

Weinberg/PPA

▶ Robert Schumm  
01/24/2000 06:46 PM  
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To: Jay Kolpon/MORT/CCD/US/BAYER@BAYER-US-NOTES  
cc: Craig Hammes/MORT/CCD/US/BAYER@BAYER-US-NOTES, Bill  
VanderHear/MORT/CCD/US/BAYER@BAYER-US-NOTES, Randy  
Koslo/MORT/CCD/US/BAYER@BAYER-US-NOTES, Terry  
Glass/MORT/CCD/US/BAYER@BAYER-US-NOTES, Winston  
Kirton/MORT/CCD/US/BAYER@BAYER-US-NOTES, Catherine  
Shook/MORT/CCD/US/BAYER@BAYER-US-NOTES, Myriam  
Castro/MORT/CCD/US/BAYER@BAYER-US-NOTES, Anne  
Coiley/MORT/CCD/US/BAYER@BAYER-US-NOTES

Subject: CHPA Yale Study Meeting 1/21/99

Jay,  
Attached is a nice synopsis of the PPA Task Force meeting that took place on Friday. As we discussed earlier today, Cathie and Winston have called an emergency meeting to figure out what our next steps will need to be. They will most likely include:

- Understanding and overcoming barriers to reformulating with pseudoephedrine (pse)
- Pulling together a public relations statement/response and longer-term action plan if needed
- Actively contributing to (if not leading) the charge with CHPA to avoid reclassification of PPA

This is potentially a huge deal for ASP. Right now, ALL of our effervescent formulations use PPA and there are apparently significant barriers to reformulating to PSE (this has been considered in the past). With a \$125mm business potentially at risk, we will need to do whatever it takes to work through this issue.

I'll keep you updated,

- rob

----- Forwarded by Robert Schumm/MORT/CCD/US/BAYER on 01/24/2000 06:36 PM -----

✍ Winston Kirton  
01/24/2000 03:05 PM

To: Terry Glass/MORT/CCD/US/BAYER@BAYER-US-NOTES, Craig  
Hammes/MORT/CCD/US/BAYER@BAYER-US-NOTES, Randy  
Koslo/MORT/CCD/US/BAYER@BAYER-US-NOTES, Terry  
Dex/MORT/CCD/US/BAYER@BAYER-US-NOTES, Catherine  
Shook/MORT/CCD/US/BAYER@BAYER-US-NOTES, Robert  
Schumm/MORT/CCD/US/BAYER@BAYER-US-NOTES  
cc: Anne Coiley/MORT/CCD/US/BAYER@BAYER-US-NOTES

Subject: CHPA Yale Study Meeting 1/21/99

Hello,

On 1/21, Anne Coiley and I participated in a PPA Task Group meeting held at CHPA headquarters to discuss the Yale Study. The meeting was attended by representatives from SmithKline, Whitehall-Robbins, Novartis, Chattem, P&G, Warner-Lambert, The Weinberg Group, and Rudder

Finn (PR firm). The meeting focused on the development of a public relations program to deal with potential adverse publicity from the Yale study results and on strategies for presenting the Industry position at the upcoming NDAC meeting.

#### Yale Study Update

- 7 out of 24 cases of stroke related to PPA Cough/Cold use are associated with ASP products. This is the highest number of cases for any product identified in the study. The methodology used to make this determination is somewhat controversial. Subjects were shown a book of various products and asked to pick out the one they remembered using prior to having the stroke.
- Novartis, Chatterm and the Weinberg Group are currently in possession of the raw data and have stated that they have been having difficulty reviewing the data because of the large volume. They have decided not to try and replicate the Yale analysis (due to short time frame), but instead look for bias and areas of concern related to the proper understanding of the results. The Group is drafting a "Points to Consider" paper on how the data should be reviewed and reported, this document should be available later this week.
- The Yale investigators are currently revising a draft manuscript report. Novartis and Chatterm are expected to receive a draft later this week.
- Yale is planning on computing an "attributable risk" for the study population and including this in its final report.
- The investigators have shared a copy of the draft report with the Scientific Advisory Group responsible for monitoring the study. CHPA is trying to contact the chair of this group, Lou Lesagne (former FDAer), to get his position on the report.

