

*Nothing Like a Little Traffic...*

Finding a theme for this newsletter that will endure for the three months of its distribution can drive us crazy. That's a short drive (...to crazy, that is...) here in the nation's capitol, where we all battle traffic daily to be here when you e-mail or call. So, this month's theme is driving and traffic. We hope you enjoy it, and welcome your feedback.

*Beep (or Bark) if You Want Cookies!*

Many readers took heed of our warning that without sufficient entries, it would be "Road Closed" for the quarterly contest. The mailbox had a veritable traffic jam of entries. The winners: Donna Topping and Nicole Benson at Northeast Georgia Medical Center; Pearl Abernathy at Mission Hospitals Cancer Program in Ashville, NC; and Hope Decederfelt at the National Institutes of Health Clinical Center Pharmacy. The real winners were Pearl's two whippets and Hope's faithful pomeranian who got fresh baked biscuits. All Donna and Nicole got were a ga-zillion calories from the gooey chocolate cookies they requested!

*Back to, "Oh YES, We Have No Bananas...."*

Many of you have called about the limited availability of select commercial agents recently. Although PMB does not follow these issues on a day to day basis, when asked, we consult a number of public web sites (noted below) that provide the most current, official information available.

<http://www.fda.gov/medwatch> - use this site to enroll in Medwatch and receive e-mails when the FDA identifies shortages

<http://www.fda.gov/cder/drug/shortages/FDA> - provides the most current drug shortage information from FDA

<http://www.ashp.org/shortage/index.cfm?cfid=4794203&CFToken=14453158>  
Information regarding shortages from the American Society of Health Systems Pharmacists.

<http://www.cdc.gov/nip/news/shortages/default.htm> CDC website for vaccine shortages

<http://www.pharmacyonesource.com> - Pharmacy One Source (Free Subscription), provides MEDWATCH and other information

■ We've posted this information on the CTEP Web page under, "Acquisition and Management of Agents." Please tell others in the research community, and encourage them to use these sites.

*Outrunning the RADAR!*

● On October 31, 2005, the FDA approved 506U78 (nelarabine, NSC 686673) for treatment of acute T-cell lymphoblastic leukemia/lymphoma. Arranon® became available on January 25, 2006, with GSK Customer Relations (phone: 1-800-877-1158) coordinating orders. PMB will no longer approve Special Exception requests for patients from US sites. Until February 28, we will accept requests for a one month supply of drug for patients enrolled prior to Feb 1, 2006. After that, all US patients must be transitioned to commercial Arranon®.

International requests will continue until March 31, 2006. After April 1, 2006, international sites must contact GSK directly to obtain 506U78.

● On December 20, 2005, the FDA approved Nexavar® (sorafenib), NSC 724772, for use in patients with advanced renal cell cancer. Sorafenib is the first FDA-approved treatment for renal cell cancer in more than a decade. The NCI currently has over 43 approved protocols and 11 protocols in review using sorafenib in various tumor types.

● And (horns blowing here, please), on January 26, 2006, the FDA approved Sutent® (sunitinib; NSC 736511) for two indications simultaneously: GIST and advanced renal cell cancer. That is a first.



*Endless Traffic Circle*

It's like getting caught in a traffic circle—information keeps whizzing by:

■ GW786034's new generic name is pazopanib and BMS-354825's new generic name is dasatinib.

■ The effects of food on AZD0530 absorption are now known. AZD0530 should be taken on an empty stomach (one hour before or two hours after meals).

■ A new oxaliplatin liquid formulation will soon be available. Unlike the powder, the 5 mg/mL solution does not need reconstitution prior to dilution in D5W. The liquid form cannot be used on all NCI sponsored oxaliplatin studies. Please contact PMB before processing any oxaliplatin transfers.



*Following McDonald's Lead*

Montanide ISA 51 VG (NSC 737063) will replace Montanide ISA 51 (NSC 675756) in the next months. The "VG" (vegetable-grade) formulation contains oleic acid of olive origin, instead of beef tallow origin, as in the original formulation. (You'll recall McDonald's made a similar change with their French fries, but to reduce the likelihood of calories, not prions!) The new product will be supplied in 5 mL single-use vials containing 3 mL of Montanide ISA 51 VG, rather than in ampules. Sorry, no drive-through orders!

*Merging! Zero to 60 in 10 Seconds!*

New clinical phase zero studies are merging slowly into the CTEP-sponsored clinical trials highway. ABT-888, an oral poly(ADP-ribose) polymerase (PARP) inhibitor, is CTEP's first agent to be tested. Phase zero studies introduce human study at the earliest stages of drug development. This may identify possible biomarkers, cytotoxicity/ tumor DNA damage, target modulation, sequence-specific effects, and activity/efficacy.



Ever wonder if the agent you need to return to the NCI is a "Dangerous Good" for shipping purposes? Check the shipping receipt. We recently added \*\*DG\*\* in the package insert field for agents requiring special shipping. Call the Local Destructions Coordinator at 301-496-5725 to find out the best way to handle the "DG" that is no longer needed at your site.

