November 8, 2011

Dr. William Loui

Queen's Medical Center- Oncologist

Power Point Presentation Re: Drug Shortages

Drug Shortages

November, 2011

Why are there so many drugs in shortage?

Over the last ten years, the number of shortages has continued increase. There are many reasons for this increase in shortages and some of the causes are unpredictable and others are not.

- At any given time, the FDA or the American Society of Health-System Pharmacists reports a list of current drug shortages.
- As of 10/18/2011 over 200 drugs are listed as being on drug shortage nationally
- QMC is typically experiencing drug shortages or limiting supplies

- National shortage.

Why are there so many drugs in shortage?

Unpredictable Causes:

- **Natural Disasters** – can cause shortage by affecting the plants involved in the sole production of a product.
- **Raw Material Shortages** – particular problem when multiple manufacturers are producing a drug product from which there is only one source of raw material
- **Non-compliance with Regulatory Standards** – when the primary or sole manufacturer of a product has its production halted by the FDA for reasons such as not adhering with Good Manufacturing Practices (GMPs)
- **Voluntary Recalls** – a recall may create shortages, particularly when one company manufactures the majority of a product. (e.g., Clindamycin premix bags)

Why are there so many drugs in shortage?

Predictable Causes:

- **Business decisions** – firms may decide to reduce or discontinue production of a drug product – due to lack of financial return, poor demand or safety issues; newer products continue to replace older products due to better safety profiles, better efficacy, more convenient dosing regimens, etc.

- **Industry Consolidations** – company mergers may result in decisions to discontinue products and narrow the focus of the product line.

- **Market shifts** – the addition of a generic product to the market may precipitate a decrease in manufacture of the innovator product and cause temporary reduction in supply; military conflict can cause temporary market shifts.

Why are there so many drugs in shortage?

Predictable Causes:

- **"Gray" Market Vendors** - vendors may create artificial shortages by selectively purchasing excessive quantities of products and thereby deplete the available stock. These vendors then resell products back to users at inflated prices.

- **Prime Vendors and Just-In-Time Inventory** – increased use of prime vendors may have contributed to the drug shortage situation by reducing the amount of product available in the supply chain. Both wholesalers and hospitals maintain minimum levels of stock (no stockpiling). Thus, manufacturer supply issues are transmitted directly to the end user without benefit of an inventory buffer.

Notification of Shortages

- Manufacturers will report shortages to FDA
- Often, the first indication of a shortage may be when we place a supply order with our wholesale distributor and are then informed by them that it is on allocation or back-order.
- Links to current drug shortages:
  - ASHP website
    - http://www.ashp.org/DrugShortages/Current/
  - FDA website
    - http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm

Once a drug is determined to be in shortage, what happens next?

- The FDA determines whether the drug in shortage is a medically necessary drug product.

- A medically necessary drug is defined as a product used to prevent or treat a serious or life-threatening disease or medical condition for which there is no other available source of that product, alternative drug or therapy available

- The approved and unapproved ("off-label") uses of a product are taken into consideration.

What can FDA do about drug shortages?

In the past, FDA has no regulatory authority over most shortages.

- Expedite review of submissions from manufacturers – these submissions may be in support of a marketing application for a new product (NDA or ANDA), or may be in support of manufacturing changes which will allow a product to be available. Identify alternate manufacturers that can initiate or ramp-up production
- Find new/additional sources of raw material
- Advise/consult with sponsors on resolution of manufacturing issues
- Allow temporary import of a non-US product, in rare instances
- New Executive Order by President Obama 11/2011
  - Advance notice of drug production stoppage
  - Expedited review of any critical drugs in short supply
  - Refer exorbitant markups for possible prosecution
  - Look for alternative sources.

Process at QMC

Per Medical Staff Policy

- In the event of medication shortages or outages, pharmacy services consults with Medical Staff leadership to conserve supply and mitigate impact
- Time permitting, substitution protocols will be developed/approved thru MNC & MEC.
- In emergent situations, substitution protocols may be approved by the MNC Chairperson and Chief of Staff.
- Communication regarding shortages through MNC, MEC and Department meetings as well as CareLink

Systems Impacts

- Outages often require significant expenditure of resources to make changes

Recent Shortages

- Bleomycin
  - Supply limited – Vials currently on back order from multiple manufacturers
- Cisplatin
  - Supply adequate – drug on backorder from multiple manufacturers (limited supply available)
- Cytarabine
  - Supply adequate – increased availability from multiple manufacturers
- Dacarbazine
  - Supply adeuate – increased availability from multiple manufacturers
- Daunorubicin
  - Few vials left. Not enough to treat patients. Currently on backorder from Bedford and limited supply from Teva.
- Dexamethasone
  - Supply adequate – intermittent backorders
- Liposomal doxorubicin
  - Patients need to be enrolled in DoxilCares program – currently patients are waitlisted as demand is greater than supply

