INSIDE PMB

When in Rome

MAY 2006

...DO AS THE ROMANS DO

Sometimes it's hard to come up with viable newsletter themes. This quarter, it was also challenging because the PMB emperor replaced the editor's stylus and wax tablet with a newer, artsy word processing program. The scribe was slaving away, wondering how to supplement the two tiny pieces that were ready–some announcements about agents and a trivial game. Suddenly she yelled, "Jupiter, I forgot about that goddess Tammy Fischer who was the only reader to submit an entry in the last contest!" That did it, we had our theme.

Congratulations Tammy, who hails from MedCenter One in Bismarck, North Dakota! She'll receive cookies for her efforts.

So, welcome to Rome. The Romans played board games often. They are credited with creating Dice (*Tesserae*), Roman Chess (*Latrunculi*), and Tic-Tac-Toe (*Terni Lapilli*) among others. It's time for you to urn your keep, so play the game on page two, or there'll be no more games.

Pay Attention Please

There once was a nurse named Phillipe,
Who could unpack an order in his sleep,
He paid more attention
When haste caused apprehension
As he sorted through trash, very deep.
Please reconcile your physical inventory count with your packing slip before tossing the packing materials.

Information Forum

? Need an Investigator Brochure for an agent for which NCI holds the IND? E-mail to ibcoordinator@mail.nih.gov or call 301-496-5725 and ask for the IB Coordinator.

? Have investigator registration questions? Have the investigator's number ready and E-mail PMBregpend@mail.nci.nih.gov or call 301-496-5725 and ask for the Registration Coordinator.

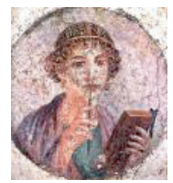
? Want to request agent for non-human use? Send an E-mail to PMBafterhours@mail.nih.gov and use the subject, "ATTN: NHU Coordinator." Or call the NHU Coordinator here at PMB.

? Have issues with investigator-held INDs? Send an E-mail to PMBafterhours@mail.nih.gov and use the subject, "ATTN: Investigator-Held IND Coordinator."

? Questions about a foreign shipment? We have a coordinator for those, too! Send E-mail to PMBafterhours@mail.nih.gov and use the subject, "ATTN: Foreign Shipment Coordinator."

NEXT ISSUE SEXTILIS 2006 (Augustus Caesar's month)

Still reading this on papyrus? Don't count on it for too much longer. See page 2!



IND Closures

As IND sponsor, part of CTEP's responsibilities when closing (withdrawing or inactivating) an IND is to recover all agent from the field and to notify investigators we are closing the IND. To fulfill that obligation we send a letter to all investigators who ever received agent from us using their current 1572 addresses. Technically, we are only required to notify investigators. We do, however, understand that the nuts and bolts are a plebian concern. So, we send the letter to the investigators' designee/shipping addresses–the people who actually received the agent and who may need to take an action.

The system is somewhat Byzantine. As shipping addresses are historical and carved in stone (non-updatable), letters are often addressed to people no longer in your institution's employ. The longer the agent's history with us and bigger the scope of the development program (with a programmus maximus including SPEX, Group C and TRC), the more deadbeat letters generated. Gaius Pharmicus, R.Ph., may have been shipping designee for Julius Caesar, MD, eons ago, but the letter will still be addressed to him even though Helena Komenos is Caesar's current designee. We apologize for multiple copies, but hasten to proclaim the only other alternative (not to send information to potentially ancient shipping designees) is to leave you at Caesar's mercy, if you will.

The only thing a site needs to do is return any remaining NCI-supplied agent. Since ordering designees never stockpile or order unnecessarily and promptly return all expired agent, most sites will have nothing to do. File the letter with your records, and encourage your PI to send you a copy of the official IND withdrawal/inactivation letter so you can start your two year sundial for record retention. Then, mimic the great fire of Rome.

Watch for the official NCI IND closure letters for topotecan (coming soon) and paclitaxel (sent 3/31/2006).

Don't Be Busted by Julian Dates

A julian date is a 5 or 7 digit number that identifies a specific day of a specific year. It is based on the Julian calendar, introduced by Julius Caesar in Rome in 46 B.C. that established the 12-month year of 365 days with a leap year every 4 years. The digits of the number represent the year and the day of the year. So a julian date of 06001 or 2006001 is January 1, 2006 and 04366 or 2004366 is December 31, 2004. PMB uses these numbers on the label of every double-blind agent and also as a part of every order, transfer or return number. So 2003182-0001 is the first regular order we processed on July 1, 2003 and T03182-0012 is the twelfth transfer we processed that day.

PROCLAMATIONS

We shall now endeavor, with clearness and precision, to describe specific issues of which you should be aware.

BMS-247550 30 mg vials (expired 2/28/06) are hereby relegated to the ranks of antiquities. Only 15 mg vials will be available until further notice.

CC-5013 is available in 21 capsule bottles or 28 capsule bottles. You shall order as proscribed by your protocol's cycle length.

Protocols using GW786034 are tricky: Whereas one protocol uses 100 mg and 500 mg tablets, all others use 200 mg and 400 mg tabs. Freedom to transfer GW786034 is not granted; contact PMB prior to all GW786034 transfers.

A crusade has begun to encourage sites to order the correct vial size of CCI-779, since it shall be dosed using flat doses, and not body surface area. We (that is the empirical we) proclaim that sites must order either the 25 mg or the 125 mg based on the protocol.

