National Forum on Federal-Regional Partnerships for Life Science Clusters

Innovation, Life Sciences and the Federal Landscape

Dr. Kathie L. Olsen, Associate Director

Office of Science and Technology Policy

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The object here today, as I understand it, is to discuss how innovation in the life sciences sector can improve regional economies and serve priority national interests. I have been invited here to discuss both the Federal landscape for research funding and my own "big-picture" view of opportunities in the life sciences sector.

As I thought about this request, I decided to take some time to discuss innovation itself – What is it and how does it happen? – because I am convinced that innovation is the key to developing and enhancing regional economies. I'll state right up front that Federal dollars are limited. We can only hope for incremental increases, particularly in the current economy. But the need is for substantial economic growth. Without innovation, the best that anyone can hope to do is move money around. Some will be winners and some will be losers, but there will be no, or at best incremental, net gain. Our country can't afford that. We need new ways to squeeze more results out of funding and incentives. We need faster ways to move research results to technology development and commercialization. We need better and brighter ideas.

The Innovation Network defines innovation as "implementing new ideas to create value." That is, in a nutshell, what we need to do and what this meeting is all about. It's the very same concept that Darwin proposed for the survival of species; "In the survival of favored individuals and races, during the constantly-recurring struggle for existence, we see a powerful and ever-acting form of selection." Regional economies are also involved in a constantly recurring struggle for existence, and the way to survive is to favorably evolve and change.

Now, this is all nicely philosophical and probably seems self-evident. What do I mean in terms of Federal-regional partnerships and Life Sciences clustering? Well, in my office at OSTP, just as I did in my previous position as Chief Scientist at NASA, I receive a lot of visitors from universities and research firms across the country. And what I have heard over and over again is a repetition of our history, which is worth repeating again. 1980 was a big year for biotechnology. The U.S. Supreme Court approved the patenting of recombinant life forms in Diamond vs. Chakrabarty. Congress passed both the Bayh-Dole and the Stevenson-Wydler Acts. These laws and subsequent amendments enabled federally funded researchers at universities, non-profit institutions, small businesses, and national laboratories to patent their innovations and create an incentive to commercialize the research for the public's benefit. Also in 1980, Herbert Boyer of UCSF and Stanley Cohen of Stanford University received a patent for gene cloning. This technology was the basis for producing recombinant human insulin in

bacteria, the first recombinant therapeutic product to be approved by the FDA in 1985. In fiscal year 1999 annual invention disclosures, which were 250 in 1980, rose to 12,324, and 5,545 patent applications were filed. Patents awarded to universities in the 80's exceed 2,000 annually. As of October 2002, there were over a dozen FDA-approved drugs and vaccines based on technologies from NIH intramural research alone. These dramatic impacts on the economy have given rise to the concept we discuss today – life sciences business-university clustering in the development of regional economies.

Then, after hearing about our history, what I hear proposed by the visitor in my office is; "We like the Michigan Life Sciences Corridor idea, or we that that North Carolina has really got something going with the Research Triangle Park. They are the clear beneficiaries of this great biotechnology advance. We want to create one of THOSE in our region." We'll, my point is, there's only one Research Triangle Park. The Michigan Life Sciences Corridor is a great idea, but it's already been done. You could look really hard at what they did and maybe figure out how to do it a little more efficiently, a little better, and you could develop something similar that would work "OK" for you, maybe even steal away some of their business. But, that's not what this country needs. That's not innovation.

Referring back to The Innovation Network, some words they associate with the outcomes of innovation are **trends, ideas, change, renewal** and **reinvention.** We have a trend going – regional life sciences clustering. We need Federal, state and local governments; industry; and academia to accept the challenge for the new ideas, the change, the renewal and the reinvention. I don't need to tell anyone that the world is changing rapidly, more rapidly than most of us find comfortable. The context of innovation is the response of the organization to that changing external world. What we all need to do is look set our sights on catching the next wave. Leave the wave currently passing for the less bold. I don't know what the best new strategies will look like, but they will be different than even the most brilliant strategies wedded to the world of the 1990s.

