

Session III

Drug Shortages



Industry Perspective



FDA/CDER Drug Shortage website



Oncology Times article

Drug Shortages in Pediatric Oncology

March 2006 ODAC

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Introduction

- Important drugs
- Recent shortages
- Reasons for shortages
- Manufacturing issues
- Problems unique to pediatric oncology
- Suggestions

Important Drug List

(COG IAC Meeting 2003)

	Year of Approval
Actinomycin d	1964
E. coli asparaginase	<i>1994</i>
Mercaptopurine	1953
Peg-asparaginase	<i>1994</i>
Preservative-free hydrocortisone	1950's
Procarbazine	1969
Thioguanine	1966
Vincristine	1963

Recent Shortages

(9 Feb 2006, CDER website)

- Ongoing (6 drugs total)
 - Oncology
 - BCNU
- Resolved (13 drugs total)
 - Oncology
 - Fluorouracil
 - Methotrexate

Reasons for Shortages

(Am J Health-Syst Pharm, 2002;59:2173-82)

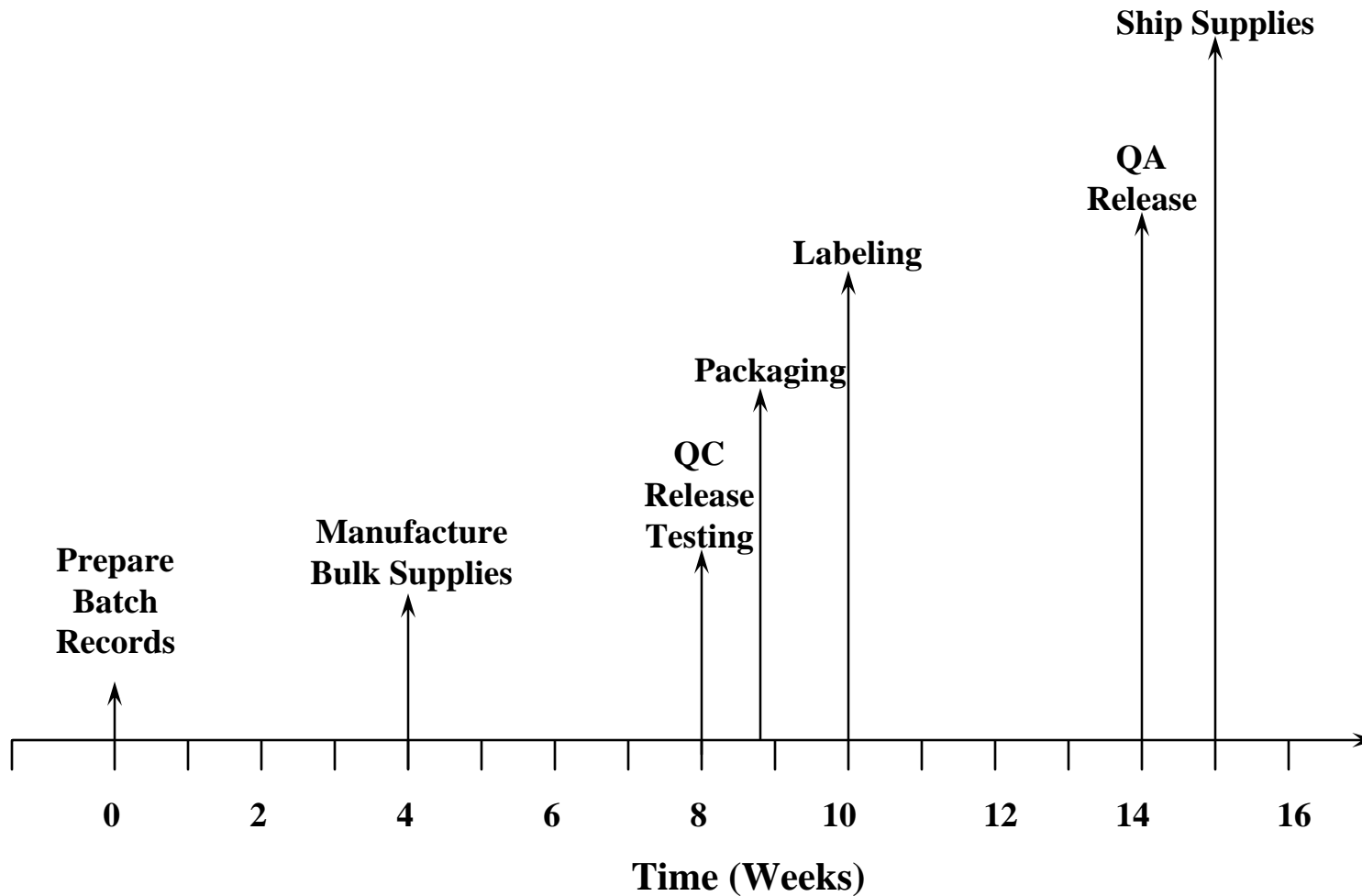
- Manufacturing
- Communication
- Economics
- Distribution and use
- Regulation and enforcement