Recent Shortages

- Famotidine
  - Adequate – backorders from multiple manufacturers
- Fentanyl
  - Limited quantity – pharmacy drawing up syringes – backorder from multiple manufacturers
- Fluorouracil
  - Stable – intermittent backorders
- Granisetron
  - Supply = 0 – allocated 20 vials of 1 mg/month. Brought in 4 mg/4ml multi dose vials
- Idarubicin
  - Adequate – discontinuation of production from multiple manufacturers
- Irinotecan
  - Adequate – discontinuation of production from multiple manufacturers
- Leucovorin
  - Adequate – still with manufacturing delays
- Methotrexate
  - 100 mg vials on backorder – still adequate supply of 1 gram vials

Recent Shortages

- Mitomycin
  - Limited supply – call pharmacy before ordering
- Paclitaxel
  - Supply stable – multiple manufacturing delays
- Thiotepa
  - US product unavailable – imported from Italy approved by FDA

SUMMARY

- Vital Drugs in Short Supply Nationwide
- Critical Shortages
  - Chemotherapy for cancer
  - Antibiotics for severe infections
  - Anesthetics for surgery
  - Pain meds
- Executive order 11/2011

Statement PhRMA

Hawaii Senate Committee on Health
Informational Briefing On Prescription Drug Shortages
November 8, 2011

Patient access to innovative treatments is the cornerstone of the drug research industry. It is for that reason the critically important issue of [1]drug shortages demands our collective attention to ensure patients can access the medicines they need in the most expeditious manner possible. America's innovative biopharmaceutical companies have long worked to prevent drug shortages in advance, and will continue to work closely with the FDA and others to prevent manufacturing disruptions and other problems that can lead to drug shortages.

While the Majority of Drugs Experience Shortages Are Generic, Innovator Companies Are Working with All Stakeholders to Identify Creative Solutions to Help Solve the Problem of Drug Shortages.

Currently, shortages are primarily affecting generic sterile injectable products. For example, in 2010-2011, sterile injectable products accounted for nearly 80% of all shortages.[2] Nevertheless, innovator pharmaceutical companies take seriously the ongoing drug shortages and have made significant financial investments to put in place processes to ensure supplies of branded medications.

Drug Manufacturers Are Already Working with FDA to Help Avert Drug Shortages. Manufacturers' Actions, in Collaboration with FDA, Have Helped to Avert 99 Drug Shortages in 2011.

In those rare instances when an innovative biopharmaceutical company may suffer an unavoidable disruption in the supply of medicines, our companies alert the FDA and work collaboratively to identify alternative options to minimize any potential disruption in patient care. Under current U.S. law, innovator and generic manufacturers of certain types of critical drugs are required to notify the FDA of a discontinuance of the manufacture of the drug at least six months prior to the date of that discontinuance. The law applies to innovator and generic drugs that are life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition. FDA currently maintains a drug shortages database of certain categories of products and there are lessons to be learned from the collaboration and coordination between industry and FDA that has helped to alleviate or prevent drug shortages. In 2011, for example, FDA and pharmaceutical companies helped to prevent 99 drug shortages.

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[1] According to the FDA, 74% of all reported drug shortages involved generic sterile injectable products in 2011, and among the approximately 80 manufacturers making sterile injectables in 2010, about 40 experienced a shortage. See "A Review of FDA's Approach to Medical Product Shortages, U.S. Food and Drug Administration" (October 31, 2011).
[2] Id.

Increased Demand and Other Problems Have Contributed In Part to the Drug Shortage Problem But Manufacturers Are Working to Respond and Meet Demand.

One government report found that the market (and demand) for sterile injectable products, particularly oncology products, is robust and growing. According to a recent White House Executive Order, the use of sterile injectable cancer treatments has increased by 20 percent, without a corresponding increase in production capacity.[3] Therefore, the current shortages appear to be at least in part a consequence of a substantial expansion in the scope and volume of products over a period of time, without a corresponding expansion in manufacturing capacity, as well as disruptions in supply through quality problems. According to the ASPE report, many manufacturers have stated they are renovating or upgrading existing facilities or building new facilities to address capacity issues. The report also states that these investments will increase capacity and should help to mitigate the shortages problems.

Imposing Hasty Draconian Solutions on the Drug Shortages Problem Will Not Solve the Problem and May In Fact Exacerbate Drug Shortages.