#### NDAC Meeting

- CHPA made contact with the FDA (Linda Ketz, OTC Division), to get confirmation on the 3/29 date of the meeting. FDA apparently has concerns with the time frame and would not confirm a date.
- The Task Group raised concerns that the FDA might accept a manuscript report from the Yale investigators in lieu of the full data. Since this would be unprecedented, the general consensus was that Industry would push for an FDA review of the data prior to the meeting.
- CHPA and the Task Group are hoping to have credible experts (epidemiologists, neurologists, and statisticians) and spokespersons (including former FDAers) aligned by this week or next. These persons would participate in the meeting as well as interact with the media. One prominent name that was discussed as the primary expert/spokesperson was Charles Hennekens, M.D., Epidemiologist.
- CHPA/Experts would present the "Points to Consider" paper focusing on the data, the methodology, and the interpretation of the results.

#### Rudder Finn - Public Relations Agenda

- Rudder Finn will be developing an Industry position for dealing with adverse publicity. This will include, a CHPA "position paper", training credible spokespersons, monitoring the media, a crisis communications readiness plan, and developing a key message.
- Rudder Finn suggests that each company designate an "internal spokesperson" to handle media inquiries.
- They will develop a uniform plan for all the companies on how consumer phone calls and internet queries should be handled.
- The Task Group raised concerns about handling bad publicity internationally. Rudder Finn

- will develop a plan to address this concern.
- It was suggested that Rudder Finn include Yale in any media outreach programs they develop. This will ensure that any comments coming out of Yale would be closely monitored. Apparently, as part of the study contract, Yale is not allowed to discuss the study results with the media directly. This would also jeopardize their publishing capabilities.

#### Other

- Commentary was provided that no events were found relative to pediatric use. Experts will be consulted as to whether this category could be spared any regulatory sanctions.
- Concerns were raised as to whether potential issues might arise for pseudoephedrine as a result of the Yale study. The general perception was that FDA would not restrict access to both nasal decongestants. It was even suggested that the Task Group might want to look into ways of protecting this ingredient should PPA have regulatory restrictions.
- Novartis confirmed that they have begun reformulating with pseudoephedrine. Their regulatory person believes that the FDA will push for a reclassification of PPA to Category II, but that FDA will only require a phase out/reformulation instead of a recall.
- Novartis also opined that the FDA might opt for a COHORT study whereby each company would have to track consumer usage and AEs over a specified period of time.
- Novartis has received results of the National Health & Wellness survey which places PPA in a favorable light. The report is being revised for distribution.
- Consultants are in process of accessing FDA AERS database for events related to PPA.
- CHPA is requiring that Task Group companies submit all AE data on PPA.
- The national Poison Control Center database is being accessed for related AEs.
- It was noted that Bob Temple (FDA) has an unfavorable position regarding PPA and efforts should be made to steer the media away from him.

My general feeling coming out of the meeting is that CHPA and the member companies of the Task Group feel that the Yale study is flawed and inconclusive. There is however, a reluctance to outright challenge the credibility of the results in an open forum because of the name attached to the study. I believe that everyone is prepared to collectively identify ways in which the data may be interpreted differently. However, because the possibility of reformulation with pseudoephedrine exists for most companies, I do not foresee a major fight should the FDA opt to reclassify PPA based on the study results. At one point in the meeting, Bill Soller, V.P., CHPA, had to redirect the discussion so that the record would not reflect that pseudoephedrine is a viable alternative.

Please contact me with any questions you may have. I will be distributing documents gathered from the meeting.

Regards,  
Winston