Given, then, that we need innovation, instead of just optimization, what are the elements that will make innovation successful? After all, a lot of new ideas are bad ideas. There's no guarantee that any particular reinvention is a **desirable** reinvention, but there are some ways to make sure you're headed in the right direction.

The first priority is to make sure that your strategy considers **all the essential components**. Major changes in a regions economy require the active involvement of governments at all levels, education at all levels, primary and secondary business and industry participants, marketing, networking, availability and flexibility of workforce, quality of life, and probably many other components I don't even know about (but you do). Take education. The university system may be more than ready to ramp up academic departments to turn out researchers and technologists in the required disciplines. But, how is the K-12 system doing? Do enough students have quality programs, chances to explore careers, and access to advice on preparing for them? Also, what about training and retraining the workforce? Are the community colleges and technical training programs onboard? If the whole system isn't part of the strategy, you deal yourself a handicap you can't afford in this Darwinian struggle for survival.

The most comprehensive strategy wins. It's that simple. Let me give you a couple examples that convinced me how important it is to cover all the details. I was

surprised to hear from the Virginia Center for Innovative Technology a few years ago that one of the key elements in their strategy to lure more biotechnology start-ups to Northern Virginia was the transportation system. That's not a strategic element that I would have anticipated, but it seems that the difficult commute and crowded state of the southern Maryland road system was one of the major factors making it difficult for Maryland to attract more life sciences start-ups and skilled workforce. Virginia could offer a better quality of life, at least in that particular. The other example that really made me think involves the Michigan Life Sciences Corridor. Batelle recently did a study for the Michigan Economic Development Corporation on what was working and how to improve their economic strategy. One of the things they found was that there is still a disconnect between the local venture capital firms and the realities of start-up life sciences businesses. The amounts of money available and when its available are not optimized for growing the kinds of businesses they want to attract. So, it's not just a matter of attracting business and accelerating commercialization. You also have to get on board all the businesses that foster and support businesses.

Another essential element of success is the **willingness to risk**. Technology is changing every aspect of the way we work, live, play and learn. The way to take advantage of that is to "do it first and do it better," and to be willing to embrace change. But, human tendency is to want to be safe and comfortable. We react to opportunity like we do to a new and strange food. Part of us wants to stay with what we know and like best. But even if we are convinced we should try it, we'll try just a little taste of it to see how we like it. We're afraid to commit to a full serving. That might be an acceptable strategy with food, but in business the ones who succeed are the ones who decide what they are going to do and then jump in with both feet. Now, even though I come from the government, I have to admit that the government also tends to "play it safe." even though our investments are in basic research—discovery research…. by the time it gets through the Administration and Congress, we sometimes end up with plans that would commit maybe 1/3rd of the necessary resources to the project (even though we expect the full result). It's not really that we don't want the project to succeed, or understand what's necessary to make it happen. But, politics just isn't kind to the politician who takes a big risk and fails, so it makes the system in general quite risk averse.---ITER is an example where we are taking a big risk.

Moreover Review Panels are very conservative… NIH is now using "innovation" as part of their criteria and NSF has the SGER grants…. As a Federal Official, I never advocate lobbying – which I think of as an "every special interest for itself" advocacy. But thoughtful feedback from academia and industry is another thing, and it is essential. We need to hear pretty quickly when we try to do things that don't make any sense and when our priorities, plans and allocated resources are on a collision course. That's why we try to do our planning out in the open, and why we invite comment and look for advice from private sector groups and advisory committees. You should make sure your voices are heard. In that way you will help us keep from shooting ourselves in the foot when our risk aversion leads us down the wrong path.

A third essential component is **leadership**. The language of Innovation uses a lot of words like passion, ideas, creativity, risk, commitment, values and struggle. These are human terms, and they derive from the leaders who develop and implement a vision. If all these human qualities are confused and directionless, then the vision will go nowhere.

You can find a lot of examples of initiatives that involve numerous related programs and incentives, but each one going off in a slightly different direction. The ideas may be great, but you're more likely to end up with a **fizzle** than a "whole that is greater than the sum of its parts." There must be a strong, central, consistent message and committed, responsive, strategically placed people who are strong enough to implement it.