The fact of the matter is drug shortages can occur for any number of reasons. Several experts, for example, have noted that the problem of drug shortages is complex and stems from economic, legal, regulatory, policy and clinical decisions that are deeply inter-connected and involve numerous stakeholders including the government, manufacturers, distributors, providers, patients and payors.[4] Some of these contributing factors may be unanticipated and at times unavoidable and defying simple solutions that can resolve the drug shortage problem quickly. Nevertheless, we all must redouble our efforts to identify what is working and work with all stakeholders to find multifaceted and sophisticated solutions to the drug shortage problem and ultimately protect patients. For that reason, PhRMA, innovator companies and other stakeholders continue to work diligently to find effective and rational options so that patients will not fact the terrible situation of a drug shortage.

[3] Executive Order, Reducing Prescription Drug Shortages, October 31, 2011.
[4] Factors that can lead to drug shortages include: shifts in clinical practices, wholesaler and pharmacy inventory practices, raw material shortages, changes in hospital and pharmacy contractual relationships with suppliers and wholesalers, adherence to distribution protocols mandated by the FDA, individual company decisions to discontinue specific medicines, natural disasters, and manufacturing challenges.

HDMA
Healthcare Distribution Management Association

November 7, 2011

The Honorable Sen. Joshua Green
Hawaii State Capitol
Room 222
Honolulu, Hawaii 96813

Dear Senator Green:

On behalf of Healthcare Distribution Management Association (HDMA) and full service wholesale drug distributor members serving Hawaii, HDMA respectfully submits the following information which may be helpful to you in light of the upcoming committee briefing on drug shortages. Each business day, HDMA's member companies ensure that nearly nine million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, nursing homes, clinics and others nationwide. In fact, approximately 90 percent of all pharmaceutical product sales in the United States flow through HDMA distributor members.

As an advocate for the safe, reliable, and efficient distribution of the nation's healthcare products supply, HDMA shares your concerns regarding public health and safety. HDMA's members are primary distributors – they buy predominately from pharmaceutical manufacturers and sell only to appropriately licensed customers, the vast majority of which are pharmacies and other healthcare providers. Pharmaceutical products are distributed through a highly coordinated supply chain that is designed to provide maximum efficiency. In sum, distributors serve to maximize efficiencies between manufacturers and healthcare providers by managing a complex supply network.

Through their unique position and close partnerships with supply chain stakeholders, HDMA members are acutely aware of the impact of drug shortages, especially on patients. Effectively addressing a drug shortage is a difficult and complex challenge for the entire healthcare community, in large part because a shortage typically occurs with little or no warning and often requires significant resources to manage.

HDMA and our member companies are working to improve communications within the supply chain and, where possible, to mitigate the impact of drug shortages. Distributors are typically notified of a shortage by either a manufacturer or provider partner. Once information is received, distributors communicate with their manufacturer partners about product availability to understand the scope and expected duration of any shortage. They then work as quickly as possible with their customers to fill orders, to the extent they are able, or if necessary, to identify alternative products.

HDMA is currently working with its distributor members, along with manufacturers and provider groups, to update voluntary industry guidelines on improving communication between supply chain partners. Also, HDMA recently testified before the House Energy and Commerce Health Subcommittee in Congress, as well as participated in FDA activities surrounding drug shortages. We hope these efforts will contribute to improved management of product shortages in the future. HDMA strongly believes that the healthcare industry as a whole, the government and stakeholders must continue to work together toward collaborative solutions that mitigate the impact drug shortages have on the most important stakeholder: the patient. To that end, I thank you again for allowing us to submit written comments and hope this overview was valuable to the Committee as it explores this important and timely topic. If you have any questions or need additional information, please do not hesitate to contact me at 703-885-0236

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Sincerely,

Daniel G. Bellingham
Director, State Government Affairs
Healthcare Distribution Management Association

November 7, 2011

To: Senator Josh Green, M.D., Chair
Senator Clarence K. Nishihara, Vice Chair
Senate Committee on Health

From: Shelby D. Fletcher, Director of Government Relations
Pfizer, Inc.

