

From: David Johnson
Sent: Tuesday, October 18, 2011 1:45 AM
To: BIOECONOMY@OSTP.GOV
Subject: Bioeconomy input

Dear federal official:

I am founder, President, and CEO of a small biotech company in San Francisco. We are using our innovative technology to characterize disease using rare cells circulating in the blood. The first application is in immunology. Our tools for immunology are like a "CT scan" for the immune system, providing unprecedented portraits of immune response to disease and disease therapy. We will address big problems in cancer, infectious disease, and transplantation. All of my 10 employees have a PhD or MD, and make over \$80,000. I've hired all 10 in 2011. We are funded with \$600,000 in federal grants and \$410,000 in venture capital. This is my second company, and I'm only 35. I can tell you a lot about innovation and what works.

I want to answer your questions directly:

- (1) Translate next-gen sequencing into clinically relevant applications. My technology is doing this already, but, VCs often get more excited about funding technology rather than clinical applications, so next-gen sequencing and other novel technology is getting stuck in University labs without much impact on patients. Recently I had an acquaintance ask me about sequencing their tumor. There are many interesting things to glean from sequencing a tumor, but it takes 10-12 weeks to do the sequencing. So, you may have a \$1k genome, but it doesn't matter if it takes 10-12 weeks, because your patient is dead. Thus -- a disconnect between University and reality. In general, I would work to support private industry more than Universities. It just doesn't make sense that SBIR is only 2.5% of the extramural NIH budget.
- (2) Move money away from Universities and towards funding small, innovative companies that want to move their inventions to market. Biotech companies are expensive to start, but they drive innovation for the entire industry. At least force Universities to publish open source so that all citizens can benefit from their research without paying tremendous fees to closed-source journals.
- (3) There are hardly any technical challenges that high-throughput methods haven't already solved. The problem is getting the technologies to clinical market. Reform and consistency in the FDA, clearer guidance in CLIA, and more consistent regulations among states would bring the methods to clinical market. Is it too much to ask to have consistency between administrations?
- (4) You could fund my company to get these data. This is exactly what we're doing, but we're struggling to get enough capital to get our products to market. Multidisciplinary sounds like a big University consortium, which would be a tremendous vortex of wasted money. Most University research goes nowhere and gets filed in a closed-source academic publication at best.
- (5) Move money from academic research to companies. Companies bring research to clinics.

What's the incentive for an academic to do this? I recommend more "matching" grants, i.e., the federal government provides money only if a VC matches the funding. VCs are sitting on a lot of money and need incentives to loosen their purses, especially for early stage investments. Also, you could somehow provide more incentive to get Universities to license their technologies. I've tried many times to license technologies from Stanford, and they were very conservative. Most inventions die in Stanford's tech transfer office, never to see commercialization. Remember also that most, if not all, of these inventions were possible only with federal grants, so Universities are in effect sitting on taxpayers' inventions.

(6) There has been a lot of commotion in Congress to change SBIR, but it's an awful, awful idea. This is just another case of well-funded special interests hijacking an excellent program. SBIR is probably the single most effective program in the federal government in terms of job creation. NSF officials told me that companies funded at NSF's SBIR program generate \$7 in tax revenue for every \$1 invested. How can you beat that? Just don't change SBIR! If you do anything, increase the percentage of the budget allocated to the program.

(7) It would be interesting to get clinical data from VA patients, ideally associated with some kind of genetic information. I know, this is highly unlikely, but a major hurdle in getting clinical genetics in motion is the phenotype data associated with the genetic data. Genetics is no longer the bottleneck. More open repositories for tissue samples would also be helpful.

(8) VC is suffering from the global economic malaise. They are becoming conservative just like everyone else -- how can you blame them? I spend a lot of time in China, and they spend a lot of time on 5- and 10-year plans. There is long term planning there, and long term stability. American business doesn't want to grow in part because they can't seem to get a handle on political uncertainty. How can you plan a business when you're getting massive stimulus giveaways one year and then spending cuts the next year? My concrete suggestion is to work harder to create stability in the government. Tax, spend, cut, regulate -- whatever, just make it consistent.

(9) I could go on and on about this. For one thing, any PhD student who gets federal funding should be *required* to do internships in the private sector. Currently, it's nearly impossible to get your department to let you take these internships. Why would they let students do this, when they're such cheap labor? The only way to make it happen would be for the feds to force them into it. This would make students better prepared for the real world, and also help them to understand what they want to do with their lives. I would also encourage more hybrid programs, such as bio-IP, bio-entrepreneurship, bio-operations, etc., which give students more breadth rather than just scientific knowledge.

(10) I have no openings for graduates of community college, and can't imagine that I ever will.

(11) Because Universities fail to provide practical knowledge, I'm forced to spend a lot of time training staff. I consider this a cost of doing business and take pleasure in mentorship, as long as the employee is motivated. I'm open to internships, but it's often difficult to find students who can take time off from their labwork.

(12) Government could preserve the SBIR and STTR programs, or grow them if possible. Government (especially local government) could work to develop more incubator spaces for small companies. San Francisco is leading the way on this with the biotech cluster near UCSF (QB3). Landlords have little incentive to rent to small companies, but small companies need specialized lab facilities. QB3 makes all that happen. These should be near Universities all around the country. Industry is entrepreneurship, so they could keep doing what they're doing. Universities could reform their tech transfer departments, which, by the way, sit on inventions funded mostly by the federal government.

(13) The FDA has issued few clear guidelines for IVD-MIA. VCs often cite this as a reason for not funding companies in the genetics field. It's often not clear which tests would fall under IVD-MIA, and which would be considered homebrew and regulated by CLIA. Again, consistency and clarity in regulations are very important.

(14) *ibid*

(15) FDA seems poorly equipped for tests that involve next-gen sequencing data. Because no tests have been approved, it's difficult to point to a specific example. None of my colleagues have even tried. We tend to go for CLIA, even if FDA might consider that test an IVD-MIA.

(16) I would never pursue public-private partnership because of government's general inconsistency between administrations.

(17) *ibid*

Thanks for taking comments.

Kind regards
Dave

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David Johnson, PhD
Founder and CEO
GigaGen, Inc.

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