

Confidential

FRED HUTCHINSON CANCER RESEARCH CENTER

Office of the Director

February 23, 1984

TO: Dr. Fred Appelbaum
Dr. Mac Cheever
Dr. Hank Kaplan
Dr. John Pesando ✓
Dr. Rainer Storb
Dr. Keith Sullivan

FROM: Dr. Robert W. Day

R. W. Day

Please find attached notes of our meeting on January 17, 1984. I trust that these are a reasonable record of our discussion. I would appreciate any suggestions for changes, additions or deletions.

Thank you.

RWD/joh

Enclosure

February 23, 1984

NOTES: Meeting on Advisory Group

RE: Monoclonal Antibody Testing

PRESENT: Drs. Appelbaum, Cheever, Day, Kaplan, Pesando, Storb and Sullivan

The group met in the Director's Office at 6:00 p.m. on Tuesday, January 17, 1984.

Dr. Day began the meeting by indicating that he had spoken with each of the members of the group individually, and had their assent to assist him as a group of informal advisors, and Dr. Kaplan in his capacity as chair of the HSR, in matters related to conflict of interest arising over the uses of monoclonal antibodies, and possibly other new products.

The issues were briefly reviewed. Dr. Day mentioned the distribution of Board of Trustees policies governing membership involvement with outside interests, patents and inventions, consultation and conflict of interest as adopted in March, 1983, and governing from that date forward all members of the scientific staff. He also recognized that conflicts of interest do exist for members of the scientific staff who have involvements with outside interests, particularly GSA and its subsidiaries. Dr. Hansen, a member in the Division of Clinical Research, continues to serve as Medical Director of Genetic Systems; Dr. E. D. Thomas, Associate Director of that Division, serves on the advisory committee to that company. Both have substantial holdings in founders stock from GSA.

Dr. Day indicated that he had requested notification from all members of the scientific staff about any involvement with outside companies, current or proposed, as well as consulting arrangements, and had also requested that the agreement relating to inventions be signed and returned. He recognized that other members of the staff may now, or in the future, have conflicts of interest due to relationships with outside interests.

He and Dr. Kaplan then briefly discussed issues that had been raised in the Human Subjects Review Committee relating some of these relationships to the testing of monoclonal antibodies, particularly anti T-cell antibodies. Records of the HSR reflect, in part, concerns of the committee about conflict of interest and concerns about how these circumstances would be handled in the future. Dr. Day spoke specifically to his view that conflicts of interest need to be recognized and dealt with forthrightly, and that conflicts of interest are bound to occur in situations where highly competent staff interact with outside interests.

Some concerns were expressed by the group about their own particular circumstances if called upon to make judgements about whether or not testing of a particular antibody should proceed, the conditions of the testing, and related matters. These concerns had to do with potential challenges to the free inquiry of other members of the staff, particularly those superior in rank. Dr. Day stated that although the potential for such conflict was recognized by all, every step would be taken to minimize specific identification of those among the group from whom advice is requested, and the implementation of that advice. He further went on to say that the group would be constructed so as to serve informally, would not be constituted as a standing committee of the Center, and would be asked for assistance when a protocol for HSR review and approval "triggered" that mechanism.

Dr. Kaplan indicated his agreement with the process as outlined in the discussion. Dr. Day indicated that he would inform Drs. E. D. Thomas and Hansen of this mechanism for managing conflict of interest and would discuss the specifics with them in the near future and at any time when an event suggested that advice from the group was needed. It was also agreed that if any members of the group had any conflict themselves (when requested to give advice) that would be notified to Dr. Day and the individual would be excused from participating in that particular issue. Dr. Day, in concluding the meeting, expressed his view that testing as well as selection of antibodies should be made impartially by others than those involved in any conflict of interest in any particular testing situation.

It was agreed that subsequent meetings of the group would be called if and when necessary.

RWD/joh