Re: Informational Briefing on Medication Shortages in Hawaii
Tuesday, November 8, 2011
10:00 a.m.
Conference Room 225
415 South Beretania Street

Dear Chair Green, Vice Chair Nishihara and Members of the Committee:

A key issue that continues to emerge both in the media and in Congress is the issue of drug shortages. Drug shortages in the US have been occurring with greater frequency in recent years and have climbed to historical highs. The FDA cites 178 shortages in 2010 and 200 shortages to date in 2011. Recent drug shortages are mostly focused on older sterile injectables (such as cancer agents and surgical anesthetics) and are largely due to manufacturing issues. **Pfizer has been actively engaged in the drug shortage conversation with key Members of Congress, patient advocates and other stakeholders, and we understand the importance of ensuring patient access to the medications and treatments they need. This is why Pfizer works hand-in-hand with our partners in the health care system to ensure as much as possible that Pfizer products are available to patients and providers to help address drug shortages.**

Pfizer not only works to prevent a disruption in supply before it occurs, but delivers quality brand and generic medicines to help resolve drug shortages in the U.S. Pfizer's overall supply performance is above 95% and we remain committed to improving our performance to help ensure that all of our patients can count on an uninterrupted supply of the many medicines we develop and manufacture. There is no higher priority than ensuring that patients have safe and effective medicines. It is critical that patients receive high quality medicines from a reliable and secure supply source. Pfizer maintains high quality standards, supplier reliability, and requires adherence to comprehensive processes and practices in the manufacturing of Pfizer medicines.

Thank you very much for the opportunity to testify.

Complexities of the Pharmaceutical Supply Chain

The pharmaceutical supply chain is the process through which prescription medicines are manufactured and ultimately delivered to the patient. The supply chain consists of all parties involved, directly or indirectly, in fulfilling a customer request. The supply chain not only includes the manufacturer and suppliers, but also transporters, warehouses, retailers, and customers themselves.

In general, the supply chain begins for pharmaceuticals as the product originates in manufacturing sites, transferred to wholesale distributors, stocked at retail, mail-order, and other types of pharmacies, priced and processed through by pharmacy benefit management companies (PBMs), dispensed by pharmacies and ultimately delivered to and taken by patients.

With the number of products, manufacturing sites, and suppliers that Pfizer has there are virtually hundreds of events occurring every day that could impact the supply of prescription drugs. This is why Pfizer works closely with the Food and Drug Administration (FDA), supply chain partners and providers to ensure a secure supply of Pfizer's high-quality products whenever and wherever they are needed around the world.

Why do shortages occur?

- **Raw Material, Shortages and Supply Problems –** Problems with or shortages of critical raw materials and active pharmaceutical ingredients (API) needed to create a medicine can cause shortages.
- **Manufacturing Difficulties –** Creating medicines is a highly complex process and pharmaceutical companies follow strict quality guidelines called current Good Manufacturing Practices. Despite a carefully managed and supervised scientific process, manufacturing difficulties can arise. Often, multiple products are produced in the same facility, which means that quickly increasing production of one product could result in a delay and potential shortages for another product manufactured on the same production line.

- **Shifts in Clinical Practice –** Temporary shortages may occur when public health recommendations are altered, such as expanding age groups to be vaccinated.

- **Increased Market Demand –** The demand may rise unexpectedly and create a shortage.
- **Hospital-Based or Pharmacy Issues/Supply Chain Issues between Distributors and Customers –** In some cases, contractual relationships with suppliers and wholesalers can cause fluctuations in the availability of certain products, and adhering to FDA-mandated distribution protocols can impair patients' timely access to medicines.

- **Inadequate Inventory –** Hospitals and pharmacies may fail to stock sufficient quantities of medicines or make advance purchases.

- **Illegitimate Market Diversion –** Third party distributors may hoard, stockpile or raise prices to create or to exacerbate a drug shortage.

- **Legitimate Market Diversion –** Medicines may be diverted to meet critical needs.
- **Market Withdrawal/Product Discontinuation –** Sponsors may replace older medicines with newer products with improved safety, efficacy or more convenient dosing. Or, the discontinuation of a medicine by one manufacturer may result in a shortage if other manufacturers cannot increase supply to meet demand.

- **Consolidation –** Individual companies may consolidate for a number of business reasons, triggering product consolidations or changes in the production pool.

- **Voluntary Recalls –** Companies may need to initiate voluntary recall of a product, for medical or manufacturing reasons, which can cause a shortage of that product and trigger shortages of therapeutic alternatives.

- **Emergencies and Natural Disasters –** Natural disasters may disrupt availability of API or final drug product, making it difficult to meet demand.

