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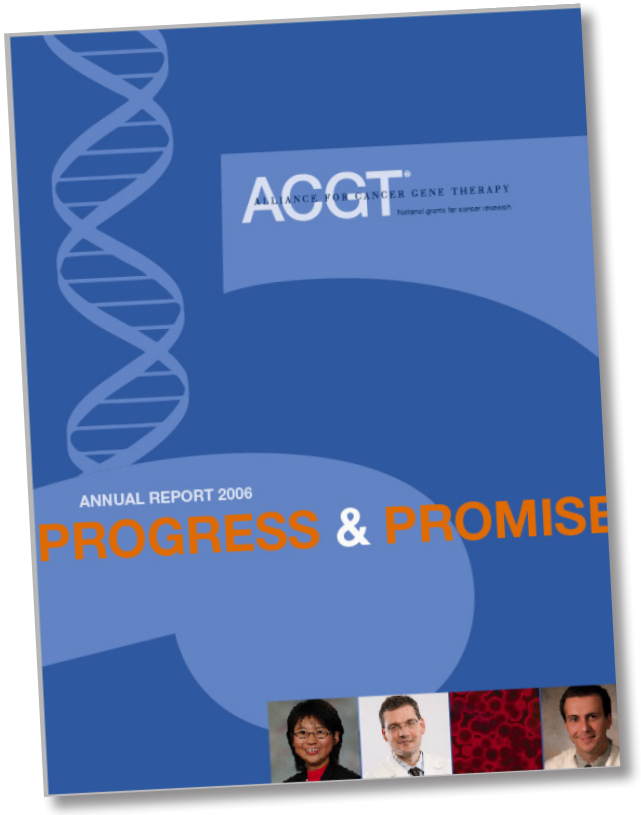

An Interview With **Dr. Jack Roth,**
2006 Appointed Member of the
Scientific Advisory Council

Q. What has drawn you to cancer gene therapy?

I'm a cancer doctor by training, lung and esophageal cancer. It's very clear these malignancies are difficult to treat. Surgery alone is not the answer. When I was at the National Cancer Institute in the 1980's, it became evident that cancer in fact is a genetic disease, that cancer starts because of mutations or deletions in certain key genes in the cell. So the idea is really simple: if cancer is a disease of genes, we can replace that gene function to alter the growth of the cancers, and prevent them from spreading

Q. How soon will we see gene therapy in practice?

Cancer gene therapy is a reality now. There are agents in late stage clinical trials that have shown efficacy in treating patients. There is actually an approval for a therapy in China.

Q. What form of gene therapy has the most promise?

It is difficult to predict which form of gene therapy will be most promising. It's a little like a horse race. There is good scientific foundation for immunotherapy, and using genes to do this has been a major advance. We can use genes to control angiogenesis, the growth of blood vessels, which is important for cancer as well as other diseases. We can use genes to restore missing functions in cancer cells, to activate cell death. All are very promising, and it's likely that within the next five to ten years all of these therapies will come into clinical practice.

Q. What will be key to moving this science forward?

There is unfortunately not enough funding, and that threatens progress. No matter how good ideas are, no matter how exciting, if you don't have the funding, you can't do the experiments, you can't get to clinical trials. However, just funding all the research proposed is not going to do the job. You have to identify the most promising projects and make sure they get adequate funding. To do that requires scientific rigor, and this can be time consuming and often controversial, but it is the best way we have of identifying projects that merit funding.

Besides funding, there are increasingly difficult regulatory hurdles. Everyone is aware of this. The question is, who's going to do something first? We're going to need a paradigm shift, some very innovative approaches, to break down these barriers, so we can get things done faster.

Q. Are there any new models for research?

We can expect multi-institutional trials to be more prevalent in the future. We have a few here at M. D. Anderson right now. These make it possible to complete the trial more rapidly, because there is access to more patients. And the results are more reliable because they are tested in different settings.

However, early research, before we are able to standardize vectors and such, will be done by individual investigators, and that is vitally important. Funding is critical, and private, innovative foundations like ACGT will play a pivotal role.

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2002 2003 2004 2005 2006

ACGT AWARDS PROCESS

1 Request for Applications (RFA)
- RFA invites scientific community to submit abstracts.
- The Scientific Advisory Council determines which abstracts conform to the RFA's research objectives.
- Qualified abstracts are invited to apply on-line.

2 Application Review
- Each application is reviewed by two peer reviewers using the NIH rating scale.
- The highest rated applications are distributed to each member of the Scientific Advisory Council.
- Two reviewers from the Scientific Advisory Council are assigned and rank each finalist, and final scores are assigned.
- The Scientific Advisory Council makes recommendations to the Board, and the Board makes the final decision and award announcement.
- Feedback is given to all applicants.

3 Contract Negotiation
- Once grantees are announced, the terms of the grant relationship are negotiated with the research institution and performance benchmarks are set.
- The agreement must include the 8 key items set forth in the application process.

4 Monitoring the Awards
- An annual review is conducted, and grant installments are made dependent upon achieving predetermined benchmarks, which conform substantially to aims outlined in the original proposal.

"There are few places that really encourage grants specifically designed to fund young investigators, so that it's very difficult to compete on a national level, especially at this time with funding being so tight. The grant from the Alliance for Cancer Gene Therapy was so instrumental in helping us complete the pre-clinical studies that were necessary for getting this trial started, that I don't know if we would be able to be at the point that we are right now without that assistance."

Thomas S. Griffith, PhD, University of Iowa, 2002 ACGT Research Fellow

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