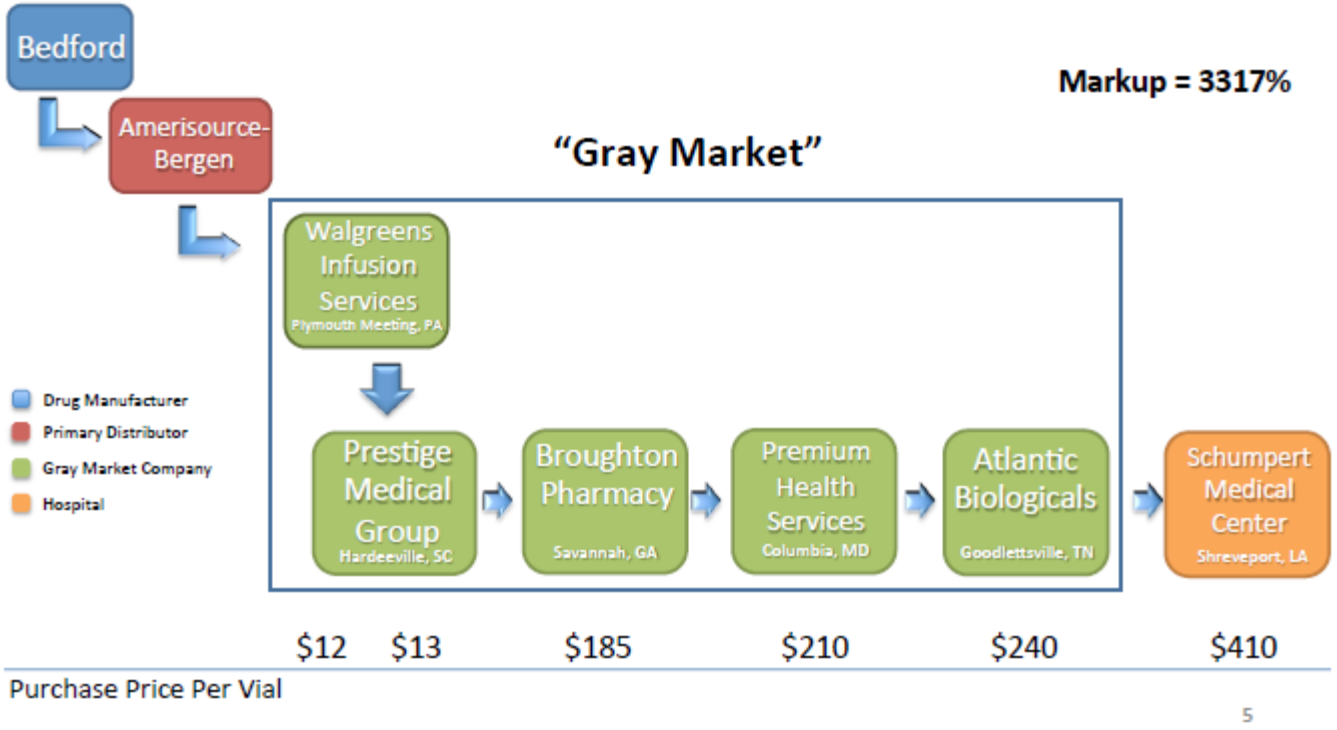
Exhibit V
"Gray Market" Drug Distribution Shipment
50 Vials of Leucovorin 200mg