Supply Chain Complexity

PLAN

- Global demand, we have a presence in virtually every country
- > 400 products, > 10,000 configurations
- Patient usage can be difficult to forecast due to dosing compliance, seasonality, distributor/wholesaler practices, etc.
- Some events can cause significant demand increases (currently 10 products with 300% – 700% increases due to competitor supply/quality issues)

SOURCE

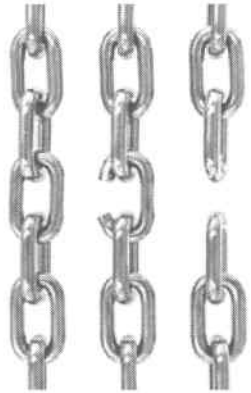
- Thousands of raw materials, can be dozens for a single product
- Thousands of suppliers, each with inherent risks
- Cost and regulatory prohibitive to mitigate risk via dual sourcing
- Limited visibility into supplier's operational risk
- Our supplier's have suppliers with similar uncertainties

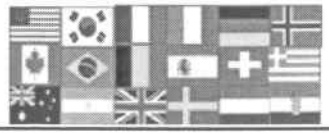
MAKE

- > 400 internal sites and external toll manufacturers
- Global manufacturing network
- Some products involve as many as 6 manufacturing steps and cross 5 manufacturing sites
- Some API's involve > a dozen synthetic steps
- Intensive testing and quality control add months to manufacturing time
- Cost and regulatory prohibitive to mitigate risk via redundant capacity

DELIVER

- Transportation outsourced and capacity constrained
- Ocean lead times 2 – 4 months
- Occurrences of truck and container theft
- Cold chain shipping more challenging





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Testimony of
Karen Ching, MD,
Hawaii Permanente Medical Group
and
Barbara Kashiwabara, RPh, PharmD,
Director, Pharmaceutical Services, Kaiser Permanente Hawaii

Before the
Senate Committee on Health
Honorable Josh Green M.D., Chair
Honorable Clarence K. Nishihara, Vice Chair

November 8, 2011
10:00 am
State Capitol Room 225

Re: Informational Briefing about medication shortages in Hawaii and nationally

Chair Green and committee members; thank you for the opportunity to provide information about medication shortages and how shortages affect our community and in particular, patients at Kaiser Permanente Hawaii.

My name is Dr. Karen Ching, I am a Nephrologist and the Chief of Pharmaceutical Services for the Hawaii Permanente Medical Group. With me is Barbara Kashiwabara, PharmD and registered pharmacist, who is the Director of Pharmaceutical Services for Kaiser Permanente Hawaii.

Medication shortages for Kaiser Permanente patients are not a new concern. In fact, it is now more "routine" than ever before, with dedicated resources and a Kaiser Permanente National webpage just for tracking & providing information to our practitioners & staff across the country about significant drug shortages. It is also well known that shortages of routine, common medications have been occurring for several years, and at a higher frequency, creating not only multiple changes in therapies & treatment regimens, but also inserting uncertainty, unfamiliarity & potentially unsafe conditions in an already complex medication use process. Despite these challenges, we are not aware of any Kaiser Permanente patient who has not received appropriate treatment for his or her condition, even if the drug of first choice was not available.

Department of Pharmaceutical Services
501 Alakawa Street, Suite 101
Honolulu, Hawaii 96817
808-432-5547
Karen.I.Ching@kp.org
Barbara.Kashiwabara@kp.org

KAISER PERMANENTE®

At Kaiser Permanente, we use an integrated, inter-departmental, multidisciplinary approach to manage drug shortages, focusing on the following goals:

- ✓ Ensure continuity of drug supply with minimal or no disruptions in patient care
- ✓ Provide appropriate communication to practitioners, members and patients, when necessary
- ✓ Develop strategies to control available inventory
- ✓ Work directly with physicians/high prescribers to identify therapeutic alternatives
- ✓ Identify potential safety concerns
- ✓ Initiate messaging in KPHC (our electronic medical record)

As you may know, the issue of medication shortages has received much attention from the federal government and Congress recently, through various hearings and workshops. And on October 31, 2011, President Obama signed an executive order that "directs the FDA to broaden reporting of potential shortages, speed up regulatory reviews that can help prevent or respond to shortages, and work with the U.S. Department of Justice to examine whether potential shortages have led to illegal price gouging or stockpiling." Kaiser Permanente welcomes any process that ensures the availability of appropriate & affordable drug therapies for our patients.

Thank you again for the opportunity to provide comments on this topic.

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HMSA

Blue Cross
Blue Shield
of Hawaii

An Independent Licensee of the Blue Cross and Blue Shield Association

November 8, 2011

The Honorable Josh Green, M.D., Chair
The Honorable Clarence Nishihara, Vice Chair
and Members
Senate Committee on Health

Re: Vital Medication Shortages

Dear Chair Green, Vice Chair Nishihara and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the invitation to comment on the issue of drug shortages. HMSA is very much aware of the concern over the problems with shortages of certain drugs, especially as they may affect the care of our members.

It is for this reason that, while we always want to ensure the quality, effectiveness, and appropriateness of medications, HMSA, generally, has not objected to the use of alternative medications, particularly as they apply to oncology cases. We are sensitive to needs of our members and the concerns of providers who care for them.

