

INSIDE PMB REGARDS TO BROADWAY AUGUST 2006

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The Vaudeville that is PMB

A faithful reader mentioned that it has been a while since we had role call in the newsletter. PMB is much like Vaudeville – “a dazzling display of heterogeneous splendor.” We try to keep our acts short and the tone light. Most of us appreciate a good guffaw. Here’s our professional cast list.

- (in order of appearance)
- Pat Schettino.....Leading Lady
 - Donna Shriner..Placebo Costume Design
 - Matt Boron.....SPEX Ringmaster
 - Rodney Howells... Biologic Pyrotechnics
 - Michelle Eby.....Mistress of Dialogue
 - Jeannette Wick.....Performing Animal Trainer
 - Cheryl Grandinetti.....Culinary Magician
 - Skip Hall.....Vicarious Villain
 - Ravie Kem.....*Femme Fatale*
 - Joseph Miree.....Stage Manager
- No vaudeville exists without the support of all the behind the scenes folks, and PMB is no different.



Vaudeville—Charles Demuth—1883-1935



- Toni Waymer.....Choreographer
- Melizza Ford.....Special Effects
- Beverly Bailey.....Investigator Ticketing
- Christy Wright.....Playbill & Brochures
- LaToya Townson.....Scenery
- Nicole Hubbard....*Chanteuse de la telephone*
- Allison Brown.....Blinded Stage Mother
- Frank Scott.....Set Designer

Bringing Down the House; Practice, Practice, Practice

Our wonderful new stage mother to the sites, Allison Brown brags eight months’ past credits in blinded studies: same script, dialogue, and drama daily. Actors ordering blinded supplies and craving fame can earn these audience responses:

Bombardment with eggs: Omit your name, phone number, and fax number on orders. Without these credits, Allison cannot contact you with questions.

A shower of rotten tomatoes: Failure to maintain the three-way relationship between the investigator, the patient, and the blinded protocol on every order. CDRs must specify the investigator who enrolled that patient on that protocol, the assigned NCI protocol number, and patient ID number assigned at randomization.

Audience attrition: Forgetting that only the shipping designee and ordering designees indicated by the investigator on their annual Supplemental Investigator Data Form (IDF) can sign agent orders for that investigator.

Luke-warm applause: Remembering that the shipping address entered on the CDR must match the shipping address provided by that investigator on their annual IDF.

Whistles and cheers: Remembering that orders for the blinded studies take an extra day to ship (2 days versus 1 day) because of the patient-specific blinding and labeling.

Standing ovation: Including the patient’s body weight in “kg” for blinded studies where the total dose is dependent on body weight (e.g., bevacizumab/placebo 15mg/kg IV every 3 weeks). In the “patient or special code” box with the patient ID and the patient initials is a great location!

Tip-Top Dancing Form

PMB’s contractor, EDJ/PSA, has unveiled the updated FDA Form 1572 (Investigator Registration) in writeable Adobe Acrobat (pdf) format. After accessing <http://ctep.cancer.gov/forms>, investigators can tap dance across the keys, entering information directly onto the Form 1572. The next scene involves a waltz with an ink pen: the writeable Form 1572 still needs the investigator’s original signature and date on the form.

Folks in the chorus line will also find the Clinical Drug Request (CDR) form; Return Drug List; and Transfer Investigational Agent Form in writeable Adobe Acrobat (pdf) format. Each requires a copy of the dancer’s signature and date, but not an original.

The form buttons located at the top of each page allow the user to easily Print, Save As, Reset, and go to the Next Page. With a little rehearsal, you’ll be a star!

TIP: Earlier versions of Adobe Acrobat may not be able to save writeable documents. Users can type in the fields and print the form, or do what they’ve always done: print a blank form and write in the information. If you are having difficulty saving the forms and wish to do so, you may need to upgrade to Adobe Acrobat 6.0 Standard, or Adobe Acrobat 6.0 Professional.