Manufacturing

- Raw materials shortages
- Regulatory issues
- Batch failures
- Limited worldwide manufacturing capacity for cytotoxics

Manufacture & Release Timeline

(Typical Batch of an Oral Pharmaceutical)



Communication

- No lead time for other manufacturers when one leaves the market
- Single source may leave the market without warning
- Pediatric oncology not tracked very well
 - Level of use is low in absolute terms
 - Level of use may spike with a new treatment protocol
 - Lack of contact with manufacturers

Pediatric Oncology

- Small population
 - Difficult for manufacturers to track
- Older drugs
- Little contact with pediatric oncology providers
- Spikes in use related to protocol-based treatment
 - Can not be anticipated without communication

Fall 2002 COG Meeting

- Establish points of contact at each company that manufactures a drug critical to pediatric oncology
- Establish a line of communication between FDA-ODSM to
 - obtain and disseminate information on shortages and the management plan in effect
 - establish COG input into management plan
- Establish communication with PharMA



U.S. Food and Drug Administration
Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

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Drug Shortages

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Drug Shortages Email Alert: To receive email notification of drug products added to the Current Drug Shortages, and Resolved Drug Shortages lists, link to <http://list.nih.gov/cgi-bin/wa?SUBED1=drug-shortages&A=1> and complete the Drug Shortages listserv form.


Introduction

It is FDA's policy to help prevent or alleviate shortages primarily of medically necessary drug products, since these can have significant public health consequences. A drug shortage may involve either an actual or a potential shortage of a drug product.

A 1997 FDA Consumer article "[Inside FDA: When a Drug is in Short Supply](#)" provides background information and an example of how FDA manages drug shortages. The article "[FDA's Role in Responding to Drug Shortages](#)" published in the American Journal of Health Systems Pharmacists {2002 Aug 1;59(15):1423-5}, provides additional information.

[Frequently Asked Questions](#)

Current Drug Shortages

Drug Name	Company Information	Reason for Shortage	Related Information
BiCNU (carmustine) Injection updated 11/8/2005	Bristol-Myers Squibb 1-800-631-5244	Manufacturing pending	Update from BMS  (updated 11/8/2005)
Celestone Soluspan (Betamethasone Injection) updated 9/16/2004	Schering-Plough Corp. 2000 Galloping Hill Rd. Kenilworth, NJ 07033-0530 908-298-4000 800-526-4099 www.sch-plough.com	Manufacturing issues	Additional Information (updated 9/16/2004)
Coreg (carvedilol) tablets 1/19/2006 New!!	GlaxoSmithKline	Manufacturing delays	Supplies of Coreg are currently limited. Pharmacists may contact GlaxoSmithKline at 1-800-877-1158 to obtain a drop shipment order until normal distribution resumes.
Fluorouracil injection updated 11/29/2005	APP (1-888-386-1300)	Manufacturing delays	Fluorouracil injection is currently available in limited supply from APP. Supplies are expected to improve over the next several months. You may contact APP Customer Service at 1-888-386-1300 regarding availability. Fluorouracil injection is also manufactured by Sicor Pharmaceuticals Inc. and

			you may call their Customer Service number at 1-800-729-9991 regarding availability.
Maxipime (cefepime)	Elan Pharmaceuticals	Manufacturing delays	You may contact Elan at 1-800-859-8586 for additional information
MERREM 1g/30ml vial (NDC 0310-0321-30) MERREM 0.5g/20ml vial (NDC 0310-0325-20) 12/7/2005	AstraZeneca Pharmaceuticals LP (Corporate Information Center 1-800-236-9933	Due to increased demand and manufacturing delays AstraZeneca is putting MERREM on allocation.	Please call AstraZeneca for additional information 1-800-236-9933.

