



Connecting Hope and Medical Science

# Focus ON THE Search

Clinical trials advancing the quest for cancer treatment, management, and prevention.

Colorado Cancer Research Program (CCRP) ■ Year End 2011 ■ Issue 17

## Upcoming Events

### ■ SAVE THE DATE



Benefitting Colorado Cancer Research Program

June 18, 2012

Wishing you the best in 2012!

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## Impact: Drug Shortages in Cancer Clinical Trials and Treatment

Colorado Cancer Research Program (CCRP) held two Cancer Research Education (CaRE) panel discussions in October on the topic of drug shortages: one in Colorado Springs and the other in Denver. Each of the panels included a medical oncologist, a hospital pharmacist, a congressional health legislative aide, and an independent consultant to the pharmaceutical industry. Importantly, seven trials that CCRP had open earlier this fall were experiencing shortages of generic drugs that were part of trial protocol. The Federal Drug Administration (FDA) is the source for the statistics in this article.

### Background

In 2010, 211 drug shortages were reported to FDA, compared with 61 in 2005. As of early November 2011, 233 shortages have been reported this year. The majority of these involved sterile injectable generic drugs. Of these drugs 16% were oncology drugs.

There are only seven manufacturers of the drugs that have shortages. Two are multi-product facilities (meaning they can only produce certain drugs at certain times or they don't produce all their products at all times). Of these seven manufacturers, too few of them are producing the older and widely used sterile injectables.

Pharmaceutical consultant and panelist, Marsha van de Boogaard, explained the process of a drug moving from a patented drug to a generic drug at each of the panel

discussions. Marsha explained, "Patents are approved for twenty years. With patent approval, the name brand manufacturer receives between seven and thirteen years (depending on R&D) of exclusivity for marketing of their drug. When the patent expires, the first company approved to produce the generic drug gets six months of exclusivity for marketing and production, after which time other companies can compete in producing/selling the generic drug." Marsha also made a critical point regarding drug manufacturing and FDA, "It is important to note currently, that drug manufacturers are not required to report information of shortages to FDA, nor the reason for the shortage, or the expected duration of the shortage."

According to FDA, their authority is severely restricted on what they are able to do in the area of drug shortages. These authorities include:

- Limited notification requirement (the only required notification is sole source discontinuation)
- No consequences to the manufacturer for failure to notify
- No authorization to dictate production quantity
- Drug shortage program primarily operates on voluntary participation of the industry
- FDA has no purview over drug pricing in the United States

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# Focus ON THE Search

*Focus on the Search* is a quarterly publication of resources for people who are current or past participants in cancer clinical trials in Colorado, for people who have been recently diagnosed with cancer and those interested in cancer research.

Colorado Cancer Research Program (CCRP) is a non-profit organization, a partnership of 17 Colorado community hospitals, and their affiliated doctors, dedicated to the advancement of cancer research and care close to home. CCRP is a Community Clinical Oncology Program, one of a nationwide network of over 50 such National Cancer Institute (NCI) approved programs nationwide.

## CCRP's Partner Hospitals

Boulder Community Hospital  
 Exempla Lutheran Medical Center  
 Exempla Saint Joseph Hospital  
 Littleton Adventist Hospital  
 Longmont United Hospital  
 McKee Medical Center  
 Medical Centers of Aurora  
 North Colorado Medical Center  
 Parker Adventist Hospital  
 Penrose-St. Francis Health Services  
 Porter Adventist Hospital  
 Presbyterian/St. Luke's Medical Center  
 Rose Medical Center  
 St. Anthony Hospital  
 Sky Ridge Medical Center  
 St. Mary-Corwin Medical Center  
 Swedish Medical Center