MARQUEE

Matinees for kids: AZD2171 will debut a children’s 2.5 mg tablet and, unlike the mature versions, it requires refrigeration.

Total Drama: New, insoluble MEK inhibitor AZD6244 masters nuance, and audiences will abhor its character. Its chilly diluent must exit stage left (the refrigerator) 30 to 60 minutes before mixing, then be mixed with the powdered drug.

Mystery Theater: Several characters are masquerading trivial names with new names: GW786034 responds to pazopanib; GX15-070MS’s alias is obatoclox mesylate; SB-715992’s stage name is ispenisib; BMS-247550 or ixabepilone wants to be called Ixempra; BMS-354825 (dasatinib) is Sprycel; and the performer once known as CCI-779 (temsirolimus) has resolved its issues, and will henceforth be called Torisel.



Role Clarification: Studies, Understudies

FAQ: Can nurse practitioners (NP), physician assistants (PA), or fellows listed as co-investigators on the protocol write orders for investigational agents?

Answer: The FDA issuance on the subject says, "312.53 Selecting investigators. A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug."

Appendix X of CTEP's Investigator's Handbook defines investigator as, "Any physician who assumes full responsibility for the treatment and evaluation of patients on research protocols as well as the integrity of the research data."

Throughout the Handbook, "investigator" refers to a physician (from the definition of the term). On the 1572 (the document investigators use to register), investigators would list NPs or PAs in section 6 before sending it to the FDA. 1572s sent to the FDA are done by individual protocol--everyone participating on the protocol is listed on a single 1572. But, the NCI's arrangement with the FDA allows each investigator to submit a single annual 1572. That single submission covers the investigator's participation on any number of NCI trials. Because of that, we don't capture associates on the 1572s.

A NP, RN, RPh, etc. can register through CTEP-AMS as an associate--a staff member working in a non-physician role, but cannot write orders.

As far as writing orders is concerned, CTEP's stance is that the only people who should be writing orders for investigational agents are individuals who could receive a shipment of the agent from PMB. In order for PMB to ship the agent, the investigator (physician) must be registered, active, and (outside of Group protocols) listed on the face sheet of the protocol. An investigator may allow a resident/fellow to write orders, but must co-sign the order.

Intermission

Every busy clinician needs a break, so try this matching game. You pass the outpatient pharmacy, and seven famous characters from Broadway are in line. Match the character to the prescription drug he or she is most likely to be filling, and win treats for you or your dog.

- | | |
|--|--|
| 1. Fantine
<i>(Les Miserable)</i> | a. oral contraceptives |
| 2. Blanche DuBois
<i>(A Streetcar Named Desire)</i> | b. fluoxetine |
| 3. Jean Valjean
<i>(Les Miserable)</i> | c. topical finasteride |
| 4. Mimi
<i>(Rent)</i> | d. rifampin, isoniazid, pyrazinamide, ethambutol |
| 5. Tracy Turnblad
<i>(Hairspray)</i> | e. lamivudine/zidovudine |
| 6. Sophie
<i>(Mamma Mia)</i> | f. disulfuram and lithium |
| 7. King of Siam
<i>(The King and I)</i> | g. orlistat |

Send your answers to pmbafterhours@mail.nih.gov, and we will enter you in our drawing.