We recognize, however, that this issue of drug shortages goes beyond Hawaii and is of national concern. We are appreciative of the President recently taking action to immediately begin addressing this issue. These actions include:

- Issuing an Executive Oder to allow the Federal Drug Administration (FDA) to require early notification of circumstances that could lead to potential drug shortages.
- The Executive Order also requires the FDA to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes.
- Reminding drug manufacturers, in writing, of their legal responsibility to report discontinuation of certain drugs to the FDA.
- Increasing the personnel resources of the FDA's Drug Shortages Program to address early notifications.

We recognize that these actions alone will not resolve the problem of drug shortages. However, we applaud the President and this Committee bringing forward this critical issue. We are appreciative of any effort that may result in the availability of drug therapies needed for the proper care of our members.

Thank you for the opportunity to provide these comments today.

Sincerely,

Mark K. Oto
Director
Government Relations

American Cancer Society®

THE OFFICIAL SPONSOR OF BIRTHDAYS.™

November 8, 2011

Senator Josh Green, Chair
Senator Clarence Nishihara, Vice Chair
Senate Committee on Health
State Capitol Room 225
415 S. Beretania Street
Honolulu, Hawaii 96813

Informational Briefing
10:00 a.m.

Comments provided by the American Cancer Society regarding Drug Shortages
Cory Chun, Government Relations Director

Thank you for the opportunity to share comments regarding drug shortages today. The American Cancer Society (ACS) is the nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy, and service.

The American Cancer Society and the American Cancer Society Cancer Action Network (ACS CAN), the advocacy arm of ACS, are both currently tracking the problem and would like to thank the Committee for bringing attention to this issue. Drug shortages have a devastating effect on health care providers, service organizations, and the treatment of patients. ACS and ACS CAN are deeply concerned over shortages of cancer therapy drugs; medications that have the ability to effectively fight cancer to prolong and enhance a cancer patient's life.

Summary of the problem

According to the U.S. Food and Drug Administration (FDA), sterile injectable drugs account for 80% of all shortage medications.[1] Sterile injectable drug shortages are generally caused by:

1) Not enough manufacturing capability;
2) Industry consolidation, including:

[1] See U.S. Food and Drug Administration, Webinar on Prescription Drug Shortages, September 30, 2011. <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm272223.htm> Retrieved on 11/3/11.

a. Fewer manufacturers making these products;
b. Only seven manufacturers make-up a large percentage of the market; and
c. Contract manufacturing – firms that contract out manufacturing or act as a contract manufacturer.

3) Lack of redundancy, having multiple products made on existing manufacturing lines;
4) Complex manufacturing processes; and
5) Production of certain drugs is generally not economically attractive.[2]

In a recent report, the FDA concluded that there are many factors that go into the drug shortage problem, including economic, legal, regulatory, policy, and clinical decisions.[3] Because of the complexity of the problem and the fact that the FDA cannot force a manufacturer to produce a certain drug, the FDA is looking the pharmaceutical industry to assist in addressing the problem.

Efforts to address the problem

The FDA has seen a significant increase of drug shortages since 2005. This increase has led the FDA to take proactive steps to mitigate the drug shortage problem. On October 31, 2011, the FDA sent a letter to all drug manufacturers asking for their voluntary participation in reporting potential shortages. The FDA also issued a report on what steps it intends to take, both short-term and long-term, in order to address the problem. The FDA's short term goals are:

- Write a letter to drug manufacturers reminding them of their current legal obligations to notify FDA in advance of the discontinuation of certain drugs and urging them to voluntarily notify FDA of other potential disruptions to the supply of drugs that are not currently required, as soon as they become aware of them;
- Develop guidance and regulations that clarify and enhance the information on potential drug shortages that is submitted by industry;
- Provide additional staffing resources for FDA's efforts to prevent and mitigate shortages;
- Support legislation that requires early notification by manufacturers for drug shortages and provides new authority to FDA to enforce these requirements; and
- Implement and maintain a database that can analyze the characteristics of drug shortages.[4]

Also on October 31, 2011, President Obama issued an executive order to allow the FDA broader authority to require drug manufacturers to provide advance notice off possible

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[2] *See* U.S. Food and Drug Administration, *Webinar on Prescription Drug Shortages*, September 30, 2011. <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm272223.htm> Retrieved on 11/3/11.
[3] See U.S. Food and Drug Administration, A Review of FDA's Approach to Medical Product Shortages, October 31, 2011, at 3.
[4] *See* U.S. Food and Drug Administration, *A Review of FDA's Approach to Medical Product Shortages*, October 31, 2011, at 36-37.

shortages. The order, while not a permanent fix to the drug shortage problem, highlights the disconnect between the FDA, drug manufacturers and those in the manufacturing chain, health care facilities, and patients. ACS CAN released a statement that same day in response to the executive order. Chris Hansen, president of ACS CAN, stated "The presidential executive order issued today is an essential step to address the growing drug shortage crisis, which is denying people with cancer access to the lifesaving medications they need."[5] The executive order is similar to the Preserving Access to Life-Saving Medications Act (S. 296 and H.R. 2245), which would give the Food and Drug Administration the ability to receive advance notification from drug manufacturers about factors that could lead to drug shortages.