Drugs in the Gray Market: 9/23/11 – 9/29/11



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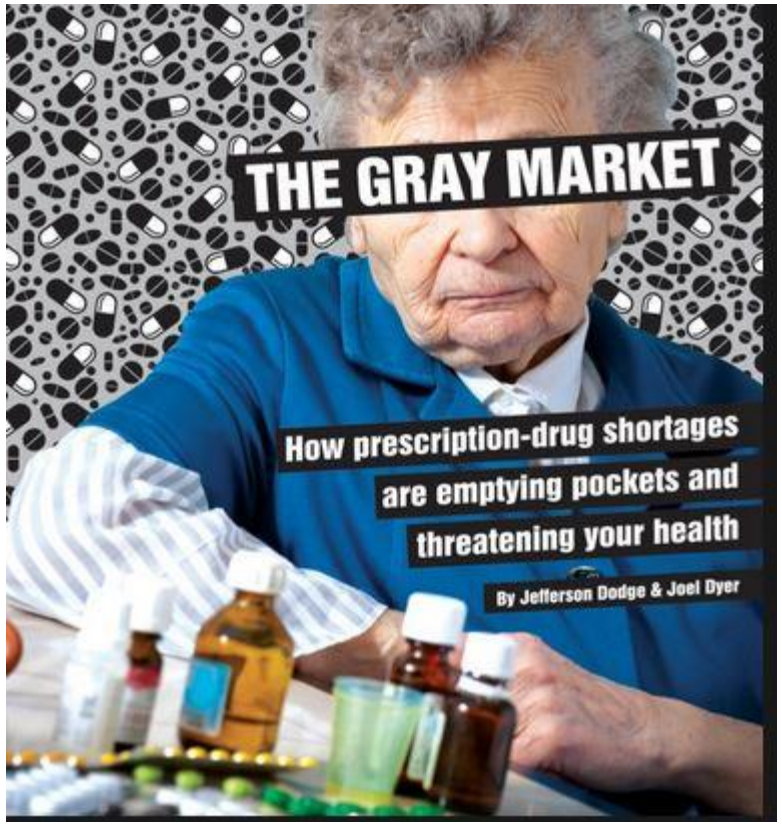
Dangers of Drugs from Gray Market

- Drugs from Gray Market may not be stored properly or they may be close to expiration
- Some of the drugs from Gray Market may be counterfeit, not approved by FDA, and lacking the active ingredient.



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in-Pharma Technologist.com

Breaking News on Global Pharmaceutical Technology & Manufacturing

NEWS IN BRIEF

FDA warns of fake Teva ADHD drug as shortage continues

30-May-2012

Related topics: Ingredients

The FDA has warned patients about counterfeit versions of a Teva ADHD drug that is on the drug shortage list.

Lab tests run by the US Food and Drug Administration (FDA) show the Adderall (amphetamine and dextroamphetamine) bought online is devoid of the four official active pharmaceutical ingredients. Instead, the tablets contain tramadol and acetaminophen, APIs used in the treatment of acute pain.

API supply problems at Teva have put Adderall on the shortages list and the FDA says counterfeit drug producers may especially target treatments consumers are struggling to find legitimately. The FDA updated its shortages list two weeks ago to say Teva is still releasing Adderall when available.

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Counterfeit Avastin: FDA Warns Of New Batch Of Fake Cancer Drug

02/06/13 11:56 AM ET EST AP

FOLLOW: Video, Counterfeit Avastin, Counterfeit Cancer Drug, Fake Avastin, Fake Cancer Drug, Healthy Living News

WASHINGTON — The Food and Drug Administration is warning U.S. doctors about another counterfeit version of the cancer drug Avastin, the third case involving the best-selling Roche drug in the past year.

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Compounding Pharmacies

- Compounding Pharmacies are a legitimate source of drugs.
- Traditional compounding is to tailor dosage forms for individual patient needs.
- But with shortages, more doctors have turned to compounders so some compounding pharmacies have been mass producing drugs.
- This has caused healthcare issues including the 2012 outbreak of meningitis causing severe illness and deaths.

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Drug Shortages in Canada

- Drug Shortages have also been a problem in Canada and we will summarize the causes and current situation of our neighbors north of the border.

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Drug Shortages Affect Clinical Trials

A longer term negative effect of the drug shortage is that clinical trials may have to be postponed due to lack of existing drug used in combination with or as comparator to the new drugs undergoing the clinical trial.

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Shortage of Doxil affected clinical trials of new cancer drugs.

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR

Published on FierceBiotech (http://www.fiercebiotech.com)

J&J's chemo drug shortage hits Amgen, Lilly, Endocyte trials

November 1, 2011 | By Ryan McBride

Got Doxil? Not only are thousands of patients waiting for their doses of the chemo drug in short supply, there's a long list of drug developers in need of Johnson & Johnson's Doxil for clinical trials of experimental therapies. *Dow Jones Newswires'* Peter Loftus took a look at how the shortage has hit home for multiple key drug programs for Amgen ($AMGN), Eli Lilly ($LLY) and small developer Endocyte ($ECYT).