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Resolved Drug Shortages

Drug Name	Company Information	Related Information
Amphotericin B injection 2/23/2005	X-GEN (formerly Pharma-Tek), Sandoz	Amphotericin B injection is now available through normal distribution.
Avonex (interferon Beta 1a) 4/12/2005	Biogen Idec (800) 456-2255	No further supply issues are anticipated.
Cortrosyn Injection (Cosyntropin) 0.25mg/vial 1/19/2005	Amphastar	Cortrosyn is now available through normal distribution. Please call Customer Service at 1-800-423-4136 for additional information.

<p>Cytovene (ganciclovir) Powder for Injection</p> <p>4/5/2005</p>	<p>Roche Professional Product Information Department 1-800-526- 6367</p>	<p>Cytovene IV shortage has been resolved and no further supply problems are anticipated</p>
<p>Marplan (isocarboxazid) 10 mg</p> <p>5/20/2005</p>	<p>Oxford Pharmaceutical (877) 284-9120</p>	<p>Marplan will resume normal distribution 5/27/2005</p>
<p>Methotrexate injection</p> <p>Posted 10/6/2005</p>	<p>Mayne Pharma 1-866-594-8420</p>	<p>Please be sure to use new NDC numbers</p>
	<p>Bedford 1-800-562-4797</p>	
	<p>American Pharmaceutical Partners 1-888-386- 1300</p>	<p>APP is not currently distributing methotrexate injection</p>
<p>Solu-Cortef (Hydrocortisone sodium succinate) for injection</p> <p>4/6/2005</p>	<p>Pfizer</p>	<p>All presentations of Solu-Cortef are now available without restrictions.</p>
<p>Solu-Medrol (methylprednisolone sodium succinate) for injection</p> <p>1/3/2006</p>	<p>Pfizer, American Pharmaceutical Partners (APP), Hospira</p>	<p>Pfizer reports availability of Solu- Medrol (methylprednisolone sodium succinate) injection. Please call Customer Service (800) 533-4535 if Solu-Medrol injection is NOT available through wholesale channels.</p> <p>American Pharmaceutical Partners (APP) has methylprednisolone sodium succinate injection available in 125 mg vials (NDC #63323-258- 03), and 1 gram vials (63323-265- 30). 40 mg vials (NDC 63323-255- 03) are currently unavailable. Please call APP at 1-888-386-1300 for additional information. (updated 1/3/2006)</p>

		Hospira has A-Methapred (methylprednisolone sodium succinate) injection available in 125 mg vials, NDC #00074-5685-02. Please call Hospira at 1-877-946-7747 for additional information.
TABLOID (Thioguanine) 40 mg Tablets 1/26/2005	GlaxoSmithKline	Please call GSK for additional information at 1-888-527-6933
Thiola (tiopronin) 100 mg tablets 1/3/2005	Mission Pharmacal Customer Service (800) 292-7364	Thiola is now available from pharmacies through normal distribution. Please contact Mission Pharmacal at 1-800-292-7364 for additional information.
Trecator SC (ethionamide) 250 mg tablets 4/1/2005	Wyeth	Trecator SC is now available through normal distribution.
Zemuron (rocuronium bromide) injection, 5 ml and 10 ml vials 2/7/2005	Organon Pharmaceuticals USA Inc. (800) 241-8812	Please call Organon Customer Service at 1-800-241-8812 for additional information
Zyflo Filmtab (Zileuton) Tablets 11/17/2005	Critical Therapeutics (866) 835-8216	Zyflo is now available through Clinical Therapeutics.

