Senator Kerry, members of the Committee, and Colleagues

Nearly a decade ago the late Rick Smalley sat before a Senate committee that was considering the National Nanotechnology Initiative. Rick won the 1996 Nobel Prize in Chemistry for his part in the discovery of C_{60} and the fullerenes. I also had a part in that – it was my dissertation work, and Rick was my Ph.D. advisor. Thus, it is a special honor to be testifying here today, and I want to recall a bit of Rick's testimony from a decade ago.

"I sit before you today with very little hair on my head .. a result of chemotherapy … I'm not complaining. Twenty years ago … I would already be dead. But twenty years from now … we will no longer have to use this blunt tool. ..Nanotechnology will have given us … engineered drugs which are nanoscale cancer-seeking missiles, a molecular technology that specifically targets just the ..cancer cells …, and leaves everything else blissfully alone …I may not live to see it, but .. I am confident it will happen."[1]

Rick was prophetic on both accounts. He didn't live to see such advances, but they are happening now. One example comes from my Caltech colleague, Mark Davis. Mark is a member of a cancer center that I direct. It is one of a few innovative cancer centers that the NCI funded a few years ago to develop nanotechnology tools for battling cancer.[2] Mark's lab developed a nanotherapeutic that begins to mimic Rick's nanoscale cancer-seeking missiles.[3] I'll begin with a story about a patient from a Phase I clinical trial of this drug. Phase I trials are a last recourse for those who have failed everything else, and this patient came to Mark's trial with late-stage, metastatic pancreatic cancer, and a prognosis of 2-3 months left to live. There are several cancer survivors in this room. However, if any of you had had metastatic pancreatic cancer, it is unlikely you would be here today. The survival rate for this terrible disease is almost zero. That patient entered the trial almost 2 years ago, and is still alive, cancer free, and went through the entire trial without even hair loss. That is a stunning result – the drug itself was a typical chemotherapeutic with toxic side effects that range in severity from hair loss to cardiac arrest. However, the delivery agent, which was a nanotechnology, permitted the dose to be lowered 20-fold, and directed more effective drug delivery to the cancer.

The scientific foundation for this drug is what the national nanotechnology initiative has delivered. Each of Mark's nanoparticles is designed to look friendly to the immune system, to stay in the blood for days until they find the tumor, and to not release their drug payload until they are inside a cancer cell.

This is just the beginning.

We are faced with some staggering scientific challenges today – ranging from energy to health care to the environment. For virtually all of these problems, nanotechnology-enabled solutions are at the forefront of the scientific search for answers.

In my lab we have developed a nanotechnology-enabled chip that carries out almost 50 diagnostic measurements from a fingerprick of blood – all before the blood even clots.[4] This chip has applications for our soldiers in Iraq and Afghanistan where shortening the time between injury, diagnosis, and treatment can save lives. It also has applications to routine health care.

Now is not the time to further regulate this field. Mark's therapeutics and our diagnostic devices go through the same demanding FDA approval processes as standard drugs and health care technologies – that process sets the global standard, and it works.

The NSF and the NIH are taking seriously the tasks of understanding the environmental and health impacts of nanotechnologies – both agencies have established significant programs to understand those risks.

However – the example of a nanodrug vastly reducing toxic side effects – not increasing them, has been the story when the foresight and resources are available to ensure that the science is done correctly. Right now, that part is working.

Finally, I want to turn to a looming crisis. I was recently at a meeting where various experts were bemoaning the fact that clinical drug trials are increasingly offshore endeavors. In fact, the entire process, from the basic science of discovery, to engineering, product testing, and manufacturing, is moving off shore – and not just for drug discovery. We are in serious danger of losing our competitive advantage in a number of high tech arenas. We achieve world scientific & technological leadership by taking on high risk, high payoff goals, and sticking with those goals. However, our scientific enterprise is becoming risk averse. Other countries see this chink in our armor, and are challenging us. The National Nanotechnology Initiative constitutes one of our high risk/high yield investments. It is clearly working, although it is a serious struggle to stay ahead of the curve. In other areas, we are losing our edge.

Our great country has a history of achieving goals by combining bold scientific vision, strong political leadership, effective public education, and significant and sustained investment in our scientific foundation. That is how we have maintained our global technological and economic leadership. Finding ways to sustain that mix, rather than finding ways to regulate an emerging and fragile field, should be the focus of this debate.

Thank you.

Jim Heath
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[1] Richard E. Smalley testimony before the Senate Committee on Commerce, Science and Transportation, May 12th, 1999

[2] The NanoSystems Biology Cancer Center is one of a few Cancer Centers for Nanotechnology Excellence (CCNEs) that the National Cancer Institute funded starting in late 2005

[3] M. E. Davis and M. E. Brewster, "Cyclodextrin-based pharmaceutics: Past, present, future," *Nat. Rev. Drug. Disc.*, **3**, 1023 (2004).

[4] Rong Fan, Ophir Vermesh, Alok Srivastava, Brian K.H. Yen, Lidong Qin, Habib Ahmad, Gabriel A. Kwong, Chao-Chao Liu, Juliane Gould, Leroy Hood, and James R. Heath. "Integrated Blood Barcode Chips," under review to *Nature Biotechnology* 4/08.