There are 30 clinical trials that involve the use of Doxil either as part of a combo treatment or as a comparator drug for a control group, *Dow Jones* reports, and several of those trials have suffered delays or had to pause because of the shortage. The story comes on the heels of President Obama's big call to action for drugmakers and regulators yesterday on myriad drugs in short supply.

For Endocyte, the Doxil shortage impacts a trial for its lead drug EC145 for treating ovarian cancer. The developer has said that a prolonged shortage of the drug could delay its trial in which its compound is used in combination with Doxil, *Dow Jones* reports. Fortunately, that study has stayed on schedule, a spokeswoman told the news service. Yet Lilly's trial of a combo of Doxil and the drug tasisulam for ovarian cancer has slowed due to the shortage. For others, the problem is even worse.

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Drug Shortages & Clinical Trials

- At least 300 clinical trials funded by the National Cancer Institute include a drug that is in short supply, a Department of Health and Human Services official told a congressional committee last month. The shortages have many causes, including stricter price limits from the federal Medicare program, industry consolidation and manufacturing-quality problems. (2011)

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How Drug Shortages Affect Clinical Trials

- The impact of drug shortages on care of patients with cancer has been on the radar for well over a year. Equally important -- especially over the long term -- is the impact of oncology drug shortages on clinical trials.
- As of October 2011, 22 of the 267 drugs in shortage in the United States were cancer drugs. Currently, about 400 cooperative cancer group clinical trials are active, and about one half of these trials have at least 1 drug on the shortage list, according to a fact sheet from the Coalition of Cancer Cooperative Groups Website.[1] The shortages extend across the large network of 1800 research sites affiliated with the cooperative groups -- albeit unevenly, depending on region. Thousands of patients who have enrolled in clinical trials are affected, and the shortages slow down progress in identifying new anticancer therapies.

Opportunities

The Drug Shortage can present opportunities for API suppliers, CMOs, and Drug Manufactures

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Opportunities:

- High quality API producers
- Contract Manufacturers
- Drug Manufacturers – overseas and domestic

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Opportunity: Becton Dickinson

BD, a medical device and diagnostics company, formed its own pharmaceutical drug division, called BD Rx, and launched line of injectable products in ready to use syringes which reduces medical errors and time.

BD Rx

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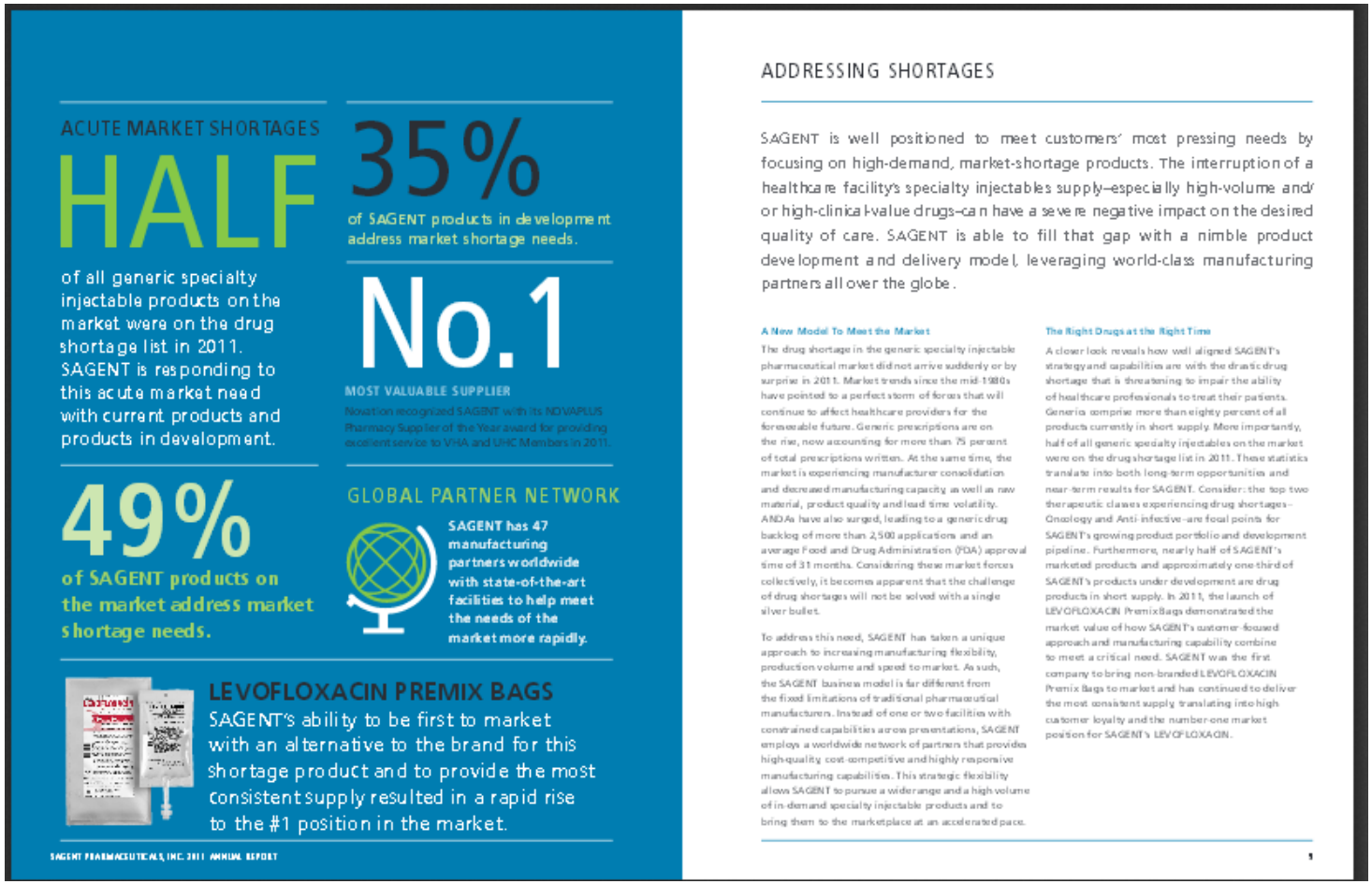
Opportunity: Sagent and Drug Shortages

