CONFIDENTIAL

BIOLOGICAL MANAGEMENT COMMITTEE

September 21, 1984

1. Minutes of Meeting of August 24, 1984 - R. Modersbach

Approved to R. Rousell memo correction.

2. Financial Update - M. Duffy (U.S.)

September Gamimune sales are lower, ca. 10,000 units, than August although, per W. Johnson, no specific problems have been noted in the market. Blood bag sales are reaching a high this month. AHF sales continue to show reduced hemophiliac usage; average price for Koate is 10.6¢ per unit. Production of a Fraction V government sale could assist the slower September sales if completed on time.

Biological Division gross profits have been improving and, at 51.3% in August, are ahead of budget after 8 months: 44.5% vs. budget of 43.7%. Year-end PBT estimate is $11.245 million.

J. Benninger (Intl.)

International sales of $84.9 million through August are $4.4 million over budget. Canada (low blood bag sales) and Latin America (economic problems, low plasma sales) have been the leading problem areas. September results will be unfavorable due to lack of Polyglobin in Japan and unfavorable exchange rates. After 8 months, Division result is $6.7 million vs. a $6.9 million budget. Year-end estimate is now $7.9 million vs. budget of $13.0 million, reflecting adverse exchange rates, additional R & D expenses. Next year's budgeted exchange rates from Bayer are substantially different from those now existing and a continuation of this year's problems with exchange translation is probable.

3. Blood Bag Update - C. Treppa

Product quality continues to be encouraging and, in division margin, the line is favorable to budget. Sales have now reached the level where profitability improves substantially. There is a good prospect of becoming a second-source supplier to Alpha and this prospect should be pursued as the added business will make at least a $1 million contribution to division margin.

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About 25% of the Hemascience automated pheresis clinicals are now complete with no improvement in the less-than-forecasted results. Haemonetic results are good and, if software costs are favorable, this is a promising alternative.

4. New Members - J. Ryan

V. Shalson and W. Johnson were welcomed by J. Ryan to the Committee.

5. Genentech Status - J. Ryan

A detailed draft agreement was approved by both parties. $5 million will be paid within 3 months from the above approval. We have marketing rights in most major countries and regions except for a number of European countries, for which negotiations are underway with Speywood.

Dr. Sternberg described as "limited feasibility" what Genentech has accomplished with the Factor VIII expression of the substance, cautioning there will still be difficulties and challenges ahead. Genetics Institute (Travenol) is probably not far behind, so we are in a race -- resources and effective use of multidisciplinary personnel and functions will be essential. The next 90 days or so will be significant as we receive the data and system and review/confirm this.

6. BCC Highlights - V. Shalson

V. Shalson highlighted main subjects considered by the above committee, including inventory vs. planned or unplanned shutdowns.

7. Core Antibody Testing - J. Hink

J. Hink summarized the background leading to this screening beginning in February, 1984. Fractionation began in May. (2nd Quarter 1985 is the projected date for a commercial HTLV-III test.)

M. Boyce recited the reasons and advantages of the test, and pros/cons discussed at an IGIV task force meeting. Questions include: does removal of HB antibody increase risk of hepatitis transmission? (a theoretical possibility); extra cost, sorting and screening; effect on I.S.G. if not blended with non-core tested plasma.

S. Ojala recounted the considerations and reasons behind the screening decision, and more recent OoB reservations (especially since different OoB personnel are now involved).

In the meantime, a "blend" will be used for Fraction II. Continuation of Core Antibody Screening will be considered when HT deactivation of AIDS retrovirus is finally scientifically confirmed.

A suggestion was made by R. Modersbach to consider exchange of HT for non-HT if and when the above confirmations are made and announced.

8. <u>HT Retrovirus Deactivation</u> - M. Mozen

It is assumed, HTLV-III, LAV and ARV are the same entity and are the cause of AIDS. Work is underway with all three to determine if heat treatment deactivates the retrovirus (so far, tests indicate this to be the case). BoB is working with HTLV-III, CDC with LAV and Cutter/Levy with ARV.

