

The Terrible Twos!

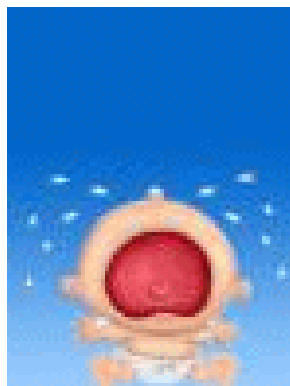
Brace yourself! INSIDE PMB turns two this month, and we feel an irresistible urge to act up! We've had an earful from readers about what you want, and many compliments (thank you).

Our accomplishments in the last year include

- On time delivery of four issues
- Expansion of electronic delivery
- Better inclusion of your questions and concerns
- Contributions from all PMB staff

Our goals for the next year?

- Increase electronic distribution
- Reformat with a cleaner fresher look, like real magazines do
- Invite reader participation and keep you chuckling while we do it.



Taking Our Marbles & Going Home

OK, so nobody wanted to play our matching game in the last newsletter. No one sent even a meager attempt, except Dominic Solimando who had issues with the extra credit question. The answer to that question (Tell us what you call pickled flower buds from the *Capparis spinosa* used as a pungent relish in various dishes and sauces) was, "Capers." So, Dominic wins this contest even though technically he didn't even play. Yvonne Bossert of Stockton, CA, has also been selected as a winner, because in her lovely letter to us, she implied she knew the answer, and hoped "nobody died laughing" here at PMB. When we hear from you two, we will make arrangements to send cookies or biscuits.

GODZILLA- vs. OXALI-: FAST FACTS TO REMEMBER:



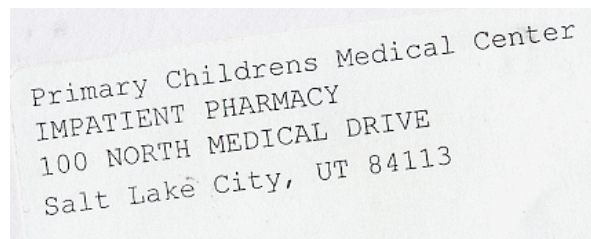
- There is no such drug as GODZILLAplatin, which was referenced in the last newsletter. We. Made. That. Up. (Oxaliplatin is real, however.) So the answer to the question, "Which studies are currently using GODZILLAplatin?" is "None."

- Note that PMB will supply some OXALIplatin (NSC 266046) studies with a new, liquid formulation; consult your protocol for preparation instructions.

Deuced Mistake

Jared Cash, Pharm.D., Pharmacy Clinical Coordinator at (one of the many)

Children's Hospitals found this PMB blooper on a mailing label. When pressed, he admitted that maybe they could be a little more patient. Thanks for sharing our blooper.



Twin Transfer Tips

Need to transfer an agent? Two tips:
Ø Transfer only full bottles of oral agents or unopened boxes of blister packs. Our system does not capture partials.

U When transferring carboxypeptidase (NSC 732443; glucaripidase), write the kit's Package Control Number (PCN) in the "Manufacturer and Lot Number" section. The PCN is normally a 5-digit number (i.e. PCN 04182) that appears on the shipping record and the bottom of the kit label. Please document the PCN on your drug accountability records routinely.



Sending Twice as Much:

BMS-247550 (ixabepilone; NSC 710428) 30 mg vials are no longer available. You can order the new 15 mg vials, or PMB will simply fill your order for 30 mg vials with twice as many of the 15 mg vials.

Look for INSIDE PMB quarterly! Next issue: November, 2005

Double Improvement

Tired of using low-protein binding, non-fiber releasing 5 micron filters for alemtuzumab (NSC 715969) ampules? No clue what the "non-fiber releasing 5 micron filter" is? Your dreams have come true! PMB now has alemtuzumab vials in a 30 mg/mL concentration, 1 mL vial. This new concentration does not require filtration!!

New Kid on the Block

The CD30 antigen primarily occurs on the surface of activated T-cells and is over-expressed in malignancies such as Hodgkin's disease (HD), and anaplastic large cell lymphoma (ALCL). The chimeric monoclonal antibody SGN-30 (NSC 731636), has a unique specificity for the CD30 antigen. Supplied by Seattle Genetics and soon to be distributed by PMB, SGN-30 is available as a 100 mg per 10 mL vial (10 mg/mL) sterile, colorless, slightly opalescent, preservative-free liquid for intravenous administration. Store intact vials under refrigeration. Never shake SGN-30! Dilute calculated doses in 0.9% Sodium Chloride Injection or D5%W to a final concentration between 1 and 5 mg/mL. The final product is stable for up to 24 hours when refrigerated.

Give It Back! Give It Back Now!

Many NCI-supplied agents have no expiration date on their labels. PMB pharmacists monitor their re-test dates and send you a "Stock Recovery Letter" directing you to return all expired stock once the manufacturer determines the agent is reaching the end of its useful life. Our letters (until now) have not said precisely how soon we expect you to return the agent to the NCI Clinical Repository. Effective immediately, they will indicate that you must return expired agents within 90 days.