So, to conclude, what do I see as the Federal landscape for life sciences clustering? I always like to end on a positive note, so I left this subject for last. The Federal landscape is definitely positive. For one thing, we are talking life sciences. Life sciences in the Federal budget is not cyclical, but on a steadily rising course. What voters aren't concerned about health or don't support the steady advances we are making against disease and disability? There isn't much else that has such a universal political backing. This doesn't mean you can expect generous new funding, but you can confidently build on a stable research funding base. And new national attention to bioterrorism threats and homeland security are bringing the life sciences increasing public attention and support.

The Federal government has several programs to promote innovative research and collaboration between government, university, non-profits, and industry. Cooperative Research and Development Agreements, or CRADAs, allow a government lab to partner with a private entity to collaborate and optimize their resources. Both participants can contribute personnel, services, facilities, and equipment, but funds may only be contributed by the private partner for research performed under the CRADA. The patent rights to discoveries made within the government lab are assigned to the government. However, CRADAs frequently provide for the private partner the right to receive a license even, in some cases, an exclusive license. The existing relationship between the partners facilitates the technology transfer to promote rapid development and commercialization. There are also two set-aside programs that benefit private sector research. They are the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. SBIRs are awarded to researchers employed at small companies, STTRs require that the business have a research collaboration with a university or non-profit research institution. In fiscal year 2001, NIH alone awarded $411 million in SBIR grants and $24 million in STTRs. The support is directed at very early phase research within a company, usually six months to two years, to allow for initial results to draw the interest of private investors. An example: the SBIR program has supported Thermogen, an international supplier of stable enzyme biocatalysts used in the pharmaceutical, agrochemical, and specialty chemical industries. Federal funding supported custom enzyme discovery to increase the availability of biocatalysts and offer alternative and improved industrial catalysis mechanisms.

Beyond what already exists, there's also a new awareness of the need for balance in research funding. For a few years, there was so much attention on doubling the NIH budget that some were concerned that physics and engineering were going under-funded. Now, there's a shift toward looking at the whole portfolio and making sure there is a balance. That's good for all of us, since discoveries don't always come from where you might expect. Those advances that have been, and I hope will be, so great for life science are often derived from great discoveries in the physical sciences.

The Federal government is also aware, as possibly never before, of the value of Federal-state-local government cooperation and partnerships, and of Federal-academia-industry partnerships. EPSCoR is an important example…. *Universities and their*

science and engineering faculty and students are valuable resources that have the potential to influence a state's development in the twenty-first century much the same way that agricultural, industrial, and natural resources did in the twentieth century.

I predict in the future there will be a lot less "top-down" Federal development and management of programs and a lot more work done in true partnerships. Right now we have a high priority group of the National Science and Technology Council looking at these issues and the changing ways of doing business in Federally sponsored science and technology.

The NSTC is active in many areas that affect biotechnology and federal-academia-industry partnerships. As part of the federal commitment to investment in the life sciences, the NSTC Subcommittee on Biotechnology has been working for over 10 years to coordinate the U.S. biotechnology research programs receiving federal support. Over 13 federal agencies have interests in biotechnology, representing both research and regulatory responsibilities. The interagency group has conducted inventories of the Federal biotechnology research portfolio, identified opportunities and priorities, and proposed strategies that focus on investments that will continue to yield high returns in health, environment, agriculture, and manufacturing biotechnology. They will be making recommendations on what needs to be done differently in this new environment. We're also looking at the Federal role in education and workforce development, and at the Federal funding and management of major scientific research facilities – all areas that are critical for the development and strengthening of regional economies and the successful implementation of new Federal-regional partnerships.

This is a great time to be asking ourselves the questions we are asking today. Biotechnology and other advances in the life sciences are beginning to realize their potential for changing the way medicine is practiced, the way food is produced and the means for manufacturing fine chemicals, plastics and many other commodities using fewer pollutants and less energy. The climate for progress and for innovative change has never been better and the opportunities are all around us. I hope today that we can begin to develop strategies that will take the best advantage of the opportunities now before us.

Thank you.