## New CCRP Trials Opened (August — November 2011)

| Disease Site                   | Protocol No. | Title   |
|--------------------------------|--------------|---|
| Amyloidosis                    | E4A08        | A Randomized Phase III Trial of Melphalan and Dexamethasone (MDex) versus Bortezomib, Melphalan, and Dexamethasone (BMDex) for Untreated Patients with Systemic Light-chain (AL) Amyloidosis Ineligible for Autologous Stem-cell Transplantation. |
| Brain                          | N107C        | A Phase III Trial of Post-Surgical Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy for Resected Metastatic Brain Disease.  |
| Brain                          | N0872        | Phase I/Randomized Phase II Double Blind Study for Recurrent Glioblastoma.  |
| Breast                         | E2108        | A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer.  |
| Breast                         | SCUSF0806    | Phase II Placebo-Controlled Trial to Reduce Cardiotoxicity in Patients with Breast Cancer Receiving (Neo) Adjuvant Chemotherapy   |
| Breast                         | RTOG 1005    | A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost for Early-Stage Breast Cancer.  |
| Cancer Control                 | N10C1        | Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo-Controlled Study.  |
| Cancer Control                 | N10C2        | Double-Blind, Placebo-Controlled Study to Reduce Menopausal Hot Flashes.  |
| Colon                          | E7208        | A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-Angiogenic Antibody, Ramucirumab (IMC-1121B) in Advanced, K-ras Wild-Type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy.        |
| Prostate                       | RTOG 0924    | Androgen Deprivation Therapy and High Dose Radiotherapy with or without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial.   |
| Renal                          | CALGB 90802  | Randomized Phase III Trial Comparing Everolimus Plus Placebo versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors.  |
| Colon, Lung, Pancreas, Stomach | SWOG S0518   | Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients   |

*For the most current information and details regarding these trials, please visit [www.co-cancerresearch.org](http://www.co-cancerresearch.org).*



Mary Alice Fullerton, and Ann and Jo Volk with their new painting "Summer of the Big Snow."

## Thank You to Local Artist Mary Alice Fullerton

CCRP wants to offer a special thanks to Mary Alice Fullerton for her support of CCRP and cancer research. On November 19th, she held a benefit with 100% of proceeds of 32 paintings going to either CCRP or the Colorado Chapter of the Alzheimer's Association or both. She chose these organizations after losing her mother to Alzheimer's and her daughter to triple negative breast cancer in 2008. Speaking of her mother and daughter, "They engaged me to find the time to develop my talent in the best possible way. This exhibit makes me feel close to them. It's a positive way to do something wonderful for them that only begins to touch the wonderful things they did for me." CCRP would like to thank Mary Alice and all of the patrons that purchased paintings. CCRP raised over \$15,000 at this special event.

## This Issue's Featured Clinical Trial

### P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer

- **Purpose:** Since the 1980s, statins have been in use as agents to help patient lower cholesterol and reduce the risk of cardiovascular disease. This randomized prevention trial is exploring the use of rosuvastatin (Crestor, launched in 2003) after surgery for stage I or stage II colon cancer to determine its effect on the occurrence of adenomatous polyps of the colon or rectum, metachronous colorectal carcinoma and colon cancer recurrence. Patients take either a placebo or rosuvastatin daily for five years and are then followed for an additional two years.

Family history of colorectal cancer is one factor taken into account since there is increased risk for the disease when there is a family history. Other factors are also considered, such as whether or not the patient had adjuvant chemotherapy. In this way, sub-group analyses can be done.

#### Resources

- <http://www.cancer.gov/cancertopics/types/colon-and-rectal>
- <http://www.cdc.gov/cancer/colorectal/>
- <http://www.cancer.gov/clinicaltrials/results/type/colorectal>

## News from the SELECT Prostate Prevention Trial

Results from the SELECT Prostate Prevention Trial that 181 men participated in through CCRP over the past ten years were released in 2008 indicating that vitamin E and selenium supplements did not prevent prostate cancer.

This fall after further analysis, the results indicate that **those men that received vitamin E alone have a 17% higher risk of developing prostate cancer.** For more information visit [www.crab.org/select](http://www.crab.org/select)

## Impact: Drug Shortages in Cancer Clinical Trials and Treatment

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Despite these limits, FDA prevented 99 drug shortages so far in 2011. The top three reasons provided by FDA for recent drug shortages are; Product Quality Issues (54%), Delay/Capacity Issues (21%), and Discontinuation of Production (11%).

Rohini Kosoglu, Health Policy Advisor to Senator Michael Bennet of Colorado offered two points including, "If there was an easy solution to this problem, it would clearly be fixed long before now. It is a very complicated problem that includes a lack of redundancy within production in the industry; products having short shelf-lives; and the production process being both expensive and complicated." She pointed out another issue, "FDA currently does not have a tracking system similar to some states that would indicate in what part of the country are there shortages versus another part that may have a surplus supply."

