Title: Is Kauffman in Touch with Reality?

I mentioned in my first blog on Kauffman's "Rules for Growth" that there would be a follow-up blog focused on Kauffman's characterization of university performance as "sub-optimal", given "innovations developed by university faculty could be commercialized more quickly and effectively." While, at heart, I believe any organization can be improved in theory, we're exploring here the rationale Kauffman provides for this "sub-optimal" performance.

Kauffman outlines three reasons for believing university technology transfer is sub-optimal. We will focus on the first of these reasons in this blog. The first reason Kauffman provides for university "sub-optimal" performance is that FDA Drug approvals have declined. At the same time, federal research dollars have increased from $20 billion in 1993 to $30 billion, for this "reason", university technology transfer is "sub-optimal." I guess the point is, you have more federal money, but FDA is approving less.

**Consideration 1: Biomedical products are developed mostly by life sciences companies**

First, one must consider that ultimately, universities typically do not commercialize biomedical products (which is the main area being focused on in the Universities and Economic Growth chapter of Kauffman's Rules for Growth). Universities perform early R&D and also form Startup companies. Nearly 100% of the biomedical products that came out of universities were transferred to the life sciences industry through some sort of licensing or other transaction in the Research, Pre-Clinical, Phase I or Phase II stage. Once transferred, it is then the responsibility of the life sciences company to perform more development and get the product through the FDA.

**Consideration 2: Developing drugs that successfully make it to market is not easy**

Now let's consider the hurdles involved when the life sciences company gets the technology:

a) The number of clinical trials to take one product to market has doubled in the last 10 years, going from 8 to 16
b) Sixty percent of clinical trials have late stage failures
c) The average cycle time to get a drug to market has increased 5 years since 1982
d) Ninety percent of clinical trials have 30-42% slippage
e) Data required for each clinical trial has increased by 30-50% depending on the indication and type of product

We could review several other complications in running clinical trials, but is it rational to state that universities have suboptimal performance, since, ultimately, they have little control of the product development after they transfer the technology? A question I leave to the people reading this blog.

**Consideration 3: Actually, the U.S. is doing pretty well with New Chemical Entities and currently leads the world in this area**

While there is an issue surrounding MAINTAINING U.S. biomedical leadership, actually, the U.S. is doing pretty well as it relates to the percent of new chemical entities from 1971 to 2010. Please see the table below from the Milken Institute's white paper "The Global Biomedical Industry: Preserving U.S. Leadership."

**Table 2: New chemical entities**
By headquarter country of inventing firm

| | 1971-1980 | | 1981-1990 | | 1991-2000 | | 2001-2010 | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **NCEs** | **% total** | **NCEs** | **% total** | **NCEs** | **% total** | **NCEs** | **% total** |
| **U.S.** | 157 | 31 | 145 | 32 | 75 | 42 | 111 | 57 |
| **France** | 98 | 19 | 37 | 8 | 10 | 6 | 11 | 6 |
| **Germany** | 96 | 20 | 67 | 15 | 24 | 13 | 12 | 6 |
| **Japan** | 75 | 15 | 130 | 29 | 16 | 9 | 18 | 9 |
| **Switzerland** | 53 | 10 | 48 | 11 | 26 | 14 | 26 | 13 |
| **U.K.** | 29 | 6 | 29 | 6 | 29 | 16 | 16 | 8 |
| **Total NCEs** | 508 | | 456 | | 180 | | 194 | |

Sources: Arthur Daemmrich, "Where Is the Pharmacy to the World? International Variation and Pharmaceutical Industry Location," Harvard Business School Working Paper, 2009; Milken Institute.

**Consideration 4: NIH's increased budget**

Let's look at the dynamics around NIH's "increased budget". Congress doubled the NIH budget between 1998 and 2003. However, since 2004, NIH funding has declined in real terms (excluding the $10 billion appropriated to NIH in 2009 for short-term stimulus under the American Recovery and Reinvestment Act); it stood at $31.2 billion in nominal terms in FY2010 and has been flat since 2007. In the recently approved FY2011 budget, NIH funding was cut by $260 million. Other countries are increasing government support of biomedical research, while the U.S. is not.

**Consideration 5: Technology Transfer transactions are understated**

To correctly capture the direct relationship between any technology transfer and a product, one has to trace all technology transfer that has ever occurred. This is easier said than done!

Let's take an example of Alopexx, who recently sealed a deal with sanofi-aventis for $375MM for SAR279356. In 2007, Alopexx licensed technology originally from Brigham & Women's Hopital & Beth Israel Deaconess Medical Center (deal not disclosed). If/when SAR279356 makes it to market, who is capturing this information in technology transfer metrics?

**Conclusion**

As you can see from the above logic, approximately 100% of the time university technology transfer performance has nothing to do with FDA approvals. Why are such claims made? It is evident that the people writing these "conclusions" have limited experience with the reality of clinical trials nor completely understand the industry dynamics.

**Thinking Point: Reinvent the University Technology Transfer Performance Management**

In light of all the discussion above, perhaps the technology transfer industry should consider defining what "optimal" really is. This would require a standard set of performance metrics measuring effectiveness (what is being done); efficiency (how well it's being done) and what the outcome is. Add into the equation the pace of innovation. This is a first principles approach to metrics. As discussed in the first blog, we have studied all the performance benchmark approaches and, while many have merit, none provide a comprehensive framework. As a result, RHT Consulting created a new performance benchmark that uses the data from AUTM to get as close as possible to a comprehensive benchmark framework.

Also, given many technology transfer organizations would like to improve, continuing to measure data points such as licensing/royalty income, just because that is what everyone else measures, will not bring about a different result. Universities may want to consider using activity based metrics that other industries use. One example of an activity based metric is the number of "connects" for a particular technology ("connects" are use in the contingent staffing industry as well as in consulting). In practical terms, "connects" are the number of relevant potential people/organizations contacted about a technology the university is trying to license. Taking this further, typically, industry has a daily and/or weekly pipeline call where several different type of connect metrics are measures, e.g., number of people called; number of people spoken with; number of people who have signed an NDA/CDA to further understand the technology; etc.

Til next time….where we will review of the two additional points of rationale Kauffman uses for university technology transfer "sub-optimal" performance.

About the Author: Rosemarie Truman

Rosemarie Truman is the President and CEO of RHT Consulting. She has 19 years of global strategy and transformation experience working with C-suites and Boards of Directors as well as senior leadership teams. She has worked with the leading companies in nearly every industry segment; this includes more than 25 growth strategies in ~10 countries for the top 10% of the fortune 50 and the top 20% of the fortune 100. Her clients have cumulatively enjoyed ~$20B in Operating Income.

One of Ms. Truman's specialties is "growth breakthrough innovation" (GBT), where she has four patents pending. Ms. Truman uses her strategy consulting background and GBT experience to conceptualize and implement a new industry-changing framework for life science companies called Industry Leading R&D Performance (ILRDP), which is also pending patent. Ms. Truman is currently working with a range of biopharmas, biotechnology and medical device companies as well as leading technology transfer government and university organizations. Key focus areas include: over arching strategy development, picking the right growth opportunities, creating breakthrough productivity in development, and redefining technology transfer paradigms.

More about Rosemarie's work can be found here: http://www.rhtconsulting.com

About the Collaborator: Brian Darmody

Brian Darmody is Associate Vice President for Research and Economic Development at the University of Maryland. Among other organizations, he sits on the board of the National Association of Seed and Venture Funds and the Maryland Venture Authority and developed the University's first technology transfer office. The views he expresses are personal, and not of any institution.

More about Brian can be found here: **http://tinyurl.com/bdarmody**