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Discontinuations





The Food, Drug and Cosmetic Act requires companies to give FDA a six-month notification of the discontinuation of sole source products that are life-supporting, life-sustaining or for use in the prevention of a debilitating disease or condition.. From time to time, FDA also receives notification for other products. These discontinuations are provided below for informational purposes only.








To locate drugs that have already been discontinued, please consult the following:



[Drugs@FDA](#)




[Orange Book Query](#)



[Orange Book Monthly Additions and Deletions](#)

Drug Name	Company Information	Related Information
Agenerase (amprenavir) 150mg capsule 9/17/2004	GlaxoSmithKline 1-888-825-5249	Letter from GlaxoSmithKline 
Calciferol injection in oil (ergocalciferol) 3/19/2004	Schwarz Pharma 6140 W. Executive Drive Mequon, WI 53092 1-800-558-5114	Schwarz has discontinued manufacturing of calciferol
CEFOTAN (cefotetan injection) 11/15/2005 New!!	AstraZeneca Pharmaceuticals LP (AstraZeneca) - Contact Corporate Information Center at 1-800-236- 9933.	The remaining inventory of CEFOTAN (cefotetan injection) will be depleted by March 31, 2006. AstraZeneca has no further plans to manufacture or distribute CEFOTAN (cefotetan injection) after March 31, 2006. For further questions, the AstraZeneca Corporate Information Center may be contacted at 1-800-236-9933.
Cylert (pemoline) tablets and chewable tablets, all strengths 5/25/2005	Abbott Laboratories	Abbott has made the decision to discontinue Cylert tablets and chewable tablets Letter from Abbott 

<p>ELAVIL (amitriptyline hydrochloride) Tablets and Injection.</p> <p>5/15/2003</p>	<p>AstraZeneca Pharmaceuticals LP (AstraZeneca) – Contact Corporate Information Center at</p> <p>1-800-236-9933</p>	<p>ELAVIL Injection is no longer available at AstraZeneca. The remaining inventory of ELAVIL Tablets will be depleted by December 31, 2003. AstraZeneca has no further plans to manufacture ELAVIL (amitriptyline hydrochloride) Tablets or Injection.</p>
<p>Flovent Rotadisk (fluticasone propionate inhalation powder)</p> <p>8/31/2004</p>	<p>GlaxoSmithKline 1-888-825-5249</p>	<p>Please see Dear Healthcare Professional letter  for additional information.</p>
<p>Fortovase (saquinavir) capsules 200 mg</p> <p>6/2/2005</p>	<p>Roche</p>	<p>Fortovase 200 mg capsules will be discontinued by February 15, 2006. Please see attached DHP letter for additional information.</p> <p>Dear Healthcare Professional Letter </p>
<p>Humulin U ULTRALENTE (HUMAN INSULIN [rDNA ORIGIN] EXTENDED ZINC SUSPENSION)</p> <p>7/6/2005</p>	<p>Eli Lilly and Company</p>	<p>Dear Doctor Letter  Patient Information </p>
<p>Humulin L LENTE (HUMAN INSULIN [rDNA ORIGIN] ZINC SUSPENSION)</p> <p>7/6/2005</p>	<p>Eli Lilly and Company</p>	<p>Dear Doctor Letter  Patient Information </p>
<p>Inulin in Sodium Chloride Injection, USP</p>	<p>Questcor Pharmaceuticals, Inc.</p>	<p>Letter </p>

9/26/2003		
Kefzol (cefazolin) all presentations 2/28/2003	Eli Lilly and Company	Letter
Kefurox (cefuroxime) all presentations 2/28/2003	Eli Lilly and Company	Letter
Lanoxin Elixir (digoxin) 6/3/2005	GlaxoSmithKline	This product has been discontinued by GSK. Roxane is producing digoxin elixir.
Mandol (cefamandole) all presentations 2/28/2003	Eli Lilly and Company	Letter
Novolin L, Lente, human insulin zinc suspension [rDNA origin] 7/15/2003	Novo Nordisk Pharmaceuticals, Inc. Contact: 1-800-727- 6500 Customer Service	Letter
NPH Iletin II (ISOPHANE INSULIN SUSPENSION, USP, PURIFIED PORK) 7/6/2005	Eli Lilly and Company	<ul style="list-style-type: none"> • Dear Doctor Letter  • Patient Information  • Frequently Asked Questions
ORLAAM (Levomethadyl hydrochloride acetate) Oral Solution, 10 mg/mL	Roxane Laboratories	Letter

