INSIDE PMB FEBRUARY 2004

KNOCK, KNOCK? WHO'S THERE? PMB! PMB WHO?

So you call the Pharmaceutical Management Branch at the infamous (301) 496-5725 number, and a personable receptionist (Christy Ford or LaToya Townson) routes your call. Why do they route the calls the way they do? How come the people who help you can't look at the drug you're discussing? Let's look at the PMB's mission and organization…

(1) The Pharmaceutical Management Branch (PMB), under the direction of Skip Hall conducts drug forecasting, drug acquisition, and inventory management of all IND agents distributed by the NCI for clinical trials.

Drug Management and Authorization is handled by 5 extraordinary pharmacists. Once the NCI decides to study an agent, one of these pharmacists is involved in everything from protocol development to forecasting the exact number of dosage units we'll need. It's art. It's science. It's….never mind. So, if you have a question about an agent (i.e. availability, pharmaceutical information, storage, etc...), your call will be routed to the agent expert. Patricia Schettino leads this section, and handles NCI-developed agents. Cheryl Grandinetti and Rodney Howells primarily deal with biologics (but have some drugs). Michelle Eby and Jeannette Wick have portfolios of primarily drugs (with some biologics). They are assisted by the talented Rahul Prakash.

(2) The PMB authorizes and distributes all NCI -sponsored Investigational New Drug (IND) agents to eligible investigators.

When you fax a Clinical Drug Request (NIH-986), our efficient, knowledgeable staff handles your orders. Marta Juarez is our new Drug Authorizer. Actual shipping is done at the NCI Clinical Repository a few miles away. They receive, store, and distribute the agents. So, if you call PMB, we can't go to the agent's shelf.

(3) **PMB manages a Treatment Referral Center (TRC) for handling special NCI clinical drug initiatives and referrals to high priority clinical trials, and provides drug and pharmaceutical information about NCI IND agents. The TRC also coordinates, authorizes, and processes all requests for Special Exception and Group C IND agents.**

Speedy Matt Boron and his trusty assistant Darshon Brown handle these issues, with Cheryl Grandinetti as back up. They handle approximately 150 inquiries a month. Once a request is approved, E-mails and faxes fly between PMB and your site so agent is shipped quickly.

(**4) The PMB registers and maintains registration records for all investigators participating in NCI clinical trials.**

Beverly Bailey is the patient, meticulous lady who deals with protocol issues that are invisible, but important to you.

(5) What (or who) did we miss?

When we call Donna Shriner our "blinded pharmacist," we aren't referring to her eyes! She handles the 25 or so large Phase III blinded studies that require special labeling and cautious supervision from start to finish - and generate a huge number of patient specific orders! Vigilant Stevie Johnson serves as her eyes, ears and authorizer.

Finally, Carl Huntley does more things invisible to our customers and also makes coffee and handles emergency infusions of chocolate for the PMB staff. Melissa Penn provides ever essential administrative support. Melizza Ford and Tonisia Hill Waymer coordinate our on-site contracts and pitch in wherever needed.

Our staff is cross trained. If someone is off duty or swamped, the receptionist knows who is covering. Thus, *it's best for you to state your problem to the receptionist*, who will then forward the call with dispatch!

Look for INSIDE PMB quarterly! Next issue: May, 2004

CARBOXYPEPTIDASE ($CPDG_2$; NSC 641273)

A new lot of carboxypeptidase has been recently manufactured. Unlike the previous lot (lot 004), this lot should be stored in the refrigerator (2 to 8 degrees Celsius). We will continue to ship domestically at room temperature, but place the product in the refrigerator immediately upon arrival.

Raining? Pouring? Just Sprinkling!

Limited supplies of R115777 (NSC 702818) 25 mg and 50 mg sprinkle capsules are now available. Initially, they will be used only for protocol AAML0122 for patients < 12 kg and those who cannot swallow tablets. They may be available for more studies in future.

And a Pediatric Liquid....

A new pediatric study is using OSI-774 (NSC 718781) in liquid form. Packaged in glass vials initially intended for IV use, the drug will only be used orally. The pharmacist will draw it up into syringes. Please don't send intact vials home with patients.

Change of Venue!!!!

Newer lots of decitabine should be stored at room temperature as reflected on the product label. Continue to store the old lots under refrigeration.

And CCI-779 News:

CCI-779 25 mg vials have arrived. If your protocol uses a 25 mg weekly dose, please order only this vial size.