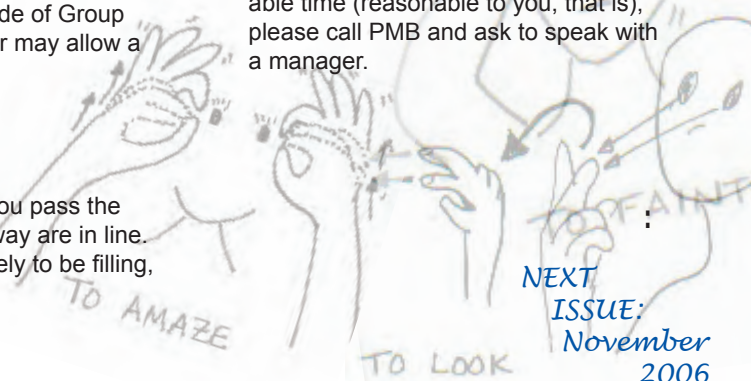
Hubbard Aspires to Challenging Role

Marta Cardenas, who played PMB Drug Authorizer for two years, has moved on. She will be sorely missed. Nicole Hubbard, who past credits include a powerfully delivered performance as PMB Technical Receptionist, auditioned for and won this role. Welcome her.

BAD REVIEW: ERATA

John Koerber took issue with our May 2006 announcement that only one person entered the November 2005 contest. He said (1) he entered, and (2) he thought he got 100% correct. The editor raised the back of her hand to her forehead, and swooned. The sign language interpreter was called, and the entire chorus line began to sort through PMBAfterHours. OH agony and ecstasy! There it was. The culinary magician got cookin' right away, and the stage manager had cookies in the mail pronto.

Congratulations to John! Which reminds us: if you contact us and do not receive an answer within a reasonable time (reasonable to you, that is), please call PMB and ask to speak with a manager.



It's Always Showtime!

Sung to the tune of A Chorus Line's "One"

One singular sensation
Ev'ry little thing you need
One thrilling combination
Telephone and Internet speed
One click and suddenly nobody else
will do

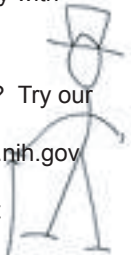
You know you'll never be lonely with

P! M! B!

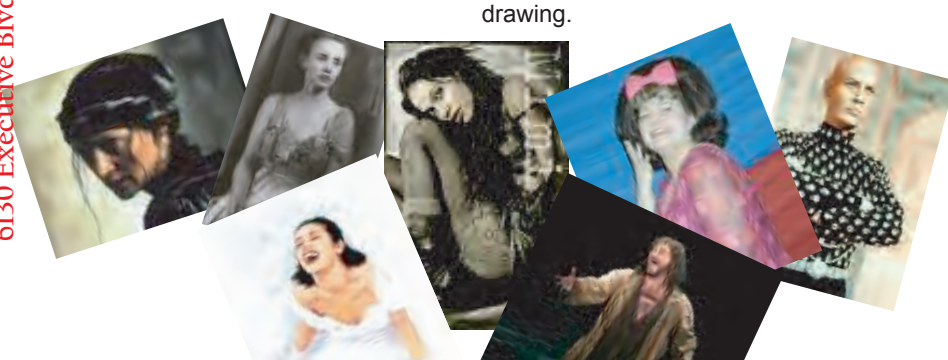
Need to reach us day or night? Try our E-mail address:

pmbafterhours@mail.nih.gov

Expect a response on the next business day!



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THE PRODUCERS: THEY CALL THE SHOTS

Mel Brooks' runaway hit *The Producers* (also an Uma Thurman movie for those of you who lack Broadway access) has won more Tony Awards than any show in Broadway history. Its story is simple: a couple of guys dream up a scheme to produce the most outrageous—as in doomed to fail—Broadway fiasco ever. The plan: raise more money than necessary, and abscond with what's left after a feeble attempt at a musical. But oops!—when the curtain goes up on their gigantic singing, dancing spectacular, their plan goes hilariously wrong. Only Mel Brooks can get away with the coarse jokes, off-color remarks, and slapstick humor in the show. Tickets sell fast.

OK, scene change to CTEP. The situation here is almost the opposite. Producers of investigational agents always hope for outrageous success: the one antineoplastic that will cure cancer, and fast. And without making the audience sick, if you know what we mean. What they usually get is a slow, costly program that consumes lots of money. Regardless, the informed consent has traditionally said that the investigational agent is free, so folks sign on.