9/2/2003		
Perchloracap (potassium perchlorate) 200 mg capsules 6/2/2005	Tyco Healthcare	Perchloracap capsules have been discontinued and supplies are anticipated to be depleted by the end of 2005.
Pre-Pen (benzylpenicilloyl polylysine) injection 4/13/2005	Hollister-Stier (800) 992-1120	Pre-Pen is no longer available.
Regular Iletin II (INSULIN INJECTION, USP, PURIFIED PORK) 7/6/2005	Eli Lilly and Company	<ul style="list-style-type: none"> • Dear Doctor Letter  • Patient Information  • Frequently Asked Questions
Serevent Inhalation Aerosol 6/10/2003	GlaxoSmithKline 1-800-340-3236	GSK anticipates that SEREVENT Inhalation Aerosol will no longer be available starting in June 2003. Dear Health Care Professional Letter from GlaxoSmithKline 
Stelazine (trifluoperazine) oral concentrate 10mg/ml Stelazine (trifluoperazine) tablets (1mg, 2mg, 5mg, 10mg) Stelazine (trifluoperazine) Injection 2mg/ml 12/18/2003	GlaxoSmithKline 1-888-825-5249	Stelazine was discontinued and withdrawn from the market. The final lots were distributed by GSK August 2003 and the final expiry date of all products in the marketplace is no later than January 31, 2004.
Suprax (cefixime)	Lederle/Wyeth	Discontinued July 2002. Stock will be

updated 2/25/2004	Pharmaceuticals	distributed until exhausted or until March 2003, whichever comes first. For additional information, please call customer service (800) 666-7248 Lupin Pharmaceuticals recently received approval for cefixime 400 mg tablets and cefixime 100 mg/5 ml suspension. For further information, please contact Lupin Pharmaceuticals at 410-576-2000 (2/25/2004)
Valstar (valrubicin) Solution for Intravesical Instillation 1/30/2004	Formerly distributed by Celltech (Celltech Customer Service 1- 888-963-3382)	No further availability planned at this time.
Velosulin BR Human, Buffered Regular Human Insulin Injection [rDNA origin] 11/3/2003	Novo Nordisk Pharmaceuticals, Inc. Contact: 1-800-727- 6500 Customer Service	Dear Healthcare Professional Letter 
1.5% Xylocaine - MPF with Dextrose 7.5% Injection (lidocaine HCl and dextrose anhydrous Injection ampules) 8/29/2005	AstraZeneca (1-800- 842-9920)	1.5% Xylocaine® -MPF with Dextrose 7.5% Injection is no longer available at AstraZeneca. The remaining inventory of 1.5% Xylocaine® -MPF with Dextrose 7.5% Injection Ampules will be depleted by August 31, 2005. AstraZeneca has no further plans to manufacture 1.5% Xylocaine® -MPF with Dextrose 7.5% Injection Ampules
Zovirax (acyclovir sodium) for injection 1000mg/20ml vial	GlaxoSmithKline Customer Service 1-800-877-1158	Letter from GSK 

1/6/2004		
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Additional Communications

APP voluntarily recalled various lots of fluorouracil injection 50 mg/mL. Please see information in the "[Current Drug Shortages](#)" section.

APP Customer Service

Customer Service Hours:
Monday - Friday, 7 a.m. - 6:00 p.m. CST
Toll Free (888) 386-1300
Fax (800) 743-7082

APP Product Return Contact Information

Quality Assurance Department
(847) 939-8138

APP Drug Correction Clinical/Technical Information

Toll Free (800) 551-7176
Fax (847) 939-8201

- [Urgent Product Recall Letter](#) 
- [Urgent Drug Correction Letter](#) 

updated 11/16/2005

Distribution Changes for Lamprene (clofazimine) (5/4/2005)

Please see the attached letter from Novartis Pharmaceuticals Corporation for information about distribution changes for Lamprene (clofazimine).