Sagent was founded in 2006 to address need for hospital products. In 2011, at height of drug shortage, Sagent went public. It was the most successful IPO that year in the biopharma space.



ACUTE MARKET SHORTAGES

HALF

of all generic specialty injectable products on the market were on the drug shortage list in 2011. SAGENT is responding to this acute market need with current products and products in development.

35%

of SAGENT products in development address market shortage needs.

No.1

MOST VALUABLE SUPPLIER

Novation recognized SAGENT with its NOVAPLUS Pharmacy Supplier of the Year award for providing excellent service to VHA and UHC Members in 2011.

49%

of SAGENT products on the market address market shortage needs.

GLOBAL PARTNER NETWORK

SAGENT has 47 manufacturing partners worldwide with state-of-the-art facilities to help meet the needs of the market more rapidly.

LEVOFLOXACIN PREMIX BAGS

SAGENT's ability to be first to market with an alternative to the brand for this shortage product and to provide the most consistent supply resulted in a rapid rise to the #1 position in the market.

SAGENT PHARMACEUTICALS, INC. 2011 ANNUAL REPORT

ADDRESSING SHORTAGES

SAGENT is well positioned to meet customers' most pressing needs by focusing on high-demand, market-shortage products. The interruption of a healthcare facility's specialty injectables supply–especially high-volume and/or high-clinical-value drugs–can have a severe negative impact on the desired quality of care. SAGENT is able to fill that gap with a nimble product development and delivery model, leveraging world-class manufacturing partners all over the globe.

A New Model To Meet the Market

The drug shortage in the generic specialty injectable pharmaceutical market did not arrive suddenly or by surprise in 2011. Market trends since the mid-1980s have pointed to a perfect storm of forces that will continue to affect healthcare providers for the foreseeable future. Generic prescriptions are on the rise, now accounting for more than 75 percent of total prescriptions written. At the same time, the market is experiencing manufacturer consolidation and decreased manufacturing capacity as well as raw material, product quality and lead time volatility. ANDAs have also surged, leading to a generic drug backlog of more than 2,500 applications and an average Food and Drug Administration (FDA) approval time of 31 months. Considering these market forces collectively, it becomes apparent that the challenge of drug shortages will not be solved with a single silver bullet.

To address this need, SAGENT has taken a unique approach to increasing manufacturing flexibility, production volume and speed to market. As such, the SAGENT business model is far different from the fixed limitations of traditional pharmaceutical manufacturers. Instead of one or two facilities with constrained capabilities across presentations, SAGENT employs a worldwide network of partners that provides high-quality, cost-competitive and highly responsive manufacturing capabilities. This strategic flexibility allows SAGENT to pursue a wide range and a high volume of in-demand specialty injectable products and to bring them to the marketplace at an accelerated pace.