### The Impact of the Problem to a Pharmacist and a Physician

Panel member and Pharmacist at Aurora Medical Center, Mike Koloscha, Pharm.D., R.Ph., shared the perspective of the problem from his position, "At Aurora Medical Center, we formed a committee that meets every two weeks where we review all the drugs in the hospital. We have a list of all the drugs that are backordered or that we anticipate will be on backorder. Every three days, we go through our list

of drugs that are going to be needed, so that our buyer can try to stay ahead of our needs."

CCRP board member and medical Oncologist, Nicholas DiBella, MD, of Rocky

Mountain Cancer Centers shared his experience, "We hope there will be an option when a patient doesn't have access to the drug that I have prescribed. If the patient has a curable malignancy, a physician will do everything humanly possible to get those drugs, including, if need be, sending them to another state or hospital. Depending on the tumor type we also may have an oral option. For palliative care, there are multiple options."

### What Can a Patient or the Public Do?

Ms. Kosoglu from Senator Bennet's office indicated action was necessary from patients and the public, "Members of

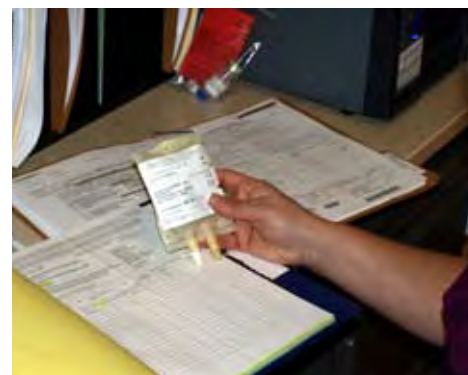


Photo: Kent Disney, RN

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Congress need to hear as many stories as possible from those directly impacted by this problem. Senator Bennet is a member of the Senate's Health, Education, Labor and Pension Committee, which will have more hearings on this issue upcoming. Other members may not be as informed on this issue."

Unfortunately, both panel discussions ended where the discussions began. The issue is incredibly complex; there are many players involved along the supply chain from the manufacturers to the distributors to the buyers to the government, and most importantly, the physicians, pharmacists and their patients that are unable to access these drugs.

Since these discussions, there have been several actions by the Federal Government which may help decrease the number of shortages, and it is our understanding that further action or hearings on the topic are to be scheduled.



Photo: Kent Disney, RN

### Resources

- [www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm](http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm)
- [www.co-cancerresearch.org/CaRE/Autumn.htm](http://www.co-cancerresearch.org/CaRE/Autumn.htm)

### Colorado Springs & Denver Panel Members

- Rohini Kosoglu, Health Policy Advisor, Senator Michael Bennet
- Marsha van de Boogaard, President and Sr. Consultant, Global Quality Alliance

### Additional Colorado Springs Panel Members

- Deb Hood, Director, National Oncology Service Line, Catholic Health Initiatives
- Michael Force, Pharm.D., R.Ph., Penrose Health-Services
- Robert Young, MD, Rocky Mountain Cancer Centers

### Additional Denver Panel Members

- Nicholas DiBella, MD, & Robert Rifkin, MD, Rocky Mountain Cancer Centers
- Michael Koloscha, Pharm.D., R.Ph., Medical Center of Aurora

## CCRP Welcomes New Partner Hospitals

This fall, Littleton Adventist Hospital and Parker Adventist Hospital joined CCRP's network of hospitals.

**Littleton Adventist Hospital**  
Centura Health.

**Parker Adventist Hospital**  
Centura Health.

## Online Cancer Resources

### National Cancer Institute:

[www.cancer.gov](http://www.cancer.gov)

### National Comprehensive Cancer Network: [www.nccn.com](http://www.nccn.com)

*A patient-oriented cancer website based on the NCCN Guidelines which set the standard of care for clinicians around the globe.*

### American Society of Clinical Oncology:

[www.asco.org](http://www.asco.org)  
[www.cancer.net](http://www.cancer.net)

*Oncologist approved cancer information, including information on cancer research and advocacy.*

### CancerCare: [www.cancer.org](http://www.cancer.org)

*CancerCare programs include counseling and support groups, education, financial assistance and practical help.*



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and Medical Science

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