- [Letter to Doctors](#) 

On May 20, 2005, Praecis Pharmaceuticals announced that it is voluntarily discontinuing the sale of Plenaxis to new patients in the United States for economic reasons. Patients currently on Plenaxis therapy may continue to receive the drug. Please [see Plenaxis Information page for additional information](#). (6/3/2005)


Drug Shortage Manual of Policies and Procedures (MaPP)

MaPPs are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities.

MaPPs define external activities as well. [All MaPPs](#) are available for the public to

review to get a better understanding of office policies, definitions, staff responsibilities, and procedures.

- [4730.1 Drug Shortage Management](#) (11/21/96). This describes CDER's Office of Compliance policy and procedures on drug shortage management. A CDER-wide MaPP is under development.

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Medical Necessity

A product is considered to be medically necessary, or a medical necessity, if it is used to treat or prevent a serious disease or medical condition, and there is no other available source of that product or alternative drug or therapy that is judged by medical staff to be an adequate substitute. Patient "inconvenience" alone is an insufficient basis to classify a product as a medical necessity.

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How to Report a Drug Shortage

To report a CDER product by email: drugshortages@cder.fda.gov

To report a CDER product by phone:

CDER Drug Information (888) INFOFDA or (888) 463-6332, or (301) 827-4570

To report a CBER product shortage (biological and related products including blood, vaccines, tissue, allergenics), by e-mail: CBERProductshortages@cber.fda.gov

To report a CBER product shortage (biological and related products including blood, vaccines, tissue, allergenics), by phone during business hours, biological product manufacturers and healthcare personnel may report a real or suspected biological product shortage by calling (301) 827-6220.

To report a CDRH or CFSAN shortage to FDA, see listings under FAQs

To report a shortage to ASHP you may use the [Drug Product Shortages Report form](#) (non-FDA site) available from the [American Society of Health-Systems Pharmacists \(ASHP\)](#) web page. When you use this form, you are reporting a drug shortage to ASHP, not FDA. CDER partners with ASHP to minimize drug shortages and report rapid accurate drug shortage information.

For background information on reporting drug shortages, please see the CDER Handbook, [Drug Shortages page](#).

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Practical Steps for Practitioners Facing Drug Shortage Situations

[ASHP Guideline on Managing Drug Shortages](#). The American Society of Health-System Pharmacists guideline describes the contributing factors to drug product shortages and recommends a general process for inventory management in preparation for and working through shortage situations.

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More Information on Drug Shortages, Product Recalls and Warnings

[FDA Product Recalls, Alerts, and Warnings](#). FDA posts press releases and other notices of recalls from the firms involved as a service to consumers, the media, and other interested parties.

Cderrecalls@cderr.fda.gov or phone (301) 827-9039

Other Drug Shortage Links

For more detailed information on all drug shortages we refer you to the following sites:

[American Society of Health-System Pharmacists](#) [External non-FDA Site]

For information on shortages of biological products, including blood and vaccines, we refer you to the Center for Biologics Evaluation and Research (CBER) shortage site: <http://www.fda.gov/cber/shortage/shortage.htm>

Comments on this Web Page

We ask you to take time to communicate with CDER about this website. Please e-mail us at drugshortages@cderr.fda.gov with feedback about this site.

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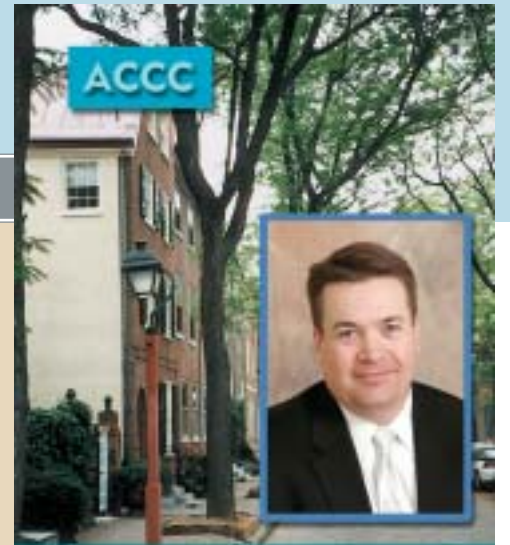
www.oncology-times.com