Reported medication shortages

We reached out to our community health and medical centers and discovered they are indeed having problems locally with a lack of medication for patients. Certain chemotherapy medications, a critical piece to cancer treatments, as well as other drugs used in cancer treatment have been unavailable for some time. While not all of the medical centers were able to respond in time, there was some information provided to us.

The following medications have been unavailable at Maui Memorial Medical Center for more than six months: Taxol, 5FU, Leucovorin, Doxil, Magnesium, Morphine, and Fentanyl. Having a shortage of these medications severely hampers the ability of health care providers to ensure the best possible individualized cancer treatment options. Some of these medications are considered the first-line therapies for cancer patients.

Effects of medication shortages

ACS and its affiliate, ACS CAN, are deeply concerned over the national medication shortage. In some instances, a lack of medication is a matter of life and death. We believe that cancer patients should have access to any life-saving medications or treatments that could potentially increase their enjoyment of life. Absence of these medications not only threatens lives, but strikes at the security and health of the entire population.

The drug shortage crisis also causes tension between patients and health care providers. Even though a physician is not the cause of a drug to be unavailable to a patient, they nonetheless are sometimes blamed for providing different treatments or therapies other than the one best suited to manage the medical condition. Dr. Amy Chen, the American Cancer Society Director of Health Services Research, says the shortages are affecting about 10% of the patients in her clinical practice.[6] When patients cannot receive medications because they are unavailable, the frustrated patients usually place the blame on her.[7]

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[5] *See* American Cancer Society Cancer Action Network, *Executive Order an Essential Step to Resolve Drug Shortage Crisis*, October 31, 2011, attached.

[6] *See* Stacy Simon, *Cancer Drug Shortages Concern Doctors and Patients*, American Cancer Society News. September 7, 2011. <http://www.cancer.org/Cancer/news/News/chemotherapy-drug-shortages-concern-doctors-and-patients> Retrieved on 11/5/11.

[7] *Id.*

Clinical drug trials are also compromised by drug shortages. When clinical trials are conducted, patients are required to maintain current dosages of a particular medication. When a shortage occurs, taking a patient off of the medication or altering the patient's daily regiment increases the likelihood of errors within the clinical data sampling. As a result, clinical trials may not produce consistent and accurate results from testing.

Moving forward

ACS and ACS CAN are committed to working with legislators at the state and federal levels to ensure that patients are able to receive life-saving medications. ACS and ACS CAN are in the process of reviewing the recent release of the executive order and the FDA's plans to address the drug shortage problem. If the Committee would find it helpful, I would be happy to provide you with an update on our positions when the review is finished.

I would like to again thank the Committee for taking the time to investigate the issues and challenges regarding drug shortages. I am available for any questions that you may have. Please feel free to contact me at 432-9149 or at cory.chun@cancer.org.

FOR MORE INFORMATION, CONTACT:
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EXECUTIVE ORDER AN ESSENTIAL STEP TO RESOLVE DRUG SHORTAGE CRISIS

Statement of Christopher W. Hansen, President,
American Cancer Society Cancer Action Network

WASHINGTON -- October 31, 2011 -- "The presidential executive order issued today is an essential step to address the growing drug shortage crisis, which is denying people with cancer access to the lifesaving medications they need.

"The availability of cancer drugs can mean the difference between life and death for someone with cancer, and the drug shortage crisis is making it difficult or impossible for some cancer patients to get the medications they have been prescribed. Patients have been forced to wait for drugs that they need immediately, to travel to alternate pharmacies or treatment centers to fill their prescriptions, and to use different and potentially less effective medications to treat their condition.

"Today's executive order takes similar steps as those called for in bipartisan legislation, the Preserving Access to Life-Saving Medications Act (S. 296 and H.R. 2245), which would give the Food and Drug Administration the ability to receive advance notification from drug manufacturers about factors that could lead to drug shortages that leave potentially lifesaving medicines out of reach for patients.

