



Date: April 29, 1993

From: Patricia R. Schettino, R.Ph., M.S.
Clinical Research Pharmacist, CRPS, PMB

Subject: Antineoplaston Minutes from April 29, 1993.

To: Attendees

Present in attendance: J. Greenblatt, R. Kaplan, M. McCabe,
D. Parkinson, P. Schettino, D. Shoemaker, M. Sznol

In addition, please distribute to: M. Friedman, A. Fallavollita,
J. High, S. Sepelak, R. Vishnuvajjala

NEXT MEETING:

Date:	May 13, 1993
Time:	8:30 am
Room:	736

1. STUDIES:
 - The protocol from MSK has arrived and is scheduled for PRC on May 6. A copy of the protocol was sent to Dr. Burzynski which he received on April 27.
2. DISCUSSION AND INFORMATION:
 - Both Dr. Young (MSK) and Dr. Buckner (Mayo) will be apply for the RFA money from OAM.
 - They should also be able to receive contract credit from ur.
 - The lawsuit against Burzynski is no longer a concern for him since the contaminate in the bag was a fairly rare organism that was also discovered in two other bags that went to patients that were not Burzynski's. It appears to be a pharmacy problem.
 - The information for the DMF should be sent to the FDA this week.
 - The information on drug delivery was Fedexed to M. McCabe this week. The information consisted of two instruction manuals--one for each of the pumps (Provider 5500 and 6000) that are apparently being used. There is no drug information.
 - The letter with the time line information was mailed out without attachment (1991 analyses data). This will be Fedexed out separately.
 - We will ask for A10 samples to be shipped to our repository and from there it will be distributed to the contractors for analysis.

- We will ask for the drug for the studies to be shipped when the IND is submitted. When those supplies arrive, we can have R. Vishnuvajjala randomly sample and test some bottles.

- Trials for pediatric brain tumors is still an issue. Apparently Burzynski has approached J. Jacobs in OAM and someone in the intramural program. Once the DMF is filed, Burzynski could do trials with any population of his choosing.

3. CONCERNS:

- Political issues are a very real concern. Berkley Bedell (former Congressman) is concerned that we are taking the antineoplastons away from Burzynski. He will be updated in a letter from M. McCabe as to our role.

- Burzynski has patents on antineoplastons.

- We are not doing drug development for the antineoplastons. There is not enough drug or resources, or a company sponsor. Our role is sponsoring confirmatory studies.

- Since phenylacetic acid may be the active component in antineoplaston, our involvement with phenylacetic acid and phenylbutyric acid has become an issue. Elan has use patents on both compounds. The CTEP role has been to apply disciplined drug development for work that had already been on-going.

4. ACTION ITEMS:

- Request for samples of each lot of A10.
- Letter to Bedell