What is SAHA?

a. An **expression of astonishment**, as in, "SAHA! I didn't know PMB distributes investigator brochures!"
b. The Society for Annihilation of Humorless Announcements (**SAHA**).
c. The **sound of laughing** with a full mouth.
d. **suberoylanilide hydroxamic acid**, a potent histone deacetylase inhibitor now in trials in various blood and solid cancers.

QUALITY SERVICE?

If you have had a "noteworthy" (you define noteworthy) experience while on the phone with one of our staff, we'd like to hear about it. Contact PMBAfterHours, Skip Hall, Pat Schettino, or Carl Huntley.

PMB AFTER HOURS

We close at 4:30. The folks in Seattle are having a post-lunch pick-me-up coffee, and the South Africans are sitting down to dinner.
So.....Need to reach us? Try our new after hours
E-mail address:
pmbafterhours@mail.nih.gov

Expect a response on the next business day!

Question of the Month

"My IRB is driving me crazy! …Yesterday they wanted to know the IND number for an agent. Today, it's a question about the incidence of an adverse event. I can hardly wait for tomorrow!"

Institutional Review Boards can certainly add an element of "excitement" to anyone's day. These multidisciplinary panels ensure that the patient's rights are addressed in advance and never violated. So, they have questions, and those questions can be difficult to answer.

One of the most common questions we receive is, "What is Agent X's IND number?" Because this question has become so common, we are now including the IND number for each CTEP IND agent on the cover page of every protocol. The NCI-supplied agent's NSC is also included. (Older protocols may still be missing the IND on the cover page.)

The most recent Investigator's Brochure (IB) will provide a good estimate of known adverse event incidence. We distribute IB's to eligible investigators, too!

"What about Special Exception, Group C and Treatment Referral Center protocols? What type of IRB approval is needed?"

- "Special Exception" allows patients early access to investigational agents. This mechanism is the functional equivalent of a compassionate IND, but differs from it in that the investigator uses the CTEP IND rather than obtaining an individual investigator IND from the FDA. Special Exception protocols are patient-specific, available to qualified investigators, and must be IRB-approved for each individual patient.
- The FDA designates an agent as "Group C" if it has shown reproducible efficacy in one or more specific tumor types. A standard protocol is available, but each patient is reviewed individually. The protocol requires IRB approval.
- For certain high-priority diseases, the NCI identifies patient populations and creates a Treatment Referral Center Protocol for the NCI-designated Comprehensive Cancer Centers. TRC protocols require IRB approval at each participating institution.

So, go easy on your IRB, They are trying to protect patients from exploitation, confusion, or harm. Let us know how we can help. (

NUMBERS

In our last issue of INSIDE PMB, we warned you about a change slated for November 10th, 2003. On that date, the PMB implemented a policy requiring orders to be signed by a shipping or ordering designee listed by the investigator on their Supplemental Investigator Data Form (IDF). Look at these numbers!

Average number of orders PMB processes daily:
220

Number of requests from clinical sites for the two page IDF for all investigators after the newsletter was published:
350

Number of investigators whose information was updated:
>2000

Number of orders per week now received that are not signed by a recognized designee:
<10!

WHAT THIS MEANS: *On November 10th, the switch over went very smoothly. Your help in making this major transition so smooth is greatly appreciated!*

Remember to update your investigator's IDF if shipping or ordering designees at your clinical site change. Contact us if you still need the two page IDF for your investigators.

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

Even Forms Expire

Like all good government forms, the NCI Drug Accountability Record Form (the DARF or OMB 0925-0240) has an expiration date of April 30, 2004. We have heard your comments: Many of you would like some changes to the form. Changing the form, however, is a major undertaking; so is implementation (at your site and with the auditors). Since our goal is to move to on-line accountability, we have decided to implement changes once our web-based ordering system is implemented within the foreseeable future.

That said, we would welcome comments about what you would like to see on an electronic agent accountability form. Please send your comments, suggestions and even complaints and frustrations to pmbafterhours@mail.nih.gov with the subject line "Barf the DARF!"

All CTEP forms are available on CTEP's web page (http://ctep.cancer.gov).

SAVE SHIPPING COSTS!

As of October 6, 2003, all **blinded studies** using PMB-distributed agents have been written or amended so that containers (i.e., bottles, boxes, kits) that have been dispensed to a patient should **NOT** be returned to the NCI. Instead, these containers should be destroyed locally, in accordance with local policies.

1. Do NOT return any container that has been dispensed to a patient, even if it is sealed and full.
2. NCI will not acknowledge and will not capture any data for returns of partial or empty containers.
3. Returning undispensed containers? Complete a Return Drug List accurately and completely with the patient ID in the lot number field and a separate line for each agent returned. The two right hand columns are for NCI use only, so NO DOODLING!

C THE END C