THE **NEWS CENTER** FOR THE CANCER CARE TEAM

New ACCC Head Cites Major Concerns, Bright Spots in Community Cancer Care

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Community Cancer Care

Recommendation from Hematologists:



Oncologists Need Hematology Training to Treat Blood Disorders
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Shortage of Key Pediatric Oncology Drug—Injectable Methotrexate

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Follicular Lymphoma: Interferon Prolongs Survival, but US Oncologists' Negative Attitude May Prevent Its Incorporation into Treatment

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TV's Extreme Makeover Makes over Arizona Transplant Center

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New Column! 'Pearls of Exchange'

Short, First-Hand, Noteworthy Clinical Experiences

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Study: Computerized



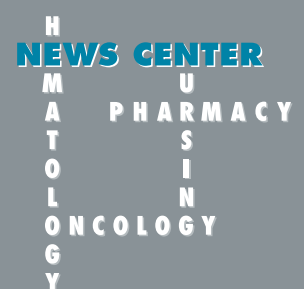
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ADVOCACY INSIGHT

Shortage of Key Pediatric Oncology Drug Raises Question of Priorities

By Eric T. Rosenthal

The quest for more effective anti-cancer drugs remains a Holy Grail—and very profitable business—in oncology.

But what happens when certain drugs that have proven effective over the years, but are no longer big money-makers, become unavailable?

Whose responsibility does it become to ensure that bona-fide life-saving medications that work are kept in adequate supply to meet the needs of current and future patients, especially when those patients are children?

Such a drug shortage was reported in the *Wall Street Journal* in mid-March.

The article, by Amy Dockser Marcus, told of the unavailability of injectable methotrexate in the United States due to quality-control issues that forced the closing of the drug's Switzerland-based manufacturing plant—the source of 85% of injectable methotrexate in this country.

Methotrexate is indicated for several adult and pediatric cancers, as well as rheumatoid arthritis, lupus, psoriasis, and Crohn's disease.

“Why, in this, the most developed country in the world, are drugs that cure allowed to be in such short supply and to become unobtainable?”

However, children being treated for leukemia, osteosarcoma, and non-Hodgkin's lymphoma require very high doses available only in the injectable form, and pediatric oncologists are delaying chemotherapy for some of the 6,000 to 7,000 patients who need it.

One of the experts prominently featured in the article was Gregory H. Reaman, MD, Chair of the Children's Oncology Group and Professor of Pediatrics at George Washington University School of Medicine and Children's National Medical Center.

When I called to discuss the matter further with him, I learned it was Dr. Reaman who “had tipped off” the *WSJ* about the situation.

“Why does something like this happen?” he asked in our conversation. “Why, in this, the most developed country in the world, are drugs that cure allowed to be in such short supply and to become unobtainable?”

“Here's a drug that's been standard treatment for some pediatric cancers for 35 to 40 years that we know is effective. It's absolutely essential, since there's no other way to cure acute lymphocytic leukemia in children other than injectable methotrexate, and supplies are extremely limited.”



Children's Oncology Group Chair Gregory H. Reaman, MD: "Who is responsible for preventing such shortages: Is it the FDA, the NCI, or some other NIH agency? It seems no one cares. The pharmaceutical industry doesn't care since there's no market for this. Maybe it needs a Congressional inquiry into why supplies can get so low and there's no mechanism to prevent it in the future."

agents as asparaginase, vincristine, and cyclophosphamide.

Dr. Reaman said that he was also interviewed on the network news, but other media outlets seemed more interested in identifying patients for the human interest angle.

He said he wonders who is responsible for preventing such shortages: "Is it the FDA, the NCI, or some other National Institutes of Health agency? It seems no one cares.

