Dr. Joshua Lederberg
Apt. 115
1230 York Avenue
New York, NY 10021-6399

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Report on visit to Quidel 8/28/87

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From: Joshua Lederberg

To: David Katz, Joe Stemler, Steven Coutts

I very much enjoyed my visit, and thank you for your hospitality.

Leaving out some of the compliments, I extract what I reported back to JDW,Inc.

1. They have just appointed Stephen Coutts to bolster their R&D effort. He seems just superb!

2. The SFA project has the potential of becoming one of the major applications of R-DNA technology: the stakes are a market measured in units of $100MM (or more!). Inevitably the odds are rather long too (or, rather, very hard to estimate.) If SFA were a sure thing, the field would be crowded with competitors. (The only visible one is Ishizaka at Johns Hopkins, who is affiliated with DNAx -- we don't know much about where they are at.)

3. SFA has been cloned (they did a superb job of that), and this has given them a source of ample material for further trials. They have interesting biological activities in vitro, and a 50% suppression of IgE production in the mouse. Nature is not always so kind in offering activity of human lymphokins in animal models. David Katz is eager to push ahead with clinical trials in the human, and this is a strategy that may well be supportable. I expressed some concerns that they had not exhausted all they could do in the mouse -- e.g. to attempt a recognizable "clinical" amelioration of allergy in the mouse; also to set up a less extreme antigenic stress that might allow SFA to exhibit more complete suppression of of IgE production. David seems to feel this is unnecessary (and that this assay would be criticized precisely because a more modest IgE reaction was being targetted.) Besides the scientific argument, they may run into trouble with an IRB or the FDA in getting approval for an IND if they have not exhausted all the feasible and relevant animal tests. It would be unfortunate to lose precious time by not anticipating these potential roadblocks.

4. We also discussed, and Steve agreed, that FDA will demand the complete sequence of SFA to be matched against their cloned material prior to any NDA (and possibly prior to any extensive IND trials). The first 20 or so N-terminal amino acids were sequenced, and this was the basis of the probe used to extract the c-DNA used in cloning. At least a peptide map might help to verify the authenticity of the sequence.

5. We also discussed the GL-nucleoside immunosuppression of anti-nuclear antibodies for use in SLE. They need to verify that the majority of total auto-immunoglobulin is antinuclear for it to be plausible that it will be clinically useful. Other auto-immune diseases (thyroiditis, myasthenia gravis, auto-immune male infertility) might be better candidates, with simpler and better understood provocative antigens. The latter is one of the commonest causes of infertility; some women also have anti-sperm antibodies secreted in cervical mucus. The antibodies are directed against flagella.

6. On the whole, QUIDEL has a splendid scientific group, and Steve's recruitment should give them a special edge in working out strategies for the most effective implementation of the R&D cycle, and bringing SFA to the market. I have to repeat that the stakes and the technical and business risks are both very large.

7. Frank Austin is in general concurrence with the above.

Joshua Lederberg

cc: F. Austen