



Stanford eCorner

A Story of Biotech Innovation

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February 02, 2011

Video URL: <http://ecorner.stanford.edu/videos/2627/A-Story-of-Biotech-Innovation>

UCSF Chancellor Susan Desmond-Hellmann shares a story to illustrate how innovation occurs in the field of biotechnology. She describes the development of an innovative cancer drug at Genentech, even in the face of great skepticism, and the team effort it took to gain regulatory approval.



Transcript

So I left Bristol-Myers Squibb in 1995 and came to Genentech, which was the first biotech company and founded in 1976 based on recombinant DNA technology. Which was co-discovered at UCSF and Stanford. So that discovery of recombinant DNA technology started an industry. And I was thrilled when I got to Genentech to find out that it could be possible to treat cancer patients potentially without the side effects of nausea, vomiting, hair loss and bone marrow suppression, trying to use biology to treat cancer instead of chemistry to treat cancer like Taxol. So, the development of Herceptin was an extremely innovative project. And let me tell you three ways in which Herceptin was fundamentally different than anything I had ever been able to bring to cancer patients. First and foremost, Herceptin was the first time ever that a monoclonal antibody, a human-like monoclonal antibody-like we all make in our immune system-could be brought in large amounts to patients with a solid tumor. A very, very scary disease, fast growing and likely to kill the patient. Now, at the time monoclonal antibodies, being natural, being humanlike, were thought to be gentler treatments. And in fact people use to have a slogan, "Could you have a kinder, gentler treatment for cancer?" And I was a little puzzled by that.

Having seen so many cancer patients, I didn't want to be kind and gentle when it came to the therapy of cancer. I wanted to wallop that cancer without causing side effects. But this monoclonal antibody therapy, for the most difficult to treat breast cancer, was completely innovative. And we were relatively pessimistic about it. One of the things I learned from that experience is don't be afraid to take risk and try something, even if everyone's skeptical. And every one was. The second thing that was innovative about Herceptin and now it seems routine, but at that time, it was incredibly innovative. Could you treat only the breast cancers that were driven by an oncogene, a growth factor for that cancer called HER2. Only one in five of the patients with breast cancer had that driver. Therefore, we would only treat that one patient out of five whose cancer was dependent on HER2 to drive its growth.

Personalized medicine, targeted therapy-now popular, while not routine, definitely the best way to treat patients but incredible novel. What that meant for the regular trade path is we had to go to FDA and ask for approval for the therapeutic and the diagnostic at the same time. Extremely hard, and very novel. And the third thing that was so special about this is that the engineers, in manufacturing, had to be ready with the biotech process for making this antibody reliably using Chinese hamster ovary cells at the same time we were ready with the therapeutic. So you had to work in teams effectively, with a large team that could go to FDA. The experience of working in biotechnology to make the first antibody that had been approved for use in breast cancer was an amazing experience for me. And in the end taught me not just all those technical things, which we were able to overcome and obtained approval in 1998, but much more importantly, not to underestimate what was possible. I always thought that you had to be in discovery, that you had to have that sort of test tube in one hand and light bulb going off over your head in the other hand to do something innovative. And as a clinician, I didn't see myself as an innovator. But that opportunity to take what have been made in the labs and bring it into clinical trials, use all those things I had learned about inference and

proof in showing that Herceptin was good for patients with HER2-driven breast cancer, I could be an innovator.

A big breakthrough for me, personally, and something that my group, who were the "D" of R&D at Genentech, could take great pride in. So a very focused product-driven innovation to bring something through the Food and Drug Administration, to patients and other regulatory agencies, to bring this product to market worldwide.