Some agents, like that Broadway show, have had remarkable success. And, consequently a few cancers that used to be rapidly terminal have been turned into chronic conditions. Which means patients may need the agent for years, not months, and meanwhile, the producer applies to the FDA and gets commercial approval. So, the fantasy that producers will provide agents free forever and the reality that they may not be able to do so collide.

So, CTEP hired the playwright Shakespeare to rewrite the informed consent script. It now reads:

The study agent, _____, will be provided free of charge by the Division of Cancer Treatment and Diagnosis, NCI, while you are participating in this study. However, if you should need to take the study agent much longer than is usual, it is possible that the supply of free study agent that has been supplied to the NCI could run out. If this happens, your study doctor will discuss with you how to obtain additional drug from the manufacturer and you may be asked to pay for it.

It's tragedy. It's history. It will be translated into several languages. It is what it is.
Any similarity between people alluded to herein and real people is merely coincidental.

The Iceman Cometh

Eugene O'Neill's so-called Greek play, *The Iceman Cometh*, uses "choral logic": the repetition and circulation of motifs among various voices ("Why wasn't my Herceptin shipped on ice?"); moments of counterpoint between multiple sets of characters ("Yes you did so used to ship it on ice!" "Did not!" "Did TOO!"); the choreography of actors passing into and violently out of sleep ("Yo, buddy, wake up and smell the coffee. It's 144 @#^%&*# degrees out here!"). It's the Long Hot Summer. You've got a breast cancer patient waiting for treatment and a trastuzumab shipment that just arrived... at room temperature!

Not to worry. Trastuzumab is stored in the refrigerator, but shipped at room temperature (RT). Our Repository uses guidelines provided by various manufacturers when creating their shipping protocol. These agents are stored in the refrigerator, but shipped at RT via FedEx next day delivery: alfa interFERON, glucarpidase (carboxypeptidase), interLEUKIN-4, trastuzumab, decapeptide, rituximab, UCN-01, and XL119. These drugs are shipped at room temperature via the US Postal Service: azacitidine, bryostatin, O6-benzylguanine. There are a few others, too. From the end of May to the beginning of September, refrigerated agents that would normally be shipped Priority Mail are shipped via FedEx next day delivery. So chill out, but feel free to engage in "choral logic" if you must.

And PS-341 is stored at RT, but shipped on ice. Go figure.

From the Orchestra Pit

Thanks to all who took the quiz in May's newsletter. We had a record number of entries. We would like to hear from you if you used any of the excuses, successfully or not so successfully. Many of you used exactly the same words ("now that you've dumbed it down") to describe why you were willing to play this game, but sat out previous versions. Without further ado, please congratulate our winners:

Joy Mitchell, CCRP
Winston-Salem, North Carolina

Christy Schaeffer, CCRP
Reading, Pennsylvania

Amy P. Adams, Pharm.D.
Charlottesville, VA

ENCORE?

NO! ENOUGH ALREADY!

If you've read this far, you've probably noticed some changes. They started when you had to visit our web site to retrieve the document. Yup, we are Thoroughly Modern Millie now, and paperless. Then, it printed on standard sized paper (Jane Abel is cheering in Missouri), that will surely Aida you. And it's our third anniversary, so our Guys 'n Dolls redesigned the set.

So what, WHAT? you ask. We don't mean to imply "I Can Do Anything Better Than You Can," but we need your help. We are still receiving protocols that include forbidden abbreviations. Mama Mia, they have been on IOM's and JCAHO's "do not use" list for two years. We know you know, but could you forward this newsletter to the folks who write your protocols? These are the biggest problems for us, but there are others.

Item	Suggested Replacement
ug	mcg
H.S.	half-strength or at bedtime
S.C.	Sub-Q, subQ, or subcutaneously
S.Q.	Sub-Q, subQ, or subcutaneously
D/C	discharge, discontinue

And please avoid those trailing zeroes.