Findings From Twin Studies

Researchers use twin studies to try to extricate the environmental and genetic influences of personality traits and disease. Although popular, these studies assume that fraternal and identical twins experience identical environments. That assumption may or may not be true. Researchers study monozygotic (identical) twins to estimate a disease's heritability. Comparing a disease's incidence in sets of identical twins to its incidence in dizygotic (fraternal) twins theoretically attributes any difference to genes, not environment. Consider these twin study findings:

- Most cases of hereditary breast cancer (BC) are not related to cumulative hormone exposure and may instead result from an unusual sensitivity to pubertal hormones.

- Childhood growth before puberty may increase risk of premenopausal BC, at least in women without a family history. Body fat distribution in young adulthood may also alter BC risk.

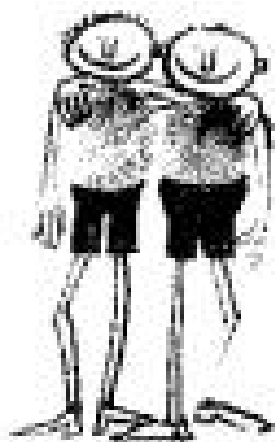
- In a Korean twin study, the difference in cancer prevalence was marked for twins born before 1926. Same gender twins showed increased recurrence risks for colorectal cancers and stomach cancers.
- Cancer patients are at increased risk for long-term cognitive dysfunction compared with individuals who have never had cancer, even after controlling for genetic and rearing environment influence.

- A Swedish study found no significant association between neuroticism +/- extroversion and cancer risk.

- The Finnish Twin Study found a near-total lack of concordance for malignant skin cancer in twin pairs. This suggests that environmental and not hereditary effects are most important in a white population with low levels of sun exposure.

Twin study designs and statistical analysis methods are improving over time, and currently, they augment basic study to include DNA sampling and molecular genetic comparisons. With multiples births on the increase because of increased use of fertility drugs and the trend to delay childbirth to a later age, maybe for the our 5th anniversary, we'll discuss "Quint Studies!"

<References available upon twin requests>



Oh YES, We Have No Bananas!

Numerous CTEP-sponsored protocols make reference to erwinia asparaginase (Erwinase™; NSC 106977). Unfortunately, they often include incorrect information (although we have asked investigators to correct the contact information). Erwinia asparaginase has been unavailable since December 2002. Routine re-validation work raised an element of uncertainty regarding the sterilizing cycle for the product stoppers. Its manufacturer recalled erwinia asparaginase worldwide early in 2003 as a precautionary measure.

In order to rectify the manufacturing situation, process validation work is currently underway. Any alterations made to the manufacturing procedures will require approval from appropriate regulatory bodies. No one can predict exactly when more erwinia asparaginase will be available.

McKesson BioServices holds the IND in the United States, so US clinicians can direct questions about its availability to Ann Thai at (301)315-8460. Clinicians outside the US can contact Dr Phil Luton, Health Protection Agency, Porton Down, Salisbury, Wiltshire SP4 0JG, telephone: 01980 612725 or e-mail phil.luton@hpa.org.uk

+* +* We Have No Bananas T0000- day!+++* <<

Fool me once, shame on you!

Whenever possible, PMB pharmacists send stock recovery letters (SRLs) 60 days in advance telling you to return agents that will expire. Sometimes, it's impossible to give that much lead time. We send the letter to the Principal Investigator's office address (as required by the FDA), and the address where the agent was shipped (because you all don't always talk to each other). Your designated shipping designee needs to share this information with others. Or, as the letter succinctly states, "IMPORTANT: If this investigational agent is being stored and distributed from another location, please ensure that this notice reaches that location." In the future, this newsletter will include a list of agents for which SRLs have been sent recently.

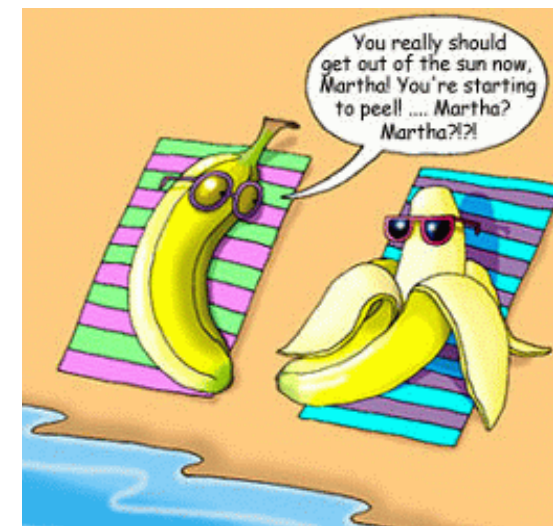
Fool me twice, shame on me!



Bananas in Pajamas

Do This...Or Else!

If you notice any dissolution difficulties, unexpected cloudiness, or similar cooties when admixing any PMB-distributed investigational agent, please contact PMB immediately. Don't wait, pul-eeze.



PMB AFTER HOURS

We are having a half price sale—two queries for the price of one—on our e-mail inquiry service. Hurry--take advantage of this limited-time offer!

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

pmbafterhours@mail.nih.gov

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