The Right Drugs at the Right Time

A closer look reveals how well aligned SAGENT's strategy and capabilities are with the drastic drug shortage that is threatening to impair the ability of healthcare professionals to treat their patients. Generics comprise more than eighty percent of all products currently in short supply. More importantly, half of all generic specialty injectables on the market were on the drug shortage list in 2011. These statistics translate into both long-term opportunities and near-term results for SAGENT. Consider: the top two therapeutic classes experiencing drug shortages – Oncology and Anti-infective–are focal points for SAGENT's growing product portfolio and development pipeline. Furthermore, nearly half of SAGENT's marketed products and approximately one-third of SAGENT's products under development are drug products in short supply. In 2011, the launch of LEVOFLOXACIN Premix Bags demonstrated the market value of how SAGENT's customer-focused approach and manufacturing capability combine to meet a critical need. SAGENT was the first company to bring non-branded LEVOFLOXACIN Premix Bags to market and has continued to deliver the most consistent supply translating into high customer loyalty and the number-one market position for SAGENT's LEVOFLOXACIN.

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Sun Pharma and Doxorubicin Liposome Injection

Hoping to Ease Shortage, FDA Fast-Tracks Generic Form of Cancer Drug

Agency says new availability of doxorubicin will help people battling malignancy

February 4, 2013 | RSS Feed | Print

HealthDay

MONDAY, Feb. 4 (HealthDay News) -- Seeking to ease potentially dangerous shortages of a key cancer drug, the U.S. Food and Drug Administration on Monday announced it had fast-tracked the approval of the first generic form of one such medication, Doxil (doxorubicin).

- FDA fast tracked Sun Pharma's ANDA due to J&J's Doxil Shortage caused by CMO's manufacturing issues and FDA consent decree

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Opportunity: Sun Pharma and Doxorubicin

In 2011, J&J's wrote Dear Doctor letter advising of shortage of Doxil which was produced at outside CMO. To relieve shortage of doxorubicin liposome injection, FDA in early 2012 allowed imports of Sun Pharma's Lipodox which was not yet approved by FDA. At the same time, FDA gave Sun's ANDA an expedited approval for their generic product.

Shot in the arm

- Doxil's chemical name doxorubicin hydrochloride liposome injection is on the USFDA's drug shortage list
- The approval is expected to boost export earnings of Sun, which has significant presence in the US
- Last Feb, the FDA allowed for the temporary importation of Lipodox, which is made by Sun Pharma

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Opportunity: Mylan Buys Agila

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Mylan Buys Agila Citing Global Injectable Drug Shortages as Driver

By Dan Stanton, 04-Mar-2013

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Mylan says its acquisition of Agila puts the generics company in a *"leading position"* in the injectables market.

During a conference call announcing end-of year results, Mylan said it had come to a definitive agreement to acquire Agila Specialities from Strides Arcolab for $1.6bn (€1.23bn), moving the generic pharmaceuticals firm further into the injectables manufacturing sector.

CEO Heather Bresch told shareholders the acquisition brings Mylan *"one of the most diversified, highest quality and state-of-the-art injectables manufacturing bases in the industry"* and that it would grow product capacity over 50 times *"overnight."*

Mylan President Rajiv Malik added that the acquisition *"helps to fill significant gaps in our injectables business in terms of contracting capacity and technical capabilities"* and is part of the company's strategy to become one of the top three injectables providers.

The deal brings more than 300 filings to Mylan's assets including 61 abbreviated new drug applications (ANDAs) approved by the FDA (US Food and Drug Administration). As for facilities, Agila comes complete with nine manufacturing plants - six in India, two in Brazil and one in Poland - of which eight have approval from the FDA.

The acquisition is Mylan's third in the market following its purchase of Merck KGaA's generic injectables division in 2007 and the 2010 takeover of Ireland's Bioniche . Furthermore, Mylan has more recently collaborated with Biocon in a long-term deal over a number of biosimilars.

Shortage of Injectables

According to Bresch, one of the main drivers for the deal was that 80% of drug shortages in the US were down to sterile injectables.

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