**Look for INSIDE PMB quarterly!  
Next issue: May, 2006**

## Blind Curve!

Blinded studies present quite the challenge because of their large size, complicated design, and patient-specific clinical supplies. Sometimes, we can anticipate that proverbial cow in the road even before we come cruising around the blind curve at breakneck speed. Join us in anticipating these problems in blinded studies opening soon at a center near you. (We have shortened the titles in the interest of space.)



**CALGB-40302:** Endocrine Therapy With or Without Inhibition of EGF and HER2 Growth Factor Receptors will include CTEP-supplied lapatinib/placebo (GW572016)

Around the Curve: CTEP will automatically supply 3 syringes of fulvestrant for days 1 and 15; after that, you'll need to use commercial supplies.



**E2805:** Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma will include CTEP-supplied sorafenib/placebo and sunitinib/placebo

Around the Curve: In order to blind the study, each patient will receive a kit containing one bottle of sorafenib or matching placebo **AND** one bottle of sunitinib or matching placebo.

Because the dosing is VERY different for the two agents, either the pharmacist or the research nurse **MUST** complete the enclosed "Patient Medication Calendar" for the patient before dispensing the kit to the patient.



**E1805:** A PSA Vaccine and GM-CSF in Androgen Ablation Refractory Prostate Cancer will use CTEP-supplied PROSTVAC-V (vaccinia) and matching control; PROSTVAC-F (fowlpox) and matching control; and GM-CSF 500mcg

Around the Curve: This will be the first Phase III/Cooperative Group/CTSUs protocol involving gene therapy and, therefore, requires protocol approval by both the clinical site's

Institutional Biosafety Committee and IRB. You must submit both approvals to the CTSU Regulatory Office before the protocol can be activated at your clinical site.



**NSABP-B-42:** Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer will include CTEP-supplied letrozole/ placebo

Around the Curve: Patients can be enrolled on the protocol anytime after completing the first two years of hormonal therapy (tamoxifen or any of the three commercially available aromatase inhibitors) for breast cancer. Once enrolled, they are eligible to receive commercial letrozole at no cost to complete their first five years of hormonal therapy. After that, patients will be eligible to continue on the protocol with randomization to an additional five years of blinded letrozole or matching placebo.

## Driving U Nuts CONTEST

Unscramble these words to make generic agent names.

1. tea of minx
2. zoo teller
3. it is a band
4. an oxtail lip
5. timid neon
6. anti demon
7. med navigations
8. plain bait
9. enable rain
10. van left ruts
11. ideations man
12. bonzai pop

Here's a hint if you think this is too hard: all of the names appear in this newsletter. Please send your answers to [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov). We will enter correct entries into a drawing on March 15, and three winners will (again) be able to select homemade cookies or dog biscuits as prizes.



### PMB AFTER HOURS

There once was a technician named Dirk  
Who was doomed to work, work, work  
He missed a good date  
When he stayed at work late  
His behavior drove others berserk!

So.....Have a question after 4:30 PM eastern time or too busy to call during normal business hours? Try our after hours E-mail address, rain or shine, at any time of the day or night:

[pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov)

**Expect an answer within one business day.**

### Two New FAQ

Two new frequently asked questions (FAQ) are available. The first is, "What should I do when a patient returns NCI-supplied clinical supplies?"



The second is actually not an FAQ.....yet. It explains what P-glycoprotein (P-gp) interactions are. Many of our newer agents appear to be affected by P-gp metabolism, and this questions summarizes what we know about P-gp interactions to date.

(next column, please....)

To get a copy of either of these FAQs, a list of all available FAQs, or an article from *The Consultant Pharmacist* that you can use to counsel friends, family, and patients when they ask how to dispose of pharmaceuticals and personal care products (that are not CTEP-supplied!) send an E-mail to [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov).

## Global Positioning Satellite for Oncology Clinicians?

What did we do before GPS allowed us to find our way anywhere with just a few key strokes? Someday, we'll say the same thing about these handy web sites that navigate oncology topics:

- PDQ: A searchable database of information on cancer topics, closed and open trials, and professional directories:  
<http://www.cancer.gov/cancertopics/pdq>
- MedlinePlus: The National Library of Medicine's portal to a variety of health topics:  
<http://www.medlineplus.gov>
- NCI Dictionary of Cancer Terms: Contains more than 3,500 terms related to cancer and medicine:  
<http://www.cancer.gov/dictionary/>
- Clinicaltrials.gov: A searchable database of NIH and industry-sponsored clinical trials:  
<http://www.clinicaltrials.gov/>
- NCI Clinical trials Website: A database of cancer clinical trials and clinical trials process:  
<http://www.cancer.gov/clinicaltrials>
- Understanding Cancer Series: Tutorials on cancer topics: some modules available in Spanish:  
<http://www.cancer.gov/cancertopics/understandingcancer>