"The pharmaceutical industry doesn't care since there's no market for this," he continued. "Maybe it needs a

Congressional inquiry into why supplies can get so low and there's no mechanism to prevent it in the future. But then, after all, this impacts only a few children, who don't vote."

Ironically, Dr. Reaman received a call from the office of a US representative from Arizona, inquiring into getting injectable methotrexate for a constituent's child.

FDA Drug Shortage Program

The FDA's Drug Shortage Program is a division of the Center for Drug

Evaluation and Research. The purpose is to ensure that safe and effective prescription, over-the-counter, and generic drugs are available in the US by responding to drug shortages that have a significant impact on public health.

When a drug shortage is identified and the drug is determined to be medically necessary, the Program looks into the cause of the shortage, and works with the company to resolve the problem.

Apparently, not many manufacturers are capable of producing injectable
(continued on page 14)

Shortage Developing Over Years

Dr. Reaman explained the shortage has been developing over the years. Injectable methotrexate was originally manufactured by the former Lederle Labs, and went off patent years ago.

He added that it is becoming increasingly more difficult to obtain the drug through the distributors—American Pharmaceutical Partners Inc., Mayne Pharma, and Bedford Laboratories, a subsidiary of Boehringer Ingelheim—and as a result, certain institutions have been stockpiling supplies, while others have little to none.

"This stockpiling caused concern, and with reports of the unavailability of the drug increasing during the last few months, we finally contacted the FDA and NCI," Dr. Reaman said.

"The FDA admitted there was a problem with the manufacture of the raw materials in a Swiss plant, which caused the shutdown. When we asked the FDA if injectable methotrexate could be prioritized for life-threatening diseases like cancer, and not rheumatoid arthritis, the agency responded well to this."

But the overall issue of preventing drug shortages prompted him to approach the media to raise public awareness.

Other Drugs Too

The *Wall Street Journal* article focused on the injectable methotrexate shortage, but also discussed the shortages of other routinely prescribed drugs—including morphine sulphate and penicillin, as well as such chemotherapy

Recommended: Oncologists Need Hematology Training to Take Care of Blood Disorders

By Mark L. Fuerst

Oncologists need hematologists to help them practice hematology. That's the consensus among leading hematologists who say that oncologists are increasingly being called upon to deal with blood

disorders, cancerous and otherwise.

"From a pragmatic point of view of current manpower and hematologist distribution in the country, those solely boarded in oncology are going to be the de facto physicians that people look toward to take care of hematologic problems," said Samuel Silver, MD,

PhD, Director of the Cancer Center Network at the University of Michigan Health System.

216 Hem/Onc Training Programs

Most graduates of hematology/oncolo-

gy fellowships opt for practicing oncology, according to the latest statistics.

In 2004, there were 216 training programs in hematology/oncology in the United States. Less than one in eight of these programs train hematologists exclusively, noted Sudha Sinha, MD, Chief Fellow in Hematology/Oncology at St. Elizabeth's Medical Center and Clinical Associate in Medicine at Tufts

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drugs, increasing this type of product's susceptibility to shortages.

The Swiss methotrexate plant is expected to get back on line in May or June. Bedford Labs—which manufactures injectable methotrexate in the US—has increased its production threefold, but is still unable to keep up with demand.

COG Has 7 Methotrexate-Related Trials, Now Delayed

In addition to ongoing treatment, the Children's Oncology Group currently has about seven clinical trials under way that use methotrexate, and treatment has been delayed for some children, according to Dr. Reaman, who expressed frustration about the fact that pediatric oncology has to focus so much attention on early access to new drugs and about why it takes 10 to 11 years for drugs to be studied in adults before being administered to children.

"Kids are therapeutic orphans," he said. "There's all this attention on new blockbuster drugs, and attention was paid on stockpiling ciprofloxacin for a potential anthrax attack, but there's still no mechanism to prevent this type of shortage from happening again in the future." □



Eric Rosenthal founded the NCI-designated Cancer Centers Public Affairs Network;

has worked with Vital Options International TeleSupport Cancer Network and The Group Room cancer radio show; has organized conferences about the media and medical/cancer communications issues; and is a member of the NCI Director's Consumer Liaison Group.