Pharmaceutical Management Branch * Cancer Therapy Evaluation Program * Division of Cancer Treatment and Diagnosis * National Cancer Institute
6130 Executive Blvd * Suite 7149 *Rockville, Maryland 20852 * Phone: (301) 496-5725 * Order fax: (301) 480-4612 * Other fax: (301) 402-0429 *E-mail: pmbafterhours@mail.nih.gov

OCCUPATIONAL HAZARDS : VESTAL VIRGINITY

In Greek, asbestos means 'inextinguishable.' Asbestos's strong silicate fibers are composed of magnesium, calcium and iron, and can be silky and curly or straight and needle-like. When processed, tiny fibers are created and can be inhaled.

The Romans quarried asbestos all over Europe and the Mediterranean. They incorporated it into everything—cloth, building materials and even the candlewicks that allowed the Vestal Virgins to keep the everlasting flame alive—for strength, insulation, and fire and corrosion resistance. (Vestal Virgins may have gotten free seats at the theater, but was it worth the risk of pulmonary disease?)

Today, asbestos is found in widely used materials for ceiling and wall tiles, insulation and auto brakes. Inhaled asbestos fibers can clog the lungs, heart, or abdomen. Scar tissue develops as the body's autoimmune system cannot destroy asbestos fibers. Cancer may follow after a common latency of 20 to 40 years. The most common asbestos injury is mesothelioma, a malignant cancer. It has no known cure. Traditional care consists of surgery, chemotherapy and radiation. The FDA recently approved pemetrexed for use with cisplatin for patients who are not candidates for curative surgery or whose malignant pleural mesothelioma is unresectable.

NCI is sponsoring three new clinical trials:

- E1B03: Phase II randomized study of premetexate disodium combined with either gemcitabine or carboplatin in patients with advanced malignant mesothelioma of the pleura
- S0509: Phase II study of AZD2171 in patients with unresectable malignant pleural mesothelioma
- 7103: A Phase II Study of AZD2171(NSC#732208) in Patients with Malignant Mesothelioma

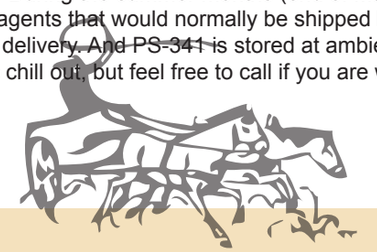
The Mercury is Rising

Caduceus-carrying Mercury, messenger and god of commercial activities, protected land and sea routes. On the Mercuralia on May 14, Roman merchants performed rituals of devotion to Mercury and beseeched him to assauge their guilt from having cheated customers and suppliers rather routinely in the last year. Our Clinical Repository's strict use of amphora (weights) and measures, supplemented with extraordinary papyrus tabulae, ensures that no cheating goes on. But sometimes, our customers raise questions about the land or sea routes we use to transport our goods, especially when the ambient temperatures start to rise.

We use manufacturer-provided guidelines when creating each shipping protocol. These agents are stored in the refrigerator, but shipped at ambient temperature via FedEx-next day delivery: alfa interFERON, glucarpidase, interLEUKIN-4, trastuzumab, depsipeptide, rituximab, UCN-01 and XL119.

These drugs are shipped at ambient temperature via the US Postal Service: azacitidine, bryostatin, and O6-benzylguanine.

There are a few others, too. During the summer months (end of May to beginning of September), refrigerated agents that would normally be shipped Priority Mail are shipped via FedEx next day delivery. And PS-341 is stored at ambient temperature, but shipped on ice. So chill out, but feel free to call if you are worried.



Bread and Circus

Beginning with Augustus Caesar, the city of Rome provided bread, oil and wine to its urban population. It also provided entertainment: Circuses with wild animals. Might we suggest some diseases that are good excuses when you need a break from or for the circus for a day? Match the "Latin" term with its English definition:

1. Dia-beuties	**a. Your crazed kitten ruined your last pair of pantyhose**
2. Rhabdo-nylon-osis	**b. Serious bad hair day**
3. In-zoo-enza	**c. You forgot to refill your son's methylphenidate, and can't send him to school like this**
4. Hyper-tense-son	**d. You were paid Friday, worked the weekend, and your denarii are burning a hole in your toga**
5. PAIDS	**e. You'd rather spend the day on a field trip with your kindergartner**

Send your answers to pmbafterhours@mail.nih.gov and you'll qualify for our next drawing. Four winners will receive homemade goodies.

PMB AFTER HOURS

Spent the day battling Barbarians,
and and now the sun is setting
on your own Eternal City?

Try our after hours E-mail address
at any time of the day or night:

pmbafterhours@mail.nih.gov

Expect a response on the next business day!

In The Aquaduct

GX15-070 (NSC 729280) is a novel antitumor agent that promotes cancer cell apoptosis by inhibiting anti-apoptotic Bcl protein family members. CTEP will study GX15-070 in combination with other agents in chronic lymphocytic leukemia, non Hodgkin's Lymphoma, small cell lung cancer, and melanoma.

AT-101 or R-(-)-gossylpol acetic acid (NSC 726190), the levorotatory enantiomer of racemic gossypol acetic acid, is a small molecule inhibitor of the anti-apoptotic proteins Bcl-2 and Bcl-XL. AT-101 will be studied as a single agent or in combination with standard antineoplastic agents.

Keeping Patient Calendars Useful

Patient calendars or diaries are important adherence tools in many clinical trials. Unfortunately, many of them have to be discarded when patients fix erroneous entries incorrectly. Please ask clinical staff to teach patients how to line through and initial erroneous entries. Include these directions on the calendar itself.

THIS IS NO JOKE: Before the end of 2006, PMB will be forced to discontinue sending INSIDE PMB with your orders. You will need to register for electronic distribution if you wish to continue receiving it.Thank you for your interest. Register at pmbafterhours@mail.nih.gov

*THE END *

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