J. Ryan outlined plans for a program on October 11 at the NHF meeting. It would feature HT benefit. It is not intended that this would be the time or event for major media release.

9. <u>Konyne HT Update</u> - S. Ojala/M. Mozen

S. Ojala reported that a final letter may be issued in 2 to 3 weeks, a favorable development if it pans out. In the meantime, J. Ryan urged everyone to be ready to launch the product.

10. <u>Koate N Update</u> - R. Cole

A meeting should be established with top Cutter management to discuss the new process. October 3 was set as the date. R. Cole will prepare an agenda, necessary documentation and make meeting arrangements.

11. <u>Plasma Separation Process Update</u> - R. Cole

Under this, filtration would replace most centrifugations used in a number of steps. Cost savings and quality improvement that result from this were described. It would be implemented in Clayton (only) to preserve capital.

J. Hjorth pointed out a new license would be needed in Japan for PPF under this process. About 13 to 15 man years would be needed and an establishment license secured for Clayton in 1st Quarter 1987. Securing a license in Japan would require ca. 5 years. About $4 million capital would be needed.

Pre-qualification filtration runs have been done and a PLA submitted for ultrafiltration for 5% NSA. The project is not budgeted in 1985 due to capital and expense limitations and, accordingly, is not active. Preliminary engineering (only) would require ca. $80,000.

The question of Japanese licensing is crucial here and, as pointed out by N. Ashworth, our experience in Japan is that licensing requirements there are unpredictable. K. Fischer believes work should be done on stability, etc., to have a start if a license is required or desired. More information will be put together on this.

12. German Koāte Requirements - S. Ojala

The matter is reportedly in abeyance with further word expected by the end of the month. As we gain information on activities of U.S. competitors, Tropon should be advised.

13. A.R. Procedure - J. Ryan

The approach is for the BMC to review and recommend, and the O.C. gives final Cutter approval.

14. Clayton IGIV A.R. - C. Turner

Additional production is required to meet sales projections and will be done at Clayton, Cutter's large volume/low cost facility. Payback is excellent with capital cost estimated at $290,000.

The A.R. is recommended by the BMC for approval.

15. Jackson, Miss. Center A.R. - R. Cole

Capital of $125,000 is required and would be expended this year. This is a relocation that is required by plasma demand and unavailability of current premises. Costs are in line with other centers.

The A.R. is recommended by the BMC for approval.

16. San Diego Lab A.R. - R. Cole

This is required by transfer of the titer lab from Berkeley (that space is needed) and the new HTLV-III (anticipated) test. Even if the requirement for the latter is dropped, space is still needed for the titer lab which should be in proximity to the antigen testing.

Construction costs are $74,000 and, with equipment and engineering, the total A.R. is $140,000. It was also noted that labor rates are very favorable in this area and a well-trained staff in place.

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It was decided that there was not a time urgency whereby an immediate decision had to be made -- in the meantime, per a suggestion by V. Shalson, Clayton will be investigated as a location and Berkeley space requirements will be evaluated vis a vis KabiVitrum.

17. Ames Quality Problem and <u>What We Should Learn From It</u> - K. Fischer

This subject was raised by K. Fischer so that Cutter might learn from it. Basically, the Ames problems are not confined to a single function but run throughout all functions. J. Cherry cited details and background of the problems, including: misfiled complaints, incorrect temperature readings and equipment calibrations, product release before final testing and numerous other items. All of this reflected inadequacies in various functions, especially centering around inadequate product knowledge.

Several past Cutter quality problems were enumerated by J. Cherry to demonstrate that we should not be complacent and, instead, should know our products and anticipate potential problems.

This theme will be continued so more of our people will be aware.

18. Cutter Or Miles Company Name <u>Display On Our Facilities</u> - K. Fischer

The question has arisen as to how we should be identified at our plant locations, Clayton being a case in point.

J. Ryan and R. Modersbach suggested that the Cutter name not be dropped from identification and that no basic changes be made. There will reportedly be an overall Miles corporate identification study at which time these questions can be addressed.

19. <u>Significant Project Dates as of 9/21/84</u> - M. Sternberg

Current projections are attached.

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