"Advance notification to the FDA from industry about the potential suspension of drug production, an interruption in manufacturing, or other production adjustments that might lead to a shortage would put the FDA in a better position to track and manage potential drug shortages. Notification would also allow government, industry, providers and the public to more systematically analyze and understand the causes of specific drug shortages as they occur, and to develop real-time solutions that are also needed to address the acute problems that cancer patients live with daily.

"On behalf of people with cancer and their families nationwide, ACS CAN commends the president for taking action allowing government, industry, health providers, and patient advocates to work together to better understand the causes of drug shortages and seek the most effective solutions to this crisis."

ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works to encourage elected officials and candidates to make cancer a top national priority. ACS CAN gives ordinary people extraordinary power to fight cancer with the training and tools they need to make their voices heard. For more information, visit www.acscan.org.

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To: Chair Senator Josh Green, MD, Vice-Chair Senator Clarence Nishihara, Health Committee Members

Hrg: Informational Briefing
Tuesday, November 8, 2011 @ 10 am, conference room 225

Re: **Addressing Vital Medication Shortages, in Hawaii and Nationally**

By: Valerie Chang, JD, Executive Director
Hawaii COPD Coalition, www.hawaiicopd.org
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I thank you for this opportunity to testify and comment regarding vital medication shortages in Hawaii and nationally. This topic is very important to our organization, especially due to our geographic isolation and the medically fragile people we represent.

My name is Valerie Chang. I am Executive Director of the Hawaii COPD Coalition. Our organization provides services and support to Hawaii's people affected by Chronic Obstructive Pulmonary Disease, more commonly known as emphysema and chronic bronchitis. COPD is now the third leading cause of death in the US and second leading cause of disability. Over 30,000 people in Hawaii have already been diagnosed with COPD and it is estimated that at least 30,000 more people may suffer from COPD but remain undiagnosed. There are over $55 million in COPD hospital charges in Hawaii each year. Our organization provides free breathing testing, resources, information and support for cessation and those with lung disease. In 2011, we have conducted over 1000 breathing tests (spirometries) in over 40 clinics, including 6 on the Big Island, 3 on Maui, 3 on Kauai, and 2 on Molokai (with a third scheduled for December 10).

We have heard of national shortages of a key medication for COPD patients, **Foradil** (afomoterol). It is a long-acting bronchodilator which helps relieve breathlessness in many patients with COPD. There has also been a shortage of **Mycomyst** (acetylcysteine). This is an inhaled medication used to break up thick, tenacious mucous. I am also obtaining additional information from many other partners about medication shortages they are experiencing or aware of and will promptly provide updated testimony as soon as the information is received.

Thanks for the opportunity to testify about this issue that is so vital to the health of Hawaii and our nation. This issue is very important to our state and our Hawaii COPD Coalition is very glad that this committee has taken a leadership role in addressing this important matter.

November 8, 2011

Senator Josh Green, Chair
Senator Clarence Nishihara, Vice Chair
Senate Committee on Health
State Capitol Room 225
415 S. Beretania Street
Honolulu, Hawaii 96813

Comments of Deborah McDonald on Drug Shortages

Chair Green and Vice Chair Nishihara, thank you for the opportunity to provide comments to the Senate Committee on Health regarding drug shortages. My name is Deborah McDonald, and I have been a resident of Hawaii for 27 years. I spent my professional career as a postal carrier for the U.S. Postal Service. My whole life changed in December of 2009 when I was diagnosed with stage 4 colon cancer. This diagnosis hit me and my family hard. I was given anywhere between 2-5 years to live. After the diagnosis and subsequent treatments, I held out hope that my cancer could be treated. So here I am, two years later. As a result of my cancer treatments, the cancer hasn't spread to my vital organs and I appear like a normal cancer-free person.

I would like to talk about drug shortages. I first learned about drug shortages when my attending nurses spent most of their time trying to track down patient medications. I have been directly affected by shortages. I am currently taking cancer-related drugs including 5fu, avastin, and leucovorin. Due to the shortages of some drugs, I have not been able to receive full dosages of leucovorin. Having inadequate dosages do not pose an immediate threat, but I am very concerned that the lesser dose could lead to aggressive cancer growth. 5fu and leucovorin work together to fight the spread of cancer. The lack of leucivorin could eventually have detrimental effects on my cancer treatment.

In an effort to try and raise awareness of this issue, I wrote to U.S. Senator Daniel Inouye to inform him of the problem. Senator Inouye's office responded to my letter regarding medication shortages, and informed me that he has been trying to get legislation passed to address this issue. I believe that his willingness to try and address the problem is reassuring, although I would encourage quicker action on a matter that impacts the health and well-being of so many people. I encourage all of you to work with State and Federal health officials to try and find a solution to this problem. Thank you.